UNIVERSITY OF LINCOLN

PROTOCOL

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

'Responding to People in Danger': Development and Feasibility Study

Protocol Final Version 1.1
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Sponsor	University of Lincoln
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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement(s).

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator: Dr Josie Solomon

Signature: .....  Date: .12...../....11../..22....

Name: Dr Josie Solomon

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FUNDER DETAILS

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR)	Funding awarded for a development and feasibility 24 month study to the University of Lincoln.

STUDY SUMMARY

Study 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 Design	**Phase 1: Co-development of the complex intervention (pharmacy response service)** A. Foundations – update literature review and evidence-base, write study documentation and apply for research ethical approval B. Co-development – 1. One-to-one scoping interviews with key stakeholders x 8 2. Lay focus groups x 2 3. Co-production workshops (with lay people and pharmacy professionals) x 3 C. Modelling – finalisation of the intervention with consideration of RE_AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance). **Phase 2: Feasibility Randomised Controlled Trial** D. Pharmacy recruitment and training – Recruit 8 pharmacies for intervention delivery and 4 to act as controls (comparators). In intervention pharmacies, recruit and train 3 members of staff from each pharmacy. Measure impact of the training using a validated tool (Continuing Professional Development (CPD) Reaction Questionnaire). E. Implementation of Intervention - Promotion of the service to the public, Implement intervention in intervention pharmacies. Collect data from service users and pharmacies over 6 months. F. Evaluation for acceptability – (Using the Theoretical Framework for Acceptability of Healthcare Interventions). 1. Post-intervention pharmacy staff focus groups x 3 2. One-to-one pharmacy customer interviews x 24 3. Public e-survey (600 responses) G. Feasibility of the intervention - Summary workshop with the staff members, plus PPI panel and steering group to explore the feasibility of the intervention as a possible service and description of the intervention. H. Feasibility of a future cluster randomised controlled trial – Analysis and evaluation by the research to team to scope the requirements of a possible future cluster randomised controlled trial.
Study Participants	**Phase 1: Co-development of the complex intervention** 1. Stakeholder interviews: Experts / representatives of support organisations

	2. Lay focus groups: Survivors or people with insight in to the issues and a special interest in supporting others with domestic abuse / suicidal ideation 3. Co-development workshops: Survivors or people with insight in to the issues and a special interest in supporting others with domestic abuse / suicidal ideation AND community pharmacy staff **Phase 2: Feasibility Randomised Controlled Trial** 1. Intervention / Control pharmacies: Community pharmacy staff 2. Clients (service users): people who access the intervention 3. Post-intervention pharmacy staff focus groups: community pharmacy staff in the intervention arm 4. Interviews with pharmacy customers: Regular customers who use the pharmacy 5. E-survey: General public in locality of intervention pharmacies 6. Summary workshop: Community pharmacy staff (those in the intervention arm of the study), members of the study's Patient and Public Involvement group and study management group
Eligibility Criteria	**Phase 1: Co-development of the complex intervention** 1. Stakeholders (representative of an organisation that supports people experiencing domestic abuse / suicidal ideation) 2. Lay survivors or those with insight of domestic abuse / suicidal ideation 3. Lay survivors or those with insight of domestic abuse / suicidal ideation AND community pharmacy staff **Phase 2: Feasibility Randomised Controlled Trial** 1. Intervention / Control pharmacies: Community pharmacy staff in the Lincolnshire area 2. Service users: ≥18 years 3. Post-intervention pharmacy staff focus groups: Pharmacy staff who delivered the intervention 4. Pharmacy customers: Identified as pharmacy-users and ≥18 years 5. E-survey: Members of the general public ≥18 years 6. Summary workshop: Community pharmacy staff (those in the intervention arm of the study), members of the study's Patient and Pubic Involvement group and study management group
Planned Sample Size	**Phase 1: Co-development of the complex intervention** 1. Stakeholder scoping interviews: minimum of 8 participants 2. Lay Focus groups: 2 focus groups with 8 participants in each 3. Co-production workshops: 3 workshops with 12 participants in each (Lay survivors of domestic abuse / suicidal ideation (8) AND community pharmacy staff (4)) **Phase 2: Feasibility Randomised Controlled Trial**

	1. Feasibility Randomised Controlled Trial (12 pharmacies - 8 as intervention and 4 controls) 2. Service users: This number is a feasibility trial outcome 3. Post-intervention pharmacy staff focus groups (3 focus groups with 8 participants in each) 4. Pharmacy customer interviews (24 participants) 5. Public e-survey (n=600) 6. Summary workshop with pharmacy staff, Patient and Public Involement group and study management group (one workshop with 24 pharmacy staff, 8 PPI members and 6 study management group members)
Study Duration	6 months intervention development (Phase 1) 18 months feasibility, including 6 months intervention in pharmacies (Phase 2) Total study duration: 24 months
Objectives	The primary aim is to co-develop and evaluate the feasibility of a community pharmacy response service / intervention for people in danger from domestic abuse or suicidal ideation and to assess the potential for this to be scaled up for a future trial, including economic and statistical considerations. **The objectives of the study are:** 1. To develop a point of contact and triage referral resource in partnership with relevant experts and local referral organisations, for both domestic abuse and suicidal ideation. 2. To co-develop (with lay survivors / people with insight and professionals) the scope and features of a discreet response intervention in community pharmacy, to include the name, logo, promotional strategy and protocol for delivery in a pharmacy. 3. To co-develop with patients / public and professionals a training package and mentoring support service for pharmacy staff delivering the intervention. 4. To deliver the intervention in a purposive sample of community pharmacies and collect feasibility data on intervention usage and consequent referrals. 5. To ascertain and evaluate client, public and professional views on accessibility, acceptability, implementation, feasibility and intervention fidelity in practice. 6. To evaluate the potential for the intervention to be scaled up for a future trial, including economic and statistical considerations. 7. To engage with the public and professionals to disseminate findings and reporting of the intervention as an output.
Outcome Measures	The primary outcome measure for this study will be the number of community pharmacy consultations for people enquiring about or seeking support for domestic violence or suicidal ideation. Secondary outcome measures are (i) to determine the levels of severity of danger that clients present and (ii) subsequent management and

	successful referrals to support organisations (iii) Cost and economic considerations.
Data Analysis	Following transcription of the qualitative data, analysis will proceed through an initial iterative process of open coding and according to the consolidated coding framework. After the coding process has been completed, a more refined and selective process of 'coding on' will be undertaken to differentiate, contrast and narrate the emerging themes that are of relevance to meeting the study's objectives. The qualitative software programme NVIVO 11 will be used to organise the data. The quantitative data analysis will use descriptive comparison between intervention and control pharmacies, and appropriate multivariable linear regression. Data will be analysed using R Version 3.

KEY WORDS

Co-development; Community pharmacy; Domestic abuse; Feasibility trial; Response service; Suicidal ideation, Suicide prevention, Controlled trial.

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LIST OF ABBREVIATIONS

CF	Consent Form
CI	Chief Investigator
CRF	Case Report Form
CTU	Clinical Trials Unit
DA	Domestic Abuse
GCP	Good Clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
ISRCTN	International Standard Randomised Controlled Trials Number
MHRA	Medicines and Healthcare products Regulatory Agency
MRC	Medical Research Council
PPIE	Patient and Public Involvement and Engagement
RCT	Randomised Control Trial
REC	Research Ethics Committee
RES	Research Ethics Service
SOP	Standard Operating Procedure
SI	Suicidal Ideation
SP	Suicide Prevention

STUDY MANAGEMENT

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor of the study is the University of Lincoln.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

STUDY MANAGEMENT COMMITTEES

Lincoln Clinical Trials Unit (LinCTU). The co-investigator GL is deputy-director of the CTU. The CTU's involvement will consist of setting up all of the progression criteria and associated data collection on CASTOR trials software. The CASTOR software will allow data recording templates to be available to the pharmacies online so that they can enter the data at the time of the consultation, and the data will go directly to the database. It also allows the research team to have access to live and comprehensive data. The CTU will ensure full GDPR compliance and that all data is stored in secure cloud access in the UK. They will assist with participant information sheets, consent forms and applying for ethical approval. The CTU will also conduct all randomisation and statistical analysis, and provide data monitoring and study support. GL and the LinCTU will play a significant role in the final evaluation of feasibility.

Study Steering Group. The Study Steering Group will meet every six months to ensure all practical details of the study are progressing well and to ensure adherence to timescales and reporting to NIHR.

Patient and Public Involvement and Engagement (PPIE) Panel. The PPIE panel will meet bi-monthly to ensure the study remains sensitive to patient and public preferences at all stages. Specifically, they will be involved in reviewing all study participant and public facing materials, co-developing the response service and evaluation of the main findings.

Study Management Group. The Study Management Group consists of the research team, co-investigators and relevant local partners. They will meet bi-monthly to discuss the progress of the study and discuss the findings as they emerge.

STUDY BACKGROUND and RATIONALE

The impact of the COVID-19 pandemic has been dramatic and far reaching. Five dimensions have been used to capture the breadth of impact on health: the effect of the virus itself, the diversion of services away from other acute conditions, reduced access to GPs, and the consequences of lockdown and social distancing on health and the economy.[1]

Two significant consequences have been an increase in mental health conditions and an increase in domestic abuse.[2, 3] The number of deaths from suicide and domestic abuse were already a concern pre-pandemic. In 2019 two women a week were killed by a current or former partner in England and Wales and an estimated 2.4 million adults experienced domestic abuse.[4] The estimated cost of domestic abuse to the economy is £66 million a year.[5] There were 6,859 suicides in the UK in 2018, which was a rise of 10.9% on the previous year.[6] It is estimated that every life lost through suicide costs the economy £1.67 million.[7]

The effects of the pandemic have worsened an already critical situation in terms of mental health crises and domestic abuse, which have been compounded by worsening mental health associated with increased alcohol consumption.[8] An increasing number of lives will be lost or seriously damaged. Much of this harm is preventable if people at risk are able to access appropriate and timely support.[6,9]

However, accessing appropriate support can be challenging, for four main reasons. Firstly, healthcare services in the UK were already under strain before the pandemic and this issue has now been compounded by the response to COVID-19[10,1]. Secondly, as distressing and stigmatising issues, both suicidal ideation and being a victim of domestic abuse carry a psychological burden and are difficult to talk about and reach out for help.[11,12] Thirdly, the fluctuating nature of these issues, often including periods of significant worsening of the problem means that timing and availability of healthcare support is an important consideration.[13-15] It is important that assistance is available and accessible at moments of need; care needs to be available opportunistically. Fourthly, the intensity of these issues varies and people need to be referred to the most appropriate service according to the level of severity of the danger in which people find themselves.[16,17]

Reduced access to general and mental health services at a time of increasing need requires innovative approaches that optimise existing services and networks and which take these challenges into account.

Evidence supporting community pharmacy

Community Pharmacists and their teams are ideally placed as an accessible service. In terms of availability, they are widely distributed in a variety of settings and provide NHS services to around 1.6m people a day.18 Throughout England more than 89% of the population have access to a community pharmacy within a 20-minute walk from home.[18] Within areas of highest deprivation this increases to almost 100%.[18] Furthermore, by nature of being a walk-in, no-appointment service with long opening hours, they enable access to care to be patient-led, at a time of their choosing.[19] They facilitate opportunistic care. This significant existing healthcare provision therefore, has the potential to increase the capacity of overall healthcare services, and allows for flexible timing as an access consideration.

The services that pharmacies offer have expanded over time to include public health and clinical services in addition to the supply and sale of medicines. Their contractual framework includes the Pharmacy Quality Scheme (PQS) and part of this scheme is the requirement for pharmacy staff to be trained in safeguarding and suicide prevention.

However, there has been increasing interest in the role of pharmacies in supporting people suffering from domestic abuse. During the first national COVID-19 lockdown in March to May 2020, many pharmacies followed other countries in Europe by offering their consultation rooms as safe spaces for victims of domestic abuse as part of the “Safe Spaces” scheme.[20,21] This offer was extended with the launch of the “Ask for ANI” initiative. Using the code word “ANI”, people suffering from domestic abuse can access support from pharmacies to call either the Police or the National Domestic Abuse Helpline.[22] However, the service remains relatively basic. The proposed intervention in our study will build on “Ask for ANI” to optimise its effectiveness.

This government initiative demonstrates a shift in political and public perceptions towards viewing pharmacies as being an appropriate response service for people in danger. Similarly, in the USA, attention is turning towards the role of pharmacies in domestic abuse interventions, with a recent study concluding that pharmacists are willing and uniquely positioned to serve as a resource for Intimate Partner Violence, but required training and referral resources.[23]

Looking at evidence-based domestic abuse services beyond pharmacies, in the wider arena of Primary Care in the UK, the IRIS service was shown to be cost-effective in a pragmatic RCT.[24] This complex intervention, which was developed using the MRC framework for complex interventions, involved having a domestic abuse “Advocate Educator” linked to GP Practices.[24]

As yet, there is no UK provision of a formal suicide prevention service through pharmacies.[18] There is evidence that the pharmacy environment and the strength of relationships between pharmacists and their customers lend themselves to pharmacists being ideally placed to engage in suicide prevention, but that staff currently feel inadequately prepared and would benefit from a more formalised facilitated training and referral pathway.[25]

A current RCT in Australia is evaluating an advanced psychiatric medication service through pharmacies and is using Mental Health First Aid training in both the intervention and the control groups.[26] Similar work is underway in Canada, through the “Bloom Program” which is a service for mental health and addiction in pharmacies, that involves advanced medication support and listening.[27]

These developments evidence the potential for pharmacies in this new role and adds further impetus to developing a formalised service, training package and referral system for people in danger from either domestic abuse or suicidal ideation.

Theory of change – client behaviour

The intervention will focus on the behaviour change of people who are in need of help, and on the behaviour change of pharmacy staff who can provide this help. The overarching theory of change that will be used for

both of these targeted behaviour change interventions is the COM-B Behaviour Change Wheel.[28] This model was also used by the Canadian Community Pharmacy "Bloom Program".[27]

In order to identify the intended mechanisms of behaviour change of people seeking help in response to danger, it is helpful to explore what is known about the psychological states of people in these situations.

Table 1: Mapping of COM-B, behaviour change and intervention components

	Description	Aspects of behaviour change	Interventions that address aspect of behaviour change, that will be used in the study
Capability	The individual's psychological and physical capacity to engage in the activity concerned. Includes knowledge and skills.*	physical capability	***Training*** (Imparting skills)*(a)
			Enablement (Increasing means / reducing barriers to increase capability or opportunity) (b)
		psychological capability	***Education*** (Increasing knowledge or understanding) (a)
			Training (a)
			Enablement (c)
Motivation	Automatic and reflective, all those brain processes that energize and direct behaviour, not just goals and conscious decision-making. It includes habitual processes, emotional responding as well as analytical decision-making	Automatic	***Environmental re-structuring*** (Changing the physical or social context) (d)
			Enablement (e)
			Modelling (Providing an example for people to aspire to or imitate) (e)
		Reflective	***Education*** (f)
Opportunity	social and physical, all the factors that lie outside the individual that make the behaviour possible or prompt it	Social	***Environmental re-structuring*** (g)
			Enablement (h)
		Physical	***Environmental re-structuring*** (i)
			Enablement (h)

**All definitions taken from Mitchie et al[28]*

Psychological burden and stigma

Both of the issues are known to be distressing, stigmatising, difficult to talk about, and may carry an element of shame.[29,30] It is well-documented that stigma and shame are barriers to help-seeking behaviour and thus hinder access to appropriate care.[30]

Although domestic abuse and suicidal ideation are separate issues there is overlap and similarities. A survey of 3,500 clients by Refuge, found that 24% of people experiencing domestic abuse had felt suicidal, with 18% having made a plan. Victims of domestic abuse can feel so trapped that they feel their only way out is suicide.[31] There is evidence that both partners in abusive relationships are at risk of suicide.[32] Furthermore, a survey of 22,559 people found that 1 in 6 adults who were exposed to chronic parental violence during childhood, (with chronic being defined as more than ten occasions before the age of six), had attempted suicide.[33] The rates or suicide attempt for exposed individuals were 17.3% compared to 2.3% of those who had not been exposed. The relationship is compounded by alcohol consumption, which is a shared risk factor for both DA and SI. Alcohol consumption is linked with abusive behaviour by perpetrators and with poorer mental health and suicides.[8,34]

Much of the evidence-base around assessing risk in patients with suicidal ideation focuses on the Interpersonal Theory of Suicide, in which the components of "perceived burdensomeness" and "thwarted belongingness", if felt to be intractable, leads to "suicidal desire".[35] If this is then combined with "capability of suicide", then there is a heightened risk of suicide. Other models echo the significance of hopelessness (feeling defeated; no means of escape) and social isolation. It is therefore conceivable that a person feeling like a burden, isolated and without hope may have considerably reduced capacity for engaging with healthcare systems and accessing help.

Timing of access to support

Similarly, domestic abuse, often features controlling and coercive behaviours by the perpetrator leading to feelings of disempowerment and lack of control. The Power Wheel is a model to understand domestic abuse,

displaying at the outer rim the manifestations of physical and sexual abuse, with the spokes illustrating the signs of: emotional abuse, economic abuse, isolation, intimidation, coercion, using children, male privilege, minimising, denying and blaming.36 At the heart of the wheel, holding the abuse in place, remains the constant of power and control.

It is therefore apparent that people experiencing DA and/or SI face considerable internal psychological barriers to asking for help. This is compounded by the requirement for help to be accessed in a timely fashion. As discussed above, a person who is experiencing domestic abuse is often under the control of his or her partner, and as such there will be limited opportunities in which he or she can break free for long enough to access help. In addition, the earlier domestic abuse model of Walker's Cycle of Abuse, based on interviews with 1,500 women suffering from abuse, describes a cycle of: building tension, incident, reconciliation and calm.[13]

It follows that the victim will be in greater need of support during the tension building and incident phases, rather than in reconciliation or calm. To add to the complexity of timing, the Stages of Change model, which has been used effectively in disclosure around domestic abuse, indicates that there are key "windows of opportunity" in which the person affected is able and willing to make changes and break free.[14] Similarly, timing of support is crucial in suicidal ideation, which can be an impulse that may pass.[37]

Level of severity of danger that clients present and urgency of management

Given that domestic abuse can encompass a wide spectrum of behaviours, with different levels of urgency and severity, and similarly that suicidal ideation can range from "feeling suicidal" to having a plan and active intention, it is clear that different levels of responses are required for different individuals at different times.

As part of the stakeholder engagement and investigation for this bid, the lead applicant JS met with a GP at the Mental Health Crisis Team (who also has expertise in safeguarding), to discuss developing a triage grid indicating the key characteristics of different levels of severity and urgency for both DA and SI. Corresponding referral options range from signposting to agencies that offer guidance, referral to advocacy agencies or healthcare services or immediate contact with the Police or Social care for protection. This approach would be developed further as part of the development stage of the study, with full consideration of the compounding complexities such as alcohol and substance misuse, and would be embedded in to local systems for appropriate referral. The key point is that many instances of DA and SI would not be appropriate for escalation to the Police, hospital Emergency Department or Psychiatric care, but do need to be taken seriously and referred to an appropriate support service.

Developing an evidence-based intervention will enable a health economic evaluation to support appropriate funding decisions. The IRIS scheme is a good example of an evidence-based complex health intervention for domestic abuse using an advocacy service, which in itself sits on a reasonable evidence base for advocacy as an intervention.[24,38]

To summarise, prevention of domestic abuse and suicides are longstanding health issues, made critical at this time. It is apparent that there is increased focus on the potential role for community pharmacies in these areas with a need to develop relevant evidence-based complex health interventions in this area. All healthcare services are under strain, and therefore the addition of a new setting by establishing a community pharmacy service would increase capacity and reach. Furthermore, community pharmacies offer the flexibility of timing to meet the needs of people in danger. Psychological burden poses a further hindrance, which will be addressed in the development of the intervention in this study, as will consideration of stratifying severity and signposting accordingly to the most appropriate service for that person at that time.

Evidence from our previous research

The proposed complex intervention, with the seven facets outlined above, builds on the foundation of previous research conducted by members of the research team. JS conducted an NHS-funded public engagement and multi-agency study on domestic abuse and child safeguarding, in which ten focus groups

were conducted with multi-agencies and the public. The most striking finding was the need for an intermediary service. They wanted somebody they could contact in an everyday setting, to reach out to without it feeling like a major decision. This was more than a request from the public; it was a desperate plea. People experiencing domestic abuse wanted a drop-in service in a neutral environment with a trusted professional who could listen to them and signpost to the most appropriate service. People did not want to be alone when contacting the major services. They wanted an easily accessible intermediary. Both professionals and the public agreed that there was a considerable amount of suffering that was "sub-threshold" for the Police or Social Care but needed addressing. An intermediary service could support people in accessing charity and voluntary sector support. Participants also reported that a simple "Are you OK?" conversation in itself was enough to trigger change, which suggests that an intermediary service would be beneficial in its own right, as well as through referrals.[39] This research was presented as oral presentations at two conferences and published as a report (with accompanying video resources that were created as part of the project) to Nottingham City Council, along with a dissemination event.[39,40,41.]

AL and JS conducted an NIHR-funded project which developed a co-produced educational intervention to support pharmacy staff in targeting pharmacy services towards under-served communities. This study highlighted the value of community pharmacy in addressing health inequalities. This study led to 6 research publications.[42-45]

This project therefore proposes to co-develop and test the feasibility of an easily recognisable, accessible and discreet response service for people who are experiencing suicidal ideation or domestic abuse, available through community pharmacies. This will be done through the development of a complex health intervention followed by an evaluation of feasibility using the MRC framework for developing complex health interventions.[46]

STUDY OBJECTIVES AND PURPOSE

PURPOSE

The primary aim is to co-develop and evaluate the feasibility of a community pharmacy response service / intervention for people in danger from domestic abuse or suicidal ideation.

PRIMARY OBJECTIVE

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?

SECONDARY OBJECTIVE(S)

The objectives of the study are:

1. To develop a point of contact and triage referral resource in partnership with relevant experts and local referral organisations, for both domestic abuse and suicidal ideation.
2. To co-develop (with lay survivors / people with insight and professionals) the scope and features of a discreet response intervention in community pharmacy, to include the name, logo, promotional strategy and protocol for delivery in a pharmacy.
3. To co-develop with patients / public and professionals a training package and mentoring support service for pharmacy staff delivering the intervention.
4. To deliver the intervention in a purposive sample of community pharmacies and collect feasibility data on intervention usage and consequent referrals.
5. To ascertain and evaluate client, public and professional views on accessibility, acceptability, implementation, feasibility and intervention fidelity in practice.
6. To evaluate the potential for the intervention to be scaled up for a future trial, including economic and statistical considerations.
7. To engage with the public and professionals to disseminate findings and reporting of the intervention as an output.

OUTCOME MEASURES/ENDPOINTS

PRIMARY OUTCOME MEASURE/ENDPOINT

The primary outcome measure for this study will be the number of community pharmacy consultations for people enquiring about or seeking support for domestic violence or suicidal ideation, categorised per issue and level of severity.

SECONDARY ENDPOINTS/OUTCOMES

Secondary outcome measures are (i) subsequent management and referrals to support organisations (ii) client quality of life (based on EQ5D) (iii) acceptability of the service to clients (iv) client demographics (v) cost and economic considerations of the service.

