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FULL/LONG TITLE OF THE STUDY
Online Psychological Treatment for People with Painful HIV-related Peripheral Neuropathy (OPEN Study): Qualitative Investigation of Treatment Needs

NCT02972606

SHORT STUDY TITLE / ACRONYM

OPEN Study: Pain management treatment needs interviews

PROTOCOL VERSION NUMBER AND DATE

- Protocol version 5.0 24 April 2017

- **This protocol has regard for the HRA guidance and order of content**

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RESEARCH REFERENCE NUMBERS

IRAS Number:	205949
SPONSORS Number:	Not Applicable
FUNDERS Number:	PDF-2015-08-059

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: 

Date:
24/04/2017

.....

Name: (please print): Dr Whitney Scott

.....

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KEY STUDY CONTACTS

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Joint-sponsor(s)/co-sponsor(s)	Not applicable.
Funder(s)	National Institute for Health Research
Key Protocol Contributors	Professor Lance McCracken Professor Andrew Rice Dr Amanda Williams
Committees	Not applicable.

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STUDY SUMMARY

Study Title	Online Psychological Treatment for People with Painful HIV-related Peripheral Neuropathy (OPEN Study): Qualitative Investigation of Treatment Needs
Internal ref. no. (or short title)	OPEN Study: Pain management treatment needs interviews
Study Design	Qualitative Semi-Structured Interviews
Study Participants	Individuals living with HIV and chronic painful peripheral sensory neuropathy.
Planned Size of Sample (if applicable)	Approximately 30 participants.
Follow up duration (if applicable)	Not applicable.
Planned Study Period	November 2016 to August 2017
Research Question/Aim(s)	To investigate the needs of people with HIV and painful sensory neuropathy for a psychological treatment to reduce the impact of pain on quality of life. To explore the acceptability of an internet-delivered psychological intervention and to tailor the content and delivery format of the intervention to the identified needs of this group.

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FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research	Financial (salary costs of the CI, and training and research costs)

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ROLE OF STUDY SPONSOR AND FUNDER

The lead sponsor, King's College London, will take primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. King's College London also provides cover under its No Fault Compensation Insurance, which provides for payment of damages or compensation in respect of any claim made by a research subject for bodily injury arising out of participation in a clinical trial or healthy volunteer study (with certain restrictions).

The funder reviewed and approved the study in the process of the Chief Investigator's fellowship application. The Chief investigator must notify the funder of any publication at the time of submission or at least 28 days prior to publication.

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ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The study steering group will consist of Dr Whitney Scott, Professor Lance McCracken, Professor Andrew Rice, Dr Amanda Williams, and two patient representatives, Paul Clift and Paul Decle. The steering group will ensure that the study adheres to the protocol, and meets recruitment, data analysis, and dissemination objectives. Dr Whitney Scott will oversee the day-to-day management of the study.

Protocol contributors

Dr Whitney Scott drafted the protocol in collaboration with Professors Lance McCracken and Andrew Rice, and Dr Amanda Williams. Two patient representatives (Paul Decle and Paul Clift) provided input on the recruitment strategy, questionnaires and interview schedule, and participant information sheet and consent form. Another HIV patient organization (UKCAB) provided feedback on patient-facing study documents.

KEY WORDS: HIV, pain, peripheral neuropathy, psychological treatment, qualitative research

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STUDY FLOW CHART

Table 1. Timeline of Study Activities

Month	Nov '16	Dec '16	Jan '17	Feb '17	Mar '17	Apr '17	May '17	Jun '17	July '17	Aug '17	Sept '17
Recruitment/ screening	X	X	X	X	X	X	X	X	X		
Informed consent, questionnaire and interview completion	X	X	X	X	X	X	X	X	X		
Transcribing	X	X	X	X	X	X	X	X	X	X	
Data Analysis	X	X	X	X	X	X	X	X	X	X	
Dissemination									X	X	X

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STUDY PROTOCOL

OPEN Study: Pain management treatment needs interview

1 and 2: BACKGROUND and RATIONALE

The human immunodeficiency virus (HIV) remains a significant global health concern. An estimated 35 million people are infected with HIV worldwide (1, 2); approximately 110,000 infected individuals are in the United Kingdom (3). Antiretroviral therapies have significantly improved survival rates. At the same time, approximately 6,000 individuals are newly infected with HIV in the UK each year (3). Consequently, the prevalence of infected individuals is growing.

