ISRCTN13692666 https://doi.org/10.1186/ISRCTN13692666

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

Submission date
17/10/2024

Recruitment status
No longer recruiting

Registration date
18/10/2024

Overall study status
Completed

Last Edited
10/02/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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 February 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).

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Integrated Research Application System (IRAS)
342394

Protocol serial number
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
Ethics approval required

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

Study type(s)
Efficacy, Treatment

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(s)
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.

Key secondary outcome(s))
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

Completion date
02/02/2026

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
160

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
14/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
The Resource, Trust Hq
Duncan Macmillan House
Porchester Road
Nottingham
England
NG3 6AA

Study participating centre
United Lincolnshire Hospitals NHS Trust
Lincoln County Hospital
Greetwell Road
Lincoln
England
LN2 5QY

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
Derby
England
DE22 3NE

Sponsor information

Organisation
Nottinghamshire Healthcare NHS Foundation Trust

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available