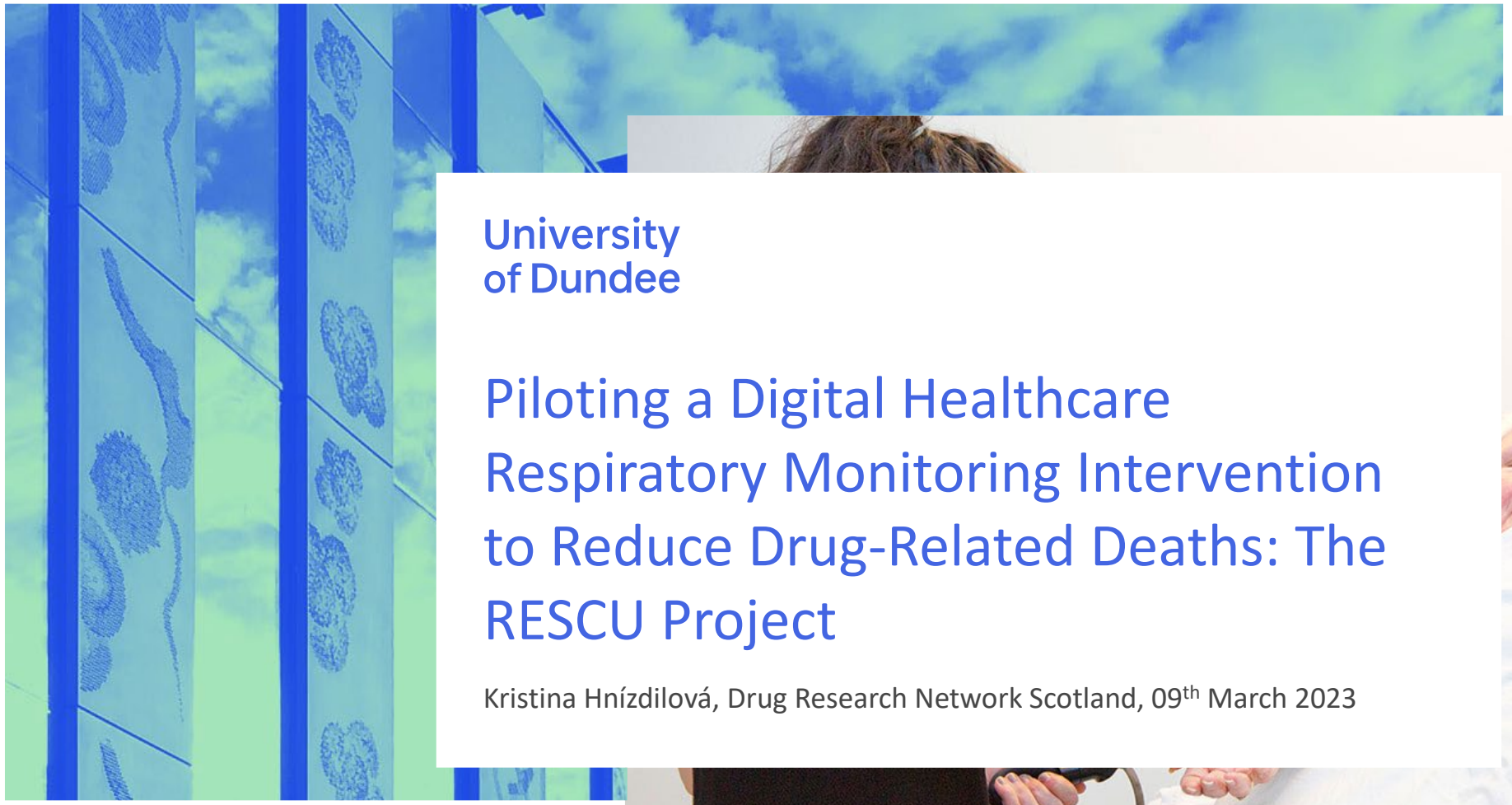

University of Dundee

Piloting a Digital Healthcare Respiratory Monitoring Intervention to Reduce Drug-Related Deaths: The RESCU Project

Kristina Hnízdilová, Drug Research Network Scotland, 09th March 2023

Disclosure Statement

PneumoWave Limited donated the study equipment; however, the study is investigator initiated and the company has no control over the data.

Kristina Hnizdilova is funded by an MRC iCASE studentship.

