Supplementary Data: Contents

Supplementary Appendix S1: Study Protocol

Early support in primary care for people starting treatment for cancer

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CONTENTS

LIST OF ABBREVIATIONS

ACCORD	Academic and Clinical Central Office for Research & Development - Joint office for The University of Edinburgh and Lothian Health Board
ACP	Anticipatory Care Planning
AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
ECOG	Eastern Cooperative Oncology Group
GCP	Good Clinical Practice
GI	Gastrointestinal
ICH	International Conference on Harmonisation
KIS	Key Information Summary
MDT	Multidisciplinary team
PI	Principal Investigator
PPI	Patient public involvement
QA	Quality Assurance
RCT	Randomised controlled trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction

INTRODUCTION

1.1 BACKGROUND

About 40% of people with cancer in the UK do not receive palliative care and many others get it too late; for just 10 weeks before death on average.[1] Delays are multifactorial including the association of palliative care with dying among patients, their informal carers and many health professionals leading to a focus on cancer treatment until the person is clearly deteriorating.[2-4] There is growing evidence that all people with incurable, progressive cancers would benefit from systematic and targeted support from diagnosis. This support should include physical, psychological and family care alongside well-coordinated care planning in the community that is integrated with hospital-based care.[5-8] Uncertainties can be acknowledged and addressed and proactive care avoids health and care crises by planning ahead to prevent avoidable admissions when patients deteriorate at home.[9] Hoping for the best while also planning for what might happen was found to be realistic and effective in recent trials of people with incurable cancer in the USA.[10-12] Quality of life improves, burdensome treatments of limited value are avoided and hospital deaths reduce. Early palliative care now needs to be developed and trialled in the UK.[3]

1.2 RATIONALE FOR STUDY

This study will evaluate the feasibility of a randomised controlled trial (RCT) of the provision of early palliative care including anticipatory care planning that is systematically triggered when patients with poor prognosis gastrointestinal cancers start palliative oncology treatment and is coordinated in primary care.

A Cochrane systematic review of completed and ongoing trials of early palliative care for adults with advanced cancer is now available.[13] The seven trials showed that in patients with advanced cancer, early palliative care may “slightly” increase quality of life and reduce symptom intensity. Effects on survival and depression were uncertain. One study reported more pain and reduced appetite. No adverse effects were reported in the others. Results from 20 ongoing studies and seven studies awaiting assessment may increase the evidence base for positive impacts of early palliative care. The reviewers noted that early palliative care is a newly emerging field so further well-conducted, controlled trials are a priority describing the timing, components and settings of early palliative care and control treatments.

Evidence for the effects of palliative care given later is still ambiguous because the time to establish beneficial effects may be too short.[14-17] Palliative interventions applied early, around the time of diagnosis of incurable cancer, may have positive effects on symptoms and disease management. Some investigators believe that a paradigm shift has already started where integrated palliative care as part of cancer care becomes the norm.[18-20] We have studied other reviews of early palliative care interventions for patients with advanced cancer to consider possible settings, interventions, evaluation tools and outcomes.[21-28] Early palliative care in cancer has so far almost exclusively been evaluated in the context of tertiary care, conceptualised as a complex intervention and consist of specialist palliative care integrated with ongoing oncological treatment as in the landmark Temel study.[10]

Trials of early palliative care delivered by other hospital specialists and primary care teams in the community are of strategic public health importance since most palliative care in the UK is in fact delivered by generalists supported by specialists. It is estimated that 75% of palliative care needs can be met by primary care teams: in the UK patients spend 90% of their last year of life living in the community. Systematic programmes to promote palliative care in the

community in five European countries have been reviewed recently but have not yet been evaluated in definitive controlled trials.[29]

We propose a timely and important feasibility randomised controlled trial of early generalist, palliative care. Findings will be highly relevant to the many people living with poor prognosis cancers across the UK where palliative care in the community is provided variably. This trial starts with early identification in hospital and is delivered in the community where the patient and carer will have an opportunity to discuss their illness and support needs and plan their future care.[30] Patients and their families will receive proactive support and care planning and primary care professionals will be involved from the outset. We will target care of people with inoperable oesophageal or gastric cancers or advanced pancreatic cancers because of their poor prognosis despite optimal cancer treatment (median survival 25 weeks).[31-32] Instead of waiting until people's health is deteriorating, we will evaluate the impact of offering coordinated, early support from their primary care team from the start of palliative chemotherapy or radiotherapy. A mixed-methods approach will be used in line with recommendations for palliative care research and clinical trial development.[30, 33]

Early palliative care, as advocated and reaffirmed in 2014 by the WHO, is already central to health and care policies across the UK.[3] The top priority of the Scottish Palliative and End-of-Life Framework is timely identification for palliative care. We will identify people with incurable cancer at initial diagnosis or relapse – a readily identifiable but rarely used time point when patients and families tend to experience significant distress.[2] This study aligns with national initiatives such as the Scottish Anticipatory Care Planning programme, UK guidance on cardiopulmonary resuscitation discussions and emergency treatment and care planning. UK primary care teams will coordinate palliative cancer care increasingly as the focus of health and social care shifts from hospital to community. 'Realistic Medicine' and 'Choosing Wisely' initiatives also seek to empower people to make informed choices about treatment and holistic care when they have an advanced illness.[34-37]

This study will also align with our work on shared decision-making in the Macmillan Cancer Support *Building on the Best* programme in Scotland and a recent Macmillan programme in NHS Fife offering specialist palliative care for all patients with lung cancer receiving best supportive care.[38] This feasibility, RCT starts earlier than the Fife project which systematised Best Supportive Care. We will evaluate patient and family experiences along with key service outcomes including hospital bed days, admissions, chemotherapy in the last phase of life, and place of death to identify suitable outcomes for a subsequent full RCT. We will also seek to identify any side-effects associated with introducing palliative care early as this aspect has been poorly studied. We have listed such possible harms in a recent review of early palliative care in Europe.[29]

2 STUDY OBJECTIVES

2.1 OBJECTIVES

2.1.1 Primary Objective

We aim to assess the feasibility and acceptability to patients and carers of a person-centred, care planning intervention based in primary care for people who have advanced oesophageal, gastric or pancreatic cancer within a feasibility phase 2, randomised controlled trial involving 50 participants.

2.1.2 Secondary Objectives

- Establish if the trial methodology and care planning intervention are feasible, acceptable, deliverable and potentially cost effective for primary care teams and hospital specialists.
- To involve and empower patients with poor prognosis cancers and their families by offering them the Scottish Anticipatory Care Planning resources soon after diagnosis and facilitating their participation in early cancer care reviews with their GP and other members of the primary care team.
- To assess the feasibility of using various types of outcome measure in this context, and gather useful information on between and within patient variability which will inform the design of the future definitive Phase III trial.
- To map the patient journey from treatment planning to death or 12 month survival and evaluate the impact of the care planning intervention on participants' treatment choices, service use (including timing and costs of chemotherapy and/or radiotherapy and hospital inpatient bed days), care coordination (including use of the Scottish Key Information Summary – an electronic anticipatory care record) and place of death.
- Assess the feasibility of a subsequent, full RCT in terms of recruitment, retention and qualitative and quantitative data collection and to identify suitable primary and secondary outcomes

2.2 ENDPOINTS

2.2.1 Primary Endpoint

The main feasibility outcomes for this feasibility study are the proportion of eligible patients willing to be recruited and randomised, and the number in the intervention group who received at least one anticipatory care planning review at their GP practice documented in a new or updated KIS.

The primary trial outcome will be health related quality of life assessed using two validated, complementary tools: the EuroQol EQ-5D-5L and the ICECAP Supportive Care Measure.

