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Using a respiratory monitoring device to reduce drug harm

Submission date 07/01/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/01/2025	**Overall study status** Ongoing	
Last Edited 18/08/2025	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
The United Kingdom is currently experiencing an opiate drug overdose crisis and we are committed to helping people who are at risk of opiate drug overdose. When someone experiences an overdose, their breathing is slowed to a dangerous, and sometimes fatal level. In the hospital, doctors and nurses can easily monitor patients' breathing. However, monitoring someone's breathing in the community, e.g., in a homeless accommodation, hasn't been possible until now. Technology is available that consists of a small, discreet sensor that sticks to the chest area and monitors chest movement and has the potential to detect when a person is experiencing abnormal breathing relating to an overdose. This device has the potential to alert individuals, household members, friends and family, or emergency services, who can come and give lifesaving naloxone. We want to conduct this study to understand if wearing the device is possible for people who are at risk of overdose, as well as to collect information to understand their normal breathing patterns.
This study is testing if wearing the device is possible for people by looking at the amount of time that data is collected when participants are wearing the sensor and by interviewing participants about their thoughts and feelings about wearing the device. We also want to collect data that can be used to understand normal breathing patterns and patterns that might trigger an emergency response if someone is experiencing an overdose.

Who can participate?
People over 18 years of age who use drugs who live in supported accommodation

What does the study involve?
At a participant's first visit, the study will be carefully explained to them by a staff member who works in the accommodation. They will have as much time as they need to think about their participation and following that, if they are happy to take part, they will be asked to sign a consent form.
The study will involve wearing the device overnight if the participant is only staying for a short time or up to 4 weeks if they are staying longer. There is an option to wear the device for longer than 4 weeks, if the accommodation staff suggest it and the participants agrees. The study will last for 1 year, this would be the longest time a participant would be asked to wear the device for. At their first study visit, after agreeing to take part, the staff member will take a brief

medical history and take their height and weight measurements to calculate their BMI, as this can impact their breathing pattern. The staff will ask the participant for some information about themselves and ask them to complete a questionnaire about their drug use. The information they provide in this questionnaire will be recorded anonymously with a participant number instead of their name and will be used to demonstrate rates of drug use to overdose risk so that the way the device works can be more effective. They will then be given instructions on how to wear the sensor on their chest area, and staff will explain where the tablet which collects data from the sensor on their chest movement is located in their room. Participants will also be supplied with and instructed on using a paper diary to record when they are taking their drugs and prescription medication. An accommodation worker will check in on participants at least once in an evening to make sure they are wearing the device, it is working correctly and they are safe.
Participants will be required to wear the sensor continuously while they are in the accommodation but should remove it and leave it in their room if they are going out. If they forget and leave the sensor on when they go out, the sensor light will flash red until it comes back into range of the tablet. If they are leaving the accommodation permanently, they should return the device to an accommodation worker. Participants should swap the side of chest the device is on once a week.
Participant data will not be monitored during the study. All analysis will be carried out after the study is completed.
After each 4-week period (or after their first evening if they are a short-stay resident), they will be asked to complete a satisfaction survey to highlight any issues with wearing the sensor.
During the participants' last study visit, they will return the device, tablet and diary. They will be asked if they would like to take part in an interview and/or focus group about their experiences, thoughts and feelings on wearing the device. They may also be asked about their thoughts on the development of an intervention pathway (creating the most effective way to refer people and encourage people to wear the device) using the device to trigger an emergency response if someone is experiencing an overdose.

What are the possible benefits and risks of participating?
There is zero to minimal risk to participants from the biosensor itself. It may be mildly uncomfortable to wear initially but participants should soon become used to it. Several Clinical Research projects have been conducted with the technology (e.g., RESCU: RESpiratory monitoring reduCing drUg harm, IRAS 301153) with over 150 participants and 15,000 hours of wear. No adverse events related to the biosensor have been reported.
There is no risk of personal data being revealed via the DC Mobile software. All chest movement data is anonymous.
Participants are people who actively use drugs and may be at risk of accidental overdose. Supported accommodation sites involved in the study have trained staff to administer naloxone, to reverse the effects of an opioid overdose or to administer first aid. Participants will be informed that the device will not issue an alert in the event of a potential overdose. Supported accommodation staff perform regular wellness checks on residents who show signs of drug use throughout the evening. Staff will continue to perform these checks on study participants, so there is no change to the risk of accidental overdose.
Sites provide advice and additional services to help residents stop using opiates and other drugs. Participants will not be disincentivised from using these services.
The study will not immediately benefit participants, but if the results of the study are positive, it may lead to a future study in which we would develop an intervention pathway that uses the device to potentially trigger an emergency response if a person is experiencing an overdose.
For taking part in the study, participants will be offered £25 per week over the 4 weeks they wear the device, providing they have been wearing it and the tablet is still in their room and working. If they are a short-stay participant, they will receive £5 each time they return the device

and tablet the morning after use – up to a maximum total of £25. If they take part in an interview, they will receive £20. If they take part in a focus group, they will receive £10. Where possible, payment will be made by using the Cash Out system. Participants will receive a text message they can show at any shop with a PayPoint sign to receive the cash value. If they do not have a mobile telephone, they will be paid in cash or receive a shopping voucher of the same value.

