ISRCTN12129699 https://doi.org/10.1186/ISRCTN12129699

# The development of a Patient Decision Aid (PDA) and Patient Concerns Inventory (PCI) for people diagnosed with recurrent head and neck cancer (HNC)

**Submission date**
24/01/2026

**Recruitment status**
Recruiting

**Registration date**
26/03/2026

**Overall study status**
Ongoing

**Last Edited**
26/03/2026

**Condition category**
Cancer

[ ] 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
Head and neck cancer (HNC) can affect the mouth, for example, the tongue/ jaw, and throat, including the voice box. They are difficult to treat and often return after the first treatment. This is called a recurrence. Once a cancer has recurred, treatment decisions are very complicated as additional treatment causes side effects. Surgery might cure the cancer by removing the recurrence. However, some patients cannot speak, eat or drink after surgery. Drug treatments are available. They extend life but do not cure the recurrent cancer. Drugs also have side effects that impact daily life. Making decisions about which treatment to have can be very difficult. People can have lots of questions, worries and concerns. Patients do not always have the opportunity to be involved in decisions or ask questions.

This study will develop two resources. One is to help patients when they are making treatment decisions, and the second is to help them share their concerns about side effects with their healthcare team.
1. The first resource is called a Patient Decision Aid (PDA). This aid will provide people with information about different treatment options. The information will be clear and easily understood. It will include details about what the treatments involve, how likely they are to work, and any risks or side effects.
2. The second resource is called a Patient Concerns Inventory (PCI). This is a list of common concerns a person may have living with recurrent HNC (rHNC). The person completes the form before meeting their healthcare team. They can identify any worries or concerns they have.

Who can participate?
Patients over the age of 18 with rHNC undergoing active treatment (immunotherapy /chemotherapy/clinical trial of investigational agents) or having undergone surgery and/or re-irradiation for HNC recurrence. Healthcare Professionals (HCPs) who have had at least 5 years of clinical experience working with patients with rHNC.

What does the study involve?
The research team plan to work as equal partners with patients to design the patient decision aid and patient concerns inventory.
The team will:
1. Assemble a group of patients and professionals to guide this project
2. Gather information that might be useful for the two resources
3. Talk to patients and healthcare professionals to seek their opinions on what to include.
4. Use this to design the first versions of the decision aid and the concerns inventory
5. Keep improving them until there is agreement that they are ready to use

Patient and Public Involvement
The researchers have spoken to people with rHNC before they wrote this project plan. The patients stated that they wanted help to understand the different treatment options because they were complicated. They also wanted to better describe the side effects of treatment and concerns they may have for the healthcare teams.

What are the possible benefits and risks of participating?
The study is not designed to give patients who participate direct benefits. However, it can sometimes be good to share one's experience with other people.

The results will hopefully benefit patients who participate and other people with HNC recurrence in future by developing tools that will support them in providing better care.

Risks not provided at time of registration.

Where is the study run from?
The Royal Marsden NHS Foundation Trust, UK.

When is the study starting and how long is it expected to run for?
March 2026 to October 2027.

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

Who is the main contact?
Dr Sofia Georgopoulou (Study Co-Ordinator), sofia.georgopoulou@rmh.nhs.uk.

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## Additional identifiers

### Integrated Research Application System (IRAS)
361069

### Central Portfolio Management System (CPMS)
62222

### Protocol number
CCR6282

## Study information

### Scientific Title
The development of a Patient Concerns Inventory and Decision aid for patients with Recurrent HNC

### Acronym

The CONSIDER Study

## Study objectives
Primary Aim
To co-design self-administered instruments to help people diagnosed with HNC recurrence with decision-making before treatment and elicit concerns and priorities following diagnosis.

Objectives:
1. To develop a prototype Patient Decision Aid for patients with HNC Recurrence (PDA HN-R).
2. To develop a prototype Patient Concerns Inventory for patients with HNC Recurrence (PCI HN-R).

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 25/02/2026, London - Brent Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; brent.rec@hra.nhs.uk), ref: 26/PR/0114

## Primary study design
Other

## Study design
Multiple methods, single-site co-design.

## Study type(s)
Quality of life

## Health condition(s) or problem(s) studied
Recurrent head and neck cancer

## Interventions
The project is a 24-month, multiple-methods study with two interlinked workstreams involving five key stages.

Workstream 1 will develop a PDA in accordance with the systematic process proposed by the International Patient Decision Aids Standards (IPDAS) and its quality criteria.

Workstream 2 will be in accordance with the systematic process used in existing PCI development.

The underlying approach to this study is one of co-design, where patients and healthcare professionals work together as equal partners in prototype development.

STAGE 1: Steering group creation

A multidisciplinary team (MDT) steering group comprised of various healthcare professionals and two expert patients will be formed to lead the study, identify potential study participants, and assist in designing and reviewing the PDA and PCI prototypes.

The team members will be approached via the International Centre for Recurrent Head and Neck Cancer (IREC) network. IReC is hosted by the Royal Marsden NHS Foundation Trust.

STAGE 2: Literature review and current evidence synthesis

Synthesis of systematic reviews, national datasets and guidelines to establish baseline survival and functional outcomes, which will be used to inform the decision aid.

STAGE 3 & 4: WORKSTREAM 1 - PDA Development (to explore what patients need to make decisions regarding their treatment for rHNC from patients' and clinicians' perspectives)

Stage 3 will involve interviews with patients.

Stage 4 will involve focus groups with clinicians.

HCPs and patient participants will be recruited across the IReC collaborative network at the Royal Marsden (host site) and across two other participant identification centres (confirmation of PICs currently in progress). Patients will be invited to participate in the study by their care team when they attend routine outpatient follow-up appointments. They will be provided with a written participant information leaflet. HCPs will be invited to participate via email. A participant information leaflet will be sent with the email invitation.

The results of both the patient interviews and professionals' focus groups will be analysed using thematic analysis using the Framework Approach with the aid of a qualitative software management tool (QSR NVivo 12).

STAGES 3 & 4: WORKSTREAM 2 - PCI prototype development

Stage 3 will involve a Delphi survey with clinicians.

Stage 4 will involve focus groups with patients.

Recruitment, sample size, and inclusion/exclusion criteria of patients and clinicians participants will follow the same process as above. To reduce the burden on participants, there will be new participants.

Focus groups will be conducted either in person or virtually using a topic guide developed with the PPI/E collaborators. Focus groups will be audio-recorded with permission.

Transcripts from the patient focus groups will be analysed thematically using a Framework Approach. Delphi survey results will be analysed quantitatively, reporting percentage consensus agreement.

The combined findings of the Delphi and patient focus groups will be used to make amendments to the existing PCI-HN to adapt the tool to meet the needs of patients with recurrent disease. The use of this Delphi Method with involvement of both HCPs and patients will ensure the content validity of the PCI-HN-R.

STAGE 5: Prototype Development

Based on the assessment of needs of key stakeholders and available evidence from the existing literature, a prototype PDA-HN-R will be drafted according to the criteria for developing

decision aids and assessed using the IPDASI V.4.0. The PDA-HN-R will likely include four main topics:

1. brief descriptions about the disease and treatment options

2. possible treatment outcomes

3. risks and benefits of treatment options

4. a value clarification exercise

The combined findings of the online MDT survey and patient-focused groups will guide the development of a prototype PCI HN-R.

Once the prototypes have been developed, they will be reviewed by the steering committee, including professionals and patients, with confirmation of face validity in preparation for further user testing.

### Intervention Type
Mixed

### Primary outcome(s)
1. Development of the prototype Patient Decision Aid for patients with HNC Recurrence (PDAHNR) measured using codesign activities that include evidence synthesis, patient interviews and clinician focus groups, analysed thematically using the Framework Approach with NVivo 12 and assessed using IPDASi v4.0 at Stages 2 to 5 across the 24-month study

2. Development of the prototype Patient Concerns Inventory for recurrent head and neck cancer (PCIHNR), measured using a clinician Delphi survey with percentage consensus analysis and patient focus groups with transcripts analysed using the Framework Approach at Workstream 2, Stages 3 to 5 across the 24-month study

### Key secondary outcome(s)
1. Prototype evaluation and refinement: Further evaluation of the PDAHNR and PCIHNR, measured using a steering committee review involving professionals and expert patients to confirm face validity at Stage 5 within the 24-month study

### Completion date
30/10/2027

## Eligibility

### Key inclusion criteria
Eligibility Criteria: Workstream 1 (PDA HN-R)
For patients to be eligible to participate in the development of the PDA HN-R in this study, a patient must meet all the following inclusion criteria:
1. Age 18 or above.
2. Competency to provide consent.
3. Adequate linguistic and cognitive skills to take part in an interview.

4. Biopsy-proven locoregionally rHNC.
5. Head and neck multidisciplinary team (HN-MDT) meeting discussion documenting > 1 potential management option.

For healthcare professionals to be eligible to participate in the development of the PDA HN-R in this study, an HCP (surgeon, oncologist, allied health professional (AHP), nurse) must meet only the following inclusion criterion:
A minimum of 5 years' clinical experience in working with patients with rHNC.

Eligibility Criteria: Workstream 2 (PCI HN-R)
For patients to be eligible to participate in the development of the PDA HN-R in this study, a patient must meet all the following inclusion criteria:
1. Biopsy-proven locoregionally recurrent HNC.
2. Undergoing systemic treatment immunotherapy/chemotherapy/clinical trial of investigational agents) OR have undergone surgery and/or re-irradiation for HNC recurrence.

For healthcare professionals to be eligible to participate in the development of the PDA HN-R in this study, an HCP (surgeon, oncologist, AHP, nurse) must meet only the following inclusion criterion:
A minimum of 5 years' clinical experience in working with patients with rHNC, as with the PDA.

### Participant type(s)
Health professional, Patient

### Healthy volunteers allowed
Yes

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
110 Years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
Patients/ HCPs not meeting all of the inclusion criteria.

### Date of first enrolment
01/03/2026

### Date of final enrolment
01/03/2027

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**The Royal Marsden NHS Foundation Trust**
Fulham Road
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# Sponsor information

**Organisation**
Royal Marsden NHS Foundation Trust

**ROR**
https://ror.org/0008wzh48

# Funder(s)

**Funder type**
Not defined

**Funder Name**
National Institute for Health and Care 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

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not expected to be made available