CHIEF SCIENTIST OFFICE

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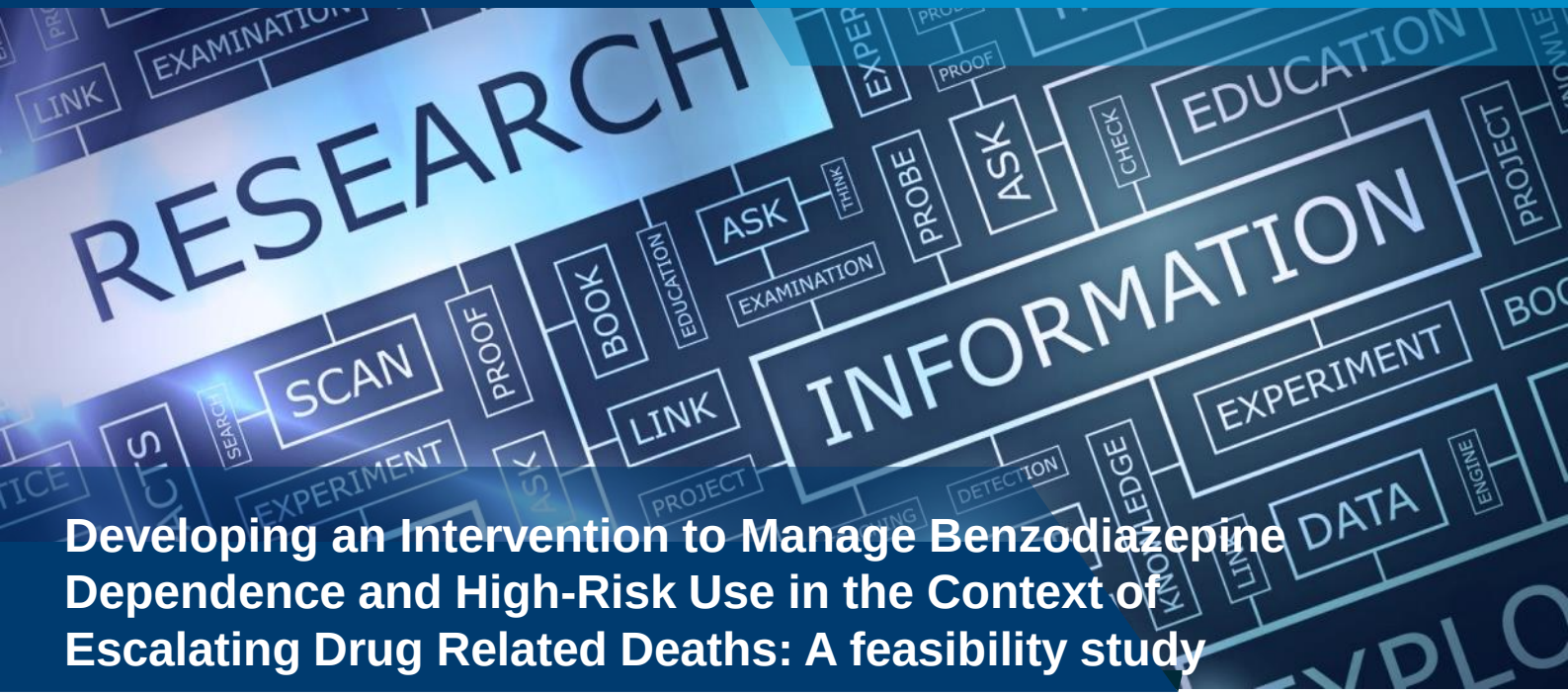

Developing an Intervention to Manage Benzodiazepine Dependence and High-Risk Use in the Context of Escalating Drug Related Deaths: A feasibility study

AIMS

The study aimed to develop a new intervention to address 'street' benzodiazepine use in people who are in opiate replacement treatment and, to conduct a single arm feasibility trial (no control) of the new intervention, in three test sites (Grampian, Lothian, Fife), in preparation for a full randomised trial.

KEY FINDINGS

- A targeted intervention was successfully developed which was acceptable to all stakeholders. (people with experience of benzodiazepine use, clinical doctors, nurses, pharmacists, psychologists and academics). It included prescribed diazepam (up to 30mg daily) and support for anxiety, sleep, pain as well as addressing past trauma and providing harm reduction advice.
- 39 patients were recruited to the receive the intervention in three sites. Of these, 30 completed the study (77%).
- There were general indications of improvements in level of anxiety, quality of life, substance use recovery and depression. Cognitive function remained stable.
- Changes in some 'street' drug use were reported by patients but oral fluid testing data was incomplete and inconclusive. This would need addressed in a larger trial.
- Recruitment was facilitated by positive and proactive research nurses, ideally working closely with the local clinical lead which helped them address concerns about inclusion criteria. This needs addressed in a larger trial with a control group.
- Fidelity to the prescribing component of the intervention was mixed.
- Interviews with patients and clinicians found general satisfaction with the intervention. The increased nursing time and strong therapeutic alliance to help address problems like anxiety was important, as was the diazepam prescription.
- Patients appreciated the prescription as a safer, regular supply compared to street drugs. Others noted the importance of being ready to make meaningful change that reduced drug use.

WHAT DID THE STUDY INVOLVE?

This study was an intervention development and feasibility study undertaken in two phases.

Phase 1: In the intervention development phase a stakeholder group and a PPI group were convened. Using guidance on developing complex interventions, we created a logic model outlining the motivations for people using benzodiazepines, and considered what was within our control. The model was refined over three PPI and stakeholder meetings. The resulting intervention was a nurse delivered bespoke intervention with prescribed diazepam (max 30mg) with monthly dose review. Nurses received specialist training in psycho-trauma, anxiety, pain and sleep management, to support patients to address benzodiazepine use. Harm reduction and safety conversations took place monthly.

Phase 2: The feasibility study tested the intervention in three sites (Grampian, Lothian and Fife) with a target of 15 patients per site. Validated tools were used to monitor outcomes covering: anxiety, depression, quality of life, substance use recovery, and cognitive function. 'Street' drug use was measured through oral fluid tests and self-report. NHS resource use was recorded. Although the intervention was for six months, follow up data for Fife was collected at four months due to limited study time. Interviews were conducted with a sub-sample of patients (N=14) and all nurses and clinicians (N=9), for their insights on delivering the intervention.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

After a slow start, 39 people were recruited (9 women, 30 men), mean age: 42 yrs. Almost all had diagnosed anxiety and depression (N=38), sleep problems were common (N=34) and over half had chronic pain (N=21). Retention was 77% at follow up (N=30).

'Street' drug use was mixed for different substances. Oral fluid test results did not reflect self-reported drug use. There was a reduction in pregabalin use and low use of alprazolam and etizolam (street drugs) but no other clear pattern. Interviews suggested there was less use in terms of quantities of street drugs. This needs to be quantified in a large multi-centre randomised controlled trial.

Economic data was well completed. Beside the intervention visit there was little primary and secondary care resource use reported. However most participants reported that they had been to outpatient department visit, which were mainly addiction support clinics.

Nurse /clinician Interviews found:

- Recruitment was helped by proactive nurse/clinician
- Fidelity to the protocol varied around the prescribing component on the intervention
- Diazepam dose of up to 40mg may be required in some cases
- The prescription was often the hook but therapeutic relationships developed thereafter.

Outcomes	Measure used and range		Mean score baseline (n=39)	Mean score follow up (n=30)
Anxiety	GAD 0- 21	improved	17.4 (2-21)	13.1
Depression	PHQ 0- 27	improved	18.8 (5-27)	13.1
Quality of Life	EQ5D L5 Utility score	improved	0.349 (-0.221-0.797)	0.508 (-0.414-0.717)
Substance use recovery	SURE 21-63	improved	40.6 (31-52)	52.3 (33-62)
Cognitive function	ACE Max 100	stable	74.4	75.9

Well basically this study has stopped me buying fake vallies [vallium]. ....and I thought like I can't go on like this so and they put on the real ones.

patient

nurse

Time. Because I'm giving my patients a full hour. Having that time just to do the psychological intervention, that was beneficial, and I hope that's what is identified through this, that there is a need for that.

WHAT IMPACT COULD THE FINDINGS HAVE?

- This study contributes to the currently limited evidence base around how to manage high risk benzodiazepine use in those in opiate replacement treatment.
- Increased consultation time was key. Time enabled the delivery of the psychological and harm reduction components as part of a therapeutic relationship. This highlights possible limitations of current practice to deliver psychosocial interventions with shorter and less frequent consultations.
- Patients engaged to varying degrees as is normal in this high-risk population. However, where they did positively engage there were potential benefits.
- From a policy perspective, the health economic component indicated little NHS resource use beyond the increased nurse consultation time. However, a randomised controlled trial is critical to allow comparison with normal care.

HOW WILL THE OUTCOMES BE DISSEMINATED?

Findings were shared with an invited audience of clinical staff and people involved in the intervention development. There was extensive interest with 94 attendees and many questions.

Findings will be presented at the International Society for Addiction Medicine conference in November 2023, the Society for the Study of Addiction conference in November 2023 and at the UK Addiction Professionals conference in April 2024. Papers are being prepared for publication and a blog article will be written for the Drug Research Network for Scotland website.

CONCLUSION

In this study we were able to develop an intervention for people using street benzodiazepines whilst in opiate replacement treatment. The intervention was well received by patients, nurses and clinicians. Retention was good and there were signs of positive clinical improvements across anxiety, depression, quality of life and substance use recovery. Cognitive function was stable. Interviews indicated there was variable engagement with different components of the intervention but the additional time combined with the prescription, facilitated the development of positive therapeutic relationships. The success of the study justifies a next step randomised controlled trial of this intervention vs standard care with benzodiazepine detoxification. However, the measurement of ‘street’ drug use needs particular attention.

RESEARCH TEAM & CONTACT

c/o Catriona Matheson
Faculty of Social Science
University of Stirling.

Email
catriona.matheson@stir.ac.uk

07870135667

Additional Information

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