

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	<input type="checkbox"/> Prospectively registered
Registration date 23/10/2023	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/12/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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 18 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

Contact name

Prof Catriona Matheson

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

304108

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Prevention, Quality of life, Safety, Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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

United Kingdom

Scotland

Study participating centre

Aberdeen City Integrated Drug Service, NHS Grampian

Royal Cornhill Hospital

Aberdeen

Scotland

AB25 2ZH

Study participating centre

NHS Fife Addiction Service

Cameron Hospital

Cameron Bridge

Windygates

Windygates

Scotland

KY8 5RR

Study participating centre

NHS Lothian Community Addiction Service

Spittal Street

Edinburgh

Scotland

EH3 9DU

Sponsor information**Organisation**

University of Stirling

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

National government

Location

United Kingdom

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/12/2025	17/12/2025	Yes	No
Funder report results			11/09/2025	No	No