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Feasibility and acceptability of the Community Outpatient Psychotherapy Engagement Service for Self-harm (COPESS): randomised controlled trial

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Background

Self-harm is widespread and often occurs in the community without resulting in hospital presentation. Individuals with depressive symptoms are at elevated risk. There are limited self-harm interventions designed for community and primary care settings. The Community Outpatient Psychological Engagement Service for Self-harm (COPESS) is a brief talking therapy intervention for self-harm based in community settings.

Aims

To assess the feasibility of evaluating the COPESS intervention in a community setting in relation to participant recruitment, retention, data collection and the acceptability of the intervention.

Method

We used a mixed-method approach and a single-blind randomised controlled trial design with 1:1 allocation to either COPESS plus treatment as usual or treatment as usual alone. Adults with depressive symptoms and self-harm in the past 6 months were recruited from general practices. Secondary outcome measures were assessed at baseline and 1 month, 2 months and 3 months after randomisation. The trial was pre-registered on clinicaltrials.gov (NCT04191122) on 9 December 2019.

Results

Fifty-five people were randomised (of an initial target of 60). Retention rates at follow-up assessments were high (>75%), as was attendance by all participants for all therapy sessions (93%). At 3 months, there were trends towards lower levels of self-harm urges, depressive symptoms and distress in the COPESS group compared with controls. Fidelity to the manualised COPESS therapy was moderate to high.

Conclusions

All progression criteria were met, supporting further evaluation of the intervention in a full-scale efficacy and/or cost-effectiveness trial. These findings add to the growing evidence base supporting the utility of brief psychological interventions for self-harm. COPESS has potential as a brief primary-care-based intervention for those struggling with self-harm.

Keywords

Self-harm; depressive symptoms; primary care; clinical trial; psychological therapy.

Self-harm, defined as any intentional act of self-poisoning or self-injury regardless of suicidal intent, is a recognised national and international public health priority.[1,2] It is estimated that there are over 200 000 self-harm presentations to hospital emergency departments in England each year,[3] incurring an estimated annual treatment cost of more than £162 million in England alone.[4] However, many people who self-harm do not 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.[5,6] In the UK, general practitioners (GPs) typically represent the first point of contact for mental health difficulties. Currently, there is a lack of interventions for self-harm embedded within primary care and GP settings. Such interventions could be valuable in enabling rapid access to support and preventing deterioration and escalation of difficulties.[7]

Self-harm is often an indicator of underlying emotional distress.[8,9] Depressive symptoms are common in those who self-harm and are predictive of future self-harm behaviour.[10,11] However, psychological therapies that focus on depressive symptoms seem to have limited capacity to improve self-harm related outcomes,[12] suggesting that treating self-harm requires therapies specifically designed for this context.[13,14] The Community Outpatient Psychology Engagement Service for Self-harm (COPESS)[15] is a brief relational intervention that has been developed to help people with self-harm and depressive symptoms. The approach has been designed so that patients can access the therapy directly through their GP practices or other primary care services. Such a community-based intervention 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[16] and the existing inequality of access to mental health services in deprived areas.[17] Psychological therapies can reduce psychological distress and repetition of self-harm,[18] although one recent review argued that effects have so far been limited.[19] There is support for cognitive–behavioural therapy (CBT)-based approaches,[1,18] but brief relation-based approaches such as psychodynamic interpersonal therapy (PIT) have also been found to reduce suicidal ideation and depressive symptoms among adults who have self-harmed.[20] Relational approaches to treating self-harm may be important, as interpersonal processes and difficulties are often relevant to understanding self-harm, and a focus on the therapeutic relationship within such work is important.[21]

Brief therapy approaches may have the advantage of being quicker to access compared with longer term therapies that often have long

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waiting lists; thus, they may be helpful in cases where more immediate support and containment is needed.[14] COPESS is a five-session relational therapy that is primarily based on PIT,[22,23] with an emphasis on building awareness and understanding of emotional states in the moment and the link these have to interpersonal relationships and conflicts. The approach also includes elements taken from cognitive analytic therapy (CAT),[24] including visual mapping of experiences and identification of exits or ways out of difficult relational and emotional patterns. Both approaches have a growing evidence base across a variety of mental health difficulties.[22,25] COPESS may help to increase a person's insight into their self-harm and their understanding of the emotional states and relational experiences linked to this, resulting in better awareness and management of emotions. COPESS was originally developed for use in a hospital emergency department setting, for patients presenting with self-harm or related difficulties.[26] Given the initial promise of the approach, it has now been adapted to provide a similar, quick-access psychological intervention, but with the focus on those presenting to their GP with self-harm.

The aim of this trial was to determine the feasibility of undertaking a larger-scale evaluation of COPESS for adults with recent self-harm and depressive symptoms, using a randomised controlled trial (RCT) design. The acceptability and safety of the trial procedures and intervention were also assessed. Participants were randomly allocated to either COPESS plus treatment as usual (TAU) or TAU alone. Although this trial focused on feasibility, clinical outcomes including self-harm ideation, self-harm urges, psychological distress and depressive symptoms were also assessed, and 95% confidence intervals for treatment effects were estimated. These estimates were used to provide an initial indication of the potential clinical promise of the approach. Effects on emotion regulation, a putative mediator, were also estimated, and the feasibility of collecting the data required for an economic evaluation of COPESS was also assessed.

Method

Design

The trial was a single-blind, randomised controlled feasibility trial with an embedded qualitative process evaluation. Following baseline assessment, 55 (of an initial target of 60) participants were randomised 1:1 to receive COPESS plus TAU or TAU alone. The number was reduced to 55 owing to high attrition. Randomisation was stratified by general practice and undertaken by an independent statistician who generated a random sequence using permuted blocks of sizes 4 and 6 in Stata version 15 for Windows (StataCorp LLC, College Station, TX, USA). The independent statistician informed the principal investigator of participant allocations, who then informed the participant and their GP. Owing to budget limits, we had only one researcher who had to be blinded; hence, the principal investigator did this, as their role also included project managing the feasibility study. Follow-up assessments were completed at 1, 2 and 3 months after randomisation. The researcher completing assessments with participants was blind to allocations. The trial was pre-registered (clinicaltrials.gov identifier: NCT04191122), and the protocol has been published.[15]

This paper adheres to the Consolidated Standards of Reporting Trials (CONSORT) statement extension to pilot and feasibility trials.[27] The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2013. All procedures involving human participants and/or patients were approved by the NHS Health Research Authority and Wales Research Ethics Committee (ref: 20/NW/0063) Integrated Research Application System on 20 February 2020. The qualitative process evaluation will be presented in a separate paper. The trial took place during the COVID-19 pandemic and associated lockdowns in the UK. Consequently, the option to have both research and therapy appointments occur online via video call was made available.

Participants

Participants were patients at GP practices with recent self-harm and depressive symptoms. To be eligible, individuals had to (a) be aged 16 years or over; (b) have self-harmed in the past 6 months; (c) score ≥14 on the Beck Depression Inventory-II (BDI-II),[28] indicating mild to severe depression; and (d) be help-seeking, as indicated by presentation at the GP practice or self-referral into the trial. Eligible participants had to have presented with self-harm thoughts and/or behaviours and also be known to have depressive symptoms. Individuals were excluded if they were non-English speaking, diagnosed with an intellectual disability as indicated by their clinical notes, suicidal or already receiving a psychological therapy for self-harm (excluding group support and counselling or regular nurse appointments that did not entail the delivery of a specific talking therapy involving a structured model using a person-centred approach).

Participants were recruited from 14 GP practices in the Liverpool metropolitan area in the north-west of England (see Supplementary Table 1 available at https://doi.org/10.1192/bjo.2025.10780 for practice size, number of letters sent, responses and patients recruited to the trial). Patient records at participating practices were screened, and potentially eligible individuals were invited by letter to take part in the trial. The review of the patient records was completed by administrators within each GP practice. As noted in the published protocol,[15] self-harm codes were searched within the GP recording systems. Patients had to have a history of self-harm, so if this had not been coded or written in patients' clinical notes, they may not have appeared on the search system within the clinical records. GPs and other clinical staff at the practice could also directly refer patients they had met with who agreed to this. Adverts were also placed in GP practices, walk-in centres and other relevant settings (e.g. psychology and counselling services), allowing individuals to self-refer into the trial. Individuals who expressed an interest in taking part were screened for eligibility by telephone or video call, and audio-recorded consent was completed by the trial researcher.

Interventions

COPESS

COPESS consisted of four weekly sessions, lasting around 50 min each, with a fifth follow-up session occurring 8 weeks after the start of therapy. Sessions could occur in person or be delivered remotely via video call, depending on preference and COVID-19 requirements. The therapy involves helping clients that experience difficult emotional states and establishing an understanding of how these are linked to self-harm. This includes developing awareness and understanding of how the client relates to themselves and their interpersonal relationships with others. The therapy focuses on experiences in the 'here and now' and encourages therapists to identify cues relating to feelings occurring in the moment and to stay with these feelings. The use of a visual map, taken from CAT, is used to help build a shared understanding of a client's experiences and difficulties and the factors underlying their self-harm. The therapy was delivered by five band 6 mental health nurses (salary ~£39 405 per year). In the UK, band 6 nurses have crucial roles in the education and training of nursing staff, healthcare assistants and students. They are responsible for facilitating learning opportunities, providing clinical supervision and contributing to the professional development of their colleagues. Training involved a 4-day short course that introduced the principles of working with PIT

