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Digital health to support physical activity in lung transplant candidates

Submission date 05/02/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 09/04/2026	**Overall study status** Ongoing	
Last Edited 09/04/2026	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims

Lung transplantation is a well-established treatment option for individuals with severe lung disease. Due to the shortage of donors, the demand for lung transplantation greatly exceeds the availability of donor lungs, resulting in extensive waiting times. In the final stages of these conditions, the lungs and muscles stop working as well as they should, causing symptoms that impact physical function and quality of life. As a result, people on the waiting list tend to be much less physically active, which can lead to deconditioning, more frequent hospital admissions, and worse outcomes after transplant.

To address this, we aim to see if a digital intervention incorporating an activity monitor, an interactive online platform and individualised remote support from a health professional could be a valuable intervention to empower individuals on the waiting list to increase physical activity in their everyday lives. The objective is to determine the feasibility of delivering this digital physical activity intervention in people on the waiting list for LTx and whether it has the potential to optimise health outcomes compared to usual clinical care.

Who can participate?

Adults aged 18 years and older who are on the waiting list for lung transplantation.

What does the study involve?

Participants will be randomly allocated (2:1) into the intervention group or usual care. Participants assigned to the intervention group will receive a 12-week digital behaviour change intervention alongside their UC. This includes: 1) a wrist activity monitor, linked to 2) an interactive, personalised, web-based dashboard, displaying multiple dimensions of physical activity data with integrated behaviour change tools; 3) one-to-one support from a dedicated mentor (6 x 20-minute sessions). After the 12 weeks, participants will continue wearing the watch during follow-up (to 24 weeks) and will have the option to access the platform and the watch once the study finishes.

The other group will receive usual care only. Participants will receive the same activity monitor and will be asked to wear the activity monitor (displaying time only) for 24 weeks without access to the dashboard or mentor support. Upon study completion, the control group will be offered the full intervention.

All participants will complete assessments (remotely) at the start of the study (0 weeks), post-

intervention (12 weeks), and follow-up (24 weeks), including questionnaires on quality of life, symptom burden and psychological well-being. A subset of participants will be invited to answer some questions in the form of a semi-structured interview to explore their experiences of the study and the digital intervention.

What are the possible benefits and risks of participating?
The digital physical activity programme is designed to help people improve their activity levels; however, benefits are not guaranteed. Individuals completing the study will have the option to keep their activity watch and access to the digital platform.
There are minimal risks to taking part in this study. There may be minor adverse reactions (e.g., muscle soreness) to the physical activity programme; however, the intervention is guided by trained healthcare professionals, and any increases in activity will be introduced gradually and tailored to fit participants' usual daily activities.

Where is the study run from?
The study is a collaboration between Northumbria University, Newcastle Hospitals NHS Foundation Trust and KiActiv. Northumbria University will be leading the study.

When is the study starting and how long is it expected to run for?
March 2026 to December 2027

Who is funding the study?
Academy of Medical Sciences (UK)

Who is the main contact?
1. Dr Emily Hume, e.c.hume@northumbria.ac.uk
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Contact information

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
356471

Central Portfolio Management System (CPMS)
69286

Grant Code
SBF0010\1061

Study information

Scientific Title
Enhancing physical activity and quality of life in lung transplant candidates through digital health: a feasibility study

Study objectives
To investigate the feasibility of randomising 45 lung transplant candidates to a study comparing a 12-week digital physical activity intervention to usual care. Feasibility will be evaluated in terms of: a) recruitment and b) retention, and acceptability evaluated in terms of c) intervention adherence and d) participants' experiences of participating in the study.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/09/2025, Wales Research Ethics Committee 1 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2920 785738; Wales.REC1@wales.nhs.uk), ref: 25/WA/0250

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lung transplant

Interventions
Arm 1: Digital Physical Activity Intervention + Usual Care
Participants assigned to the intervention group will receive a 12-week digital behaviour change intervention alongside their usual care. This includes: 1) A wrist activity monitor, linked to; 2) an interactive, personalised, web-based dashboard (KiActiv® Health), displaying multiple dimensions of physical activity data with integrated behaviour change tools; 3) one-to-one support from a dedicated mentor (6 x 20-minute sessions).
After the 12-week intervention, patients will retain access to the dashboard and activity monitor for continued self-management to 24 weeks.

Arm 2: Usual Care (UC)
The control group will receive UC only. After 24 weeks, the control group will be offered the full intervention.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility will be assessed through:
1. Recruitment: number of participants approached, screened, screen-failed, consented, as well as reasons for declining participation, measured using a screening log throughout the study
2. Retention: proportion of consented participants completing the study, measured using a study completion log at the end of the study
3. Acceptability: participants' perceptions and experiences of the intervention and study procedures, assessed via qualitative interviews at 24 weeks
4. Adherence: uploading of physical activity data and completeness of patient-reported outcomes, assessed via the digital platform at 0, 12, and 24 weeks
5. Usage of intervention components assessed via the digital platform during the intervention phase (0 to 12 weeks) and follow-up phase (12 to 24 weeks)

Key secondary outcome(s))
1. The amount, duration and intensity of physical activity undertaken will be assessed through device-based activity monitoring continuously over 24 weeks

Outcomes assessed at baseline (0 weeks), post-intervention (12 weeks) and follow-up (24 weeks):
2. Health-related quality of life (HRQoL) measured using EQ-5D-5L questionnaire
3. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS)
4. Self-efficacy measured using the Self-Efficacy for Managing Chronic Disease Scale
5. Dyspnoea measured using the Dyspnoea-12 questionnaire
6. Fatigue measured using the Functional Assessment of Chronic Illness Therapy Fatigue Scale (FACIT)
7. Mental well-being measured using the Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)
8. Adverse events measured using adverse event log

Completion date
01/12/2027

Eligibility

Key inclusion criteria
1. Candidates on the waiting list for lung transplant (LTx) with any underlying disease diagnosis
2. Aged 18 years or above

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unable to speak or read English
2. No home internet
3. Presence of any other significant disease or disorder which, in the opinion of the researcher may affect the participant’s ability to participate in the study

Date of first enrolment
09/04/2026

Date of final enrolment
01/10/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Northumbria at Newcastle
Northumberland Building
Newcastle upon Tyne
England
NE1 8ST

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Sponsor information

Organisation
Northumbria University

ROR
https://ror.org/049e6bc10

Funder(s)

Funder type
Government

Funder Name
Academy of Medical Sciences

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication