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Testing a new intervention to support people who are dependent on opiate and benzodiazepine drugs

Submission date
18/10/2023

Recruitment status
No longer recruiting

Registration date
23/10/2023

Overall study status
Completed

Last Edited
10/06/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Scotland has the highest rate of drug-related deaths in Europe. It is a feature of deaths in Scotland that people use combinations of drugs which increases the chance of a drug-related death. Many of these combinations involved benzodiazepine drugs which come from illegal sources. People who use opiates can be prescribed a safer replacement drug (e.g. methadone). Guidance on the management of benzodiazepine use highlights that there is little evidence to support replacement prescribing. However, the evidence is conflicting. This study aims to test a new intervention, designed by consulting people who use ‘street’ benzodiazepines and clinicians.

Who can participate?
Anyone over who is being treated for opiate dependence in a specialist addiction clinic but is also using illicit, unregulated 'street' benzodiazepines

What does the study involve?
The intervention is a combination of prescribed diazepam as a safer supply alongside psychosocial support which targets the motivations for use. Questionnaires and interviews will be used to assess whether the intervention is feasible.

What are the possible benefits and risks of participating?
The benefits could be better support to deal with the reasons people use illicit benzodiazepines and hopefully a move away from using these highly risky drugs. The risks are that any benzodiazepine alongside an opiate brings a risk of sedation and respiratory depression (slow and ineffective breathing).

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

When is the study starting and how long is it expected to run for?
May 2021 to August 2023

Who is funding the study?
The Chief Scientist Office of the Scottish Government (UK)

Who is the main contact?
Prof. Catriona Matheson, catriona.matheson@stir.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Prof Catriona Matheson

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304108

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 304108, CPMS 53238

Study information

Scientific Title
Developing an intervention to manage benzodiazepine dependence and high-risk use in the context of escalating drug deaths: a feasibility study

Study objectives
This was a feasibility study to test an intervention aimed at reducing the harmful use of illicit benzodiazepines in people also being treated for opiate dependence.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/10/2021, North of Scotland Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 21/NS/0135

Study design
Single-arm feasibility trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community, Other

Study type(s)
Prevention, Quality of life, Treatment, Safety

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
High-risk illicit drug use

Interventions
The intervention tested was a prescription of diazepam at a maximum dose of 30 mg, and a fortnightly nurse session addressing: anxiety, sleep and pain management and harm reduction support to reduce high-risk use of illicit drugs. Duration: 6 months for intervention and follow-up.

Intervention Type
Mixed

Primary outcome measure
Use of illicit benzodiazepines measured using self-report and oral fluid testing monthly during the study

Secondary outcome measures
1. Cognitive ability assessed using Addenbrooke's Cognitive Evaluation (ACE III) at baseline & follow-up (6 months)
2. Quality of life assessed using EQ5D-5L monthly during the study
3. Anxiety assessed using General Anxiety Disorder (GAD-7) at baseline & follow-up (6 months)
4. Depression assessed using Patient Health Questionnaire-9 (PHQ-9) at baseline & follow-up (6 months)
5. Self-assessed substance use recovery assessed using SURE questionnaire at baseline & follow-

up (6 months)
6. Economic evaluation using NHS service use questionnaire completed monthly during the study
7. Satisfaction with professional care assessed using Consultation and Relational Empathy Measure (CARE) at follow-up (6 months)

Overall study start date
01/05/2021

Completion date
31/08/2023

Eligibility

Key inclusion criteria
1. People in NHS drug treatment services who have achieved a stable dose of ORT (methadone or buprenorphine)
2. Have the capacity to provide informed consent
3. Experiencing ongoing risk of harm from street benzodiazepine use. 'Risk of harm' was defined as: an overdose event in the last 6 months in which a street benzodiazepine was implicated (from toxicology or clinical profile) and/or persistent self-report of daily street benzo use that is confirmed by toxicology screening and/or self-report of regular use of high doses/quantities of street benzodiazepines

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
45

Total final enrolment
39

Key exclusion criteria
1. Co-occurring harmful alcohol use
2. Co-occurring harmful stimulant use
3. Pregnancy
4. Participation in any other research study
5. Diagnosed serious mental illness or severe cognitive impairment that clinical staff consider

poses a risk to safety (of patient or staff)
6. Non-English speaking
7. People who do not have the capacity to provide informed consent
8. 'Harmful' alcohol or stimulant use was use at a level in which it was the dominant problem for that individual

Date of first enrolment
01/05/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Aberdeen City Integrated Drug Service, NHS Grampian
Royal Cornhill Hospital
Aberdeen
United Kingdom
AB25 2ZH

Study participating centre
NHS Fife Addiction Service
Cameron Hospital
Cameron Bridge
Windygates
Windygates
United Kingdom
KY8 5RR

Study participating centre
NHS Lothian Community Addiction Service
Spittal Street
Edinburgh
United Kingdom
EH3 9DU

Sponsor information

Organisation
University of Stirling

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Sponsor type
University/education

Website
https://www.stir.ac.uk/

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Three publications are planned:
1. A feasibility trial description
2. A qualitative paper describing the experiences of the intervention
3. Description of the intervention development process

Intention to publish date
30/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study will be available on request from Catriona Matheson (catriona.matheson@stir.ac.uk).
The type of data that will be shared: the dataset of the outcome measure data collection could be shared on request.
Dates of availability: after publication, not known precisely when that will be.
Whether consent from participants was required and obtained: not obtained but it will be anonymised at the point of sharing.
Comments on data anonymization: the data is anonymised and uses a study participant ID. However, it will need further removal of site to a site ID.

IPD sharing plan summary
Available on request