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Evaluating the impact of an intervention providing support with ART

Submission date
21/02/2014

Recruitment status
No longer recruiting

Registration date
21/02/2014

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Antiretroviral therapy (ART) reduces the likelihood of illness and lowers the chances of passing HIV on to others. However, the benefits of these treatments are dependent on timely uptake (starting treatment when it is recommended) and adherence (taking doses as prescribed), which are both suboptimal.
This study has been designed to assess whether a new programme that supports people with the decision to start HIV treatment and with adhering to their treatment, is more helpful than what people are currently being offered (standard care).
The main objective is to find out whether a treatment support programme is more effective than usual care in promoting timely uptake of treatment (starting treatment when it is recommended) and subsequent adherence (taking medication as prescribed).

Who can participate?
HIV patients aged 18 years and older for whom starting treatment has been recommended. These patients will be from NHS HIV clinics across England.

What does the study involve?
In the first stage, you will be asked to fill out a questionnaire on your beliefs about treatment. This assesses eligibility for the trial. If not eligible for the trial, you will be followed up over the next 12 months, and data on your changes in beliefs about treatment and data on clinical outcomes will be collected. If you are eligible to participate in the trial, you will be invited to take part in the second stage of the study. You will be randomly allocated to one of two groups: one group will receive standard
care while the other group will receive our support programme in addition to standard care. Patients in the standard care group will receive care as it would usually be delivered in their usual HIV clinic.
The treatment support programme consists of four sessions with a specially trained nurse which have been adapted to the individual patients needs, addressing beliefs about treatment and practical barriers to starting and maintaining treatment. Patients in this group will also receive standard care, meaning that the clinic will be offering the same services as they usually would. Data will be collected at 1, 3, 6, and 12 months. We will compare the group that received standard care and the group that received our programme by looking at the information from

questionnaires (e.g. beliefs about medicines, illness perceptions, anxiety and depression) clinical data, and adherence data.
The studys findings will be used to provide the NHS with tools in supporting people who are making decisions about taking treatment and helping people to get the most from their treatment.

What are the possible benefits and risks of participating?
You will receive reimbursement of expenses incurred by the extra appointments at the hospital to complete the research visits. Participants in the intervention group will receive treatment support, which should improve how you feel about treatment and your diagnosis, and should provide self- management skills. If the intervention promotes timely uptake and optimal adherence, you may gain clinical benefit from this research by experiencing reduced viral load (HIV virus), a higher CD4 count (immune function), better mental health, greater quality of life, and so on. If these interventions improve rates of uptake and adherence to treatment, longer term benefits for you and the public include a decreased chance of mortality, less drug resistance, a lower chance of transmitting HIV, and reduced likelihood of transmitting resistant strains of HIV.
Although patients in the standard care arm will not receive immediate benefit, their participation may benefit future patients living with HIV who could receive supplementary treatment support.

Where is the study run from?
The study will be co-ordinated from the UCL School of Pharmacy in London, and will run in four centres in Greater London, including Homerton University Hospital, Kings College Hospital, North Middlesex Hospital and Queen Elizabeth Hospital.

When is the study starting and how long is it expected to run for?
The study started in January 2014. Participants will be enrolled in the study for 12 months. The study is expected to finish in October 2016.

Who is funding the study?
National Institute of Health Research (NIHR), UK.

Who is the main contact?
Chief Investigator : Professor Rob Horne, r.horne@ucl.ac.uk
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
15162

Study information

Scientific Title
Applying the Medical Research Council guidance to evaluate an intervention to support uptake and adherence to antiretroviral therapy for HIV

Acronym
SUPA

Study objectives
The objectives of this study are to:

1. Assess the success of an intervention to promote optimal adherence in patients for whom starting ART is recommended
2. Assess how patients beliefs about ART change over time and how this may predict adherence and engagement in care
3. Assess the costs and cost-effectiveness of providing the intervention in the short- and long-term antiretroviral therapy

Antiretroviral therapy (ART) reduces the likelihood of illness and lowers the chances of passing HIV on to others. However, the benefits of these treatments are dependent on timely uptake (starting treatment when it is recommended) and adherence (taking doses as prescribed), which are both suboptimal. This study has been designed to assess whether a treatment support programme providing treatment initiation and subsequent support is successful in promoting timely uptake and adherence to ART, in comparison with regular care.

Adults in HIV outpatient clinics in London for whom treatment is recommended will be recruited. This study will utilise a two-stage consent/enrolment process. In the first stage patients will consent to take part in an observational cohort study, which also establishes eligibility for the intervention trial. If the patient is not eligible for the trial, they will continue to be followed up for 12 months and throughout they will fill out measures about their beliefs about ART. If they are deemed eligible to participate in the trial, they will be invited to take part and will be randomised to either a treatment support intervention or care as usual for 12 months. The principle objective of the trial is to evaluate whether a treatment support programme is more effective than usual care in promoting timely uptake of treatment (starting treatment when it is recommended) and subsequent adherence (taking medication as prescribed). The treatment support programme consists of tailored sessions with a specially trained nurse addressing the perceptual (e.g. beliefs about treatment) and practical barriers (e.g.

capacity to take treatment) to starting and maintaining treatment. The results of this study will be used to provide the NHS with tools in supporting people who are making decisions about taking treatment and helping people to get the most from their treatment.

