ISRCTN95063724 https://doi.org/10.1186/ISRCTN95063724

Responding to people in danger. A project to develop and test a community pharmacy response service for people in danger from domestic abuse or feeling suicidal.

Submission date
15/12/2021

Recruitment status
No longer recruiting

Registration date
15/09/2022

Overall study status
Completed

Last Edited
16/01/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The COVID-19 pandemic has increased the number of people feeling suicidal and has increased domestic abuse. Both situations are distressing and can be fatal. However, these deaths are preventable and harm can be minimised if people are able to access timely and appropriate help. Community pharmacies may be suitable places to access this help as they are highly accessible with long opening hours and no requirements for appointments. This study aims to co-develop and then test the feasibility of a community pharmacy response service for people in danger from either suicide or domestic abuse.

Who can participate?
Pharmacy staff aged 18 years or over

What does the study involve?
There are two stages to this project:

Stage 1 (service co-development): This will be achieved by one-to-one interviews with experts, lay focus groups and co-development workshops (with members of the public and pharmacy staff). The researchers will co-develop and refine the name, concept, design and resources for the new service. Resources will include developing a pharmacist clinical assessment and referral tool, and a training package for the pharmacy staff.

Stage 2 (feasibility test in pharmacies): Following its development, the service will be tested for feasibility in 12 pharmacies. Eight will deliver the service and four will not. The researchers will train three pharmacy staff members from each of the eight pharmacies and collect data on service usage and the number of referrals made. Focus groups will be held to understand how pharmacy staff felt about delivering the service.

To understand public acceptability, the researchers will interview pharmacy customers and do a public survey. A final workshop with all will be arranged with all pharmacy staff, research team and the public and patient advisory panel.

What are the possible benefits and risks of participating?
The researchers cannot promise that the study will help participants themselves but the information from the study will help them to better understand how best to develop the pharmacy response service and to deliver this in practice.
The involvement in the project activities may cause inconvenience. The researchers will seek to minimise this by arranging these at a time that is convenient to most participants. As mentioned, talking about people in danger can be sensitive and could lead to participants becoming upset. Participants are asked to carefully consider these issues before deciding whether to take part. The researchers will hold all activities in a sensitive way and use an appreciative approach where all views are respected and valued.

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

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

Who is funding the study?
National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
309018

National Institute for Health and Care Research (NIHR)
133132

Study information

Scientific Title
Responding to people in danger. A development and feasibility study to co-develop a community pharmacy response service for domestic abuse and suicidal ideation.

Study objectives
How feasible and acceptable is a co-produced community pharmacy response intervention for identifying and referring people in danger from suicidal ideation or domestic abuse?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/05/2022, North West - Preston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8233; preston.rec@hra.nhs.uk), ref: 22/NW/0016

Study design
Intervention co-development followed by randomized feasibility trial and evaluation

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Suicide prevention and prevention of domestic abuse

Interventions
Current intervention as of 16/01/2023:
This study will co-develop and evaluate the feasibility of an intervention in community pharmacies to respond to people in danger from either suicidal ideation or domestic abuse, with parallel engagement of a steering group and PPI panel.

Development: Qualitative interviews will be held with eight representatives from referral organisations, followed by two lay focus groups and three co-production workshops with eight lay people and four pharmacy staff in each workshop.

Feasibility: Purposive sampling will be used to recruit 12 pharmacies, based on rural or urban location, sole pharmacy or co-located. The pharmacies will then be randomised to give eight

intervention and four control pharmacies. A minimum of three members of staff from each intervention pharmacy will be trained, followed by implementation of the intervention for 6 months. Service use and referral data will be collected from the intervention pharmacies and data on requests for assistance from control pharmacies over 6 months. Public acceptability will be measured using an e-survey and interviews with three customers per intervention pharmacy. A feasibility workshop will be held with the 24 intervention participants, steering, and PPI group.

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Previous intervention:
This study will co-develop and evaluate the feasibility of an intervention in community pharmacies to respond to people in danger from either suicidal ideation or domestic abuse, with parallel engagement of a steering group and PPI panel.

Development: Qualitative interviews will be held with eight representatives from referral organisations, followed by two lay focus groups and three co-production workshops with eight lay people and four pharmacy staff in each workshop.

Feasibility: Purposive sampling will be used to recruit 12 pharmacies, based on rural or urban location, sole pharmacy or co-located. The pharmacies will then be randomised to give eight intervention and four control pharmacies. Three members of staff from each intervention pharmacy will be trained, followed by implementation of the intervention for 6 months. Service use and referral data will be collected from the intervention pharmacies and data on requests for assistance from control pharmacies over 6 months. Public acceptability will be measured using an e-survey and interviews with three customers per intervention pharmacy. A feasibility workshop will be held with the 24 intervention participants, steering, and PPI group.

Intervention Type
Behavioural

Primary outcome(s)
The number of community pharmacy consultations for people enquiring about or seeking support for domestic abuse or suicidal ideation, measured using pharmacy records of numbers of requests at monthly timepoints during the intervention

Key secondary outcome(s))
1. The levels of severity of danger that clients present with, assessed and measured using a triage and referral grid in the consultation that classifies the categories of domestic abuse and suicidal ideation at three levels of risk: signs of concern, active concern and urgent concern. Measured at monthly timepoints during the intervention.
2. The subsequent management and successful referrals to support organisations, measured by recording the name of the referral organisation that clients are referred to during the intervention consultation. Measured at monthly timepoints during the intervention.
3. The intervention cost: data will be collected on the length of time that each consultation takes and the staff grade of the person conducting the consultation to enable the cost of the intervention to be calculated. Measured at monthly timepoints during the intervention.

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Pharmacy members of staff
2. Aged 18 years or over
3. Employed by an intervention pharmacy

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Locum or temporary staff

Date of first enrolment
30/09/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Lincoln
Campus Way
Lincoln
United Kingdom
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Sponsor information

Organisation
University of Lincoln

ROR
https://ror.org/03yeq9x20

Funder(s)

Funder type
Government

Funder Name
Health Services and Delivery Research Programme

Alternative Name(s)
Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The researchers do not expect to make their qualitative data from the co-development or process evaluation phases available, due to its sensitivity and the difficulties of anonymisation. They will provide a full data sharing plan for the quantitative feasibility trial data at a later date, once they have assessed the dataset and identified whether it can be safely or usefully shared. They will share anonymised questionnaire data from the customer survey on request, available via email from Jsolomon@lincoln.ac.uk, with accompanying metadata. This will become available 12 months after the study end date, to allow time for publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No

Participant information sheet	version 1.0	14/12/2021	16/12/2021	No	Yes
Protocol file	version 1.1	12/11/2022	16/01/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes