Improving outcomes in patients who self-harm - Adapting and evaluating a brief pSychological inteRvention in Emergency Departments (ASsuRED).

Work packages 1 - 4

PROTOCOL VERSION NUMBER & DATE: Version 8.0, 13/08/2021

This protocol has regard for the HRA guidance and order of content;

Full Title:	Improving outcomes in patients who self-harm - Adapting and evaluating a brief pSychological inteRvention in Emergency Departments (ASsuRED).
Short Title:	ASsuRED
Sponsor	City, University of London Contact person: Alison Welton School of Health Sciences City University London, Northampton Square London, EC1V 0HB Phone: 020 7040 5704 Email: a.welton@city.ac.uk
Co-sponsor	Devon Partnership NHS Trust Contact person: Tobit Emmens Wonford House Hospital Dryden Road Exeter EX2 5AF Phone: 01392 674114 Email: tobit.emmens@nhs.net
IRAS Number:	257373
REC Reference:	19/LO/0778
NIHR Grant Reference:	RP-PG-0617-20004
Chief Investigator	Professor Rose McCabe City, University of London School of Health Sciences Room M130, Myddelton Street Building, London EC1V 0HB Phone: 020 70404333
Sites	Newham University Hospital, East London NHS Foundation Trust St Helier Hospital, South West London & St George's Mental Health NHS Trust East Surrey Hospital, Redhill, Surrey and Borders Partnership NHS Foundation Trust Royal London Hospital, East London NHS Foundation Trust.

PROTOCOL VERSION NUMBER & DATE: Version 8.0, 13/08/2021

1. KEY STUDY CONTACTS

Chief Investigator	Rose McCabe Professor of Clinical Communication City, University of London School of Health Sciences Room M130, Myddelton Street Building, London EC1V 0HB Tel: 020 70404333
Study Co-ordinator	Sally O'Keeffe City, University of London School of Health Sciences Myddelton Street Building, London EC1V 0HB Tel: 020 70405323
Sponsor	City, University of London Contact person: Alison Welton, Research Governance Officer School of Health Sciences, Northampton Square London, EC1V 0HB 020 7040 5704 a.welton@city.ac.uk
Joint-sponsor(s)/co-sponsor(s)	Devon Partnership NHS Trust Contact person: Tobit Emmens Wonford House Hospital Dryden Road, Exeter EX2 5AF Phone: 01392 674114 Email: tobit.emmens@nhs.net
Funder(s)	National Institute for Health Research Programme Grant for Applied Research Central Commissioning Facility Grange House, 15 Church Street, Twickenham, TW1 3NL
Co-applicants and Key Protocol Contributors	Prof Rose McCabe Dr Peter Aitken Dr Vera Araujo Soares Professor Richard Byng Professor Chris Dickens Professor Sandra Eldridge Dr Domenico Giacco Professor Navneet Kapur Dr Will Lee Professor Borislava Mihaylova Professor Stefan Priebe Dr Peter Riou Ms Mary Ryan Professor Alan Simpson Dr Helen Smith
Committees	Programme Management Group (co-applicants) Programme Steering Group Lived Experience Advisory Group

1. GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
ED	Emergency Department
LEAP	Lived Experience Advisory Panel
LEG	Lived Experience Group
Participant	An individual who takes part in a clinical trial
PI	Principal Investigator
PSC	Programme Steering Committee
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SUGAR	Service User and Carer Group Advising on Research

2. 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.
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.

For and on behalf of the Study Sponsor:

Signature: Date: 14/05/2019

.....

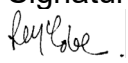
Name (please print): Tobit Emmens

Position:

Managing Partner, Research & Development, Devon Partnership NHS Trust

Chief Investigator:

Signature: Date: 14/05/2019



.....

Name: (please print): Professor Rose McCabe

Statistician Agreement Page

The clinical study as detailed within this research protocol (Version 3, dated 05/12/2019), or any subsequent amendments, involves the use of an investigational medicinal product and will be conducted in accordance with the Research Governance Framework for Health & Social Care (2005), the World Medical Association Declaration of Helsinki (1996), Principles of ICH-GCP, and the current regulatory requirements.

Signature **Date:**
27/05/2019

.....

Statistician Name (please print): Professor Sandra Eldridge

3. SUMMARY

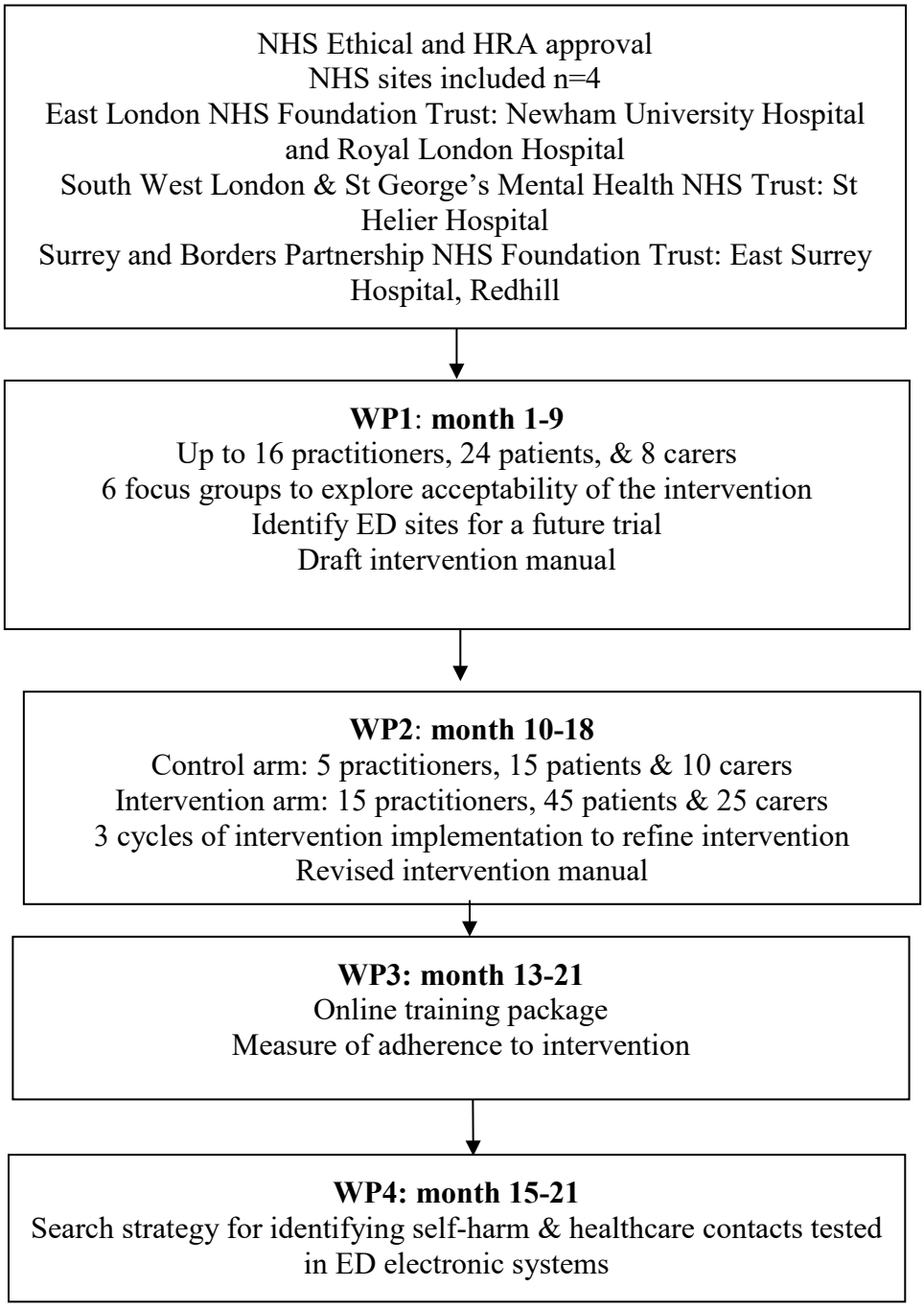
Study Title	Improving outcomes in patients who self-harm - Adapting and evaluating a brief psychological intervention in Emergency Departments.
Short Title	ASsuRED
Methodology	Work package one (WP1) will conduct 6 focus groups with practitioners, patients and carers to adapt existing evidence-based intervention components and write an intervention manual. Work package two (WP2) will further adapt the intervention and test the feasibility of the study design for a trial. The pilot study will take place in 4 Emergency Departments (EDs). In the control arm, 5 practitioners and 15 patients will be recruited. In the intervention arm, 15 practitioners and 45 patients will be recruited (with each practitioner in the intervention arm delivering the intervention to ~3 patients). There will be 3 cycles of intervention implementation, feedback and iteration. Work package three (WP3) will develop a training module and online training package to train practitioners in the intervention. Work package four (WP4) will involve data extraction from different IT systems across the 4 EDs from WP2, to identify self-harm episodes, other healthcare contacts and resource use. Work in WP 1-4 will inform a decision about whether to conduct a randomized controlled trial. If this is the case, a separate ethics application will be made for the randomized controlled trial.
Research Sites	WP2 Newham University Hospital, East London NHS Foundation Trust. St Helier Hospital, South West London & St George's Mental Health NHS Trust East Surrey Hospital, Redhill, Surrey and Borders Partnership NHS Foundation Trust Royal London Hospital, East London NHS Foundation Trust
Objectives/Aim(s)	The aims are WP1: To adapt, and explore the acceptability of, a brief psychological intervention to reduce self-harm, among practitioners, patients and carers WP2: To test and adapt the intervention for the NHS and to test the feasibility of conducting a randomised controlled trial WP3: To develop a training package and specify how to assess whether the intervention is delivered as planned (i.e. adherence/fidelity to the intervention) WP4: To test the strategy for identifying repeat self-harm and healthcare contacts/resource use, across the different electronic record systems.

Number of Participants	WP1 6 focus groups with 6-8 people per focus group (total: 36-48) 2 focus groups with practitioners: 6-8 practitioners per group (total: 12-16 people) 3 focus groups with patients: 6-8 patients per group (total: 18-24 people) 1 focus group with carers: 6-8 carers per group (total: 6-8 people) Interviews with primary care staff: 3-4 General Practitioners (GP's; total: 3-4) WP2: Feasibility study: 20 practitioners and 60 patients: • Intervention arm - 15 practitioners, 45 patients (up to 3 patients per practitioner) and approximately 25 carers. • Control arm – 5 practitioners, 15 patients (up to 3 patients per practitioners) and approximately 10 carers. Individual interviews to be carried out with a sub-sample of those from the feasibility study: 10 practitioners, 30 patients and 10 carers.
Main Inclusion Criteria	WP1 Mental health practitioners: employed by participating NHS Trusts. Patients: people of different ages, sex, ethnicity, clinical presentation and histories of attending the ED with self-harm or suicidal ideation. Carers: aged over 18; informal carer of a family member or friend of a patient with history of attending the ED with self-harm or suicidal ideation. WP2: Mental health practitioners: employed by participating NHS Trusts. Patients: ≥16 years of age in the ED presenting with self-harm, i.e., an intentional act of self-poisoning or self-injury, irrespective of the motivation or apparent purpose of the act (NICE, 2004); or suicidal thoughts/behaviour. Can be admitted for a brief admission to the acute hospital after self-harm (i.e. up to a few days). Patient's carers: aged over 18; informal carer of a family member or friend of the patient. All participants (i.e. healthcare practitioners, patients and carers) will have the capacity to provide informed consent and the ability to communicate in English.

Proposed Start Date	01/05/19
Proposed End Date	31/12/21
Study Duration	32 months. Practitioners will stay in follow-up contact with each patient, and a carer if available, for up to 9 months (WP2)

KEY WORDS: Self-Harm, Suicide, Emergency Department, Psychological Intervention

STUDY FLOW CHART



4. INTRODUCTION

BACKGROUND

In the U.K., approximately 6000 people take their own life each year (National Confidential Inquiry into Suicide and Homicide 2016). Death by suicide is a catastrophic loss of life for the person and the people they leave behind; children, partners, family and friends. Each death by suicide generates immeasurable personal suffering and impacts on around 20 family members, 20 friends and 20 colleagues (Berman 2011).

The most important risk factor for suicide is self-harm. Self-harm refers to intentional self-poisoning or self-injury, irrespective of motive or the extent of suicidal intent (NICE 2004). It includes acts intended to result in suicide (attempted suicide), those without suicidal intent (e.g., as a coping mechanism to deal with traumatic experiences and reduce unpleasant feelings) and acts where there is a mixed or unclear motivation (Saunders and Smith 2016). The risk of suicide is 100s of times greater among people who self-harm than among the general population (Owens et al. 2002).

Each year, ~220,000 episodes of self-harm by 150,000 people are managed by emergency departments (EDs) in England (Cooper et al. 2015). The majority of self-harm episodes in the ED involve self-poisoning by overdosing or ingesting a harmful substance (80.8%), approximately one in six (15.6%) self-injure and the remainder both self-poison and self-injure (Hawton et al. 2015). Self-injury is most commonly cutting, but other methods include burning, hitting or mutilating body parts, and attempted hanging or strangulation. When people engage in self-poisoning and self-injury, they take a risk that this is the last time as they may inflict sufficient damage to end their life. In many cases, self-harm occurs shortly before suicide with 15-43% of people attending the ED in the year before death (Gairin et al. 2003, Da Cruz et al. 2010). The Government's Suicide Prevention Strategy (Department of Health 2012) has identified those presenting with self-harm as a priority group and highlighted the importance of the ED in effective treatment.

For patients, self-harm is associated with significant personal suffering, poor mental health, poor quality of life and needs for support from carers and services (Goldman-Mellor et al. 2014, Sinclair et al. 2011). For younger people, this is exacerbated by poorer educational outcomes (Saunders and Smith 2016) setting them on a negative life trajectory. The assessment and treatment of people who self-harm uses substantial NHS resources. Most of this direct cost is accounted for by attendances at the ED and subsequent medical and psychiatric care (Yeo, 1993).

NICE recommends psychosocial assessment by specialist mental health practitioners in the ED for people who present with self-harm (NICE 2004). Most EDs have a psychiatric liaison team staffed by specialist mental health practitioners. They conduct psychosocial assessments to engage patients, assess their current and future health and social care needs and make onward referrals. Although much progress has been made, psychosocial assessment of people attending emergency departments in the UK has been described as inadequate and characterised by low

assessment rates in parts of the country (Geulayov et al. 2016). Moreover, there is an untapped opportunity to use psychological interventions in liaison work in the ED (e.g. Guthrie 2006, O'Connor et al. 2017) to improve routine self-harm contacts in the ED.

While many people need further support, referring patients to specialized mental health services is often not a realistic option because a) there is not enough capacity in these services; b) specialized treatment is very costly; and c) many patients do not attend or drop out early (Monti et al. 2003). Intervening to change routine meetings when patients are seen in the ED, rather than developing a new service enables a much wider reach including patients who would not be referred to or pursue specialist mental health treatment. This offers considerable potential for intervening at scale to reduce self-harm.

RATIONALE

In order to improve quality of life, reduce future self-harm and reduce suicide risk, effective ED interventions are needed. In this context, mental healthcare practitioners have a unique chance to intervene at scale. Quality evidence from recent international trials indicates that brief, low cost, psychological interventions delivered by specialist mental health practitioners in EDs are effective in reducing self-harm and suicide. If effective, a brief psychological intervention would be low cost and relevant to 220,000 patient contacts in EDs each year in England. Training existing mental health teams to deliver the intervention would be relatively inexpensive making wider rollout in the NHS attractive.

A systematic review by our team has found that brief psychological interventions in the ED are effective in reducing self-harm and suicide (McCabe et al. 2018). Key evidence is provided by four high-quality trials involving 3412 participants. In Switzerland, Gysin-Maillart et al. (2016) found that a psychological intervention involving 3-4 sessions and follow-up letters reduced self-harm over 24 months. In the U.S., Miller et al. (2017) found that safety planning and follow-up phone calls for one year reduced self-harm. A brief information session and contact over 18 months tested in 5 low and middle income countries reduced suicide (Fleischmann et al. 2008). The most effective interventions were implemented over 18-24 months and the common active components across interventions are enhanced psychosocial assessment (Gysin-Maillart et al. 2016), safety planning (Gysin-Maillart et al. 2016, Miller et al. 2017, Fleischmann et al. 2008) and follow-up contact (Gysin-Maillart et al. 2016, Miller et al. 2017, Fleischmann et al. 2008).

THEORETICAL FRAMEWORK

Effective interventions in settings most similar to the U.K. are based on psychological theories underpinning suicidal behaviour, psychological techniques to explore motivation for change and safety plans, collaboratively developed by the practitioner and patient (Gysin-Maillart et al. 2016, Miller et al. 2017). These interventions enhance psychosocial assessment by engaging the patient in treatment and

understanding self-harm. This is challenging given the stigma and shame associated with self-harm (Diggins et al. 2016). Patients themselves are often ashamed, guilty and hence ambivalent about addressing self-harm and engaging in treatment (Lizardi and Stanley 2010). Practitioners can also approach questions about suicidal thoughts and plans in a way that closes down rather than opens up avenues of inquiry about the full extent of patients' suicidality (McCabe et al. 2017a). Hence, psychological techniques can equip practitioners with the skills to help patients to:

- fully disclose suicide attempts and plans
- understand what happens when they are in crisis in heightened states of emotional arousal
- identify triggers and warning signs for self-harm
- improve emotion regulation
- identify internal and external coping strategies
- engage in action planning and
- use coping strategies to overcome helplessness and despair.

The most effective intervention – showing a 69% relative risk reduction in self-harm - emphasised the practitioner-patient therapeutic alliance along with follow-up contact by the same rather than different practitioners. A better therapeutic alliance was associated with fewer repeat suicide attempts at follow-up (Gysin-Maillart et al. 2017). Patients report that willingness to fully disclose distressing thoughts and plans is highly dependent on trust and the therapeutic alliance (Cole-King & Lepping 2010; Ganzini et al. 2013). This is consistent with evidence on the effectiveness of psychological therapies, where the therapeutic alliance is the strongest predictor of patient outcome and more important than the specific model of therapy (McCabe and Priebe, 2004, Thompson and McCabe 2012, Wampold and Imel 2015). As stated in the NICE self-harm guidance (NICE 2004) "engaging the service user is a prerequisite".

This study will adapt and test a brief psychological intervention delivered by existing specialist mental health practitioners in the ED to patients presenting with self-harm. The intervention is designed to reduce repeat self-harm and improve mental health and quality of life. It will:

(a) enhance psychosocial assessment in the ED to better engage patients in treatment and understanding self-harm

(b) conduct safety planning focusing on warning signs, internal and external coping strategies, informal and formal support and restricting access to means of self-harm to improve self-management of future self-harm

(c) handover the safety plan to others involved formally and informally in supporting and caring for the patient to integrate patient care

(d) include three follow-up meetings with the patient (and carers) after attending the ED and three personalised letters to support crisis resolution over a 9 month period.

We will train staff in brief psychological techniques to be used flexibly to engage patients in treatment (narrative interviewing, exploration and validation of patient distress) and in understanding their self-harm (mentalisation based techniques), collaboratively develop a safety plan (goal setting, problem solving, motivational interviewing, solution-focused techniques) and support patients after leaving the ED (ongoing engagement, goal implementation, connecting with support systems). These techniques have been used in effective interventions in the aforementioned trials (Gysin-Maillart et al. 2016, Miller et al. 2017 based on Stanley & Brown 2002). We hypothesise that three main processes will have a synergetic effect in reducing repeat self-harm: better engagement of patients in safety planning in the ED, increased ability to self-manage future crises and a more integrated formal and informal support system. Based on this evidence, our logic model for a brief psychological intervention is that training ED mental health staff in delivering a brief psychological intervention, to include a psychological assessment and follow-up contact, will improve engagement and the therapeutic alliance with onward improvement in health outcomes, quality of life and a reduction in repeat self-harm.

The aforementioned evidence was collected in trials in countries with different social and health care systems, suggesting good generalizability. However, none of the available interventions have been developed for implementation in the NHS. Hence, a brief psychological intervention for NHS delivery requires adapting to optimize feasibility and sustainability in the NHS and evaluating in the NHS context.

5. OBJECTIVES

The overarching aim of the study is to adapt and feasibility test a brief psychological intervention to reduce self-harm in the ED. The research questions for each work-package are:

Work-package 1: Adapt and develop intervention, assess acceptability & sites

1. Can we adapt existing evidence-based intervention approaches and materials for use in the NHS?
2. Is the intervention acceptable and implementable in the NHS?
3. What are the potential barriers to implementation among practitioners, patients and carers?
4. Can we identify sufficient ED sites for a large national trial?

Work-package 2: Implementing the intervention and testing feasibility

1. How many patients and practitioners can we recruit? How can we increase recruitment?
2. It is feasible to assign patients to intervention vs control practitioners in the ED setting?
3. Can practitioners implement the intervention in routine practice in the NHS?
4. What barriers and facilitators to implementing the intervention are experienced by practitioners, patients and carers?
5. Is it feasible for patients to rate outcome measures in the ED setting for the trial?

6. What are the main resources involved in implementing the intervention?

Work-package 3: Training module with online training package

1. What behaviour change objectives and techniques should be targeted in practitioner training in the intervention?
2. What is the best way to assess whether the intervention is delivered as planned (i.e. adherence/fidelity to the intervention)?

Work-package 4: Testing search strategy for identifying repeat self-harm and healthcare contacts

1. What electronic record systems are used across the ED trial sites?
2. Does the search strategy for identifying repeat self-harm work across the different electronic record systems?
3. How well do the procedures for identifying healthcare contacts/resource use (e.g., types of contacts with patient, duration of consultations/contacts; type of personnel involved) from electronic databases work in practice?

6. METHODOLOGY

There will be four work packages (WPs).

WP1: Adapt intervention for the NHS, explore acceptability, write intervention manual and identify sites for a future trial

Objectives:

1. Adapt existing evidence-based intervention approaches and materials for use in the NHS
2. Explore the acceptability of the intervention and potential barriers to implementation among practitioners, patients and carers
3. Write a draft intervention manual
4. Identify ED sites for the trial.

WP1 (1) Adapt Intervention

Based on existing evidence from international RCTs, the intervention will consist of *enhanced psychosocial assessment and safety planning in the ED* when practitioners assess patients presenting with self-harm along with *three follow-up meetings and three personalised letters for up to 9 months after attending the ED*.

We will form an intervention development group in month 1. McCabe, Byng, Aitken and Professor Michel who developed the intervention in the aforementioned Swiss trial (Gysin-Maillart et al. 2016) will be the core members. They will work with a small group of up to 4 expert practitioners and two members of the LEAP. The group will meet regularly until month 22 when the trial starts and on a flexible basis thereafter. The intervention development will follow the Intervention Mapping framework. The needs assessment is clear (220,000 ED patient contacts per year). Previous interventions have been shown to be effective in addressing this need and we have access to the content and techniques constituting those interventions. We will focus

particularly on the content and techniques used in the Attempted Suicide Short Intervention Program (ASSIP) intervention in the Swiss trial which showed the greatest reduction in repeat self-harm. We have identified three common components that provide a foundation for the logic model underpinning our intervention, namely, enhanced psychosocial assessment, safety planning and follow-up contact. Best professional practice across these components will be specified as a series of three to five core practices that can be learned and used by practitioners. With respect to psychosocial assessment, we will focus on narrative interviewing, exploration and validation of patient distress and mentalisation-based techniques. For example, this is likely to involve replacing a mental health state assessment with an open invitation to the patient to describe the experiences that have brought them to the ED in their own words supported by verbal and non-verbal active listening and validation techniques. With respect to safety planning, we will focus on goal setting, problem solving, motivational interviewing and solution focused techniques with practitioners negotiating and tailoring practical plans that the patient supports and feels confident to enact.

With respect to follow-up contact, we will focus on maintaining the therapeutic alliance. This is likely to include exploration of patient's situation and applying coping strategies and the patients' support system to solve patient-defined problems and resolve crises. The core behaviour patterns will be described in detail with multiple examples and also modelled/demonstrated in training materials. This will form the core of the intervention which will be designed to enable practitioners to habitually deliver improved ED consultations. The intervention will be fully described using the TIDieR checklist (Hoffman et al. 2014).

<u>WP1 (2) Explore acceptability</u>

We will need to specify how current practice can be modified to achieve standards set by interventions shown to be effective. It is likely that the intervention will need to be briefer than previous interventions so that it can be integrated into routine NHS care and it will be delivered by different practitioners than those in the aforementioned trials. To clarify what changes need to be made, we will discuss intervention content and process in 2 focus groups with practitioners, 3 focus groups with patients and 1 focus group with carers to explore the content and acceptability of the intervention along with barriers to implementation. We will explore what is likely to work well/ less well, additional time to conduct enhanced psychosocial assessment and safety planning along with the timing and mode of follow-up contacts. The intervention will be presented in sufficient detail to gain relevant feedback. Particular behavioural routines to enhance psychosocial assessment, safety planning and follow-up contact, based on previous intervention content, will be described to practitioners and patients to assess their acceptability and feasibility in NHS ED contexts. This work will allow us to develop recommended practice routines and corresponding training materials that will be acceptable to practitioners and patients.

Sample Size

6 focus groups with 6-8 people per focus group

2 focus groups with practitioners: 6-8 practitioners per group (total: 12-16 people)
3 focus groups with patients: 6-8 patients per group (total: 18-24 people)
1 focus group with carers: 6-8 carers per group (total: 6-8 people)
Interviews with GP's: 3-4 GP's

We plan to carry out 6 focus groups, but may carry out additional focus groups if further stakeholder feedback is required to inform the intervention development.

Participants
Practitioners, Patients and Carers

Inclusion Criteria
Practitioners: We will recruit practitioners from a range of professional backgrounds including psychiatry, mental health nursing, social work, occupational therapy, support work and primary care. All practitioners, except for primary care practitioners, will be recruited from the ED and involved in delivering the intervention. We will include a balance of male and female practitioners with varying lengths of experience working in the ED.

Patients: We will recruit people of different ages, sex, ethnicity, clinical presentation and histories of attending the ED. One of the focus groups will involve young people aged 16-20 to explore the particular issues raised by the intervention for them (e.g. handing over a safety plan to teachers). Many issues are different for this age group who have one foot in childhood and one in adulthood. In particular, parenting and schooling are important differences. Patients will be recruited by advertising in the ED and via service user organisations and PPI networks.

Carers: We will recruit carers of different ages, sex, ethnicity and relationship to the patient (e.g. partner, parent, friend).

Focus Groups
Focus groups will be run by a facilitator and co-facilitator and video recorded. Video recordings assist in identifying who is speaking and participants in the team's previous studies have been accepting of video recording. However, if participants would prefer, the groups will be audio-recorded. If it proves logistically difficult to include all practitioners in focus groups due to shift patterns and work commitments, we will conduct individual interviews.

Data Analysis
Focus groups will be transcribed, anonymised during transcription and analysed thematically (Miles & Huberman 1994) using the stages of data reduction, data display and conclusion drawing/ verification to move from descriptive line-by-line to more conceptual pattern coding. Researchers, members of the LEAP and project team members (RM, PA, RB) will be involved in the analysis. Nvivo software will be used to organise and manage the data. To optimise validity, we will (1) ensure attention is paid to negative cases and (2) conduct respondent validation by checking the analytic interpretation with patients/practitioners. Inter-rater reliability in applying second level codes (or categories) will be calculated on 20% of the data.

The data should provide a wide range of views, identify common feedback and refine the intervention for exploratory testing in the NHS.

WP1 (3) Recruit sites for a future trial

We will approach EDs to participate in a future trial. EDs will be recruited to take part in the trial. We will obtain sites to be represent both rural and urban locations and range in the deprivation of the hospital catchment areas. For logistical reasons to ensure the success of the trial, geographical clusters of sites will be selected to minimize travel between sites for the researchers. We will obtain data from these sites on rates of repeat self-harm so that the validity of our assumption of a 30% rate of repeat self-harm over 18 months in our sample size calculation for a trial can be assessed. This rate is based on 20% of patients re-attending the ED with self-harm over 12 months (Carroll et al. 2014).

Lee and Aitken are part of the project team and are liaison psychiatrists who lead the annual psychiatric liaison service survey. Hence, they have excellent knowledge of and links with the service leads in the EDs across England.

WP1 (4) Draft intervention manual

Based on the focus group analyses, we will refine the intervention content and write a draft intervention manual to deliver training to practitioners in WP2.

Milestones

1. Month 1: Intervention development group formed
2. Month 8: Focus group findings
3. Month 9: Draft intervention manual.

WP2: Implementing the intervention and testing the feasibility of aspects of the trial design

WP2 Objectives:

1. Test the feasibility of carrying out a RCT
2. Exploring how to maximise recruitment for a future RCT
3. Pilot patient-rated outcome measures in the ED setting for a future trial
4. Conduct 3 cycles of intervention implementation, feedback and iteration
5. Identify barriers to implementing the intervention
6. Identify the main resources involved in implementing the intervention.
7. Pilot collection of practitioner-report data

This WP will be guided by the conceptual framework for feasibility studies developed by Eldridge et al. (2016) to address the main uncertainties around: implementing the intervention within the constraints of routine NHS practice, collecting primary outcome data from ED databases and the acceptability and burden of secondary outcome measures on patients.

Testing the feasibility of implementing the intervention in EDs

This pilot study seeks to test the feasibility of conducting a RCT of a brief psychological intervention for self-harm in EDs. We will recruit mental health practitioners from psychiatric liaison teams who conduct psychosocial assessments with patients presenting with self-harm in EDs. Practitioners in the intervention arm will receive training in the intervention.

In each site, approximately four practitioners will be assigned as intervention practitioners. Four EDs will be included to allow consideration of different local contexts and more/less well organised EDs. The sites will be Newham University Hospital and the Royal London Hospital (East London NHS Foundation Trust), St Helier Hospital (South West London & St George's Mental Health NHS Trust), East Surrey Hospital, Redhill (Surrey and Borders Partnership NHS Foundation Trust).

Testing the feasibility of assigning patients to the intervention vs control arm

This pilot study will test the feasibility of carrying out a RCT in which practitioners in the ED are randomized to the intervention or control arm. We have demonstrated the feasibility of randomizing practitioners in previous trials (McCabe et al., 2016, Priebe et al., 2007, Priebe et al., 2015), so randomization of clinicians will not be piloted in this study. We have not previously tested the feasibility of recruiting and allocating patients to practitioners in the ED context, some of who are delivering an intervention and others who are control practitioners. This pilot study will assess the feasibility of recruiting patients to the study in the ED context, obtaining consent and assigning patients to practitioners in the control vs. intervention arm. We will assess the acceptability of the recruitment and consent process.

The control arm will be piloted in one Trust only, to allow us to assess the feasibility of assigning patients to a study arm in the future RCT. Practitioners in the control arm will not receive training and will deliver treatment as usual.

This process will involve recruiting and consenting patients in the ED. They will be informed that they may be assigned to one of two approaches, depending on the training their allocated practitioner has received.

Sample Size

In total, 20 practitioners and 60 patients will be recruited:

- Control arm: 5 practitioners and 15 patients will be assigned to the control arm
- Intervention arm: 15 practitioners (Approximately four practitioners from each of four EDs) will implement the intervention with up to 3 patients each providing up to 45 practitioner-patients dyads in the intervention arm.

The difference in sample sizes is due to the requirement for a larger sample in the intervention arm to adequately test and refine the intervention, whereas a smaller sample size in the control arm will be sufficient to ensure the recruitment processes are suitable for the future RCT.

We expect a consent rate of ~50%. We will closely monitor the consent rate and screen more patients if necessary.

Inclusion/Exclusion Criteria:

Patients
Inclusion Criteria:

- *≥16 years of age*
- presenting in the ED
- presenting with self-harm, i.e., an intentional act of self-poisoning or self-injury, irrespective of the motivation or apparent purpose of the act, or suicidal thoughts or behaviours
- on presenting to the ED, can be admitted for a brief admission to the acute hospital

Exclusion Criteria:

- Patients admitted to a psychiatric hospital
- Patients with cognitive (e.g. dementia) or other psychiatric difficulties interfering with ability to participate
- Experiencing a psychotic episode
- No capacity to provide written informed consent
- Needing an interpreter
- Ministry of Justice patients subject to a restriction order
- Receiving intensive psychological input e.g. DBT

Practitioners: NHS practitioners working in psychiatric liaison teams (e.g. mental health practitioners, psychiatrists, psychologists, nurses, occupational therapists).

<u>WP2 (2) Exploring how to maximise recruitment for a future RCT</u>

We will explore how to maximise recruitment in a future RCT by closely monitoring recruitment. We will record all patients screened for eligibility, to record how many patients are approached and consented. We will work with the sites to explore how to maximise recruitment.

<u>WP2 (3) Pilot patient-rated outcome measures</u>

We will assess the acceptability of outcome measures and the burden on patients, including self-reported self-harm. This will be conducted in the ED, over the phone or by video meeting or in patients' homes (according to preference). Participants will be given the option of completing self-report measures on paper or online via a secure REDCap database. Researchers will interview patients twice to collect outcome measures: once at baseline on the day they attend the ED/ within one week of attending the ED and once after 6 months. We will test disease-specific and more generic quality-of-life outcome measures. We will collect data on response rates and feedback on the following outcome measures:

- the therapeutic relationship, self-rated by patients on the Helping Alliance Scale (Priebe & Gruyters, 1993)
- suicide severity, administered by researchers on the Columbia–Suicide Severity Rating scale (Posner et al. 2011)
- quality of life measured with CORE-OM (Barkham et al. 2001, Mavranezouli et al. 2011)
- Social outcomes, measured with the Social Outcomes Index (SIX) (Priebe, Watzke, Hansson, & Burns, 2008)
- Quality of Life, measured with the Manchester Short Assessment of Quality of Life (MANSA; Priebe, Huxley, Knight, & Evans, 1999)
- Experiences of attending Accident & Emergency Questionnaire, devised for this study

Each month for six months after they leave the ED, participants will be sent an email to an electronic survey to collect:

- self-reported self-harm data

Self-reported self-harm will be collected via an online survey: participants will receive an email inviting them to complete the survey. This survey has been co-designed with the Lived Experience Advisory Panel.

At the end of the 6 month intervention period, we will collect data on:

- Repeat self-harm identified by searching ED electronic records (using the gold standard approach developed in the Multicentre Study of self-harm in England (Clements et al. 2016).

Death by suicide, i.e., cause of death is intentional self-harm or undetermined intent derived from NHS/ local authority/coroner records.

Maximising retention of participants

We will attempt to maximise follow-up outcome data by arranging multiple appointments, using phone/text reminders and collecting data by phone, an online database, post or face-to-face, depending on the preference of participants. At baseline we will obtain as many modes of contact as possible. This will include mobile phone number, landline phone number, email address and postal address. We will also ask for social media contact details (e.g. Facebook) and for contact information for an alternative person who they agree to us contacting in the event we are unable to contact them. These contacts will be used to re-establish contact if necessary (e.g. if a participant has changed their phone number). If a carer is present, we will obtain contact details for them. We will send postcards and newsletters to the participants to maintain contact with participants throughout the study.

<u>WP2 (4) Implementing the intervention</u>

Practitioners willing to test the intervention will be recruited as at this stage it will be important to work with practitioners who are engaged and willing to implement a new way of working.

As described above, fifteen practitioners will implement the intervention with up to 3 patients, providing 45 practitioner-patient dyads. Practitioners will be trained in delivering the intervention. Identified barriers to implementation and feedback on outcomes will be collected and synthesised to guide refinement of the intervention, and this data will be collected using interviews with patients, carers and practitioners. The intervention manual developed in WP1 will be used to train practitioners. We will follow guidance by the Department of Health and the Royal Colleges on Information Sharing and Suicide Prevention.

Methods

Each practitioner will implement the intervention with one patient each for three months (month 10-12) and provide feedback to refine the intervention. They will then implement the intervention with one further patient for 3 months (13-15) and provide feedback to refine the intervention. Finally, they will implement the intervention with one further patients for 3 months (16-18) and provide feedback to refine the intervention. Practitioners will stay in follow-up contact with each patient, and a carer if available, for up to 9 months. They will meet with the patient three times over the first two months, and will send three personalised letters to the patient for the seven months after their final meeting. Carers will be family members, partners, carers or friends involved in supporting the patient.

Subject to ethical approval and written informed consent, each practitioner will video-record meetings with patients each in the ED and audio record the subsequent follow-up phone contacts to explore how the intervention is being implemented and adherence to the intervention. Practitioners will keep meeting notes and a diary to record the frequency, mode, duration and content of contacts with patients during the intervention. We will record how many patients presented to the ED during this time who would be eligible for the intervention.

<u>WP2 Data management</u>

The CRFs and databases created for WP2 will inform the development of the databases in the trial (WP5). The PCTU will develop, build and host the database for WP2 data. A data management plan will be developed by the study team and PCTU to cover all aspects of managing the data.

<u>Data management system and data storage</u>

All study data will be uploaded onto a REDCap study database developed by the PCTU data management team. The database is on a secure server which is only accessible to the appropriate members of the PCTU and the ASsuRED study team. All data analysis of the WP2 data will be carried out on the secure server. The data collection will be captured by the study researcher on the paper CRF or entered directly onto the database.

The online survey will be administered on the REDCap system. QMUL BCC IT Security is responsible for the security of the QMUL REDCap service. Any data entered is securely stored at PCTU safe haven (BCC) in their Enterprise level data

centres. Data will be backed up daily. Access to the system for data entry staff requires a user account which will be issued and controlled by the PCTU Data Management Team.

WP2 (5) Barriers to implementation

We will closely monitor the barriers to implementation on an ongoing basis and address them in a timely manner. We anticipate that barriers will include time pressures (including time to conduct the follow-up contacts) and lack of information/ motivation/skills to change behaviour. Time pressures will be addressed with ED team leads, clinical directors and senior NHS Trust management to identify how staff can be facilitated in implementing the intervention. Researchers will communicate informal feedback from practitioners and teams to the local investigator on a weekly basis (e.g. things that should be happening that are not happening, things happening that shouldn't be happening, new ideas). This feedback will be collated by the programme manager and discussed by the project team in their regular communication.

Interviews
Ten practitioners, 30 patients and ~10 carers (subject to availability of carers) in the intervention arm will also be interviewed to explore their experience of the intervention - exploring what changes were brought about in assessment, safety planning and follow-up contact- and their views on the outcome measures. Practitioners will be recruited across the four sites. Patients will be purposively sampled to include patients of different age, sex, ethnicity, clinical presentation and living in urban/rural area. Carers will be family members, partners, carers or friends involved in supporting the patient.

Barriers to implementation will be explored along with solutions that were identified. A semi-structured topic guide will be developed with the Lived Experience Advisory Panel. Interviews will be audio-recorded. Interviews and video-recorded meetings will be collected in 3 waves following the 3 cycles of intervention implementation. If there are delays getting the first cycle started, we will reduce the cycles accordingly.

Data Analysis
Subject to consent, video recordings of practitioner-patient meetings in the ED and audio recordings of follow-up phone contacts will be analysed focusing on whether and how practitioners are using the core skills targeted in the training. The recordings will be transcribed and anonymised to remove names and places. The analysis will focus on (1) what core skills the practitioners are using (e.g. enhanced psychosocial assessment) using the skills checklist and (2) how they are using these skills. We will conduct tape assisted recall with practitioners to elicit their feedback on how they are using/ not using the core skills (Elliott and Shapiro 1988, Pomerantz 2005). In healthcare encounters, practitioners mostly ask patients questions. Evidence shows that subtle differences in how practitioners ask patients questions have different consequences for patient disclosure about suicidal thoughts and plans (McCabe et al. 2017a), the therapeutic relationship (Thompson et al. 2016) and how patients are involved in decisions about their care (Thompson & McCabe 2018).

Moreover, nonverbal aspects of communication are fundamental in the quality of communication: these are only observable from video recordings. This has proved to be a key resource in previous intervention development studies by the team: practitioners consider video recordings to be very beneficial so they can see where their practice deviates from recommended practice and explore why this is the case (Priebe et al. 2015, McCabe et al. 2017b). Proforma data will be summarised and triangulated with the interview and (if available) video data.

Interviews with practitioners and patients will be transcribed, anonymised during transcription and analysed thematically (Miles & Huberman 1994) using the stages of data reduction, data display and conclusion drawing/verification to move from descriptive line-by-line to more conceptual pattern coding. Researchers, members of the LEAP and project team members (RM, PA, RB) will be involved in the analysis. This will be coordinated by McCabe and Ryan. Nvivo software will be used to organise and manage the data. To optimise validity, we will (1) ensure attention is paid to negative cases and (2) conduct respondent validation by checking the analytic interpretation with patients/practitioners. Inter-rater reliability in applying second level codes (or categories) will be calculated on 20% of the data, as recommended in the literature (Joffe, 2011). If available, data from interviews and recordings from the same practitioner-patient source will be triangulated as a further validation procedure.

The intervention development group will meet in month 18 to review the key barriers to implementation and work with practitioners to identify strategies to overcome them.

<u>WP2 (6) Identify the main resources involved in implementing the intervention</u>

Resources for training practitioners and implementing the intervention will be documented. The study team will keep records on resources needed for training practitioners including time and staff category of trainers and trainees, training materials, and venue costs. Practitioners will use a proforma to collect data on appointments (what they did, for how long, involvement of carers/others) and other contact with patients to identify resources required for implementation and provision of the intervention in ED and ways to collect this data during in the future trial. Resource use identified by patients during interviews will be noted and used to guide subsequent resource use data collection needs in the trial.

Furthermore, the study team will explore the hospital electronic record systems (e.g. check whether contacts with patients are logged into the systems and whether these are submitted to NHS Digital). This will inform the framework for data collection for the trial.

Milestones
1. Month 18: Revised Intervention manual
2. Month 18: Main costs of implementing the intervention identified.

<u>WP2 (7) Pilot practitioner-report data</u>

We will pilot collecting data from practitioners using a practitioner CRF. This will enable us to assess the acceptability of practitioner completion of a CRF to collect data on their demographics and staff burnout. We will collect practitioner demographics and a validated measure of staff burnout measure: the Maslach Burnout Inventory (Maslach, Jackson and Leiter, 2016). Practitioners will be asked to complete:

- Practitioner CRF Assessment 1: At the beginning of their participation on the study, practitioners will be asked to provide basic demographic information and to complete the Maslach Burnout Inventory.
- Practitioner CRF Assessment 2: At the end of their participation in the study (after they have completed follow-ups with their participating patients), practitioners will be asked to complete the Maslach again.

Covid-19 contingency

This study is taking place in the context of the Covid-19 pandemic. The arrangements for the delivery of the intervention and research meetings will be flexible to avoid unnecessary face-to-face contact. Intervention sessions and research meetings may be conducted over the phone, video meeting (using Attend Anywhere or Microsoft Teams) or face-to-face, where it is safe to do so.

WP3: Training module with online training package

WP3 Objectives:

1. Develop a face-to-face training module to train staff in the intervention
2. Develop an online training package hosted on an interactive website to support the face-to-face training and disseminate the intervention
3. Specify how to assess whether the intervention is delivered as planned (i.e. intervention adherence/fidelity).

WP3 will develop a training module with an online training package, drawing on the iterative cycles of intervention implementation and feedback. Training will be based on the Information (knowledge), Motivation and Behavioural skills model (Fisher & Fisher 1992), i.e., behaviour change occurs when individuals are well informed, highly motivated and have the necessary skills.

Behaviour change objectives: We aim to change how staff conduct assessment, safety planning and follow-up contact with patients. We will define core behaviours across these 3 areas. For each area, a range of psychological techniques (e.g. mentalisation-based techniques, solution focused techniques, problem-solving techniques, motivational interviewing techniques) will be incorporated to be used flexibly depending on the patient presentation.

Behaviour change techniques: To illustrate core behaviours, we will produce video clips to model the behaviours based on real cases. In previous training, it has been helpful to also identify unhelpful behaviours that should be avoided. For each target behaviour, we will develop categories of patient presentations and matched

responses, thereby defining and illustrating recommended staff behaviour and clarifying the context in which those actions are appropriate.

The video clips will present a range of patient presentations with a brief introduction about the patient's history and context (different diagnoses, levels of distress, previous histories). This will allow training in which staff members recognise types of patient presentation and match these to appropriate responses in the form of, "If the patient acts/says X then try response Y". This, in turn, will enable rehearsal of recommended responses so they become routine or automatic over time, thereby, enhancing staff skills. Participants will work with actors to try out their new skills. They will be videoed and the videos will be reviewed immediately in the session by a facilitator. Following facilitator feedback, participants will practice their skills again, be videoed and receive further feedback until they have mastered the skills.

We will work with an award-winning company specializing in interactive digital learning (Binary Vision) to produce these video clips and accompanying video interviews with practitioners/ patients, printable materials (intervention aides-memoire) and links to external resources. The video clips may be re-constructed by professional actors and we will have a film director and crew. The clips, materials and resources will be collated in an online training package hosted on an interactive website.

One self-report and one observer-rated checklist will assess the impact of the training on practitioner knowledge, motivation and skills. (i) A self-report questionnaire assessing knowledge and motivation will be self-rated before and after the training. Elements of motivation that may be assessed include changes in attitude, norms, emotional reactions and self-efficacy in relation to conversations with patients about suicidal ideation (Fishbein et al. 2001). (ii) An observer-rated skills checklist will be administered after the training. Both measures will be developed during the study and based directly on the aforementioned information, motivation and skills targeted in the training. All 15 practitioners in WP2 will complete the self-rated questionnaire and video their meetings with ~2 patients each. This will allow comparison of self-report and observer-rated competence for up to 32 cases. We will explore the use of meeting notes, checklists and recordings of patient-practitioner meetings in WP2 (as far as can be collected) for assessing adherence/fidelity to the intervention.

Milestones
1. Month 19: Behaviour change targets
2. Month 21: Training materials in an online training package
3. Month 21: Self-report questionnaire and skills checklist
4. Month 21: Measure of adherence to the intervention.

WP4: Working with electronic databases to test search strategy for identifying repeat self-harm and healthcare contacts

WP4 Objectives:

1. Identify the different electronic records systems across the ED and hospital trial sites
2. Test the search strategy for identifying repeat self-harm across the 4 sites in WP2
3. Test the procedures for identifying healthcare contacts/resource use from electronic databases to inform the economic evaluation (e.g., types of contacts with patient, duration of consultations/contacts; type of personnel involved).

In preparation for a future trial, WP4 will identify the different IT systems across the ED trial sites. We will test our search strategy for identifying repeat self-harm and healthcare contacts/resource use by patients for the four sites in WP2, with the consent of participants from WP2. It is possible to interrogate the databases successfully as demonstrated in previous studies (detailed below). However, we will check the search strategy in different electronic record systems to identify any issues that require addressing before the trial. The ED electronic records will be screened by a member of the research team, and details of repeat self-harm attendances will be extracted and entered onto an excel spreadsheet, with details of the number of repeat attendance(s) and the date(s).

Self-harm will be identified by searching ED electronic records, using the same approach as the Multicentre Study of self-harm in England (Hawton et al. 2015), which identifies 98-100% of self-harm cases (Clements et al. 2016): researchers will search records using an extensive list of search terms (including Self-Harm, Limb Problems, Overdose/Poisoning, Unwell Adult, Mental Illness, Behaving Strangely, Collapsed Adult, Wounds, Burns/Scalds) to identify possible self-harm cases. This is an inclusive approach so that cases not clinically coded as self-harm are still identified. Each record will then be screened for evidence that the presentation was due to self-harm. An end point committee of clinical experts will review the data to identify self-harm. The end point committee will be blinded to treatment allocation for the study duration. They will be given clear criteria, and the evidence for these criteria will be documented so that the decisions will be transparent and can be checked. Any subjective element would be the same in both arms.

Also under WP4, we will finalize plans for data collection to support economic analysis. This is likely to require combination between centrally held data (NHS Digital); data from local information systems and data collected directly from patients, practitioners and researchers contributing to the study. We will initiate NHS Digital data request for the participants' healthcare data to support trial analysis.

Milestones:
1. Month 21: Self-harm search strategy tested across sites for the trial
2. Month 21: Procedures for identifying resources use tested

7. STUDY PROCEDURES

Recruitment

WP1 -practitioner focus groups

Practitioners will be recruited in the participating EDs and Royal Exeter and Devon NHS Foundation Trust. GPs will be recruited in primary care via NHS Trust networks and ED practitioner contacts.

WP1 -patients and carers

Patients and carers will be recruited by distributing posters and leaflets via service user organisations, PPI networks and wider community settings. We will recruit via EDs (Royal London Hospital, Homerton Hospital) and specific PPI groups and networks. The Service User and Carer Advisory Group on Research (SUGAR) has recommended the following channels:

- Mind in Stratford
- Homeless shelters
- Generation R – young people's patient research ambassadors
- Asian community Mosque Whitechapel: East London Mosque outreach centre
- Campaign Against Living Miserably
- Self-harm group, Isle of Dogs
- Groups specifically for men
- LGBT groups
- Mind – self-harm group

WP2 -Feasibility study and interviews

Patients presenting with self-harm will be asked to participate. People presenting with self-harm are referred to a specialist mental health team called a psychiatric liaison team either by (1) a triage nurse in the ED or (2) from a brief stay inpatient ward (e.g. an acute medical unit). A healthcare practitioner will assess whether the patient has capacity to consent to participate in a research study and ask potential participants if they are willing to be approached by a researcher. The two patient pathways are as follows:

1) People who attend the ED are first seen by a triage nurse and then referred to the psychiatric liaison team. The practitioner in the psychiatric liaison team will assess whether they deem the person has capacity to consider participating in a research study and if they have capacity, the liaison practitioner will ask if they are happy for a researcher to approach them.
2) Patients are also referred to the psychiatry liaison team from inpatient wards. A nurse in the inpatient ward or psychiatric liaison practitioner will initially approach the patient to assess capacity to consent to participate. If they have capacity, the practitioner will ask if they are happy for a researcher to approach them and talk to them about the study.

Informed Consent Procedures

Consent forms will be sought from all participants, and copies will be stored in the site file, medical records and a copy will be given to the participant.

Practitioners:

Practitioners will be approached by researchers who will discuss the study (e.g., in team meetings), provide written information and an opportunity to ask questions and receive further information. Researchers will obtain written informed consent from those who are interested in taking part. Practitioners will be informed of which study arm they are allocated to prior to consent (i.e. the intervention or control arm). Separate consent and information sheets will be provided for practitioners in each study arm.

Patients:

Two consent procedures will be in place: one for sites recruiting to the intervention arm only, and a second for sites recruiting to both the control and intervention arms. Consent will take a two-step approach. This will allow us to assess how to maximise recruitment in the future RCT.

Step 1: Consent procedures for sites recruiting to the intervention arm only:
Patients will initially be approached by a practitioner in the liaison psychiatry team and asked if they are interested in taking part in the study. They will provide the participant with the Summary PIS and will obtain verbal consent from the participant that they wish to take part. The consent may also be taken by a researcher, if they are on-site when the patient presents to the ED. Participants will be informed they will be offered the intervention.

Step 1: Consent procedures for sites recruiting to the intervention and control arms:
Patients will initially be approached by a generalist practitioner in the ED and asked if they are interested in taking part in the study. They will provide the participant with the Summary PIS and will obtain verbal consent from the participant that they wish to take part. The consent may also be taken by a researcher, if they are on-site when the patient presents to the ED. Based on the principle of equipoise, patients will be informed that practitioners have been trained in different ways of conducting assessments and follow up case, and they will use the approach they have been trained in.

Step 2: After potential participants verbally agree with a practitioner to speak to a researcher and they have had their psychosocial assessment, a researcher will discuss the study with the participant. At this point the urgency will have passed so the participant will be given the full length Patient Information Sheet (PIS) by the researcher and they will have time to read it. They will be given the opportunity to ask questions or for further information about the study. Written informed consent will then be obtained from those who wish to take part. Participants will be considered enrolled in the study after written consent is obtained.

We will seek written consent in WP2 from patients to (a) participate in interviews after their meeting with a psychiatric liaison practitioner (b) complete outcome measures at 6 months and (c) access the patient's medical records to identify repeat self-harm and healthcare resource during the 6-month follow-up period and 6 months preceding recruitment for WP4.

Covid-19: During the pandemic, researchers will not be on-site to take consent unless permitted by the site and a risk assessment is in place. Thus, the initial approach will be undertaken by a practitioner who will introduce the study with the Summary PIS and will take verbal consent to take part in the study. The research team and LEAP have prepared a video to introduce the team and study, which the practitioner can play to patients prior to asking for verbal consent. This will also be available in audio format, which can be used if preferred by participants. After verbal consent is obtained, written consent will be obtained either: (1) by an onsite member of the team (either researcher or member of the clinical team trained in obtaining informed consent) or (2) the researcher will contact the person to take written consent via a secure REDCap database. If it is not possible to obtain written consent, audio-recorded verbal consent will be obtained (e.g. if they do not wish to meet in person and do not have internet access), by asking the participant whether they agree to each clause in the consent forms.

Carers:

Carers accompanying the patient, will be asked to participate only after the patient has agreed to participate and has consented for their carer(s) to be approached to consider participating**.** They will be provided with the carers information sheet, an opportunity to ask questions about the study and if they agree to participate, will provide written informed consent.

