Study Title: Assessing the acceptability and feasibility of developing and implementing a problem solving training model to improve symptoms of depression, anxiety and suicidal/self-harm ideation.

Public title: **I**n-Patient **S**ecure: **D**epression, **A**nxiety and **S**elf-**H**arm (IS-DASH)

Ethics Reference:

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Website:	https://www.york.ac.uk/healthsciences/research/mental-health/projects/problem-solving-secure-environments/

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ABBREVIATIONS

CI	Chief Investigator
RA	Research Assistant
UoY	University of York
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
NHS	National Health Service
RfPB	Research for Patient Benefit
PIS	Participant Information Sheet
PSS	Problem Solving Skills

Lay Summary

Problem solving skills (PSS) are a structured cognitive behavioural intervention that provides people with skills to help them face major negative life events and daily challenges. PSS have been extensively used with populations in the community and some work has been conducted in the prison environment. Despite the brief nature of the intervention, promising results show how the skills can help to support a reduction in symptoms relating to depression, anxiety, allied constructs such as hopelessness and repeat self-harm behaviour. Patients in secure in-patient forensic hospital settings face many problems; and to our knowledge the skills have not been evaluated with this population. The purpose of this study is to assess the feasibility and acceptability of using a six-step problem-solving model to develop and implement an intervention to help support people to address problems in a more proactive manner.

Aims and Objectives

The purpose of this study is to assess the feasibility and acceptability of using a six-step problem-solving model to develop and implement an intervention to help support people to address problems in a more proactive manner.

The project has five key objectives: (i) to identify what problems patients experience and who they prefer to speak to about their problems, (ii) to review with staff and patients the current training package and delivery of the skills, (iii) to train and randomize patients (n=40) to receive problem-solving skills plus care as usual vs care as usual only to use the skills and assess the acceptability and feasibility of the training and delivery, (iv) to disseminate the findings and scheme through a larger service-led event. The team are a group of collaborative academics, clinicians and services users representing all elements of the studies requirements. The study will last approximately 24 months and participants will be involved in various research activities consisting of surveys, workshops and problem solving skills intervention.

Background and Rationale

Problem-solving therapy (PST) is one example of a psychosocial intervention that has been extensively tested with a range of health patients in the community[1-4]. Trials of PST report reductions in depression and allied constructs such as hopelessness [3,5,6]. Such skills can be delivered by a range of professional groups and lay persons and are used by the World Health Organization to help those dealing with international crisis situations[4,5]. Many people who display symptoms of depression, self-harm and/or violent behaviour report the main immediate cause as being problems in their lives [1,7,8]. For these reasons, the simplicity of the skills and their mode of delivery lends itself to support patients in secure hospitals who often experience complex problems during their stay. Previous UK studies have shown promising results for the use of problem-solving skills in the community and prisons, but not in groups of forensic mental health patients within a secure hospital [9-12].

Problem solving skills are cited in current National Institute of Health and Care Excellence (NICE) Guidelines as one possible tailored treatment to support the management of self-harm and co-morbid mental health problems such as depression and anxiety. Delivery of the PSS has been demonstrated by a number of professional and lay person groups making the intervention potentially accessible to many different staff groups and patients [3].

Such an initiative has not yet been tested in a secure inpatient environment where the management of depression, anxiety and suicidal intent/self-harm is key to the prevention of suicidal behaviour. The aim of this study is to assess the feasibility and acceptability of a problem-solving model for use in forensic inpatient settings using a consultation process, delivery of the skills by patients and evaluate the findings.

Study Design

There are several stages to this study which are detailed below:

Phase 1 - preliminary PPI consultation work

Prior to starting the study we will (i)) identify what problems patients experience and who they prefer to speak to about their problems and (ii) review the current materials and training package and agree on the model of implementation.

(i) identify what problems patients experience and who they prefer to speak to about their problems

To identify the problems patient's experience in a secure hospital environment participants will attend a 'United Voices' group within the forensic inpatient service user group based at Tees Esk and Wear Valleys (TEWV) Foundation Trust. Three virtual meetings will help to facilitate awareness of the project, gather views and thoughts on initial problems and get feedback from the group on the initial survey design. In particular, this group will help to identify the experiences and problems of those patients in secure accommodation and identify who patients prefer to talk to when they have a problem.