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=15162

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Commitee East of England, 16/09/2013, ref.: 13/EE/0235

Study design
Interventional and observational

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Infection; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

Interventions
The study has two components:
1. Observational cohort following patients over 12 months
2. Interventional trial, nested within (1), involves a two-arm randomised multi-centre controlled trial

ART treatment support: the treatment support programme consists of four sessions with a specially trained nurse, which have been adapted to the individual patients needs, addressing beliefs about treatment and practical barriers to starting and maintaining treatment; follow-up length: 12 month(s)

Patients in the intervention arm will receive treatment initiation support within one month of enrolment into the intervention trial. This support will be in the form of two tailored treatment support sessions utilising a Cognitive Behavioural Therapy (CBT) approach. The first session will be conducted face-to-face, and patients will choose to conduct the following 23 sessions in person or via telephone. The sessions will communicate a rationale for the personal necessity of medication, elicit and address concerns (practical/physical/emotional/cognitive) about medication, and problem-solve potential perceptual and practical barriers to adherence. The specific timing of the sessions will differ according to different patients needs and availability; however, all the sessions will take place within one month of enrolment

Booster sessions providing additional support will be offered at 3 and 6 months randomisation. Patients will choose to conduct the booster sessions in person or via telephone. These sessions will utilise the same approach as in the initial session, but will elicit/address existing barriers to adherence. Patients who have experienced no difficulties or concerns will discuss progress and receive positive reinforcement. Patients will be followed up at 3, 6 and 12 months.

If patients delay or decline ART when treatment is offered by their Clinician, they will continue in the study. They will be asked to attend follow-up sessions at 3, 6, and 12 months. For patients randomised to Condition 2, sessions at 3 and 6 months will continue to focus on barriers to starting treatment, rather than provide ongoing support with
adherence. The participant will be followed up at 12 months for outcome measures, like other participants, and data will be collected on whether they have started treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Proportion of months under follow-up where adherence = 90% using AARDEX MEMS; Timepoint (s): 12 months post randomisation

Key secondary outcome(s))
1. Change in perceptual and practical barriers; Timepoint(s): Baseline, 3, 6, 12 months post randomisation
2. Disengagement from care at 12 months; Timepoint(s): 12 months post randomisation
3. Health and social service use; Timepoint(s): Baseline, 3, 6, 12 months post randomisation
4. Quality of life; Timepoint(s): Baseline, 3, 6, 12 months post randomisation
5. Rate of ARV regimen switching; Timepoint(s): 12 months post baseline
6. Ratings of anxiety and depression; Timepoint(s): Baseline, 3, 6, 12 months post randomisation
7. Referral out of the intervention; Timepoint(s): 12 months post baseline
8. Treatment failure; Timepoint(s): 12 months post randomisation

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. Male or female, aged 18 years and above
2. Known HIV infection
3. Have never been prescribed ART in outpatient clinic care
4. Being offered antiretroviral therapy treatment according to the BHIVA guidelines (may be subject to change throughout duration of study) OR as deemed appropriate by the patients clinician.
5. If patients are pregnant, treatment should be recommended following pregnancy for at least 12 months following enrolment, according to BHIVA guidelines.
6. Able to provide written informed consent and available for long-term follow-up
7. If the patient is assessed as being at high risk for nonadherence on the Beliefs about Medicines Questionnaire-Highly Active Antiretorivral Therapy BMQ-HAART, they are eligible to participate in the intervention trial.

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Exclusion criteria for both observational and interventional components:
1. Patients who do not speak English
2. Patients who will be leaving the country for 12 months after their treatment offer and hence will not be available for the follow-up appointments or telephone follow-ups
3. Patients who lack capacity to consent for themselves
4. Patients who have been hospitalised for a mental disorder in the past 2 years
5. Current suicidality or self harm
6. Pervasive developmental disorders
7. Active substance misuse/dependence in last three months which renders the patient unable to adhere to the study protocol in the opinion of the physician or investigator
8. Patients who have ever received antiretroviral therapy in outpatient care
9. Psychiatric or addictive disorders which could preclude obtaining informed consent

Criteria for discontinuation
Participants may be discontinued from participation in either the observational or interventional components of the study at any time, at the discretion of the Investigator. Specific reasons for discontinuing a participant from the study are:
1. Withdrawal of informed consent
2. Development of exclusion criteria or other safety reasons during the study
3. Incorrect enrolment or randomisation of the subject

Date of first enrolment
06/01/2014

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Pharmacy
London

United Kingdom
WC1H 9JP

Sponsor information

Organisation
Brighton and Sussex University Hospitals NHS Trust (UK)

Funder(s)

Funder type
Government

Funder Name
National Institute for Health (NIHR) (UK) - Research Central Commissioning Facility; Grant Codes: RP-PG-0109-10047

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/07/2019	17/12/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V2.0	04/03/2014	15/12/2017	No	Yes
Participant information sheet	version V1.1	29/08/2013	15/12/2017	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes