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How changing HIV treatment affects sleep, mood, quality of life and health in people around or after the menopause and older adults living with HIV

Submission date
01/07/2026

Recruitment status
Recruiting

Registration date
02/07/2026

Overall study status
Ongoing

Last Edited
05/08/2026

Condition category
Other

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with HIV are living much longer. In many countries, more than half of people with HIV are now 50 or older, and this number is still growing. As people get older, their bodies change. Some people have problems with sleep or mood or feel side-effects from medicines. Women going through or after the menopause can also have new difficulties like these.
HIV medicines are tested in clinical trials, and these trials have shown that a treatment called bictegravir/emtricitabine/tenofovir (B/F/TAF; Biktarvy) works well and is safe. But the people in trials do not always match the people who use the medicine in real life. For example, fewer older people and fewer women are often included. Trials also do not always measure everyday things that matter, like sleep, mood, quality of life or how satisfied people feel with their treatment.
Doctors often use B/F/TAF for older adults because it can be gentler on the kidneys and bones. But we still need more real-world information about how it feels to take this treatment, especially for older people and for women around menopause.
The PEARL study will collect information from several hospitals. It will look at older adults and people going through or after the menopause. By combining medical information with people's lived experiences, we can learn which treatments suit them best. The results will help clinics give more personalised HIV care.

Who can participate?
Adults with HIV who fall into one of two populations:
a) Adults who are 60 years of age or older
b) Individuals assigned female sex at birth who are between the ages of 40 to 60

Participants must also fall into one of these two groups:
i) Individuals receiving B/F/TAF or who have ever received B/F/TAF as HIV treatment.
ii) Individuals switching HIV treatment to any treatment regimen.

What does the study involve?
If individuals provide their consent to participate, the staff members at their HIV clinic will complete a questionnaire with data on their gender, age, date of HIV diagnosis, routine blood results, medical treatment, and illnesses. The data will be extracted from their medical records. Following this, 1-2 months and 6-8 months after their enrolment, they will collect data from their routine visits to the clinic, including laboratory data and weight, medical history and other medications, HIV treatment history, drug-related clinical event at each of these timepoints.

The study will not test any drugs and will not interfere with any treatment the participants may receive at the clinic. Participants are consenting to allow the researchers to gather routinely collected information about them and their care.

Participants in group (ii) above, will be required to complete a questionnaire at three timepoints: the time of enrollment, after 1-2, and after 6-8 months. The questionnaire will take a maximum of 30 minutes to complete. It can be completed online in the comfort of their own home or at the clinic. After the completion of each questionnaire, participants will be given a £20 shopping voucher as a thank you for their time and effort.

What are the possible benefits and risks of participating?
Participation in the PEARL study does not include any additional risks , although some people may find completing questionnaires tiresome. While there are no immediate benefits , many people enjoy knowing that their input will further knowledge about different treatment choices, and hopefully improve HIV care in perimenopausal and older adults.

Where is the study run from?
The study is being run by the University of Sussex and taking place in different UK HIV clinics.

When is the study starting and how long is it expected to run for?
May 2026 to July 2027. The first HIV clinic will start running the study in May 2026. Each HIV clinic will run the study for 1 year and each participant's involvement will last no more than 8 months.

Who is funding the study?
The PEARL study has received funding from Gilead Sciences who are the manufacturers of Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF).

Who is the main contact for the study?
Please contact the study manager Dr Kate Alford - K.Alford@bsms.ac.uk or the chief investigator Dr Fiona Cresswell - F.Cresswell@bsms.ac.uk

Contact information

Type(s)
Principal investigator

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Public, Scientific

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Integrated Research Application System (IRAS)
362137

Central Portfolio Management System (CPMS)
70086

Study information

Scientific Title
Perimenopause and older adults treatment outcomes and lived experience

Acronym
PEARL

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/02/2026, London - Dulwich REC (Health Research Authority 2nd Floor 2 Redman Place Stratford, London, E20 1JO, United Kingdom; +44 20 7 104 8000; dulwich.rec@hra.nhs.uk), ref: 26/LO/0056

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Experiences of adults in the peri/post-menopausal period or aged ≥60 years switching HIV treatment

Interventions
This is a multi-centre, mixed-methods observational study conducted at UK NHS HIV treatment centres, incorporating both prospective and retrospective components, alongside a nested qualitative element.

