Title: Acceptability and feasibility of a Community Outpatient Psychotherapy Engagement Service for Self-harm: COPESS a mixed methods study

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Abstract

Background: Self-harm refers to any intentional self-injury or self-poisoning, with or without the intention to end one's life. People who self-harm are at high risk of suicide, and often experience a range of social and mental health issues as well as considerable emotional distress. Around 70% of people who self-harm also experience symptoms of depression. There is very little help available from health and mental health services designed specifically for people who self-harm, and many receive no help at all. Most self-harm happens in the community but there have been very few attempts to develop self-harm specific services in community settings, such as GP practices. Readily accessible brief talking therapies show promise in helping people who self-harm, but further evaluation of these approaches is needed. The Community Outpatient Psychological Engagement Service for Self-Harm (COPESS) is a brief talking therapy intervention for depression and self-harm.

Objectives: The objectives were to assess the feasibility of conducting a trial of the COPESS intervention in a community setting in relation to participant recruitment, data collection, the acceptability of the intervention and retention in treatment and study.

Design: A mixed-method study, using a single-blind randomised controlled trial (RCT), assessing the acceptability and feasibility of the COPESS intervention for people with depression who self-harm, and purposefully collected qualitative data.

Setting: GP practices in Northwest England.

Participants: Individuals aged >16 years who had depression and self-harmed in previous six months.

Interventions: The COPESS intervention is a psychological 'talking' therapy designed to help people who self-harm. It is made up of a short course of sessions with a therapist, that are available quickly after self-harm has been identified by that person's GP. People were randomised 1:1 to receive either COPESS plus treatment-as-usual (TAU) or TAU alone.

Main outcome measures: The primary outcome was the feasibility and acceptability of COPESS for people in the community with self-harm and co-existing depression. Secondary outcome measures were assessed at baseline, with follow-up assessments occurring at 1-month, 2-months and 3-months.

Results: Findings indicated that COPESS was both acceptable and feasible, with all progression criteria being met. Fifty-seven people were recruited into the trial. Fifty-five were then randomly allocated to receive either the COPESS therapy (28 people) or treatment as usual only (27 people). Primary care staff and COPESS therapists based in a

mental health trust reported the intervention fitted and complemented existing services, and patients reported that they favoured the rapid, self-harm focused, person-centred approach of the intervention. The response to the therapy was very positive, with most participants attending all sessions. There were early indications that receiving COPESS may lower levels of depression, general distress and urges to self-harm compared to treatment as usual. Qualitative interviews were completed with participants, therapists, and primary care staff and feedback was positive about the COPESS intervention.

Limitations: Due to the COVID-19 pandemic the COPESS intervention was delivered remotely only, therefore the experiences of the patients in the feasibility trial may not be representative of therapy delivered in person. Furthermore, the pandemic and associated disease control measures (i.e., lockdowns) may have had a general impact on outcomes, including recruitment into the study (both GP surgeries and participants), and experiences of participants and therapists.

Conclusions: All progression criteria were met supporting further evaluation of the intervention in a full-scale clinical effectiveness trial. COPESS has potential as a brief primary-care based intervention for those struggling with self-harm.

Future work: Further work involving stakeholder engagement is needed to refine the delivery of the intervention across multiple sites and conduct a full-scale efficacy trial.

Trial registration: NCT04191122.

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Contents

LIST OF TABLES

LIST OF FIGURES

LIST OF SUPPLEMENTARY MATERIALS

LIST OF ABBREVIATIONS

ABUSI	Alexian Brothers Urge to Self-Injure Scale
AE	Adverse Events
AEP	Adverse Experiences in Psychotherapy
BDI-II	Beck Depression Inventory - II
CAT	Cognitive Analytic Therapy
CBT	Cognitive Behavioural Therapy
CONSORT	Consolidated Standards of Reporting Trials
COPESS	Community Outpatient Psychotherapy Engagement Service for Self-harm
CORE-10	Clinical Outcomes in Routine Evaluation
CRN	Clinical Research Network
CSRI	Client Service Receipt Inventory
DBT	Dialectical Behavioural Therapy
ERQ	Emotional Regulation Questionnaire
EQ-5D	EuroQol five-dimension scale questionnaire
GP	General Practitioner
HOPE	Hospital Outpatient Psychotherapy Engagement
HTA	Health Technology Assessment
IAPT	Improving Access to Psychological Therapies
ITT	Intention-To-Treat
LJMU	Liverpool John Moores University
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NHS	National Health Service
PAG	Public Advisory Group
PC	Primary Care
PI	Principal Investigator
PIT	Psychodynamic Interpersonal Therapy
RCT	Randomised Controlled Trial
SAE	Serious Adverse Events
SITBI	Self-Injurious Thoughts and Behaviours Interview Short Form
STATA	Statistics and data
TAU	Treatment-As-Usual
TC	Therapist COPESS

PLAIN ENGLISH SUMMARY

Self-harm refers to any intentional self-injury or self-poisoning, with or without the intention to end one's life. People who self-harm are at high risk of suicide, and often experience a range of social and mental health issues as well as considerable emotional distress. Around 70% of people who self-harm also experience symptoms of depression. There is very little help available from health and mental health services designed specifically for people who self-harm, and many receive no help at all. Most self-harm happens in the community but there have been very few attempts to develop self-harm specific services in community settings, such as GP practices.

The Community Outpatient Psychotherapy Engagement Service for Self-harm (COPESS) is a psychological or 'talking' therapy designed to help people who self-harm and have depression. It is made up of a short course of sessions with a therapist, that are available quickly after self-harm has been identified by that person's GP. The main purpose of this trial was to find out whether there was a need for this type of therapy in community settings, whether people wanted to take part, if they would attend all the therapy sessions they were offered, and if they found the therapy useful in reducing self-harm and symptoms of depression. The results of this first trial (a 'feasibility' trial) were intended to tell us whether the therapy would be suitable for a second larger trial (an 'efficacy' trial), where we will assess how helpful the therapy is for people who self-harm.

The results of the trial indicate that the COPESS therapy is suitable for a larger trial, as all the aims of this feasibility trial were achieved. Fifty-seven people were recruited into the trial. Fifty-five were then randomly allocated to receive either the COPESS therapy (28 people) or treatment as usual (27 people) as defined within National Institute for Health and Care Excellence (NICE) guidance 2018. The response to the therapy was very positive, with most participants attending all sessions. There were early indications that the COPESS intervention may lower levels of depression, general distress and urges to self-harm compared to treatment as usual. COPESS was shown to have potential as a much-needed self-harm specific therapy.

SCIENTIFIC SUMMARY

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. Given the increased risk of repetition immediately after an act of self-harm, rapid access to follow-up care and interventions are recommended. Readily accessible brief talking therapies show promise in helping people who self-harm, but further evaluation of these approaches is needed. The Community Outpatient Psychological Engagement Service for Self-Harm (COPESS) is a brief talking therapy intervention for depression and self-harm that combines elements of psychodynamic interpersonal therapy and cognitive analytic therapy. The COPESS intervention consists of four therapy sessions, delivered within a month of the initial contact with the participant's contact/referral into the trial. A version of this therapy was previously commissioned for use in people who self-harm and attended the emergency department in a single hospital site and showed promise in reducing self-harm and levels of distress among patients who took part. However, most self-harm takes places within the community and does not come to the attention of acute hospital and secondary mental health services. General practitioners in primary care settings may be an important point of contact for people who self-harm, but offers of self-harm specific interventions are rare, with long waiting lists for more general mental health support services (e.g., Improving Access to Psychological Therapies [IAPT]).

Objectives

The overall aim of the COPESS trial was to assess the feasibility of delivering the COPESS intervention in a community setting, and whether the trial procedures were acceptable and appropriate for future implementation in a full-scale efficacy randomised control trial.

The specific study objectives were:

(1) To assess the feasibility of delivering a full-scale clinical trial of the COPESS intervention by, (a) to meet recruitment targets and assess recruitment rates into the trial, (b) to assess retention rates across the study period (with an aim of retaining 70% of participants by the final three-month follow-up), (c) to examine the utility of the selected secondary outcomes measures (e.g. standardised scales) in terms of data completeness, and (d) to assess the delivery of the COPESS therapy based on feedback from participants and therapists.

(2) To explore the acceptability of the COPESS intervention for people who have self-harm and depression by, (a) looking at overall uptake of the trial by people referred in as potential participants, (b) interviewing a stratified sample of participants who took part in the therapy arm of the trial, (c) interviewing therapist who delivered the COPESS therapy to

assess the suitability of COPESS for addressing the needs of the target population, and delivering the therapy within a community setting, and (d) assessing training, competency, and fidelity to the manualised COPESS therapy.

(3) Evaluate the safety of the COPESS intervention by recording any adverse events (AEs) or serious adverse events (SAEs) that took place during the COPESS trial period.

Methods

The trial was a single-blind, randomised controlled feasibility trial with an embedded qualitative process evaluation. Participants were recruited via GP practices and self-referral in Northwest England and were randomised 1:1 to receive COPESS plus treatment-as-usual (TAU) or TAU alone. Participants were eligible for the study if they had an episode of self-harm within 6 months, alongside current symptoms of depression and recent self-harm. GPs of participants who self-refer were informed of their participation, in line with participant consent procedures.

Inclusion criteria included being aged 16 years or over, having a self-reported episode of self-harm within the last 6 months along with a score of 14 or greater on the Beck Depression Inventory-II (BDI-II) [36], and actively seeking-help, operationalised as attendance at GP practices or self-referral into the trial. Exclusion criteria included not being fluent in English, being diagnosed with an intellectual disability as determined by review of clinical notes (the therapy has not yet been adapted for working with these populations), being unable or unwilling to give written informed consent to participate, and people currently receiving psychological talking therapy for self-harm (potential participants will not be excluded due to group counselling or regular nurse appointments).

Primary outcome measures included a recruitment target of 60 participants (subsequently reduced to 52 due to a high retention rate across both trial arms), retention of 70% of trial participants across the therapy sessions and study follow-up, completion of study measures, and a good level of acceptability of the intervention based on thematic analysis of interview transcripts from participants and therapists. Secondary outcome measures were changes in scores on specific standardised scales and tools measuring self-harm thoughts and behaviours, depression and distress (Self-Injurious Thoughts and Behaviours Interview Short-Form [SITBI], Alexian Brothers Urge to Self-Injure Scale [ABUSI], Beck Depression Inventory-II [BDI II]), Emotion Regulation Questionnaire [ERQ], Clinical Outcomes in Routine Evaluation [CORE-10]), assessment of the patient-therapist relationship (Helping Relationship Questionnaire [HRQ]), health-related quality of life (EQ-5D), and healthcare resource utilisation and absences from work were collected for each patient during the trial follow-up period (Client Service Receipt Inventory, [CSRI]). Scores on the secondary

outcome measures were summarised for all participants and compared between groups (e.g., by trial arm).

Results

The results of the feasibility trial indicated that COPESS was both acceptable and feasible, with good recruitment rates, high retention rates, and all progression criteria being met.

Objective 1:
(a) Recruitment targets were met, with 55 participants were recruited and randomised during the study period, exceeding the revised target of 52; 28 received COPESS plus TAU, and 27 received TAU only (targets were revised down from 60 to 52 due to high retention rates across both arms of the trial).
(b) Retention of participants was high with 76% of participants across both trial arms completed the full three-month follow-up period, and 93% of participants allocated to the COPESS plus TAU arm taking part in all therapy sessions.
(c) Data completeness of secondary outcomes measures was good. All baseline measures were completed by participants in both trial arms, and 75% of participants completed the 3-month follow-up measures. [completeness of items on individual scales ranged from 95-99%].
(d) Delivery of the COPESS intervention was considered appropriate and successful by both participants and therapist.

Objective 2:
(a) Overall uptake of the trial among potential participants was good with 12% of potential participants initially contacted indicating an interest in taking part in the COPESS trial. Of those screened as eligible to take part (n=62) 89% went forward to randomisation (n=55).
(b) Interviews with participants indicated high acceptability of the COPESS intervention, highlighting the specific focus on self-harm, and use of tools (e.g., maps and letters) as particularly valuable aspects of the therapy.
(c) Interviews with therapists who delivered the COPESS intervention indicated high acceptability of the COPESS therapy for addressing the needs of the target population, and delivering the therapy within a community setting
(d) Training, competency, and fidelity to the manualised COPESS therapy was judged to be acceptable and moderate delivery fidelity is evidenced by auditing the COPESS.
(e) Interviews with primary care staff indicated high acceptability of recruitment processes.

Objective 3:
Evaluate the safety of the COPESS intervention by recording any adverse events (AEs) or serious adverse events (SAEs) that took place during the COPESS trial period.

Conclusions

All objectives set out in the trial protocol were met, and in some cases exceeded expectations. The evidence provided by the COPESS feasibility trial therefore supports the need for further evaluation of the intervention in a full-scale clinical effectiveness randomised control trial. As a rapid-access brief intervention COPESS has shown good potential to help meet the care needs of people who self-harm in the community, a group known to be at high risk of further self-harm, and suicide mortality.

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CHAPTER 1 INTRODUCTION

Definition of Self-harm

In this study self-harm is defined as any intentional act of self-poisoning (this may include overdoses of street drugs, taking more medication than prescribed, or ingesting other toxic substances) or self-injury (such as cutting or stabbing the body as well as attempted hanging, or attempted suffocation) regardless of motivation or suicidal intent associated with the act.[1] This definition is in line with the definition used in NICE (The National Institute for Health and Care Excellence) guidance on self-harm and is the definition typically used in research on this topic in the UK and beyond.[2]

Prevalence of self-harm

Reduction and prevention of self-harm is a national and international public health priority, and people with a history of self-harm have been identified as a high-risk group in the National Suicide Prevention Strategy for England. [1–6] In England, there are over 200,000 self-harm presentations to hospital emergency departments each year. [7-12] It is one of the most common causes of attendance at emergency departments incurring an estimated annual cost of more than £162 million in England alone.[13-14] But many people who self-harm never present to hospital or to other health services and such figures are likely to substantially underestimate the true occurrence of self-harm across the whole population. Rates of self-harm presentations based on information from primary care are estimated to be double those of hospital admissions, also substantial evidence from primary care data that service contacts for self-harm have increased over time [15]. Community based survey data on self-harm is sparce and tends to focus on younger people rather than all age groups, but evidence generally supports the presence of much higher rates of self-harm in community settings, with an estimated 10% of young people reporting self-harm at some point in their lives.[16] Work looking at the relative incidence of suicide, hospital presentations for self-harm, and self-harm in the community, showed that in young people there were between 18-28 cases of self-harm in the community for each emergency department presentation for self-harm.[17] There is also substantial evidence from primary care data that service contacts for self-harm have increased over time.[15]

Care for people who self-harm

Self-harm is often a sign of underlying distress, associated with a range of psychological problems and poor outcomes, as well as broader social and economic costs. [13,14,18] Around 20% of people who self-harm will have a repeat episode of self-harm within a year with many people repeating within the following month. Risk of suicide is also increased

between 30-150 times after a hospital presentation for self-harm, compared to the risk in the general population. [14]

General Practitioners 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. [19,20] National policy and guidance [2,6] emphasises the need for rapid access to community-based services for self-harm, but referral pathways and treatment options are often unclear to both patients and health professionals, a situation compounded by a lack of self-harm specific support and intervention.[20] There remains a disconnect between current national suicide and self-harm prevention policy and clinical service provision.[2] This lack of clinical support unnecessarily increases individual suffering and perpetuates unhelpful coping strategies, with significant personal, societal, and economic repercussions.

