

Assessing the Supportive Care needs of patients with advanced colorectal cancer (ACRE)

Protocol version 1.2

Protocol Date: 08/05/2026

Research Reference Numbers

IRAS Number: 369447

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UoL002024**

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

Date:

...../...../.....

.....

....

Name (please print):

Position:

Chief Investigator: Dale Vimalachandran

Signature:

Date:

...

Key Study Contacts

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Sponsor	University of Liverpool
Key Protocol Contributors	Mr Dale Vimalachandran Dr Daniel Monnery Dr Stephen Mason

Study Summary

Study Design	A regional, multi-centre, cross-sectional study that will examine, map, describe and understand the patient experience at different stages and in different populations of patients with incurable colorectal cancer. Using validated questionnaires 100 consenting patients will complete the EORTC-QLQ-CR29 and a MYMOP2 at baseline and 100 consenting caregivers will complete a CSNAT questionnaire. Approximately 40 participants thereafter (20 patients and 20 caregivers) will be invited to participate in semi-structured interviews. Stakeholders (approximately 2 surgeons, 2 oncologists, 2 palliative care doctors, and 5 palliative care nurses or colorectal nurse specialists) will be invited to participate in semi-structured interviews or facilitated engagement discussions to explore how the needs of this patient population are perceived from an MDT perspective
Study Participants	• Patients over the age of 18 with advanced (newly diagnosed and/or recurrent) colorectal cancer from the Cheshire and Merseyside region, belonging to the below groups. • Those with potentially resectable cancer but for whom surgery would be too high risk • Those with metastatic disease at presentation and able to receive palliative treatment • Those with metastatic disease at presentation and unable to receive palliative treatment • Carers over the age of 18 who are currently caring for a patient that fits the above criteria. • Stakeholders who have clinical experience in the care of patients with colorectal cancer including • 2 colorectal surgical consultants • 2 oncologists • 2 palliative care doctors • 5 palliative care or colorectal nurse specialists
Planned Size of Sample (if applicable)	211
Follow up duration (if applicable)	N/A
Planned Study Period	1.5 years
Research Question/Aim(s)	What are the needs of patients with colorectal cancer and those important to them and do these needs vary according to type of presentation?

	What services exist across the region to address these needs and to what extent are they successful? In areas where services exist, do discrepancies exist between availability of and access to services?
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Funding and Support in Kind

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
	Northwest Cancer Research have provided funding (APPLICATION NO NWCRLIV2024.01.) of £20,000.

Protocol Contributors

This protocol has been developed with support from previous studies by Mr Dale Vimalachandran. Dr Daniel Monnery who is a palliative care consultant provides expertise in enhanced supportive needs as well as study oversight and governance arrangement. Dr Stephen Mason provides study oversight as well as an extensive background in qualitative analysis. Neither funders or sponsors have been involved in the design of the protocol of this study nor will they be in control of the dissemination of the results.

Key Words:

Colorectal cancer, palliative care, supportive care needs, frailty, survivorship needs

Glossary of Abbreviations

AE	Adverse Event
ACRE	Assessing the Supportive Care needs of patients with advanced colorectal cancer
CI	Chief Investigator
CRC	Colorectal Cancer
DGH	District General Hospital
ESC	Enhanced Supportive Care
GCP	Good Clinical Practice
GDPR	General Data Protection Regulations
HRA	Health Research Authority
ICB	Integrated Care Board
MDT	Multi-disciplinary Team
MRC	Medical Research Council
NHS	National Health Service
NIHR	National Institute of Health Research
NOK	Next of Kin
OID	Organisation Information Document
PI	Principal Investigator
PPI	Patient and public Involvement
PIS	Patient Information Sheet
REC	Research Ethics Committee
REDCap	Research Electronic Data Capture

SAE	Serious Adverse Events
UoL	University of Liverpool

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INTRODUCTION

This protocol describes the ACRE study (Assessing the supportive care needs of patients with advanced ColoRectal canCEr) and provides information regarding study procedures, recruiting participants, safety reporting and governance requirements.

