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Prolonged-release opioid for recovery

Submission date	Recruitment status	[ ] Prospectively registered
08/04/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/04/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/07/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

A body of literature describes the experience of stigma and shame that people who use drugs (PWUD) are subjected to, within both the wider community and in healthcare settings. PWUD are often considered to live outside of the everyday social norms of society. As a result they can be described as having tainted identities and regarded as second class citizens. One consequence of this is that PWUD are deprived of choice, options and inclusion.

The use of pharmacological approaches has been a mainstay of UK treatment for opiate dependency for many years. The use of opiate substitution therapy (OST) is well evidenced, and for the vast majority of patients prescribed on a daily dispensing (supervised or unsupervised) basis. However, OST is often criticised for oppressive and "normalising" effects, with very little change happening for those prescribed. A body of work describes the mechanics of the delivery of OST as a factor in producing an environment in which change is difficult to achieve. The “methadone queue” is often perceived as stigmatising and in which the behaviours experienced and the obligatory social relationships negotiated make it difficult to make the desired identity change.

A new OST option is now available. Prolonged-release subcutaneous buprenorphine can be administered at weekly or monthly intervals. The introduction of prolonged-release subcutaneous buprenorphine products provides an opportunity to deliver OST in an alternate way, allowing greater flexibility for both clinician and patient.

This study will investigate if prolonged-release buprenorphine can be the catalyst for change over an 18-month period. It will investigate if it allows those receiving this type of OST to create a new identity, strengthen or make new relationships and mobilise new resources such as increased wellbeing, employment and education opportunities and social inclusion to aid a recovery journey.

Who can participate?

Patients aged 18 years or over who are receiving buprenorphine from Drug and Alcohol Recovery Services in Tayside. Up to 10 staff participants from these services can also participate

What does the study involve?

This study involves three appointments with researchers from the University of Dundee over the course of 18 months. These appointments will be face-to-face or by telephone call. The researchers will collect information about patient participants' lives, including their living arrangements, employment, and financial situation. They will also record information about their

medical history, including past and current drug use. Patient participants will be asked to complete some questionnaires about how they are feeling and how much they are in control of what happens in their lives. The researcher will also interview patient participants about being prescribed buprenorphine and how it affects their lives. The interviews will be recorded, which will then be typed up and analysed for themes.
The second appointment will be 3-15 months after the first one and the final appointment will be 1-2 years after the first.
Staff participants will be recruited from the teams caring for people prescribed prolonged-release buprenorphine (Buvidal). Their views and experiences with Buvidal will be captured using semi-structured interviews and/or focus groups.

What are the possible benefits and risks of participating?
The study may not benefit participants directly but it is hoped that it will give a better understanding of the effect of different types of OST on people's lives and help determine the right type for people in the future. It is possible that some of the questions in the questionnaires or in the interview may cause participants distress or discomfort. Participants can stop the interview at any time and the researcher will be trained to support participants. In thanks and compensation for their time they will be offered a supermarket voucher. A £10 voucher will be offered after visit 1 and 2 and £20 voucher after visit 3.

Where is the study run from?
Drug and Alcohol Recovery Services in NHS Tayside, conducted by researchers based in NHS Tayside and the University of Dundee (UK)

When is the study starting and how long is it expected to run for?
June 2021 to January 2025

Who is funding the study?
Camurus (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305675

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 305675, Sponsor 3.08.21, Protocol 3.08.21, CPMS 52198

Study information

Scientific Title
Agent for recovery: the opportunity for enhancing social inclusion afforded by prolonged-release buprenorphine formulations

Acronym
PROP

Study objectives
Does Buvidal provide the opportunity for an individual to gain a greater sense of belonging to a community through social identity change?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/01/2022, North West- Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0) 2071048009; gmeast.rec@hra.nhs.uk), ref: 21/NW/0358

Study design
Mixed methods ethnographic case study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Patient participants prescribed a buprenorphine formulation by NHS Tayside Drug and Alcohol Recovery Services for their opioid dependence

Interventions
Up to 60 patient participants will be recruited from drug and alcohol recovery services in Tayside, Scotland. Patient participants will be recruited from patients receiving prolonged-release subcutaneous buprenorphine, weekly or monthly, as per standard pathway of care (up to n=30) and a control arm (up to n=30) of those currently prescribed oral buprenorphine formulations as per the standard pathway of care. This study has no influence on the prescribing choices of the drug and alcohol recovery services or patients.

An estimated 10 staff participants will be recruited from the multidisciplinary drug and alcohol recovery service teams providing care to the patients receiving prolonged-release subcutaneous buprenorphine to capture their views and experiences through semi-structured interviews and /or focus groups.
Patient participants will be followed up over an 18-month period and interviewed at three timepoints (visit 1 [baseline], visit 2 [9 months (+/- 6 months)], visit 3 [18 months (+/- 6 months)]) by the researchers to provide a long-term view on the individual and societal benefits of prolonged-release buprenorphine.
Semi-structured interviews will be used to describe the views, meanings and values for individuals of their OST treatment at three timepoints over an 18-month period. A study topic guide will be used as the baseline for the semi-structured interviews. The interviews will be audio-recorded and transcribed verbatim. The resulting transcripts will be thematically analysed with themes coded.

