ISRCTN12188385 https://doi.org/10.1186/ISRCTN12188385

Motivating core-muscle exercises with wearable sensors, haptics and interactive gaming

Submission date
10/06/2026

Recruitment status
Recruiting

Registration date
12/06/2026

Overall study status
Ongoing

Last Edited
12/06/2026

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
Low back pain is a common problem that can affect daily life and work. Exercise can help, but people do not always perform the exercises correctly or keep up with them. This study is testing a wearable belt that measures muscle activity and gives real-time feedback through a mobile app. The aim is to find out if using this belt alongside standard care can reduce pain, improve movement and daily function, and help people stick to their exercise programme compared with standard care alone.

Who can participate?
Adults aged 18 years or older who have had non-specific low back pain for at least 6 weeks in the past 12 months may take part. Participants must have a moderate level of pain or disability. People cannot take part if they have serious spinal conditions, recent spinal surgery, certain serious health problems, are pregnant or recently gave birth, or cannot safely do exercise.

What does the study involve?
Participants are randomly placed into one of two groups. Both groups complete a home-based core muscle exercise programme lasting 8 weeks, doing 20 to 30 minutes of exercise at least 5 times per week. One group uses a wearable biofeedback belt and mobile app during exercise to guide muscle use. The other group follows the same exercises using a booklet and videos but without the belt. All participants attend an initial session to learn the exercises. They complete questionnaires about pain, daily function and quality of life at the start, after 8 weeks, and again 3 months later. Researchers also monitor how well participants follow the exercise programme.

What are the possible benefits and risks of participating?
Participants may benefit from improved pain, better movement, and greater confidence in doing their exercises. The wearable system may also help them stay motivated. Risks are likely to be low but may include mild discomfort from exercise or irritation from wearing the belt. As with any exercise programme, there is a small risk of strain or injury.

Where is the study run from?
The study is run from Imperial College London, with additional participation at Surrey Physio Group in Mitcham, England.

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

Who is funding the study?
UK Research and Innovation
Medical Research Council

Who is the main contact?
Dr Paul Bentley, p.bentley@imperial.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Paul Bentley

ORCID ID
https://orcid.org/0000-0001-9645-1196

Contact details
10L21, Charing Cross Hospital, Charing Cross Campus
London
United Kingdom
W6 8RP
+44 20 3311 1194
p.bentley@imperial.ac.uk

Type(s)
Scientific, Public

Contact name
Dr Reneira Seeamber Balaghee

Contact details
10L21, Charing Cross Hospital, Charing Cross Campus
London
United Kingdom
W6 8RP
+44 7496682750
rs4318@imperial.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT07555795

Study information

Scientific Title
A randomised controlled trial evaluating the effects of a wearable biofeedback belt for home exercise therapy + standard treatment compared with standard treatment alone on pain, disability and exercise adherence in adults with chronic low back pain

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/03/2026, ICREC (Research Office Level 1, Mediaworks Building 191 Wood Lane, London, W12 7FP, United Kingdom; +44 (0)20 7594 9456; rgitcoordinator@imperial.ac.uk), ref: 19IC5674

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Crossover

Purpose
Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Prevention and treatment of chronic low back pain

Interventions
Experimental : Exercise with real-time muscle biofeedback
Device: MMG-biofeedback belt
The intervention consists of a wearable belt incorporating mechanomyography (MMG) sensors to detect muscle activity in the abdominal and lower back regions, paired with a mobile application that provides real-time visual feedback on core muscle activation during exercise. The system is designed to guide users in engaging the correct muscles, improve exercise performance, and support adherence to a prescribed exercise programme during both supervised and home-based sessions.

Participants will be randomised in a 1:1 ratio to either the intervention group (smartbelt plus conventional care) or control group (conventional care alone). Randomisation will be performed using a computer-generated randomisation sequence created by an independent researcher not involved in outcome assessment. Allocation will be concealed using sequentially numbered, opaque, sealed envelopes prepared in advance. Following completion of baseline assessments, participants will be allocated to their assigned group according to the next envelope in sequence.

Protocol: Participants randomised to the intervention arm will receive a standardised lab session on the use of the MMG-biofeedback belt and mobile application. A physiotherapist or trained researcher will demonstrate how to perform each exercise, correct belt positioning, app navigation, calibration procedures, and how to interpret the real-time muscle activation feedback. Participants will be issued the MMG-biofeedback belt and app after training and will use the system throughout their prescribed home-based exercise sessions for the full eight-week intervention period. Participants are asked to perform the exercise programme (20-30 mins) at least 5 times a week. The app will provide real-time feedback on muscle activation, progress summaries and reminders. Participants are asked to carry on any other treatment as usual. Aside from routine data collection and belt troubleshooting, participants in the control group will not receive additional input from the research team.

No Intervention : Exercise without biofeedback (waitlist control)
Participants randomised to the control arm will receive a standardised lab session, whereby core strength and endurance measures are taken. A physiotherapist or trained researcher will demonstrate how to perform each exercise. Participants will be issued with a booklet containing the exercise programme with exercise video links and are asked to perform their prescribed home-based exercise sessions for the full eight-week intervention period. Participants are asked to perform the exercise programme (20-30 mins) at least 5 times a week. No MMG-biofeedback belt will be provided to this group, participants are asked to carry on any other treatment as usual. Aside from routine data collection, participants in the control group will not receive additional input from the research team.

Follow up for 3 months in both groups.

Intervention Type
Device

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
UPPITT: MMG-biofeedback belt

Primary outcome(s)
1. Functional disability and quality of life impairment due to acute or chronic lower back pain measured using Oswestry Disability Index (ODI) at enrolment to 3 months after the end of treatment period (8 weeks treatment)

2. Pain measured using Visual Analogue Scale (VAS) at enrolment to 3 months after the end of treatment period (8 weeks treatment)

Key secondary outcome(s))

1. Quality of life measured using EuroQol 5-Dimension 5-Level (EQ-5D-5L) at enrolment to 3 months after the end of treatment period (8 weeks treatment)

2. Musculoskeletal health measured using Musculoskeletal Health Questionnaire (MSK-HQ) at enrolment to 3 months after the end of treatment period (8 weeks treatment)

3. Exercise Adherence measured using Survey/ Wearable belt measurements (duration) at enrolment to 3 months after the end of treatment period (8 weeks treatment)

4. Participants' experiences of using the smartbelt and accompanying application. Areas explored include ease of use, comfort, perceived usefulness, confidence performing exercises, motivation to exercise, satisfaction with the feedback provided, barriers and facilitators to use, and suggestions for improvement measured using Qualitative user surveys analysed using thematic analysis at enrolment to 3 months after the end of treatment period (8 weeks treatment)

5. Strength and Endurance measured using Maximal Voluntary Contractions (MVCs) in flexion and extension are recorded using the Cybex dynanometer. The peak torque (Nm) is measured during three repetitions of each MVC as a measure of isometric strength. Endurance was measured as the amount of time the participant could hold 50% of their MVC in flexion and extension using the Cybex dynanometer. Endurance measures were also performed using McGill's Torso Muscular Endurance Test Battery (trunk flexor and extensor)/ Biering-Sorenson Test at enrolment to the end of treatment at 8 weeks

Completion date
20/04/2027

Eligibility

Key inclusion criteria
1. Over the age of 18 years
2. Non-specific LBP for at least 6 weeks in the past 12 months
3. Pain 4/10 on a visual analogue scale or more or Oswestry Disability Index over 20%

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. Serious spinal pathology (red flags) such as
1.1 history of malignancy with new onset back pain suggestive of recurrence
1.2 unexplained weight loss, fever, or systemic symptoms
1.3 recent significant trauma (e.g., fall from height, road traffic accident)
1.4 suspected or confirmed spinal infection (e.g., discitis, osteomyelitis)
1.5 cauda equina symptoms, including urinary retention or incontinence or saddle anaesthesia
1.6 progressive neurological deficit (e.g., worsening weakness, loss of reflexes)
2. Recent spinal surgery or invasive spinal procedures within the past 3 months
3. Severe cardiovascular or respiratory disease that prevents safe participation in mild to moderate exercise (e.g., unstable angina, uncontrolled heart failure)
4. Pregnant women or those less than 3 months postpartum
5. Known allergy to materials used in the belt (e.g., lycra or related fabrics)
6. Cognitive impairment that prevents informed consent or ability to follow exercise instructions
7. Concurrent participation in another intervention trial that may interfere with the study outcomes

Date of first enrolment
20/04/2026

Date of final enrolment
20/11/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College London
Imperial College London White City Campus
80 Wood Lane
London
England
W12 7TA

Study participating centre
Surrey Physio Group
409-411 London Road
Mitcham
England
CR4 4BG

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

De-identified individual participant data (IPD) underlying the results reported in publications will be made available to other researchers upon reasonable request. This will include participant-level data for primary and secondary outcomes (e.g. disability scores, pain scores, adherence metrics), along with relevant baseline characteristics.

Raw sensor data (e.g. MMG signals) and proprietary algorithms will not be shared in full due to intellectual property considerations. However, processed or aggregated data derived from these signals may be shared where appropriate to support reproducibility of findings.

All shared data will be fully anonymised in accordance with GDPR and institutional data protection policies.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 10.0	23/02/2026	12/06/2026	No	Yes