Participant Information Sheet / Information about the research (Pharmacy staff)

(Final Version 1.0, 14.12.2021)

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

Name of Lead Researcher: Dr Josie Solomon (Contact Details are given at the end).

We'd like to invite youto take part in our research study. Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our study team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about 10 minutes. Please feel free to talk to others about the study if you wish.

What is the purpose of the study?

Compounded by the COVID-19 pandemic, the number of people experiencing domestic abuse and feeling suicidal is sadly increasing. Both situations are very distressing and at worse can result in fatalities. However, suffering and deaths are preventable, and harm can be minimised if people are able to access timely and appropriate help. The researchers consider that pharmacies could be ideally placed for people to seek help if they are in danger. Community pharmacies have long opening hours and no requirements for people to make appointments. The range of services they offer have also expanded over time to include healthy living services and health checks, in addition to the supply and sale of medicines.

This two-year study aims to work with patients and professionals to jointly develop a new community pharmacy response service for people in danger from either suicide or domestic abuse. We have worked with lay people, health professionals and experts to co-develop a new community pharmacy response service for people in danger from either suicide or domestic abuse. We are now in the process of evaluating the feasibility of the service in practice. The evaluation will involve recruiting and then randomising 12 pharmacies. Eight will deliver the service and four will act as controls (4). We are seeking permission from your Pharmacy's Head Office / Owner and from the pharmacy staff employees whether you would like to take part. From this test we will be able to determine how effective this service is, its acceptability to clients and pharmacy employees and feasible in practice. This will help us assess the potential for it to be adopted more widely.

Why have I been invited?

We are interested in whether the response service will work in real-world practice. We are therefore inviting 12 pharmacies in Lincolnshire to act as 'intervention' or 'control' pharmacies. We are asking for three members of staff within each pharmacystaff to take part to help us collect information that will help us assess how effective the service is.

Do I have to take part?

It is up to your organisation and pharmacy staff to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your employment or legal rights in any way.

What will happen to me if I take part?

We will initially seek permission from the pharmacy's Head Office / Owner before approaching a pharmacy. Once permission is granted we will invite the pharmacy staff to the study. Be aware that offering the service and talking about domestic abuse / suicide thoughts may be considered sensitive and challenging issues to discuss. We would like you to consider this carefully before you decide whether or not you would like to take part. If the pharmacy team agrees, we will randomly assign pharmacies to either deliver the service or act as controls.

For pharmacies that are randomly allocated to deliver the response service:

You as one of the three members of staff (one of them being a pharmacist) will be invited to receive interactive training over two evenings to ensure they are fully equipped to the service and collect data for the study. You and your colleagues will then implement the service in your pharmacy for a period of 6 months. This will involve displaying promotional materials, wearing identifiable lanyards and responding to people in danger who ask for assistance. You will be provided with a comprehensive triage and referral tool to assist you in the consultation. We will ask you to record data on a secure online database (i.e. information on service enquiries, requests for assistance and pharmacy onward referral). We will support your pharmacy team through routine visits to ensure your team is fully supported at all times. You will also have monthly access to an online support session with a psychotherapist to help you debrief or discuss any emotional aspects of being involved in the service. Access to the psychotherapist is voluntary and confidential.

Once the 6 months period is over, we will invite you and your colleagues to participate in a focus group. This will be held either at the School of Pharmacy, University of Lincoln or online It will last about two hours and be led by Josie Solomon who is the lead for the study. Before starting, we will seek permission for the discussion to be audio-recorded. To ensure confidentiality, we will ask all participants not to disclose any what is discussed outside the focus group. The purpose of the focus group is to discuss how participants felt delivering the service, what went well / less well, barriers / facilitators to implementation and what the research team can learn about improving the service in practice.

Finally, you will be invited to a summary workshop which will last about four hours. This will be held at the School of Pharmacy, University of Lincoln. The summary workshop will be attended by other pharmacy staff who delivered the service as well members from the study's patient and public involvement and engagement group and project steering groups. The purpose of this summary workshop will be to reflect on your own experiences and overall findings from the study.

To summarise, if your pharmacy is selected as an intervention pharmacy, you will be required to attend: two evening training sessions, one focus group and one summary workshop. You will be required to offer the service in your pharmacy for 6 months, along with two other colleagues in your pharmacy. As part of the delivery of the service you will be required to collect data from the consultations and to enter it on to our secure online platform. You will have monthly support visits to your pharmacy by the researcher. You alsohave the option of having confidential monthly support sessions with a psychotherapist in case you wish to debrief on any emotional aspects of being involved in the study.

For pharmacies acting as controls:

We will ask the pharmacy team to record data on the number of requests for assistance from patients/customers in regard to suicidal feelings or domestic abuse. These will be recorded on a secure database to help us understand how often these issues normally present themselves in a pharmacy. As a control pharmacy, the information we will collect from your pharmacy will help the research team compare and assess how effective our promotional strategy has been in those pharmacies who deliver the service.

Expenses and payments

Your pharmacy organisation will receive a small expenses fee for participating in the study. If you are in an intervention pharmacy, you will be offered travel expenses and refreshments for the training, focus group and summary workshop. All participants at the final summary workshop will additionally receive £75 (with a choice of receiving as a direct payment or as an Amazon voucher).

What are the possible disadvantages and risks of taking part?

The involvement in the study involves you and two other members of your pharmacy team potentially being allocated to the intervention (delivering the response service). You will be invited to take part in the training, focus group and summary workshop. This may cause inconvenience to participants and the wider team. We will seek to minimise this by arranging the focus group and workshop at a time and place that is most convenient to participants. Please also be aware that offering the service and offering support on domestic abuse or suicidal ideation may be considered sensitive and challenging. We would like you and your pharmacy team to carefully consider how you would feel about your engagement before you decide whether or not you would like to take part.

What are the possible benefits of taking part?

We cannot promise the study will help you but you will receive free training and support on handling patients with sensitive issues, such as suicide and domestic abuse.. The information we get from the feasibility study will help us better understand how this service is received, implemented and received in real-world practice.

How will we use the information about you?

The data collected from pharmacies will be anonymised collated and compared. The focus groups and final summary workshops will be audio recorded and then transcribed, with the removal of any identifiable information so that they are anonymous. Similarly, we will also transcribe and anonymise any information written on flipcharts. This will allow us to analyse the groups/workshops, and use anonymised quotes in any future research reports. The process of anonymisation means that you will not be able to be identified in any way. Your involvement in the study will remain confidential. However, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. Because of the investment, we would ideally like you to be involved in all aspects of the study until the end. We would therefore ask you to think carefully about what is involved for you and your pharmacy team before deciding to participate.

Where can you find out more about how your information is used?

The University of Lincoln is the lead organisation for this study. You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- Research Participant Privacy notice https://ethics.lincoln.ac.uk/research-privacy-notice/ will explain how we will be using information from you in order to undertake this study and will be the data controller for this study.
- by asking one of the research team
- by sending an email on compliance@lincoln.ac.uk or by post at Information Compliance, Secretariat, University of Lincoln, Brayford Pool, Lincoln, LN6 7TS.

What will happen to the results of the research study?

We will aim to publish the findings from the study throughout the course of the project and at the end of the study (September 2023). You can keep up-to-date with the study and all published findings from our dedicated study website [INSERT STUDY URL]. As mentioned, you will not be identifiable from any of these reports or publications.

Who is organising and funding the research?

This research is being organised by the University of Lincoln and is being funded by the National Institute for Health Research (NIHR) through the Health Services and Delivery Research (HS&DR) programme.

Who has reviewed the study?

All research in the NHS, is reviewed by an independent group of people, called a Research Ethics Committee - to protect your rights, dignity and wellbeing. This study has been reviewed and given favourable opinion by [NAME OF COMMITTEE] Research Ethics Committee.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The lead researcher's contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting ethics@lincoln.ac.uk.

For further information and contact details of the Lead Researcher:

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