Research data will be collected in quiet rooms within facilities of participating Trusts/Universities. Researchers will follow the lone worker policy of their respective participating NHS trusts.

Payment

For WP1, patients and carers will receive a £20 voucher for participating in the focus group. Practitioner participants will not be reimbursed for their time as the research will take place during their working hours.

For WP2, patients taking part in baseline and follow-up interviews will be offered £15 cash or voucher as a reimbursement for their time for each interview (maximum £30). In WP2, carers will not be offered reimbursement as they will be in a supporting role for their friend/ family member. Practitioner participants will not be reimbursed for their time as the research will take place during their working hours. The participation of the practitioners will be discussed with their line managers and team leads.

We will be unable to pay travel expenses, but meetings will be arranged at a place convenient to participants.

8. ETHICS

Ethical issues arise from the participation of people at risk of further self-harm or suicide who present in crisis at the emergency department. There are four main issues:

1. Informed consent

The procedures for approaching people, providing information about the study and obtaining consent have been developed with people with lived experience of suicidal thoughts and suicide attempts attending the ED, which include members of the Lived Experience Group (LEG) at the University of Exeter and the Lived Experience Advisory Panel (LEAP), Recovery Devon.

In the proposed study, there will be a three-step consent process, to reaffirm consent throughout the process:

i. Consent will initially be obtained verbally to minimize burden on patient at the point at which they are in crisis
ii. Consent will be reaffirmed during assessment by the mental health practitioner (Liaison Psychiatry team member).
iii. Written consent will be obtained by the researcher after the assessment with the mental health practitioner, at which time the participant will have time to decide whether they wish to take part or withdraw.

2. Risk of causing distress

Participating in a study whilst people are in distress may present a risk of further distress to people who are emotionally vulnerable. If the practitioners or the researchers feel that the research is too overwhelming, they will stop the process immediately. We discussed risk of causing distress with our lived experience group members (Lived Experience Group (LEG) and the Lived Experience Advisory Panel (LEAP)), who confirmed that while there is the possibility of causing additional distress, participating in the study may also be beneficial to patients as it may help people feel that they are contributing and are able to help improve services. There are also benefits in terms of being able to talk and being listened to.

3. Video-recording the conversations

We will video record sensitive mental health practitioner-patient meetings which could potentially affect people in various ways. When the researchers first approach the participants to explain the study and obtain informed consent, they will clearly explain how the video-recordings will be used and stored. This is also explained in the information sheets. The different purposes for which brief video-clips might be

used, e.g. in academic meetings or training, are clearly stated on the consent forms and participants can opt-out of specific uses of their video-recordings. Participants faces would be blurred out and voices disguised when using the video-recordings for these purposes, unless additional consent was sought from participants to use the identifiable video-recordings. We are currently using this process with our participants in the Relate study (PI McCabe, 'What is a therapeutic conversation with a mental health practitioner in the emergency department?', 17/LO/1234) and have received positive feedback. The consent rate of eligible participants who were approached in the ED is 64.2%.

A copy of the signed consent form will be given to participants.

4. Follow up interviews

There is a possibility that patients may indicate that they feel suicidal in the follow up interviews. If this happens the researcher will follow the study's Suicide Risk Protocol (available on request from the Study Co-ordinator) procedure and contact the relevant healthcare practitioner, i.e. GP or care coordinator in a community mental health team if the person has a care coordinator.

AMENDMENTS

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor will submit a valid notice of amendment to the REC for consideration. The amendment history will be tracked via version and date control of protocols, with changes to the protocol will be highlighted.

9. SAFETY CONSIDERATIONS

Risks of the project and measures to prevent them

We do not foresee any significant ethical, legal or management issues arising from this study.

Participation: Participating in a study whilst people are in distress may present a risk of further distress to people who are emotionally vulnerable. Biddle et al. (2013) found that the majority of patients participating in self-harm and suicide research reported improvement in their mood, with many describing the cathartic value of talking. However, a minority reported lowering of mood as they were reminded of difficult times or current issues. They anticipated that their distress would be transient and it was outweighed by a desire to contribute to research. With this in mind if the practitioners or researchers feel that the research is adding to people's distress or it is too overwhelming, they will follow the study's Suicide Risk Protocol.

Consent: Given that people will be presenting in crisis and we will record sensitive information (outcome data, interviews, clinical meetings), we will adopt a three-step consent process. A mental health practitioner will ask the patient if they are willing to be approached by a researcher. Capacity to consent to taking part in research will be assessed using the study's Capacity Checklist (available from the Study Coordinator, on request). If patients consent to participate after being fully informed, the researcher will obtain written informed consent. The mental health practitioner will confirm consent when they assess the patient. Finally, the researcher will re-affirm consent after the clinical assessment with the mental health practitioner. When the researchers first approach the patients to explain the study and obtain informed consent, they will explain how each type of data will be used and stored. This will be clearly described in the information sheets and written consent forms provided to patients. In our ongoing Relate study (PI McCabe, 17/LO/1234), participants were interviewed within 2 weeks of their meeting in the ED with a mental health practitioner. During the interview they were asked for feedback on their experience of participating in the research. They suggested that it was a positive experience and all interviewees stated that the reason for wanting to participate was to help others with mental health problems: "if it can help somebody else then I'm quite happy to do it" (Patient); "if someone sees it [video recording of the clinical assessment] then they'll learn something won't they?". On being video-recorded, they stated: "*if it's a good thing that they're there and being recorded then I'd like to help with that"* and *"I didn't even notice the cameras were there"*.

Recording practitioner-patient meetings in the ED/ follow-up contacts: Researching and recording sensitive mental health practitioner-patient meetings after self-harm could potentially add further distress to people. During these contacts, practitioners will be present and will be alert to this possibility and the potential need to reassure patients or terminate the research process if it is adding to the person's distress.

Research interviews: Researching and recording sensitive interviews about receiving support in the ED for self-harm could potentially add further distress to people: the in-depth interview may cause discomfort to some participants, whereas others might find it therapeutic to discuss their experiences. The interview will involve questions about self-harm and meetings with mental health practitioners, which involve emotional pain and stigma. The potential risk of causing distress to patients by asking them about these sensitive issues, will be addressed by taking a sensitive approach to the interview. We will draw upon the experiences of the Lived Experience Advisory Panel (LEAP) to develop the interview questions, and the interview questionnaire will be piloted with a member of the LEAP prior to conducting interviews. Interviewers will check whether participants feel comfortable or want to discuss specific issues, i.e. by asking "Is it alright if we talk (a bit more) about that?". In case significant distress arises during the research interviews, we will inform patients that the research team is able to contact their practitioners if they would like further support.

10. DATA HANDLING AND RECORD KEEPING

Confidentiality: To protect the identification of participants, study IDs will be created and assigned for each individual, and person-identifiable data will be stored separately in a locked filing cabinet at each participating Trust. An electronic file with restricted access (to the core ASsuRED research team only) will be maintained at each site. An ID list and NHS number will be transferred to the central study team, for the purpose of linking the data extracted from NHS Digital. This information will be held in a password-protected file on the secure university network, only accessible to the core ASsuRED research team. Only in the cases in which the researcher has concerns regarding the participant's safety or the safety of others, through participant disclosures of thoughts/plans of harming themselves or others, or through criminal disclosures, the researcher will be obliged to break confidentiality and inform the relevant clinical teams, services and/or authorities. This will be made clear to the participant on the information sheet and during the consent process to ensure their understanding.

To further protect confidentiality, we will:

- Ensure that participants understand during the informed consent process where interviews, and meetings might be recorded, the purpose of this, how the files will be stored, and who will have access to these files
- Remind all participants that they do not have to answer any questions or make any personal disclosures if they do not wish to
- Refrain from using participants' names during audio-recorded interviews.

Use and storage of personal data: All participant data (quantitative and qualitative data) collected will be pseudonymised and handled in line with the Data Protection Act 1998, the General Data Protection Regulation (GDPR, 2018) and other applicable study procedures. All case report forms will be stored in locked cupboards only accessed by the study team. Screening logs and any document linking IDs with names and personal contacts (required for the follow-up) will be stored in electronic forms in password-protected files only accessible to the study teams at different sites. All recorded data will be captured in encrypted and password protected files. Data will be handled and stored in accordance with the conditions set out by the study sponsor (Devon Partnership NHS Trust/ City, University of London). All database building, data handling and management activities will be carried out according to applicable procedures and other regulatory and information governance requirements. To protect patient confidentiality on the case report form (CRF) we will only record partial postcode (first half) and Lower-layer Super Output Area codes (LSOA) that each postcode falls within. Although we are collecting participant's full postcodes for administrative purposes, we will convert postcodes to the LSOAs. CRF is pseudo-anonymised and participants will not be identifiable from their partial postcodes or LSOA codes. LSOA codes are more confidential than full postcodes, given the average population of 1500 people vs. 15 households for each full postcode.

The qualitative interviews with patients and practitioners and some intervention sessions will be recorded, stored on an encrypted device and an NHS-approved professional transcription company will be used to transcribe the data. The company will receive the files over a secure, encrypted connection and all identifiable data (name of participants or any information that by itself, or in conjunction with other

material, may identify participants or other people) will be removed from the transcripts.

11. SAFETY REPORTING

The study will consist of focus groups, testing an intervention in the ED, an individual interview on the day/within one week of being seen in the ED and a further interview after 6 months. The intervention is an addition to patients' usual care. Adverse events and the need for Urgent Safety Measures are not anticipated for WP2.

Adverse Events (AE)
Any adverse events will be recorded in the study file and the participant's records, if appropriate. The participants will be followed up by the research team.

Serious Adverse Event (SAE)
SAEs that are "related" and "unexpected" will be reported to sponsor within 24 hours and to the main REC within 15 days of learning of the event.

Urgent Safety Measures
In the case of urgent safety measures being required, the CI will inform the sponsor and the REC of the event immediately via telephone. The CI will then inform the REC in writing within 3 days.

Annual Safety Reporting
If required by the REC, the CI will send the Annual Progress Report to the main REC and to the sponsor.

Overview of the Safety Reporting responsibilities
The CI will ensure that safety monitoring and reporting is conducted in accordance with the sponsor's requirements.

Research Ethics Committee (REC) and other Regulatory review & reports

We will obtain ethical approval (and full sponsorship and research governance approvals) prior to the start of the study. In the feasibility work (WP2), all participants will continue to receive treatment as usual. In addition to treatment as usual, practitioners participating in the feasibility work (WP2) and in the intervention arm will use the new intervention with their patients so they will receive enhanced care.

DATA PROTECTION AND PATIENT CONFIDENTIALITY

All researchers and study staff will comply with the requirements of the Data Protection Act 1998 and the General Data Protection Regulation (GDPR, 2018) with regards to the collection, storage, processing and disclosure of personal information and will uphold the core principles of both frameworks.

