
A qualitative study exploring patient experiences of comfort during radiotherapy and radiographer views of managing patient comfort during the delivery of radiotherapy

A Data Management Plan created using DMPonline-test

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Project abstract:

For this study we wish to gain a greater understanding of patient and radiographers experiences and views of comfort to inform the development of a radiotherapy comfort intervention. In healthcare, physical and psychological interventions have been used to improve the comfort of people and, specifically in radiotherapy, there are some examples where relaxation methods have improved patient comfort. The focus of this research is based on the comfort of patients who are receiving treatment that lasts more than 10 minutes in one radiotherapy session. Patients have informed us that the longer they have to remain in position the more uncomfortable they feel. Therefore we would like to do something to improve patient comfort starting with interviewing patients and radiographers. We would like to interview up to 25 patients and 25 radiographers to better understand their experiences of comfort and how it is best managed. We will recruit patient from Radiotherapy at Taunton and Somerset NHS Foundation Trust for a face to face interview at a time and place of their choosing. Radiographers will be recruited nationally at conferences at special interest groups and interviewed via telephone or skype at a time of their choosing. Interviews will take up to 60 minutes.

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Data Collection

The data collected will include some demographic information for each participant contained on an electronic eligibility proforma (EEP) . For patient participants the EEP will contain full name, date of birth, cancer diagnosis and radiotherapy treatment details. For radiographer participants the eEP will contain their full name, date of birth, job title and years of experience. Each participant will be assigned a unique identifying number which is given on the eligibility proforma, on consent forms the unique identifier and participants initials. For both patients and radiographers the interviews will be audio-recorded and transcribed. On transcripts only the unique identifier will be used. The contact details of patients will be kept on the electronic patient record Mosaik as standard at Musgrove Park Hospital. For radiographers an e mail and phone number will be retained for the purposes of the interview and also if participants would like to sent the interview findings.

Access to data will be limited to the minimum number of individuals necessary for quality control, audit, and analysis. Personal data will be regarded as strictly confidential. All trial study will be securely stored and access restricted to staff involved in the study. The chief investigator (CI), Simon Goldsworthy, who will enter data onto a secure electronic database at Musgrove Park Hospital, and then transferred to OneDrive within 1 week which is securely maintained by the University of the West of England. Data will be entered using participant unique interview study numbers only. Access to the databases will be password protected and limited to the CI and the research team when necessary.

Participant data:

Source data will be collected and created electronically by the CI Simon Goldsworthy for consent forms, eligibility proformas, field notes and for interview transcripts which will be anonymised. Each participant will be given a unique identifier and age at interview, for patients this will be P1 to Pn and for radiographers this will R1 -Rn. For both patients and radiographers the interviews will be audio-recorded and transcribed. Transcribed data will be saved for example 'P1 Consent Comfort Interview 301018' / 'P1 Eligibility Comfort Interview 301018' and then saved in a folder as described below.

Folders and files:

Files will temporarily be stored for a maximum of 1 week in electronic folders at Musgrove Park Hospital in the following location which has restricted access: S:\Clin_Trials\Trials - Oncology - Radiotherapy\COMFORT study.

The subfolders will be titled: Draft set up documents, Consent forms, eligibility proforma, study logs (participants approached and registered), withdrawal forms, audio recordings of interviews, interview transcripts, data queries, correspondence, delegation log, SAE/ SUSAR.

This same folder and filing system described above for Musgrove Park Hospital will be used to store the data on OneDrive which is managed and governed by the University of the West of England (Who is the sponsor of this research). After study completion the data will be archived on University of the West of England data archive.

Anonymised interview transcripts will be uploaded and thematically analysed in a qualitative software tool NVivo that is managed and controlled by the University of the West of England.

Quality assurance:

The PhD supervisory team for Simon Goldsworthy will quality assure the processes prior to opening the study. Then once on study, members of the supervisory team who are independent of the interviews will be asked to review the quality of procedures such as the interview process, methods of transcription, and then review data collection and storage practices.

Documentation and Metadata

Data from NVivo qualitative data analysis software will be stored for 10 years at the University of the West of England. The data will include a report of thematic analysis.

This includes indexes in transcripts, the formulation of codes and themes and sub themes.

Ethics and Legal Compliance

Informed consent:

All potential patient participants will be given the study participant information sheet (PIS) and approached by the chief investigator for informed consent about whether they would like to participate in the interview.

Full written informed consent will be provided by signing , dating and initialling the consent form (paper or electronic), which will be witnessed by CI who has documented and delegated responsibility so to do. The original signed consent forms will be retained electronically on OneDrive at the University of the West of England, with a copy filed in the clinical notes and a copy provided to the patient.

Anonymisation:

To preserve anonymity, participants will be known by a unique study identification code only for patients P1 - Pn and Radiographers R1 -Rn.

Legal compliance:

Patients and radiographers will be informed that in the unlikely event that any disclose any safeguarding issues about themselves, a relatives, radiographers, or patients in their care, a referral to appropriate services/organisations will be made.

Simon Goldsworthy will be the custodian of the data and the University of the West of England will be the data controller. There will no license or restrictions other than when the research is published. Patenting is not foreseen with this research.

Storage and Backup

Data storage:

A laptop is provided by employer Musgrove Park Hospital and has NHS security. OneDrive with a student account will be used to analyse and store data, and will be governed by the University of the West of England. Both sites have sufficient data storage.

Data back up at Musgrove Park Hospital:

The study data will be backed up regularly in line with NHS IT protocol and recovery disaster plans. In the event of disaster a backup server will be brought into use.

Data back up at the University of the West of England:

The study data be backed up regularly using Microsoft OneDrive platforms and recovery of the user profile being possible through a restore feature. In the event of disaster the University of the West of England would be consulted to contact Microsoft with support

Access to drives and folders will be password protected and limited to the chief investigator and the research team when necessary.

Selection and Preservation

All temporary data held electronically at Musgrove Park Hospital such as eligibility proformas, consent forms, interview transcripts and field notes will be transferred to OneDrive at the University of the West of England for storage in under 1 week by the custodian Simon Goldsworthy. Consent forms and eligibility proformas will be deleted at the completion of PhD studies.

Interview transcripts and field notes will be stored on OneDrive until completion of studies and publication. It would then be retained at the University of the West of England for 10 years.

Data Sharing

The interview transcripts and field notes will be shared initially with Simon Goldsworthy's PhD supervisory team, using OneDrive for the purposes of this study. Once stored a formal request to share the data will be formally made to the University of the West of England and permission sought from Simon Goldsworthy or supervisory team (or representative).

long term sharing managed by the University of the West of England.

Responsibilities and Resources

Simon Goldsworthy will be the custodian of the generated data, including the implementation of the DMP, data capture, quality, storage and initial archive.

Musgrove Park Hospital is responsible for the temporary storage backup and recovery data
The University of the West of England will maintain the storage of data archive on OneDrive and future sharing.

We have all the resources required.