Community Outpatient Psychotherapy Engagement Service for Self-harm (COPESS): A Feasibility Trial Protocol

Pooja Saini
Liverpool John Moores University https://orcid.org/0000-0002-4981-7914
Anna Hunt
Liverpool John Moores University
Peter Taylor
The University of Manchester Division of Psychology and Mental Health
Catherine Mills
Mersey Care NHS Foundation Trust
Caroline Clements
The University of Manchester School of Psychological Sciences: The University of Manchester Division of Psychology and Mental Health
Helen Mulholland
University of Liverpool
Cecil Kullu
Mersey Care NHS Foundation Trust
Mark Hann
The University of Manchester
Rui Duarte
University of Liverpool
Felicity Mattocks
Penny Lane Surgery
Else Guthrie
University of Leeds
Mark Gabbay (✉ m.b.gabbay@liverpool.ac.uk)

Study Protocol

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Abstract

Background: People who self-harm are at high risk for future suicide and often suffer considerable emotional distress. Depression is common among people who self-harm and may be an underlying driver of self-harm behaviour. Self-harm is often repeated, and risk of repetition is highest immediately after an act of self-harm. Readily accessible brief talking therapies show promise in helping people who self-harm, but further evaluation of these approaches is needed. A brief talking therapy intervention for depression and self-harm, has been designed for use in a community setting. This mixed methods feasibility study with repeated measures will examine the feasibility and acceptability of the Community Outpatient Psychological Engagement Service for Self-Harm (COPESS) for people with self-harm and depression in the community compared to routine care.

Methods: We will recruit 60 participants with a history of self-harm within the last six months, who are also currently depressed, to take part in a feasibility single blind randomised controlled trial (RCT). We will randomise participants 1:1 to receive COPESS plus treatment as usual (TAU) or TAU alone. Recruitment will take place via GP practices and self-referral. Assessment of feasibility and acceptability will be assessed via quantitative and qualitative methods including measures of recruitment and retention to the trial, participants' experience of therapy, completion / completeness of outcome measures at relevant time-points and completion of a service use questionnaire.

Discussion: The results will indicate whether it is feasible to conduct a definitive trial to determine whether COPESS is a clinically, cost-effective intervention for those who self-harm in the community. The qualitative and quantitative data will help identify the potential strengths or challenges of brief community-based interventions for self-harm.

Trial registration: NCT04191122 registered 9th December 2019, https://clinicaltrials.gov/ct2/show/NCT04191122?term=NCT04191122&draw=2&rank=1

Background

Self-harm is a public health priority and people with a history of self-harm now feature in the Suicide Prevention Strategy for England as a priority group.[1,2,3] Self-harm defined as *any intentional act of self-injury or self-poisoning regardless of motivation or suicidal intent*[4] is often a sign of underlying distress, predictive of psychological problems and suicide, and associated with premature death by other causes.[5-9] In England there are over 200,000 self-harm presentations to hospital emergency departments (ED) annually.[10-12]. Rates of self-harm in primary care are estimated to be double the rates of hospital admissions and the prevalence of self-harm in the community is substantially higher.[13-15]

General Practitioners (GPs) are often the first point of contact for mental health issues in the community, but report feeling under skilled in relation to managing self-harm.[16,17] National policy and guidance[4]

emphasises the need for rapid access to community-based services for self-harm, but referral pathways and treatment options are often unclear to participants and health professionals.[18]

Depressive symptoms are common among people who self-harm and thought to be related to the initial occurrence and subsequent repetition of self-harm.[19,20] However, talking therapies designed for treating depression do not necessarily reduce self-harm or improve self-harm-related outcomes.[21] It has been argued that self-harm interventions need to be specifically developed for this context.[22,23]

Two studies show that talking therapies that target the psychological processes underlying self-harm can reduce repetition of self-harm[24-7] and depressive symptoms.[26,27] The latter review found that cognitive behavioural therapy (CBT) and psychodynamic interpersonal therapy (PIT) had evidence of effectiveness.[27] The Cochrane review [24] makes a distinction between brief therapies that are usually provided for people who present following self-harm in acute distress and higher intensity therapies (such as Dialectical Behavioural Therapy[28]) which are designed to help people who struggle with multiple self-harm and other co-existing life problems. The evidence base concerning the former remains limited and there is a need to further evaluate brief therapies that benefit individuals with recent self-harm. Community Outpatient Psychological Engagement for Self-harm Service (COPESS) belongs to this category of interventions. It is a low intensity therapy, which addresses the reasons precipitating the self-harm and associated depression.

COPESS is a modified version of psychodynamic -interpersonal therapy (PIT) which has previously been evaluated in two randomised trials for self-harm[26] and has also been used in NHS self-harm services in England.[29] PIT has undergone two modifications for the purposes of this trial. Elements of another closely linked therapy, Cognitive Analytic Therapy (CAT),[30] have been added to the intervention with the use of visual mapping and a focus on identifying “exits” or solutions to clients’ difficulties. Previous evaluation of this therapy approach within ED settings found that 64% of referred individuals attended at least one therapy session, with nearly half (n=26, 49%) attending all four sessions.[29] There was also evidence of a reduction in distress over the therapy period.

Aims

The aim of this study is to examine the feasibility and acceptability of both delivering COPESS in a community setting, and the study procedures for a future trial.

The key feasibility outcomes we will examine via the proposed protocol concern methodological, procedural and clinical uncertainties [31-33]. These include estimates of recruitment and retention rates; feasibility and acceptability of data collection instruments and data collection procedures; feasibility, acceptability and safety of the intervention.

Methods And Analysis

This protocol is reported according to guidelines presented in the Consolidated Standards of Reporting Trials (CONSORT)[34] 2010 statement extension for randomised pilot and feasibility studies and clinical trial protocols.

Design

The study is a single blind, randomised controlled trial with an embedded qualitative process evaluation. Participants will be randomised 1:1 to receive COPESS plus treatment-as-usual (TAU) or TAU alone.

Eligibility criteria

Participants with current depression and recent self-harm will be recruited through participating GP practices and self-referral (see Figure 1). Participants who self-refer into the trial will be informed that their GP will be notified about their participation, in line with participant consent procedures.

Inclusion criteria

- Adult or adolescent, aged 16 years or over
- A recent episode of self-harm in the last six months (self-reported) defined as an act of direct, intentional harm to oneself irrespective of suicidal intent, including behaviours such as cutting, scratching burning or hitting oneself, or taking an overdose.[4]
- A score of 14 or greater on the Beck Depression Inventory-II (BDI-II)[35]
- Help-seeking, defined as attendance at GP practices or self-referral into the trial

Exclusion Criteria

- Non-English speaking
- Diagnosed with an intellectual disability as determined by review of clinical notes - the therapy has not yet been adapted for working with this population
- Unable or unwilling to give written informed consent to participate in the study
- Currently receiving face-to-face psychological talking therapy for self-harm. If they attend group counselling or have regular nurse appointments this will not exclude them from the study

Recruitment

The eligible population consists of adults or adolescents who self-harm in Liverpool, a large city in the North of England. There are approximately 300-350 hospital presentation of self-harm per annum to the Royal Liverpool Hospital[38] and we estimate at least double this number in the community.

Participants will be identified and recruited via GP practices by three methods:

1. Practice database searches with GP letters informing them of the study;

2. Participants consulting with their GP for self-harm and related difficulties during the study recruitment period;
3. Advertising material displayed or available in waiting rooms where participants may seek help for self-harm within community settings (primary care, student counselling services, walk-in centres and Talk Liverpool).

Recruitment of GP Practices

The Clinical Research Network (CRN) will assist with recruitment of GP practices. Twelve medium to large research-active GP practices will be identified and invited to participate in the trial. This is to ensure the maximum efficiency in recruitment for the trial within the study period. Initially four of the practices recruited will be monitored for recruitment rates into the trial over a two-month period. We will recruit four more of the GP practices if required and follow the same procedure. If recruitment rates are not being met after 4 months then the final four GP practices will be included. All GPs within the participating practices will be informed about the project and given a welcome pack by the researcher. This may be followed up by a telephone/skype/face-to-face contact from the researcher to ascertain level of interest, and if appropriate, to arrange to discuss the study in more detail.