Personal information:

Personal data will be stored in accordance with the Data Protection Act.
All participants will be assigned a participant ID number and this will be used for all data processing purposes. Participants' names and contact details will be retained (with their permission) to share research findings. As the project linked to this is funded for five years, it is envisaged that participants might want to know how their information and suggestions have helped to shape the service on offer.
Directly identifiable patient data (participants' names, contact details, socio-demographic data) and the list linking these data with participant ID number will be password-protected and stored on secure servers at participating research sites', which will only be accessible by the research programme (ASsuRED) team members on a need-to-know basis. All hard copies of data including socio-demographic forms, consent forms, patient receipts will be kept in lockable filing cabinets in participating sites, and only accessible to the research team members on a need-to-know basis. Any electronic data transfer between members of the research team will be carried out securely. Lists linking participant names to participant ID numbers will remain with local sites.

Audio/video recordings
With participants' permission, practitioner-patient meetings in the ED will be video recorded. The focus groups will be video recorded, however, if participants would prefer, the groups will be audio-recorded. Interviews will be audio-recorded. Video and audio recordings will be stored on secure servers in participating Trusts, with access restricted to appropriate members of the research team. Audio recordings from participating sites will be transferred to the host site using encrypted USB sticks and then transcribed using a professional transcription company with secure transfer of data and deletion once completed. Once transcribed, all identifiable information will be omitted or replaced with pseudonymised labels.

Confidentiality: To protect the identity of participants, study IDs will be created and assigned for each individual, and person-identifiable data will be stored separately in a locked filing cabinet at each participating Trust. An electronic file with restricted access (to the core research team only) will be maintained at each site. Only an ID list (which will not contain any patient identifiable data) will be transferred to the central study team. A log will document any formal changes to the ID list document. Only in the cases in which the researcher has concerns regarding the participant's safety or the safety of others, through participant disclosure of thoughts/plans of harming themselves or others, or through criminal disclosures, the researcher will be obliged to break confidentiality and inform the relevant clinical teams, services and/or authorities. This will be made clear to the participant on the information sheet and during the consent process to ensure their understanding.

To further protect confidentiality, we will:

- Ensure that participants understand during the informed consent process where interviews, and assessments might be audio or video-recorded, the purpose of this, how the files will be stored and who will have access to these files

- Remind all participants that they do not have to answer any questions or make any personal disclosures if they do not wish to
- Refrain from using participants' names during audio-recorded interviews.

Record retention and archiving
In accordance with the UK Policy Framework for Health and Social Care Research and Devon Partnership NHS Trust Record Management and IM&T Information and security policies, research data will be securely archived as per Devon Partnership NHS Trust procedures and kept for 20 years. The Chief Investigator will be data custodian.

12. PROGRAMME COMMITTEES

Programme Steering Committee (PSC)

The Programme Steering Committee is independent of the team and will provide expert advice during the conduct of the programme.

Patient & Public Involvement (PPI)

Twenty-two individuals from three PPI groups have contributed to this programme:

1. The Lived Experience Group (LEG: University of Exeter)
2. The Lived Experience Advisory Panel (LEAP: Devon Partnership NHS Trust).
3. Service User and Carer Advisory Group on Research (SUGAR) at City University.

Firstly, a core group of ten people (from the LEG and LEAP) with lived experience of self-harm or suicide attempts, three carers and two mental health practitioners have worked with us in 5 workshops (03.04.14, 22.01.15, 13.05.15, 07.03.17, 27.07.17) developing this application. Secondly, a further 10 people with similar lived experience from SUGAR also provided feedback. SUGAR recently won the National Award of the Co-ordinating Centre for Public Engagement in the Health and Well-Being category.

A new Lived Experience Advisory Panel (LEAP) will be set up. The 7 people who have worked with us in developing this proposal are keen to be part of the Lived Experience Advisory Panel (LEAP). We will extend the group to approximately 10 individuals. The LEAP will meet approximately every four months, advise on the research, review material, and support public engagement and dissemination. We will recruit members from relevant networks, i.e., the Lived Experience Group (University of Exeter), the Lived Experience Advisory Panel (Devon Partnership Trust) and the Service User Advisory Group (SUGAR) based in City University. To ensure diversity, we will set up a Black and Minority Ethnic (BAME) subgroup formed of members from the Service User and Carer Advisory Group on Research (SUGAR) in City University which has a very diverse membership due to its location in East London.

LEAP meetings will be facilitated by qualified, experienced mental health practitioners who will develop a culture of open reflective communication and trust, which will be modelled by the facilitators themselves. Open dialogue about any concerns or upsetting experiences or emotions will be actively encouraged with staff and facilities available to provide emotional support. Contact telephone numbers and email addresses for staff will also be provided for members who may wish to make contact and discuss or explore any issues in private with the dedicated independent clinical psychologist. Referral to suitable counselling/psychological/mental health services will be made if more serious safeguarding concerns are identified. Written guidelines for the LEAP will include this information and encouragement to raise concerns.

Training to participate in data analysis will be offered to members of the LEAP. There will be ongoing supervision and guidance from researchers during the analysis process. We will request permission from the ethics committee to consider members of the LEAP, who have been trained in data analysis and confidentiality, as members of the research team. We would request permission for them to analyse transcripts of focus groups/interviews which will be anonymised with any identifying characteristics (e.g., names of organisations, staff, etc) removed prior to analysis.

Ryan (PPI co-applicant) will attend regular meetings of the project management team and feed in advice from the LEAP. She will have a leading role in coordinating all PPI activities throughout. Two members of the LEAP will sit on the Programme Steering Group: two members encourages confidence to contribute to steering group meetings. Simpson (co-applicant) will lead on setting up and support the PPI work throughout.

Access to the final study dataset

Access will be restricted to appropriate members of the research team.

13. FINANCE AND FUNDING

The study has been subjected to high quality peer review. It has been funded by the National Institute for Health as a Programme Grant for Applied Research. As part of this two stage application process, it was reviewed twice by multiple independent experts with a range of expertise (including statistical, qualitative, health economic, behaviour change, and self-harm expertise) and then by the Programme Grant for Applied Research Panel of experts.

National Institute for Health Research
Programme Grant for Applied Research
Central Commissioning Facility
Grange House, 15 Church Street, Twickenham, TW1 3NL

14. INDEMNITY

The study will have indemnity through a standard NHS insurance scheme. NHS indemnity does not offer no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm. They are able to consider an ex-gratia payment in the case of a claim.

15. DISSEMINATION OF RESEARCH FINDINGS

Dissemination activities will be influenced and supported by the LEAP. Throughout all phases of the research, we will disseminate information about the activities of the programme through social media and a project specific website in order to reach a wider audience. The website will provide information for patients, practitioners and service commissioners; and will be linked to other websites of local authorities, the participating NHS Trusts, and the academic institutions of the applicants.

We will disseminate the study via

- A social-media launch and engagement plan
- A regularly updated project website
- Lay summaries by the LEAP group
- Peer-reviewed publications in scientific journals
- Conference presentations to psychiatrists, nurses, social workers etc.
- Interactive web site with online training package. Binary Vision will provide expertise in exploring how the online training could be adapted for wider / future use.
- Dissemination to e.g., Health Education England, E Learning for Health and curriculum leads in professional training bodies (e.g. Royal College of Psychiatrists, Royal College of Nursing, Royal College of Emergency Medicine, British Association of Social Workers), the Rapid Assessment Interface and Discharge (RAID) network, Mental Health Nurse Academics UK which represents 60 UK Higher Education Institutions providing Mental Health Nursing education (Simpson is a member/former Chair)
- Ongoing engagement with our 2 commissioner collaborators: Nicola Bray, Transformation Lead, Northern, Eastern and Western Devon Clinical Commissioning Group and Ann Redmayne, South Devon and Torbay Clinical Commissioning Group.

A custom-built interactive website will host both the training materials (i.e. video clips, printable materials, curated links), and implementation plans on delivery within NHS. This will be developed in collaboration with Binary Vision, who have won awards for their health training outputs. Binary Vision will produce a brief promotional video of the training, which can be shared, for instance via YouTube. The website will be used to widely disseminate the intervention. The team has experience of producing high quality training resources (e.g. http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/profiles/TEMPO_full_manual.pdf, http://www.binaryvision.com/ourwork/goodattitude.cfm).

The outputs of this study will be

1. A brief intervention to address self-harm in the ED
2. An interactive website hosting the training package for wider implementation of the intervention
3. Scientific publications in peer-reviewed journals
4. Lay summaries of the findings written by the LEAP group.

Authorship eligibility guidelines and any intended use of professional writers

Authorship will be determined by contribution to the study design, data collection, data analysis and writing up of the study. No professional writers will be used to write study reports.

16. REFERENCES

Appleby, L., Kapur, N., Shaw, J., Hunt, I. M., Flynn, S., Ibrahim, S., & Daud, H. (2016). The National Confidential Inquiry into Suicide and Homicide by People with Mental Illness. Making mental health care safer: annual report and 20-year review. University of Manchester, Manchester, available at: http://research. bmh. manchester. ac. uk/cmhs/research/centreforsuicideprevention/nci/reports/

Barkham, M., Margison, F., Leach, C., Lucock, M., Mellor-Clark, J., Evans C, et al. (2001). Service profiling and outcomes benchmarking using the CORE-OM: Toward practice-based evidence in the and outcomes benchmarking using the CORE-OM: Toward practice-based evidence in the psychological therapies. *Journal of Consulting and Clinical Psychology*, 69:184.

Beck, A.T., & Steer, R.A. (1987). *BDI, Beck depression inventory: Manual*. New York, NY: Psychological Corporation.

Beck, A.T., & Steer, R.A. (1993). *Beck Hopelessness Scale manual*. San Antonio, TX, Harcourt Brace.

Berman, A. L. (2011). Estimating the population of survivors of suicide: Seeking an evidence base. *Suicide and Life-Threatening Behavior*, 41(1), 110-116.

Biddle, L., Cooper, J., Owen-Smith, A., Klineberg, E., Bennewith, O., Hawton, K., ... & Gunnell, D. (2013). Qualitative interviewing with vulnerable populations: Individuals' experiences of participating in suicide and self-harm based research. *Journal of Affective Disorders*, *145*(3), 356-362.

Carroll, R., Metcalfe, C., & Gunnell, D. (2014). Hospital presenting self-harm and risk of fatal and non-fatal repetition: systematic review and meta-analysis. *PLoS One*, 9(2), e89944.

Clements, C., Turnbull, P., Hawton, K., Geulayov, G., Waters, K., Ness, J., Townsend, E., Khundakar, K. & Kapur, N. (2016). Rates of self-harm presenting to general hospitals: a comparison of data from the Multicentre Study of Self-Harm in England and Hospital Episode Statistics. *BMJ Open*, 6(2), p.e009749.

