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RAPPORT: Reduce Anxiety for Patients with Physicist appOintments in RadioTherapy

Submission date
24/04/2025

Recruitment status
Recruiting

Registration date
29/04/2025

Overall study status
Ongoing

Last Edited
15/05/2025

Condition category
Cancer

[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
It is known that up to half of radiotherapy patients experience heightened anxiety and distress. This can lead to a lower quality of life, worse side effects, and even lower survival. With the general trend of radiotherapy treatment regimes getting shorter, patients have less time to get accustomed to the daunting environment and machines. Therefore, approaches for a renewed focus on patient-centred care are needed. This research proposes an additional patient appointment with a medical physicist. These staff, traditionally having no direct patient care, take responsibility for aspects ranging from maintenance and calibration of treatment machines, quality assurance and legislative compliance, to treatment planning. They have a unique overview of the radiotherapy pathway, and the proposed intervention will aim to address patients' questions on technical aspects of their care.

Who can participate?
Patients referred for radical radiotherapy at UHD's satellite radiotherapy centre at Dorchester County Hospital.

What does the study involve?
Participants will be asked to complete a questionnaire packet at radiotherapy planning, 1st treatment and last treatment. Participants randomised to the intervention arm will receive an additional 20-30 minute consultation with a medical physicist on the day of their first radiotherapy treatment.

What are the possible benefits and risks of participating?
Expected benefit for participants on the intervention arm are the additional consultation and a potential lowering of anxiety. There is a small risk of increased anxiety from additional information.

Where is the study run from?
University Hospitals Dorset NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2025 to September 2026

Who is funding the study?
NHS England via National school of healthcare science (NSHCS)

Who is the main contact?
Charlie Martin, Charlie.Martin@uhd.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
352379

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 66435

Study information

Scientific Title
Radiotherapy patient anxiety: its correlation with treatment setup and reduction with medical physicist consultations

Acronym
RAPPORT v1.0

Study objectives
Primary objective: To determine if an additional patient consultation with a medical physicist influences patient-reported anxiety compared to standard of care (no consultation with a medical physicist).

Secondary objectives:
1. To determine whether the magnitude of patient set-up errors correlate with patient-reported anxiety.
2. To determine whether data reported by Surface Guided Radiotherapy (such as surface variability) correlate with patient-reported anxiety.
3. To determine whether there is a difference in technical satisfaction between the intervention and control arms.
4. To determine if treatment adherence (attendance, treatment preparation such as bladder filling) is influenced by having more technical information.
5. To collate patient questions and report common themes
6. To explore patient experiences, including their interest in physicist consultations as a clinical service, and their information requirements.
7. To determine the staff time requirement for physicist consultations

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/04/2025, East Midlands – Nottingham 2 REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8065; nottingham2.rec@hra.nhs.uk), ref: 25/EM/0066

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Radiotherapy patient anxiety

Interventions
Participants will be invited to the study when receiving their first radiotherapy appointment (for a planning CT scan). If they consent to join the study at this appointment they will provide some demographic data and fill in baseline questionnaires. The participant will be randomly assigned by sealed envelope to have the additional appointment with a medical physicist (those on the 'control' arm will receive their radiotherapy as per standard of care). The additional appointment will happen on the day of the first radiotherapy appointment, and all participants will fill in questionnaires on this day. A final questionnaire is given on the last day of treatment.

Intervention Type
Behavioural

Primary outcome measure
Anxiety is measured using the state trait anxiety inventory (STAI) at baseline, first radiotherapy treatment and last radiotherapy treatment

Secondary outcome measures
Magnitude of radiotherapy treatment set-up shifts collected from the participants medical record (data that is already collected during treatment). This will primarily be analysed at first and last treatment (in conjunction with anxiety)

Overall study start date
23/01/2025

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Referred for radical radiotherapy at the Robert White Radiotherapy Centre (RWRC)
2. Histological or radiological diagnosis of cancer, or appropriate referral for benign condition
3. Provision of informed consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Under 18 years old
2. Patients who are unable to understand the study information or unable to complete questionnaires or the consultation, for example unable to speak English fluently
3. The documentation of an ongoing psychiatric condition in the patients' medical notes to which the researchers have access
4. Is participating in another patient-reported outcome investigation that may interfere with this study
5. Referred for palliative or emergency radiotherapy treatment
6. Prisoners in the custody of HM Prison Service

Date of first enrolment
19/05/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Management Offices
Poole Hospital
Longfleet Road
Poole
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BH15 2JB

Sponsor information

Organisation
University Hospitals Dorset NHS Foundation Trust

Sponsor details
Management Offices, Poole Hospital, Longfleet Road
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Sponsor type
Hospital/treatment centre

Website
https://www.uhd.nhs.uk

ROR
https://ror.org/02pa0cy79

Funder(s)

Funder type
Government

Funder Name
NHS ENGLAND

Results and Publications

Publication and dissemination plan
The results from this study will form part of a doctoral thesis due to be submitted in September 2026. We aim to publish the results in a peer-reviewed journal and where possible, at appropriate scientific meetings/conferences. We also intend to provide participants directly with a summary of the results where they have indicated they would like to receive one.

Intention to publish date
30/09/2027

Individual participant data (IPD) sharing plan
Anonymised dataset will be made available on request from the chief investigator or sponsor for up to 10 years. Raw data will be made available to NHS or academic staff contracted to a UK university or a HCPC registered clinical scientist working in radiotherapy physics for repeat or alternative analysis. Consent from participants on use of data is based on anonymous use only.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	08/04/2025	28/04/2025	No	Yes
Protocol file	version 1.1	08/04/2025	28/04/2025	No	No