Trial-GP

A trial-specific GP Site principal investigator (PI) will be identified at each practice who will have some of their time costed to make referrals, and encourage and support others at the practice to refer into the study.

Recruitment of participants

Once potential participants have been identified through GP practice searches and referrals they will be matched against the eligibility criteria to assess suitability for invitation to the COPESS trial. Participants that meet the inclusion criteria will be sent an introductory pack that comprises: an explanatory letter from the practice; a participant information sheet about the study, an expression of interest form; and, a freepost return envelope by DocMail.

People who are identified through community advertising methods (e.g. posters), who contact the study team directly will be asked to provide details of their GP. The study team will contact the GP to make them aware of the study and confirm patient eligibility. This will facilitate communicating about high risk and allow any potential disclosures or adverse events during the study to be captured.

We will monitor recruitment rates from the different recruitment methods, including proportion of eligible participants who consented, and the number of participants recruited compared against target.

Informed consent, screening and baseline

After receiving an expression of interest from potential participants, a brief telephone/video call (e.g. Skype) screening interview between one of the research team will determine eligibility. Contact will be attempted a maximum of three times before the patient is listed as “uncontactable”. Potential participants, who meet the eligibility criteria will be invited for a baseline assessment. Within the public consultation, service users requested that participants be given a choice of communication methods (e.g. telephone/video call/face-to-face). Eligibility and safety checks will be undertaken by the Research Assistant through contacting the potential participants’ GP or nurse practitioner with the patient’s consent. Signed informed consent would be sought from participants at this initial baseline meeting for all eligible individuals who wish to take part.

Due to the on-going impact of COVID-19, participants taking part in the study will be offered the option to complete the COPESS therapy sessions either remotely (via an online method such as Zoom or Skype or the telephone) or face-to-face (either in the participant’s home or in a community setting such as a health centre or clinic). This choice will be decided solely on participant preference and will not be part of the randomisation process. Similarly, participants will be offered the researcher visits either remotely (using an online method or telephone) or face-to-face. Safety for the therapist and/or mobility for the patient will be reviewed throughout the recruitment period. Participants in the COPESS arm of the trial will also receive TAU.

Reasons for non-participation and withdrawal of participation

Potential participants who consented to take part in the study but later decided not to progress to the trial or leave before completion will be contacted and asked about their reasons for not participating, to help improve full trial design.

Participants can withdraw from the trial at any time for any reason, without their care being affected. For participants in the COPESS arm of the trial, therapy will continue if they choose to withdraw from the research element of the project. Where possible, data already collected will continue to be used in the trial. The reasons why participants withdrew from the study will be documented where possible. GPs will be informed of patient withdrawal and / or if a patient ceases communication with the study team.

Randomisation

Following the collection of baseline data, eligible and consenting participants will be randomly allocated (1:1) by the study statistician, to receive COPESS plus TAU or TAU alone. An algorithm within STATA 15 ill be used to generate random allocation sequences in blocks of size of 4 or 6. Block sizes will occur with equal frequency and will be determined at random. The statistician generating the randomisation schedule will be independent from other elements of the project to maintain allocation concealment. Once randomisation has taken place the statistician will inform the local PI of patient arm allocation. The PI will inform both the patient and their GP, keeping the researcher masked to treatment allocation. Researchers completing study assessments will be masked to treatment allocation, facilitated by briefing members of the research team and participants on the need to avoid disclosure of treatment details (See

Figure 2). A record will be kept of how many times accidental unblinding occurs. See Figure 3 for full timeline of events.

Sample Size

A conventional power calculation is not necessary to achieve the stated aims of this feasibility study, as we will not be formally testing the effectiveness of the intervention. Instead, we aim to recruit 60 participants, following recommendations that this is sufficient to assess feasibility outcomes and estimate key parameters, such as the standard deviation of potential outcomes, with adequate precision in order to inform the sample size for a definitive trial.[36,37] For example, with N = 60, an attrition rate of up to 35% can be determined to within 12 absolute percentage points with 95% confidence. To avoid high attrition rates, we will keep participants engaged via text and/or telephone reminders.

