ISRCTN24248527 https://doi.org/10.1186/ISRCTN24248527

Wearable technology in post breast surgery upper limb rehabilitation

Submission date
27/03/2025

Recruitment status
No longer recruiting

Registration date
12/04/2025

Overall study status
Ongoing

Last Edited
09/04/2025

Condition category
Musculoskeletal Diseases

[ ] 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
Breast cancer is the most common cancer worldwide, with over 55,000 patients diagnosed in the UK each year. Axillary surgery, which includes procedures like Sentinel Lymph Node Biopsy (SNLB) and Axillary Node Dissection (AND), is crucial for staging breast cancer but can lead to shoulder problems such as pain, reduced movement, lymphoedema, and decreased quality of life. This study aims to explore the benefits of a digital rehabilitation system called OnTrack, which uses a smartwatch and smartphone to help breast cancer patients recover arm function after surgery.

Who can participate?
Adults aged 18 and older who are scheduled for sentinel node biopsy or axillary node clearance as part of their breast cancer treatment can participate. Participants must be able to provide informed consent.

What does the study involve? (for participants)
Participants will use the OnTrack system, which provides real-time activity feedback and remote physiotherapy support through a smartwatch and smartphone. This system is designed to help manage arm rehabilitation effectively.

What are the possible benefits and risks of participating?
Benefits include reduced pain and lymphoedema, improved shoulder mobility, and enhanced quality of life. The study also aims to generate cost savings for patients. Risks may include mild discomfort from using the wearable devices, but these are expected to be minimal.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?

Who is funding the study?
Imperial MedTechOne (UK)
Wellcome Trust (UK)

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327556

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
23CX8516

Study information

Scientific Title
A study to investigate the use of wearable technology in upper limb rehabilitation post breast and axillary surgery

Study objectives
Wearable technology can facilitate remote shoulder rehabilitation post breast and axillary surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/02/2024, London - Surrey Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8131; surrey.rec@hra.nhs.uk), ref: 24/PR/0049

Study design
Randomized prospective parallel group non-blinded trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Shoulder disfunction post breast and axillary surgery

Interventions
Control Arm: Standard NHS care post breast and axillary surgery. This involves patients receiving an exercise leaflet and asked to perform exercises at home. Some patients will have an inactivated activity monitor on the arm to track their arm movement and some will have no monitor at all. Patients will be followed up for up a minimum of 1 month post surgery.

Intervention arm: patients will be asked to wear a wearable rehabilitation platform (OnTrack App on Apple Watch) for a period of 1 month post surgery in addition to the standard NHS care. The App tracks their movement, gives real-time feedback on activity along with push notifications to encourage movement, allowing remote rehabilitation and remote clinician input. They will also be followed up for 1 month.
Randomisation will be using block randomisation via the Sealed Envelope online platform.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
OnTrack Rehab

Primary outcome measure
1. Patient perceptions, satisfaction and acceptability regarding the use of OnTrack measured using semi-structured interviews and a System Usability Scale at the end of the study period.
2. The effect of OnTrack on post-operative upper limb pain measured using validated pain analogue scale at baseline and 1 month after surgery.
3. The effect of OnTrack on post-operative upper-limb movement in the affected limb measured using patient reported outcome measures (DASH questionnaire) along with range of movement, using a goniometer and upper limb strength using a dynamometer, at baseline and 1 month after surgery.
4. The effect of OnTrack on patient's post operative health related quality of life measured using EQ5D5L QoL questionnaire at baseline and 1 month post surgery

Secondary outcome measures
1. Healthcare professionals' (surgeons, nurse specialists and physiotherapists) perceptions and acceptability regarding the use of OnTrack measured using semi-structured interviews at the end of the study period.
2. Impact on the workload of healthcare professionals measured using semi-structured interviews at the end of the study period.

Overall study start date
15/11/2024

Completion date
30/09/2025

Eligibility

Key inclusion criteria

1. Age ≥ 18 years
2. Planned for sentinel node biopsy or axillary node clearance as part of their breast cancer management
3. Participants must be able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
56

Key exclusion criteria
1. Unstable medical condition
2. Pre-existing pre-operative shoulder disability affecting shoulder movement
3. Patients unable to provide informed consent

Date of first enrolment
30/03/2025

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
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Sponsor information

Organisation
Imperial College London

Sponsor details
Research Governance and Integrity Team
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Sponsor type
University/education

Website
https://www.imperial.ac.uk

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
University/education

Funder Name
Imperial MedTechOne

Funder Name
Wellcome Trust

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/10/2026

Individual participant data (IPD) sharing plan
The datasets generated and or analysed during current study will be available upon request from Ahmed Latif ahmed.latif@imperial.ac.uk

IPD sharing plan summary
Available on request