Where is the study run from?
Supported accommodation for homeless people in Scotland and England.

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

Who is funding the study?
Scottish Government Office of Life Sciences

Who is the main contact?
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Feasibility of virtual safe drug consumption technology, using respiratory monitoring to reduce drug harm

Acronym
RESCU-2

Study objectives
Recently, technological developments in wireless ‘wearable’ devices have enabled real-world, real-time measurement of physiological functioning. Remote measurement of respiratory, cardiovascular, and motor function has the potential to detect opioid overdose automatically and reliably (Goldfine, 2020). However, currently available wearable devices have no ability to detect respiratory depression and have limited utility for use as regulated medical devices. Existing chest-worn vital sign sensors are not practical or economically viable for individual use in the community. In addition, little research into the efficacy of remote overdose detection has been conducted. A chest sensor that reliably detects the overdose breathing signature could alert the emergency services and save lives when fully developed and used in the community. Qualitative study results indicate that this technology would be positively accepted by people who use drugs.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/12/2024, University of Dundee Schools of Medicine and Life Sciences Research Ethics Committee (Tower Building, Nethergate, Dundee, DD1 4HN, United Kingdom; +44 (0) 1382383000; smed-sls-ethics@dundee.ac.uk), ref: 24/107

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Charity/Voluntary sector, Community

Study type(s)
Prevention, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Substance-induced respiratory depression

Interventions
PneumoWave DC chest biosensor is a small cylindrical device (40 mm diameter 14mm height) that sticks onto the chest using a small plastic patch (an ECG sticker) and measures chest motion. The study will involve wearing the device overnight if the participant is only staying for a short time or up to 4 weeks if they are staying longer. There is an option to wear the device for longer than 4 weeks, if the accommodation staff suggest it and the participants agrees.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I

Drug/device/biological/vaccine name(s)
PneumoWave DC chest biosensor

Primary outcome measure

Evidence of reduced chest movement collected by the PW DC system captured as a waveform throughout the duration of the study

Secondary outcome measures
1. User and staff experience and acceptability captured via responses to a questionnaire completed at least once during the study and via an interview and/or focus group participation at the end of the study
2. Potential causes for substance-induced respiratory depression captured via a drug use diary completed by the participant throughout the study

Overall study start date
01/01/2025

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Over 18 years of age
2. Living in supported accommodation
3. Participant reported current opiate drug use
4. Willing to wear biosensor device while living in supported accommodation
5. Able to provide informed consent (not intoxicated at time of consent)
6. Able to converse in and understand English

Participant type(s)
Resident, Service user

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Does not meet one or more of the inclusion criteria
2. Skin sensitivity to ECG electrode patch
3. Broken skin over chest area
4. Implanted pacemaker device in-situ
5. Not suitable for enrolment in the opinion of site staff or investigators

Date of first enrolment

09/01/2025

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Hillcrest Homes
1 North Grimsby
Arbroath
United Kingdom
DD1 1NU

Study participating centre
Gowrie Care
67 Portman Street
Glasgow
United Kingdom
G41 1EJ

Study participating centre
Hillcrest Futures
1 St John's Hill
The Pleasance
Edinburgh
United Kingdom
EH11 1DQ

Study participating centre
Martha Jones House
Wendle Court
131-137 Wandsworth Road
London
United Kingdom
SW8 2LH

Study participating centre
St Mungo's
83 Endell Street
London
United Kingdom
WC2H 9DN

Study participating centre
St Mungo's
12-14 Endsleigh Gardens
London
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WC1H 0EH

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Mare Street
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146 Mare Street
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E8 3SG

Study participating centre
No Second Night Out
Discovery House
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Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Scottish Government

Alternative Name(s)
The Scottish Government, Scottish Executive, Riaghaltas na h-Alba

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Chest movement data will be stored an analysed by PneumoWave Ltd.
Participant data and participant and staff interview data will be stored and published by University of Dundee and Kings College London.
All electronic data will be stored on password-protected computers in secure staff access-controlled offices at investigator sites. All data and laboratory notebooks will be retained for at

least ten years, in accordance with general RCUK guidelines.
The report will be made available to the funder. The report can be used for publication and presentation at scientific meetings. Study investigators have the right to publish study results orally or in writing. The criteria for authorship will follow the criteria of the International Committee of Medical Journals.
Publications will be reviewed according to the agreed contractual terms but will not restrict the general rights outlined above for the Investigators to publish the results of the study.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to PneumoWave owning the intellectual property of the study which will be used to develop a commercially available device.

IPD sharing plan summary
Not expected to be made available, Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	03/12/2024	07/01/2025	No	Yes
Protocol file	version 2	03/12/2024	07/01/2025	No	No
Protocol article		07/07/2025	08/07/2025	Yes	No