Interventions

COPESS plus TAU

COPESS consists of four 50-minute weekly sessions of face to face psychological therapy. One further follow-up session is offered four weeks after the end of therapy. Therapy is usually completed within eight weeks, but we will monitor variations from expected schedule, associated reasons and drop-out rates etc. The therapy involves working collaboratively with a patient to identify patterns or conflicts in emotional experiences and interpersonal relationships, linked to depressed mood and acts of self-harm. The therapist works with the patient to build a shared understanding of these experiences. The first session will focus on the participant's most recent episode of self-harm and the interpersonal events that precipitated the episode, and the participant's associated low mood. Risk assessment and safety planning will also be incorporated into the initial session. The three remaining sessions will focus upon the links between mood, relationship difficulties and self-harm. PIT techniques include picking up cues, staying with and exploring feelings about relationships and interpersonal problem- solving in the here and now. CAT techniques will be used to help the participant to map out their relationships and understand the reciprocal nature of relationships. Therapy will take place either in the participant's home or in a community setting (e.g. health centre or clinic) depending on patient preference. Safety for the therapist and/or mobility for the patient will be reviewed throughout the study. Participants in the COPESS arm of the trial will also receive TAU.

TAU

There will be no restrictions on the care that can be provided as TAU. Participants randomised to TAU will be provided with information about how to refer to local statutory or non-statutory services and GPs will be encouraged to follow the NICE guidance.[4]

Therapy Fidelity and Adherence

COPESS will be delivered by five therapists. Therapists will receive a combined Psychodynamic Interpersonal Therapy (PIT) and Cognitive Analytic Therapy (CAT) Level 1 training. This is a five-day short course that introduces the principles of working with PIT and CAT and the application within clinical practice. Ongoing supervision from a Consultant Clinical Psychologist will occur on a fortnightly basis. If the standard therapy approach is not being adhered to, therapists will be offered feedback. All sessions will be recorded with the consent of participants. A subset of 10% of recorded sessions will be rated by an independent psychotherapist with experience of the approach using a modified version of the Sheffield rating scale [39] to ensure adherence to the approach. All therapists will receive fortnightly supervision. Each therapist will see approximately six participants (anticipated maximum range 4-8).

Primary Outcome

The primary outcome of this pilot study is the feasibility and acceptability of COPESS for people in the community with self-harm and co-existing depression. Feasibility will be defined as the ability to recruit the target sample size and retain at least 70% of participants in both arms of the trial over the three-month follow-up period. Acceptability of the intervention for participants will be assessed by the percentage of participants who engage and are retained in therapy (acceptability requires > 40% randomised to COPESS to attend all sessions) and more contextual and detailed data will be collected from semi-structured qualitative interviews focusing on the experience of the therapy. Acceptability of the intervention for therapists will be assessed by semi-structured qualitative interview. Acceptability of the trial measures will be defined as the proportion of participants who complete each of the measures at all assessment points (acceptability requires at least 80% of questionnaires completed), supplemented by semi-structured interview data about the experience of the trial.

Secondary outcomes

Follow-up assessments will be conducted at 4, 8- and 12-weeks post randomisation. See Table 1 for the full schedule of assessments. The assessments will take place either face to face (at the patient's home, general practice or in the community), via telephone, Skype or an online questionnaire. Participants will complete a batch of standardised questionnaires at each assessment. Participants will continue to be invited to follow-up assessments (including those who have left therapy early) unless they have withdrawn from the trial.

Self-Injurious Thoughts and Behaviours Interview Short-Form (SITBI)

The SITBI is a brief interview-based measure that uniformly assesses the presence, frequency and characteristics of information on self-harm related thoughts and behaviours. Repeated self-harm during the trial period will be captured within the interview. The SITBI has demonstrated interrater reliability, test-retest reliability and convergent validity.[40]

Beck Depression Inventory-II (BDI II)

The BDI II is an established self-report measure of depressive symptoms over the past two weeks. There is evidence for the reliability and validity of this measure in the general population.[35,41] Each of the 21 items on the questionnaire has a choice of four answers scored from 0 – 3. A combined score 0 – 13 is considered minimal depression, 14 – 19 mild depression, 20 – 28 moderate depression and 29 – 63 severe depression. The questionnaire takes approximately 10 minutes to complete.

Frequency/Intensity of self-harm urges - Alexian Brothers Urge to Self-Injure Scale (ABUSI)

The ABUSI is a validated tool designed to evaluate the frequency and intensity of urges to self-injure over the past seven days.[42] The scale has demonstrated good psychometric properties. The scale measures urge, regularity and strength of self-injurious thoughts across five 7-point scales. Higher scores (up to a maximum of 30) indicate a stronger desire to self-harm.

Emotion Regulation Questionnaire (ERQ)

The ERQ is a widely validated ten item questionnaire that assesses the way in which individuals regulate their emotions, including the use of re-appraisal and suppression of emotions.[43] The scale has demonstrated good psychometric properties. Higher scores (up to a maximum of 70) indicate greater use of a particular regulation strategy.

Clinical Outcomes in Routine Evaluation (CORE-10)

The CORE-10 is widely validated, brief ten-item measure of psychological distress over the past seven days.[44] Higher scores signpost higher levels of psychological distress. A combined score of less than 10 falls in the non-clinical range, 11 to 14 indicates mild psychological distress, 15 to 19 moderate psychological distress, 20 to 24 moderate psychological distress and 25 or above indicates severe psychological distress.

The Helping Relationship Questionnaire (HRQ)

The HRQ is an 11-item questionnaire that measures patient's perception of the therapist-patient relationship.[45] The questionnaire is validated and has established psychometric properties. The questionnaire uses a six-point scale, with higher total scores indicating greater therapeutic alliance

EQ-5D

The EQ-5D-5L is a validated six-item questionnaire measuring quality of life across five health dimensions (mobility, usual activities, self-care, pain/discomfort and anxiety / depression). Five items are measured on a five-point scale considering health that day. The final question asks individuals to signpost their health today on a 100-point scale (with zero indicating the worst health imaginable and 100 indicating the best).[46]

The Client Service Receipt Inventory (CSRI)

The Client Service Receipt Inventory (CSRI)[47] will be used to collect healthcare resource use. This includes information on use of other primary and secondary care services, use of social services, disability payments received, personal costs related to mental health (e.g. expenditure on over-the- counter medication, expenditure on prescriptions), time off work and unpaid activities.

Statistical analysis

This is a feasibility study, so we will not be carrying out hypothesis testing to determine if the intervention is effective. Data analysis will follow an Intention-To-Treat (ITT) protocol and will be used to inform power calculations for a definitive trial in addition to other sources. Attrition and reasons for drop-out will be recorded where possible. We will assess rates of missing data and which elements in particular, and proportions of dropouts at different trial stages. We will also assess whether any of the measures display floor and/ or ceiling effects. Guidance will be sought from the Patient Advisory Group on how to manage and minimise attrition over the study period.

We will calculate and present in a CONSORT[34] flow chart: the proportion of people with depression and self-harm consenting to the study; the proportion completing the baseline assessment and entering the randomised phase; the number of therapy sessions attended and the proportion completing all sessions; the proportion completing follow-up assessments at 4-, 8–– and 12-weeks post-randomisation.

We will summarise, as appropriate (e.g. mean/ standard deviation; median/ inter-quartile range; proportion/ 95% confidence interval; data range) data for all potential participants to compare the continuous scores on repetition of self-harm and depressive symptoms and urges to self-harm, overall and by group. The standard deviation of the secondary outcome measures, along with the estimated attrition rate and the average number recruited per practice (plus the range of this data), will be used to help inform the sample size calculation for the large-scale RCT.

Health economic analysis

The feasibility study will be used to develop a framework for a subsequent cost effectiveness analysis to be undertaken alongside a future RCT. In particular, economic evaluation methods will be developed and tested regarding the collection of resource use, costs and outcome data. Health care resource utilisation and absences from work will be collected for each patient during the study follow-up period using the CSRI questionnaire. Data from the feasibility study will be used to inform adaptation of the CSRI prior to a definitive trial. Generic health-related quality of life (HRQoL) data will be collected using the EQ-5D-5L instrument.

Qualitative study

At the time of trial consent, all participants will be asked if they are willing to be contacted for possible participation in a one-to-one interview. In–depth interviews will be conducted with participants from both arms of the trial at 4-8 weeks post-randomisation. We also aim to include participants who did not attend

all COPESS therapy sessions. A purposive sample of approximately 16-20 participants will be interviewed to capture maximum variation in views and experience of those participating in the study. Sampling parameters will include: 1) sociodemographic variables, 2) type of self-harm (injury or poisoning) and 3) trial arm allocation. Participants will be selected from both arms of the trial to provide an insight into experiences of COPESS and TAU, and to allow for comparison of these experiences. The interviews will assess understanding of, and acceptability of intervention received (content and contexts, setting etc), perceived benefits and mechanisms of action, challenges to engagement, and contextual factors seen to affect the impact of intervention. They will also ask about experience of trial participation. Interviews will be analysed in batches and sampling will continue until no new themes emerge.

GPs at participating recruitment sites will be invited to be interviewed about their experience of recruiting participants for this study. Mersey Care NHS Foundation Trust will train five of their current therapists (Mental Health Nurses and Assistant Psychologists) in the COPESS therapy. Those therapists will then be invited to be interviewed about their experience of being trained in the therapy and delivering the therapy. Therefore, in addition, all therapists delivering the intervention and participating GPs will be invited to be interviewed in order to gain a detailed understanding of the perceived effectiveness and acceptability of the treatment, implementation challenges and any barriers to its uptake in a community setting. Interviews will last no longer than 60 minutes and will be audio-recorded and transcribed verbatim.

Qualitative data analysis

Transcripts of interview data will be analysed via Thematic Analysis using the framework approach.[48] We will also adopt Normalisation Process Theory (NPT)[49] as a broad framework through which to make sense of the qualitative data and draw conclusions relating to how readily COPESS might be implemented amongst participants and embedded into health care systems. Framework analysis was developed to meet information needs and to provide practical outcomes and recommendations.[50] It offers a highly visible and systematic approach to data analysis, showing very clearly how findings are derived. Analysis will follow the five stages of framework analysis; familiarisation with the data; identifying a thematic framework; indexing the data; charting the data; and mapping and interpretation.[51] To monitor and limit the possible bias of a single-analyst perspective, additional members of the research team with experience in qualitative methods will examine a sample of transcripts to compare their perceptions of the interview data and analysis with the main analyst's interpretation. Themes will be discussed and refined further in multidisciplinary research team meetings. NPT provides a framework for understanding the barriers and facilitating processes that underlie the implementation and integration of complex interventions into healthcare systems.[51, 52]

The theory identifies four key processes that underlie the adoption of new interventions; coherence of intervention; cognitive participation; collective action; and reflexive monitoring. Previous research has shown that NPT can be applied effectively to qualitative data in healthcare contexts to aid interpretation.[53] NPT will be used to map the links between qualitative themes and the core processes outlined in NPT. This process will be aided through use of the NPT toolkit (normalizationprocess.org) and

application of the NPT statements generated by May and colleagues.[51] To further promote integrity and rigor during the data analysis process, field notes will be written immediately after interviews and a reflective diary maintained. Thus, aiming to reduce the potential for the researcher's values, beliefs and preconceptions to influence subsequent findings.[52,53]

Data handling

All confidential data will be stored securely on the University research centre site with strictly limited access. Participants will be allocated an ID code which will be used on documents such as questionnaires to maintain confidentiality and minimise the use of personal data. The trial Sponsor is Liverpool John Moores University who takes primary responsibility for ensuring that the design of the study meets appropriate standards in accordance with Good Clinical Practice (GCP) guidelines. All data will be handled according to the General Data Protection Regulation (GDPR) 2018. Confidential data will be stored securely on site with limited access. It was agreed that a DMC was not required due to the research being a feasibility trial.

Safety monitoring

Adverse events and risk standardised operating procedures will be developed and will be followed by all researchers and therapists working on the trial. Adverse events are defined as significant negative episodes, or significant deterioration in condition, which happen to participants during their time in the trial. These will be reported by research assistants and trial therapists to senior trial staff, who will ascertain whether these are thought to be linked to participation in the trial, and keep records of each event on an adverse events database. The Adverse Experiences in Psychotherapy (AEP) self-report measure [54] will identify adverse experiences liable to occur within psychological therapy. All serious adverse events (SAE) of an unexpected and unrelated nature will be reported to the main Research Ethics Committee, the study Sponsor and Trial Steering Committee (TSC). Suicide risk will be closely monitored. If the individual is considered to be high risk, the participant's GP will be contacted and information passed to them within two working days. The participant will also be given advice about local crisis teams, and other relevant support services. In cases where SAE are potentially linked to the trial, withdrawal of participants, halting or terminating the trial will be considered as required.

Discussion

COPESS aims to provide robust evidence as to the cost-effectiveness and efficiency of a community outpatient psychological support service. The main purpose of this study is to find out whether it is possible to recruit people to take part in this intervention, and to see if they will attend all sessions. The results from this study will help the researchers design a larger trial to assess how effective the intervention is at reducing depression and self-harm.

There will also be benefits beyond the immediate trial results. If COPESS proves to be an effective intervention then this new model of care has the potential to be delivered more widely within the National

Health Service, as an effective, low cost, convenient, safe and easily deliverable intervention.

Declarations

Ethics approval and consent to participate

Ethical approval has been granted by the Health Research Authority (HRA) on 10/06/2020 for the trial. Additionally, all participating therapists and GPs will provide fully informed, written consent prior to being interviewed. Liverpool Central Research Ethics Committee Approval Reference: 275047. Trial registration: NCT04191122 Registered on December 9th 2019.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

PS, PT and CK conceived of the study. PS, CK, HM, PT, MG, RD, MH, FM, CM, CC and EG participated in the design of the study. AH and PS drafted, and CK, HM, PT, MG, RD, MH, CM, CC and EG revised the manuscript. All authors read and approved the final manuscript.

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Trial status: Approved. Trial start was been delayed due to COVID-19, the intervention and data collection then adapted for the pandemic and commenced late 2020.

This article describes protocol version 1.8 dated 18/09/2020; when all initial approvals (REC, HRA and IRAS) were received, the protocol was version 1.0 dated 06/12/2019

Competing interests

The authors declare that they have no competing interests.

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Tables

Table 1: *Timing of outcome measurement*

List of Questionnaire	*Baseline*	*Follow Up 1*	*Follow Up 2*	*Follow Up 3*
Demographic Information	*X*			
ABUSI	*X*	*X*	*X*	*X*
AEP Form (A / B)		*X*		*X*
Beck Depression Inventory	*X*	*X*	*X*	*X*
CORE-10	*X*	*X*	*X*	*X*
ERQ	*X*	*X*	*X*	*X*
EQ-5D	*X*			*X*
HAq-II	*X*	*X*	*X*	*X*
SITBI 2.1	*X*	*X*	*X*	*X*
CSRI				*X*

Figures

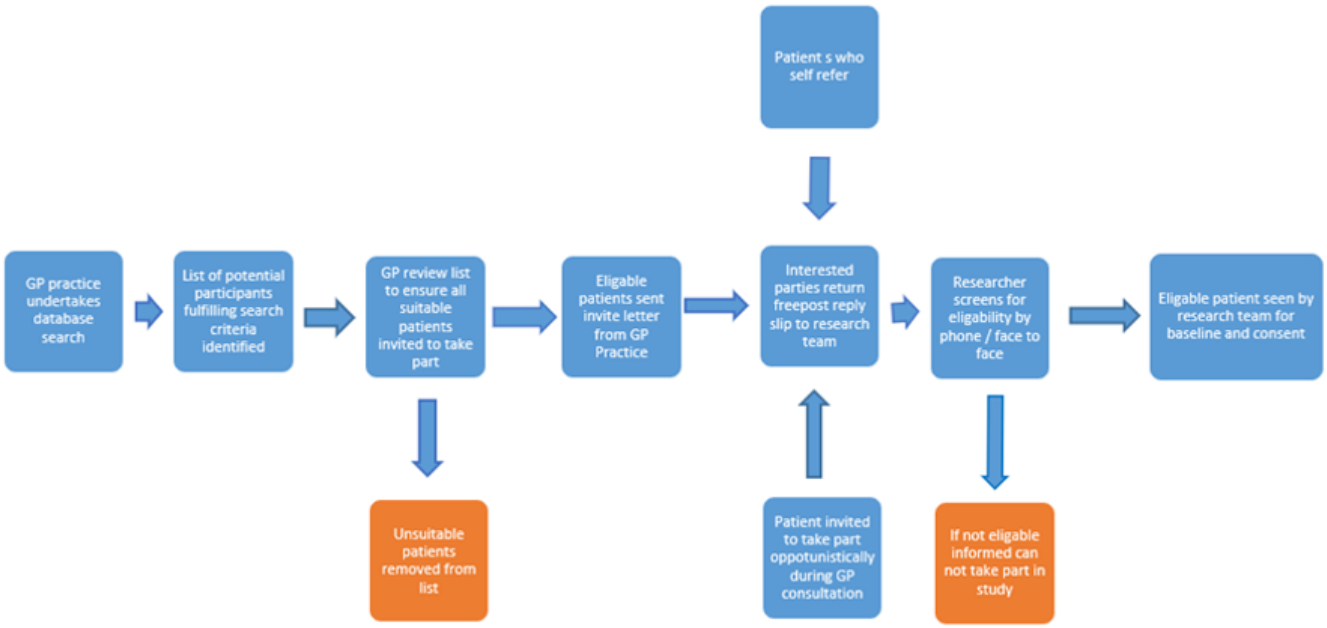

Figure 1

Recruitment Flow Chart

Figure 2

Randomization Flow Chart

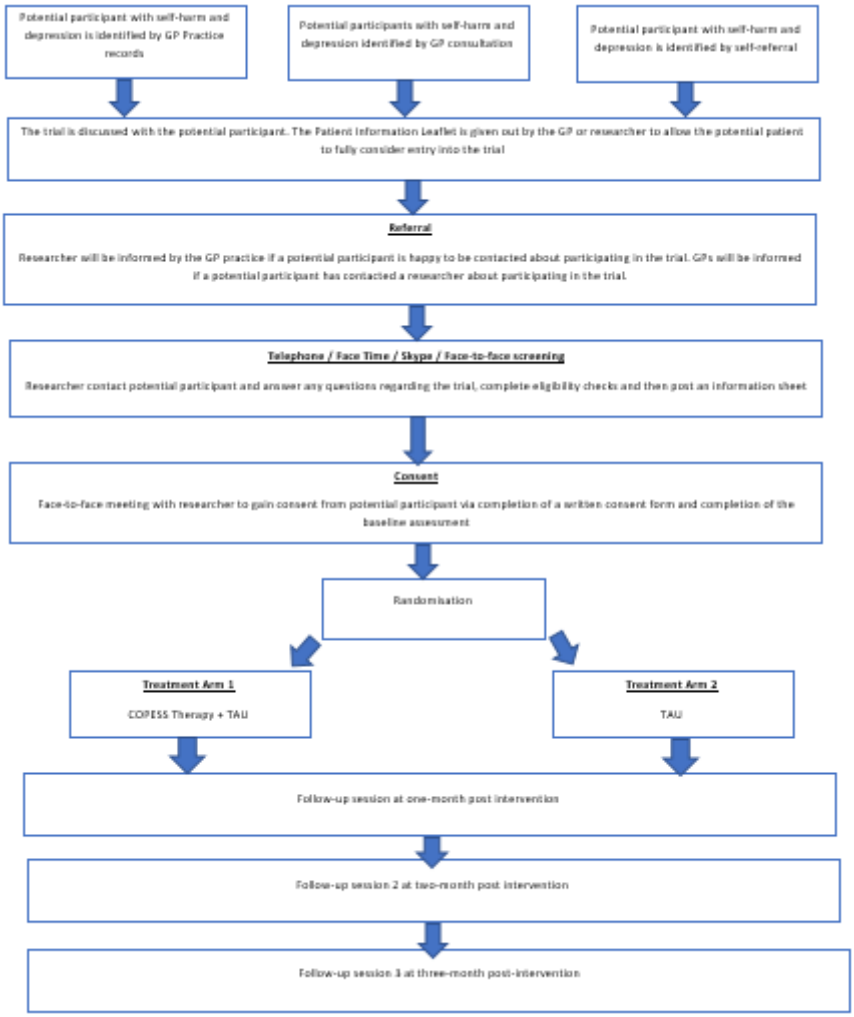

Figure 3

Summary of the sequence of study-related assessments, procedures and activities

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