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The remaining authors declare no conflicts of interest.

Background - Scotland

Scotland has the highest drug-related death (DRD) rate per capita out of any EU country and approximately 3.5 times that of England and Wales (National Records of Scotland, 2020; Office for National Statistics, 2020).

The majority of DRDs are caused by opioid induced respiratory depression (OIRD).

The most common drugs implicated in DRDs in Scotland in 2021 were opioids and street benzodiazepines.

Background - Dundee

Dundee City has the highest age-standardised drug misuse death rate of all local authority areas (45.2 per 100,000 population for the 5-year period 2017-2021) (National Records of Scotland, 2021)

In 2021, 68% DRDs in Tayside occurred when people who use drugs (PWUD) used substances alone (Tayside Drug Death Review Group, 2022).

Naloxone administration relies on bystander presence, so serving PWUD who use drugs alone is an unmet need.

Place of death	2018		2019		2020		2021	
	Number	%	Number	%	Number	%	Number	%
Own Home	51	65%	56	63%	64	72%	53	68%
Other's Home	15	19%	20	22%	18	20%	15	19%
Supported Acc.	6	8%	5	6%	1	1%	4	5%
Other	6	8%	8	9%	6	7%	6	8%

(Tayside Drug Death Review Group, 2022)

PneumoWave Respmeter

The biosensor passively collects respiratory data. Participants wear the sensor which attaches to the skin with an ECG electrode.

The data is transferred to a gateway device (‘the hub’) via Bluetooth.

The hub stores the data on an internal drive (SD Card). At the end of the data capture period, data is uploaded to the cloud via secure wi-fi by the clinical research team and automatically deleted from the hub.

The data stored on the hub and cloud is identified only by hub and biosensor serial number and is non-identifiable by any patient details