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and CAT and their applications in clinical practice. Clinical supervision was provided fortnightly by a psychotherapist with experience of the approach (band 7 therapist; salary ~£48 526 per year). Band 7 nurses possess extensive clinical knowledge and skills in their specialised area of practice. They use their expertise to assess and diagnose patients accurately, develop appropriate treatment plans and deliver high-quality care. They also provide supervision to band 6 nurses as described above. To ensure the standard therapy approach was being adhered to, therapists were offered feedback during supervision. All sessions were recorded with the consent of participants.

TAU

Participants in either arm were able to continue to access usual care while taking part in the trial, except for talking therapies. At the point of randomisation, the participant could not be receiving a talking therapy. They could be referred and on a wait list (as the majority were) but not actively participating in sessions. If they were randomised to TAU, they could carry on as normal and take part in therapy (e.g. CBT) when the opportunity arose. All the participants in the study were still waiting for therapy once they had completed their final follow-up. Although there is no clear treatment pathway for people who present to primary care services for self-harm, the trial team provided additional information to clinicians regarding the care recommended by the National Institute for Health and Care Excellence (NICE) for people who self-harm, on the basis of the latest guidelines available at the time.[1] The NICE guidelines advise against the use of pharmacological treatments for self-harm; instead, they recommend psychological interventions tailored to self-harm that may involve problem-solving, cognitive–behavioural or psychodynamic elements. This information was provided to help ensure TAU adhered to NICE recommendations.

Therapy fidelity

All sessions for nine participants who had received and completed the COPESS intervention were reviewed. These were randomly selected from a potential 28 completed cases during the trial study period. The fidelity measures focused on whether the COPESS therapists delivered COPESS in adherence to the COPESS manual and training. We reviewed the cases for nine participants who started but did not complete the intervention as well as those who attended every session. Document analyses of internal records auditing a random sample of selected cases were performed to evaluate fidelity of adherence to the planned delivery of COPESS. A total of nine cases represented three cases per three COPESS therapists. Recorded sessions were rated by the therapy supervisor using a bespoke COPESS therapy fidelity assessment to ensure adherence to the approach (Supplementary Table 2). Each item was rated on a seven-point Likert-type scale ranging from 1 (item not at all present) to 7 (item considerably present). For each item, a competency seven-point Likert-type scale was developed, ranging from 1 (not adherent) to 7 (fully adherent), with 3 indicating 'some adherence' and 5 'quite a lot'. Adherence and competency were calculated by averaging the points awarded (Supplementary Table 3). A score of less than 3 (range $0 < 3$) was considered to indicate an unacceptable level of fidelity, and scores of 4 and above were acceptable (range 4–7).

Outcomes

The primary outcomes for the trial concerned feasibility, acceptability and safety of COPESS and the trial procedures. Progression targets, outlined in Table 1, included successful recruitment and randomisation of participants, participant retention at follow-up assessments, attendance at therapy sessions, and rates of missing data on clinical outcome measures. Acceptability of the intervention was further investigated via the embedded qualitative component; the results of this investigation will be presented in a separate paper. The safety of the COPESS trial and intervention was assessed through monitoring of adverse events and serious adverse events (SAEs) across both trial arms. In addition, the Adverse Experiences in Psychotherapy self-report measure[28] (Supplementary Table 5) was used to identify adverse experiences that occurred within the COPESS therapy. Hospital admission 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.

A series of standardised tools and scales were used for secondary outcome measures. Data completeness (overall and by scale) at each follow-up point was assessed to help us to judge the suitability of the measures for inclusion in a future efficacy RCT. The measures are summarised below, and further details are provided in the protocol.[15] Clinical outcomes related to self-harm and depressive symptoms. The Self-Injurious Thoughts and Behaviours Interview Short-Form[29] sections on non-suicidal self-injury thoughts and behaviours were delivered in a questionnaire format. The Alexian Brothers Urge to Self-Injure Scale[30] was used to assess the severity of urges to self-injure over the preceding 7 days. This self-report measure has scores ranging from 0 to 30, with higher scores indicating more severe urges. In this data-set, the item was scored 1 to 7 (versus 0 to 6); therefore, the scores ranged from 5 to 35. The BDI-II was used to assess depressive symptoms occurring over the past 2 weeks. This is a widely used and well validated self-report measure; scores range from 0 to 63, with higher scores indicating greater depressive symptomology.[28] Psychological distress was assessed with the Clinical Outcomes in Routine Evaluation scale (CORE-10).[31] This ten-item self-report scale assesses psychological distress over the preceding week, with scores ranging from 0 to 40 and higher scores indicating greater distress.