STUDY DESIGN

- Phase 1: Intervention co-development involving one-to-one interviews, focus groups and co-production workshops.
- Phase 2: Training of pharmacy staff followed by a Feasibility Cluster Randomised Control Trial (in community pharmacies) and evaluation (qualitative focus groups, customer interviews, e-survey and summary workshop).

DATA ANALYSIS

All data analysis will be undertaken by the research team at the University of Lincoln.

Qualitative data

Qualitative data will be generated in the interviews, focus groups and workshops. Following transcription, data will be analysed using framework analysis.[51] This will involve an initial iterative process of open coding and according to a coding framework. After the coding process has been completed, a more refined and selective process of 'coding on' will be undertaken to differentiate, contrast and narrate the emerging themes that are of relevance to meeting the study's objectives. The qualitative software programme NVIVO 11 will be used to organise the data.

Quantitative data

There are three sets of quantitative data: the evaluation of pharmacy staff learning, the intervention measures and the community e-survey. To assess the impact on pharmacy staff learning (using the CPD Reaction Questionnaire), baseline and post-training data scores will be compared.[56] For both the CPD Reaction Questionnaire and the community e-survey, categorical variables will be analysed using the chi-squared test or Fisher's exact test as appropriate. Continuous data will be analysed using the within-group t-test or Wilcoxon signed rank-test as appropriate. Statistical significance will be assessed at the 5% (two-sided) level. All statistical analyses will be conducted using IBM Statistical Package for Social Sciences (SPSS) 22.

All client and pharmacy intervention / control data will be processed using R Version 3. The demographics and characteristics of the samples will be initially summarised using frequencies and percentages for categorical variables and mean and standard deviation (if normally distributed) or median and interquartile range (if not normally distributed) for continuous variables.

The main outcome in this feasibility study is the number of community pharmacy consultations for people enquiring about or seeking support for domestic violence or suicidal ideation per issue and level of severity. Descriptive comparisons will be made between intervention and control pharmacies. Appropriate multivariable linear regression models will explore differences between intervention and control groups in means and 95% CIs. As the feasibility study is not powered to detect effectiveness, the focus will be on whether 95 % CIs include a meaningful difference. This will seek to inform a sample size calculation for a future definitive trial.

The final evaluation of feasibility will involve the integration of the qualitative and quantitative data and will include an economic evaluation. In the economic analysis, a societal perspective will be taken into consideration. Business data including staff time will be used to inform the findings. Cost per client will be estimated by dividing the costs of the response service by the total number of clients accessing the service in the intervention group. An incremental cost-effectiveness ratio (ICER) will be determined to explore the affordability and potential cost-effectiveness of the intervention and inform a future trail rather than provide a definitive comparison

STUDY SETTING

- One-to-one interviews will take place in a setting that is most convenient to the participant.
- Focus groups and all workshops will take place at the School of Pharmacy, University of Lincoln.
- The feasibility study will involve community pharmacies recruited from the Lincolnshire area.

SELECTION OF PARTICIPANTS

ELIGIBILITY CRITERIA

Inclusion Criteria
Phase 1: Co-development of the complex intervention

Stakeholders (for interviews)

(a) Aged ≥18 years

(b) Representative of an organisation(s) that offer domestic abuse / suicide prevention or related services (for example, drug & alcohol services)

Lay people (for focus groups)

(a) Aged ≥18 years

(b) Survivor of domestic violence, suicidal ideation beliefs or interest/experience in supporting others in these circumstances

(c) Person with insight into and interest in supporting others for domestic abuse / suicidal ideation

Pharmacy staff (for workshops)

(a) Aged ≥18 years

(b) Current or recently worked for a community pharmacy organisation

Phase 2: Feasibility cluster Randomised Control Trial

Pharmacy staff (to be trained, deliver the intervention, and participate in focus group and feasibility workshop)

(a) Aged ≥18 years

(b) Employed by a community pharmacy that is in the study

Clients (service users, (recipients of the intervention)

(a) Aged ≥18 years

(b) Asking about or requiring support about domestic abuse / suicidal ideation

Pharmacy customers (for interviews)

(a) Aged ≥18 years

(b) Familiar with the intervention pharmacy

General public (for community e-survey)

(a) Aged ≥18 years

(b) Resident in Lincolnshire

Exclusion Criteria
Phase 1: Co-development of the complex intervention

Stakeholders

(a) Those without specialist knowledge of delivering services to people experiencing domestic abuse / suicidal ideation and related issues

Lay people (for focus groups)

(a) Unable or unwilling to give consent

(b) People in an acute state of distress

Pharmacy staff (for workshops)

(a) Pharmacy staff who are in non-customer facing roles

Phase 2: Feasibility cluster Randomised Control Trial

Pharmacy staff

(a) All staff in pharmacies where consent is absent from the Pharmacy's Head office / Pharmacy Owner
(b) Pharmacy staff in pharmacies that are not in the study
(c) Locum pharmacy staff (not on a regular employed contract with the pharmacy
(d) Pharmacy staff in a non-customer facing role

Clients (service users)

(a) Aged under 18 years
(b) Any participant unwilling or unable (i.e. lacking capacity) to provide consent

Pharmacy customers

(a) Aged under 18 years
(b) People who have accessed the response service
(c) Any participant unwilling or unable (i.e. lacking capacity) to provide consent

General public

(a) Aged under 18 years

(b) Not resident in Lincolnshire

Sampling
Phase 1:

Stakeholder interviews = 8 participants

2 x Lay focus groups (8 participants in each focus group) = 16 participants

3 x Co-development workshops (8 lay people and 4 pharmacy staff representatives in each workshop) = 36 participants

Phase 2:

A minimum of 3 x Staff per intervention pharmacy (after sampling of the pharmacies and randomisation to intervention/control = 24 participants

3 x Focus groups with pharmacy staff members (who delivered the intervention) = 24 participants (as above)

Customer interviews (up to three from each pharmacy) = 24 participants

E-survey = 600 participant responses

Summary workshop (24 staff members - NB already countered above, plus PPIE panel (~8) and Study Management Group (~6) = 46 participants

Size of sample
The sample size for the qualitative elements of the study will enable us to capture both a wide range of views and diverse perspectives to enable us to meet the objectives of the study.

This is a feasibility study so the sample size for the number of pharmacies has been pragmatically determined and to ensure sufficient data can be collected so the objectives of the research can be met.

For the e-survey, we compute that the estimated proportion of people who would say yes (i.e. are aware of the service) will be between 10% (precision 8.3% - 11.7%) and 30% (precision 27.4% to 32.6%) with a p-value for 95 confidence interval set at 0.05.

Sampling technique
For qualitative interviews, focus groups and workshops: purposive sampling will be used to ensure a wide range of lay and professional views to inform the intervention.

Phase 2: Sampling of pharmacies

A sampling framework will be used to recruit three pharmacies per the following category with a spread across different socio-economic areas (based on deprivation index from Office for National Statistics):

• Rural small pharmacy / rural large pharmacy

• Non-rural small pharmacy / Non-rural large pharmacy

Randomisation will then be conducted to give 2 pharmacies from each of the four categories as interventions (total of 8), and 1 pharmacy from each of the four categories as a control (total of 4).

RECRUITMENT

Phase 1:

1. **Scoping interviews**

Scoping interviews will be held with relevant representatives of relevant referral organisations (for example – Women's Aid, Samaritans, Emergency Department, Mental Health Crisis Team, Adult Social Care Domestic Abuse Co-ordinator, the Police, Addaction (now known as "We are with you")). The CI already has existing contacts with many of these organisations, from the development work. The CI will e-mail representatives from each organisation, supply information about the study and/or offer an introductory call. If the representative expresses an interest in participating the CI will forward the participant information sheet and consent form, and will make arrangements for an interview at a convenient time for the participant.

2. **Lay focus groups**

Members of the public will be invited to participate from relevant patient forums, relevant charities, survivor support groups, the local Recovery College etc. via distribution of a flyer (and social media post). This will be done through a contact at those organisations.

3. **Co-development workshops**

Lay people: Members of the public will be invited from relevant patient forums, relevant charities, survivor support groups, the local Recovery College etc. via distribution of a flyer (and social media post) through a contact at those organisations. Expressions of interest will be followed up with a participation information sheet, consent form and a phone call from the researcher. In addition, participants from the lay focus groups will be invited to continue with the study and participate in a co-development workshop.

Pharmacy staff representatives: Pharmacy staff will be identified via the Lincolnshire Training Hub. To ensure that different staff are invited in the co-production workshops and intervention delivery, recruitment to both research activities will be conducted in parallel. This will ensure there is no contamination in the delivery of the intervention.

Phase 2:

1. Delivery of the service in pharmacies

Pharmacies will be identified and invited through the Local Pharmaceutical Committee (LPC) using purposive sampling. These will be randomised to intervention / control.

Pharmacy staff will be recruited from each intervention pharmacy. The Pharmacy Staff will consent to being trained and delivering the intervention, attending a feedback focus group and participating in the summary workshop, in one consent process at the beginning.

Service users will be recruited from intervention pharmacies, at the point where they make access to the service (i.e. clients make their own approach to use the service, and recruitment is part of accessing the service). There are two categories of data collected in the intervention consultation, Part A data consists of the essential information required to deliver the service to the client. Part B consists of supplementary data for the purposes of the research study. In emergency cases where time is pressured, or where the client does not consent to Part B data, the service will still be offered to the client without collecting Part B data. Pharmacy staff have a normal duty of care to offer care to customers and patients approaching them for help. This study will not interrupt that normal duty of care.

2. Focus Groups with pharmacy staff who delivered the intervention

These participants will be those who have consented to be trained and deliver the intervention. If participants are unable to attend a focus group, we will offer a one to one interview instead. We will ensure that we collect feedback from all 24 participants in a manner that is convenient to them.

3. Customer interviews

Customers will be identified by pharmacy staff and who are regular 'general customers' rather than specific clients who have asked to use the service.

4. Public survey

Participants for the e-survey will be identified through distribution by local community venues, such as supermarkets, post offices, sports venues, faith venues etc.

5. Summary workshop

Participants at the summary workshop will consist of the Pharmacy Staff who delivered the intervention, the PPIE Panel and the Study Management Group (research team).

In all of the above cases, the researcher will inform the potential participant of all aspects pertaining to participation in the study. It will be explained to the potential participant that entry into the trial is entirely

voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and we will seek consent to use the data in the final analyses where appropriate.

Participant Payment
Should any participant be required to travel to a venue for the study, reasonable reimbursement of travel expenses will be offered.

Phase 1:

- Lay focus groups: £40 Amazon gift voucher per participant as a token of appreciation.
- Co-production workshops: £75 appreciation payment per participant or Amazon voucher (participants can choose a direct payment or a voucher).

Phase 2:

- Pharmacies: Intervention pharmacies will receive an expenses payment of £1500, and control pharmacies a payment of £500.
- Customer interviews: Customers will receive a £15 Amazon gift voucher as a token of appreciation of their participation.
- Public e-survey: Prize draw of 1 x £100, 1 x £60 and 2 x £40 Amazon vouchers (appreciation payments)
- Workshop: Pharmacy staff participants will receive a £75 fee for participating as a token of appreciation (or a voucher if preferred), as this will be an additional event after the 6 months implementation, for which the pharmacy received a fee.
- Refreshments will be provided at training, focus groups and workshops.

CONSENT

All participants shall provide written consent. The Informed Consent Form (ICF) will be signed and dated by the participant before they enter the study. The consent process will involve a discussion between the potential participant the researcher to ensure that the individual is fully informed about the research, including the nature and objectives of the study and possible risks associated with their participation. Opportunity will be given for potential participants to ask questions. Mental capacity will be assumed unless proven otherwise.