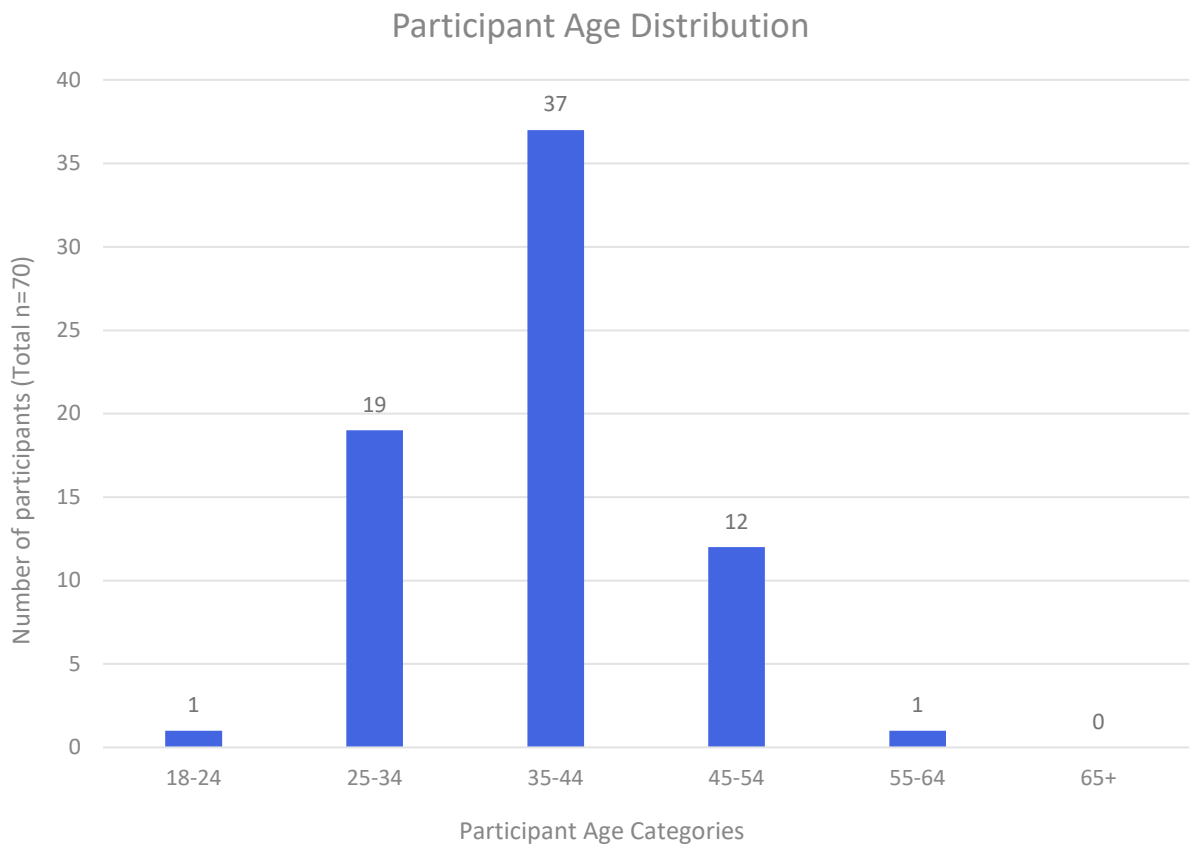
RESCU

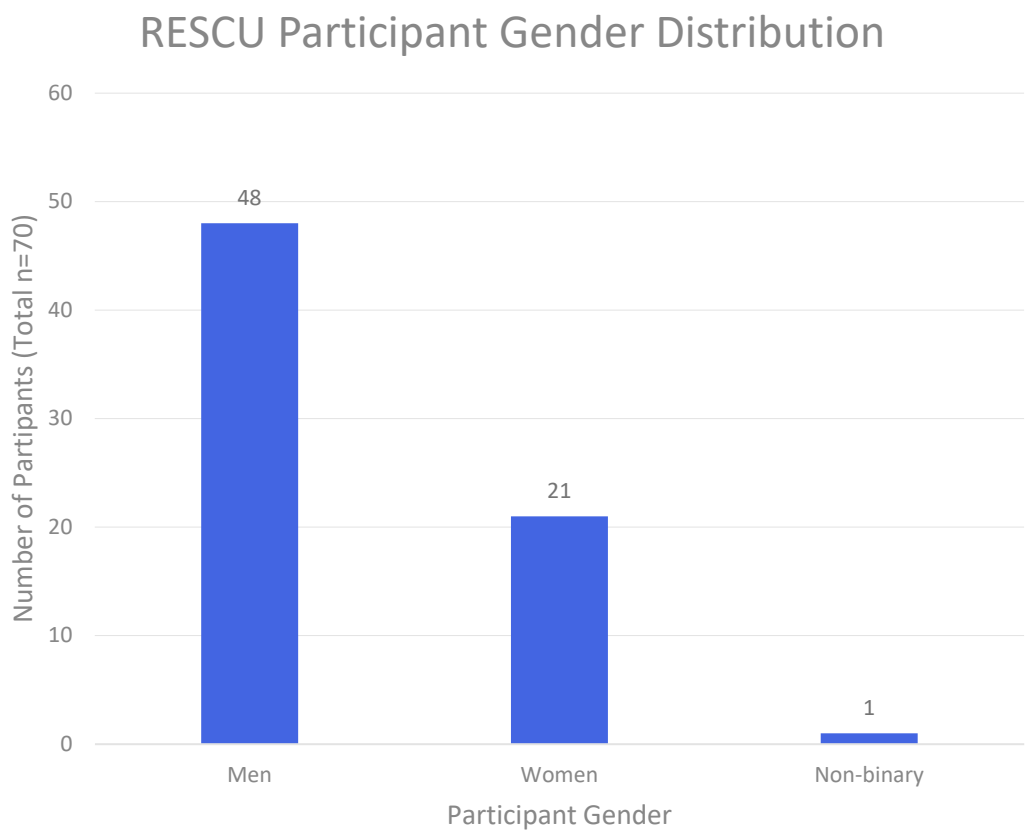
- RESCU is a mixed-methods observational cohort study commenced January 2022
- The quantitative study assessed if an accelerometer sensor attached to the chest can accurately and reliably capture respiratory patterns of people who use drugs.
- The qualitative study assessed if the device is acceptable to people who use drugs and stakeholders.

RESCU Quantitative Study

- Participants (n=70) wore a respiratory monitoring device on their chest for four weeks.
- Participants were asked to keep a diary of their substance use for the duration of the study.
- Participants came to the needle exchange weekly for data download and to hand in their drug diary, a total of 5 visits.

Participant Age and Gender Distribution





Participant Age and Gender Distribution

Participant Age and Gender Distribution							
Gender	Number	%	Mean Age	SD Age	Age Category	Number	%
Men	48	68.57%	39.23	6.88	18-24	1	1.43%
Women	21	30.00%	37.00	5.36	25-34	19	27.14%
Non-binary	1	1.43%	31.00		35-44	37	52.86%
					45-54	12	17.14%
Total	70	100.00%	38.44	6.85	55-64	1	1.43%
					65+	0	0.00%

Participant Living Circumstances

Participant Living Circumstances	Number	%
Homeless e.g living on the streets	2	2.86%
Living in temporary accommodation e.g. shelter or hostel	26	37.14%
Staying with friends or family	11	15.71%
Living in own home	31	44.29%
Total	70	100.00%

Participant Medical History

Participant Medical History	Number	%
No Declared Medical Issues	41	58.57%
Diabetes	1	1.43%
Documented coronary heart disease (angina, CAD or previous MI)	1	1.43%
Cerebrovascular disease (stroke or TIA)	0	0.00%
Asthma	12	17.14%
COPD	6	8.57%
Sleep Apnoea	3	4.29%
Pulmonary embolism	7	10.00%
Overdose in last 6 months	5	7.14%
Other	6	8.57%
Total of Participants	70	100.00%

Data

70 participants had either completed, or partially completed, the study protocol

Data were reviewed after running prototype apnoea detection and movement artefact algorithms that are not yet clinically validated.

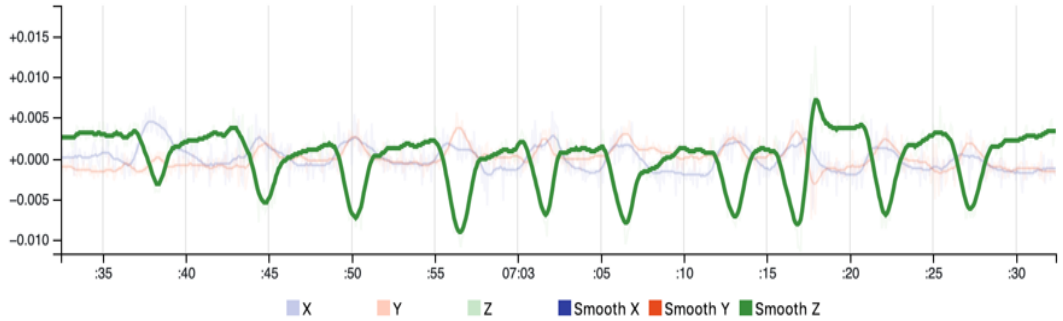
Study Completion Status	Number	%
Completed	37	52.86%
Lost to follow-up	26	37.14%
Withdrew	7	10.00%
Total	70	100.00%

Data

Example of data without apnoea

Patient CC/003

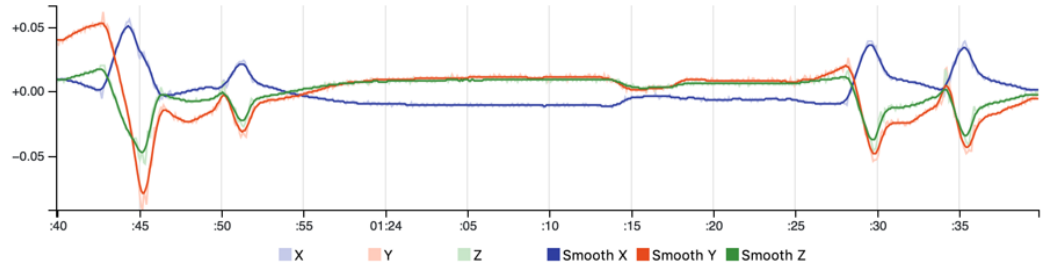
- Included as a subject that does not appear to have any breathing disorder
- 36-year-old male, states homeless and living on the streets
- Chest movement is typically at a rate consistent with normal breathing



Example of data with apnoea

PATIENT CC/004

- 45-year-old male, living in own home, prescribed methadone and mirtazapine
- Throughout the 4-week data capture period, this patient appears to have extensive sleep disordered breathing with prolonged apnoeas
- In the 4-hour period from 24/3/22 at 2200hrs to 25/3/22 at 0145 hrs, **340** high probability apnoeas were noted.
- Drug diary shows extensive groin injection of heroin plus oral diazepam and pregabalin with occasional smoking of crack. No recorded ingestion timings coincide with any detailed respiratory data



