# RAPPORT: Reduce Anxiety for Patients with Physicist appOintments in RadioTherapy

Submission date	<b>Recruitment status</b> Recruiting	[X] Prospectively registered
24/04/2025		[X] Protocol
Registration date	Overall study status Ongoing	Statistical analysis plan
29/04/2025		Results
Last Edited	Condition category	Individual participant data
09/09/2025	Cancer	[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.martin4@nhs.net

### **Contact information**

#### Type(s)

Public, Scientific, Principal investigator

#### Contact name

Mr Charlie Martin

#### Contact details

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#### Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### Integrated Research Application System (IRAS)

352379

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

**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

#### Study type(s)

Other

#### 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)

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

United Kingdom

# Study participating centre University Hospitals Dorset NHS Foundation Trust

Management Offices Poole Hospital Longfleet Road Poole United Kingdom BH15 2JB

# Sponsor information

#### Organisation

University Hospitals Dorset NHS Foundation Trust

#### **ROR**

https://ror.org/02pa0cy79

# Funder(s)

#### Funder type

Government

#### Funder Name

**NHS ENGLAND** 

## **Results and Publications**

#### 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

Participant information sheet	version 1.1	08/04/2025	28/04/2025 No	Yes
<u>Protocol file</u>	version 1.1	08/04/2025	28/04/2025 No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes