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Improving the assessment of overweight and obesity in people living with HIV and/or chronic hepatitis B

Submission date
01/11/2025

Recruitment status
No longer recruiting

Registration date
03/11/2025

Overall study status
Completed

Last Edited
03/11/2025

Condition category
Infections and Infestations

[_] 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
People living with HIV and/or chronic hepatitis B (HBV) are at higher risk of developing health problems related to how fat and muscle are distributed in the body, such as heart disease, diabetes, and liver damage. These risks may be linked to long-term inflammation caused by the viruses and the effects of some treatments.
Current NHS tools like Body Mass Index (BMI) do not give enough information about where fat is stored or how much muscle someone has. This is important because fat stored deep inside the body (such as around the organs) can be more harmful than fat just under the skin. Better tools are needed to assess body composition in people living with HIV and/or HBV.
This study aims to find out how acceptable three different body composition tools are for people in this group:
-Bioelectrical Impedance Analysis (BIA)
-3D Body Scanning
-Stunkard Figure Rating Scale (a visual body shape scale)
The goal is to understand whether these tools could be used more widely in clinics to support better care.

Who can participate?
Adults aged 18 or over who are living with HIV (with a stable, undetectable viral load) and/or chronic hepatitis B infection can take part. People with certain medical devices (such as pacemakers), those who use wheelchairs, or those recently treated for hepatitis C or taking weight-loss injections will not be eligible for safety or technical reasons.

What does the study involve?
Participants will be asked to attend one study visit at the Mortimer Market Centre in London, which will take about 2 hours. During the visit, they will:
Have their height, weight, blood pressure, and body shape measured
Give a fasting blood sample (for cholesterol and blood sugar)
Complete physical function tests (such as grip strength and walking balance)
Complete the three body composition assessments (BIA, 3D scan, and body shape scale)

Fill in a short questionnaire about how acceptable they found each assessment
Some participants (20 people) will also be invited to take part in a short interview (about 30 minutes, either in person or by phone) to share their experiences in more detail.
All data will be anonymised and handled confidentially. Participants will receive a £20 voucher as a thank you, and an additional £15 if they take part in the interview.

What are the possible benefits and risks of participating?
There is no direct medical benefit to participants, but the results may help improve how body composition is measured and monitored in future clinical care for people living with HIV and/or HBV. Participants may also gain insights into their own body shape and health risks.

The procedures are safe and non-invasive. Some people may feel uncomfortable discussing weight or body shape, but the research team is trained to be sensitive and supportive. Any participant who becomes upset will be offered information about further support. People with implanted medical devices or limited mobility will not be able to participate due to equipment limitations.

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

When is the study starting and how long is it expected to run for?
The study aims to start recruitment in September 2025 and close recruitment in April 2026.

Who is funding the study?
The study is funded through the UCL Naughton/Clift-Matthews Global Health Fund 2024.

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)
341062

Protocol serial number
179908

Study information

Scientific Title
Improving the assessment of overweight and oBEsity in people living with HIV and/or chronic hepatitis B

Acronym
BEHIVe

Study objectives
Primary objective:
To assess the acceptability of BIA, 3D Scan and the SFRs in people living with HIV and/or chronic HBV using a validated framework for assessing acceptability of healthcare interventions, and to capture additional process outcomes such as completion rates and time required for assessments.
Secondary objectives:
1. To describe body composition using BIA, 3D Scan, anthropometry, and to assess cardiometabolic risk through metabolic profiling, functional assessments and risk scores.
2. To compare the participants assessment of their own body shape using the SFRS to characteristics of the participants avatar created through 3D body imaging
3. To compare the patient and clinicians' assessment of body shape through the SFRS

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/09/2025, East of England - Cambridge East Research Ethics Committee (2 Redman Place, London, EC20 1JQ, United Kingdom; +44 2071048000; cambridgeeast.rec@hra.nhs.uk), ref: 22/EE/0198

Study design
Single-centre cross-sectional cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
People living with Human Immunodeficiency Virus (HIV) and/or chronic Hepatitis B Virus (HBV)

Interventions

This cross-sectional study will recruit 100 people living with HIV and/or chronic HBV from the Mortimer Market Centre in London. Participants will undergo body composition assessments using BIA, 3D scanning, and the Stunkard Figure Rating Scale, anthropometric and sarcopenia measurements, alongside validated questionnaires to evaluate the acceptability of these interventions. A subset of participants will take part in qualitative interviews to explore their perceptions of weight and health, their preferences for body composition assessment methods and experiences with these tools. Quantitative data will assess acceptability as well as any potential correlation between measurement methods, while qualitative data will provide insights into patient perspectives.

Intervention Type
Mixed

Primary outcome(s)
Acceptability of three body composition assessment tools measured using a validated questionnaire (based on the Theoretical Framework of Acceptability) immediately after each assessment. Completion rates and time taken to complete each assessment will also be recorded.

Key secondary outcome(s))
1. Body composition and cardiometabolic risk profiling using data from BIA, 3D scans, and standard anthropometric measures (e.g. BMI, waist circumference). We will also assess cardiometabolic risk using blood tests (lipids, HbA1c), blood pressure, QRISK3 score, liver fat (CAP score), and sarcopenia risk (Short Physical Performance Battery and grip strength)
2. Comparison of self- and clinician-perceived body shape with 3D scan data using the Stunkard Figure Rating Scale with the quantitative data from the 3D body scan (e.g. fat percentage, body proportions)
3. Participant experiences and perceptions. Qualitative interviews with a subset of participants will explore feelings about body image, weight monitoring, and preferences for body composition assessment tools

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. HIV-1 positive with viral load <200 copies/ml at time of enrolment AND/OR Chronic Hepatitis B Virus diagnosed as presence of Hepatitis B surface antigen (HBsAG) in the blood for ≥6 months
3. Provision of written informed consent
4. Able to stand unaided for >30 seconds

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Wheelchair users
2. People with artificial electrical implants, such as pacemakers or defibrillators
3. People who have had bariatric surgery or are currently taking/recently completed a course (within <6 months) of GLP-1 receptor agonist therapies
4. Person living with HIV and/or chronic HBV and active Hepatitis C co-infection or who has completed HCV treatment within the previous 6 months

Date of first enrolment
27/09/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Mortimer Market Centre
Mortimer Market
London
United Kingdom
WC1E 6JD

Sponsor information

Organisation
University College London

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Naughton/Clift-Matthews Global Health Fund

Funder Name
NIHR HPRU BBSTI Pre-Application Support Fund

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date