Interventions for people who self-harm

Different interventions for reducing self-harm repetition, including both pharmacological and psychological treatments have been evaluated.[21,22] The NICE guidelines advise against the use of pharmacological treatments for self-harm, instead recommending psychological interventions tailored to self-harm that may involve problem solving, cognitive behavioural or psychodynamic elements.[6] The evidence is uncertain about the potential benefits and harms of pharmacological treatments. In contrast, research suggests that talk-based therapies that target the psychological processes underlying self-harm can reduce psychological distress and repetition of self-harm.[23-30] One approach to managing SH is to target negative emotional states which commonly underpin SH behaviour.[28] This may be particularly important as service-users can be ambivalent about stopping SH if used as coping mechanism for negative emotional or depressive states.[28] Previous research suggests that targeting the difficulties that underlie SH are more appropriate than focusing on reduction of SH alone.[23-25] Depressive symptoms are common among people who SH and thought to be related to the initial occurrence and subsequent repetition of SH.[21,22] But talking therapies designed for treating depression do not necessarily reduce SH or improve SH-related outcomes. It has been argued that SH interventions need to be specifically developed for this context.[28] Systematic reviews show that talking therapies that target the psychological processes underlying SH can reduce repetition of SH and depressive symptoms.[25-27] Hetrick and colleagues[27] found that cognitive behavioural therapy (CBT) (RR 0.77, 95% CI 0.64-0.93) and psychodynamic interpersonal therapy (PIT) (RR 0.31; 95% CI 0.12-0.78), reduced the risk of SH over 12 months;[27] however, this data should be interpreted cautiously as it is inconsistent with a review that notes primarily evidence for emotion-regulation group-based psychotherapy, dialectical behaviour therapy (DBT) and mentalisation.[30] There is some evidence that CBT and psychodynamic interpersonal therapy (PIT) were effective in reducing some self-harm behaviours in the short-term [31]. A recent Cochrane review [32] makes a distinction between brief therapies,

usually provided for people who present following self-harm in acute distress, and higher-intensity therapies (such as DBT [30]) which are designed to help people who struggle with self-harm and multiple co-existing life problems. There is evidence to suggest that brief psychological therapies will help those who self-harm.[33] Brief therapies may therefore have an important role however as part of the repertoire of support offered for people who self-harm, as such approaches require lower resources than longer-term approaches, and so can be provided more rapidly, providing more immediate containment and support.

Development of the COPESS intervention.

Background

The COPESS intervention is based on an existing hospital-based intervention known as the 'Hospital Outpatient Psychotherapy Engagement' (HOPE) service [31]. This intervention was designed to offer brief intervention for people experiencing a self-harm related crisis who presented to the emergency department following self-harm. HOPE therapy was based on Psychodynamic Interpersonal Therapy (PIT) supplemented with principles from Cognitive Analytic Therapy (CAT). A pilot evaluation within a single hospital emergency department found that 64% of referred individuals attended at least one therapy session, with nearly half (n=26, 49%) attending all four sessions [31], highlighting the feasibility of this approach. There was also evidence of a reduction in clients' distress over the therapy period.[31] Given the recognised need for self-harm services for people who self-harm in the community, the approach used successfully in HOPE was adapted for use in community-based primary care settings with the aim of addressing self-harm earlier and in a way readily accessible to a wider population. A community-based intervention also has the advantage of being able to better meet the needs of more diverse or deprived neighbourhoods which is important given the link between socioeconomic deprivation and self-harm, and the existing inequality of access to physical and mental health services in deprived areas.[9,15] We named this approach the Community Outpatient Psychological Engagement for Self-harm Service or COPESS.

Delivery of COPESS

COPESS is a rapid access talking therapy delivered over a brief time period, which addresses causes that precipitate self-harm and associated symptoms of depression. COPESS is a modified version of PIT and PIT has been evaluated as effective in two randomised trials for self-harm [28] and used in NHS self-harm services in England [31]. PIT has undergone two modifications for the purposes of this feasibility trial. Elements of another approach, CAT [34], have been added to the intervention with the use of visual mapping and a focus on identifying "exits" or solutions to clients' difficulties. is a relational-based psychotherapeutic intervention that seeks to address the underlying reasons for self-harm and learning to sit with avoided emotions and recognising relational conflicts and patterns that are linked to

self-harm. COPESS therapy has the potential to increase accessibility to support for self-harm in the community (a key aim of recent NHS transformation policies), to reduce poor outcomes and distress for the individual, and thereby, to also reduce additional health service use (e.g., hospital admissions), costs, and waiting times through quick patient turnaround.[17-18]

CHAPTER 2 OBJECTIVES AND FEASIBILITY CRITERIA

The aim of this trial was to examine the feasibility and acceptability of delivering the COPESS intervention in a community setting, as well as to assess the feasibility and acceptability of the trial procedures themselves, with a view to future implementation in a full-scale efficacy randomised control trial. The key outcomes therefore do not relate to the direct efficacy of the COPESS therapy, but concern methodological, procedural and clinical uncertainties [35–37] including estimates of recruitment and retention rates; feasibility and acceptability of data collection instruments and data collection procedures; feasibility, acceptability and safety of the intervention.

Objective 1: *To assess the feasibility of delivering a full-scale clinical trial of the COPESS intervention.*

Recruitment and retention was assessed in terms of; the number assessed for eligibility to participate; the number eligible to be randomised into the trial; recoding of any reported reasons for ineligibility to take part in the trial; the number of eligible potential participants who participated and the number who did not participate; the number of consented participants that dropped out of the trial during the study period.

Specific criteria were:

- Ability to recruit 60 patients over a period of 18 months;
- Ability to retain and conduct 1-month follow-up on ≥80% of COPESS patients;
- Ability to retain and conduct 2-month follow-up on ≥75% of COPESS patients;
- Ability to retain and conduct 3-month follow-up on ≥70% of COPESS patients;

Objective 2*: To explore the acceptability of the COPESS intervention for people who have self-harm and depression.*

Acceptability of the COPESS intervention and trial procedures was assessed via qualitative interviews with patients who completed the trial (intervention or control arm); interviews with people who dropped out of the trial; interviews with primary care staff involved in recruitment processes; interviews with therapists who delivered the COPESS intervention, assessments of fidelity to the manualised COPESS therapy, and by number of proportion of participants who completed secondary outcome measures at one, two, and three-month follow-up.

Specific criteria were:

Objective 3*: To assess the safety of the COPESS intervention.*

Safety of the COPESS trial and intervention was assessed in terms of adverse events (AEs) and serious adverse events (SAEs) via; the Adverse Experiences in Psychotherapy self-report measure [38] to identify adverse experiences that occurred within the COPESS therapy; ongoing routine monitoring of any AEs or SAEs identified among participants in either arm of the trial. Given the nature of the trial and the risk associated with self-harm behaviour, hospitalisation for any reason, medically serious acts of self-harm and self-reported suicidal crises, such as a participant having a suicide plan and intent to make an imminent suicide attempt, were regarded as SAEs.

CHAPTER 3 DESIGN OF THE COPESS FEASIBILITY RTC

Design

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

Summary of the trial arms

COPESS therapy plus TAU

COPESS is a manualised rapid-access psychological intervention for adults (aged 16 year plus) consisting of 4 sessions that last 50 minutes, with one-session scheduled per week followed by one follow session at 8 weeks. The therapy involved working collaboratively with a patient to identify patterns or conflicts in emotional experiences and interpersonal relationships, linked to self-harm and depressed mood, to build a shared understanding of these experiences. Therapy was intended to take place face-to-face either in the participant's home or in a community setting such as a health centre or clinic, depending on the participant's preference – however the onset of the COVID-19 pandemic resulted in a move to online therapy (see Chapter 4 for further details). Any additional treatment-as-usual e.g., from the GP, was continued. A baseline assessment was carried out by the trial research assistant, with further assessments at one, two, and three-month follow-up.

Treatment-as-usual

Participants continued to be treated as usual e.g., by the GP. While there is no clear treatment pathway for people who present to primary care services for self-harm, while negotiating access to GP surgeries for participants recruitment the Trial team did provide additional information to clinicians' regarding the NICE recommended care for people who self-harm[69]. As in the intervention arm, baseline assessment were carried out by the trial research assistant, with further assessments at one, two, and three-month follow-up.

Participants

Participants with current depression and recent self-harm were recruited through participating GP practices and self-referral. GPs of participants who self-referred into the trial were asked to provide details of their GP, who were then informed of the participation of one of their registered patients, in line with participant consent procedures and safety protocols.

Inclusion criteria:

- Adults aged 16 years or over as SH is especially prevalent in young adults and often this transitional age is neglected.[39] This study will offer at least TAU which young people may not otherwise access.
- An act of self-harm within the last 6 months (self-reported or stated in GP records).
- A score of 14 or greater on the Beck Depression Inventory-II (BDI-II), a score of 14-19 is considered to indicate mild symptoms of depression.[40]
- Help-seeking, operationalised as either attendance at GP practices or self-referral into the trial.

Exclusion criteria:

- Non-English speaking as will not be able to participate in data collection or therapy.
- 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.
- Currently receiving face-to-face psychological talking therapy for self-harm (potential participants will not be excluded due to group counselling or regular nurse appointments).
- Experiencing severe problems with addiction to alcohol or illicit drugs
- Psychotic and/or severely depressed and unresponsive to treatment as judged by clinical team.

Setting

Participants were recruited primarily via community-based General Practices in the Liverpool Local Authority Area. This area includes areas of socioeconomic and ethnic diversity, as well as a large student population. This city region is representative to other Northern cities in England.

Recruitment of General Practices

The National Institute for Health Research Clinical Research Network (NIHR CRN) assisted with recruitment of GP practices. Preliminary searches of four local practices for patients who self-harmed within the previous six months produced n=55 potential participants. The CRN and local GP were confident about successfully identifying patients eligible for the trial. The aim was to include an additional recruitment strategy to advertise the study in waiting rooms of practices, and other community-based SH support services, as well as recruiting through consultations – this was not possible during most of the trial period due to the Covid-19 pandemic restrictions. Although record searches were imperfect due to an unknown false negative rate, part of the feasibility evaluation was to test these different

methods of recruitment – however as above we were not able to do this. Once GP practices identified potential participants they were matched against the inclusion/exclusion criteria to assess suitability for invitation to the COPESS trial. Patients that met the inclusion criteria were sent an introductory pack that comprised: an explanatory letter from the practice; a participant information sheet, an expression of interest form; and, a freepost return envelope by DocMail. The primary aim of the trial was to ascertain feasibility of a future efficacy trial. We monitored recruitment rates from the different recruitment methods, including: proportion of eligible patients who consented, and the number of participants recruited during the recruitment stage of the feasibility trial compared with the target. Practices with existing links to members of the research team were approached directly and others were recruited via the CRN. During the study period the CRN sent out study information to 97 GP practices in the area via their newsletters and the research team were invited to present the COPESS study within organised CRN Primary Care trial recruitment meetings. In total 14 research-active GP practices were identified and signed up to take part.

Recruitment of Participants

Participants were identified via GP practices by three methods:

1. Practice database searches for self-harm. GP electronic patient records were searched to identify potential participants. These individuals were sent an initial letter and the patient information sheet by the GP surgery. Before potential participants were sent a recruitment pack their record was reviewed by the GP to ensure there were no inappropriate contacts made – such as sending letters to recently deceased individuals.

2. *GP consultations for self-harm.* General practitioners could introduce the trial to potentially eligible patients at a consultation where self-harm was discussed, give them the patient information sheet to read at home and ask for their permission for release of their contact details to the local trial team.

3. *Advertising the COPESS trial* displayed where participants may seek help for self-harm within community settings for example primary care, student counselling services, walk-in centres and Talk Liverpool (Talk Liverpool is a free NHS service that offers psychological therapies in Liverpool to adults who are feeling anxious or depressed).

Sample Size

A conventional power calculation was not necessary to achieve the stated aims of the feasibility study, as the efficacy of the intervention was not being formally tested. A recruitment target of n=60 was set as sufficient to assess feasibility outcomes and estimate

key parameters, such as the standard deviation of potential outcomes, with adequate precision to inform the sample size for a definitive full trial.[35,37]

Procedure

Consent

Once potential participants had been identified and confirmed as viable by the GP, they were sent an introductory trial pack via Docmail (a mail service used by GP practices for research trials) that comprised of an explanatory letter from the practice and a participant information sheet about the trial that included the research teams contact details. Patients who wished to take part or wanted to know more about the study then contacted the research team directly, to discuss the details of the trial and what taking part might involve. Researchers remained blind to patient information until initial contact was made by the potential participant.

Potential participants who contacted the trial team directly in response to community advertising methods (e.g., posters) were sent a copy of the Participant Information Sheet. These self-referred potential participants were asked to provide details of their GP. The trial team then contacted the GP to make them aware of the trial, confirm patient eligibility, identify any potential risks.

Patients were informed that they could withdraw from the trial at any time, without giving a reason, and without it effecting their legal rights or clinical care.

Baseline data collection

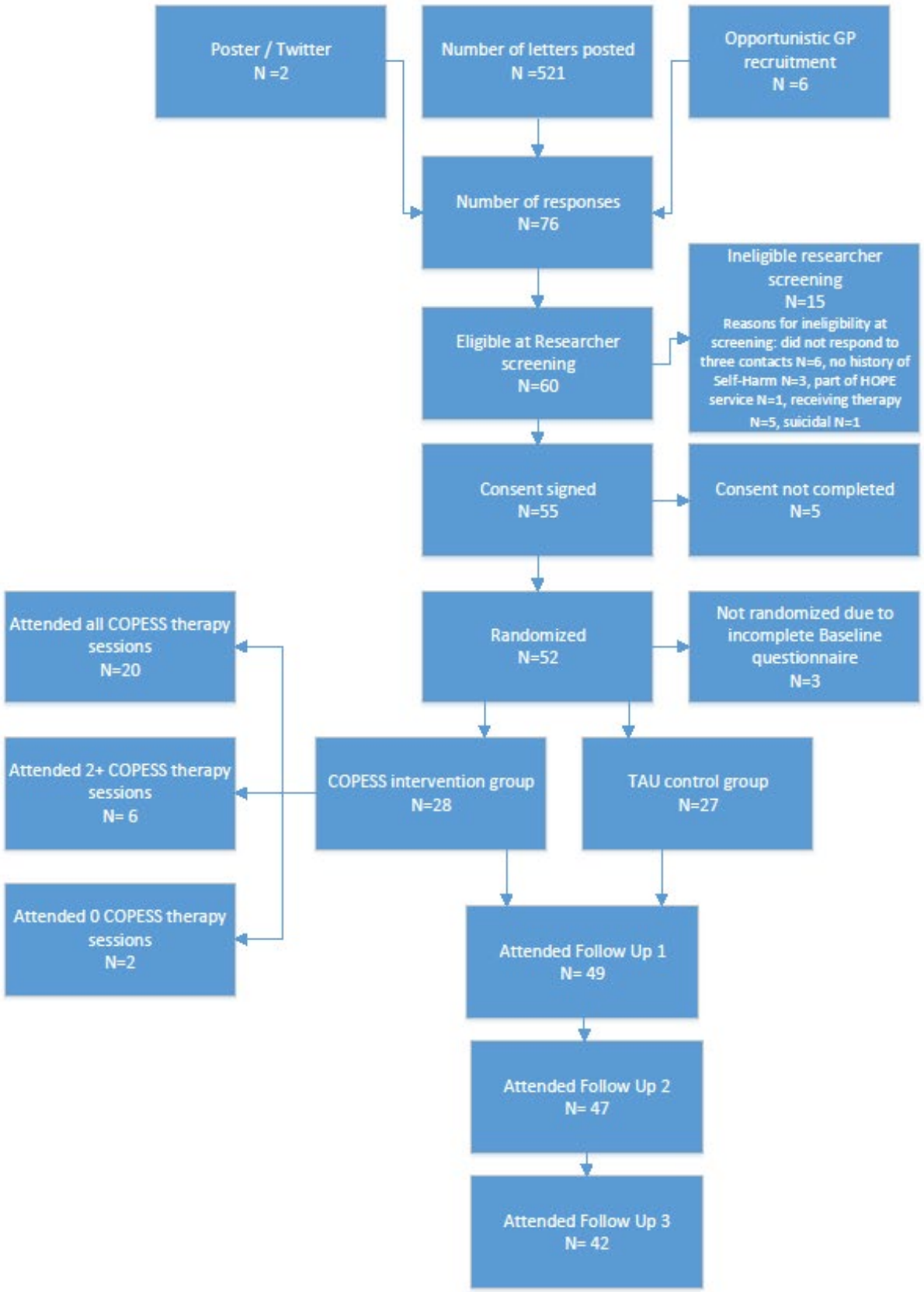
Once a potential participant had been consented to take part in the trial, a baseline assessment was conducted, either face-to-face, over the phone, or via Zoom during pandemic restrictions. Participants were asked to complete a number of standardised scales to establish initial scores for later comparison with scores at follow-up (i.e., the BDI-II, SITBI, ABUSI, ERQ, CORE-10, and HRQ – these scales are described below). Demographic and some brief clinical history data were also collected at this point, prior to randomisation (see Figure 1 for details of trial timelines and assessments).