For mechanistic variables related to emotion regulation and the therapeutic relationship, we used the Emotion Regulation Questionnaire,[32] which assesses the ways in which people regulate their emotions across two subscales relating to emotional suppression and re-appraisal. Scores range from 10 to 70, with higher scores indicating greater use of that emotion regulation strategy. We report data for the two subscales with ranges of 6 to 42 (cognitive reappraisal) and 4 to 28 (expressive suppression). We also used the Helping Relationship Questionnaire-II,[33] which measures participants' perceptions of the therapeutic relationship. Scores range from 19 to 114, with higher scores indicating a greater therapeutic alliance. This scale was completed as part of the online follow-up questionnaires and was only directed to those who stated they were in the COPESS arm of the trial.

We also assessed the feasibility of collecting the data required for an economic evaluation of COPESS by investigating completion rates of two measures: the Client Service Receipt Inventory,[34] which was used to collect data on participants' healthcare service use during the course of the trial; and the EQ-5D-5L,[35,36] a questionnaire measuring perceived quality of life across multiple domains, which can be used to estimate quality-adjusted life years as part of an evaluation of the cost-effectiveness of an intervention.

Procedure

Participants were invited to a baseline eligibility assessment which took place remotely via video call (owing to COVID-19 restrictions) before consent was obtained. Baseline and follow-up questionnaires were completed remotely via online surveys at three time points (1, 2 and 3 months) (Supplementary Table 4). Participants were randomised following baseline data collection.

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Table 1 Trial progression criteria

Progression criteria	Red (stop)	Amber (discuss and amend)	Green (go)
Patient participant recruitment (targeting n ~60)	<20% of eligible patients	20–69% of eligible patients	≥70% of eligible patients at a rate of three per month
Acceptability of intervention	<20% of patients to attend all sessions	20–40% to attend all sessions	≥40% of patients to attend all sessions
Outcome data completeness	Missing data ≥60%	Missing data <60%	Missing data <20%
Participant retention by T3	<40% participant retention at T3	40–70% participant retention at T3	≥70% participant retention at T3

T3: Follow-up timepoint 3.

Statistical analysis

We aimed to recruit 60 participants, following recommendations that this is sufficient to assess feasibility outcomes and estimate key parameters (such as the standard deviation of potential outcomes) with adequate precision to determine the sample size for a definitive full trial. Owing to high retention, the number was reduced to 52 participants. Analyses followed an intention-to-treat approach. Frequencies and percentages with associated 95% confidence intervals were used to summarise recruitment, retention and therapy session attendance rates. Adverse events and SAE were also summarised overall and by trial arm. Clinical and mechanistic outcomes were summarised with descriptive statistics at baseline and at the 3-month follow-up point for both arms. Rates of missing data were also reported for each outcome as frequencies and percentages. Treatment effects were estimated via linear regression models, where trial arm was the independent variable and age, gender and baseline scores for the outcome were included as covariates. Analyses were undertaken in Stata version 15 for Windows.

Public and patient involvement

The trial included six members of the public and patients who had lived experience of self-harm and depressive symptoms. They were involved from the outset of the study, including its design. Public advisors, who are members of the public and/or patients with knowledge of COPESS and the locality in which it is delivered, were involved in a series of meetings to make decisions about data collection materials, recruitment strategies and the planned analysis. Three public advisors (C.M., K.K.-M. and N.T.) are co-authors of this paper and contributed to the drafting of the paper and interpretation of the results.

Ethics approval and consent to participate

Ethical approval was granted by the Health Research Authority on 10 June 2020 for the feasibility trial. All participating therapists and GPs provided fully informed written consent before being interviewed, as did all research participants with a history of self-harm before being randomised. The trial was registered on 9 December 2019 (registration: NCT04191122; Liverpool Central Research Ethics Committee approval reference: 275047). The start date of the trial was delayed owing to COVID-19, and the intervention and data collection were adapted for the pandemic and commenced in late 2020.

Results

Recruitment

Fourteen GP practices were recruited into the study between September 2020 and August 2021, covering a total of $n = 170\,592$ registered patients (Supplementary Table 1). GP record searches identified 521 potentially eligible patients, who were each sent an invitation letter. A median of 20 patient invitation letters were sent per site; however, the total range was large (0 to 262). 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 of 521 (15%) contacted the research team, and 62 of 521 (12%) people were screened as eligible. The first participant was recruited on 16 November 2020. A total of 55 of 521 (11%) participants were randomised: 28 to COPESS and 27 to TAU. The flow of participants through the trial is shown in Fig. 1.

Sample characteristics

Table 2 shows demographic information for all participants included in the trial. Most participants were aged 16 to 30 years ($n = 42$, 76%), split evenly between the two trial arms. More men were allocated to the TAU arm ($n = 10$, 37%) compared with the COPESS arm of the trial ($n = 3$, 11%). The sample was largely White British. Of those participating in the trial, 31 (71%) were students.

Participant attrition and therapy engagement

Participant attrition, including reasons for leaving the study, is indicated in Fig. 1. In total, 43 participants (78%) completed all assessment points. The progression criteria regarding attrition were therefore met. Reasons for participants leaving the study early are unknown. Rates of attrition were similar between the two arms of the trial. Twenty participants (71%) of the 28 allocated to COPESS attended all treatment sessions, six (21%) attended three or more sessions and two (7%) did not attend any sessions. Owing to participants not responding to researcher contact, reasons for non-attendance of sessions were not known.

Data completeness

All 43 participants who were still in the study at 3 months fully completed the clinical outcomes; hence, the progression criterion was met.

Safety

No reported adverse experiences were attributed to the trial. On the Adverse Experiences in Psychotherapy measure[37] (Supplementary Table 5), there were eight instances of scores of 3 or above (agree 'quite a lot' or 'very much') endorsing adverse experiences. Three participants reported that taking part in the therapy had not helped their problems, and one of these people reported that taking part led to their mood becoming very low. One person reported that they did not feel ready to talk about their problems, and two reported that taking part made them think too much about bad things that had happened in the past and that they felt embarrassed talking about their problems with people they had not met before.

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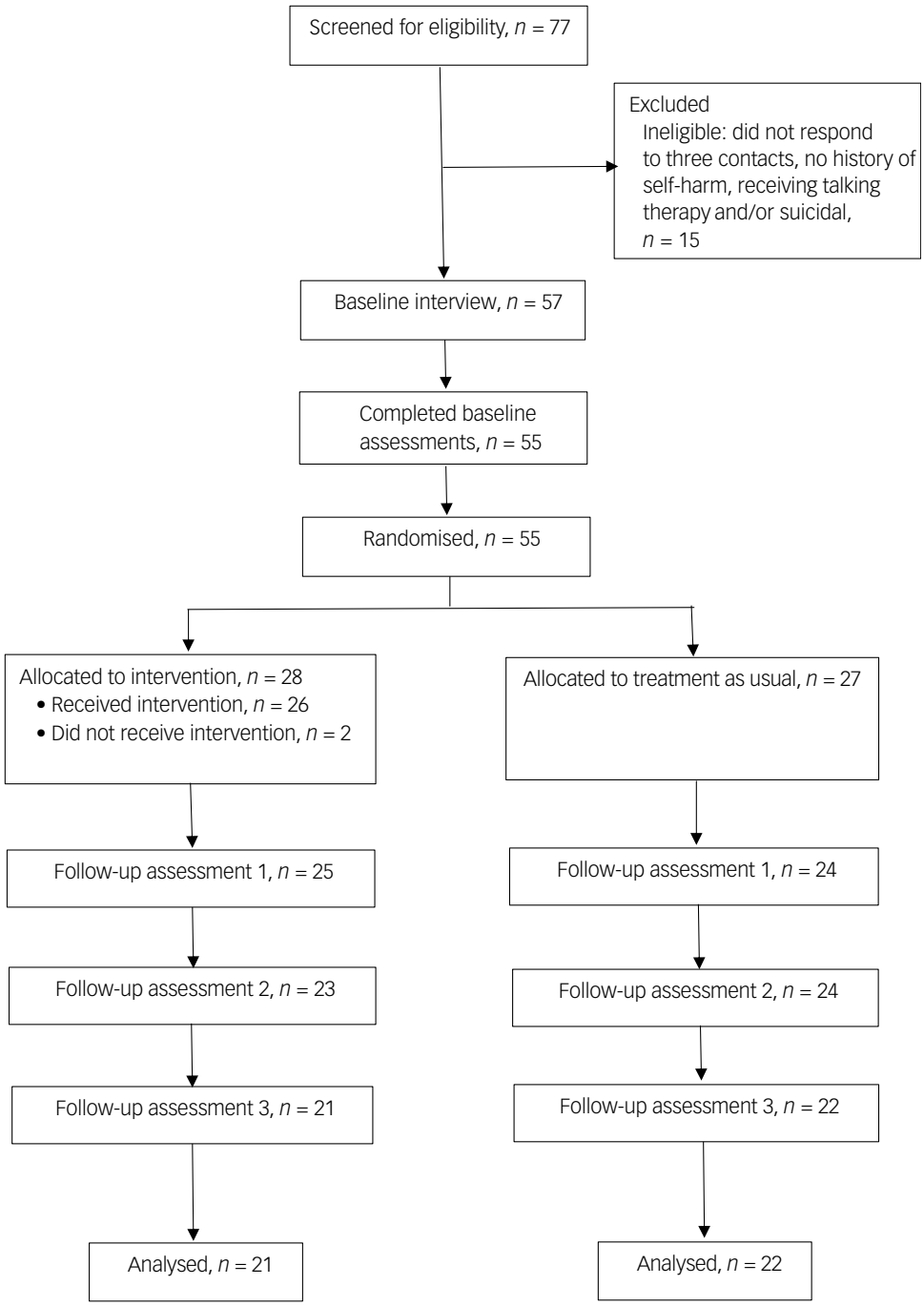

Fig. 1 CONSORT flow chart of the Community Outpatient Psychotherapy Engagement Service for Self-harm trial design.

Two participants indicate that their problems had improved to the point that they no longer needed the intervention.

One SAE was reported for a participant randomised to the intervention arm, via the COPESS therapist, who became aware that the participant had attended a hospital emergency department multiple times since entering the trial for worsening mental health and increased suicidal intent. However, this SAE was not attributed to the trial and became apparent when the therapist contacted the participant. Following consultation with the trial team and trial steering group, this was not deemed to be related to the trial. Following the COPESS therapist's consultation with the participant, it was agreed that the participant should be referred to secondary mental health services for stepped-up care within the mental health trust. Baseline assessment included thoughts during the 7 days before assessment and therefore preceded the start of the COPESS therapy but followed enrolment in the study more generally. Of the 55 participants, at baseline, 15 people (27%) indicated acts of self-harm within the previous week, compared with 14 (of 49, 29%) at follow-up 1, nine (of 47, 19%) at follow-up 2 and six (of 42, 14%) at the final follow-up. Following consultation with the trial team and trial steering group, this was not deemed to be related to the trial. All participants who reported self-harm or suicidal ideation at baseline and follow-up met the inclusion criteria for the study as they were judged not to be at imminent risk by both their GP and the research team.

Therapeutic alliance

Therapeutic alliance between participants and COPESS therapists was high (Supplementary Table 6).

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Table 2 Sociodemographic characteristics of patients by treatment group

Demographic characteristics	All patients, *n* (%)	COPESS group (*N* = 28), *n* (%)	TAU group (*N* = 27), *n* (%)
Age group (*n* = 55)			
16–20 years	20 (36.4)	10 (35.7)	10 (37)
21–30 years	22 (40.0)	11 (39.3)	11 (40.7)
31–40 years	7 (12.7)	4 (14.3)	3 (11.1)
41–50 years	2 (3.6)	2 (7.1)	0 (0.0)
51–60 years	4 (7.3)	1 (3.6)	3 (11.1)
Gender (*n* = 55)			
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)
Ethnicity (*n* = 35)			
White British	33 (94)	17 (94.4)	16 (94.1)
Mixed ethnicity	2 (6)	1 (5.6)	1 (5.9)

COPESS, Community Outpatient Psychotherapy Engagement Service for Self-harm; TAU, treatment as usual.

Fidelity outcomes and adherence ratings

Audit results indicated a good level of adherence to the planned delivery of COPESS. Forty-five sessions were rated for adherence to the model. Across the domains of the fidelity assessment, two therapists were adherent to each aspect of model delivery, and one was adherent to most elements of model delivery (Supplementary Table 3). Most participants engaged with all components of the intervention, including high attendance at therapy sessions, completion of co-produced 'maps' and engagement with the 'goodbye letter'.

Secondary outcomes

Table 3 reports descriptive statistics for each outcome measure at baseline and at 3-month follow-up. All outcomes appeared to have sufficient variation in their individual scores, and no obvious floor or ceiling effects were present. The average improvement in scores on the CORE-10 (indicating lower levels of psychological distress) was greater in the COPESS intervention arm (8.3 units improvement) than in the TAU arm (2.4 units improvement). Only one participant in the former group reported an increase in psychological distress, and this was only by two units. Average improvement in BDI scores (indicating lower levels of recent depressive symptoms) was also greater in the COPESS intervention arm (10.8 units improvement) than in the TAU arm (2.4 units improvement). Only three participants in the former group reported an increase in depressive symptoms. Changes on the Emotion Regulation Questionnaire subscales were more modest in both groups. In the TAU group, average scores increased at follow-up by one unit on both subscales. By comparison, average cognitive reappraisal scores increased by 5.4 units in the COPESS intervention arm, indicating improvement (i.e. more frequent usage) in this aspect of emotional regulation. Average scores on the Alexian Brothers Urge to Self-Injure Scale 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 it was greater in the COPESS intervention arm (2.9 units) than in the TAU arm (1.2 units).

A preliminary treatment effect estimate was calculated, along with 80% and 95% confidence intervals, for the difference between treatment groups using linear regression (Table 4). The intention was to help inform a power calculation for a larger trial, not to test intervention effectiveness (hence *P*-values are not quoted). The outcome in the regression model was the 3-month post-treatment score on each variable, with the respective baseline score, age group (recoded as 16–20, 21–30 or >30 years to help overcome the problem of small numbers in the regression analysis), gender (male or 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 identified as male at later follow-up sessions and was included as male in the analysis. Treatment effects appeared to favour COPESS for improvements in psychological distress (CORE-10) and depressive symptoms (BDI-II); however, a larger effectiveness trial is needed.

Discussion

This trial was the first in the UK to explore the feasibility and acceptability of the delivery of COPESS for self-harm within UK community settings. The primary objective of this study was to determine whether the delivery of a brief psychological intervention for self-harm is feasible and acceptable within UK community settings. The findings of this study have potential implications for patients presenting after self-harm, their carers, allied health professionals, academics and health services in England. We found that the intervention and trial methods were feasible and acceptable to participants, and all progression criteria outlined in the trial aims for a future RCT were met.

These findings add to the growing evidence base supporting the utility of brief psychological interventions for self-harm. Our results suggest that frequency of self-harm and urges to self-harm were significantly reduced in patients randomised to COPESS compared with patients receiving TAU. Patients receiving COPESS also had significant reductions in distress and symptoms of depression and an improvement in emotional regulation. Data completeness of secondary outcomes measures was high. Training, competency and fidelity to the manualised COPESS therapy were judged to be acceptable, and positive delivery fidelity was evidenced by auditing the COPESS intervention. No adverse events were recorded, and COPESS was deemed to be a safe intervention.

With specific regard to COPESS, the flexibility, simplicity and practicality of the intervention and interactions with the researcher were reported as important facilitators of initial and ongoing engagement in the trial. Although the intervention was manualised, there was flexibility within its delivery to meet the needs of each individual participant. Similar findings have been reported with respect to the positive role of person-centred care within brief psychological interventions for self-harm,[19] particularly the lasting effects of collaborative tools that can be used after therapy sessions have been completed. However, owing to completion of the 'maps' being online, therapists needed to conduct more work out of sessions than they would have had the sessions been face to face. Long term, this may have been seen as a barrier; however, the future trial should include face-to-face sessions, which may remove this potential issue.

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Table 3 Descriptive statistics for each outcome measure at each of the assessment points

Outcome	Trial arm 1				Trial arm 2			
	Baseline	Baseline (if response at month 3)	Month 3	Change (month 3 to baseline)	Baseline	Baseline (if response at month 3)	Month 3	Change (month 3 to baseline)
N	28[a]	21[a]	20	20[a]	27	22	21	21
CORE-10, mean (s.d.), median (IQR), observed range	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)
	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)
	7 to 36	7 to 36	4 to 34	−27 to 2[b]	10 to 35	12 to 35	9 to 38	−16 to 11
BDI, mean (s.d.), median (IQR), observed range	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)
	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)	−1 (−9, 2)
	7 to 51	7 to 51	3 to 50	−32 to 7[c]	16 to 53	16 to 51	13 to 58	−26 to 22
ERQ-CR, mean (s.d.), median (IQR), observed range	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)
	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)
	7 to 34	11 to 34	6 to 40	−7 to 18[d]	6 to 32	6 to 32	6 to 36	−12 to 18
ERQ-ES, mean (s.d.), median (IQR), observed range[a]	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)
	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)
	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 (s.d.), median (IQR), observed range	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)
	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)
	5 to 34	5 to 34	5 to 34	−24 to 8	5 to 35	5 to 35	5 to 35	−19 to 22

ABUSI, Alexian Brothers Urge to Self-Injure Scale; BDI, Beck Depression Inventory; CORE, Clinical Outcomes in Routine Evaluation; ERQ-CR, Emotion Regulation Questionnaire cognitive re-appraisal subscale; ERQ-ES, Emotion Regulation Questionnaire emotional suppression subscale; IQR, interquartile range.
a. *N* is one less than the value stated for the ERQ-ES outcome.
b. Only one value was >0.
c. Only three values were >0.
d. Only three values were <0.

Table 4 Linear regression for differences between treatment groups at 3-month follow-up

Outcome	80% CI	95% CI
CORE-10	3.15, 9.54	1.38, 11.31
BDI-II	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

ABUSI, Alexian Brothers Urge to Self-Injure Scale; BDI, Beck Depression Inventory; CORE, Clinical Outcomes in Routine Evaluation; ERQ-CR, Emotion Regulation Questionnaire cognitive re-appraisal subscale; ERQ-ES, Emotion Regulation Questionnaire emotional suppression subscale.

Fidelity of the intervention

Fidelity to the manualised COPESS therapy was moderate to high. Expansion of the COPESS intervention and the inherent involvement of more therapists delivering COPESS will need to be reviewed in a larger trial. Here, fidelity referred to the extent to which the COPESS intervention was delivered as planned.[37,38] Assessment of fidelity determined whether the COPESS intervention outcomes could be attributed to intervention content and components, rather than unaccounted factors such as variations in the intervention's implementation and/or omission of intervention components.[39] For a future trial, it will be pertinent to understand the degree of fidelity adherence in the delivery of COPESS to ensure confidence in the interpretation of reported outcomes and replication when the trial is conducted across multiple sites.

Strengths and limitations

In terms of trial procedures, including recruitment, data collection and follow-up, no major barriers were encountered despite the trial taking place during the COVID-19 pandemic, and the trial progressed as planned. The number of invitational letters sent out seemed low compared with the 5% estimated levels of self-harm in primary care. However, searches depended on GP practices coding for self-harm or recording self-harm within patients' clinical notes. If this was not present, some people may not have been identified to participate in the trial. McManus et al[40] reported that although the prevalence of non-suicidal self-harm has increased in England, the resultant service contact remains low. This may be another reason the numbers in primary care were lower than the estimates. In addition, for a talking therapy, there needs to be readiness to engage with the therapy, which will limit the proportion responding. This may have been exacerbated by the therapy being offered as part of a research study but also potentially mitigated by the offer of rapid access to therapy through participation in a trial, if allocated the intervention arm. Of those participants who initially contacted the researcher about the COPESS trial, almost 80% agreed to take part in the trial, and none subsequently withdrew. Public involvement and engagement were embedded in the trial from the outset. We recommend using the same process of public involvement in future trials and will aim to engage with more young adults in any future trial to reflect the typical ages of the trial participants (19–24 years). Some further limitations were encountered during the trial. Participants in both trial arms were asked to provide information via online surveys, but this was reliant on accurate self-reports. We did not control for the non-specific effects of the psychological intervention in this trial, and the effects of COPESS may have resulted from non-specific factors such as increased contact with therapists. However, other studies that have involved a similar intensity of clinical contact did not show a significant improvement on several of the outcomes,[41] although some CBT-based interventions have been reported to be superior to routine care.[42] University students made up a significant proportion of the sample (71%), and the overall sample was a young adult rather than lifespan adult group. We recognise that some of the participating GP practices were in university areas. Owing to COVID-19, the trial was completed fully online, and younger adults and students may therefore have been more open to accessing the trial intervention. Student counselling is now largely delivered in partnership with the National Health Service, with 'in house' services focusing on student support rather than therapeutic interventions. With regard to access to pastoral and psychological care within university settings, previous research[15] has found that some students prefer to access mental health support via their GP so that it does not affect their studies. Finally, the proportion of participants who identified as being from ethnic minority backgrounds (6%) was lower than that of the local populations (9%; 49). We note that cultural differences can affect help-seeking for self-harm, and that people from ethnic diverse groups are more likely to present late to accident and emergency departments. Owing to the lack of diversity in the sample, future trials should widen participation to more diverse locations with more varied demographics. It will also be important to explore whether the intervention needs further tailoring for those of different ages and from ethnic minority backgrounds; thus, trial sites should include GP practices in areas with higher levels of diversity.

Clinical implications

The preliminary results of this feasibility trial, which indicated that the COPESS intervention may bring about a reduction in self-harm morbidity and an improvement in health-related quality of life, offer a foundation for future research and may aid the translation of findings into action in primary care and community settings. A future trial will explore implementation outcomes in addition to efficacy and/or cost-effectiveness to confirm the utility of COPESS in primary care settings. Individuals who present to health services after an episode of self-harm offer a critical opportunity for targeted intervention to reduce the risk of further harm. For patients who consult in primary care with a recent history of self-harm, we have shown that frequency of self-harm, urges to self-harm, distress and depressive symptoms can be significantly reduced after a brief psychological intervention.

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Supplementary material

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Data availability

The data that support the findings of this study are available from the corresponding author, P.S., upon reasonable request.

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Author contributions

P.S., P.T., H.M. and C.K. conceived the trial. P.S., C.K., H.M., P.T., M.G., R.D., M.H., A.M., C.M., C.C. and E.G. participated in the design of the trial. A.H., P.T. and P.S. drafted the manuscript, and C.K., H.M., M.G., R.D., M.H., C.M., C.C. and E.G. revised it. All authors read and approved the final version.

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Declaration of interest

None.

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