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Remote psychosocial interventions to prevent avoidable psychiatric hospital admissions in people with serious mental health problems: a multi-arm multi-stage trial

Submission date
16/06/2022

Recruitment status
No longer recruiting

Registration date
20/06/2022

Overall study status
Ongoing

Last Edited
19/08/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

People with serious mental health problems (SMHP) are more likely to be admitted to psychiatric hospital following contact with crisis services. Pressure on hospital beds is made worse by the extra impact on crisis care, and hospital admissions can be traumatic; because of COVID-19 admitting someone to hospital can be additionally problematic. People with SMHP are vulnerable to COVID-19 due to increased risk of underlying physical health problems, medication effects and engagement with services. There is an urgent need for treatments to address suicidal thoughts/behaviours and reduce avoidable hospital admissions. We will conduct a multi-site trial to find out which brief and remotely delivered treatments are helpful for people with SMHP with recent suicidal thoughts/suicide attempt. The main question is whether the treatments are more effective in reducing hospital admissions over a 6-month period compared to usual treatment (TAU), and if these treatments provide value for money. We will assess the impact on suicidal thoughts and behaviour, hope, recovery, anxiety, and depression.

Who can participate?

People aged 16 years or older, with SMHP with recent suicidal thoughts/suicide attempt.

What does the study involve?

All treatments will be delivered remotely. We will compare the following treatment groups delivered for 3 months: 1) Structured peer support, 2) A safety planning approach delivered by assistant psychologists, and 3) TAU. Treatment allocation will be decided by chance. 200 people will participate in a smaller trial to see if there is interest in the study. 791 people to take part in the main trial. We will complete questionnaires with people at baseline, 3 months, and 6 months to see if the treatments have been helpful. To understand whether the treatments are working, we completed a planned interim analysis using the results from 365 people recruited to SAFETEL, PREVAIL and TAU. Following the planned interim analysis the trial design changed from a three-arm to a two-arm trial with one intervention (SAFETEL) in comparison to TAU.

What are the possible benefits and risks of participating?
Possible benefits: although we cannot guarantee it, we hope that people receiving one form of support will find it helpful for coping with distressing thoughts and feelings. The findings from the trial may also help advance and increase the support other people with similar problems in the future. This is because if any of the two forms of remote support are shown to work, then we will aim to make them more widely available within the NHS. Possible risks: It is possible that talking about some mental health experiences either during the research assessment or as part of the support sessions the content may be upsetting.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
April 2022 to January 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Melissa Pyle, melissa.pyle@gmmh.nhs.uk

Study website
https://www.psychosisresearch.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
307657

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52806, IRAS 307657

Study information

Scientific Title
Remote Approaches to Psychosocial Intervention Delivery

Acronym
RAPID

Study objectives
Compared to TAU, our brief, remote interventions plus TAU will lead to:
1. Reduction in psychiatric hospital admissions over 6 months (primary outcome)
2. Reduction in psychiatric hospital admissions over 3 months
3. Reduction in suicidal ideation over 3 and 6 months
4. Improvement in user-defined recovery and quality of life over 3 and 6 months
5. Interventions will be cost-effective over 6 months in comparison to TAU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/06/2022, London – Stanmore Research Ethics Committee (2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 207 104 8387; stanmore.rec@hra.nhs.uk), ref: 22/LO/0326

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Serious mental health problems

Interventions
Current interventions as of 19/09/2024:
Following the results of the planned interim analysis, RAPID will move to a two-arm trial in Stage 2 with one brief and remotely delivered intervention in comparison to TAU. The intervention in Stage 2 is SAFETEL.

Previous interventions as of 12/06/2023:
The RAPID Trial will evaluate the clinical and cost-effectiveness of two, brief and remotely delivered interventions in comparison to TAU. An overview of each intervention is provided below.

SAFETEL
SAFETEL is a brief, innovative evidence-based clinical intervention and participants will be offered up to 12 sessions over 12 weeks. It is remotely delivered either by telephone or MS Teams and is implemented by assistant psychologists (APs).
In the initial phase of delivery, a safety plan is developed collaboratively. It has six components: i) identifying warning signs of an impending suicidal crisis; ii) utilising internal coping strategies; iii) engaging social contacts & social settings to distract from suicidal thoughts; iv) contacting social supports for assistance in resolving the suicidal crisis; v) contacting mental health professionals; vi) minimising access to lethal means.). The suitability and likelihood of employing these strategies during a suicidal crisis are explored, as well as examples of such strategies being provided. Follow-up contacts are provided over a period of 12 weeks. The follow-up calls comprise three components: 1) suicide risk assessment and mood check; 2) review of the participant's safety plan, with revisions made if required; 3) supporting treatment engagement through exploration of barriers to engagement, motivational enhancement, problem-solving and support.

The core element of SAFETEL is the collaborative development of the Safety Plan (within the 1st session). This is a prioritised list of coping strategies and supports that individuals can use during or preceding suicidal crises. It has been developed to also address challenges in continuity of care across vulnerable transitions. SAFETEL incorporates telephone follow-up to conduct periodic risk assessment and mood checks. This allows for the continuous review of the Safety Plan and provides opportunities to problem-solve obstacles to treatment and help with linkage to services, if necessary. It actively incorporates evidence-based suicide prevention strategies, including facilitation of problem-solving and coping skills, identification and use of social supports and emergency contacts, lethal means restriction, service linkage, and motivational enhancement to promote community treatment engagement.

PREVAIL (Peers for Valued Living)
Up to 12 remotely delivered sessions of PREVAIL over 12 weeks (choice of telephone or video-conferencing delivery will be offered). It is delivered in three phases: i) assessment and getting to know you ii) active involvement and iii) ending and consolidation. The intervention utilises common elements of PS, including supportive listening and sharing of one's own recovery story; such activities are adapted to working with people at high risk for suicide. In addition to adherence to the principles and values of PS (shared lived experience; reciprocity and mutuality; validating experiential knowledge; choice and control; discovering strengths and making connections), semi-structured conversations incorporate suicide prevention strategies derived from cognitive behavioural therapy (CBT) and motivational interviewing, including goal setting,

distress tolerance, and increasing optimism and social connectedness. These conversations use a standardised format including the steps of Invite, Learn, Share, and Motivate (ILSM). In the Invite step, permission is sought from the participant to have a conversation about a hope or belongingness-related topic. During the Learn step, information regarding what the participant has already tried and what the participant thinks might be helpful or relevant to their situation is elicited. During the Share step, helpful
suggestions are made on the basis of the PSW's personal experience or knowledge. Finally, the Motivate step engages the participant in "change talk," including how taking action might be helpful to them and how they might implement changes.

These sessions also involve safely addressing suicidal crises; to detect and address acute suicide risk, PSWs ask about suicidal thoughts or behaviours at each encounter. If endorsed, the PSWs use a scripted risk assessment algorithm to gather additional information regarding any recent suicidal behaviours, whether suicidal ideation has worsened since the thoughts were last discussed with a clinician and the person's level of intent to act upon their thoughts. If any of these risk factors are present, the PSW would then immediately contact the mental health clinician on-call for the study to review the assessment with the patient still present, and it would be the clinician's responsibility to determine the necessary next steps to ensure safety.

It is expected that the final phase, focusing on endings, consolidation and future directions (including future access to peer support) will span sessions 11-12 (approximately), although endings and the time-limited nature of PREVAIL will be regularly discussed throughout all phases. The PSW may transition to a step-down phase at session 10 by moving to fortnightly contact. The aim of the final sessions is to consolidate learning, review what has been helpful and develop a plan to maintain gains. The format of this work will be flexible.

It is expected that peer relationships will offer emotional and instrumental support and promote hope through role modelling. PSWs will offer validation of the person's suicidal experiences and concerns by showing understanding through their own experiences and enabling the participant to engage in talking about their experiences and concerns relating to suicide and hopes for the future. These principles will be reflected in the fidelity checklist to ensure principles are adhered to; fidelity will be monitored using both PSW reports regarding session content and audio recordings of sessions. Adherence to the intervention will be defined as attending at least two peer support sessions.

The PSWs will be NHS employees with NHS mandatory training on safeguarding vulnerable adults.

Comparator
The control condition is treatment as usual (TAU), consisting of multi-disciplinary care delivered by HBTTs. Different psychosocial interventions are recommended in NICE guidelines for the different diagnostic groups, so there is no single active comparator that would be suitable. We will not ask referrers to withhold any treatment. All routine or additional treatments will be monitored.

Previous interventions:
The RAPID Trial will evaluate the clinical and cost-effectiveness of three, brief and remotely delivered interventions in comparison to TAU. An overview of each intervention is provided below.

SAFETEL
SAFETEL is a brief, innovative evidence-based clinical intervention and participants will be

offered up to 12 sessions over 12 weeks. It is remotely delivered either by telephone or MS Teams and is implemented by assistant psychologists (APs).
In the initial phase of delivery, a safety plan is developed collaboratively. It has six components: i) identifying warning signs of an impending suicidal crisis; ii) utilising internal coping strategies; iii) engaging social contacts & social settings to distract from suicidal thoughts; iv) contacting social supports for assistance in resolving the suicidal crisis; v) contacting mental health professionals; vi) minimising access to lethal means.). The suitability and likelihood of employing these strategies during a suicidal crisis are explored, as well as examples of such strategies being provided. Follow-up contacts are provided over a period of 12 weeks. The follow-up calls comprise three components: 1) suicide risk assessment and mood check; 2) review of the participant's safety plan, with revisions made if required; 3) supporting treatment engagement through exploration of barriers to engagement, motivational enhancement, problem-solving and support.

The core element of SAFETEL is the collaborative development of the Safety Plan (within the 1st session). This is a prioritised list of coping strategies and supports that individuals can use during or preceding suicidal crises. It has been developed to also address challenges in continuity of care across vulnerable transitions. SAFETEL incorporates telephone follow-up in order to conduct periodic risk assessment and mood checks. This allows for the continuous review of the Safety Plan and provides opportunities to problem-solve obstacles to treatment and help with linkage to services, if necessary. It actively incorporates evidence-based suicide prevention strategies, including facilitation of problem-solving and coping skills, identification and use of social supports and emergency contacts, lethal means restriction, service linkage, and motivational enhancement to promote community treatment engagement.

PREVAIL (Peers for Valued Living)
Up to 12 remotely delivered sessions of PREVAIL over 12 weeks (choice of telephone or video-conferencing delivery will be offered). It is delivered in three phases: i) assessment and getting to know you ii) active involvement and iii) ending and consolidation. The intervention utilises common elements of PS, including supportive listening and sharing of one's own recovery story; such activities are adapted to working with people at high risk for suicide. In addition to adherence to the principles and values of PS (shared lived experience; reciprocity and mutuality; validating experiential knowledge; choice and control; discovering strengths and making connections), semi-structured conversations incorporate suicide prevention strategies derived from cognitive behavioural therapy (CBT) and motivational interviewing, including goal setting, distress tolerance, and increasing optimism and social connectedness. These conversations use a standardised format including the steps of Invite, Learn, Share, and Motivate (ILSM). In the Invite step, permission is sought from the participant to have a conversation about a hope or belongingness-related topic. During the Learn step, information regarding what the participant has already tried and what the participant thinks might be helpful or relevant to their situation is elicited. During the Share step, helpful
suggestions are made on the basis of the PSW's personal experience or knowledge. Finally, the Motivate step engages the participant in "change talk," including how taking action might be helpful to them and how they might implement changes.

These sessions also involve safely addressing suicidal crises; to detect and address acute suicide risk, PSWs ask about suicidal thoughts or behaviours at each encounter. If endorsed, the PSWs use a scripted risk assessment algorithm to gather additional information regarding any recent suicidal behaviours, whether suicidal ideation has worsened since the thoughts were last discussed with a clinician and the person's level of intent to act upon their thoughts. If any of

these risk factors are present, the PSW would then immediately contact the mental health clinician on-call for the study to review the assessment with the patient still present, and it would be the clinician's responsibility to determine the necessary next steps to ensure safety.

It is expected that the final phase, focusing on endings, consolidation and future directions (including future access to peer support) will span sessions 11-12 (approximately), although endings and the time-limited nature of PREVAIL will be regularly discussed throughout all phases. The PSW may transition to a step-down phase at session 10 by moving to fortnightly contact. The aim of the final sessions is to consolidate learning, review what has been helpful and develop a plan to maintain gains. The format of this work will be flexible.

It is expected that peer relationships will offer emotional and instrumental support and promote hope through role modelling. PSWs will offer validation of the person's suicidal experiences and concerns by showing understanding through their own experiences and enabling the participant to engage in talking about their experiences and concerns relating to suicide and hopes for the future. These principles will be reflected in the fidelity checklist to ensure principles are adhered to; fidelity will be monitored using both PSW reports regarding session content and audio recordings of sessions. Adherence to the intervention will be defined as attending at least two peer support sessions.

The PSWs will be NHS employees with NHS mandatory training on safeguarding vulnerable adults

BrighterSide
BrighterSide mobile app is an interactive self-help app for adults designed to help those with suicidal thinking to understand their thoughts and develop the best skills and strategies to help manage them. This smartphone app consists of five modules of four components each: (1) theory; (2) a weekly assignment; (3) 2 to 3 exercises; (4) optional exercises to help consolidate relevant information and skills. Participants are instructed to complete one module per week and to spend 30 minutes per day using the programme. The programme contains five modules that use elements of cognitive behavioural therapy (CBT), and dialectical behavioural therapy (DBT). The module topics are: 1. Understand Your Thoughts; 2. Prevent a Crisis; 3. Navigate your Emotions; 4. Navigate Your Thoughts; 5. Plan for the Future.

BrighterSide was developed with significant input from people with lived experience of suicidality and involved five key design principles: Safety First – safety is paramount to protect the user from harm, and suicidal thought escalation - especially in high intensity periods; Respect –engagement with the Lived Experience community regarding the use of language within the app to ensure the design could better acknowledge and support our audience in their time of need; Empowerment – After downloading BrighterSide, users can access all modules, and can choose which pathway or activities they wish to complete and users can also revisit favourite activities they find helpful via their toolbox on the homepage; Simplicity – the flow and navigation within the app has been tested with our Lived Experience community to ensure it is intuitive for our end-users and to ensure they can quickly navigate with minimal effort; Trust – gaining the users' trust and acceptance that the content will help them, and that they are not alone on their journey.

BrighterSide allows users to personalise their experience with the following key features:
Safety Plan: Users can begin to create their Safety Plan during onboarding or wait to build it when they're feeling okay. The Safety Plan is designed to help users stay safe in a crisis or prevent an escalation and can be accessed from any screen within the app.
Daily Check-ins: taking a moment to check in can help users connect with their feelings. It is

optional, so can be skipped if preferred.
Coping Tools: This feature gives users access to calming and distracting techniques as recommended by our Lived Experience community. These tools can help users cope through the tough times or even reduce the intensity of thoughts in the event of a crisis until such time as they feel ready to speak to someone for further help.
Pathway selection: users can select the full program which takes them through the logical step-by-step approach, or they can try the thought, feeling or action-focused approach to access the program content. By allowing users to choose their own pathway it can better help support their needs and learning style.
Favourites: users can save their favourite activities and content, which gets added to a saved content folder on the home page, so users can quickly access these as needed.
BrighterSide will be provided to participants by an AP who will help to install the app and train them to use it, providing follow-up support if necessary. BrighterSide collects usage data that will facilitate the monitoring of fidelity and adherence to the intervention. Adherence will be defined as engagement with at least two of the five modules.

Comparator
The control condition is treatment as usual (TAU), consisting of multi-disciplinary care delivered by HBTTs. Different psychosocial interventions are recommended in NICE guidelines for the different diagnostic groups, so there is no single active comparator that would be suitable. We will not ask referrers to withhold any treatment. All routine or additional treatments will be monitored.

Intervention Type
Behavioural

Primary outcome measure
Psychiatric hospital admission (yes/no) over a 6 month period measured using patient records

Secondary outcome measures
Measured at baseline, 3 and 6 months
1. Suicidal thoughts and behaviours using The Columbia–Suicide Severity Rating Scale
2. Recovery assessed using The Process of Recovery Questionnaire
3. Health status using the EQ-5D-5L
4. The Recovering Quality of Life (ReQoL-10)
5. Wider NHS and social care use assessed by the Economic Patient Questionnaire
6. Anxiety measured using the GAD-7
7. Depression measured using the PHQ-9
8. Hope using the Adult HOPE Scale
9. Entrapment measured using the 4-item self-report Entrapment Scale Short-Form
10. Adverse effects measures on exit from the study at 6-month assessment

Overall study start date
01/04/2022

Completion date
31/01/2026

Eligibility

Key inclusion criteria

Current inclusion criteria as of 05/06/2023:
1. Currently receiving care from a Home-Based Treatment Team/Crisis team or have done so within the last 14 days, since referrals to HBTT/Crisis Team are associated with increased risk of a psychiatric hospital admission in the near future
2. Aged 16 years or above
3. Meet criteria for a diagnosis of SMHP (schizophrenia spectrum, bipolar, major depressive disorder, EUPD, PTSD or cPTSD) since these diagnoses account for the majority of PHAs for mental health difficulties
4. Experienced suicidal ideation or attempt within the last month / current crisis episode, as operationalised by answering 'yes' to items 1 or 2 of the Columbia-Suicide Severity Rating Scale.
5. Able to provide informed consent
6. Receiving care from a Community Mental Health Team or Early Intervention Service, to ensure ongoing specialist mental health support following discharge from HBTT.

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Previous inclusion criteria from 09/01/2023 to 05/06/2023:
1. Currently receiving care from a Home-Based Treatment Team/Crisis team or have done so within the last 14 days, since referrals to HBTT/Crisis Team are associated with increased risk of a psychiatric hospital admission in the near future
2. Aged 16 years or above
3. Meet criteria for a diagnosis of SMHP (schizophrenia spectrum, bipolar, major depressive disorder or EUPD) since these diagnoses account for the majority of PHAs for mental health difficulties
4. Experienced suicidal ideation or attempt within the last month / current crisis episode, as operationalised by answering 'yes' to items 1 or 2 of the Columbia-Suicide Severity Rating Scale.
5. Able to provide informed consent
6. Receiving care from a Community Mental Health Team or Early Intervention Service, to ensure ongoing specialist mental health support following discharge from HBTT.

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Previous inclusion criteria:
1. Receiving care from a HBTT (referrals to HBTT are associated with increased risk of a PHA in the near future)
2. Aged 16 years or above
3. Meet criteria for a diagnosis of SMHP (schizophrenia spectrum, bipolar, major depressive disorder or EUPD) since these diagnoses account for the majority of PHAs for mental health difficulties
4. Experienced suicidal ideation or attempt within the last month / current crisis episode, as operationalised by answering 'yes' to items 1 or 2 of the Columbia-Suicide Severity Rating Scale.
5. Able to provide informed consent
6. Receiving care from a Community Mental Health Team or Early Intervention Service, to ensure ongoing specialist mental health support following discharge from HBTT.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 991; UK Sample Size: 991

Key exclusion criteria
Current inclusion criteria as of 05/06/2023:
1. Organic impairment, as this could be the cause of mental health symptoms rather than a SMHP
2. Non-English speaking, since two of the interventions are remotely delivered talking therapies and one of the interventions is a smartphone app which has only been developed in English. Provision for non-English speakers would be impossible on both financial and logistical grounds.
3. Primary diagnosis of a drug or alcohol dependence, as this could be the cause of mental health symptoms rather than a SMHP
4. Moderate to severe learning disability as confirmed by the participant's responsible clinician in their care team.
5. Immediate risk to others, for ethical and safety reasons
6. Currently receiving psychiatric inpatient care (since people in recent contact with crisis teams may have already been admitted to hospital)

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Previous inclusion criteria from 09/01/2023 to 05/06/2023:
1. Organic impairment, as this could be the cause of mental health symptoms rather than a SMHP
2. Non-English speaking, since two of the interventions are remotely delivered talking therapies and one of the interventions is a smartphone app which has only been developed in English. Provision for non-English speakers would be impossible on both financial and logistical grounds.
3. Primary diagnosis of a drug or alcohol dependence, as this could be the cause of mental health symptoms rather than a SMHP
4. Moderate to severe learning disability as confirmed by the participants responsible clinician in their care team, since the BrighterSide app has not been developed or tested with people with moderate to severe learning disability.
5. Visual impairment, severe enough to prevent engagement with the BrighterSide app as provision would be impossible on both financial and logistical grounds.
6. Immediate risk to others, for ethical and safety reasons
7. Currently receiving psychiatric inpatient care (since people in recent contact with crisis teams may have already been admitted to hospital)

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Previous inclusion criteria:
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2. Non-English speaking, since two of the interventions are remotely delivered talking therapies and one of the interventions is a smartphone app which has only been developed in English. Provision for non-English speakers would be impossible on both financial and logistical grounds.
3. Primary diagnosis of a drug or alcohol dependence, as this could be the cause of mental health symptoms rather than a SMHP
4. Moderate to severe learning disability as confirmed by the participants responsible clinician in their care team, since the BrighterSide app has not been developed or tested with people with moderate to severe learning disability.
5. Visual impairment, severe enough to prevent engagement with the BrighterSide app as provision would be impossible on both financial and logistical grounds.
6. Immediate risk to others, for ethical and safety reasons

Date of first enrolment
01/07/2022

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Hospital
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Headington
Oxford
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Study participating centre
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Study participating centre
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Robert Dolan House

9 Alie Street
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Study participating centre
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
On completion of the trial the data will be analysed, and a final trial report prepared for the National Institute for Health Research (NIHR) to be published in Health Technology Assessment here: https://www.journalslibrary.nihr.ac.uk/hta/#/ . The Draft Final Report is due 14 days after the end date of the study. A number of high-quality peer-reviewed open access publications are expected from the body of research. The primary outcome paper will be published within one year after the overall trial end date. This definitive research will provide evidence from a single study regarding clinical and cost effectiveness of a range of interventions that are brief and accessible. This output will address a number of unmet needs including improving the efficacy and accessibility of psychosocial interventions.

Intention to publish date
30/05/2026

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	25/05/2022	17/06/2022	No	Yes
Participant information sheet	version 4.0	17/10/2022	09/01/2023	No	Yes

Participant information sheet	version 5.0	24/04/2023	12/06/2023	No	Yes
Protocol file	version 4.0	06/10/2022	12/06/2023	No	No
Protocol file	version 5.0	06/03/2023	12/06/2023	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 6.0	02/05/2023	25/09/2023	No	No
Protocol file	version 7.0	18/08/2023	25/09/2023	No	No
Participant information sheet		18/08/2023	20/02/2024	No	Yes
Protocol file	version 8.0	27/11/2023	20/02/2024	No	No
Protocol article		06/07/2024	08/07/2024	Yes	No
Participant information sheet	version 7.0	07/06/2024	19/08/2024	No	Yes
Participant information sheet	version 8.0	11/08/2024	19/08/2024	No	Yes
Protocol file	version 9.0	07/06/2024	19/08/2024	No	No