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Feasibility study of the use of the Comprehensive Geriatric Assessment for older people living with HIV

Submission date
08/09/2021

Recruitment status
No longer recruiting

Registration date
09/09/2021

Overall study status
Completed

Last Edited
24/11/2025

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
People with HIV are living longer thanks to effective HIV care. However, many experience age-related health problems. These include frailty, weakness, and falls. Whilst common problems for older people, for people with HIV, they are happening at younger ages.
People with HIV have ageing-related problems as young as 50. Experts in elderly care are specialists in managing these problems. However, people with HIV may not be able to see these specialists as they are too young. Therefore, they may not receive the care that they need.
Currently, older people with HIV are cared for by HIV experts and GPs. However, it is not known which is better: care from HIV experts with GPs, or with elderly care experts?
Experts in elderly care use a Comprehensive Geriatric Assessment (CGA). This is an assessment of a person's physical, emotional and social needs. A plan is then put in place to help them to get on better day-to-day. It helps them to remain independent and aims to stop them from having to go into hospital unless they really need to. This approach is helpful for older people living with many long-term conditions. However, it has not been tested for older people with HIV.
This is a feasibility trial recruiting 84 older people with HIV and frailty. They will be put into two groups at random after being screened for frailty during their routine HIV annual health check. One group will receive usual care (from HIV experts and GPs). The other group will have a CGA (from HIV and elderly care experts). The researchers want to find out if enough people will participate, if they're asking the right questions, and if their plans for the larger trial will work.

Who can participate?
Older people with HIV and frailty

What does the study involve?
Participants will be put into two groups at random after being screened for frailty during their routine HIV annual health check. One group will receive standard care (from HIV experts and GPs). The other group will have a comprehensive geriatric assessment (from HIV and elderly care experts).
The Comprehensive Geriatric Assessment is a careful assessment of a person's physical, emotional and social needs. A plan is then put in place to help them to get on better day- to-day.

It helps them to remain independent. It also aims to stop them from having to go into hospital unless they really need to. This approach is helpful for older people living with many long-term conditions. However, it has not been tested for older people with HIV
The researchers will use questionnaires and interviews to answer the following questions:
1. Are older people with HIV happy to be tested for frailty?
2. How do they feel about having a Comprehensive Geriatric Assessment?
3. Does a Comprehensive Geriatric Assessment help older people with HIV?
4. Were they able to recruit enough people into the study?
5. Was the study acceptable to older people with HIV?
These results will help the researchers to design a larger trial. They will also be fed back to people with HIV and health professionals.

What are the possible benefits and risks of participating?
As interviews will be exploring possible challenges associated with living with HIV and frailty, possible distress to participants could occur when recounting these experiences. To try to mitigate this, participants will have the possible risk explained in the participant information sheet, so that they may consider this before taking part. Sources of support will also be included in the participant information sheet and it will be made clear that participants may withdraw from the study at any point, should they wish.
There are no direct benefits to the study participants. However, the benefit of conducting research includes advancing scientific understanding of HIV infection and other related infections and illnessess and their complications and risk factors for these conditions; this knowledge guides international and European treatment recommendations to the benefit of people living with HIV or at high risk of HIV.

Where is the study run from?
University of Sussex (UK)

When is the study starting and how long is it expected to run for?
March 2020 to October 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Natalie St Clair-Sullivan
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
300599

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 50361, NIHR201060, IRAS 300599

Study information

Scientific Title
Testing the feasibility and acceptability of case-finding and subsequent comprehensive geriatric assessment intervention for older people with HIV

Acronym
The Silver Clinic V1

Study objectives
The researchers hypothesise that screening for frailty and the use of the Comprehensive Geriatric Assessment will be both acceptable and feasible for older people living with HIV.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/09/2021, East Midlands – Leicester Central Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8070; leicestercentral.rec@hra.nhs.uk), ref: 21/EM/0200

Study design
Randomized; Interventional; Design type: Treatment, Process of Care, Education or Self-Management, Complex Intervention, Physical, Management of Care, Rehabilitation, Active Monitoring

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Older people with HIV

Interventions
Why this study design and methodology?
Whilst the Silver Clinic is already running and here is where the Comprehensive Geriatric Assessment is carried out, it is not known whether it is better than 'usual care'. Therefore a control arm is necessary, which will be 'usual HIV care,' so that this can be compared to the Silver clinic (intervention arm). As such a RCT feasibility trial will be used to ascertain the acceptability of the Comprehensive Geriatric Assessment and the feasibility of it being evaluated in a full trial.