Corrections or amendments may be necessary however this will be circulated to investigators in the study following confirmation of study sponsorship and approvals.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act 2018 and the UK GDPR as amended from time to time and any successor legislation in the UK and any other directly applicable regulation relating to data protection and privacy as well as any other regulatory requirements as appropriate.

BACKGROUND

Colorectal cancer is the second commonest cause of cancer deaths and accounts for 10% of all cancer deaths in the UK[1]. The mainstay of treatment is surgical resection with a focus on curative treatment. However, there are a proportion of patients that cannot undergo curative treatment due to frailty, or the advanced nature of the disease at presentation. Despite initial curative treatment, 20-30% of patients develop recurrence [2]. Despite the implementation of the colorectal cancer screening programme, a significant proportion of patients present as an emergency. Approximately 20% of colorectal cancers can present this way and remain associated with poorer long-term outcomes[3]. Patients with incurable disease suffer with a wide range of physical and emotional symptoms and have a variety of supportive care and survivorship needs, however uncertainty exists about the optimal management for these patients. The majority of literature focusses on survivors of colorectal cancers or patients who have had intervention with curative intent such as the CREW study [4].

Clinical management of these patients focuses around 2 predominant themes:

- Prolonging survival e.g. Palliative chemotherapy
- Improving quality of life e.g. Management of symptoms from the primary tumour e.g. Obstruction, pain, anaemia, nausea and side effects of chemotherapy treatment.

More work needs to be done to assess the needs of patients with advanced colorectal cancer and to understand how these needs change and evolve across their health journey. Importantly there is little work investigating whether there are different care needs across the domains of physical/daily living, psychological, sexuality, patient care and support and health system and information [5] within the different groups of patients with advanced or palliative colorectal cancer. The proposed study will investigate if there are differences in supportive care needs from a patient's perspective as well as their carers.

Inequalities in access to supportive and palliative care significantly influence the outcomes of patients with advanced colorectal cancer, particularly those with complex or enhanced care

needs. While models such as Enhanced Supportive Care (ESC), endorsed by NHS England and supported by the UK Association for Supportive Care in Cancer (UKASCC), advocate for early, proactive integration of supportive care alongside active treatment, their implementation is inconsistent across the UK[6]. Nationally, patients from socioeconomically deprived areas, rural communities, and ethnic minority backgrounds experience delayed access to palliative services, reduced involvement in decision-making, and higher symptom burden at end of life [7, 8]. These systemic barriers not only impact quality of life but are also associated with increased healthcare costs and poor patient and carer satisfaction[9, 10].

RATIONALE FOR CURRENT STUDY

The contributors have previously looked at the unmet needs of patients with colorectal cancer and identified several themes including information provision, coping mechanisms and emotional response [11]. Many of these patients had undergone surgical treatment and this dominated much of the discussion. Whilst this study revealed gaps in current pathways it did not specifically look at advanced disease where curable treatment was not an option. The defined group of patients with advanced colorectal cancer this study will be assessing for care needs are

- Those with potentially resectable cancer but for whom surgery would be too high risk
- Those with metastatic disease at presentation and able to receive palliative treatment
- Those with metastatic disease at presentation and unable to receive palliative treatment.

The Northwest research collaborative have also launched a study looking into the decision making and outcomes in colorectal cancer patients with specific reference to frailty assessment (DECAF study)[12], however this study again looks at frailty factors in patients with surgically resectable colorectal cancers.

The Association of Coloproctology of Great Britain and Ireland (ACPGBI) conducted the IMPACT study [13] which did specifically look at gaps in care for patients with advanced colonic or rectal cancer aiming to support the regionalisation of access to surgery. This study identified nine themes, although many of these were based on pathways for determining attempts at curative treatment and the results are not necessarily applicable to patients with advanced disease at presentation [13].

Addressing the supportive care needs of patients with incurable malignancy has been demonstrated to reduce secondary care usage in the last year of life [9, 10].

Conversely, correlation has been demonstrated between low levels of support and increased secondary care usage including an increased likelihood of dying in hospital [14]. The same report also demonstrated that Cheshire and Merseyside was the worst performing integrated care board in England in this regard [14], indicating an urgent need to focus on support services' availability and accessibility in this region to address inequality and improve outcome.