For the Phase 2: e-survey, return of the questionnaire will imply consent.

In some instances, electronic consent may be appropriate (i.e. if there are future COVID-19 restrictions and face-to-face interactions are not allowed). The University of Lincoln e-Consent guidance will be followed which is produced in accordance with the joint HRA and MHRA statement on seeking consent by electronic methods.

The recruiting Investigator will explain the details of the study and provide a Participant Information Sheet (and any other study related literature), ensuring that the participant has sufficient time to consider participating or not. Opportunity will be given to the participant to ask any questions they may have concerning study participation. For the e-survey, information about the study will be provided.

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP), and any other regulatory requirements that might be introduced. The researcher and the participant shall both sign and date the Informed Consent Form before the person can participate in the study.

One copy of the ICF will be kept by the participant, one will be kept by the Investigator. Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended Consent form which will be signed by the participant.

STUDY PROCEDURES/REGIMEN

STUDY FLOWCHART

This is a two-stage development and feasibility study to develop a complex intervention.[46]

Table 2 : Overview of research design

<table>
<tr><td rowspan="3">ENGAGEMENT

Regular Study Steering Group, and Study Management Group meetings

Regular Public and Patient involvement & Engagement meetings

On-going collation of mailing list of interested parties, with regular distribution of updates

Project website</td><td>DEVELOPMENT – 6 months

A. Foundations – update literature review and evidence-base, write study documentation and apply for research ethics committee approval.

B. Co-production - components of the intervention through a series of scoping interviews with a minimum of 8 key stakeholders (representatives from organisations that offer DA and SP services), followed by 2 lay focus groups and then 3 co-production workshops with 8 lay people and 4 pharmacy staff representatives in each workshop (total of 36 participants).

C. Modelling – finalisation of the above intervention elements, with consideration of RE_AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance)[47] plus ethics, data monitoring and finalisation of outcomes for feasibility study.</td></tr>
<tr><td>FEASIBILITY – 18 months

D. Recruitment and Training - Recruit 8 x pharmacies for intervention and 2 x pharmacies as comparisons, purposive sampling to cover rural/urban, small pharmacy/commercial store and differing socio-economic areas. Recruit and train a minimum of 3 members of staff from each pharmacy in intervention (total 24 staff).

E. Implementation of Intervention - Promotion of the service to the public, Implement intervention in the 8 pharmacies, data collection over 6 months in 8 x intervention pharmacies and 4 x comparison (control) pharmacies.

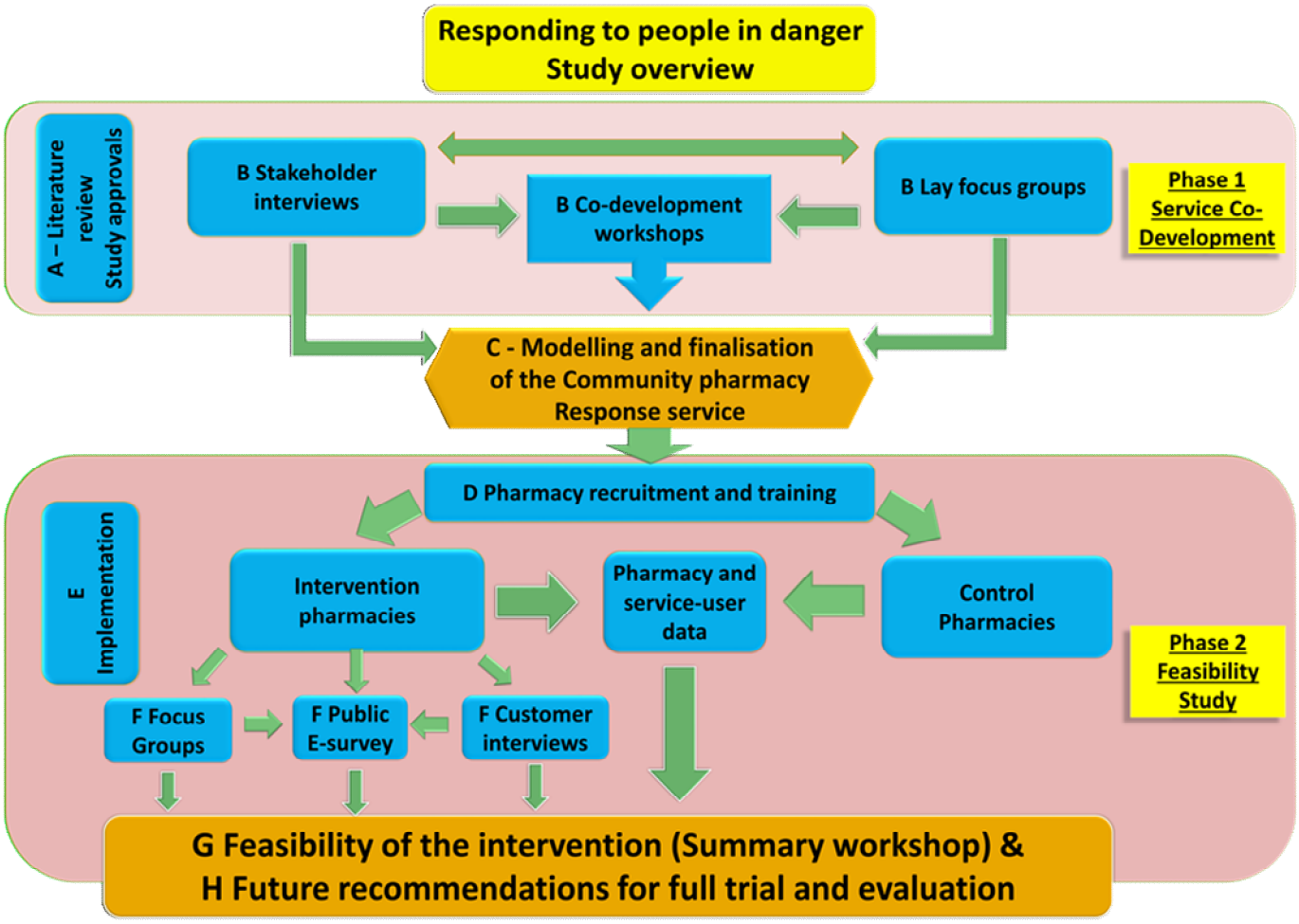
F. Evaluation for acceptability - Using the Theoretical Framework for Acceptability of Healthcare Interventions.[48] These will be investigated with pharmacy staff in 3 x focus groups with 8 staff in each (total 24 participants), followed by interviews with 2 to 3 regular customers per intervention pharmacy (not people who have use the intervention) (total 16-24 participants). An e-survey will then be designed from the qualitative analysis themes, and distributed widely to members of the public, electronically using social media, with the aim of having 600 completed surveys.

G. Feasibility of the intervention - Summary workshop with the 24 staff members, plus PPIE panel and Study Management Group to explore the feasibility of the intervention as a possible service and description of the intervention.

H. Feasibility of a future cluster randomised controlled trial – Analysis and evaluation by the research to team to scope the requirements of a future cluster randomised controlled trial possible.</td></tr>
<tr><td>DISSEMINATION – throughout study, and towards end of study

Report qualitative findings using COREQ template[49], and the details of the intervention using TIDieR[50]. Active dissemination via presentations and meetings with all partner and stakeholder organisations, and via mailing list and social media. Research publications: (i) reporting development and co-design; (ii) report of service use; (iii) report of focus group evaluation data.</td></tr>
</table>

Schematic overview


Responding to people in danger
Study overview
A – Literature review
Study approvals
B Stakeholder interviews
B Co-development workshops
B Lay focus groups
Phase 1
Service Co-Development
C - Modelling and finalisation of the Community pharmacy Response service
D Pharmacy recruitment and training
E Implementation
Intervention pharmacies
Pharmacy and service-user data
Control Pharmacies
Phase 2
Feasibility Study
F Focus Groups
F Public E-survey
F Customer interviews
G Feasibility of the intervention (Summary workshop) &
H Future recommendations for full trial and evaluation

Methods – development phase

A. Foundations

The literature review will be updated. Research Ethics Committee (REC) approval will be sought from the NHS Research Ethics Service (RES).

B. Co-development

1. One-to-one scoping interviews with key stakeholders

A minimum of 8 scoping interviews will be held with representatives of relevant referral organisations (for example – Women's Aid, Samaritans, Emergency Department, Mental Health Crisis Team, Adult Social Care Domestic Abuse Co-ordinator, the Police, Addaction (now known as "We are with you")). They will be recruited via targeted e-mails followed up with a participant information sheet and consent form. In-depth semi-structured interviews will be conducted, using scenarios to map and ascertain appropriate referral and support pathways for different levels of severity and urgency for suicidal ideation or domestic abuse (and any accompanying alcohol or substance misuse), and appropriate content of an education and training resource for pharmacy staff delivering the intervention. Views will also be sought on requirements for appropriate mentoring of pharmacy staff in case of distress during the study, on the requirements for clinical record keeping and on the content of the client self-report evaluation questionnaire (to be used in the evaluation). Interviews will be recorded and transcribed. Data will be analysed using framework analysis.[51] Recruitment and interviewing will continue until consensus and data saturation are achieved. These interviews will contribute to the development of the triage and referral tool. This will be an iterative process to create and embed appropriate referral pathways.

2. Lay focus groups

Alongside these interviews, two lay focus groups will be held: one for lay people with experience of domestic abuse, and one for lay people with experience of suicidal ideation. These groups will explore the lived experience and barriers to access for each issue, and will start the co-production process of the intervention. Representatives from each group will be invited to carry forward with the project, in to the co-production workshops. Each of the two groups will have 8 participants.

Members of the public will be recruited from relevant patient forums, relevant charities, survivor support groups, the local Recovery College etc. via distribution of a flyer (and social media post), or through contacts at those organisations. Expressions of interest will be followed up with a participation information sheet, consent form and a phone call from the researcher. Inclusion criteria are adults over 18 years of age, capable of informed consent, and an interest in supporting others suffering from suicidal ideation or domestic abuse. People in an acute state of distress would be excluded.

3. Co-production workshops (with lay people and pharmacy professionals)

Three co-production day workshops will then be held, with 8 lay people and 4 pharmacy staff representatives in each (total of 36 participants). The lay people will be recruited from the previous focus groups, in addition to local networks and organisations (as above).

Pharmacy staff will be recruited via the Lincolnshire Training Hub. The recruitment of pharmacies, and the staff within those pharmacies, that will be participate in the intervention delivery and feasibility stage, will be conducted in parallel to the recruitment of the pharmacy staff for the co-production workshops, to ensure that different staff are used in the co-production workshops, with no contamination into the intervention delivery. All participants will receive a £75 fee as a token of appreciation (or voucher) for participating in the co-production workshops.

In the workshops, interactive techniques will be used such as brainstorming, story-boarding, role play and principles in line with nominal group techniques[52] to co-produce:

- A conceptual design including the name, code-word or use of symbol for discreet access

- Criteria for the pharmacy site and staff taking on the role (safe person and safe space
- A protocol for delivering the service in a pharmacy setting
- Content for an education and training resource for pharmacy staff
- A promotional strategy and marketing materials

Data will be collected on flipcharts, post-its and discussion sessions will be audio-recorded. There will be pre- and post- correspondence with workshop participants to review proposed materials and gather views. Data will be analysed using framework analysis, and integrated with the findings from the scoping stakeholder interviews.[51] The qualitative software programme NVivo 11 will be used.

The collated findings will inform the final components of the intervention (protocol for delivery of the intervention in community pharmacy including criteria for the staff member and the consultation room; the triage and referral resource; education and training resource; mentoring support protocol; the name of the service as a symbol or code for discreet access, the promotional strategy).

Further development by the research team will be required for the education and training package. Learning outcomes will be developed based on the findings from the framework analysis and the method of delivery will be designed to stimulate active learning, be interactive, for example using scenarios and role play with feedback on competencies. This will support the development of the learner from “knows” through “knows how” and “shows” to “does” in accordance with Miller’s Prism of Clinical Competence.[53] A handbook for trainers and a workbook for learners will be written.

Similarly, further development of the triage and referral resource will be required by the research team, with iterative input from the local referral organisations. We have the support of the Domestic Abuse and the Suicide Prevention networks through Lincolnshire County Council.

The triage and referral tool will be a cornerstone of the study. It will consist of consultation questions, criteria and a triage grid of risk. Each level of risk on the grid will be mapped to the appropriate referral organisations. These will be agreed with the referral organisations during the co-development and will take into account their criteria for referrals and capacity. Initial work on a tool has commenced with the Crisis Team. For basic illustrative purposes only, please see the table below. The finalised grid will be accompanied by full details of clinical guidelines, contact details of referral organisations, consultation questions and protocols. A Pharmacy Operating Manual will be developed from the co-development work that contains the entire specification for the intervention including the final triage tool and signposting and referral pathways.

Table 3: Draft indication of levels of severity assessed during triage

	Level 1 – Signs of concern	**Level 2 – Active Concern**	**Level 3 – Immediate danger**
Domestic Abuse	Uncomfortable with relationship, made to do things don’t want to do. Sometimes feels frightened or threatened. +/- drug or alcohol misuse	Wanting to escape / make safety plans. Needs assistance, for example legal, housing or financial help, and/or, adverse effect on mental health, sexual or physical harm. +/- drug or alcohol misuse	Fear of death or serious psychological / sexual / physical harm, and/or suicidal as a means of escape. +/- drug or alcohol misuse

Suicide	Wanting change, wouldn't care if died, and/or considering death as an option to avoid something. Ambivalence about life and death. +/- drug or alcohol misuse	Wanting to be dead, contemplating killing self, vague plans, but still retains some sense of being future focused. +/- drug or alcohol misuse	Overwhelming hopelessness, taking action to prepare for suicide, finding opportunities to be alone and avoid discovery. +/- drug or alcohol misuse
Referral Options	**INFORMATION – guidance and general support** • The Samaritans • Women's Aid • Psychological interventions • Freedom programme • Consider antidepressant treatment • Drug & alcohol services as appropriate	**ASSISTANCE – one to one assistance needed** • The Samaritans • Women's Aid • Tailored psychological interventions and support with a specific person • GP / psychiatry • Drug & alcohol services as appropriate • Social care	**PROTECTION – immediate intervention required** • A&E, Specialist services, Mental Health Crisis Services, the Police • Drug & alcohol services as appropriate • Social care

The draft grid consists of three levels of risk: Level 1 – Signs of Concern, Level 2 – Active Concern and Level 3 – Immediate Danger. These levels are applied to the categories of: Suicidal Ideation, Suicidal Ideation with drug/alcohol misuse, Domestic Abuse, Domestic Abuse with drug/alcohol misuse. Signs and symptoms are listed for each category and level of risk, plus details of appropriate referral organisations.

Clients accessing the service will be guided through a series of questions in the consultation that will allocate them to a level and type of risk section of the triage grid. Options for onward referral or management will be discussed with the client in a shared-decision making manner and the recommendation or actual referral will be recorded. Health status questions based on an EQ5D assessment will be asked as part of the consultation.[54] This will enable us to map EQ5D to each of the type and level of risk sections and scope the feasibility of health economic assessment measures.

Referrals will either be made directly by the member of staff, or the client will be advised to make contact with an agency if less urgent and agreed. The logistics of getting to a referral is important. In level 3 risk, help would come directly to the client. We will ensure that our resource contains details of locations, public transport and consideration of care of dependents.

Documentation and templates will be written to support appropriate record keeping and of text to be used to support any referrals made in writing (e-mail or letter). Marketing materials will be produced in-line with the promotional strategy.

Protocols will be produced for the requirements of pharmacies taking part (e.g. sound-proof consultation room), the person delivering the intervention, the process for receiving the client and directing to the consultation room, the conduct of the consultation and the record-keeping after the consultation. These protocols will form the basis of the fidelity checks at the monthly support visits.

C. Modelling – The entire intervention and its components will be finalised, with consideration of RE_AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance)[47], preparation of documentation for data collection in the feasibility stage and finalisation of outcomes for feasibility study.

Phase 2: Feasibility Randomised Control Trial

D. Recruitment and Training – 12 community pharmacies will be recruited to take part in the study, with 8 as interventions and 4 as controls. Purposive sampling will be used to recruit three pharmacies per category of rural/small pharmacy, rural/commercial store, uon-rural/small pharmacy, non-rural/commercial store, with a spread across different socio-economic areas (based on deprivation index from Office for National Statistics[55]). Randomisation will then be conducted to give 2 pharmacies from each of the four categories as interventions (total of 8), and 1 pharmacy from each of the four categories as a control (total of 4).

A minimum of three members of staff from each pharmacy will be recruited in the intervention pharmacies, with one of them being a pharmacist (total of 24 staff). Recruitment will be through the Local Pharmaceutical Committee (LPC) and will involve consent from the pharmacy employer for chain pharmacies. The LPC are partners in this study and as such are very supportive and do not foresee any problems with recruiting pharmacies. Information sheets and consent forms will be provided, both for consent of the pharmacy to take part, and for staff participants. Intervention pharmacies will receive an expenses payment of £1500, and control pharmacies a payment of £500.

The participating staff will then be trained in two evening sessions, which will be interactive and involve active learning. The pharmacy sites will be visited to ensure they meet the requirements for the study, which are to have regular staff and pharmacist (not locums), and to have a consultation room that is sound-proof. Participants will be asked to complete the Continuing Professional Development (CPD) Reaction Questionnaire before and after the training.[56] This is a validated tool for assessing the impact of CPD activities on health professionals' behaviour intentions in clinical practice. This will allow us to assess their perceived level of knowledge, skills and attitudes for delivering the intervention. Each participating member of staff will also undertake 2 mock consultations with a member of the research team to embed their learning in situ. One consultation will be on suicide prevention and one on domestic abuse.

E. Implementation of Intervention – The service will be promoted through a variety of settings including social media, supermarkets, pubs, community centres, sports centres, religious venues and hairdressers (depending on COVID-19 restrictions), in addition to a press release, a radio advert and the website.

The service will be implemented for 6 months (see Appendix 2 for client flow diagram). During this time the participating pharmacy staff will have monthly supervisory follow up visits from the researcher to check on fidelity of service delivery and offer support, plus access to a monthly online mentoring session with a psychotherapist to debrief on any distress that may have been incurred or any ethical issues that have been encountered.

Data collection

Following triage, intervention pharmacies will collect the following data:

a. Usage and referral data

The rationale for this intervention is to lower access barriers. The primary area of interest is therefore the number of consultations, severity of danger and number of referrals made as a consequence of the consultation. Other measures we will explore include the reasons why the client chose the service, whether the client was considering or had accessed other services in the last 3 months,

The member of staff conducting the consultation will record the date, time, length of consultation, job role of staff member and the category of issue. Following triage, the informed consent will be received from the client. Data to be collected will include asking the client what services he/she has accessed in the last 3 months, and whether he/she has accessed this service previously. The client will then be asked some simple questions about reasons for choosing this service based on the four access barriers (capacity, psychological burden, timing and level of severity), for example: no appointment needed, convenient location, everyday environment, identified with the name and logo, convenient timing, familiar environment, familiar staff, whether their visit was opportunistic or planned, and basic demographic data.

Brief acceptability data will also be collected along with basic demographic details plus an indication of whether (for a future trial) completing a questionnaire and having a follow-up contact would be acceptable or not.

Staff will be trained to respond ethically in all cases of acute and severe distress by prioritising the safety and wellbeing of the client over the need to consent and collect data for the study. In some cases, this may mean that it may not be appropriate under very distressing circumstances to collect all of the client's study data.

b. Business data

Business data will be collected in order to evaluate whether taking on the service detracts or enhances normal pharmacy activity. Data will include prescription and service items. . These data will be collected at the beginning of the study retrospectively for the 6 months prior, and during the 6 months of the implementation. All costs of the intervention will also be recorded.

In the control (comparison) pharmacies, the same business data will be collected in addition to the number of queries or interventions made for domestic abuse, and for suicidal ideation, and whether any of these were through an alternative scheme (for example "Ask for ANI"). We are including control pharmacies as this will provide useful data for a future trial and because we anticipate that the baseline levels of requests for assistance with DA will increase with public awareness of "Ask for ANI".

F. Evaluation for acceptability

1. Post-intervention pharmacy staff focus groups

In-depth qualitative focus groups will be held with all staff that participated in the intervention (x3 with 8 participants in each). A topic guide will be devised to cover perceptions of the acceptability and effectiveness of the training and the entire intervention, using the Theoretical Framework for Acceptability of Healthcare Interventions.[48]

2. One-to-one pharmacy customer interviews

Similarly, in-depth qualitative interviews will be held with 2-3 regular customers (using purposive sampling for demographics) from each of the eight participating pharmacies (16-24 in total). Customers will be recruited through the pharmacy by approaches from the pharmacy staff with a flyer and expression of interest response box / e-mail. These will be general customers rather than clients who have used the service, with the aim of ascertaining community perceptions towards the use of a pharmacy for this service and impact of the response service on other services. Customers will receive a £15 gift voucher as an appreciation of their participation. Interviews will be offered in English, Polish, Lithuanian, Hindi and Urdu.

Both the focus groups and interviews will be audio recorded and then transcribed verbatim. All identifiable information will be removed during the transcription. Participants will be given a study code as an identifier. The data will then be analysed using framework analysis, and the qualitative software programme NVivo 11 will be used to facilitate organisation of the data.

3. Public e-survey

The themes from the combined qualitative analysis will be used to form the basis of a quantitative e-survey. The rationale of the community survey is to measure the wider awareness of the service.

The e-survey will be distributed through local community networks (the same as were used in the promotional strategy), and the intervention pharmacies, and will evaluate public awareness and attitudes towards acceptability and accessibility. The survey will contain a participant information section. A total of 600 responses will be aimed for. Assuming a response rate of 50%, 1200 people will need to be specifically targeted. Students will be employed through the University of Lincoln's "Campus Jobs" scheme to conduct market research by approaching passers-by in community settings and promoting on social media. Data from the survey will be analysed using descriptive and comparative statistics for different demographic groups.

G. Feasibility of the intervention - A summary workshop will be held with the 24 staff members, plus PPIE panel and Study Management Group will be held to explore the feasibility of the intervention as a possible

service and to review and finalise the intervention. Consideration will be given to: any unintended or adverse consequences, the degree of local adaptation that would be required, who would deliver the training, who would deliver the mentoring, factors that facilitate/hinder the intervention, and its overall benefits and limitations of the intervention. This would enable us to fully describe the intervention, and its components, plus the extent to which it can be adapted, so that it can be reproduced faithfully. The topic guide for the workshop will be based on the Consolidated Framework for Implementation Research.[57] Pharmacy staff participants will receive a £75 for participating as a token of appreciation (or a voucher if preferred), as this will be an additional event after the 6 months implementation, for which the pharmacy received a fee.

The workshop will use breakout rooms to work in small groups, with audio recording of each group, and then a plenary as one large group, which will also be audio recorded. The recordings will be transcribed verbatim. Analysis will proceed through an initial process of open coding and according to the consolidated coding framework.[57] After the coding process has been completed, a more refined and selective process of 'coding on' will be undertaken to differentiate, contrast and narrate the emerging themes that are of greatest relevance to the study's objectives.