25/03/22 at 01:23 – apnoea of >30 seconds duration

Data

The apnoea algorithm processes raw accelerometer data to detect apnoea of >10s duration and identifies apnoea with 3 levels of probability depending on the number of axes where features consistent with apnoea are detected simultaneously:

Axis	Number of Apnoeic Episodes Detected
1 axis	21952
2 axes	9399
3 axes	8614

Data

- Focusing on the highest probability of apnoea detection only, there were **8,614 episodes of >10s duration detected in a total of 6,202.08 hours of data (22% of detected apnoeic episodes)**
- Data were manually reviewed where clusters of apnoea were noted. The majority of these clusters were consistent with sleep disordered breathing, potentially due to chronic opioid use. The common pattern is 10-15 seconds of apnoea followed by 2-4 breaths lasting several hours.
- The prototype movement artefact filter aims to detect waveforms that are inconsistent with respiration in duration and amplitude. A small number of instances were noted on manual data review where the movement filter had not activated in error generating a false apnoea.

Qualitative Study

We interviewed participants who had completed the study protocol (n=20) about their experiences wearing the device in order to determine how it could be incorporated into an intervention pathway to prevent drug related deaths among PWUD. We are currently interviewing participants who had partially completed the study.

We carried out focus groups (n=8) with:

- **Members of the Scottish Ambulance Service**
- **Harm Reduction Workers**
- **Dundee Non-fatal Overdose Group**
- **Harm Reduction Nurses**
- **Support group members and staff**

Qualitative Study

- We use reflexive thematic analysis (Braun & Clarke 2006; Braun & Clarke, 2019) to analyse interview transcripts
- Preliminary coding and proposed themes have been reviewed by Dr Andrew Radley (Co-Investigator) and Mr Brian Stephens (Research Nurse; Outreach Specialist)
- The themes were interpreted through COM-B (Michie, van Stralen & West, 2011) and NPT (May et al., 2009).

Themes

Participant Interviews:

- Identity and Experience of Substance Use
- Intervention Receptiveness and Incentivisation
- Emergency Response and Responsibility

Stakeholder Focus Groups:

- Barriers between PWUD and Services
- Intervention Integration into Existing Services
- Emergency Response Pathway

COM-B DIAGRAM OF FACTORS INFLUENCING PATIENTS' BEHAVIOUR

Capability	
Physical	Ability to attach device to their body Ability to rotate sites for device attachment
Psychological	Cognitive faculties Executive function Mental Health

Motivation	
Automatic	Witnessing OD/DRD Denial of risk Attitude to risk Mental health
Reflective	Desire to live Feeling at risk of an overdose Therapeutic Relationship with staff Personal priorities

Opportunity	
Physical	Housing Security Access to Services Access to electricity Income
Psychological	Relationship with Friends and Family (positive vs negative)

Behaviour
Wearing the PneumoWave device and adhering to intervention plan

Normalization Process Theory Diagram

Coherence:

- Focus group participants understood intervention.
- Spoke about comparable interventions: e.g., safe consumption rooms, Glasgow virtual spotting phone line.
- Spoke about assertive outreach, stressed importance of immediacy.

Cognitive Participation:

- Death of a friend or family member identified as a motivating factor for participation
- Some patients may not be ready for an intervention of this type; intervention is not a cure-all.

Collective Action:

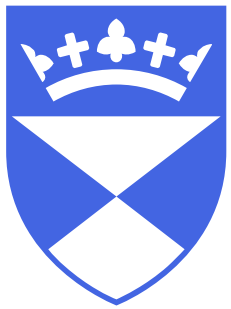
- Incentivisation – transport and electricity identified as a barrier
- Issue of responder consent and mental health
- Nurses/Overdose prevention workers need to be trained
- Device may not be a priority for areas with low funding
- Intervention needs to be integrated into existing interventions such as Assertive Outreach

Reflexive Monitoring:

- Main outcome – lowering overdose fatalities
- Secondary outcomes – improved engagement with substance use services; engaging patients in their own healthcare

Conclusion and Future Study Aims

- Data suggest that the device successfully captures respiratory anomalies.
- Quantitative data analysis is ongoing.
- Experiences with overdose or drug related death were identified in current qualitative data as motivating factors for device wear. First responder groups stressed the importance of patient choice and device accuracy.
- A future aim is to refine the trigger point for an emergency call response. Data from other trials utilizing the device will inform the apnoea detection algorithm alongside the data collected in this study.



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