The ACRE study is uniquely positioned to explore how these inequities manifest within a defined region and patient population. By mapping variations in perceived and actual access to care across Cheshire and Merseyside, this study aims to inform the design of more responsive and equitable supportive care services, in line with NHS palliative care ambitions and international best practice frameworks.

While patient's and carer's experience will be the main focus of our study, surgeons, oncologists, palliative care doctors and palliative care nurses views will also be interviewed to understand if there are unmet needs in these groups of patients from an MDT perspective. Patients often describe interactions with oncologists or surgeons as more task-focused or centred around clinical decision-making, which may limit open communication about non-medical needs [15]. In contrast palliative care nurses or colorectal nurse specialists are frequently perceived by patients as more approachable, empathetic, and available for in-depth discussions. Although direct comparisons remain scarce, these insights support the inclusion of palliative care nurses' colorectal nurse specialist's perspectives in studies of unmet supportive care needs, particularly for patients with advanced colorectal cancer whose priorities may shift over time.

THEORETICAL FRAMEWORK

The proposed study is underpinned by multiple frameworks incorporating principles from Enhanced Supportive Care (ESC), the World Health Organization (WHO) public health model of palliative care, and quality standards for end-of-life and supportive care. This study will build upon how enhanced supportive care has a beneficial impact on patients quality of life [6]. Together, these provide a comprehensive and clinically relevant foundation for assessing the multifaceted needs of patients with advanced colorectal cancer.

Enhanced Supportive Care promotes early, proactive, and patient-centered interventions delivered alongside active treatment, aiming to improve symptom control, quality of life, and shared decision-making through the systematic use of patient-reported outcome measures [6]. The integration of tools such as the EORTC QLQ-CR29[16], MYMOP2[17], and CSNAT[18] in this study reflects these principles, enabling individualised care informed by both patient and caregiver perspectives.

There have been many studies looking at clinicians' opinions on supportive care for patients with CRC however many of these investigate attitudes following curative surgery or on CRC survivors. Acknowledging the significant variability in management of CRC survivors [19] should be a core concern for clinicians, however the potential differences in care needs between different groups of advanced CRC patients is also vital

Our study design, particularly the mapping of services across Cheshire and Merseyside and the exploration of disparities in access, aligns with WHO's emphasis on system-level responsiveness [20] and health equity as well as aligning with the NHS Ambitions for Palliative and End-of Life Care [7] particularly the ambitions to provide fair access to care, prioritise individual preferences, and ensure coordinated, holistic support.

RESEARCH QUESTION/AIM(S)

5.1. Objectives

The primary aim of this study is to assess and characterise the supportive care needs of patients with advanced colorectal cancer and their caregivers, and evaluate how these needs vary by clinical presentation, geographical location and access to services.

Study Objectives include

- 1) Profile of supportive care needs and variation in needs by patient group
- 2) Geographically map supportive care needs in the Chester and Merseyside area, highlighting variations across locations, and assess how these needs align with the availability and accessibility of existing healthcare services.
- 3) Discrepancy in access vs availability. Identify if there is a disparity between existing services and perceived access by caregivers and patients.
- 4) Patterns of unmet needs vs secondary care usage. Explore if there is a correlation between unmet care needs and secondary care admission.

5.2. Outcome

The findings of this study should inform the design of supportive care services across Cheshire and Merseyside to benefit patients and their caregivers.

STUDY DESIGN AND METHODS OF DATA COLLECTION

All patients discussed in regional colorectal MDTs clinic over a one-year prospective period will be offered recruitment into the study, as will their main caregiver. We aim to recruit 100 patients and 100 caregivers over the course of the study.

The sample size calculation has been achieved using the EORTC QLQ-CR29 validated questionnaire as the primary measurement tool between the three groups of patients and performing a one-way ANOVA test. Allowing for a medium effect size and a dropout rate of 25%, 30 patients per group would be required. Given expected and unexpected mortality during the study this has been inflated to 100 patients in total (approximately 33 patients in each group).

The regional MDTs will include the 9 sub ICBS of Cheshire and Merseyside. MDT co-ordinators will be contacted at participating hospitals to provide a list of all patients discussed. Appropriate patients that fit the study criteria will be approached by their clinical team. Introduction of the study will ideally be done at the end of the consultation where treatment options and pathways have already been discussed with patients and their carers. Those who give consent will be grouped according to the severity of their needs as recorded in the initial questionnaire and geographical location that they live. In the case of caregivers, they will be group according to the severity of need recorded on CSNAT and the geographical location of where they live. A smaller percentage of patients present with

advanced colorectal cancer as an emergency admission either through a clinic appointment or accident and emergency. Recruitment of these patients during their admission will be up to the discretion of the clinical team and the appropriateness of discussing the study based on each individual case. If the clinical team feel appropriate relevant materials can be provided to the patient and the carer of their choice.

Each patient participant will complete 2 validated questionnaires (EORTC-QLQ-C29 and MYMOP2) and each carer will complete CSNAT.

Following this, purposive sampling of patients will select approximately 20 patients and 20 caregivers for semi-structured interview ensuring spread of representation from different geographical areas and severity of need. Purposive sampling will ensure a wide range of patients are included. This will include patients with protected characteristic (i.e age, sex, ethnicity, different education levels) but also include under-served groups highlighted by the NIHR in the INCLUDE project such as those with language barriers, digitally excluded/disadvantaged patients, religious minorities and people living in alternative residential circumstances [21]. The sampling method will ensure selection from a range of patients from different populations including those with frailty, metastatic disease and those approaching end of life to ensure that their views are captured.

The interview questions will be iteratively informed by the results of the questionnaires and patients and caregivers will be asked to reflect on the summary findings of the questionnaires and discuss how services currently meet (or do not meet) their needs and how they may be designed to better suit the needs of patients and caregivers at each stage of treatment. Interviews will be conducted individually or in focus groups according to participant wishes. Focus groups will be stratified by participant type, with separate groups conducted for patients and for carers with a minimum of two participants and maximum of four participants. Mixed groups will not be undertaken. This is to ensure confidentiality and to promote open, independent discussion, recognising that patients and carers may have differing perspectives and may feel constrained in expressing these fully in a mixed setting.

Alongside patient and caregiver interviews, the study will incorporate a structured stakeholder engagement process involving key clinical and service-level stakeholders across the Cheshire and Merseyside region. This will include surgeons, oncologists, palliative care doctors, and palliative care nurses who are directly involved in the care of patients with advanced colorectal cancer. Rather than solely conducting clinician interviews, this phase will engage stakeholders as partners in identifying unmet needs, service gaps, and opportunities for enhanced supportive care. Stakeholders (approximately 2 surgeons, 2 oncologists, 2 palliative care doctors, and 5 palliative care nurses) will be invited to participate in semi-structured interviews or facilitated engagement discussions to explore how the needs of this patient population are perceived from an MDT perspective, how care needs differ across clinical presentations, and how existing service pathways support or fail to support these needs. This engagement aims to capture the breadth of professional experience, illuminate systemic or organisational barriers to care, and ensure that emerging recommendations reflect the realities of frontline service delivery as well as patient and caregiver priorities.

RECRUITMENT AND PARTICIPANT ENTRY

7.1 Eligibility Criteria

Patients with advanced colorectal cancer that have been deemed by the local MDT not for curative treatment will be reviewed. All patients must be aware of their diagnosis and prognosis.

Inclusion Criteria- Patients

- Above age of 18
- Patients with colorectal malignancy that are not fit for surgical/curative intervention
- Patients with metastatic colorectal malignancy that have/will undergo chemotherapy with palliative intent
- Patients with metastatic colorectal malignancy that will not undergo chemotherapy
- Patients who have returned to the colorectal MDT with metastatic/metachronous disease that have had previous curative intent

Exclusion Criteria- Patients

- Refusal or inability to consent.
- Patients who are unaware of their diagnosis or prognosis
- Paediatric patients.
- Patients with colorectal cancer that MDT have deemed for curative treatment.

Inclusion Criteria – Carers

- Above the age of 18
- Caring for a patient that has advanced colorectal cancer of one of the inclusion criteria set out for patients

Exclusion Criteria - Carers

- Refusal or inability to consent
- Withdrawal of consent from patient

Inclusion Criteria – Clinicians

- Colorectal surgical consultants – two clinicians who work and treat patients with advanced colorectal cancer within the Cheshire and Merseyside area.
- Oncologists – two clinicians who work and treat patients with advanced colorectal cancer within the Cheshire and Merseyside area.
- Palliative care doctors who work and treat patients with advanced colorectal cancer within the Cheshire and Merseyside area.
- palliative care nurse who work and treat patients with advanced colorectal cancer within the Cheshire and Merseyside area .
- Colorectal nurse specialists who work and treat patients with advanced colorectal ,cancer within the Cheshire and Merseyside area.

Exclusion Criteria – Clinicians

- Clinicians who do not work within Cheshire and Merseyside area
- Clinicians who do not work with patients with advanced colorectal cancer or their carers.
- Refusal or inability to consent

Recruitment

Participants will be identified via

- 1) Prospective participants will be identified through each centre's local and the advanced regional MDT.
- 2) A smaller group of participants may be identified in each centre through emergency admissions due to symptoms or disease progression. This group of patients will be identified by and approached if only deemed appropriate by the clinical team during their admission.
- 3) Social media and advertisement of study. The ACRE study will be advertised in each recruitment centre and in the lobby of Clatterbridge cancer centre as well as Maggie's (charity). Patients or carers that approach will be given patient study information sheets and carer information sheets. If they would like to be recruited for the study, they will then contact the research team and sign a separate consent form to allow the research team to ensure their eligibility for the study. If deemed appropriate for recruitment will then be contacted by research team to discuss consent. A social media post may be platformed by the Clatterbridge Cancer Centre. If patients or carers choose to get in contact with the research team they will be provided patient and carer study information sheets and asked to a consent form to allow the research team to access clinical records to ensure eligibility.

- 4) Clinicians will be approached following patient and carer interviews from sites recruited to the ACRE study. They will be provided with Clinician information sheets and given approximately one week to review the information. They will then be contacted by the research team and if express interest in contributing to the study, will then be contacted for consent.

Informed Consent

MDT co-ordinators at all participating sites will be contacted to provide a list of patients with colorectal cancer that will be discussed. Appropriate patients that fit the study criteria will be approached by a member of their clinical team. It will be reiterated at this time by their clinical team that their participation in the ACRE study or decline, will not affect their clinical care in any way. The study will ideally be introduced towards the end of their consultation. Clinicians will introduce the concept of the study and only if the patient or carers express interest will further information be given. Patients who give consent to be contacted by a member of the research team will then be approached and given patient information sheet (PIS) and consent forms for them to review. They will also be asked at this time if they would be amenable for a carer of their choice to be nominated to also be recruited to the study. If a carer is nominated at this time a carer PIS and consent form will be provided for the participants to review.. Patients will have time to review and consider the information given them. Patients will then be approached via phone call after a period of approximately one week to assess interest or if they have any questions. It will be reiterated during this discussion that the participants involvement in the study will not affect their or their loved one's medical care at any stage whether they choose to participate or if they decline. . If patients confirm agreement, they will be asked to return the signed copy of consent form to the research team on site. This can be done at any appointment the patient attends at their respective hospital site. If the patient gives permission, their carer be contacted and asked if they have had time to review the carer information sheet and asked to sign a separate consent form.

If a patient withdraws consent for participation they will be asked in a private setting if they also withdraw consent for their carers continued participation. If a carer withdraws consent, the patient will be given the opportunity to continue on in the study. The consent form will also include whether they give consent for their carer to continue to participate in the event of the patient dying or losing capacity during the course of the study.

If a patient loses capacity during the course of the study, no further study activity will be undertaken with that participant. If a patient dies or loses capacity during the study that information already gathered may be included in the study results.

All consent forms will be stored securely on the UoL servers.

Structured interviews will be recorded via Microsoft teams with the inbuilt transcriptions service used. The type of data that will be collected will be qualitative in nature and include information on emotional, physical, emotional burden and service needs. These will be both questionnaires as well as structured interviews which will be recorded for later analysis. A combination of REDCAP and a request for ActiveDataStore will be put in place. As Microsoft teams will be used, only pseudo-anonymised transcripts will be saved onto UoL managed drives .

Patients and carers will be given the option of filling out questionnaires either electronically or manually. For patients with altered eye- sight a larger font option will be provided. If requested by patient's they will also be given the option of a member of the research team contacting them via telephone or video call and filling out the questionnaire on their behalf while verbally asking them the questions verbatim. If this option were to be chosen, the member of the research team would need to initial each questionnaire filled and submit a separate form giving reasoning for them to fill out the questionnaires on behalf of the patient or carer. Patient's telephone number will be obtained either verbally from the patient or via contact information held via the MDT co-ordinator team. No phone numbers will be stored once the questionnaire's have been filled or if patient / carer completes or declines participation in interviews. Translations of the validated questionnaires are available, however if the required language is not, attempts will be made to ensure that patients can fill these out through the use of a translational service such as language line which is used across the recruitment sites. This can be done via a telephone call with the translational service, research team member and patient or carer.

Selected patients and their carers will be invited to participate in individual interviews to explore their enhanced care needs. Participants will be informed that they may have a support person present during the interviews if they wish. It will be reiterated that patients and carers will not be interviewed together as a dyad. This approach is intended to create an environment that promotes expression and maintain confidentiality without concern that their responses may be constrained or influenced. They will also be asked if they would prefer to be interviewed individually or in a focus group. Focus groups will be conducted separately for patients and for cares with a maximum number of four participants to support discussion of complex or emotionally sensitive topics. Patients may choose to pause, skip a question/ topic or stop the interview process at any stage if they wish to do so. This will be reiterated at the beginning of the interview or if the interviewer feels that the participant is showing signs of discomfort, agitation or emotional distress.

For patients and carers invited to semi structured interviews, according to patient and carer preference this can be done face to face or via electronic means. If the participant prefers a face to face interview, this can be accommodated at a recruitment site of their choice in a dedicated room. For patients or carer's who are admitted onto a ward, a secure private room on the ward will be found

in order to carry out the interview. For participants who prefer to be in their home environment, an online Microsoft teams meeting will be held.

Clinicians and stakeholders will be approached from sites that have been recruitment centres for the ACRE study. If they agree to take part in the semi-structured interviews the same conditions given to patients and carers will be offered to the clinicians. Clinicians will be offered individual or group (maximum of four clinicians) structured interviews that will be recorded and transcribed via Microsoft teams. The pseudoanonymised transcriptions will be saved onto UoL servers. Clinicians will be offered interviews face to face, over the phone or via Microsoft Teams meeting.

If any costs were to be incurred during this such as car park fees/transport fees, patients will be remunerated for these in accordance with standard NIHR rates[22].

Relevant pathology and clinical data will be shared with the research team however this will be anonymised following purposive sampling. All questionnaire data will be anonymised prior to analysis.

ADVERSE EVENTS

9.1 Definitions

Given the nature of the study it is unlikely that an adverse event (AE) related to this research will occur. An AE is defined as any untoward medical occurrence in a patient or clinical study subject, including unfavourable and unintended signs, including abnormal laboratory results, symptoms or a disease associated with treatment.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- Results in death
- Is life-threatening
- Requires hospitalisation, or prolongation of existing inpatients' hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly or birth defect

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

However in relation to this study, as deaths and hospital admission are likely to occur given the characteristics of the patients, a separate form should be filled in and submitted to the PI. If there are concerns that this may be related to the study this should be highlighted to the PI and an AE form filled.

Further potential adverse events for this study relate to the emotional well being of patients and their carers. If any concerns are raised by participants, carers, family members or the medical teams providing care for these patients they will be offered immediate withdrawal from the study as well as being sign posted or actively put in touch with appropriate charities or medical/mental health professionals if the participant provides consent.

9.2 REPORTING PROCEDURES

9.2.1 Non-serious Adverse Events (AEs)

Non-serious AE will be recorded in patient's notes and a specific case report form will be sent to the CI.

9.2.2 Serious Adverse Events (SAEs)

In the case of a serious AE occurring the PI should complete the SAE form and send it to the CI and ACRE study team within 24 hours. It is the responsibility of the CI to notify the Sponsor of all SAE as well as ensuring as ensuring the HRA Non-CTIMP safety report to REC form is appropriately filled out.

Contact details for reporting SAEs

Dheepa.Nair@nhs.net

STATISTICS AND DATA ANALYSIS

Quantitative data will be entered and stored onto a REDCap database. The EORTC-QLQ- C29, MYMOP and CSNAT questionnaire data will be scored according to their manuals. Descriptive data will be presented overall and for each treatment group with mean scores compared using one-way analysis of variance to determine if there is a statistically significant difference between the corresponding population means. The data will be analysed to determine areas of high need both thematically within the questionnaires and geographically. Furthermore, questionnaires will also be analysed to determine if there are systematic differences in needs between those with metastatic disease (with or without chemotherapy) and those with resectable disease but with prohibitive frailty at presentation. Subsequent semi- structured interviews will be thematically reviewed to determine needs and perceived interventions which may support patients and caregivers at different stages of treatment and the geographical representation and accessibility of such services within Cheshire and Merseyside from the perspective of the service users.

Interviews will be recorded using Microsoft Teams and the transcription will be pseudonymised and confidentially stored on UoL servers. . Qualitative data from interviews will be anonymised, and analysed using reflexive thematic analysis. Coding and theme development will be conducted by with attention to positionality and reflexivity. Analysis will aim to describe key attributes of supportive care needs, unmet care needs, service distribution, access and utility across Cheshire and Merseyside.

REGULATORY ISSUES

11.1 Ethics Approval

Approval from the UK Health Department Research Ethics Service will be obtained for the study protocol as well as consent forms, patient information leaflets and any other relevant documents. Health Research Authority (HRA) approval will also be sought. The study will also be submitted to each research site for confirmation of approval. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

11.2 Confidentiality

The CI will uphold the confidentiality of all participants in this study and will abide by the Data Protection Act 2018 and the UK GDPR.

11.3 Indemnity

The University of Liverpool holds Indemnity and insurance cover with Newline Insurance Company, which apply to this study.

11.4 Audits

The study may be subject to inspection and audit by the University of Liverpool under their remit as Sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research (v3.2 10th October 2017).

END OF STUDY

The end of study will be the date on which the last participant (either patient, carer or clinician) completes their final participation in an interview or completion of questionnaire. Data pseudo anonymisation, transcription, analysis and dissemination of results will continue following this date and does not constitute part of the active study period.

The CI will notify the Sponsor committee at the end of the study as in accordance with HRA and REC guidance. All study data will be securely archived in line with UoL policies.

DISSEMINATION POLICY

13.1 Dissemination policy

The findings of this study should inform the design supportive care services across Cheshire and Merseyside to benefit patients and their caregivers. We will use social media and Patient Information Days and Support Groups (informed by our patient and caregiver collaborators) in the dissemination of the information about how services in the region need to be optimised to avoid a postcode lottery of access and improve the overall standard of care. A lay summary will be available for all participants to receive if they so wish.

On a wider scale, this study will be written up for peer reviewed publication and presented at conferences relating to supporting patients with colorectal cancer e.g. MASCC and ACPGBI annual conference.

The findings of this work will also inform wider work. The national ESC steering committee within the UK Association of Supportive Care in Cancer (UKASCC) is currently undertaking a national scoping review of ideal models of delivery for supportive care to inform the national ESC service specification.

13.2 Authorship eligibility guidelines and any intended use of professional writers

A final study reports will be provided at the end of the study to outline any key findings and progress.

ARCHIVING

Data and all appropriate documentation should be stored for a minimum of 10 years after the completion of the study, including the follow-up period, unless otherwise directed by the funder/sponsor/regulatory bodies.

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APPENDICES

16.3 Appendix 1 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.2	08/05/26	Dheepa Nair	