Randomisation and blinding

Following the collection of baseline data, consenting participants were randomly allocated (1:1) by a statistician, to receive COPESS plus TAU or TAU alone.

An algorithm within STATA 15[41] was used to generate random allocation sequences in blocks of 4 or 6. Block sizes occurred with equal frequency and were determined at random. The statistician generating the randomisation schedule was independent from other

Figure 1 Timeline of trial assessments, procedures and activities.



elements of the project to maintain allocation concealment. Blinding is an important methodologic feature of an RCT that aims to reduce bias [37]; however, in psychotherapy trials, complete blinding is not possible as the participants cannot be blind to whether they receive therapy or not. Participants were asked by the trial research assistant to keep the researcher blind to their allocation arm of the trial. Once randomisation had taken place the statistician informed the Principal Investigator (PI) of patient arm allocation. The PI informed both the patient and the patient's GP of the allocation. The Trial research assistant completing the assessments was masked to treatment allocation throughout.

Secondary Outcome Measures

A series of standardised tools and scales were used as secondary outcome measures. Assessment of data completeness (overall and by scale) at each follow-up point was intended to help identify suitability of the measures for inclusion in a future efficacy RCT, in terms of acceptability to the patient, and to detect changes in symptoms over time. Eight measures were included, as listed below. The derivation of the clinical questionnaire variables used in the trial are listed in Table A1 (see Supplementary materials).

Self-Injurious Thoughts and Behaviours Interview Short-Form (SITBI)
The SITBI is a brief interview-based measure that assesses the presence, frequency and characteristics of information on self-harm related thoughts and behaviours. Following consultation with the public advisory groups a shortened version of the SITBI was used which excluded the interview and included the questions relating to recent the first section on suicidal ideation and self-harming thoughts and behaviours. The public advisory group felt that the questionnaire was too long and may be more distressing if all questions about historical suicide and self-harm attempts were included. The SITBI has demonstrated interrater reliability, test-retest reliability and convergent validity.[42]

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 good evidence for the reliability and validity of this measure.[40,43] 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.[40] The questionnaire takes approximately 10 minutes to complete.

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.[44] 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.[45] 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.[46] 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.[47] 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 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).[48]

The Client Service Receipt Inventory (CSRI)
The Client Service Receipt Inventory (CSRI)[49] was 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. This scale was used to help establish cost-effectiveness of COPESS, as a future efficacy RCT would require inclusion of health economic analysis. Data from the feasibility trial will be used to inform adaptation of the CSRI prior to a definitive full trial.

Statistical analysis

Data analysis followed an Intention-To-Treat (ITT) protocol.

A CONSORT [37] flow chart was generated reporting the number of people referred, the proportion of those found eligible, the proportion who 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, and the proportion completing follow-up assessments at 4, 8, and 12-weeks post-randomisation.

As this was a feasibility trial, hypothesis testing was not conducted to determine if the intervention was effective. Instead, we calculated descriptive statistics such as the range, the mean, and the standard deviation for continuous outcome measures and frequencies and percentages for count outcomes (e.g., self-injurious behaviour).

To quantify the 'promise' of the intervention, confidence intervals for the 'treatment effect' from linear regression analysis are presented for each clinical outcome. In each regression model the dependent variable is the value of the outcome at three months, whilst age-group, gender and the corresponding baseline outcome value are covariates (in addition to trial arm allocation). This is presented in the supplementary materials (see section B1).

Findings from the descriptive analyses (e.g. the standard deviation), the regression analyses (e.g. the treatment effect) and data on recruitment and retention will be used to inform power calculations for a definitive full trial (in addition to other sources).

Data management

The data in all phases of this study were collected and processed in accordance with the Data Protection Act 2018 and the General Data Protection Regulation 2018.[50] Study data were collected by an experienced research assistant who had been trained to work with high-risk populations. Regular supervision by the chief investigator, and Trial research team ensured the ongoing reliability of data collection.

Participants completed assessment measures using the online Qualtrics database, a secure web application for building and hosting online surveys (www.qualtrics.com). If a participant chose to complete the measures on paper, or over the phone with the help of the research assistant, these data were then entered on to the system by the research assistant after completion. A master log of participants who were randomised was kept in the trial master file managed by the Chief Investigator, detailing names and randomisation codes. Paper forms were kept in a locked filing cabinet, and electronic files were kept in an encrypted hard drive and on the LJMU secure data platform. Screening data and consent forms signed

online were completed via audio recording and photo uploads and stored on the LJMU encrypted hard drive. Audio-recordings of interviews were similarly stored on the LJMU encrypted hard drive.

Safety monitoring

The project adopted a comprehensive safety protocol which guided the management of risk and responses to experiences of distress. This protocol was developed jointly by researchers, clinicians and individuals with lived experience of self-harm.

Adverse events were defined as significant negative episodes, or significant deterioration in condition, which happened to participants during their time in the feasibility trial. SAEs were events that indicated serious increased risk to the participant, such as being admitted to hospital following self-harm or suicide attempts. These were reported by research assistants and trial therapists to senior trial staff, who ascertained whether these were linked to participation in the trial with input from the trial steering group. Records were kept of each event on an adverse events database. The Adverse Experiences in Psychotherapy (AEP) self-report measure [38] identified adverse experiences liable to occur within psychological therapy. As COPESS is specifically designed to help people who have had recent episodes of self-harm (e.g., within the last six-months), there is a reasonable expectation that participants may continue to self-harm during enrolment in the trial. Therefore, self-harm is considered an AE rather than a SAE in this context, as long as the associated risks, for example of increased suicidal intent, were not also increased.

Suicide risk was closely monitored throughout the trial. Where an individual was considered high risk (usually when completing suicide risk measures), the participant's GP was contacted within two working days and a member of the COPESS research team spoke to the participant to ensure they were ok to continue within the trial. All participants who met these criteria were not deemed to be at increased risk by their GP and the researcher was informed of this. The participants were continually given advice about local crisis teams, and other relevant support services during each email contact. In cases where SAE were potentially linked to the feasibility trial, withdrawal of participants, halting or terminating the feasibility trial would have been considered as required by the trial steering group.

Ethics approval and research governance

NHS Research Ethics Service approval was obtained via the Liverpool Central Research Ethics Committee (Approval Reference: 275047). The project was hosted by Mersey Care NHS Foundation Trust. The study sponsor was Liverpool John Moores University.

CHAPTER 4 TRIAL MANAGEMENT AND SERVICE USER INPUT

Study management

The study was run and monitored primarily by the multidisciplinary Trial research team, with support from a Trial Steering Committee with an independent chairperson and the recommended independent members (subject experts and a public member) convened in accordance with guidelines for the NIHR Health Technology Assessment (HTA) programme. The Trial research team met monthly to monitor progress of the study, and the Trial Steering Committee met at least once every 6 months to guide the conduct of the study, agree details of project set-up, initiation and changes to the design and supervision of the study. A Participant advisory group was created to provide patient and public insight and guidance into the conduct of the Trial. The group met at least once a quarter and provided ongoing feedback on methods, materials, and progress across the life of the Trial.

Impact of the Covid-19 pandemic

The unexpected event of the COVID-19 pandemic within weeks of the original start date of the COPESS trial inevitably had a significant impact and several changes to the original protocol and planned procedures were necessary. The study commenced in February 2020 following receipt of funding and appointment of the Trial research assistant. The first national 'lockdown' disease prevention order took effect on 23rd March 2020. Many organisations, including Universities, had taken the decision to ask staff to work remotely sometime before this. There multiple subsequent lockdown periods and some lesser forms of social distancing rules were in place until February 2022. These changes were kept in place for the remainder of the trial.

During the study, we submitted two non-substantial amendments for changes to data access within the NHS trust for the participants receiving the COPESS therapy, changes to conduct remote therapy sessions due to COVID-19.

Changes to timeline and procedures:

1. Recruitment was planned to start around March 2020, however NIHR requested a 6-month pause to all recruitment activities from April 2020 to October 2020.
2. Therapy sessions moved online via AccessNow (an online system used by the Mental Health Trusts to record therapy sessions via video call) with participants able to access the service via a laptop, mobile phone or tablet.
3. Data collection sessions for all participants moved online to the survey platform Qualtrics and the SITBI interview questions were delivered as a questionnaire instead. Participants were emailed a link to the questionnaires that could be accessed via a laptop, mobile phone or tablet.

4. The one-to-one interviews were all conducted online using Microsoft Teams sur to the changes made during the pandemic. Once restrictions were lifted, participants were asked their preference of face-to-face or remote online interviews and all opted for online.
5. The research team/assistant contacted and kept in touch with participants via video call and mobile phone.
6. The recruitment target was reduced from 60 to 54 in June 2022 due to the attrition at follow up being higher than anticipated at 85%.

Feedback from primary care staff indicated that the pandemic had an impact on recruitment. As recruitment took place through Primary Care, which was also faced with ongoing unprecedented demand during and after the pandemic restrictions were lifted. Most services (including consultations) moved online, and many practices were involved in the role-out of COVID-19 vaccines and unable to prioritise participation in research work.

Patient and public involvement

Involvement of people with lived experience of self-harm and carers of people who self-harm was integral to the trial from inception. A diverse focus group reviewed and discussed the outline of the trial and proposed materials (e.g., standardised measures) during the develop of the trial protocol. A study-specific Patient Advisory Group (PAG) was then created before the start of the trial to provide input into all aspects of delivery. The PAG included patients, carers, and people with lived experience of self-harm, providing a diverse range of perspectives and insight.

At the start of the project six public advisors made up the group which included men and women and people of non-white ethnicity. However, over the course of the trial this reduced to four due to personal reasons unrelated to the study. We recruited people with lived experience from diverse populations through the adverts, social networks and an existing public and patient group at Mersey Care NHS Foundation Trust. The PAG met quarterly and due to Covid-19 restrictions, most of these meetings took place online via video call. Guidance was sought from the PAG on a variety of topics including trial design, ethics, materials (such as information sheets and posters), interview transcripts and dissemination.

The PAG was led and co-ordinated by the Service User and Carer Lead, CM, from Mersey Care NHS Foundation Trust who herself has lived experience of mental health problems. CM, an experienced public advisor was closely involved in the early stages of the study, in setting up and refining the study procedures. The PAG was developed with CM and once members were recruited, they were involved at all stages of the process from the outset to the dissemination stage to ensure their input was meaningful. For example, this group recommended that some of the data collection measures were not suitable due to being

written negatively and how this could have a depressing effect on those completing them. The research team then found alternative measures that were approved by the lived experience members as they used more positive language to ascertain the same outcomes (e.g., for hopelessness). The group also encouraged the voucher payments to thank participants for completing the screening questionnaires at all time-points and participating in interviews. The PAG members were appropriately supported by the study team and remunerated for their time in accordance with NIHR payment guidelines.[51]

Key aspects of the trial design and conduct were guided by input form the PAG. Suitability of design, content, and locations for displaying recruitment posters were led by the group who decided that GP surgeries, student wellbeing centres and walk-in centres would be the suitable places to display posters. The PAG was essential in helping the trial adapt following restrictions imposed on face-to-face contact during the COVID-19 pandemic. While the PAG itself was required to move to online video meetings, the group was consulted extensively about the necessary adaptation of the COPESS therapy to online video delivery and how this may be incorporated as an option going forward into a full efficacy RCT.

At the end of the trial period, an in-person focus group explored the experiences of the PAG members and their role during the trial. A key learning point was that carers and people with lived experience of self-harm enjoyed being able to directly contribute to research intended to help other people who self-harm. They felt that their voices were valued and did have influence on the conduct of the trial. Some PAG members expressed a wish to continue participating in the development and conduct of any future trial related to this work.

CHAPTER 5 QUANTITATIVE FEASIBILITY RESULTS

Recruitment of General Practices

Fourteen GP Practices were recruited into the study for the purpose of identifying potential trial participants covering a total of n=170,592 registered patients (Table 1), a median of 20 Trial invitation letters were sent per site, however the total range was large (0 to 262). The first sites were recruited in [September 2020] and the last joined the study in [August 2021].

Table 1: Recruited GP sites, letters sent and consented participants.

GP Practice	Patients registered	Letters sent out	Replies	Consent signed
1	51422	262	39	31
2	8465	24	10	8
3	9044	35	4	3
4	7443	23	4	3
5	8418	45	3	2
6	11801	0	1	1
7	9087	17	2	2
8	5854	0	0	0
9	6596	6	0	0
10	11525	34	4	4
11	19434	5	1	1
12	9555	6	0	0
13	4774	37	2	1
14	7174	5	1	1

Recruitment of Participants

The GP record search identified 521 potentially eligible patients who were sent an invitation letter. Another six potentially eligible patients were referred during GP consultations and two people self-referred into the trial (e.g., via posters). Of these patients, 77 got in touch with the research team and 62 people were screened as eligible.

Of the 15 participants who were not eligible, reasons were: no response to three contacts by researcher (n=6); no history of self-harm (n=3); currently receiving a talking therapy (n=6); and serious suicide risk (n=1). A total of 55 participants were randomised: 28 to COPESS and 27 to TAU. The flow of participants through the trial is shown in Figure 1.

Of the 55 participants randomised into the trial, 49 (89%) participants completed the one month follow up, 47 (85%) completed the two month follow up and 42 (76%) completed the

final three month follow up. For those participants in the COPESS intervention arm of the trial 26 (93%) completed all sessions of the COPESS intervention.

All progression criteria relating to recruitment and retention in assessment of the feasibility of rolling out the COPESS therapy to a full efficacy RCT were met.

Participant Baseline Characteristics

Age and gender of randomised trial participants are summarised in Table 2. More detailed socio-demographic data was collected only on patients who were still participating at 3-months post-intervention.

In total 55 people took part in the trial. Forty (72.7%) identified as female, 13 (23.6%) as male, and two (3.6%) as 'other' at baseline. Most participants were in the 16 to 30 years age range (n=42, 76.4%), split evenly between the two trial arms. More men were allocated to the TAU arm (n=10, 37.0%) compared to the COPESS arm of the trial (n=3, 10.7%).

More detailed demographic data were collected for participants that completed the three-month follow-up assessments. In total 43 (78.2%) completed these assessments. Of these 31 (72.1%) were students at the time of taking part in the trial. Thirty-five participants reported ethnicity; 33 (94.3%) were White British, and 2 (5.7%) were of mixed ethnicity.

Table 2 : Demographic characteristics of participants in the trial

Demographics	All Patients (N = 55)	Trial Arm = COPESS (N = 28)	Trial Arm = TAU (N = 27)
Age-Group			
16-20	20 (36.4%)	10 (35.7%)	10 (37%)
21-30	22 (40.0%)	11 (39.3%)	11 (40.7%)
31-40	7 (12.7%)	4 (14.3%)	3 (11.1%)
41-50	2 (3.6%)	2 (7.1)	0 (0.0%)
51-60	4 (7.3%)	1 (3.6%)	3 (11.1%)
Gender			
Female	40 (72.7%)	23 (82.1%)	17 (67.0%)
Male	13 (23.6%)	3 (10.7%)	10 (37.0%)
Other	2 (3.6%)	2 (7.1%)	0 (0.0%)

Follow-up outcome measures descriptive statistics

Table A2 reports the descriptive statistics for each outcome measures at each of the assessment points (see supplementary materials). The average improvement scores are

shown in Table 3 below. The average improvement in scores on the CORE-10 was greater in the COPESS intervention arm (by 8.3 units) than in the TAU arm (by 2.4 units). Average improvement in BDI scores was greater in the COPESS intervention arm by (8.5 units) than in the TAU arm (by 2.4 units). Changes in the ERQ subscales were more modest. In the TAU group, the average scores increased at follow-up by one unit. In comparison, average cognitive reappraisal scores increased by 5.4 units in the COPESS intervention arm, indicating improvement in this aspect of emotional regulation. Average scores on the ABUSI in both groups declined from baseline to follow-up, indicating a reduction (i.e., an improvement) in self-harm urges. The average improvement was modest in both groups, but greater in the COPESS intervention arm (by 2.9 units) than in the TAU arm (by 1.2 units).

Table 3: Change in average scores between baseline and final follow up for both trial arms.

Outcome Measure	**COPESS Intervention plus TAU N=20***	**TAU only N=21**
CORE-10 (mean (SD)	-8.3 (7.38)	-2.4 (6.73)
CORE-10 (median (IQR)	-6.5 (-11, -3.5)	-2 (-8, 1)
CORE-10 range	27 to 2 $	-16 to 11
BDI mean (SD)	-10.8 (11.2)	-2.4 (11.0)
BDI median (IQR)	-8.5 (-16.5, -3)	-2.4 (11.0)
BDI range	-32 to 7 &	26 to 22
ERQ-CR (mean (SD)	5.4 (6.53)	1.0 (6.66)
ERQ-CR (median (IQR)	6 (1.5, 10)	3 (-2, 4)
ERQ-CR range	-7 to 18 ^	-12 to 18
ERQ-ES* (mean (SD)	-2.3 (5.64)	1.0 (4.80)
ERQ-ES*(median (IQR)	0 (-7, 1)	0 (-2, 4)
ERQ-ES* range	-13 to 7	-8 to 13
ABUSI (mean (SD)	-2.9 (8.17)	-1.2 (10.1)
ABUSI (median (IQR)	0 (-5, 1.5)	0 (-6, 4)
ABUSI range	-24 to 8	-19 to 22

Table A3 reports the responses for how the participants in the intervention arm found the COPESS therapy at three months follow-up (see supplementary materials). The responses indicated that the participants experience of the therapy were positive.

The AEP self-report measure [38] identified adverse experiences that may have occurred within the delivery of COPESS. Table A4 reports on any adverse experiences for participants in the intervention arm at three months follow-up (see supplementary materials). Three participants reported that taking part in the therapy had not helped their problems. Of those, one person reported taking part led to their mood becoming very low, another that they did not feel ready to talk about their problems and two of them reported that taking part made them think too much about bad things that have happened in the past and felt

embarrassed talking about their problems with people they had not met before. Interestingly, therapists did not report knowing that this is how some of the participants may have been feeling. Their feedback overall was positive. Three people reported that their problems had improved to the point whereby they no longer feel that they need help following on from the COPESS therapy.

Data completion requirements were met for the health economic EQ-5D measure. All five items were completed which would be required to calculate an overall score. Across the entire sample for those who did not dropout of the trial, the overall mean health went up from 51.6 at baseline to 62.1 at 3 months (possible range: 0 to 100).

Outcome measure feasibility

One hundred percent of all baseline measures were completed by the 55 participants. Scores on all measures were similar across both groups of participants (see Table 5). No problems were reported regarding completing the battery of measures in either arm of the trial.

Three-month follow-up data were obtained for 41 (75%) participants. The level of questionnaire completion at three-month follow-up was very good. Other than participants who were not/could not be followed up, two participants did not complete any of the questionnaire items. In terms of missing data within-scales, only very minimal data was missing, and only on 3 of the scales used. Thus, missing data was not an issue on the questionnaires and the scales seem to be acceptable to most participants.

Adverse events

AEs and SAEs were captured from participants who were engaged with both arms of the follow-up data collection, COPESS therapists, the COPESS researcher and the participants GP. No AEs other than occurrences of self-harm were reported during the study and only one SAE was identified, either through completion of follow-up questionnaires or via the COPESS therapist.

The single SAE related to a person in the COPESS intervention arm who attended a hospital emergency department multiple times since entering the trial for worsening mental health and increased suicidal intent. Following consultation with the trial team and trial steering group as per the safety protocol, the participant was withdrawn from the study due to evidence of increased suicidal intent, and were referred back into secondary mental health services for stepped up care within the mental health trust.

In terms of self-harm AEs, these were monitored from baseline assessment to three-month follow-up. Baseline assessment included events during the 7 days prior to assessment and therefore precedes the start of the COPESS therapy, but follows enrolment in the study more generally. At baseline 15 people (27.3%) indicated acts of self-harm within the previous week, 14 (of 47, 29.8%) at follow-up one, 9 (of 41, 22.0%) at follow-up two, and 6 (of 42, 14.3%) at final follow-up. No participants were deemed to be at increased risk by their GP, as this was basis for inclusion in the study.

Dissemination

A crucial patient and public involvement part of this study was the organisation of the study dissemination event for all stakeholders following on from the study in February 2023. This was a half-day, free event, during which we presented the project and preliminary findings from the researcher, academic, service user lead and therapist perspectives. The event was very well received, with an audience that included those working in the field of self-harm and suicide prevention, such as commissioners, healthcare professionals, researchers and experts by experience. People who could not attend the event, particularly GPs, were very pleased to receive the final study newsletter with a summary of the findings.

CHAPTER 6 QUALITATIVE STUDY DESIGN AND RESULTS

Study Design

Semi-structured interviews were conducted to explore the experiences and perspectives of participants randomised to each arm of the trial, therapists who were trained in COPESS and delivered the service, and primary care staff involved in recruitment processes.

Participants

During the consent procedure participants from both trial arms were asked if they would be willing to take part in one-to-one interviews about their participation. All COPESS therapists were asked if they would be willing to take part in one-to-one interviews about COPESS training and the delivery of the COPESS intervention. All participating GP practice staff involved in the COPESS study were asked if they would be willing to take part in one-to-one interviews about the processes for patient recruitment and the perceived need for the COPESS intervention within community settings.

Interviews

Trial Participants
Interviews were conducted between 8 to 12 weeks post-randomisation with those who agreed to participate. Interviews were carried out remotely (using Microsoft Teams) by an experienced mental health researcher who received regular supervision from a senior researcher.

A purposive sample of 16 participants were interviewed to capture maximum variation in views and experiences of those participating in the trial. Sampling parameters included: 1) gender and 2) feasibility trial arm allocation. Participants were selected from both arms of the feasibility trial to provide an insight into experiences of the COPESS intervention (n=9) and TAU (n=7). Interviews were analysed in parallel with ongoing recruitment and sampling continued until thematic saturation was achieved.[52]

The interviews assessed:

- understanding of, and acceptability of the 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 the intervention.

For participants in the TAU arm the researcher asked about

- their experience of trial participation (with a focus on feasibility, study procedure and issues that may lead to attrition)
- as well as patient experience of mental health pathways within the NHS to date.

Interviews lasted between 30 to 60 minutes and were audio-recorded and transcribed verbatim.

Therapists

All therapists delivering COPESS were invited to be interviewed about their experience of being trained in and delivering the therapy. Interviews were conducted once all therapy sessions were completed for the trial with those therapists who agreed to participate. Interviews were carried out remotely (using Microsoft Teams) by an experienced mental health researcher who received regular supervision from a senior researcher.

Five therapists were trained in COPESS, but one therapist left the role part way through the trial. Four therapists were interviewed.

These interviews investigated therapists' understandings and experiences of

- the usefulness of the COPESS manual and training programme
- the delivery of the COPESS therapy
- the perceived effectiveness and acceptability of the COPESS intervention
- implementation challenges

Interviews lasted between 30-45 minutes and were audio-recorded and transcribed verbatim.

Primary Care staff

GPs and primary care staff at participating recruitment sites were invited to be interviewed about their experience of recruiting participants for this trial. Interviews were conducted once all recruitment from primary care was completed for the trial. Interviews were carried out remotely (using Microsoft Teams) by an experienced mental health researcher who received regular supervision from a senior researcher.

Four primary care staff were interviewed. This included two GPs, one research nurse and one administrator involved in conducting data searches.

These interviews investigated GPs' and primary care staff understandings of

- the process of recruitment for the trial
- the perceived effectiveness and acceptability of the COPESS intervention
- implementation challenges

- any barriers to its uptake in a community setting.

Interviews lasted between 15 to 25 minutes and were audio-recorded and transcribed verbatim.

Qualitative data analysis

Interview transcripts were analysed using the framework approach to undertake thematic analysis.[52,53] Framework analysis was developed to meet information needs and to provide practical outcomes and recommendations.[53] It offers a highly visible and systematic approach to data analysis, showing very clearly how findings are derived.

Analysis followed the five stages of framework analysis; familiarisation with the data; identifying a thematic framework; indexing the data; charting the data; and mapping and interpretation.[52] To monitor and limit the possible bias of a single-analyst perspective, additional members of the research team with experience in qualitative methods examined a sample of transcripts to compare their perceptions of the interview data and analysis with the main analyst's interpretation. Themes were discussed and refined further in multidisciplinary research team meetings that included members of the PAG.

Results

Key themes from the interviews are described below. Each of the themes is explored in more detail with examples of typical responses to illustrate the voice of interviewees. The data from trial participants, therapists, and primary care staff interviews about the acceptability of the intervention are addressed separately in this report.

Trial Participants

Five key themes about experiences of being in the COPESS trial were identified from interviews with trial participants. These were: *Lack of support for self-harm within health services; Positive experience of COPESS therapy**;** Use of tools; Remote versus face-to-face therapy; and Rapid access to a brief psychological therapy for self-harm.*

Lack of support for self-harm within health services

Many participants reported previous difficulties in getting support from primary care in relation to self-harm. While some had conversations with their healthcare providers about their self-harm, there was rarely any concrete solutions offered to directly address the behaviour, *"...there wasn't really that direct support with someone*" [P1017], "*Yes, they (GP) just try and shoo you away, I feel, with some tablets and that is it…*" [P1103]. Where

potential solutions were offered, the expectation of long waiting times discouraged continued engagement.

> *"I have had conversations with previous GPs over the years, but I have never really gone through anything, because the wait lists are so long. It is sometimes like, "Oh, what is the point? I am going to be waiting three years."* [P1012]

Participants described a lack of support in primary care for people who self-harm and problems being able to access therapy services for their mental health (such as cognitive behavioural therapy) and self-harm. Mental health support is usually provided through the Increasing Access to Psychological Therapies services (IAPT) or more in-depth support with clinical psychology services. IAPT will accept self-referral, but often patients with self-harm are refused and instead a GP referral to clinical psychology is recommended. The latter usually have significantly longer waiting lists than IAPT.

Positive experience of COPESS therapy

All interview participants allocated to the COPESS arm of the trial described having a positive experience of the therapy, with indications that there may be some reductions in self-harm behaviours as a consequence, *"It has made me think a lot more. It has certainly reduced my self-harm, at the minute"* [P1102]. The limited number of sessions was initially a concern for some participants but welcomed by others who preferred getting "*deep straightaway"* rather than *"dragging it out for weeks"*. A clear management of expectations, along with explanations given by the therapists at the start of each session, helped to ease patients' fears about the limited nature of COPESS;

> *"I do not want it to end, but it is fine. We can still… It is a step in the right direction, and I can still progress from it. It just will not be the same person or therapy," kind of thing. But it has not disheartened me. I kind of had it in my head that it was a short period anyway, from the get-go."* [P1012]

Overall, participants were happy to have something that had a clear and specific focus on a addressing their self-harm;

> *"I've been going through this for about six years now, self-harming, and then to have like something so specified come along to help you get to the root of the problem, it was crazy."* [P1001]

Participants also voiced satisfaction with, and were welcoming of, the intervention's specific and clear focus, and the explicit boundaries given as to what would be addressed in

the therapy. This enabled participants to use each session more effectively to address their specific problems and to understand how to do so.

Use of tools

Participants found the use of tools, such as developing a 'map' and the 'goodbye letter' given by the therapist at the end of the therapy that summarises the discussions that have taken place, very helpful both in the moment and to reflect on after sessions were complete. The maps enabled thoughts and feeling surrounding self-harm to be examined in a visual way, which helped participants to organise their thoughts around self-harm and underlying issues that might be linked to them. It *"link[ed] everything together"* [P1102], helping to develop a sense of control by making sense of the pathways, and potential exits, that lead up to self-harm behaviours.

> *"It was really useful to draw the map together... having things put on paper in such a visual way, that was helping, having things written down and feeling that everything was a bit more organised."* [P1017]

> *"When I'm struggling now, I do find myself referring back to that map. I think, "Right, this is where it links in, and we've said this is the exit strategy from this point, so I've got it there."* [P1102]

The letter sent out by the therapist at the end of the sessions was also very well received by participants, who found it helpful and a good way to draw the therapy to a close.

> *"It was quite a surreal experience to hear it written down, somebody who actively tried, and as far as I could figure, almost entirely understands me. So, that was a nice way to end this, and I know that I've got the letter as well if I needed it, which is quite nice."* [P1004]

Remote versus face-to-face therapy

Due to the COVID-19 pandemic, therapy had to be moved from face-to-face to online video sessions. There were mixed opinions on whether online or in-person therapy was better, but overall, participants were happy with online video delivery. The comfort of being in their own space, feeling less pressured and more able to express themselves, and the added distance of online communication (e.g., not having someone physically present when crying), were all given as examples of the benefits of online video therapy.

> *"Like, if you get upset or you're crying, in fact, it's almost reassuring sometimes to know that they're just here and if you're in a room that's quiet and calm and alone, that could be an even better environment for some people."* [P1001]

There were also practical reasons given for this preference. It took up less time as no travel was required, and participants could immediately spend time reflecting on the session afterwards in their own space.

> *"I preferred being at home because I could be just like in my own element, and then just have the therapy, and then reflect on it in my own room, and then I can go back to normal life."* [P5002]

However, this was not universal. While all participants were accepting of the change to online video delivery due to the implementations of COVID-19 lockdown measures, some still saw the value in face-to-face delivery, "*Any technology is good but can never replace a face-to-face session.*" [P1017]

Rapid Access

A key feature of the COPESS intervention was the short period between seeing the GP, referral into the trial, and the therapy. As mentioned in the section above on the lack of specific self-harm services, when help is offered—especially in the form of psychological therapies—there are usually extremely oversubscribed waiting lists. COPESS is delivered within four weeks of a potentially eligible participant being identified, and help is therefore given when it is most needed.

> *"So, when I needed the help, I couldn't get the help that I actually needed, and by the time I actually got the help that I needed about six months prior to that, it didn't benefit me as much as it did this time because I got it near enough straightaway, which was what I needed and when I needed it…"* [P5002]

Therapist interviews

Four key themes were identified from interviews with therapists about their experience of the training in and delivery of the COPESS therapy. These were: *Placement of the COPESS intervention*; *Focus on a specialised self-harm specific intervention; Use of tools; Location of therapy - online versus in person.*

Placement of the COPESS intervention

Therapists involved in the initial stages of COPESS reflected on one aspect of the delivery of COPESS that was not resolved in the feasibility trial due to the COVID-19 pandemic. Initial discussions took place about where COPESS should be delivered, for example within GP practices, community health centres, or outpatient clinics. However, the pandemic forced a change to the delivery of the COPESS intervention to online video calls rather than face-to-face. This aspect of where the COPESS intervention should delivered within current health pathways still needs to be reviewed in a future trial.

> *"You know, before everything kicked off with COVID, it was like, "What is going to happen? Where are we going to see people? It's all down to indemnity," and stuff like that."* [Therapist COPESS (TC)1]

Another area of discussion that arose during therapist and trial participant interviews was the possibility of the COPESS intervention being delivered to children and young people presenting in primary care with self-harm.

> *"Personally, I think it should be something that's done at a much younger age. And I know there is something looking about going into schools and stuff like that. But I think if this was delivered to 12–16-year-olds, or something like this, it would have a massive effect on, generally, the rate of self-harm in the future. So, yes, I think that timely access is critical, really."* [TC1]

Focus on a specialised self-harm specific intervention

The brief nature of the therapy and the specific focus on self-harm were seen as positive aspects of the COPESS intervention by therapists. Therapists also commented on how the therapy was not gender or age specific and that it met the needs of a diverse group of patents.

> *"I think I've worked with a range of people as well, so it's not just been students. I've seen males and females, different ages. Some have got very similar, present with very similar complaints and problems."* [TC1]

There was evidence that the intervention may have encouraged increased monitoring of triggers and warning signs by patients, and increased knowledge of potential positive actions, impacting upon one's ability to personalise and use of the knowledge and strategies developed during the COPESS intervention with a sense of enhanced self-efficacy as a result.

"Because it was focused on self-harm, there was something to focus on and the reasons that were triggering that. Because it was all quite fresh, you got so much done… you're not normalising it but you're just acknowledging the distress and validating their feelings. Asking them to be able to almost acknowledge and be more compassionate to themselves rather than noticing when they're falling because that's what we're saying." [TC2]

Being limited to four sessions helped to focus the work on the most salient issues around self-harm for each patient.

"It gets the most out of the sessions, I think, rather than things being a bit untethered" [TC4];

"…definitely, there's a place for that sort of really brief therapy when there's a specific goal to work on that you can really focus on. Yes, there's absolutely a place for therapy within primary care that focuses on self-harm especially." [TC3]

This limited-session structure also helped in setting realistic expectations of what could be achieved during the intervention, and in combination with *"such a targeted goal around self-harm […] made it much, much, easier to keep [the goals of the therapy] on target"* [TC4]. However, there was also a common observation that much of the first session was taken up with more administrative-type tasks and relationship building, reducing the therapeutic time to three and a half sessions rather than four. There was a recommendation, to be implemented in any larger efficacy trial, that an additional session be included to ensure at least four full sessions are available to the patient.

"I feel like people are being short-changed a little bit, in that the four sessions should have been four solid sessions. Four therapeutic sessions, not three and a half therapeutic sessions, and then your follow-up." [TC1]

"Yes, maybe just one more. Yes, maybe if it was five sessions and then a review" [TC3]

Use of tools

Regarding the therapy tools used in COPESS, trial participants and therapists were again aligned in their opinions. The visualisation used with the 'map' was seen as helpful in guiding sessions for both the therapist and the patient in maintaining focus.

"…they're quite a helpful tool, not just because of the content of it but also to make sure that we're getting the most out of such a brief therapy. If we're noticing a

patient going off on a tangent or maybe avoiding talking about something, the map is really helpful in bringing things back to this focus." [TC4]

It was also a potentially valuable resource for the patient to use outside of the therapy, with some patients, *"[sharing] their maps with people that were important to them, family, so I think it helped them, maybe, express themselves a little bit more easily or better to explain why they'd self-harmed…*" [TC3]

The move to online video delivery of the therapy had an impact on the development of these maps and prompted some innovative ways of working and was not seen as having a specifically negative impact on the therapy. However, it did increase the workload for therapists out of session and removed some of the ownership of the map from patients.

"I think if it was face-to-face it would've been, probably, easier to collaborate on the maps together with the participants….I found some of the work on the map, or quite a lot of the work on the map, was done outside a session. Laying it out, sending it to them by email, asking them what they thought, and then looking at the next session together, doing it that way." [TC3]

"I think it possibly took away from the participant owning the map as much as if you'd been in a room with them and they'd physically been drawing onto that. That's, maybe, one of the downsides of remote working. [TC4]

The letter sent by the therapist at the end of the intervention was also seen as a valuable tool to help the patient maintain the progress made once the sessions were over.

"I think it is a really nice gift to give to somebody, to remind them of things that they've probably forgotten about. Things that have stood out, and quotes they might have said. And it's almost, like, this story of what the sessions have been, which is almost a word representation of the map." [TC1]

"You do the goodbye letter and everything sort of… The blocks all come away and they feel so understood and the barriers come down. It is a really meaningful, impactful, sort of piece of work" [TC3]

Location of therapy - online versus in person

An interesting point from the therapist interviews was that they were unsure whether it would be possible to deliver the COPESS intervention without a remote element. People who would previously not have been able to attend, for example due to work or caring

commitments, being unable to travel to another location, or not wanting to leave their house, were able to fully participate in the intervention.

> *"So I think COVID was really timely, in that all of a sudden, we overnight changed the way we worked. Which meant we can see people this way, which has opened the door for a lot of people who wouldn't have been able to come"* [TC1]

> *"I think anything that aids engagement and giving people more options to overcome any barriers to coming along for sessions has got to be a positive."* [TC4]

Although there was caution against moving to a fully online model of delivery, as this may impact on the ability of the therapist to pick up on and respond to more subtle interpersonal factors (e.g., body language), there was general agreement that online delivery had potential benefits and should be offered in any future trial.

> *"I think it should be something that's offered going forward, but you also can't take away from being in a room with somebody. I think for me, as a really infant therapist in this therapy, I can feel how different it would be if you were face to face. It's undoubtedly better face to face, but you can still achieve some really good work with this way. So, it's definitely got its benefits, and its pros and cons."* [TC1]

Primary care interviews

Five key themes were identified from interviews with staff from primary care. These were: *Need for self-harm specific interventions within primary care settings; Recruitment process in primary care; Timing and rapid access, Feedback from patients; and, Impact of COVID-19.*

Need for self-harm specific interventions within primary care settings

All interviewees working within primary care alluded to the need for a self-harm specific service. This was seen as particularly important where practices served more deprived populations, where suicide and self-harm are more prevalent.

> *"It's a huge, huge need with our [local] population, a very deprived population. There are a lot of suicidal attempts and people who have recurrent suicide attempts and issues of self-harm." [PC4, GP]*

Primary care staff discussed the difficulties they previously faced referring people who self-harm to available services (e.g., the crisis team), often having people referred or "*bounced back [PC4, GP]"* to them. Staff felt that having a service specific for self-harm would help

with some people getting more appropriate help. GPs discussed the rejection and abandonment known to be reported by people who self-harm and have negative experiences with not 'fitting' any current service criteria. These experiences can add to their feelings of worthlessness or hopelessness – both risk factors for suicide.

> *"I know at one stage someone was I think too suicidal to be referred in. […] We'd already had the experience with the crisis team for that person, but they just get bounced back. Unless they've visibly got a gun to their head or whatever it's really hard to get adequate help. When you have poor mental health generally those people have a sense of rejection, abandonment in any case which has led to their mental health, or trauma or whatever. Just all these extra non-eligibility things contribute to their sense of low self-worth. "Not me, I'm not good enough." It's quite important for those people." [PC4, GP]*

There was also reflection about a similar self-harm service that had shown to be effective in A&E and how it would be more useful to have the service available in primary care due to more people consulting in primary care for self-harm. This could also help in reducing further presentations to emergency departments.

> *"There's often not very specific therapies offered for those who are self-harming. And I know obviously there's work being done at The XXX [local hospital] with those that are attending A&E, that's been successful. So I think it was important to try and, sort of, roll that out to primary care, because often we are the first point of contact for patients, rather than actually A&E." [PC2, GP]*

Timing and rapid access

Primary care staff commented on the positive aspect of the rapid access to the COPESS intervention as often people who self-harm need to be seen at the time they are reporting distress or soon after (risk of self-harm repetition is highest within the first week and month following an episode of self-harm). The staff also reported being surprised on how quickly the intervention would be offered and again welcomed this as a means to help people avoid ending up in crisis. GPs and therapists both highlighted that seeing people when they have recently self-harmed could also help with the effectiveness of the therapy.

> *"People often self-harm on and off. There are all sorts, some people are non-stop self-harming. For them you could say they could wait. Often if there's really, really strong ideation either to self-harm or for ending their lives, then you can nip it in the bud and really provide them with that support at a time of greatest distress to prevent it from happening or to prevent it from happening again if it's just happened…That's a crucial time also for change … Often people will feel guilty after self-harming and feeling they*

do want to change and they don't know how to. Tapping into that time is really important." [PC4, GP]

Recruitment process in primary care

Primary care staff involved in conducting searches of patient records to identify potentially eligible participants for the COPESS trial reported that the process was ***"****in terms of actually setting up the study and getting everything sorted it was really streamlined and really straightforward compared to some of the other studies that we worked on." [PC3, Admin].* Some alluded to the fact that the data retrieved and number of people to be sent information packs depended on how self-harm may have been coded within the practice (coding of self-harm is notoriously poor across health services) and sometimes it was useful to check if any may have been missed or were not actually relevant.

> ***"****No, the search was fine. Obviously, that's always an issue for anybody in research. You're looking at the search that's produced by the study team and you hope that it pulls out the patients you actually need. I always think, it's better to keep going through everything because you never know." [PC1, RN]*

> *"I think, what we found is that the coding of self-harm is not the best. It's often free-texted within consultations, perhaps if somebody's presenting with mood issues, their underlying depression and/or anxiety may be coded, but not necessarily the self-harm. So I think that was a problem for identifying patients that were perhaps suitable."* [PC2, GP]

Feedback from patients

Primary care staff did not have much information on what the people referred into COPESS thought about the intervention. One GP had had some feedback and reported that if a person was in a place to want to make change, the COPESS intervention seemed effective. However, they were conscious that some people referred into the trial may not have been ready to participate in the therapy and was therefore concerned that the intervention may not be recognised as being effective;

> *"The feedback I got, some of the people I sent there, it's very dependent. People who self-harm are quite chaotic, so sometimes they just don't go and we accept that or they go and they don't really feel they get benefit. They're not in that place to want to change even. For those who did, my gosh it was great. I think we need more of that kind of service. I'm just hoping that it shows, fingers crossed, that it's been effective. Certainly anecdotally I felt it had for those who are ready for change. That's*

always the limiting factor and I hope that's taken into account with how the data is analysed." [PC4, GP]

Impact of COVID-19

Some patients seemed to engage in less self-harm behaviour in lockdown due to feeling safer and happier at home whereas others increased their self-harm due to stress (e.g., job losses, more caring responsibilities, ill-health, bereavement). There was initially a reduction in remote consultations (when only remote was available) for self-harm and then a sudden influx once people could not cope anymore or when they felt they had permission to contact their GP again.

> *"I've had regularly whole sessions, 12 patients in a row who are all mental health. Half of whom have been self-harming. It is huge numbers. I'd say even on the phone that's okay, what would it be if we were face to face? I think there are a lot more people who are not calling about it and who are not vocal about it that we just don't know about." [PC4, GP]*

GPs indicated that people were perhaps more reluctant to discuss self-harm in remote consultations.

> *"So perhaps, sort of, you know, they found it more difficult to disclose self-harm when they couldn't see us, when they were just talking to us? They may have felt less likely to call up in the early part of the pandemic, because there was definitely a dip in general practice, sort of, demand in the very early pandemic. That has certainly, sort of, reversed, now, and so. [PC2, GP]*

All the primary care staff reported being surprised that the number of people in mental health crisis did not increase substantially early on during the pandemic. This is in line with research from community surveys and patient records showing that there was no increase in self-harm in the early stages of the pandemic.

> *"I was quite surprised we didn't see a marked increase, but then I suspect it was down to what was actually making people get to that point in their life so. I don't think it impacted it or us in that sense. I would have thought the numbers would have been higher" [PC1, RN]*

Summary

Qualitative work is increasingly recognised as an important element of intervention trials in clinical settings. For the COPESS feasibility trial we included an interview study to help meet

a number of objectives; (1d) assessing the feasibility of delivery of the COPESS therapy based on feedback from participants and therapists; (2b) to explore the acceptability of the COPESS intervention by interviewing a stratified sample of participants who took part in the therapy arm of the trial, and (2c) interviewing therapists who delivered the COPESS therapy to assess the suitability of COPESS for addressing the needs of the target population, and delivering the therapy within a community setting.

While the results of the qualitative work have been presented above as separate groups of interviewees (i.e., participants, therapists, and primary care staff) for ease of interpretation, there were many commonalities between themes. The need (and wish) for self-harm specific services like COPESS to be made available in primary care settings was clear. This was often contrasted with recent or historical examples of difficulties accessing/referring to mental health services. The rapid access to COPESS, within four-weeks of referral, was also a very positive point across interviews, with an emphasis on the benefit of people being seen when they need the help instead of many months later. Tools used in therapy sessions were seen as very valuable by patients and therapists and were used in a number of different ways such as an aide memoir, or a way to share experiences with loved ones.

In terms of the practicalities of delivering the COPESS intervention, primary care staff and therapists were very positive, and found the protocols and procedures simple and easy to follow. There was broad discussion of whether online video sessions were a benefit or not, but there was unanimous agreement that the sessions were still successful in delivering the therapy, and some indication that this may be a preferred delivery method for some participants and may have encouraged engagement and retention across sessions.

These results show the potential of the COPESS intervention to fill a well-recognised self-harm-specific gap within primary healthcare services (and potentially beyond). Participant and therapist interviews show that delivery of COPESS therapy can be effective in primary care settings. Themes show very positive experiences of taking part in the trial and the COPESS therapy, and demonstrate a high-level of acceptability across all groups, but especially participants in the trial.

CHAPTER 7 THERAPY TRAINING, SUPERVISION, AND FIDELITY

Design

A mixed methods design was used. Two facets of fidelity to the intended delivery of the components comprising COPESS were assessed; 1) adherence/competency to content of COPESS during delivery (fidelity of content); and 2) the number of sessions delivered (fidelity of duration). Semi-structured interviews assessed therapists' perceived acceptability and views of fidelity to delivery of COPESS.

Fidelity of the intervention

The fidelity of delivery of the COPESS intervention has now been formally assessed. Expansion of the COPESS intervention and the inherent involvement of more therapists delivering COPESS across more English regions will bring, alongside the adaptability of the model, potentially risk diminution in fidelity. Fidelity refers to the extent an intervention is delivered as planned.[54-56] Assessment of fidelity determines whether intervention outcomes can be attributed to intervention content and components, rather than unaccounted factors, such as variations in an intervention's implementation and/or omission of intervention components.[57] It is pertinent to understand the degree of fidelity adherence in the delivery of COPESS to ensure confidence in interpretation of reported outcomes and replication of this once the trial is conducted across multiple sites. We aimed to understand the fidelity of delivery of COPESS within a community therapeutic setting for people attending in primary care for recent self-harm (within six months). The perceived context-specific facilitators and barriers of COPESS were explored to provide insights into the adherence of COPESS in practice and its acceptability by trial participants.

COPESS Intervention

The COPESS therapy was delivered by five therapists initially as one left during the trial. Therapists received a combined PIT and CAT Level 1 training. This was a 5-day short course that introduced the principles of working with PIT and CAT and the application within clinical practice. Ongoing supervision from a Lead Mental Health Practitioner took place on a fortnightly basis. If the standard therapy approach was not being adhered to, therapists were offered feedback.

All therapy sessions were recorded with the consent of participants. A randomised subset of 10% of recorded sessions were rated by an independent psychotherapist with experience of the approach using a modified version of the Sheffield rating scale [58] to ensure adherence to the approach. Each therapist treated between four and eight patients.

Treatment-as-usual (TAU)

There were no restrictions on care provided as TAU. Participants randomised to TAU were provided with information about how to refer to local statutory or non-statutory services and GPs were encouraged to follow the NICE guidance on care for people who self-harm.[6] The COPESS researcher shared the NICE guidance with GPs at the initial presentation with participating GP practice sites.

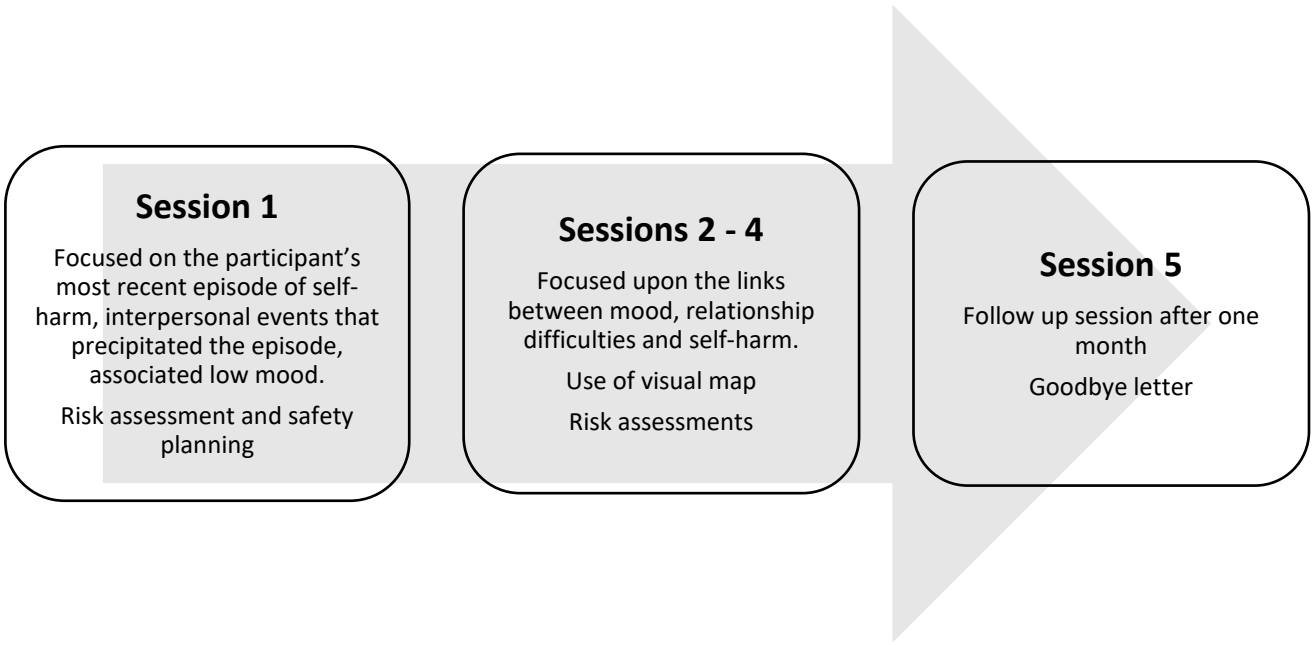
COPESS plus TAU

The COPESS therapy consisted of four 50-min weekly sessions of psychological therapy with a trained Mersey Care NHS Foundation Trust therapist (Grade 6 mental health nurse practitioners) that took place remotely due to COVID-19 restrictions. A further follow-up session took place 4 weeks after the end of therapy. Mersey Care NHS Foundation Trust trained five of their current therapists (Grade 6 Mental Health Nurses) in the COPESS therapy. The therapy is based on Psychodynamic Interpersonal Therapy (PIT), including a focus on the development of a strong therapeutic relationship, and the recognition of different aspects of emotional experience and identification of conflict.[59,60] This has been adapted with principles and concepts from Cognitive Analytic Therapy, including the use of visual diagrams or maps to help build a shared understanding of the clients' problems, and the use of therapeutic letters.[34] The therapy involved working collaboratively with the patient to identify patterns or conflicts in emotional experiences and interpersonal relationships, linked to depressed mood and acts of self-harm. The therapist worked with the patient to build a shared understanding of these experiences.

COPESS therapists were given a manual to follow which was introduced and utilised within the COPESS training and therapy. The therapy manual describes the background of the issue, the sources used to develop the therapy, detailed information on how the therapy should be delivered and it provided examples throughout. The first session focused 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. The main aims of the first session are for the therapist: engage with the client; establish a shared understanding of the structure of the therapy and practical arrangements including confidentiality; explore the story of the client's last self-harm episode (and possibly previous self-harm episodes); carry out a risk assessment of further self-harm or suicide and safety planning. The three remaining sessions focused upon the links between mood, relationship difficulties and self-harm and the process of mapping becomes a more central part of the therapy. These sessions include using PIT techniques including picking up cues, staying with and exploring feelings about relationships and interpersonal problem. Therapists also continued to monitor suicidal thoughts and thoughts/acts of self-harm and conduct risk assessments at each session. The final session can be the most difficult in brief therapy and therapists were informed that participants may

find it difficult to accept that the therapy is coming to an end, and it is not unusual for their symptoms to recur or become worse as the final session approaches. A goodbye letter is written by the therapist – whether or not the participant finishes the entire course of the therapy. The following activities were included in the last session: Acknowledging the ending; Reviewing presenting problems including self-harm; Reviewing new shared understanding of their difficulties capturing through mapping; Reviewing changes; Discussing the goodbye letter; Considering work that can be continued and saying goodbye. Figure 2 summarises the content of the sessions.

Figure 2: Specification of the COPESS intervention



Participants

Nine trial participant sessions were reviewed, each of whom had received and completed the COPESS intervention. These were randomly selected from a potential 28 completed cases during the trial study period. The qualitative element of this study involved four therapists (4 female) trained to deliver the COPESS).

Quantitative Phase: Procedure and analysis

Document analyses of internal records auditing a random sample of selected cases were assessed to evaluate fidelity of adherence to the planned delivery of COPESS. A total of nine cases represented three cases per three COPESS therapists. The audit was conducted by a psychotherapist with experience of the approach (Grade 7 therapist based at Mersey Care NHS Foundation Trust) using a modified version of the Sheffield rating scale [58] to ensure adherence to the approach. The audit tool was co-produced with the COPESS intervention trainer, a clinical psychologist and a psychotherapist. A Likert scale was used by the assessor to complete the COPESS therapy fidelity assessment (see table A5, supplementary

materials). Each item is rated for adherence on a 7-point Likert-type scale ranging from 1 (item “not at all” present) to 7 (item “exceptionally” present). Additional delivery features were assessed including the number of sessions delivered and duration of time men accessed the service. For each item a competency 7-point Likert-type scale was developed ranging from 1 (“very incompetent”) to 7 (“exceptional”) with 4 being “satisfactory”. The adherence/competency was calculated by averaging the points awarded (see table A6, supplementary materials). COPESS deemed a score of less than 4 (range 0<4) as an unacceptable level of adherence and a score of 4 and above as acceptable (range 4-7).

Qualitative Phase: Procedure and analysis

The primary researcher conducted semi-structured interviews with therapists to explore their views on fidelity of delivery of COPESS, including barriers and facilitators that may influence their delivery of the intervention. Perceived acceptability of COPESS was explored to understand service-user related factors that may affect fidelity. Interviews were conducted online using MS Teams (n=4). Interviews were audio-recorded using a Dictaphone and ranged in duration from 30 to 45 minutes. All interviews were transcribed verbatim and analysed using thematic analysis.[52] Each interview was read by the primary researcher, and initial codes and themes developed. Five team members including three experienced qualitative researchers and two public advisors (AH, CC, CM, NH and PS) reviewed the data. Codes and themes were developed to ensure transparency and consensus within the developed codes and themes.

Results

Quantitative Findings

Audit results confirmed adherence scores indicated a medium level adherence to the planned delivery of COPESS. Twenty-two people attended all sessions, four people attended at between two and five sessions and two people did not attend any sessions. The trial progression criteria relating to recruitment and retention in assessment of the feasibility of rolling out the COPESS therapy to a full efficacy RCT regarding attendance of therapy sessions were met.

Adherence ratings

Forty-five sessions concerning nine different clients from three different therapists were rated for adherence to the model. Across the domains of the tool Two therapists were adherent, and one was partially adherent to the model.

Qualitative Findings

Four inter-related themes were developed. These reflect the perceived context-specific facilitators and barriers of delivery of COPESS from the perspective of therapists trained to deliver COPESS and implementation fidelity compared to the planned delivery of COPESS. The first theme, *Therapeutic Environment* relates to the importance of therapy setting and the role of the therapist in engendering this. The second theme identified was *Specialised Self-Harm Therapy Training* in COPESS which facilitated therapist understanding and expertise in self-harm prevention and application of the COPESS intervention. The third theme was *rapid access to brief psychological therapy* and encompasses improved engagement in therapy among people who have recently self-harmed. The final theme, *Person-Centred Care,* related to co-production of therapy with participants and timeliness of introducing the map and goodbye letter components of COPESS. Each theme is discussed further below.

Therapeutic Environment

The importance of therapy setting and the role of the therapist in engendering this was discussed. Therapists shared how each participant reacted differently to where therapy was taking place. For some participants being in their own environment during therapy sessions seemed positive and did not negatively impact the delivery of the COPES therapy:

> *"I think they felt a bit safer and maybe less anxious in their own environment, they could choose where they were going to be for the therapy. I don't think it necessarily impacted on the therapeutic relationship or on how the sessions went."* [T3]

Alternatively, therapists reported that there were some participants who would have preferred to not have therapy in their home environment and there were times when therapists were concerned about other people attending participant sessions without their knowledge:

> *"Other people want to come out of their own environment and don't want to do therapy in their own house because they want to leave it where it is and go home."* [T2]

Although therapists reported the value of being able to offer the COPESS therapy remotely, all of them thought it should be delivered face-to-face going forwards now that most restrictions have been removed. Three of therapists were keen for the first option to be face-to-face therapy sessions with the option of a hybrid model to capture some people who may not otherwise access the therapy:

"Yes, I think it should be something that's offered going forward, but you also can't take away from being in a room with somebody. I think for me, as a really infant therapist in this therapy, I can feel how different it would be if you were face to face. It's undoubtedly better face to face, but you can still achieve some really good work with this way. So, it's definitely got its benefits, and its pros and cons." [TC1]

Therapists reflected on the potential benefits of being able to offer COPESS within GP surgeries as they thought it would then be more accessible for participants, be delivered in an environment they are familiar with and to provide support in a timely manner:

"I think that if there's the opportunity to base a brief therapy option within the community, within a GP surgery, where someone can access it really quickly and quite easily, somewhere that they're familiar with if they're going there in person or… Somewhere that they align it with, "I saw my GP three weeks ago and I've got this brief intervention in relation to that already, that's really, really, positive."… I think it definitely instils hope for recovery in patients as well, it kind of gives that sense of being heard and being listened to and having support in place at the right time when it's needed." [TC4]

Specialised Self-Harm Therapy Training

The COPESS therapy training facilitated therapists' understanding and expertise in self-harm prevention and the application of the COPESS intervention. All of the therapists reflected on the positive aspects of the training and how they thought the structured approach suggested for therapy sessions was both appropriate and useful. The focus on self-harm was well-received as therapists reported that it gave them guidance in how the sessions should be structured for COPESS:

"Because there was such a targeted goal around self-harm, I think that made it much, much, easier to keep it on target. I think when we've used that model of therapy on a wider basis in other parts of our service, because there hasn't been that specific goal, at that point it's much easier to come off-model I think. I'd say that the combination of the focus, specifically, on self-harm and the PIT model being used over those four to five sessions, for me that made it quite easy to keep it on topic, really, and not divert too much." [TC4]

Although the feedback from the training was positive, particularly the structure and use of the workbook, therapists reflected that most of their learning occurred once they started delivering the COPESS therapy and through their supervision:

"I think that, because of the way it was structured, because we knew that there was an engagement, introductory, session at the beginning, there was the goodbye letter and completing the PIT map at the end, and there were two very focused sessions in the middle to get all of that information from the participants. That was really helpful, for me, as a novice to the therapy as well. Because of the structure there, it gave me a lot of guidance." [TC4]

"The face-to-face training was really good and helpful to really show us the map work. I think he gave us an example of a map that he'd used and a letter that he'd used. That was really helpful, his examples. I think I can remember him breaking down what you might do in each session, so what would you do with the first session, almost like setting this agenda for the therapy and the structure." [TC3]

"I think that was probably where I learned the most about the therapy. It would be in the supervision after the initial training, just because at that point we were putting it into practice." [TC2]

Therapists discussed how beneficial the face-to-face element of the training was and that they would have preferred all of the training to have been delivered this way. They did still report the benefit of the training although some was delivered online remotely, but felt more long-term value in role playing and physical completing the course tasks:

"Yes, it was half online and half face to face. I must confess, the things that I remember more about the training were the face-to-face elements of it. That was probably because we were sat in the room and we were physically doing the tasks and writing out the maps ourselves, as opposed to the sort of theoretical stuff. The blended approach, it did work. I think that, from a training perspective as a new therapy, it was more helpful for me to have, that hands-on, somebody sat next to you watching you write out a map and directing you in that way." [TC1]

Rapid access to brief psychological therapy

Rapid access to COPESS was discussed by all therapists in how it encompasses improved engagement in therapy among people who have recently self-harmed. Therapists discussed the benefits of being able to treat participants when the self-harm was recent as a benefit within their recovery as they were not required to think back many months to when they had previously self-harmed or they had not had time to become more distressed whilst waiting for therapy:

"I think it's really helpful for it to be rapid access, rather than a here and now problem and then you're sitting on a waiting list for months. You need that rapid

access, don't you, for that acute problem? ...I think it's difficult with demands on services but there's definitely a need for rapid access absolutely." [TC3]

Therapists reported that offering people who attend in primary care for self-harm rapid access to a brief psychological intervention i.e., COPESS could reduce future rates of self-harm. One therapist also highlighted that this therapy could be beneficial for younger people and again could help reduce the future rates of self-harm:

"They might have gone to the GP for something, having just, you know, their mental health, or whatever it is, and self-harm is apparent. Being able to access a therapy within a few weeks at that level, it's pretty good. It's a pretty good standard of care. And if that was to be able to be offered, I think we'd get a lot less people actually going down this road in the first place…I think if this was delivered to 12-16 year olds, or something like this, it would have a massive effect on, generally, the rate of self-harm in the future. So, yes, I think that timely access is critical, really." [T1

Person-Centred Care

Therapists described how structured the model was but equally how flexible in relation to the co-production of therapy with participants and timeliness of introducing the map and goodbye letter components of COPESS. They were all very positive about the use of this model and additional CAT component that was added to the PIT approach. The person-centred care approach was used as therapists worked with each individual participant to understand what was important for their specific needs. This helped to build their therapeutic alliance and shaped the visualisation of the map and helped them summarise within the goodbye letter:

"It was a really lovely therapy to offer because patients did engage with it so well. Because a lot of the focus was about that interpersonal response between the participant and the therapist, you could establish a really good connection with somebody whether that was remotely or otherwise. As I said, when we would end our sessions with the goodbye letter, people would often feel really, really, validated. To feel like, "Gosh, you've understood, you've heard what I'm saying. I've not had the space to talk about this before." There'd be quite a lot of emotion in that session from the participant but, quite often, from us mushy therapists, as well, that would be really appreciative that they'd had that response and obviously there'd been a therapeutic relationship there." [TC4]

"With the letters and stuff, and introducing the idea at the beginning, I think people generally felt comfortable, and therefore they felt that relationship quite quickly. And I think the type of therapy helped to develop that instantly." [TC1]

Therapists also discussed how participants might use the tools developed within their sessions following on from the end of the therapy. This highlighted how the therapy may be sustainable after the brief intervention has been completed:

> *"Because it is a collaborative process. Then I put down a picture, but then I've basically written it out it in words. So the two things together, if they refer back to them in future, they've got that, they go together. So if they just look back at the map and go, "I don't know what that was about," they can read the letter and go, "That was that." And because it was happening with them, they'll know, and they'll be able to attach the feelings, and then the memories, and the things that came up for them at the time, with the stuff that they can see. That's how I imagine it to be. I think both parts of it are really important. Without it, I'm not sure it would have as much of an effect."* [TC1]

Therapists also reflected on the time and effort needed to co-produce the tools and this was impacted by the remote nature as therapists worked more outside of the sessions than they would usually need to if the therapy had been face-to-face. However, they reflected on how rewarding and worthwhile it was for them and the participant:

> *"As much as it's really time-consuming and it's a lot of work outside of the session, I think, the letter, especially, is quite meaningful to people."* [TC3]

The co-production element of the therapy was discussed repeatedly, and therapists felt that participants valued and appreciated being involved in their recovery. Many about participants feeling validated and heard, some for the first time

> *"Although we are guiding it, as therapists, the participant has a lot of opportunity to speak freely and to speak from an emotional point of view and to describe things really metaphorically and figuratively. They really like that, they really get that, alongside the visual stuff that we do with the map and with the goodbye letter at the end as well… people would often feel really, really, validated. To feel like, "Gosh, you've understood, you've heard what I'm saying. I've not had the space to talk about this before.""* [TC4]

Summary

This chapter reports on objective 2d) assessing training, competency, and fidelity to the manualised COPESS therapy. Training, competency, and fidelity to the manualised COPESS therapy was judged to be acceptable and moderate delivery fidelity is evidenced by auditing the COPESS intervention.

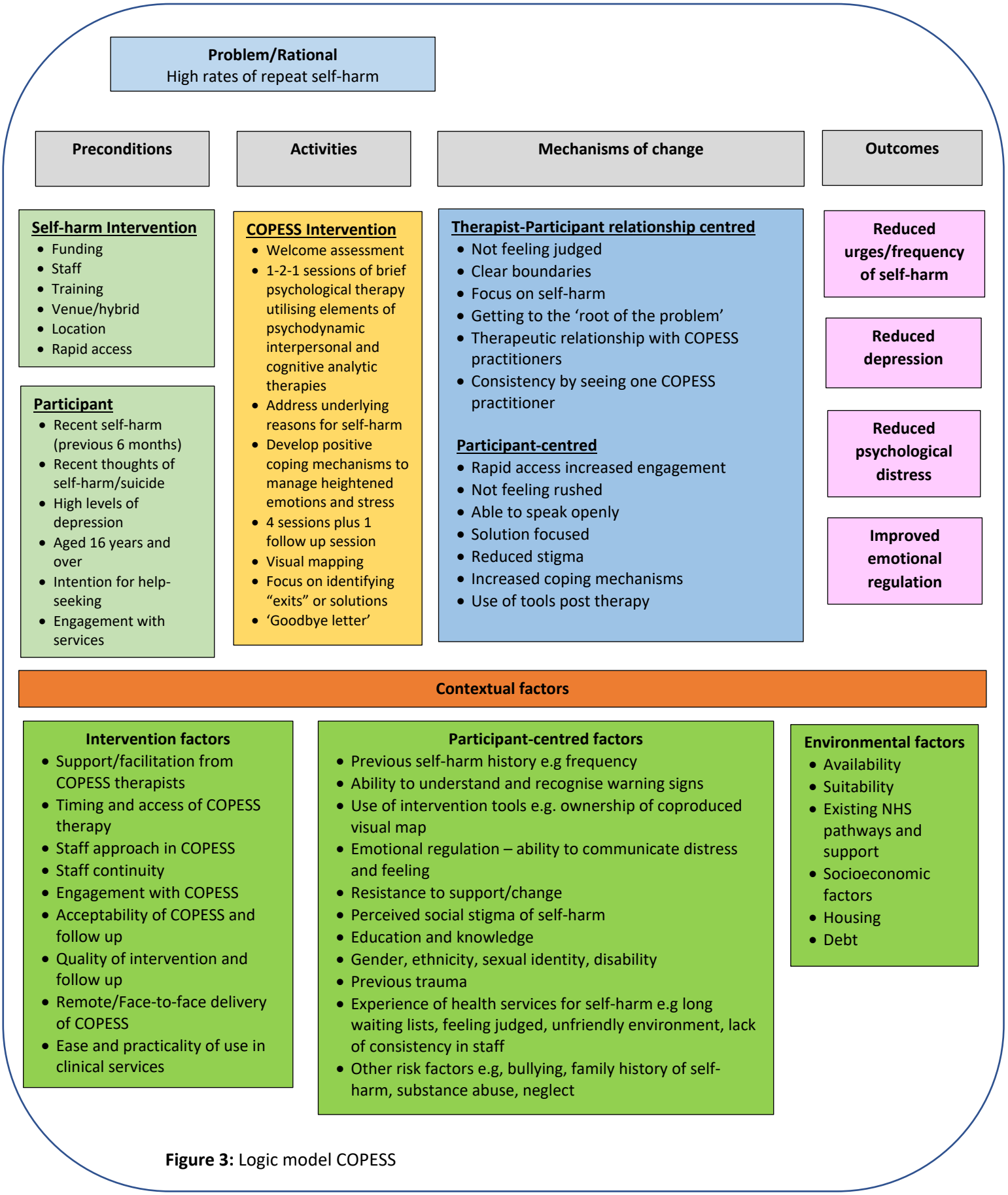


Figure 3: Logic model COPESS

CHAPTER 8 SUMMARY AND ASSESSMENT OF FEASIBILITY

Acceptability and feasibility of proposed intervention

Figure 3 presents a logic model of the COPESS intervention which shows good potential for reducing urgency or frequency of self-harm, psychological distress, depression, and improving emotional regulation. The results of the feasibility trial indicated that COPESS was both acceptable and feasible, with good recruitment rates, high retention rates, and all progression criteria being met. Data completeness of secondary outcomes measures was high and the delivery of the COPESS intervention was considered appropriate and successful by both participants and therapists. Therapists indicated high acceptability of the COPESS therapy for addressing the needs of the target population, and for delivering the therapy within a community setting. Training, competency, and fidelity to the manualised COPESS therapy was judged to be acceptable and moderate delivery fidelity was evidenced by auditing the COPESS intervention. Interviews with primary care staff indicated high acceptability of the recruitment processes and supported the use of these methods in any future trial. There were no adverse events reported beyond those related to self-reported suicidal ideation or self-harm. One serious adverse event was reported for a participant who was deemed at serious risk and they decision was made to remove them from the trial and the mental health service offered steeped up care. COPESS was deemed to be a safe intervention.

Qualitative data supported the intervention programme as summarised in the trial logic model (Figure 3). A design that offers the choice of both face-to-face and remote therapy might be most appropriate for a larger trial as this has the dual focus on clinical effectiveness and patient choice. These findings add to the growing evidence base supporting the utility of brief psychological interventions for self-harm.[25-33] Participants emphasised the importance of the therapeutic relationship and ongoing support by the trial researcher in maintaining engagement. Interviews with participants supported all mechanisms of the COPESS intervention. There was evidence that the intervention encouraged increased monitoring of triggers and warning signs and increased knowledge of potential positive actions. This helped to personalise the knowledge developed during the COPESS intervention (for example by using the visual map and 'goodbye' letter) and create a sense of enhanced self-efficacy. In addition, positive interactions with the intervention researcher increased participants' motivation to engage with the process of completing follow up questionnaires and potentially to be contacted by their GP where suicide risk was reported.

COPESS research staff reported that trial procedures were generally feasible and acceptable. However, two key issues need to be considered in a full trial: 1) ensuring that demographic data collection is conducted at baseline and not at the final follow-up only and 2) all

recruitment meetings or calls were conducted remotely, thus travel time or face-to-face meetings being scheduled were not evaluated as part of the feasibility trial. Conducting some aspects of the trial recruitment process remotely may have benefitted recruitment, attendance at therapy sessions, and attrition for data collection. Remote procedures should be considered as part of hybrid recruitment and data collection methods in any future trial. Overall, the feedback provided by intervention arm participants was positive about both the experience of taking part in the trial and the COPESS intervention. TAU only participants also reported a positive experience with the trial, some reporting that they had found completing the trial measures beneficial; however, some reported negative feelings about being randomised to the TAU only condition and felt they would have really benefited from the intervention. Some participants asked to be involved in the future trial.

Relationships with primary care sites were largely positive, however, the research team reported variation in levels of commitment to supporting the trial. Although all primary care sites indicated that they used the same methods for conducting searches on their systems (as specified by the research team), for patients who had consulted for self-harm in the past six months, there were large variations in how many participants were identified using the search criteria. It was not clear whether this was a result of local changes to the search strategy or other factors, such as how self-harm was recorded at each site. This may have had an impact on the number of trial information packs that were sent to potential participants at each site thus reducing the potential reach to more people. More precise instructions on what codes to search for in primary care records, and checks for consistency between sites, may be helpful in a future trial. Primary care staff reported that accommodating recruitment at their site and the associated remote presence of intervention research staff was feasible and acceptable. Primary care staff who were interviewed reported positive interactions with the research team and did not feel that accommodating trial recruitment had put any unacceptable burdens on them, or created disruptions to existing GP practices. However, they noted that workload issues could be a barrier to staff assisting with recruitment in a future trial due to increasing demands within primary care. There were suggestions of minor alterations that staff reported could have made the adoption of the study search processes smoother (e.g. research staff attending primary care team meetings in person) and utilising GP practice information boards more (e.g. poster boards and TV monitors with messaging for the study).

Therapists reported positively on the training they received for COPESS and the delivery of the COPESS intervention. They reported that patients found the intervention helpful, and they thought that the tools used within the sessions would be utilised by patients after the intervention had been completed. Therapists agreed that the intervention could be delivered remotely but would have preferred the option to deliver it face-to-face as originally planned. Reasons given for this preference included; not being able to see a person’s body language or visual cues during a sessions, other people being present in the

room during sessions at home, and not being able to develop ‘maps’ together within a session. Fidelity to the manualised COPESS therapy was moderate to high.

Most participants had not previously taken part in any intervention similar to COPESS, however, some had discussed their self-harm with other services or attended therapy in the past. Many reported previous therapy had not been helpful (e.g. online talking therapy computer sessions or group cognitive behavioural therapy) or that they were not offered anything. All participants in this study had symptoms of depression and NICE guidance indicates referral to IAPT would be appropriate for people in the study population. However, participants’ accounts highlighted difficulties in gaining access to any form of talking therapy. Those who had prior experience with talking therapies consistently reported that self-harm was not a primary focus within their previous therapy sessions. Participants in the TAU condition did not report receiving any talking therapies during the trial study period..

Most participants engaged with the intervention. All those interviewed discussed the content of COPESS sessions with the intervention researchers at follow-up, in particular the ongoing use of the ‘map’ they developed, and the ‘goodbye letter’ given to them by therapists at their final session. These are both components of CAT.[34] Therapeutic letters provide an opportunity to consolidate reflections and insights from the therapy, and also provide clients with a form of transitional object that can help keep them connected to what they gained from the sessions. [61] This may be especially important given the brief nature of the intervention. From a self-harm prevention perspective, it is encouraging that all of those interviewed who received COPESS reported using their tools at least once during the follow-up period and beyond the completion of the trial. This finding is noteworthy because greatest risk of repeated self-harm is usually within weeks of contact with health services for self-harm. [62]

Engagement in the trial seemed to be driven by at least four factors; disappointment of previous contact with ‘inappropriate’ health services following self-harm; rapid access to the intervention; altruistic desire to help with research; and the participants’ wish to improve their own self-harm behaviours. The importance of timing was highlighted, as the participants in the intervention arm were contacted within 48 hours of randomisation by the therapists to book their first session in the coming days. Feedback from those who received the intervention indicated that when someone is having thoughts of self-harm or suicide and are in an acute mental health crisis, the sense of immediacy facilitated their agreement to take part. Similar feedback was given by therapists about the benefits of treating people when they are in the state of crisis rather than months later when they may not recall the feelings they had at the time. However, some people also reported initially feeling anxious about being seen so quickly as they were used to being placed on long waiting lists.

Strengths

This trial is the first in the UK to explore the feasibility and acceptability of the delivery of a community outpatient psychotherapy engagement service for self-harm to reduce self-harming behaviour within UK community settings. Following NICE guidance to provide talking therapy to people consulting in primary care following self-harm, we coproduced a research programme evaluating a self-harm specific talking therapy that could be offered to patients. In terms of trial procedures, including recruitment, data collection and follow-up, no major barriers were encountered, and the trial progressed as planned. Of those participants who initially contacted the researcher about the COPESS trial, almost 80% agreed to take part in the trial, and no one subsequently withdrew. Public involvement and engagement was embedded within the trial from the outset. Members of the public advisory group reflected on the positive experience they had personally through being part of the COPESS trial team. We would recommend using the same process for public involvement in future trials and would aim to engage with more young adults in any future trial to reflect the typical ages of the trial participants.

Limitations

There were some limitations encountered during the trial. Several practical issues around managing communications with primary care staff and high staff workload were identified for both researchers and therapists. All were managed well in the trial and did not impact delivery of the study objectives, however, a full-scale trial could be optimised by ensuring enough experienced research staff are recruited. Ideally, one research staff member to manage each regional trial area, in addition to allocated administrative support, would aid recruitment and intervention delivery. This would be beneficial for recruitment across multiple GP sites, and any move to conduct more visits face-to-face..

The number of participants who identified as being from ethnic minority backgrounds was lower than the proportion of people from ethnic minorities residing in the local area (or GP catchment area) where recruitment took place. It would be useful to explore whether the intervention needs work to make it more suitable for people from different ethnic minority backgrounds. Ensuring trial sites include GP practices in areas with higher levels of diversity may help with this.

Participants in both trial arms were asked to provide information about any engagement with services at the final follow up point but this was reliant on accurate self-reports. To improve the accuracy of information on reporting of AEs or SAEs and service contacts during the trial period, future trials may include the element of contacting primary care for further information on participants service usage during the trial period (with participant consent).

Unfortunately, it was not possible to interview any participants who disengaged with the trial and/or did not complete all follow-up assessments. Providing more information about a future potential interview at the time of recruitment, clarifying that the interview is important for understanding reasons for nonengagement, may help encourage people who disengage and help provide important information on how to avoid losing participants from the trial.

Further research

All objectives set out in the trial protocol were met, and in some cases exceeded expectations. The evidence provided by the COPESS feasibility trial therefore supports the need for further evaluation of the intervention in a full-scale clinical effectiveness randomised control trial. As a rapid-access brief intervention COPESS has shown good potential to help meet the care needs of people who self-harm in the community, a group known to be at high risk of further self-harm, and suicide mortality.

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Consent for publication

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

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Supplementary Materials

Table A1: The derivation of the clinical questionnaire variables used in the trial.

Questionnaire	Number of Items	Item Score Range	Minimum Items Required for Valid Total Score	Total Score Range
CORE-10	10	0 to 4	9	0 to 40
BDI	21	0 to 3	17	0 to 63
ERQ-CR	6	1 to 7	5	6 to 42
ERQ-ES	4	1 to 7	4	4 to 28
ABUSI	5	0 to 6	5	0 to 30

CORE-10 higher score = poorer clinical outcome
BDI higher score = more severe depression
ERQ-CR higher score = better cognitive reappraisal
ERQ-ES higher score = better expressive suppression
ABUSI higher score = greater difficulties/ urges

Table A2: Descriptive statistics for each outcome measures at each of the assessment points.

	Trial Arm 1 (COPESS plus TAU)				Trial Arm 2 (TAU only)			
Outcome Measure	Baseline	Baseline (if response at M3)	M3	**Change (M3 – B/L)**	Baseline	Baseline (if response at M3)	M3	**Change (M3 – B/L)**
N	28*	21*	20	**20***	27	22	21	**21**
CORE-10 (mean (SD)	25.2 (7.35)	24.9 (7.88)	16.5 (8.68)	**-8.3 (7.38)**	25.9 (6.81)	26.0 (6.35)	23.7 (8.26)	**-2.4 (6.73)**
CORE-10 (median (IQR)	26.5 (21.5, 30.5)	26 (21, 31)	16.5 (9.5, 23)	**-6.5 (-11, -3.5)**	26 (21, 32)	25.5 (21, 32)	25 (17, 28)	**-2 (-8, 1)**
CORE-10 range	7 to 36	7 to 36	4 to 34	**27 to 2 $**	10 to 35	12 to 35	9 to 38	**-16 to 11**
BDI mean (SD)	36.4 (10.1)	33.9 (10.1)	23.5 (14.1)	**-10.8 (11.2)**	37.6 (10.5)	37.9 (10.1)	36.0 (12.1)	**-2.4 (11.0)**
BDI median (IQR)	38 (31, 43.5)	35 (28, 38)	25 (10.5, 35)	**-8.5 (-16.5, -3)**	40 (31, 46)	40.5 (31, 46)	37 (28, 46)	**-2.4 (11.0)**
BDI range	7 to 51	7 to 51	3 to 50	**-32 to 7 &**	16 to 53	16 to 51	13 to 58	**26 to 22**
ERQ-CR (mean (SD)	21.1 (6.66)	21.8 (6.28)	27.1 (7.88)	**5.4 (6.53)**	18.3 (7.25)	18.8 (7.84)	19.3 (8.04)	**1.0 (6.66)**
ERQ-CR (median (IQR)	23 (16, 26)	23 (16, 26)	26.2 (23, 32.5)	**6 (1.5, 10)**	18 (13, 23)	18 (15, 25)	20 (14, 23)	**3 (-2, 4)**
ERQ-CR range	7 to 34	11 to 34	6 to 40	**-7 to 18 ^**	6 to 32	6 to 32	6 to 36	**-12 to 18**
ERQ-ES* (mean (SD)	17.1 (4.79)	18.1 (4.63)	16.0 (5.98)	**-2.3 (5.64)**	16.4 (4.46)	16.1 (4.51)	17.0 (4.15)	**1.0 (4.80)**
ERQ-ES*(median (IQR)	17 (14, 20)	18 (15, 21.5)	17 (13.5, 20)	**0 (-7, 1)**	16 (13, 20)	16 (13, 19)	18 (13, 21)	**0 (-2, 4)**
ERQ-ES* range	8 to 26	10 to 26	4 to 27	**-13 to 7**	8 to 26	8 to 26	8 to 23	**-8 to 13**
ABUSI (mean (SD)	18.1 (7.85)	18.3 (8.05)	15.3 (8.84)	**-2.9 (8.17)**	20.8 (10.1)	20.2 (10.2)	19.3 (8.97)	**-1.2 (10.1)**
ABUSI (median (IQR)	17.5 (11.5, 23)	17 (14, 22)	14 (7.5, 21.5)	**0 (-5, 1.5)**	25 (13, 29)	22 (13, 29)	20 (12, 25)	**0 (-6, 4)**
ABUSI range	5 to 34	5 to 34	5 to 34	**-24 to 8**	5 to 35	5 to 35	5 to 35	**-19 to 22**

*N is one less than the value stated for the ERQ-ES outcome. $ only one value was >0. & only three values were >0. ^ only three values were <0. M3: Month 3 follow up

Table A3: Adverse Experiences in Psychotherapy – Summary of Responses at 3 Months

Item	Not at All	Very Little/ A Little	**Quite a Lot/ Very Much ***	N/A	Missing
Taking part hasn't helped me with my problems	11	6	**3**	17	4
Taking part made my problems worse	20	2	**0**	17	4
Taking part made me feel more anxious.	15	7	**0**	17	4
Taking part took up too much time.	20	2	**0**	17	4
Taking part led to my mood becoming very low.	17	4	**1**	17	4
Taking part made me feel more angry and irritable.	21	2	**0**	16	4
I didn't feel ready to talk about my problems.	16	5	**1**	17	4
Taking part made me think too much about bad things that have happened in the past.	12	8	**1**	17	4
Taking part meant I stopped looking after myself properly.	20	2	**0**	16	5
Taking part made me feel more suspicious.	21	1	**0**	17	4
Taking part required too much energy or motivation.	14	8	**0**	17	4
Taking part increased my thoughts of killing myself.	20	2	**0**	17	4
I didn't feel listened to or believed by care staff.	21	0	**0**	18	4
Taking part made my voices or visions worse.	22	0	**0**	17	4
Taking part was making me fall out with my family or friends.	21	1	**0**	17	4
Taking part was having a bad effect on my self-esteem.	21	1	**0**	17	4
Taking part was making me want to harm myself.	17	5	**0**	17	4
I didn't like or feel I could trust my care team.	21	0	**0**	18	4
I felt embarrassed talking about my problems with people I had not met before.	6	14	**1**	18	4
Taking part made me have thoughts of harming other people.	22	0	**0**	16	5
Taking part was making me feel hopeless about the future.	17	4	**0**	17	5
Taking part meant I had to increase my medication in order to cope.	20	1	**0**	18	4
Taking part involved too much hard work.	20	2	**0**	17	4
Taking part made me worry that people would think badly of me because of my diagnosis.	17	5	**0**	17	4
Taking part made me fall out with my doctor or care team.	21	0	**0**	18	4
Taking part made me worry about losing control of my mind.	19	3	**0**	17	4
My problems have improved to the point whereby I no longer feel I need help.	4	15	**2**	16	5

Table A4: Health Alliance Questionnaire – Summary of Responses at 3 Months

Item	Strongly Disagree	Disagree/ Slightly Dis.	Slightly Agree/ Agree	Strongly Agree	N/A or Missing
I feel I can depend upon the therapist	0	0	5	16	19/ 3
I feel the therapist understands me.	0	0	4	16	20/ 3
I feel the therapist wants me to achieve my goals.	0	0	2	19	19/ 3
At times I distrust the therapist's judgement*	10	9	0	0	21/ 3
I feel I am working together with the therapist in a joint effort.	0	0	6	13	21/ 3
I believe we have similar ideas about the nature of my problems.	0	0	6	13	21/ 3
I generally respect the therapist's views about me.	0	0	5	15	20/ 3
The procedures used in my therapy are not well suited to my needs.*	7	11	0	1	21/ 3
I like the therapist as a person.	0	0	6	13	21/ 3
In most sessions, the therapist and I find a way to work on my problems together.	0	1	5	13	21/ 3
The therapist relates to me in ways that slow up the progress of the therapy.*	5	9	2	1	22/ 4
A good relationship has formed with my therapist.	0	0	9	10	21/ 3
The therapist appears to be experienced in helping people.	0	0	4	15	21/ 3
I want very much to work out my problems.	0	0	4	16	20/ 3
The therapist and I have meaningful exchanges.	0	0	4	15	21/ 3
The therapist and I sometimes have unprofitable exchanges.*	7	11	1	0	21/ 3
From time to time, we both talk about the same important events in my past.	0	0	10	9	21/ 3
I believe the therapist likes me as a person.	0	1	14	4	21/ 3
At times the therapist seems distant.*	12	6	1	0	21/ 3

* negatively worded items

Table A5: COPESS Therapy Fidelity Assessment

Scale assessment units
1. STATEMENTS: Did the therapist use statement, rather than questions, to explore feelings, bring feelings into the 'here and now' and 'stay with feelings' 2. UNDERSTANDING HYPOTHESES: Did the therapist offer statements of empathic understanding in response to cues? 3. NEGOTIATING STYLE: Did the therapist express his/her views concerning the patient's experiences and circumstances as tentative statements, open to correction, and inviting elaboration and feedback? 4. LANGUAGE OF MUTALITY Did the therapist use the language of shared endeavour ("I" and "we")? 5. THERAPY RATIONALE: Did the therapist provide a rationale which emphasised that working on understanding and changing the client's characteristic patterns of feeling and action in relationships would help overcome the client's difficulties and symptoms? 6. CUE BASIS: Did the therapist explicitly pick up or acknowledge cues (verbal and non-verbal) when supplied by the client? 7. METAPHOR: Did the therapist encourage and elaborate the client's use of metaphor or use metaphor themselves to deepen feeling or understanding? 8. FOCUSSING: Did the therapist focus on the 'here and now' experience of the client in the session, encouraging the client to stay with feelings before any attempt to 'explain' them? 9. EXPLORATION OF FEELINGS: Did the therapist help the client to explore her/his feelings related to an interpersonal relationship? 10. PATTERNS IN RELATIONSHIPS: Did the therapist draw parallels or point out patterns in two or more of the client's relationships for the purpose of helping the client understand how she/he functions in interpersonal relationships? 11. CAT TOOL: Did the therapist refer to or update the map (either diagrammatic or verbal, as appropriate) when exploring the links between the client's experiences or discussing patterns within relationships?

Table A6: Data auditing scheme

Therapist	Statements	Understanding hypotheses	Negotiating style	Language of mutality	Therapy rationale	Cue basis	Metaphor	Focussing	Exploration of feelings	Patterns in relationships	CAT tool	Total score	Competency score
A1	3	4	5	6	5	5	3	2	6	5	4	48	4.36
A2	3	6	5	6	4	5	5	4	5	4	4	51	4.64
A3	3	6	4	5	6	5	2	5	5	6	7	54	4.91
B1	3	4	3	4	5	2	2	4	4	4	5	40	3.64
B2	2	5	2	3	5	2	6	2	6	3	4	40	3.64
B3	2	5	2	6	6	2	4	2	6	6	3	44	4.00
C1	7	6	6	6	6	7	5	6	5	5	6	65	5.91
C2	6	6	5	6	6	6	3	6	7	5	6	68	6.18
C3	7	7	6	7	7	6	6	7	6	6	7	72	6.55

Section B1: Treatment effect estimates

Data analysis followed an Intention-To-Treat (ITT) protocol. The CONSORT [38] flow chart (Figure 1) shows the number of people referred, the proportion eligible, the proportion who consented, completed baseline assessments, were randomised, attended therapy, and the proportion completing follow-up assessments at four, eight, and 12-weeks post-randomisation.

A preliminary treatment effect estimate was conducted to derive 80% and 95% confidence intervals for the difference between treatment groups (see Table A7). The outcome in the regression model is the 3-month post treatment score on each variable, with the respective baseline score, age-group (recoded as 16-20, 21-30, >30 to help overcome the issue of small numbers in the regression analysis), gender (male, female) and trial arm as covariates. Two participants identified as 'other' gender during baseline assessments. One was 'lost to follow-up' at 3 months, the other later identified as male at later follow-up sessions and has been included as male in the analysis. As baseline data was used in the analysis the patient who identified as 'other' was omitted from the regression, as it would not be possible to give a reliable regression estimate based on one person.

Given the trial focus is on feasibility, these treatment effects should be interpreted with caution, and are not a robust test of treatment efficacy. We plan to use this information, along with the baseline pooled SD, the estimated attrition rate and the average number recruited per practice (plus the range of this data), in addition to other (published) sources, to help inform the sample size calculation for an RCT of clinical and cost effectiveness. We will use the lower limit of the 80% confidence interval for the CORE-10 along with the baseline standard deviation and the overall trial attrition rate to help inform the power calculation for the effectiveness trial.

Table A7: Linear regression for differences between treatment groups at three-month follow-up.

Outcome	80% Confidence Interval	95% Confidence Interval
CORE-10	3.15, 9.54	1.38, 11.31
BDI	6.56, 16.33	3.85, 19.04
ERQ-CR	-7.26, -1.29	-8.91, 0.36
ERQ-ES	0.82, 5.27	-0.41, 6.50
ABUSI	-0.27, 6.97	-2.27, 8.98