Members of the research team and TEWV United Voices staff will attend each ward and introduce themselves to the patients. Patients will be approached to see if they are willing to take part in the survey, members of the research team will help patients complete the survey, patients will understand that their responses are confidential. Confidentiality will be broken if there is cause for concern relating to risk (e.g., self-harm, suicidal intent, physical or verbal abuse) to the patient or other patients or staff on the ward. The findings from this survey will inform the consultation workshops (in ii) which will include a review of the training materials. These meetings will be documented and the record of work circulated to ward areas and the Forensic Research Group.

(ii) To review with staff and patients the current training package and delivery of skills

Three 2-hour patient workshops with up to a total of 10 people will be used to demonstrate some of the problem-solving skills, develop some new case study materials for the workbooks, discuss the findings of the survey, review the case studies, and introduce the idea of the training workshops. Workshops will be attended by trained 'expert by experience' service users, staff and patients. Each workshop will be recorded using the materials produced in each session and from note taking.

The evidence will be collated to produce a series of themes that might summarise and inform a plan of implementation through the Recovery College (an onsite provision of educational and vocational courses). Staff will be consulted on the resulting materials using a number of different mechanisms including face to face and virtual meetings, telephone consultations and feedback using attendance at existing Trust meetings.

Phase 2:Delivery of the intervention using a feasibility randomized controlled trial (RCT)

Objective

Our overall objective is to assess the feasibility and acceptability of a brief problem-solving intervention and report on clinical outcome measures of depression, hopelessness and suicidal intent in a group of forensic inpatients.

Feasibility trial design

The trial design proposed is an individual randomized controlled feasibility trial with two conditions of treatment (brief problem-solving intervention plus care as usual (CAU) vs control (CAU only).

Study setting

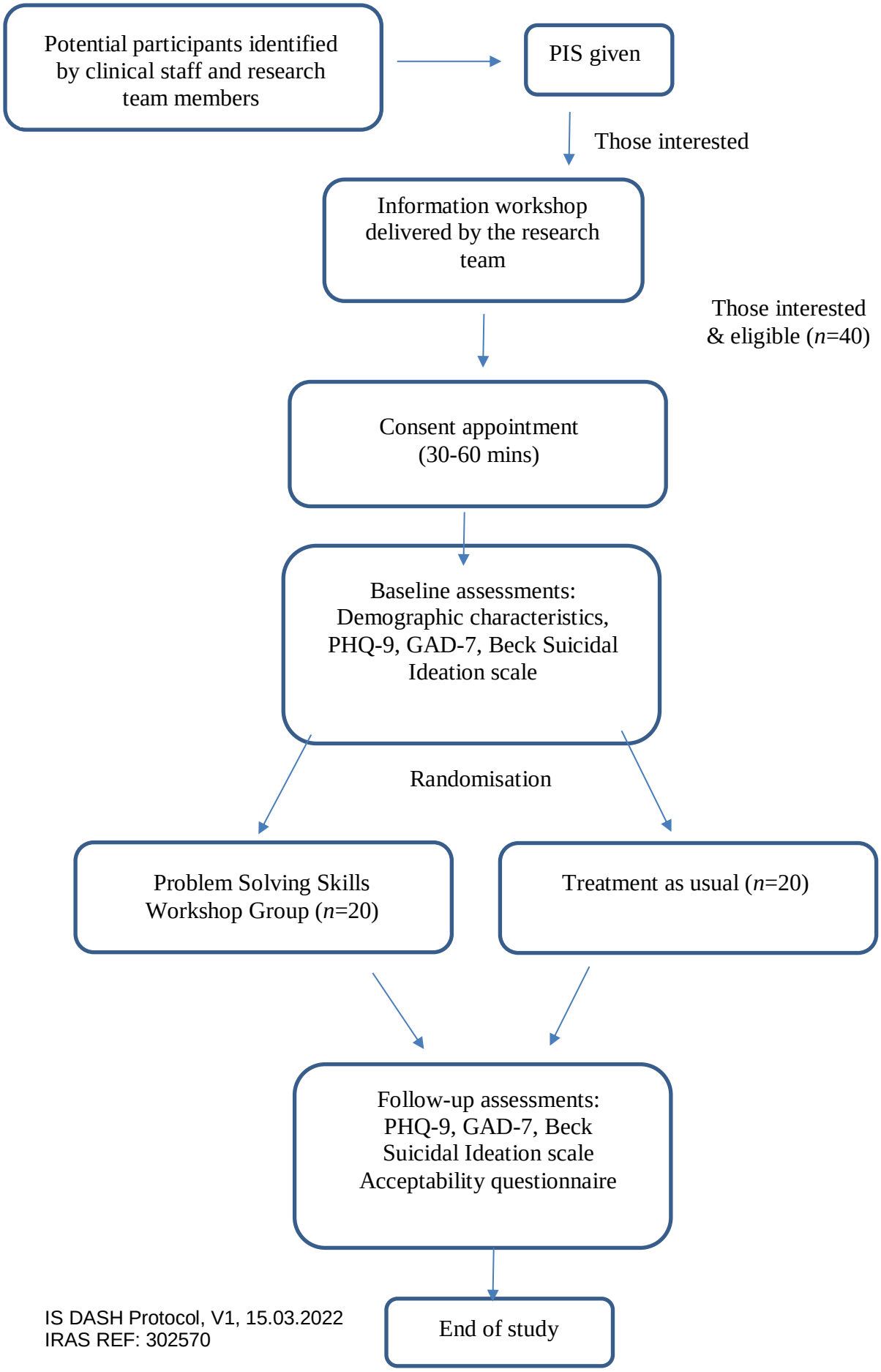
The study will take place in a series of forensic inpatient wards with patients within Tees Esk and Wear Valleys (TEWV) NHS Foundation Trust, Roseberry Park Hospital in Middlesbrough, UK. Together the 17 wards hold up to 180 male and female adult patients; three wards hold patients that aren't sufficiently well enough to engage with the study and are therefore excluded (Mallard, Sandpiper and Fern). A further three wards are utilised for patients with specific learning disabilities and or autism spectrum disorder (Kestrel/Kite;

Runswick/Hawthorne and Ivy/Clover). The remaining 11 wards house patients with no specific learning diagnoses. Across all 17 wards males and females reside on wards that are differentiated by level of security (either low or medium) and gender.

Recruitment

Recruitment will be a staged process, initially the study will be promoted to ward staff with the aim of clinicians helping to identify eligible individuals (Figure 1). Our target sample is 40 willing volunteers to take part in the study. Eligible participants will be identified and approached initially by a member of the clinical team until recruitment has achieved our target number. The clinical team giving a brief overview of the study and supplying an invitation letter and PIS (participant information sheet). The PIS details the exact nature of the study; what it will involve for the participant; and the possible risks and benefits involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time without giving a reason without their care or legal rights being affected.

Figure 1: IS DASH study RCT procedure flow chart Version one 15/3/2022



If after reading the PIS the individual is interested they can contact the study team via the details on the sheet or help from ward staff. A member of the research team will then contact them to discuss further and answer any questions they may have. If after this they still wish to participate an informed consent appointment will be arranged. The time between receiving the PIS and taking consent will vary, patients will be given at least 24 hours to make a decision.

If this method struggles to recruit the target amount of participants, caseload screening will be carried out. This screening will be completed by a research assistant employed by the Trust who has the relevant permissions to access clinical notes. Posters will be placed around the wards to aid recruitment and the research team will attend regular staff meetings to update staff on the trial progress.

Sample size for the trial

The sample size calculations are based on estimating recruitment and attrition rates and standard deviation of the primary outcome measure. We will randomise up to 40 participants, (20 into each arm of the trial). This will estimate recruitment of (50%) and follow up rates (80%) to be estimated within a 11% and 12% margin of error [13].

Randomization procedures

Participants will be randomised using a web-based randomisation system developed by York Trials Unit. Allocation to the trial arms will be in the ratio of 1:1. The group allocation will be disclosed after baseline data has been collected for each participant. The allocation outcome will be entered into the secure shared database so that all members of the research team can view the allocation.

Blinding of trial procedures

The pragmatic trial design does not allow us to blind participants, facilitators nor TEWV staff to the intervention. AP at the University of York will be blind to the outcome assessment data.

Eligibility criteria

(i) Inpatient on forensic ward,

(ii) English ability sufficient for understanding study materials without the need for a translator,

(iii) Adult males and females > 18 years of age,

(iv) Remaining within the hospital for 6 months or more.

Patient exclusion criteria:

(i) Individuals currently experiencing a mental health crisis,

(ii) Individuals unable or unwilling to provide consent,

(iii) Individuals that pose a risk to the research team,

(iv) Individuals not remaining on the ward for the duration of the study,

(v) Individuals that are currently participating in another research intervention study.

Informed Consent

Consent will be taken by the CI or a CRN employed research assistant, both of whom have completed GCP and informed consent training. Prior to any research activities taking place the participant must personally sign and date the latest approved version of the informed consent form. This will then also be signed and dated by the person obtaining the informed consent. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site. Participants will understand that they can withdraw from the study at any point in time. Participants will understand about the importance of disclosure of risk to patients and others on the ward.

COVID-19

Due to COVID-19 there may be instances where the researchers are unable to obtain consent face-to-face, therefore the option for informed consent to be taken over the phone or online will be used. If consent is taken verbally, this will be documented on the consent form. The research team will comply with all COVID-19 TEWV Trust policy requirements

including mask wearing, social distancing and test using a lateral flow test prior to entry onto the wards.

Intervention description

The brief problem-solving intervention involves delivery of a well-established social problem solving theory. AP will deliver the intervention in groups of up to ten patients in a series of five two hour workshops. The delivery of the intervention will involve (i) demonstration of the skills, (ii) completion of a series of workbooks that follow a six-step problem solving model (iii) and practice of the skills. The model comprises of: Step one: is there a problem? Step two: describe the problem; Step three: getting information; Step four: think of options; Step five: choose an option; and Step six: make a plan.

All participants regardless of their assignment will also receive usual care. Usual care comprises of treatment provided by TEWV NHS Trust staff and medical staff using normal practices and use of medication where appropriate. Usual care will be recorded for each person taking part to ensure we have a full description of what each patient has received. Patient records will be accessed by the research team where needed to record usual care for each participant.

Primary outcomes

The primary outcomes of interest in the feasibility study are recruitment, retention, acceptability and engagement.

1. To assess the recruitment rate of patients joining the trial.
2. To assess retention of patients by estimating 3-month follow-up
3. To investigate the acceptability of the peer-led intervention in terms of adherence and attendance to the intervention and completion rates on questionnaires
4. To collect data to inform key parameters of the sample size calculation based on recruitment rates, outcomes and adherence

5. To determine the acceptability by addressing barriers to implementation to develop an optimal plan for delivery of the complex intervention in the main trial.

Data will be collected on the number of eligible patients; numbers of those who consent to take part and withdraw (with reasons); follow-up and attrition rates, assess whether outcome data can be reliably and feasibly collected (completion rates); record the number of sessions attended and proportion that successfully complete; timing of the sessions and collect information from practitioners about what constitutes treatment as usual and measurement of acceptability and barriers to implementation for the definitive trial: during and up to 3 months post randomization.

Secondary outcome measures

1. Bespoke demographic questionnaire (including measurement of usual care): baseline only.
2. Measurement of depression: The PHQ-9 [14] has shown diagnostic validity in a study of 3,000 adult patients. Each item is rated on a scale of 0 to 3, giving a maximum score of 27. Cut-off scores are used to label depression severity as: 0 to 4, minimal depression; 5 to 9, mild depression; 10 to 14, moderate depression; 15 to 19, moderately severe depression; 20 to 27, severe depression: Baseline and up to 3 months post randomization.
3. Measurement of anxiety: The GAD-7 measures the severity of anxiety over time[15]. The GAD-7 score is calculated by assigning scores of 0, 1, 2, and 3, to the response categories of “not at all,” “several days,” “more than half the days,” and “nearly every day,” respectively, and then adding together the scores for the seven questions. GAD-7 total score for the seven items ranges from 0 to 21: Baseline and up to 3 months post randomization.
4. Measurement of suicidal ideation: The Beck Suicidal Ideation Scale (BSSI) [16] is a 19 item scale that measures suicidal intent relating to active and passive suicidal plans and specific plans for suicide : Baseline and up to 3 months post randomization.

Participant timeline

Table 1 shows the overall trial design with recruitment and measurement time points.

TIMEPOINT**	STUDY PERIOD May -November 2022			
	Enrolment	Allocation	Intervention delivery	3 month post randomization
	$-t_1$	0	t_1	
ENROLMENT:				
Eligibility screen	X			
Information sheet/privacy notice	X			
[Informed consent]	X			
Allocation		X		
INTERVENTIONS:				
[Problem solving intervention plus usual care]			X	
[usual care only]			X	
ASSESSMENTS:				
Demographic questionnaire	X			
PHQ-9, GAD, BSSI	X			X
Feasibility and Acceptability Measures	X	X	X	X

Minimizing harm

It is possible whilst participating that individuals may become upset or uncomfortable. If this happens participants are free to leave the group, this will be made explicitly clear at the beginning of each research activity. The researcher will also inform the duty manager and key worker about any concerns should they arise as a duty of care, this will be made clear

on the consent form. All contact with service user from the research team will be documented in the individual's electronic health records.

The data collection will include three questionnaires collected at two time points (baseline and 3 months post-randomization). The data collection procedures and questionnaires will include the following elements:

(i) Check eligibility criteria (first meeting with participant). Research team explain the study and request informed consent.
(ii) Gather baseline demographic information (using a specifically devised questionnaire, pre only)
(iii) Gather baseline mental health measurement of depression using PHQ-9 (pre and post)
(iv) Gather baseline general hopelessness using BHS (pre and post)
(v) Gather baseline suicidal intent using the BSSI measure (pre and post)
(vi) Measure acceptability and feasibility (post only)

Data Analysis

The flow of participants through the trial will be detailed in a CONSORT flow diagram. The numbers of people screened, randomly assigned, receiving the intervention, completing the study protocol, and providing outcome data will be summarized overall and by randomized group. The number of individuals withdrawing from the intervention and/or the trial and any reasons for withdrawal will be summarized by group.

This feasibility study is not powered to formally assess the size of the treatment effect, rather to estimate the recruitment rate. However, the totality of the data collected will be used to assess the feasibility of a definitive large RCT; recruitment rate being the driver of the feasibility study design on the basis that unless a reasonable recruitment rate can be achieved no formal trial would be possible.

The recruitment rate will be estimated based on data collected and a 95% confidence interval determined for this measure. The outcome measures (PHQ-9; BHS, BSSI) will be reported descriptively and completion rates compared between study groups. All outcomes will be summarized descriptively using mean, SD, median, 25th and 75th percentiles for continuous outcomes and the number of events and percentages for categorical data. To quantify the acceptability of the intervention the number of sessions attended and acceptability responses will also be summarized. Missing data will be summarized for each outcome overall and by study group.

Data management

Consent forms containing participant identifiable information will be held in a locked filing cabinet at the University of York (UoY) separately to that of any other data e.g. questionnaires/transcripts. For logistical reasons some consent forms may be temporarily stored on Trust premises in a locked filing cabinet until they are able to be transferred to the UoY. This transfer will be carried out by the RA using a locked briefcase that only they and the CI have the passcode for. A log will be created to check documents/data out of TEWV premises and into UoY to ensure all documents are accounted for at all times.

In accordance with University of York (UoY) policies the length data can be stored or accessed after the study has ended is project specific. Any physical documents with personal data will be stored in a locked filing cabinet in a locked office at UoY.

Any electronic data will be stored on secure NHS and University networks and accessed through secure, password protected NHS and University computers. If restrictions require us to record the workshops then this would be conducting using an NHS laptop and the audio file would be stored securely. Any electronic data transfer will be conducted using a 'drop off' protected server process initiated by UoY and in compliance with GDPR, 2018.

Access to data

Throughout the study only the research team working on the study will have access to study data.

Risk to the research team

All patients attending the workshops will be vetted by NHS staff to ensure that those participants pose no threat to the researcher. The research team members have been provided with key access to the site and other NHS staff members will be present in the room.

Any other participating members of the research team who may join the workshop sessions will be fully briefed on what to expect, rules and protocol about how to conduct oneself. Other members of the team will not be left alone with a patient and approval for access must to be granted in advance by the Trust.

Participant Confidentiality

Consent forms will be stored separately from any data in a locked filing cabinet at the UoY which only those working on the study have access to. Participant codes will be used for surveys and questionnaires to keep participant identifiable information separate from the data. A participant code match up key will be stored securely on a password protected database that only the researcher will have access to. This is to allow for identification if a participant chooses to withdraw from the study.

Disclosure of participant confidentiality

If participants were to disclose an intent to cause harm to themselves or others, or criminal activity, confidentiality would need to be broken in line with Trust policy, and their care teams informed. Disclosure of any information that might be upsetting or criminal disclosure will be addressed with members of the research team, reported to our advisory group and documented using Trust policy guidelines. All guidance on managing cases will be addressed on a case by case basis with communication to health care staff.

Ethical issues

We do not anticipate any major ethical issues. Where participation in the trial is felt to be detrimental to health and wellbeing, we will not make an approach to participate. Participants will not be denied any form of care that is currently available in TEWV. The trial does not involve new medicinal products or any invasive/potentially harmful procedures and is therefore considered low risk for participants. All participants will receive usual care,

and therefore no treatment will be withheld by participating in this trial. The research team will be guided by TEWV staff as to any risk posed by approaching individuals to take part in the trial. Written informed consent will be obtained from every participant. Permission to conduct the study has been granted by TEWV Trust.

Dissemination plan

A dissemination event will be led with service users to show the findings of the study. The study will throughout explore how the information can be made accessible to staff and patients, for example, via the ward computers and reception television services. Reporting of the study progress to the Forensic Research Group, Quarterly Forensic Newsletter and through the staff Research Champion's (whose role it is to disseminate research information on each ward). The structure and will lead to the write up and a peer reviewed academic publication.

Quality assurance procedures

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

Early discontinuation/withdrawal

It is unlikely that this intervention would cause significant adverse events. However, all adverse events would be recorded throughout our research and reviewed at team meetings. If the Trust review identified any concerns linked to recorded adverse events and our research project we would follow any Trust guidance in stopping our research in accordance with their policy. Because this is a feasibility study, at this stage we do not have any pre-determined criteria for electively stopping the research prematurely.

Declaration of Helsinki

This study will be conducted in accordance with the principles of the Declaration of Helsinki.

Adverse events reporting and harm

This study is non-CTIMP (Clinical Trial of an Investigational Medicinal Product) and is therefore not subject to any additional restrictions. Decisions regarding prescription of any medications will made by the participant in conjunction with their usual care, participation in the study will have no bearing on this process. This study will record details of any Serious Adverse Events (SAEs) that are required to be reported to the Governance Committee at the University of York, TEWV Trust. Under the terms of the Standard Operating Procedures for RECs [49]. An SAE is defined as a 'related'* and 'unexpected'** untoward occurrence that:

(a) Results in death.
(b) Is life threatening.
(c) Requires hospitalization or prolongation of existing hospitalization.
(d) Results in persistent or significant disability or incapacity.
(e) Consists of a congenital anomaly or birth defect; or
(f) Is otherwise considered medically significant by the investigator.
* 'related' is defined as: resulting from the administration of any research procedures.
** 'unexpected' is defined as: a type of event not listed in the protocol as an expected occurrence.

In the context of the current study, an occurrence of the type listed in (a) to (f) above will be reported as an SAE only if:

a)It is suspected to be related to an aspect of the research procedures (e.g. completion of follow up questionnaires, participation in delivery of the intervention).

Or

b) It is an unexpected occurrence. Hospitalization's, disabling / incapacitating / life-threatening conditions and deaths are expected in the study population due to the age of the cohort, they will therefore only be reported as SAEs if they appear to be related to an aspect of taking part in the study.

SAEs will be reported to the main REC within 15 days of the PI becoming aware of the event. A SAE Form will be completed, and a copy stored in the participant's records.

Protocol changes or amendments

Changes to the protocol (e.g., changes to eligibility criteria, outcomes, analyses) will be notified to relevant parties (e.g., investigators, governance committees, trial participants, trial registries, journals, regulators). An updated version number of the protocol will be published to reflect any changes.

Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and HRA (where required) and host institutions for written approval. The Chief Investigator will seek approval from the above parties for all substantial amendments to the original approved

Monitoring and audit of the trial

Reporting an updating of the trial data will be provided to monthly Forensic research meetings held within TEWV and Chaired by a Clinical Director of the Trust. Individual updating of the research on a week-by week basis will be monitored by the line manager of the RA in TEWV and the Research and Development Manager in the Trust. The research team includes a Trust clinical director and Head of Psychology services, management support from the Trust will help to ensure this piece of research is incorporated into Trust policy and guidance through regular meetings.

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