After receiving information about the study and providing informed consent, participants enter one of two cohorts:

Prospective patient-reported outcomes cohort: Participants who are changing HIV treatment to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) or another oral HIV treatment have routine clinical information collected from their medical records by the local research team. Before or at the time of the treatment change, they also complete questionnaires about sleep, mood, quality of life, treatment satisfaction, frailty and, where applicable, menopausal symptoms. The clinical information and questionnaires are repeated approximately 2 months after the treatment change and approximately 6 months after the change . A subgroup of participants who change to B/F/TAF will be invited to take part in one interview about their experiences between 2 and 6 months after changing treatment.

Routine clinical data cohort: Participants who are currently receiving, or have previously received, B/F/TAF will give permission for their local research team to collect routinely recorded information from their medical records. Information is collected from the most recent record before the treatment change to B/F/TAF, and then at approximately 6-month intervals where available. The total observation period is up to 5 years from starting B/F/TAF. Observation ends when B/F/TAF is discontinued, 5 years after it was started, or at study closure, whichever occurs first. No additional medical tests or treatment changes are required for the study.

Separately, HIV clinicians involved in treatment decisions are invited to participate in a one-off focus group about treatment choices for older adults and people around or after the menopause.

Intervention Type
Not Specified

Primary outcome(s)
1. Patient-reported outcomes before and after switch of HIV treatment measured using patient-reported outcomes on sleep (PROMIS questionnaire), mood Patient Health Questionnaire-9 (PHQ-9), treatment satisfaction (HIV Treatment Satisfaction Questionnaire (HIVTSQs12)), and quality of life (HIVPROM questionnaire) at baseline, then 2 months and 6 months post HIV treatment switch

Key secondary outcome(s)
1. Lived experiences of switch to B/F/TAF measured using qualitative data from in-depth interviews with patient participants analysed using reflexive thematic analysis at 2-6months post switch to B/F/TAF

2. Clinician perceptions and experiences of HIV treatments including B/F/TAF measured using qualitative data from focus groups with clinical teams analysed using reflexive thematic analysis at at any point during the study

3. Treatment durability measured using proportion of participants who remain on B/F/TAF without discontinuation at over 12, 24, 36, 48 and 60 months

4. Virological efficacy (routine data cohort) measured using cumulative proportion of participants maintaining undetectable HIV viral load (<50 copies/mL) and cumulative incidence of virological failure at at 12, 24,36, 48 and 60 months post-switch

5. Safety outcomes (routine data cohort) measured using Renal function (eGFR), bone density (T score at hip and spine via DEXA scan), weight and incidence of clinically significant weight gain, Hb1Ac and lipid profiles (blood test), CD4 T cell count (blood test) at from start of regimen for the duration of follow-up in the routine data cohort

6. Frailty measured using FRAIL scale score at baseline, then 2 months and 6 months post HIV treatment switch

Completion date
08/08/2027

Eligibility

Key inclusion criteria
1. Adults with HIV-1
2. The potential participant has the mental capacity, and is willing to, provide informed consent to participate in the study.
3. The individual falls into one of the two populations of interest:
3.1. Adults who are 60 years of age or older
3.2. Individuals assigned female sex at birth who are between the ages of 40 to 60 years
4.The participants must belong to one of two cohorts:
4.1. Routine data cohort: The individual is already receiving B/F/TAF, or has received B/F/TAF any time in the past
OR
4.2. PROMs prospective cohort: The individual will be switching HIV treatment to either B/F/TAF or to an alternative ART regimen

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. In the opinion of the research team, the individual is unable or will be unwilling to comply with the study requirements
2. The individual has not provided informed consent
3. Data completeness is inadequate in the eyes of the site principal investigator

Date of first enrolment
08/06/2026

Date of final enrolment
08/01/2027

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing
England
BN11 2DH

Study participating centre

University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
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Study participating centre
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Royal Free London NHS Foundation Trust
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Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
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Study participating centre
East of England Community Health and Care NHS Trust
Norwich Community Hospital
Bowthorpe Road
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Sponsor information

Organisation
University of Sussex

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type

Funder Name
Gilead Sciences

Alternative Name(s)
Gilead, Gilead Sciences, Inc., Oligogen

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3	04/12/2025	01/07/2026	No	No