Cole-King, A., & Lepping, P. (2010). Suicide mitigation: time for a more realistic approach. *British Journal of General Practice,* 60.570: e1-e3.

Cooper, J., Steeg, S., Gunnell, D., Webb, R., Hawton, K., Bennewith, O., House, A., & Kapur, N. (2015). Variations in the hospital management of self-harm and patient outcome: A multi-site observational study in England. *Journal of Affective Disorders*, 15;174:101-5.

Da Cruz, D., Pearson, A., Saini, P., Miles, C., While, D., Swinson, N., ... & Kapur, N. (2010). Emergency department contact prior to suicide in mental health patients. *Emergency Medicine Journal*, emj-2009.

Department of Health (2012). Preventing suicide in England: A cross-government outcomes strategy to save lives. (https://www.gov.uk/government/publications/suicide-prevention-strategy-for-england). Accessed on 08/07/19.

Diggins, E., Cottrell, D., & House, A. (2016). Management of patients presenting with self-harm. *British Journal of Hospital Medicine*, *77*(9), C144-C147.

Eldridge, S. M., Lancaster, G. A., Campbell, M. J., Thabane, L., Hopewell, S., Coleman, C. L., & Bond, C. M. (2016). Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework. *PloS One*, *11*(3), e0150205.

Elliott, R., & Shapiro, D. A. (1988). Brief structured recall: A more efficient method for studying significant therapy events. *Psychology and Psychotherapy: Theory, Research and Practice*, *61*(2), 141-153.

Fishbein, M., Triandis, H.C., Kanfer, F.H., Becker, M., Middlestadt, S.E. & Eichler, A. (2001). Factors influencing behavior and behavior change. In Baum, A., Revenson, T.A. and Singer, J.E. (eds), *Handbook of Health Psychology*. Lawrence Erlbaum, Mahwah, NJ, pp. 3–17.

Fisher, J. D., & Fisher, W. A. (1992). Changing AIDS-risk behavior. *Psychological Bulletin.* 111(3):455-74.

Fleischmann, A., Bertolote, J.M., Wasserman, D., De Leo, D., Bolhari, J., Botega, N.J., De Silva, D., Phillips, M., Vijayakumar, L., Värnik, A., *et al* (2008). Effectiveness of brief intervention and contact for suicide attempters: a randomized controlled trial in five countries. *Bulletin of the World Health Organization*, 86:703-709.

Gairin, I., House, A., & Owens, D. (2003). Attendance at the accident and emergency department in the year before suicide: retrospective study. *The British Journal of Psychiatry*, *183*(1), 28-33.

Ganzini, L., Denneson, L. M., Press, N., Bair, M. J., Helmer, D. A., Poat, J., & Dobscha, S. K. (2013). Trust is the basis for effective suicide risk screening and assessment in veterans. *Journal of General Internal Medicine*, *28*(9), 1215-1221.

Geulayov, G., Kapur, N., Turnbull, P., Clements, C., Waters, K., Ness, J., ... & Hawton, K. (2016). Epidemiology and trends in non-fatal self-harm in three centres in England, 2000–2012: findings from the Multicentre Study of Self-Harm in England. *BMJ Open*, *6*(4), e010538.

GDPR (2018). EU GDPR Information Portal. https://www.eugdpr.org/.

Goldman-Mellor, S. J., Caspi, A., Harrington, H., Hogan, S., Nada-Raja, S., Poulton, R., & Moffitt, T. E. (2014). Suicide attempt in young people: a signal for long-term health care and social needs. *JAMA Psychiatry*, *71*(2), 119-127.

Guthrie, E. (2006). Psychological treatments in liaison psychiatry: the evidence base. *Clinical Medicine*, *6*(6), 544-547.

Gysin-Maillart, A., Schwab, S., Soravia, L., Megert, M., & Michel, K. (2016). A Novel Brief Therapy for Patients Who Attempt Suicide: A 24-months Follow-Up Randomized Controlled Study of the Attempted Suicide Short Intervention Program (ASSIP). *PLoS Medicine*, 13(3):e1001968.

Hawton, K., Bergen, H., Cooper, J., Turnbull, P., Waters, K., Ness, J., & Kapur, N. (2015). Suicide following self-harm: findings from the multicentre study of self-harm in England, 2000–2012. *Journal of Affective Disorders*, 1;175:147-51.

Hoffmann, T.C., Glasziou, P.P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D.G., Barbour, V., Macdonald, H., Johnston, M., & Lamb, S.E. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *British Medical Journal*, 7;348:g1687.

Joffe, H. (2011). Thematic Analysis. In D. Harper, & A. R. Thompson (Eds.). *Qualitative research methods in mental health and psychotherapy: A guide for students and practitioners*. Chichester: John Wiley & Sons.

Lizardi, D., & Stanley, B. (2010). Treatment engagement: a neglected aspect in the psychiatric care of suicidal patients. *Psychiatric Services*, *61*(12), 1183-1191.

Maslach C, Jackson S, Leiter M. Maslach Burnout Inventory Manual. 4th ed. Menlo Park, CA: Mind Garden; 2016.

Mavranezouli, I., Brazier, J.E., Young, T.A., & Barkham, M. (2011). Using Rasch analysis to form plausible health states amenable to valuation: the development of CORE-6D from a measure of common mental health problems (CORE-OM). *Quality of Life Research*, 20:321-33.

McCabe, R., John, P., Dooley, J., Healey, P., Cushing, A., Kingdon, D., Bremner, S., Priebe, S. (2016). Training to enhance psychiatrist communication with patients with psychosis (TEMPO): cluster randomised controlled trial. *The British Journal of Psychiatry,* 209(6):517-24.

McCabe, R., & Priebe, S. (2004). The therapeutic relationship in the treatment of severe mental illness: a review of methods and findings. *International Journal of Social Psychiatry*, 50:115-28.

McCabe, R., Sterno, I., Priebe, S., Barnes, R., & Byng, R. (2017a). How do healthcare professionals interview patients to assess suicide risk? *BMC Psychiatry*, 17(1), 122.

McCabe, R., John, P., Dooley, J., Healey, P., Cushing, A., Kingdon, D., Bremner, S., & Priebe, S. (2017b). **T**raining to **E**nhance Psychiatrist Co**m**munication with **P**atients

with Psychosis (TEMPO): A Cluster Randomised Controlled Trial. *British Journal of Psychiatry*. 209(6), 517-524. doi:10.1192/bjp.bp.115.179499.

McCabe, R., Garside, R., Backhouse, A., & Xanthopoulou, P. (2018). Effectiveness of brief psychological interventions for suicidal presentations: a systematic review. *BMC Psychiatry*, 18;1.

Miles, M.B., Huberman, A.M. (1994). *Qualitative data analysis: An expanded sourcebook*. Sage.

Miller, I.W., Camargo, C.A., Arias, S.A., Sullivan, A.F., Allen, M.H., Goldstein, A.B., Manton, A.P., Espinola, J.A., Jones, R., Hasegawa, K., *et al* (2017) Suicide Prevention in an Emergency Department Population: The ED-SAFE Study. *JAMA Psychiatry*, 74(6):563-570

Monti, K.M., Cedereke, M., & Ojehagen, A. (2003). Treatment attendance and suicidal behavior 1 month and 3 months after a suicide attempt: A comparison between two samples. *Archives of Suicide Research*, 7, 167–174.

NICE (2004). Self-Harm: The short-term physical and psychological management and secondary prevention of self-harm in primary and secondary care, CG16. London: NICE.

O'Connor, R. C., Ferguson, E., Scott, F., Smyth, R., McDaid, D., Park, A. L., ... & Armitage, C. J. (2017). A brief psychological intervention to reduce repetition of self-harm in patients admitted to hospital following a suicide attempt: a randomised controlled trial. *The Lancet. Psychiatry*, *4*(6), 451.

Owens, D., Horrocks, J., & House, A. (2002). Fatal and non-fatal repetition of self-harm. *The British Journal of Psychiatry*, *181*(3), 193-199.

Priebe. S,, & Gruyters, T. (1993). The role of the helping alliance in psychiatric community care: A prospective study. *Journal of Nervous and Mental Disease*, 181: 552–557.

Priebe, S., Kelley, L., Omer, S., Golden, E., Walsh, S., Khanom, H., Kingdon, D., Rutterford, C., McCrone, P., & McCabe, R. (2015) The effectiveness of a patient-centred assessment with a solution focused approach (DIALOG+) for patients with psychosis - a pragmatic cluster randomised controlled trial in community care. *Journal of Psychotherapy and Psychosomatic*s. 84 (5): 304–313.

Priebe, S., McCabe, R., Bullenkamp, J., Hansson, L., Lauber, C., Martinez-Leal, R., Roessler, W., Salize, H., Svensson, B., Torres-Gonzales, F., van den Brink, R., Wiersma, D., & Wright, D. (2007). Structured patient-clinician communication and 1-year outcome in community mental healthcare. Cluster randomised controlled trial (DIALOG). *British Journal of Psychiatry*, 191:420-426

Pomerantz, A. (2005). Using participants' video stimulated comments to complement analyses of interactional practices. *Conversation and Cognition*, 93-113.

Posner, K., Brown, G.K., Stanley, B., et al. (2011). The Columbia-Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American Journal of Psychiatry*, 168(12):1266-1277.

Saunders, K. E., & Smith, K. A. (2016). Interventions to prevent self-harm: what does the evidence say?. *Evidence-based Mental Health*, ebmental-2016.

Sinclair, J.M.A., Gray, A., Rivero-Arias, O., et al. (2011). Healthcare and social services resource use and costs of self-harm patients, Social Psychiatry and Psychiatric Epidemiology, 46: 263. https://doi.org/10.1007/s00127-010-0183-5.

Stanley, B., & Brown, G. K. (2012). Safety planning intervention: a brief intervention to mitigate suicide risk. *Cognitive and Behavioral Practice*, *19*(2), 256-264.

Thompson, L., Howes, C., McCabe, R. (2016). The effect of psychiatrist questions on the therapeutic alliance and adherence. *The British Journal of Psychiatry*, 209 (1) 40-47; DOI**:** 10.1192/bjp.bp.114.151910.

Thompson, L., & McCabe, R. (2018). How psychiatrists recommend treatment and its relationship with patient uptake. *Health Communication*. Nov 2;33(11):1345-54.

UK Index of Multiple Deprivation Score, DCLG 2015 Department for Communities and Local Government, 2015. English Indices of Deprivation 2015. Available from: https://www.gov.uk/government/statistics/english-indices-of-deprivation-2015 (accessed 05.07.19).

Wampold, B. E., & Imel, Z. E. (2015). *The great psychotherapy debate: The evidence for what makes psychotherapy work*. Routledge.

Yeo, H. M. (1993). The cost of treatment of deliberate self-harm. *Emergency Medicine Journal*, *10*(1), 8-14.

17. APPENDICIES

Appendix 1 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made