This process will be used to refine and describe the entire intervention, each individual intervention component, the acceptability (for both provider and service user), intervention fidelity and delivery of the intervention and the process of implementation.

If the intervention is found to be cost-effective in a future trial, it is envisioned that the service could be adopted under the national pharmacy contract as an advanced service, in a similar way to the Medicines Use Review (MUR) / New Medicines Service (NMS), which requires pharmacists to be trained and accredited by a Higher Education provider. JS has experience in this area, having led the provision of MUR accredited training to a major multiple pharmacy and AL's PhD was on the MUR service and postdoctoral work on NMS. If adopted nationally, regional triage and referral resources would need to be developed to ensure effective local implementation.

Economic considerations

The final evaluation of the feasibility of the intervention will take into account economic considerations. We will determine whether a cost-effectiveness, cost- consequences or cost-benefit study will be most appropriate. In our planning, we have proposed a cost-utility study using the EQ-5D as the preferred approach. We will use the standard methods for establishing cost-effectiveness against a societal threshold based upon the reference case method suggested by NICE. In keeping with common practice, we will use a societal perspective for the cost-utility analysis but will also consider the appropriateness of adopting a health and social care perspective.

We will use a resource use approach to costing, and we will build a cost model using price weights derived from national sources such as PSSRU. The main outcome measure for the economic analysis will be the EQ-5D, but a cost-effectiveness analysis will also be undertaken using the primary clinical outcome measure chosen after feasibility study. We will collect resource use and outcome data using a self-reporting questionnaire. This data will be used to build an economic model, which will inform the cost-utility and cost-benefit analysis. The model type and structure will be determined during the feasibility study. For example, the EQ5D measurements will enable us to model QALY and will inform a future Markov model for economic impact of the intervention to other NHS services and quality of life.

We will test the feasibility of a full-scale economic evaluation using the following criteria: (i) Can cost and outcome data be successfully collected? (ii) Can a viable model be built that produces robust data for an economic study? (iii) Can an appropriate form of evaluation study be performed using robust methods? (iv) Does the economic modelling align with the objectives of the clinical study? (v) Can results be presented in a way useful to NHS decision-makers and can accompanying uncertainty analysis be performed?

Our main economic analysis is designed to provide NHS decision-makers with the information they need to assist commissioning. In addition, we will also build a cost/profit model for pharmacy providers, as a means of demonstrating the net benefits of providing the services described. In this model, we will take a pharmacy

perspective and will consider the costs of hiring additional staff and running the service. We will then perform a sensitivity analysis that estimates profitability for a range of cost and NHS fee scenarios. We will present the results from this analysis alongside the main economic modelling.

H. Feasibility of a future cluster randomised controlled trial - A final analysis and evaluation will be conducted by the research to team to scope the requirements of a future cluster randomised controlled trial. We are working with LinCTU who will facilitate collection of data and analysis. A detailed list of criteria for progression to full trial, with an indication of red/amber/green specifications has been developed (See Appendix 1).

Engagement and dissemination

To inform communication, the key findings for acceptability, feasibility, potential effectiveness, cost-effectiveness and impact on pharmacy business will be refined put into a table of activities and messages for LinCTU. The co-investigator GL is deputy director of this CTU. Their involvement will consist of setting up all of the progression criteria and associated data collection on CASTOR trials software.

This will ensure full GDPR compliance and that all data is stored in secure cloud access in the UK. They will assist with participant information sheets, consent forms and applying for ethical approval. The CASTOR software will allow data recording templates to be available to the pharmacies online so that they can enter the data at the time of the consultation, and the data will go directly to the database. It also allows the research team to have access to live and comprehensive data. They will conduct all randomisation and statistics and provide data monitoring and study support. GL and the CTU will play a significant role in the final evaluation of feasibility.

A Study Steering Group and PPIE panel have been established. There will be on-going engagement with these groups throughout the study, with regular meetings. A database of partners and interested people/ parties will be held and updated throughout, with updates sent to those on the database. Participants will have the option to receive updates on the project. This will be accompanied by active engagement and dissemination with partners, for example update presentations at the Lincolnshire Suicide Prevention Steering Group. There will be a project website and social media will be used.

In terms of formal reporting, the qualitative findings will be reported for publication using the COREQ template, and the details of the intervention using TIDieR.[50] The study protocol will be submitted for the publication as well as the final outcomes (co-development publication and feasibility publication). A detailed report of the completed project produced for the NIHR library will be published and freely available on our website and NIHR website.

RANDOMISATION AND BLINDING

A sampling framework will be used to recruit three pharmacies per the following category with a spread across different socio-economic areas (based on deprivation index from Office for National Statistics):

• Rural small pharmacy / rural large pharmacy

• Non-rural small pharmacy / non-rural large pharmacy

Randomisation will then be conducted by the CTU, to give 2 pharmacies from each of the four categories as interventions (total of 8), and 1 pharmacy from each of the four categories as a control (total of 4).

Because of the nature of the intervention and promotion, pharmacy staff, participants and researcher working with pharmacies will not be blinded.

STUDY REGIMEN

SCHEDULE OF PROCEDURES

Data collection measures and time points for Phase 2: Feasibility Randomised Control Trial

Procedures	**Screening**	**Intervention delivery**	**Post intervention**
Pharmacies allocated to intervention			
Service users			
Service user assessment for eligibility		X	
Informed consent		X	
Demographics & health Status		X	
Satisfaction		X	
Pharmacy staff			
Recruitment, informed consent and training	X		
Service delivery		X	
Usage and referral		X	
Business data		X	
Focus Group at UoL or online			X
Summary workshop at UoL			X
Pharmacies allocated to control			
Number of enquiries and referrals		X	
Business data		X	

WITHDRAWAL

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw, the data collected to date may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and may still be used in the final analysis.

ETHICAL AND REGULATORY CONSIDERATIONS

ASSESSMENT AND MANAGEMENT OF RISK

Sensitive nature of this research

This project includes clients from vulnerable groups who are survivors, patients or people with an interest in helping people experiencing domestic violence / suicidal ideation. As such, the research will need to be accomplished with great skill and sensitivity. At all times we will use listening and non-judgemental techniques to create an open yet confidential safe space for people to discuss their views.

Experience of research leads and research team

The study will be carried out by an experienced research team with appropriate clinical, research expertise and experience with working with vulnerable groups. The Chief Investigator (Solomon) is the CI and co-lead for this study with Latif. Both are experienced pharmacists, academics and have successfully delivered projects that have involved co-production, evaluation and working with marginalised and vulnerable groups.

Specifically, Solomon has expertise in psychological interventions, engagement projects on domestic abuse and child safeguarding, and pharmacy education. She also holds counselling qualifications. Latif is an experienced mixed-methods pharmacy practice researcher who has expertise in co-production and evaluation methods and working with marginalised groups including children and young people who have self-harmed. He has also served a full term as an expert member of the NRES Nottingham 2 Research Ethics Committee (2012-17). The wider research team is also highly experienced with expertise in psychological interventions, participatory research and health intervention economic evaluations.

Phase 1:

1. Interview with professional stakeholders

These interviews are not expected to raise any significant ethical issues, cause distress or make the participant upset. This is because they will be centred on service development issues i.e. help us to map referral pathways, advise on appropriate content of the pharmacy's education and training resources and other procedural aspects of the service (e.g. advice on clinical record keeping).

2. Lay focus groups

Two lay focus groups will be held. One for lay people with experience of domestic abuse, and one for lay people with experience of suicidal ideation. These groups will explore the lived experience and barriers to access for support for each issue.

All participants will receive an information sheet at least 24 hours before the focus group, be fully informed beforehand about the topic to be discussed and be informed that participation is entirely voluntary and that they can withdraw at any time.

Before the workshop, will also inform everyone that the focus group will be run under 'Chatham House Rules' to ensure people are able to express themselves without fear of disclosure of what is said directly or indirectly by any participant. These are potentially emotive topics and there is possibility for participants to become upset. We will discuss issues relating to domestic abuse / suicidal ideation in a sensitive way and seek to frame the discussion positively i.e., focus on the opportunity for the research team to learn and for this to be then applied to provide better support to individuals.

We are aware of potential gender-power issues and so JS will lead on discussions relating to domestic abuse. During the focus group, should any participant appear to become upset during the workshop, there will be sufficient facilitators to be able to accommodate their needs. Should they wish, the participant will be invited to leave the discussion / room as long as is needed. They may either withdraw or come back to the group depending on their preferences. JS has training in counselling and has experience of research on sensitive issues. Latif is also an experienced pharmacist-academic who has run co-production workshops with vulnerable people before.

All participants will be invited to carry forward with the project, in to the co-development workshops if they should wish.

3. Co-development workshops

All participants will receive an information sheet and be informed about the nature of the workshop at least 24 hours beforehand. Written informed consent will be received before the workshop. Like the focus groups, we will inform everyone that the workshop will be run under the Chatham House Rules and use the same measures as the focus groups should any participant appear to become upset or want to leave the discussion. We will use a mix of small group work, and larger group discussion with a facilitator mingling between groups to ensure that everybody has the chance to speak. We will encourage participants to respect the views and opinions of others. As such, it is not anticipated that any participants will feel marginalised during the workshops.

Phase 2: Feasibility study

1. Service Delivery

A. Potential burden on pharmacists and pharmacy staff

Once permission is granted from the Head Office / Owner, the pharmacy staff will be invited to take part. It will be made clear to all pharmacy teams what will be involved. They will receive at least 24 hours to decide whether or not to take part. It will be made clear that their decision regarding participation in the study will be entirely voluntary and that any staff member can withdraw from delivering the service and study at any time should they wish to do so. As employees they will be assured that not taking part will not disadvantage them in terms of their appraisal / salaries etc.

If they agree, pharmacy staff will receive training and support to fully prepare them to deliver the service. Training will include how to manage and respond to requests for help, study procedures and training on the principles of GCP. The pharmacy will be randomly allocated and receive support costs according to whether they deliver the service / or act as controls. At the end of the study, recruited pharmacy staff will take part in a focus group discussion and summary workshop.

The pharmacy staff will receive monthly support visits from the researcher, and can contact the researcher in-between visits for additional support or advice.

B. Delivering the pharmacy response service delivery: disclosure of sensitive information

All pharmacy staff will be trained on the ethical issues around the disclosure of sensitive information. We expect there to be a range of service-user needs. The training will involve roleplay and scenarios to prepare pharmacy staff for eventualities including what to do if the service-user is in immediate danger. These are complex issues that the feasibility study will seek to explore and understand how well pharmacy staff can cope with managing such situations.

C. Collecting data from service-users at the time of accessing the service

We recognise that clients (service-users) are likely to be distressed at the time of accessing the service. We aim to achieve an ethical balance between gathering sufficient service data for us to be able to assess the feasibility of the service, and not over-burdening them at a difficult time.

Including data and the views of clients is important, to ensure that the final intervention that will be produced at the end of feasibility is appropriate and relevant to this client group. Excluding such individuals could introduce bias as the sample would not be representative of the population and it may reduce the utility of the research findings. Furthermore, it is argued that vulnerable groups should be protected through research, rather than from research.

However, our priority is the welfare of the client. We have taken a number of steps to safeguard the clients in the research process.

The pharmacy staff will be trained to ensure the wellbeing and safety of service-users accessing the service will be the paramount consideration. There will be a clear assessment of risk before the service-user is invited. We anticipate that most requests for the service will be for lower-level support. (See table 4) i.e. Levels 1 (Signs of concern) or Level 2 (Active concern). We do not anticipate many will be at the highest level (Level 3 - Immediate danger). Pharmacy staff will be trained to invite potential participant who are categorised at Level 1 & 2. For those in Level 3, pharmacy staff will be trained to manage these case with discretion, urgency and compassion.