In well-resourced countries, the shift in HIV from a terminal illness to a chronic condition has contributed to a greater focus on disease and symptom management (4). Pain in the feet is one of the most predominant symptoms associated with HIV infection and treatment. Approximately 40 to 60% of people with HIV have peripheral sensory neuropathy (HIV-SN); 50-90% of these experience neuropathic pain (5-7).

Painful HIV-SN is associated with increased disability in daily activities, unemployment, and reduced quality of life (8). Additionally, painful HIV-SN is associated with numerous comorbidities, including depression, panic disorder, post-traumatic stress disorder, and substance abuse (9-13). Thus, untreated painful HIV-SN may contribute to significant individual, societal, and economic burden.

Presently, there are few options for medically managing painful HIV-SN. A systematic review of 19 randomized controlled trials (RCTs) of pharmacological treatments for painful HIV-SN indicated that efficacy was found only for topical capsacin, smoked cannabis, and subcutaneous nerve growth factor; however, only capsaicin is clinically feasible (14). Additional negative RCTs of pregabalin and capsaicin have since been published (15, 16). It has been concluded that there is an 'urgent need' to evaluate novel strategies to manage painful HIV-SN (14).

Psychological treatments, including Cognitive Behavioural Therapy (CBT), represent a potentially viable addition to the treatment of painful HIV-SN. In meta-analyses, CBT is associated with improved pain, function, and depression among individuals with chronic pain that is primarily musculoskeletal in origin (17). The development of accessible and cost-effective Internet-administrations of CBT for pain is another promising development in this area (18).

Within the broad category of CBT, Acceptance and Commitment Therapy (ACT) is a more recent treatment technology with growing support for individuals with chronic musculoskeletal pain. There are now 11 RCTs and numerous effectiveness studies supporting the efficacy and effectiveness of ACT for long-term improvements in pain, function, distress, and healthcare utilization (19, 20). ACT is a particularly promising innovation given its explicit theoretical basis—the psychological flexibility model. This model provides a unifying framework for targeting processes of change, evaluating treatment mechanisms and, ultimately, refining treatment (21). Additionally, the psychological

flexibility model and ACT are transdiagnostic, with applicability and demonstrated efficacy across a wide range of health conditions (22-24). Indeed, preliminary findings suggest an association between pain acceptance and improved HIV-related pain outcomes (25).

Despite advancements in research on CBT and ACT for musculoskeletal pain conditions, comparable research does not exist for individuals with painful HIV-SN. One systematic review of CBT for neuropathic pain identified only 3 RCTs (26). Only one of these RCTs focussed on HIV-related pain; this study had an unacceptably high dropout rate of 57% (27). Two additional observational cohort studies of group-based CBT for HIV-related pain showed similarly poor adherence (28, 29). There is a clear need for improving psychological interventions for individuals with HIV-related pain. Patient representatives and clinicians practicing in the area of HIV and pain management have been consulted with respect to this issue and have identified the need for better development and implementation of psychological treatments for pain in this population.

Improving psychological treatments for painful HIV-SN will likely require greater consideration of the psychosocial complexities associated with this condition. For example, HIV is most common among gay men, women, ethnic minorities, and intravenous drug users (3, 30). There is recognition of important healthcare disparities and under treatment of pain in these groups (31-33). However, the unique perspectives and needs of individuals in these groups are not typically incorporated into psychologically-based pain management interventions such as CBT/ACT. Moreover, findings from the available qualitative literature suggest that social stigma and interpersonal distrust may influence treatment engagement among individuals with HIV (34-38). However, research is needed to understand how these psychosocial issues can best be addressed within CBT/ACT for pain.

This study will use in-depth interviews to examine the needs of people with painful HIV-SN for a psychologically-based pain management treatment that may be delivered over the Internet. Interview questions will examine the impact of pain on people's lives and how they cope with pain, and participants' treatment needs in terms of treatment content and delivery format. Men, women, ethnic minorities, and people who use recreational drugs will be purposively sampled to ensure that interview responses reflect the views of people most commonly suffering from this condition.

3 THEORETICAL FRAMEWORK

Broadly speaking, the study is framed within a biopsychosocial understanding of the experience of chronic pain. The purpose of the study is to understand, from the perspective of people living with HIV-related painful peripheral neuropathy, people's needs for and views about a psychological approach to pain management delivered over the internet. As such, data collection and analysis will follow a grounded theory approach. Following this approach, meanings and themes that emerge from the interviews will be used to develop a conceptual understanding of participants' experiences of pain and their views about a new pain management intervention.

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4 RESEARCH QUESTION/AIM(S)

4.1 Objectives

The purpose of this study is to explore the needs of people with painful HIV-SN for a psychologically-based treatment for managing chronic pain.

4.2 Outcome

The interview responses will be used to develop and tailor an internet-delivered version of ACT for people with painful HIV-SN. Once developed, the new treatment will be tested in a feasibility trial (another study). It is hoped that tailoring the online ACT treatment based on the qualitative interview responses will increase the acceptability of the treatment and will improve treatment adherence rates.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Participants will complete semi-structured interviews. Prior to the in-depth interview, participants will complete a questionnaire package at home to bring to their interview appointment (20-30 minutes to complete). The questionnaire package will consist of demographic and medical history questions, and symptom and functioning questionnaires. Individual in-depth semi-structured interviews will be conducted given the potentially sensitive nature of the questions and to maintain participants' anonymity. Participants will be given the choice to complete the interviews at the Imperial College London campus of Chelsea & Westminster Hospital or Guy's Hospital Campus of King's College London, according to their preference.

At the beginning of the interview appointment, the interviewer will conduct a 5 minute clinical examination to assess of symptoms and signs related to peripheral neuropathy. In the event that questionnaires are not completed prior to the interview session, participants will be asked to complete the questions at the interview appointment or at home and to mail them back in within 2 weeks. Participants who have not completed the questionnaires 3 weeks after the interview will receive a telephone reminder.

Pre-Interview Questionnaires

Demographic, Medical History, and Internet Use Questions: Participants will be asked to report on the following demographic and medical history questions: age, gender, ethnicity, sexual orientation, education, employment status, living situation, date of HIV diagnosis, history of and current antiretroviral treatment, duration of foot pain, other chronic pain diagnoses, mental health diagnoses, current pain medications, current alcohol and drug use, and frequency of Internet use.

Pain intensity and interference: The Brief Pain Inventory (BPI) will be used to assess pain intensity and the interference of pain with daily functioning in seven domains: general activity, mood,

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walkingability, relations with others, sleep and enjoyment of life. The BPI has been shown to be a reliable and valid measure for use with people with neuropathic pain conditions, including peripheral neuropathy (39). Participants will also be asked to fill in a body map to indicate where they feel pain.

Neuropathic Pain Interview: The 7-item DN4-i (Douleur Neuropathique 4-interview, English version) interview (questionnaire version) will be conducted to identify the probability that the participant has neuropathic pain. A score of ≥3 out of 7 reflects a positive diagnosis of neuropathic pain (40) (41).

Patient Health Questionnaire (PHQ-9): The PHQ-9 (42) is a 10-item measure of the severity of depression symptoms based on the DSM-IV diagnostic criteria for depression. Each item is rated on a four point scale between 0 (not at all) and 3 (nearly every day). The PHQ-9 has shown reliability and validity as a measure of depressive symptoms and is commonly used as an outcome measure in studies of patients with chronic pain (42).

Interview Appointment

Assessment of neuropathy signs and symptoms

The Clinical HIV-associated Neuropathy Tool screening tool (12) will be administered at the beginning of the interview appointment (5 minutes). This 4-item tool comprises two subjective symptom questions (self-report of foot pain and foot numbness), and two objective signs on clinical examination (loss of vibration sense and loss of ankle reflex). Clinical examination of these signs does not require specialist medical training. Based on a previous study using the CHANT, patients are considered to have peripheral neuropathy if they are positive for one symptom and one sign in a bilateral distribution (43). Previous data indicate that the CHANT has 100% sensitivity and 85% specificity for diagnosing HIV-SN in a London-based sample in relation to a more comprehensive neurological examination (The Utah Early Neuropathy Score) as the reference standard (43). Information from the physical examination of the CHANT will be used to further support the case definition of peripheral neuropathy from the telephone screening. However, findings of positive signs from the physical examination are not a requirement for study inclusion and all participants will proceed to the semi-structured interview.

Semi-structured interview

The interview schedule was developed on the basis of previous qualitative studies on psychological factors and treatments for pain in general and specifically in people with HIV (44, 45) and online CBT for pain management (46), and patient input. Participants will first be asked general questions about the impact of pain on their lives and how they currently cope with pain. They will also be asked more specific questions about their thoughts about an online psychological treatment for managing pain. While an interview schedule has been developed for the study, we expect questions to be further developed and revised during the study as data and themes emerge that require further probing.

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Dr Whitney Scott will conduct the interviews, which are expected to take approximately 1 hour each. Field notes will be made during/immediately after the interview to record the interviewer's impression of the participant's responses and the interview process. All interviews will be recorded using a dictaphone, transferred to a password-protected computer, and anonymised by Dr Whitney Scott. Dr Whitney Scott and a Bachelor's level (or higher) student or volunteer will transcribe the anonymized audio recordings verbatim.

Thematic analysis will be used to analyse the data following the recommendations of Braun and Clark (2006): Each transcript will be read in its entirety several times to establish familiarity. First level-descriptive codes will be annotated in the margin of the transcript. Second level codes will be used to summarize the most significant/frequent first-level codes; third-level codes will be used to identify higher order themes around which lower order themes are integrated. Quotes reflecting second-level themes will be extracted to demonstrate second-level themes for the final report (47). The NVivo 11.0 software program will be used to assist in data analysis. This process will be initially conducted by one coder; two additional coders will code 10% of the transcripts to establish the validity of the codes. Validity will also be established through use of the constant comparative method whereby the transcripts will repeatedly be reviewed to check that identified 2nd and 3rd level themes correspond to the data.

6 STUDY SETTING

Participants will primarily be recruited from St Stephen's Centre at Chelsea and Westminster Hospital and affiliated HIV and pain clinics in London. St. Stephen's Centre is one of the largest HIV centres in Europe. Recruiting participants from Chelsea and Westminster Hospital NHS Trust will ensure participants recruited into the study are representative of the population of interest.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

- Adults aged 18 years or older.
- Living with HIV.
- A positive screen for peripheral sensory neuropathy, as indicated by: presence of self-reported bilateral foot pain and/or numbness in a symmetrical distribution (43).
- Positive screen for symptoms of neuropathic pain in the feet, as indicated by a score of ≥3 on the patient reported outcomes section of the Neuropathic Pain Interview, which has

previously been shown to have greater than 80% sensitivity and specificity for identifying people with neuropathic pain conditions (48, 49)

- Pain in the feet present most days for at least 3 months.
- Average pain intensity of ≥4 on a scale from 0 (no pain) to 10 (pain as bad as you can imagine)(50).
- Average interference of pain with daily activities is ≥4 on scale ranging from 0 (no interference) to 10 (unable to carry on any activities) (51).

7.1.2 Exclusion criteria

- Presence of excessive alcohol consumption, hypothyroidism, vitamin B12 deficiency, diabetes, exposure to isoniazid or chemotherapy drug treatment, or a known history of a neuropathy due to a cause other than HIV or antiretroviral treatment (12, 52)
- Unable to conduct interview in English.
- Current diagnosis of dementia or learning disability.
- Unwilling to provide written informed consent.

7.2 Sampling

7.2.1 Size of sample

Approximately 30 participants will be recruited, with roughly equal representation of men, women, ethnic minorities, and people who use recreational drugs. Recruitment will terminate once saturation of themes has been achieved. Thus, while an approximate sample size has been estimated on the basis of convention in qualitative methods and the range of demographic characteristics being sought (53, 54), an exact sample size cannot be determined a priori.

7.2.2 Sampling technique

Men and women, ethnic minorities, and people who use recreational drugs will be purposively sampled through HIV and pain clinics and community organizations and through chain referral sampling. Purposive sampling across participants with the range of demographic backgrounds identified will ensure that the interview responses are reflective of people with painful HIV-SN who might ultimately be referred to and receive the psychologically-based pain management treatment being developed.

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7.3 Recruitment

7.3.1 Sample identification

Participants will be recruited from St Stephens Centre at Chelsea and Westminster Hospital NHS Trust and associated HIV and chronic pain clinics in London (e.g., Kobler Day Care Unit, John Hunter Clinic, Dean Street Clinic, and the 10 Hammersmith Broadway Clinic). Consultants at these clinics will identify potentially eligible participants in the course of their routine clinical care and will ask patients for permission to give their name and contact information to the study coordinator (Dr Whitney Scott). For patients who agree to this, the study coordinator will conduct eligibility screening either in person at the clinic or over the telephone. We will also post recruitment advertisements in the waiting areas of these clinics which will instruct interested patients to contact the study coordinator directly to discuss the study and conduct eligibility screening.

Patients with HIV and painful peripheral neuropathy that have participated in a previous study at Chelsea and Westminster Hospital (the HIV-POGO Study) who have explicitly consented to be re-contacted for future studies will also be contacted to ask to inform them of the current study. A member of the research team from the HIV-POGO study will provide Dr Whitney Scott with the contact information of individuals who have previously consented to be contacted for future studies. Dr Whitney Scott will then contact these individuals by letter and telephone to provide information about the study and conduct eligibility screening.

Recruitment advertisements will also be sent to local HIV community groups to post in their centres and on their websites and social media accounts. Advertisements posted with these groups will ask potentially eligible and interested people to contact the study coordinator for further information and screening. Recruitment advertisements will likewise be posted on social media accounts for the study (e.g., Twitter). Lastly, eligible participants will be asked to give recruitment flyers to other potentially eligible individuals from their social network. Chain referral sampling is often used in qualitative research to recruit minority and stigmatized groups that are difficult to access *(55)*.

In the recruitment process, potential participants will be informed that they will receive a £20 voucher and travel expenses up to £15.

7.2.2 Consent

Following screening, the study coordinator will review the participant information sheet with eligible participants either in person or over the telephone to describe the nature and objectives of the study and possible risks. Potential participants will be given the opportunity to ask the researcher any questions at this time. Potential participants will be given up to 1 month to consider the information and to decide whether they want to participant or not. Eligible individuals will be mailed a copy of the information sheet along with two copies of the consent form, and the pre-interview

questionnaires. Participants will be asked to bring the completed consent form to their interview appointment. The right to refuse to participate without giving a reason will be respected. We will emphasize that participants are free to withdraw at any time without consequence.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

Participants' involvement in the study will contribute to further developments in psychological treatments for people with painful HIV-related peripheral neuropathy. Participants will receive a gift voucher as compensation for their time. We cannot guarantee any further benefits to participants for their involvement in the study.

Adverse events arising from this observational study are expected to be rare. However, it is possible that participants could become distressed in the course of the interview given the potentially sensitive nature of the questions. Dr Scott will debrief participants about any distress that comes up in the interviews. The interviewer, Dr Whitney Scott, is a registered clinical psychologist and will remain sensitive to this issue. All participants will be informed of their right to stop the interview at any time and that information will be kept strictly confidential. Participants can request to withdraw parts or all of their data.

We will write a letter to the GP to inform him/her of the participant's involvement in the study. Participants who score 10-14 on the PHQ-9 will be made aware of their score and will be recommended to contact their GP if they are concerned about this. Participants who score 15 or greater on the PHQ-9 will be informed of this, and will be told that Dr Scott will directly contact their GP to discuss this. A similar procedure will be followed if we discover any other symptoms that might pose a risk to a participant's health or well-being during the course of the interview appointment.

8.2 Research Ethics Committee (REC) review & reports

NHS REC approval will be obtained prior to beginning the study. Substantial amendments will not be implemented prior to REC approval. All correspondence with the REC will be retained. The Chief Investigator will submit an annual report as required, and will notify the REC of the end of the study and will submit a final report.

8.3 Peer review

This study was reviewed by the National Institute for Health Research in the process of reviewing a fellowship application that was awarded to Dr Whitney Scott. Two independent, expert reviewers reviewed the study as part of this fellowship application.

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8.4 Patient & Public Involvement

Paul Decle and Paul Clift are patient representatives located at St. Stephen's Centre at Chelsea and Westminster Hospital and at King's College Hospital, respectively. Paul and Paul were consulted about the study during the application for funding of a fellowship to undertake a larger project to develop and test the feasibility of an online psychologically-based pain management treatment for people with painful HIV-SN. Both Paul and Paul were enthusiastic about the potential benefits of the new treatment, but identified patient engagement as an important issue. This input solidified the need to incorporate a qualitative study of barriers to patient engagement for the proposed online treatment, which will feed into further treatment development.

The patient representatives were involved in the design of the research in several ways. Paul Clift suggested that a multi-pronged recruitment strategy was the most appropriate to ensure we capture the views of the diversity of people with painful HIV-SN. This informed our recruitment strategy. Paul Decle did not feel that peer/patient interviewers for the qualitative study were appropriate, and, therefore, it was decided that a researcher (Dr Whitney Scott) would conduct the interviews. Paul Decle also suggested suitable remuneration (e.g., vouchers) for participants in the interview study. Paul and Paul reviewed study documents (e.g., recruitment adverts, information sheet, consent form, questionnaires, and interview schedule) and made several suggestions for re-wording, which were incorporated into the current version of the documents. UKCAB, which is an advocacy group of people living with HIV, also provided feedback on the study documents, which was also incorporated.

Paul and Paul will be consulted to provide input on the themes coded from the transcribed interviews to ensure their relevance and appropriateness. Paul and Paul will also review a study report that will be given to patients following completion for the study to ensure its comprehensibility and sensitivity.

8.5 Regulatory Compliance

The Chief Investigator will ensure that the study is conducted in compliance with the principles of the Declaration of Helsinki (1996), and in accordance with all applicable regulatory requirements including the Research Governance Framework. The Chief Investigator will ensure that NHS Research and Development (R&D) permission has been granted from the relevant site prior to beginning research at those sites. The project is eligible for inclusion in the NIHR Clinical Research Network portfolio and this will be applied for via the IRAS system.

8.6 Protocol compliance

Any serious breaches from the approved protocol will be documented by the Chief Investigator and reported to the Sponsor immediately.

8.7 Data protection and patient confidentiality

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All investigators will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information.

For patients recruited from Chelsea and Westminster Hospital (C&W), or participants recruited from the community who complete study procedures at C&W, participant identifying information will be stored on a secure NHS computer at C&W along with the anonymization log. Paper copies of consent forms will be stored in a locked filing cabinet in a locked room at C&W. All participants will be given an anonymous study identification number that will be used for screening, questionnaires, audio files and transcripts, so no identifiable information will be linked with these data. Anonymous questionnaire data will initially be collected on paper case report forms (CRF), which will be stored in a locked filing cabinet in a locked room at C&W. Data from paper CRFs will subsequently be entered in an electronic database stored on a secure computer.

Interviews will be recorded using a password protected dictaphone. The audio recording of interviews will be uploaded to a secure computer and any interview responses that identify the participant will be removed. Audio recordings will be erased from the dictaphone after being transferred to the computer. The anonymized audio files and questionnaire database will be transferred to a secure King's College London computer for analysis using an encrypted USB stick.

The identifying data of participants recruited from community organizations who complete study procedures at King's College London will be stored on a secure King's College London (KCL) computer at Guy's Hospital. Hard copies of consent forms will be stored in a locked filing cabinet in a secure room at KCL. Paper copies of anonymized questionnaires will likewise be stored in a locked filing cabinet in a secure room at KCL. The anonymized electronic questionnaire database, audio files and transcripts will be stored on a secure KCL computer. All audio files will be destroyed after they have been transcribed.

Only researchers associated with the study (from King's College London, Imperial College London, and University College London), the two patient representatives, and the study sponsor (King's College London) will have access to the data for the purpose of carrying out the research as described and monitoring the quality of the research. Dr Whitney Scott will be the custodian of the data. Data will be securely kept for 10 years following completion of the study.

8.8 Indemnity

King's College London will serve as the sponsor for the study and will provide indemnity for any harm to participants arising from the research.

8.9 Amendments

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The Chief Investigator will decide whether amendments are substantial or non-substantial. For all amendments, Dr Whitney Scott will notify the study sponsor, NHS REC, and the Research and Development teams at all study sites. Substantial amendments will be submitted via IRAS to the lead CRN. No amendment will be implemented prior to approval from sponsor, REC, and R&D. A study document list will be used to track the most recent versions of the protocol and other study documents.

8.10 Access to the final study dataset

Dr Whitney Scott, Professors Lance McCracken and Andrew Rice, Dr Amanda Williams, Paul Clift and Paul Decle will have access to the final anonymized study dataset. A Bachelor's-level (or higher) student (not yet identified) may also have access to the anonymous dataset as part of his/her thesis project. Only Dr Whitney Scott will have access to the anonymization log that contains participant identifiable information.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

King's College London will own the data arising from the study. The study protocol will be made publicly available through registration with clinicaltrials.gov prior to commencing study recruitment. Following completion of the study and data analysis, the study will be written up for submission for conference presentations and publication in peer-reviewed journals; published journal articles which will be made available through open-access where possible. NIHR will be acknowledged as the funder of the study in all publications. NIHR will be notified at the time of submission of any publication (oral or written) or 28 days prior to the intended publication date, whichever is earlier (according to the funding agreement). Anonymized data will also be presented community dissemination events (e.g., at meetings of relevant patient groups). A newsletter drafted in collaboration with Paul Clift and Paul Decle will be sent to participants to notify them of the study results and posted on the study website. A study newsletter will also be sent to clinicians working in the area of HIV and chronic pain.

9.2 Authorship eligibility guidelines and any intended use of professional writers

All listed contributors to this protocol are expected to gain authorship on any publication arising from this study. The following criteria will determine eligibility for authorship as per the International Committee of Medical Journal Editors: 'Substantial contributions to the study conception or design of the work, or data acquisition, analysis, or interpretation; contributing to the manuscript draft and revisions, and approving the final draft; and, agreement to be accountable for all aspects of the work.'

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