

# Improving psychological support for cancer patients: a study on readiness and resources

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/10/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/10/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims?

Cancer patients are up to three times more likely to experience common mental health issues, such as depression, which can lead to reduced adherence to cancer treatments, increased healthcare costs, and poorer overall health outcomes. While psychological therapies effectively treat depression in cancer patients, many face long waits before starting therapy. This delay can worsen mental health, but timely, accessible brief interventions may help. This study aims to evaluate the effectiveness of a brief Therapy Preparation Intervention (TPI) for adult cancer patients awaiting psychological therapy for moderate-to-severe depression. The TPI includes an initial session on psychoeducation, goal setting, and motivational interviewing, followed by automated text reminders until therapy begins.

### Who can participate?

Adults receiving cancer care who are experiencing moderate-to-severe depression and are awaiting psychological therapy will be invited to participate. Referrals will be made through NHS cancer care services and GP practices across the East Midlands.

### What does the study involve?

Participants will be randomly assigned to receive either the TPI combined with Treatment as Usual (TAU) or TAU alone. The TPI includes a session at the start of the wait for therapy, covering psychoeducation, goal setting, and motivational interviewing, followed by automated text reminders. Follow-up assessments will occur at 4, 8, 12, and 24 weeks to evaluate symptoms of depression and anxiety, mental well-being, functioning, quality of life, therapy dropout rates, and patient activation. Additionally, 20-30 participants from the TPI+TAU group will be interviewed about their experiences with the intervention.

### What are the possible risks and benefits of participating?

The risks of participating in this study are minimal, as the TPI is a brief intervention designed to support patients while they wait for psychological therapy. The benefits include potentially improved mental health, greater readiness for therapy, and reduced dropout rates. The qualitative interviews will also help refine the intervention for future use, potentially benefiting a broader range of patients.

Where is the study run from?

The study is being conducted at the East Midlands Cancer Alliance Centre for Psychological Health (EMCA CPH), which provides psychological therapy for cancer patients and training for cancer care staff. The study is supported by the East Midlands Cancer Alliance (EMCA). All the study activities, including the TPI, the psychological therapy, and the assessments will be remote.

When is the study starting and how long is it expected to run for?

December 2023 to March 2026

Who is funding the study?

The study is funded by the East Midlands Cancer Alliance (EMCA), which is committed to improving cancer care and outcomes across the region. Additional funding will be provided by the NIHR (National Institute for Health and Care Research) ARC EM (Applied Research Collaboration East Midlands).

Who is the main contact?

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

342394

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

164804/2024 , CPMS 61828

## **Study information**

### **Scientific Title**

Psychological therapy readiness and resourcing in oncology – support to promote an enhanced response (PROSPER): a randomised controlled trial

### **Acronym**

PROSPER

### **Study objectives**

1. Participants allocated to the TPI (Therapy Intervention Preparation) and treatment as usual (TAU) group (active group) will report greater reduction in depressive symptoms than those receiving TAU alone.
2. Participants receiving TPI and TAU will report a lower dropout rate related to the psychological therapy than those receiving TAU alone.

### **Ethics approval required**

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**Ethics approval(s)**

Approved 26/09/2024, Bromley Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 1048124; bromley.rec@hra.nhs.uk), ref: 24/LO/0610

**Study design**

Two-arm multicentre single-blind randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Internet/virtual, Telephone

**Study type(s)**

Treatment, Efficacy

**Participant information sheet**

Not available in web format. Please use contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Patients in cancer care being referred for psychological therapy following difficulty with mental health, particularly depression

**Interventions**

Randomisation is conducted online via REDCap, with data password-protected and accessible only by an unblinded trial coordinator or their nominee. Participants are randomised in a 1:1 ratio to either TPI + TAU or TAU alone. Researchers completing trial assessments will be blind to arm allocation. Follow-up assessments are conducted at 4, 8, 12, and 24 weeks post-randomisation. Semi-structured interviews of participants receiving TPI + TAU will be nested in the study to gather qualitative data.

**Treatment as Usual (TAU) Group:**

Participants in this group will receive standard psychological video-therapy and a pre-therapy document during the waiting period. The standard psychological therapy sessions will be conducted as per usual care protocols.

**Therapy Preparation Intervention (TPI) + Treatment as Usual (TAU) Group:**

Participants in this group will receive the standard psychological video-therapy and pre-therapy document, along with the TPI. The TPI includes a one-hour video or telephone consultation with a practitioner, followed by personalised SMS-based smart-messaging delivered via an automated messaging system. The TPI is provided during the waiting period before the standard psychological therapy sessions.

**Intervention Type**

Behavioural

**Primary outcome measure**

Depression symptoms via the Patient Health Questionnaire 9 (PHQ-9) over 24 weeks with measures at baseline, and then at four, eight, twelve and twenty-four weeks post randomisation.

### **Secondary outcome measures**

1. Anxiety is measured using the Generalised Anxiety Disorder 7 (GAD-7) at baseline, 4, 8, 12, and 24 weeks post randomisation
2. Impact of health on daily functioning is measured using the Work and Social Adjustment Scale (WSAS) at baseline, 4, 8, 12, and 24 weeks post randomisation
3. Mental wellbeing is measured using the Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) at baseline, 4, 8, 12, and 24 weeks post randomisation
4. Participant's knowledge, skills, confidence, and behaviours related to managing their own health and healthcare are measured using the Patient Activation Measure (PAM) at baseline, 4, 8, 12, and 24 weeks post randomisation
5. Participants' willingness or readiness to make a change in their behaviour is measured using the Readiness for Change Ruler at baseline, 4, 8, 12, and 24 weeks post randomisation
6. Health economics and quality of life are measured using the Client Service Receipt Inventory (CSRI) and the Euroqol (EQ5D5L) at baseline and 24 weeks follow up assessment

### **Overall study start date**

01/12/2023

### **Completion date**

01/03/2026

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 years or older
2. Able to engage with psychological therapy sessions conducted in English
3. Competent to give informed consent
4. Diagnosed with cancer and awaiting psychological therapy with EMCA CPH for symptoms of moderate-to-severe depression during the recruitment period of the study
5. A score of 10 or more on PHQ-9

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

150

### **Total final enrolment**

**Key exclusion criteria**

1. Immediate risk to self or others
2. Currently receiving psychological therapy with another service.
3. Unable or unwilling to receive care remotely.

**Date of first enrolment**

17/10/2024

**Date of final enrolment**

01/09/2025

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****Nottinghamshire Healthcare NHS Foundation Trust**

The Resource, Trust Hq  
Duncan Macmillan House  
Porchester Road  
Nottingham  
United Kingdom  
NG3 6AA

**Study participating centre****United Lincolnshire Hospitals NHS Trust**

Lincoln County Hospital  
Greetwell Road  
Lincoln  
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LN2 5QY

**Study participating centre****University Hospitals of Derby and Burton NHS Foundation Trust**

Royal Derby Hospital  
Uttoxeter Road  
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# Sponsor information

## Organisation

Nottinghamshire Healthcare NHS Foundation Trust

## Sponsor details

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## Sponsor type

Hospital/treatment centre

## Website

<http://www.nottinghamshirehealthcare.nhs.uk/>

## ROR

<https://ror.org/04ehjk122>

# Funder(s)

## Funder type

Government

## Funder Name

East Midland Cancer Alliance

## Funder Name

National Institute for Health Research Applied Research Collaboration East of England

## Alternative Name(s)

Applied Research Collaboration East of England, NIHR ARC East of England, ARC East of England, NIHR Applied Research Collaboration East of England, NIHR Applied Research Collaboration (ARC) North East, National Institute for Health Research (NIHR) Applied Research Collaboration (ARC), ARC EoE, NIHR ARC EoE

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

We will disseminate our findings through various channels, including publications in peer-reviewed journals, conference presentations, and reports. Additionally, we will use accessible formats such as infographics and plain language summaries to reach a broader audience.

On completion of the study, the data will be analysed, and a final anonymous, report prepared. This report will be published in a peer-reviewed academic journal and presented at academic conferences. The National Institute for Health and Care Research (NIHR), Health Education England (HEE), and Nottinghamshire Healthcare NHS Foundation Trust need to be acknowledged as funders and supports of the study in any publications.

Participants who consent to be contacted about trial results will be invited to a study dissemination event where study results will be shared with participants, public contributors, and stakeholders.

The results will also be disseminated through the regional and national groups of service leads for psychological care in NHS cancer services. The results will also be disseminated across the East Midlands Cancer Alliance and through the national cancer alliance network nationally.

**Intention to publish date**

01/09/2026

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to the absence of consent for data sharing in public repositories.

**IPD sharing plan summary**

Not expected to be made available