A number of questionnaires will also be used to capture patient experience, wellbeing and social identity:
1. Social Identity Mapping: The participants will be asked to place their social networks on a mapping tool that will provide a graphic representation of the social network at that point in time. The participant's name will not be recorded on the map, only the participant ID number. The map will demonstrate the number of social contacts within the network, a measure of the relationship (inner circle, outer circle and influence) and the substance use status of the members of the network. Participants will be asked to assign pseudo identities for their social network members as the participant needs to be able to classify the individuals within their own network and document how this may change over time. The pseudo-identity is known only to the participant and will be insufficient for the researcher to identify an actual person. The participant will rate the importance of their social network members (indicated by placing them in the inner or outer circle) and indicate their status as user, non-user or in recovery. Social contact pseudo identities will be assigned coloured dots to indicate their status: red for active user, green for non-user and blue for individuals in recovery. This tool provides a quantitative measure of their social network and will be mapped at each interview stage so that longitudinal insights into the change in social influences may be clearly described.
2. Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWS): Patient participants will be asked to complete the self-reported short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) with assistance from the researcher if required. The measure is a list of seven positive mental health statements with five response categories assigned scores and the total scores calculated. Movements in the total wellbeing score have been evaluated using the wellbeing valuation method and represent the additional money the average individual would need to improve their wellbeing, which is the same as the improvement in their SWEMWBS score. This measurement can then be used to calculate a social value impact.
3. Financial Inclusion Data: Participant data will be collected at visit 1 (baseline), 2nd visit and 3rd visit to record age, gender, ethnic background, financial inclusion, household income and employment data, current and/or previous treatment for problematic substance use. The questions included are part of the Scottish Survey Core Questions and are recommended for use in other surveys as they have been extensively tested.
4. Citizenship Measure: A measure of citizenship (Yale University's 5R's of citizenship tool) will provide a description of how these participants are able to reclaim citizenship. Citizenship is similar, yet distinct from quality of life and wellbeing. This tool measures the ability of people to reclaim citizenship, defined by Rowe as the 5R's of citizenship: Relationships, Resources, Responsibilities, Rights and Roles. The measure is a 46 item tool that measures demographic factors, sense of community, and social capital as predictors of citizenship, recovery, and well-being.
5. Observational field notes: Observational notes will be maintained by the researcher during the time period under investigation to allow for description and understanding of the order of events and actions. The researcher will record participant observations to provide rich verbatim descriptions of the specific situations, events and behaviours of the participants. These observations will be included in the thematic analysis of the data and clearly reported as observations differentiated from participant descriptions. Explicit description of the researchers' analytical thinking will be maintained using field notes with a clear description of the decision-making process while developing initial and final themes.

Intervention Type
Other

Primary outcome measure

The thematic narrative of semi-structured interviews describing the views, meanings and values of participants at baseline (visit 1), visit 2 and visit 3

Secondary outcome measures
Measured at baseline (visit 1), visit 2 and visit 3:
1. Wellbeing of the population described using the Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS)
2. Social and financial characteristics of the population described using financial inclusion data from Scottish Core Survey Questions (captured on Case Report Form)
3. Shifts in social networks described using social Identity mapping
4. Social inclusion of the population described using the 5R's of citizenship tool

Overall study start date
14/06/2021

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Adult (aged 18 years or over) males and females
2. History of problematic substance abuse
3. Treated in NHS Tayside with either Buvidal (prolonged-release buprenorphine) or sublingual /oral lyophilisate buprenorphine
OR
4. A member of the multidisciplinary alcohol and drug recovery service team in NHS Tayside (staff participant only)
AND
5. People of any ethnic origin who are able to speak English and are willing to talk about and reflect on their experiences with the phenomenon under study
6. Willing to have the semi-structured interviews audio recorded
7. Able to give informed consent

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

60 patient participants (n=30 receiving prolonged release buprenorphine subcutaneous injection [Buvidal] and n=30 control arm receiving oral formulations of buprenorphine). Plus up to 10 staff participants.

Total final enrolment
57

Key exclusion criteria
1. Individuals will not be enrolled on the study if they are participating in the clinical phase of another interventional study or have done so within the last 30 days
2. Individuals who are participating in the follow-up phase of another interventional trial/study, or who are enrolled in an observational study, will be co-enrolled where the CIs of each study agree that it is appropriate

Date of first enrolment
19/04/2022

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NHS Tayside
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
NHS Tayside

Sponsor details
Research Governance
Tayside Medical Science Centre (TASC)
Ninewells Hospital & Medical School
Dundee
Scotland

United Kingdom
DD1 9SY
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Sponsor type
Hospital/treatment centre

Website
http://www.nhstayside.scot.nhs.uk/index.htm

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Industry

Funder Name
Camurus AB

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal and presentation at relevant conferences.

Intention to publish date
31/03/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request from SDonaldson001@dundee.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	07/01/2022	08/04/2022	No	Yes
Participant information sheet	version 2.0	07/01/2022	08/04/2022	No	Yes
HRA research summary			28/06/2023	No	No