We have divided the data to be collected in the consultation in to two parts. Part A contains the data necessary to be able to effectively triage the client and refer appropriately. Part B consists of supplementary data for the purposes of evaluating the feasibility of the study. Clients will be invited to consent to both parts, but if the client is unwilling to consent to Part B, they will still be offered the service with the collection of Part A data only. Similarly, the pharmacy staff may use their judgement in cases of considerable distress or urgency to omit Part B and deliver Part A only, so as to respond swiftly and effectively to their needs.

To ensure we collect data about service use and acceptability, we will seek to collect basic demographic data and brief views on service acceptability when service-users access the service. The pharmacy staff will explain this is a trial service and invite the individual to offer their views. The data will be collected during the consultation. The consultation will take place in a private consultation area to ensure privacy. Potential participants will be informed that all data collected for the research is anonymised.

Consent (for Part A and Part B as appropriate) will be obtained at the time of contact. Clients will be provided with a Participant Information Sheet and Participant Consent Form. Because of the nature of the service, prior consent is not possible and there is a limited time frame for the initiation of the intervention being tested. We recognise that the usual 24 hour notice period will therefore not apply.

The pharmacy staff will go through the participant information sheet with the service user. They will be invited to take this away if they choose. Information sheets will be made available in the additional languages of Polish, Lithuanian, Hindi and Urdu.

It will be explained that offering study information is entirely voluntary and declining to provide this additional information will not affect the care they receive in any way. Pharmacy staff will check for understanding and provide the opportunity for potential participants to ask questions and withdraw their consent at any time.

In terms of data collection, all of the client data is collected in the consultation. We did not feel that contacting participants after the service to collect follow up data would be appropriate (risk of breach of confidentiality / potential to raise suspicions with abusive partners).

The study data collected will not be extensive. It will comprise of simple demographic data, brief views about acceptability, satisfaction and health status. We already have extensive PPIE input in the design of these procedures. We will further test these as part of Phase 1 (co-development) of the study where we anticipate there will be further refinement of the triage process, referral and data collection tools.

D. Psychotherapist support for pharmacy staff

The wellbeing of the service users and the pharmacy staff will form an important part of the evaluation of feasibility. The core research team (JS, AL and appointed researcher) will be in regular contact with staff during the implementation phase and be available to respond to queries that may need to be made in light of any ethical issues that arise.

All pharmacy staff recruited to the study, will be informed at the beginning and throughout the feasibility study that they have access to an online mentoring session with a trained clinical psychotherapist to debrief on any distressful events that may have been encountered or any ethical issues that have arisen. All pharmacy staff will be reminded of this during the monthly supervisory follow up support visits from the researcher. We will

ensure pharmacy staff are aware that the psychotherapist is not part of the research team / evaluation team and that she can be accessed anonymously should they wish to do so.

Public views

2. Participation in customer interviews

Regular customer users of the pharmacy will be invited to a one-to-one interview. It will be explained that the participation is entirely voluntary, not talking part will not affect their usual care and they can withdraw at any time.

These customers will be deemed well, are considered 'appropriate' and are not likely to become upset if invited to participate in the research. This 'appropriateness' will be determined by their usual care team who will know the customer well. The aim of these interviews is to establish the views of customers on any effect the intervention may have had on the routine pharmacy services, and customer acceptability towards the new service.

3. Public Questionnaires

This brief and optional e-survey will seek to measure general awareness of the service in the wider community and attitudes towards acceptability and accessibility. Participating in the questionnaire may present a minor inconvenience but has minimal physical risks or burden. Participants will be informed in the information sheet that participation is voluntary and they can choose not to answer any question.

There will also be contact details of self-help support services at the end of the questionnaire should these be needed. Return of the questionnaire will imply consent.

Personal information / data confidentiality

We will ensure that participants' identifiable details are stored securely at the University of Lincoln. Transcriptions of qualitative recordings and verbatim quotes will be anonymised to prevent participants being identified. We will abide by the Data Protection Act and the NHS Code of Confidentiality.

Source documents will be archived as per protocol at the University of Lincoln. Only study staff will have access to study documentation other than the regulatory requirements. In compliance with the GCP and University guidelines, the CI will maintain all records and documents. These will be retained for at least 7 years, archived at secure archive facilities at the University of Lincoln.

Inclusivity

This study will seek to be as inclusive as possible. We are guided by our PPPIE Panel who have advised using an appreciative approach, where all participant views are valued, throughout. The CI will work closely with Khatri who is the PPIE representative and co-applicant for the study.

We have costed for information sheets to be made available in a range of different languages. Translator costs have also been included for the customer interviews.

Mandatory text: Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted. Medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

ADVERSE EVENTS

A risk assessment has been conducted for this intervention, and risks for the intervention will continue to be considered and discussed during the co-development. There are two sets of main risks. The first is potential risks to clients accessing the service. Because they may be in a vulnerable and distressed

situation, we must ensure that the intervention does not add to their distress or vulnerability. The protocol for conducting the intervention (from the point of client entry into the pharmacy, through the consultation, and then back out of the pharmacy) will take into account discretion, confidentiality, compassion and sensitivity. Similarly, the triage and development tool, and the staff training package will be designed to protect the clients from any harm. The second set of risks is the risk of harm to pharmacy staff from delivering the intervention. This may include them becoming upset themselves, being stressed by having increased demands on top of their routine work and the potential for feeling intimidated or under threat in the consultation room. To safeguard against these risks, we will include all aspects of safety and wellbeing in the training, we have incorporated the psychotherapist debriefing sessions and consultation rooms will be checked to ensure they have a panic alarm. We note that pharmacy staff are currently expected to manage patients in distress and have very little training or resources for this purpose. By developing this intervention, we aim to make these types of interactions safer (and more effective) for both patients/customers and pharmacy staff.

With regards to the rest of the research study (focus groups, workshops, interviews and survey) the risks are more minimal. We will ensure that there is always an extra facilitator at public/lay focus groups and workshops so that a facilitator can spend time with a participant individually should they become upset.

ETHICS REVIEW AND COMPLIANCE

The study shall not commence until the study protocol, information sheets and consent forms have been reviewed and approved from a Research Ethics Committee and relevant NHS/Social Care permission is obtained

The sponsor will be responsible for deciding whether amendments are substantial and non-substantial in collaboration with the Chief Investigator.

Where an amendment is required to study documentation that required REC approval, changes will not be implemented until REC approval and HRA categorisation is received. Where an amendment requires local approval, this shall be sought prior to the amendment be implemented at each site in accordance with the categorisation given on the HRA approval letter.

Should an amendment be required to eliminate an apparent immediate hazard to participants this may be implemented immediately and the REC/HRA and R&D will be notified as soon as possible.

Minor amendments for logistical or administrative purposes may be implemented immediately

Amendments will be logged on the Sponsor's Study Amendment Log and stored in the Trial Master/Site File(s).

Annual Progress Reports shall be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given – until the end of the study.

A final report shall (where possible) be submitted to the REC within one year after the end of the study.

If the study is terminated prematurely the CI will notify the REC, including the reasons for premature termination.

PEER REVIEW

The project has received external peer reviewed and has received funding by the NIHR (HS&DR).

PUBLIC & PATIENT INVOLVEMENT

The research proposal has been developed with extensive patient and public involvement and engagement (PPIE). The project has a PPIE advisory and oversight steering group. Both advisory groups will meet to

ensure the project is conducted sensitively, with a people-centred approach and ensure rigorous external review.

Initial involvement:

The initial idea for this project emerged from Solomon's previous safeguarding study consisting of 10 focus groups with the public and professionals. All groups requested a drop-in service, in an everyday environment, for people to access to get advice and advocacy for domestic abuse. Members of the public did not feel that they could contact the major services alone. After the study, a total of 38 participants from this study were approached (in 2015 / 2017) to discuss an "in-between" service for domestic abuse. Solomon also met with 6 members of Lincolnshire Recovery College in August 2019 where they spoke about pharmacists as approachable intermediaries for people living with mental health conditions.

In 2020-21 we consulted with 11 individual members of the public (6 females and 5 males, early 20s - 70s), with BAME and LGBT representation. 6 of the people had experienced suicidal feelings or domestic abuse.

We have also consulted with: Women's Aid, Samaritans, Mental Health Trust, a GP in the Crisis Team, a community researcher, 4 individual pharmacists, 2 psychotherapists and an Approved Mental Health Worker, in addition to giving presentations at the Lincolnshire Suicide Prevention Steering Group (contains local NHS Trusts, Uni/colleges, Police, Transport Police, Highways Agency, Voluntary sector, Public Health) and the Local Pharmaceutical Committee (Boots, Well Pharmacy, Co-op Pharmacy and independents). JS met with the Home Office to discuss complementary approaches with Ask for ANI.

Key findings from PPIE engagement:

Views on pharmacy setting were positive as pharmacy staff are trusted professionals. Pharmacies can offer a discreet service (one can go into pharmacies for a range of reasons). Few barriers (i.e. no 'GP type receptionists'). Can walk into any pharmacy and can make excuse to partner to go alone (i.e. purchases of feminine hygiene products).

The link between abuse and suicide was noted, particularly if divorce is culturally unacceptable. It was recommended therefore that the service should cover both domestic violence and suicidal ideation.

The proposed name of "Lifeguard" with a life-ring symbol had an overwhelmingly positive response and was deemed to be wholly appropriate. Suggestions on how the service would work in practice were also made including having a card to hand in at the chemist counter to act as a 'nudge'.

Possible barriers were also detailed including pharmacists' skills, the ad hoc nature may mean other customers would having to wait, and if children were brought to the pharmacy.

Engagement with support organisations / professionals was positive and their views have influenced the service design (i.e. development of the triage, referral resources and mentoring for pharmacy staff). A representative from Women's Aid was disappointed in the "Safe Spaces" scheme saying that it was a good idea, but that scheme did not seem well implemented. Our project will specifically look at implementation / feasibility issues so the final service can be implemented effectively.

Planned on-going involvement:

The input from patients / service users and the public will remain central throughout the study and will continue through 4 main routes.

- Firstly, members of the public are directly involved as participants in the lay focus groups,co-production workshops, the customer interviews and survey.
- Secondly, we have established a PPI panel which will meet regularly during the study.
- Thirdly Mr Khatri is our PPI lead and co-applicant. As a co-applicant, he will be regularly involved with all aspects of the study. We will use his lay expertise to ensure public facing materials and study

information are accessible. Mr Khatri is registered blind and from a BAME background. His input throughout the study will enhance the study's inclusivity and diversity.
- Fourthly, we will establish a database and mailing list of people and organisations with an interest in the project. They will receive regular updates and will be invited to give comments, ideas and feedback.

The engagement with the public will be accompanied by continued and extended engagement with professionals and relevant organisations. There are three main routes for this engagement.

- Firstly, as participants in the study in the scoping interviews, and for pharmacy staff as direct participants in coproduction, being trained and implementing the intervention, in the staff interviews and in the final workshop.
- Secondly, there will be continued regular contact with the LPC, the Suicide Prevention Committee and other relevant organisations.
- Thirdly, via the same database and mailing list of interested parties, professionals will be included and asked for feedback. Solomon will continue the dialogue with the Home Office about developments with Ask for ANI and has been invited to be a member of their advisory group.

PROTOCOL COMPLIANCE

This study will be conducted in accordance with this protocol. Accidental protocol deviations may occur at any time. Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

DATA PROTECTION AND PATIENT CONFIDENTIALITY

All study staff and investigators will comply with the principles of the Data Protection Act (2018) in protecting the rights of study participants with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's/Regulations core principles.

Each participant will be assigned a study identity number, for use on CRFs other trial documents and the electronic database.

Personal data, research data and the linking code will be stored in separate locations. When stored electronically, this will include using encrypted digital files within password protected folders and storage media. Personal information shall be stored separately to research data and will be kept secure, and maintained.

Personal data will be stored for 12 months following the end of the study, so that the Chief Investigator may provide participants with a summary of the research (should they wish to receive a copy).

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Lincoln representatives, the REC, local R&D Departments and the regulatory authorities.

INDEMNITY

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Lincoln as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance.

ACCESS TO THE FINAL DATASET

The Chief Investigator (JS) and Co-lead (AL) will have access to the final dataset. The dataset will be fully anonymised and uploaded anonymously to the University's repository.

DISSEMINATION POLICY

The data custodian will be the Chief Investigator on behalf of the University of Lincoln. The findings will be disseminated in peer reviewed scientific journals, internal report, conference presentations, publication on website and other publications.

Authorship eligibility guidelines and any intended use of professional writers

We will be guided by the International Committee of Medical Journal Editors (ICMJE) who have defined authorship criteria for manuscripts submitted for publication. The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Appendix 1

Proposed progression criteria to trial

	Criterion	Data Collection	Green	Amber	Red*	Comments
1	Favourable opinion by HRA REC	N/A	Favourable opinion		Non-favourable opinion	
2	Scoping interviews with referral organisations and setting up referral pathways	Recruitment for scoping interviews and subsequent engagement	Successful engagement with all major local referral organisations for both issues	Engagement with some but not all of major local referral organisations for both issues	Failure to engage with at least one appropriate referral organisation for each issue	
3	Views of intervention from participants in lay focus groups and co-production workshops	Lay focus groups and co-production workshops	Favourable view towards intervention from all participants in lay focus groups and co-production workshops	Mixed views as to suitability of the intervention	Majority view not in support of the intervention	
4	Development of all aspects of the intervention	Co-production workshops and modelling	Successful development of all 7 aspects of the intervention	Partial failure to develop any one aspect of the intervention	Failure to develop any one aspect of the intervention	
5	Recruitment of pharmacies (control and intervention) across rural/urban, small pharmacy / commercial store	Recruitment of pharmacies	Recruitment of 3 pharmacies per category: a. urban/large commercial b. urban/small pharmacy c. rural/large commercial d. rural/small pharmacy	Failure to recruit at least one pharmacy for any of these categories	Failure to recruit any pharmacies	
6	Randomisation procedures - are pharmacies willing to be allocated to the control group	Randomisation	All 12 agree to be randomised	At least one pharmacy was not willing or able to be randomised	None of them were willing or able to be randomised	
7	Recruitment of staff within pharmacies (3 per pharmacy, of whom one should be a pharmacist)	Staff recruitment	Recruitment of at least 2 per pharmacy	Recruitment of 1 per pharmacy	None recruited	
8	Ability to deliver training to all staff (2 sessions, 24 staff)		All 24 intervention staff attended and training delivered	Staff from half of the pharmacies attended training	Failure to train anyone in a particular pharmacy	
9	Assessment of change in behavioral intention after training – CPD Reaction Questionnaire	CPD Questionnaire and feedback	All staff completed the questionnaire with positive indication of feeling adequately trained to undertake the intervention	50% completed, and or results show 50% of staff do not feel adequately trained to undertake the intervention	0% completed and / or all staff feel unprepared	
10	Monthly visits to pharmacies – support and fidelity	Monthly visits	All visits completed		Failure to complete one pharmacy visit	
11	Feasibility of running the intervention – drop out of staff or pharmacy (min of one member of trained staff remaining in the intervention for the whole time period)	Monthly visit	All pharmacies complete the intervention	One or more pharmacies fail to complete	100% drop out	

12	Deviation from the intervention as stated in the protocol (fidelity)	Monthly visit checklist	No significant deviations from the protocol	Any significant deviations would require pause and adjustment to the protocol	All pharmacies have deviated significantly from the protocol – the intervention needs considerable amendment or is deemed unfeasible	
13	Use of psychotherapist mentoring	Monthly mentoring / assessment	Level of mentoring required is deemed to be sufficient, or more than needed, by pharmacy staff participants	One pharmacy, or three members of staff are finding the level of mentoring inadequate	More than half of the pharmacies, or more than half of staff are finding the level of mentoring support inadequate	
14	Numbers & details of any significant ethical or distressing cases	From monthly visits, or from mentoring	Staff feel able to respond to more difficult cases without causing undue distress to themselves		Two or more pharmacists feel unable to respond to more difficult cases	
15	Client experience	From monthly visits, mentoring or staff focus groups	Client is successfully managed / referred following interactions with pharmacy staff		Any report of a client appearing to be adversely affected by a consultation would require review according to the protocol	
16	Intervention used by clients	From data collection in pharmacies and monthly visits	Intervention being accessed by clients in all pharmacies	No usage of the intervention in over half of the pharmacies after	Intervention not used / accessed in any pharmacy	
17	Levels of demand for the intervention by clients	From data collection in pharmacies and monthly visits	All pharmacies able to cope with the levels of demand for the intervention, without unduly adversely affecting other aspects of the pharmacy's activities		Half or more of the pharmacies unable to cope with the high levels of demand for the intervention	
18	**Number and details of consultations per pharmacy** (date, time, alone or with other and who, time taken, member of staff, if client had attended before)	Data sheets in pharmacies	Staff able to complete all details for all clients	Failure to record at least 50% of the data for at least 50% of the clients	Failure of the pharmacy staff to record any data on the intervention	
19	Other services accessed by client in last 3 months	Data sheets in pharmacies	Staff able to complete at least 80% of the data for at least 80% of the clients	Failure to record at least 30% of the data for at least 30% of the clients	Failure to capture any data	
20	**Issue and level of severity** (from triage grid) – to give overall number of consultations per box of triage grid - data collected in consultation	Data sheets in pharmacies	Staff able to complete all details for all clients	Failure to record at least 50% of the data for at least 50% of the clients	Failure of the pharmacy staff to record any data on the intervention	
21	**Outcome from consultation** – advice / self-management, signposted to another service, direct referral made, and to which organisations	Data sheets in pharmacies	Staff able to complete all details for all clients	Staff able to complete at least 80% of the data for at least 80% of the clients	Failure to record at least 50% of the data for at least 50% of the clients	

22	Reasons for accessing this service (based on 4 access barriers of capacity, psychological burden, timing, level of severity) – drop-in, convenient location, familiar environment, in person, familiar staff, everyday setting etc. - data collected in consultation	Data sheets in pharmacies	Staff able to complete at least 80% of the data for at least 80% of the clients	Failure to record at least 50% of the data for at least 50% of the clients	Failure to record at least 30% of the data for at least 30% of the clients	
23	Opportunistic or planned access by client - data collected in consultation	Data sheets in pharmacies	Staff able to complete at least 80% of the data for at least 80% of the clients	Failure to record at least 50% of the data for at least 50% of the clients	Failure to record at least 30% of the data for at least 30% of the clients	
24	Client basic demographic data collected in consultation	Data sheets in pharmacies	Staff able to complete at least 80% of the data for at least 80% of the clients	Failure to record at least 50% of the data for at least 50% of the clients	Failure to record at least 30% of the data for at least 30% of the clients	
25	Willingness to be followed up	Data sheets in pharmacies	Staff able to complete at least 80% of the data for at least 80% of the clients	Failure to record at least 50% of the data for at least 50% of the clients	Failure to record at least 30% of the data for at least 30% of the clients	
26	Pharmacy business data - prescription and service items. These data will be collected at the beginning of the study retrospectively for the 6 months prior, and during the 6 months of the implementation (for both control and intervention)	Pharmacy companies	Able to collect at least 90% of the data from 90% of the intervention pharmacies		Failure to collect at least 50% of the data from 50% of the intervention pharmacies, or an indication from this data that the intervention is having a deleterious effect on the business and staff wellbeing in any one of the pharmacies.	
27	Control pharmacies – number of queries for SI or DA, and if any Ask for ANI / safe space requests	Pharmacy companies	Able to collect at least 80% of the data from all 4 intervention pharmacies		Failure to collect 50% of the data from any one of the intervention pharmacies	
28	Community survey responses	Community survey	Completion of 600 full responses to community survey within the time period	Completion of 400 full responses to community survey within the time period	Completion of 300 or less full responses to community survey within the time period	
29	Acceptability and effectiveness of training using the Theoretical Framework for Acceptability of Healthcare Interventions – in staff focus groups	Staff focus Groups	All staff reporting that the training and ongoing support had sufficiently prepared them for completed the undertaking the intervention	Four or more staff reporting that the training and ongoing support had not sufficiently prepared them for completed the undertaking the intervention	Half or more of all staff (12/24) reporting that the training and ongoing support had not sufficiently prepared them for completed the undertaking the intervention	
30	Acceptability and effectiveness of intervention using the Theoretical Framework for Acceptability of Healthcare Interventions - in staff focus groups	Staff focus groups	All staff reporting that the intervention was mostly acceptability (only minor issues unacceptable and these could be fixed)	Four or more staff reporting major areas of unacceptability, or many staff reporting numerous minor issues that need to be addressed before proceeding	Half or more staff reporting that the intervention is unacceptable in one or more major, fundamental ways	

31	Acceptability of the intervention from a customer perspective – interviews	Customer interviews	80% or more of customers reporting positive views about acceptability of the intervention from the perspective of a customer accessing the normal pharmacy services.	50% or more of customers reporting positive views about acceptability of the intervention from the perspective of a customer accessing the normal pharmacy services.	30% or more of customers reporting positive views about acceptability of the intervention from the perspective of a customer accessing the normal pharmacy services.	
32	Feasibility of each of the components of the intervention and as a whole - Consideration will be given to: any unintended or adverse consequences, the degree of local adaptation that would be required, who would deliver the training, who would deliver the mentoring, factors that facilitate/hinder the intervention, and its overall benefits and limitations of the intervention.	Feasibility workshop	Overall favourable opinion from all participants at the feasibility workshop (with due consideration of all feasibility data presented at the workshop), or reporting of only minor issues that could be fixed	One quarter or more of participants reporting major areas of unacceptability, or many participants reporting numerous minor issues that need to be addressed before proceeding, at the feasibility workshop (with due consideration of all feasibility data presented at the workshop)	One half or more of participants reporting that the intervention is unacceptable in one or more major, fundamental ways, at the feasibility workshop (with due consideration of all feasibility data presented at the workshop)	
33	Effectiveness of dissemination and promotion of intervention		70% of more or customer survey respondents aware of the service (intervention)	50% of more or customer survey respondents aware of the service (intervention)	30% of more or customer survey respondents aware of the service (intervention)	
34	Final consideration of the feasibility of the actual intervention. Are all the components of the intervention feasible and needed? Are there any other components that should be added?	Consideration of: 2,3,4,9,10,11,12, 14,15,16,17,18, 20,21,30,32, 33 &34 By research team, PPI panel and CTU				
35	Feasibility of a future trial – Is a trial possible? What will be primary and secondary outcomes in a future cluster RCT? What are the feasible differences in primary outcome between the intervention and control groups, and the estimated intraclass correlation? Would stratification be required in the trial (type of pharmacy,	Consideration of: 1,5,6,7,8,10,11,12, 14,15,16,17,18,19, 20,21,22,23,24,25, 26,27,28,29,30,31, 32 & 34 and questions in 35 Research team and CTU				

	urban/rural location, socioeconomics of area, ethnic diversity of area)? Should sub-groups be considered? Is it feasible to randomise? Is it feasible to recruit controls? Power calculation and sample size required, for whole sample and any sub-groups. Possible sources of contamination, for example staff moving between pharmacies. How data would be analysed? Can quality of life, acceptability and satisfaction, and other health economic criteria be measured? What would be the requirements for future funding?					

***It is expected that should a criteria be recorded as red, this will be reviewed by the study team and adjustments made accordingly to any future design.**

Table of versions

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