Where interviews will take place?
The interviews will take place via telephone or video call, or face to face at the Lawson unit where the participant usually receives their HIV care. This will be dependent on the participants choice.

Collaborators will be blinded to the screening and randomisation process as they will have no knowledge of when patients are screened for frailty nor have any influence on the randomisation process minimising the possibility of selection bias.

To reduce the possibility of researcher bias during the data analysis of the qualitative interviews an iterative process will be used to construct an initial coding frame. This will then be refined with the steering group including PPI members, and subsequently applied to all interviews. Analysis will be reviewed by the steering group, including PPI members, and revisited to develop a theoretical model of person-centred care for older people living with HIV and frailty. Ensuring that the data is reviewed and analysed by multiple stakeholders.

The researchers plan to use existing sources for data collection including the HIV Electronic Patient Record (EPR) system currently used in the clinic and data from GP patient records. The HIV EPR system at University Hospitals Sussex, Brighton collects data on social care service utilisation and community care. These data combined with patient's record data routinely collected at GP surgeries or community care registration will help reduce recollection bias.

Sampling and participant identification
This is a feasibility trial and therefore not powered to test the effectiveness of the intervention compared to usual care. However, data will be used to conduct exploratory analyses to inform sample size calculation for a future definitive trial. Based on the local patient numbers (cohort of 2450; 54% over 50 years old), the aim is to identify 10 patients per week, and recruit and retain at least 8 each week giving 84 patients in 3 months. It is anticipated that this number will be sufficient to enable the selection of the primary outcome and provide estimates of effect size for a possible definitive trial.

A purposive sample of up to 15 participants from each group of the trial will be interviewed on completion of trial participation to examine experiences of: recruitment to the trial; management of their priority concerns during the course of the trial; referral to the Silver Clinic, experience of the Silver Clinic and perceived impact upon priority outcomes (intervention arm only); and satisfaction with care.

The sample size is 84 older people living with HIV, identified as frail on the FRAIL scale at their annual HIV health check at the Lawson Unit, Royal Sussex County Hospital. The FRAIL scale is a measure consisting of a questionnaire regarding mobility, fatigue, weight loss and co-morbidities. Once a person has been identified as eligible, they will be informed of the study and given a participant information sheet, that has been reviewed by the PPI. If they are interested, they will be put in contact with the study research assistant or research nurse for more information and to ask any questions they may have.

Those who decline to take part in the study will be provided with an information leaflet about frailty and their physician will be informed about the frailty screening as part of their HIV usual care. They will then not have access to the Silver Clinic for the duration of the trial. Their HIV clinician can refer to the Silver clinic as per normal pathways, once the feasibility study is complete.

If it is felt by an individual's HIV clinician that they must be seen in the Silver Clinic then they cannot be invited to join the study, due to the randomisation process.

If they would like to be involved with the study a process of informed consent will be undertaken and an appointment will be made for them to attend their baseline assessment.

Both groups will undertake three visits, first at baseline, which should be within 28 days of the screening visit and also at 6 months and 12 months. All of these visits will take place at The Lawson Unit, Royal Sussex County Hospital. During these visits participants will complete a number of questionnaires alongside their HIV nurse and some physical tests such as a timed walking test and a grip strength measure. These appointments will take around 40 minutes to complete. 15 participants from each group will also be invited to take part in a single one-to-one interview regarding their experiences of being involved in the study, which should take no longer than 60 minutes. This can be done via video or audio call or face to face at the Lawson Unit, whichever the participant prefers.

The participants in the intervention arm, which is the Silver Clinic, will have an additional appointment at the Lawson Unit within 6 weeks of their baseline appointment. This will be with a specialist joint HIV and geriatrics team, who are experts in working with people with HIV and /or physical limitations. They will conduct a comprehensive assessment of the participants physical, psychological and social needs, and come up with an individualised care plan. This might include appointments with other relevant services if helpful, and/or changes to existing care. They will share this plan with the participant's GP and/or HIV physician, who might help deliver the care plan. This should take no more than 1 hour.

For the control group, which is usual care, they will continue to attend their usual HIV care and appointments and where possible we will add their study appointments to their regular follow-up appointments.

PPI involvement
PPI involvement was sought for the participant information sheet and consent forms. Prior to this study commencing a qualitative study is being conducted with people living with HIV and healthcare professionals working with people living with HIV, to explore what frailty means to people living with HIV and the acceptability of case finding for frailty as part of routine HIV care. It will also explore health and social care professionals' views about routine case-finding for frailty as part of HIV care and/or primary care. This will then be used to inform the design of this trial.

Timetable
-6-0 months: protocol development, ethics applications, staff recruitment, setup of steering groups
1-3 months: study set up
3-15 months: feasibility RCT
9-15 months: nested qualitative study
9-18 months: data analysis
18-21 months: write up, publications
21-24 months: final report, and dissemination
18-24 months: development of full protocol and application for a definitive multicentre trial

Intervention Type
Behavioural

Primary outcome(s)
The feasibility of a definitive trial, determined using recruitment rates, completion rates of study outcome measures, and retention at specific timepoints. A priori criteria for trial feasibility are as follows:
1. Recruitment of 20% of eligible patients
2. Recruitment of 84 patients within 3 months from first patient randomised
3. Retention of 70 patients (allowing up to 15% attrition) to primary endpoint (6 months)
4. Outcome measure completion for 90% of available participants at each timepoint

Key secondary outcome(s))
1. Symptoms and concerns measured using the Positive Outcomes HIV PROM at baseline, week 26 (first follow up) and week 52 (final visit)
2. Quality of life measured using the EuroQol 5D-5L at baseline, week 26 (first follow up) and week 52 (final visit)
3. Social care related quality of life measured using the Adult Social Care Outcomes Toolkit

(ASCOT) at baseline, week 26 (first follow up) and week 52 (final visit)
4. Services and support participants have accessed measured using the Client Service Receipt Inventory (CSRI) at baseline, week 26 (first follow up) and week 52 (final visit)
5. Patient-rated experience measure of the interpersonal quality of healthcare encounters measured using the Consultation and relational empathy measure (CARE) at baseline, week 26 (first follow up) and week 52 (final visit)
6. Frailty measured using the Fried Frailty Phenotype measure at baseline, week 26 (first follow up) and week 52 (final visit)
7. Frailty measured using the FRAIL Scale at baseline, week 26 (first follow up) and week 52 (final visit)
8. Functional mobility measured using the Time up and go test at baseline, week 26 (first follow up) and week 52 (final visit)
9. A person's level of vulnerability to poor outcomes, measured using the Rockwood clinical frailty scale at baseline, week 26 (first follow up) and week 52 (final visit)

Completion date
11/10/2023

Eligibility

Key inclusion criteria
1. Older people with HIV, with evidence of frailty 3+ on the frailty screening, using the Frail scale
2. Consent to contact the GP

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
25

Key exclusion criteria
1. Those not defined as frail
2. Attended the Silver Clinic during the last 12 months

Date of first enrolment
04/10/2021

Date of final enrolment
24/02/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
England
BN2 5BE

Sponsor information

Organisation
University of Sussex

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (https://figshare.com/s/6087848f5126329266f6). The type of data that will be shared will be an SPPS dataset. These data will become available following the publication of the manuscript related to the data and will be available for 10 years. Access to the data is upon request from CI: Jaime Vera, j.vera@bsms.a.c.uk. Consent was obtained from participants to share data and data will be anonymised.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/11/2025	24/11/2025	Yes	No
Protocol article		19/05/2023	22/05/2023	Yes	No
Basic results			25/06/2025	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1		09/09/2021	No	Yes