2.2.2 Secondary Endpoints

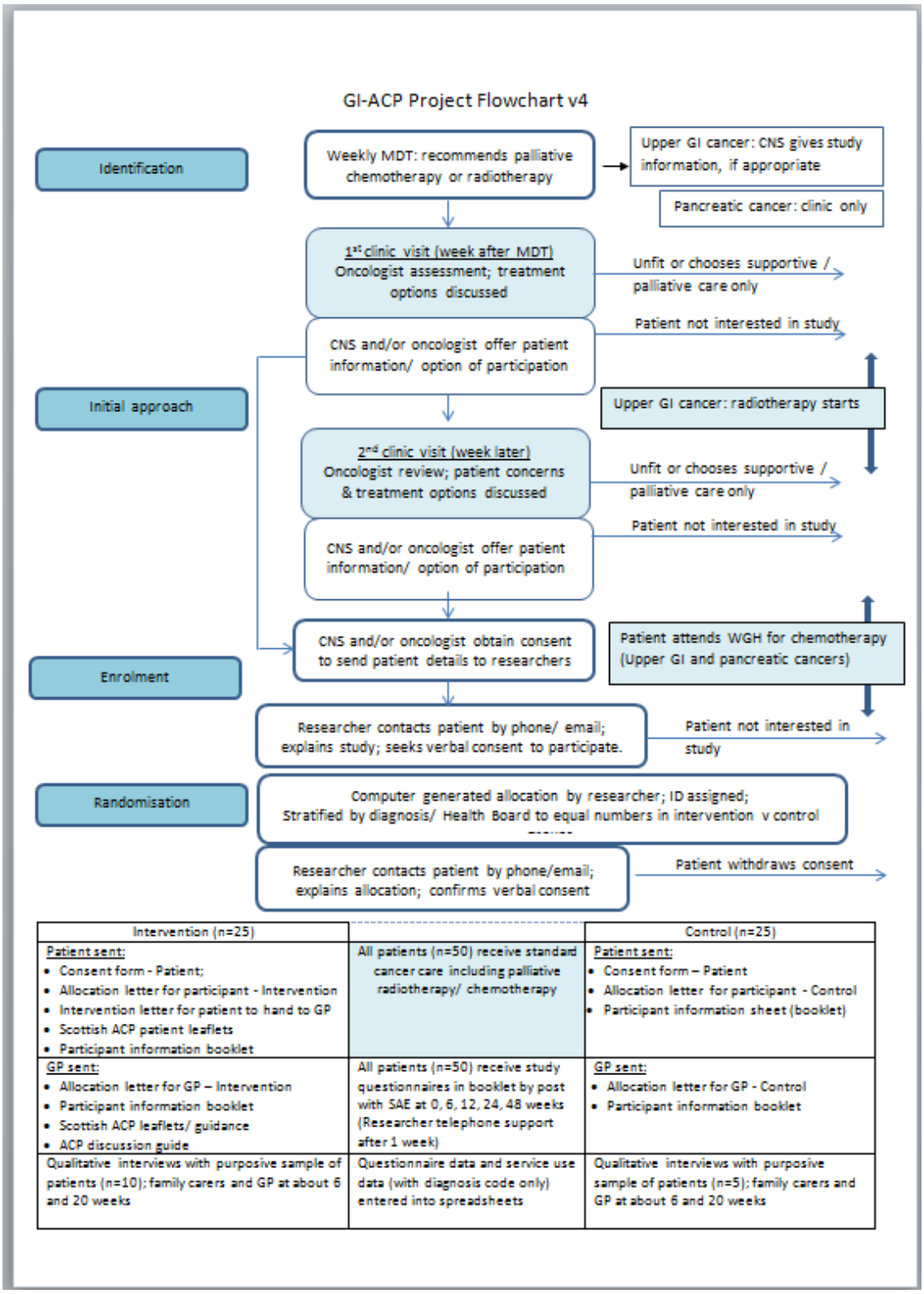
Formal evaluation of early palliative care interventions in the UK health context is essential. This study addresses an important evidence gap and for the first time the key role played by primary care in the delivery of widely accessible early palliative care. This study will yield important feasibility data to inform a multi-site RCT as follows:

- A multi-dimensional assessment of the feasibility and acceptability to patients and families of a randomised controlled trial (RCT) of person-centred, care planning for people who have advanced gastric, oesophageal or pancreatic cancer and are starting palliative chemotherapy/ radiotherapy.
- An assessment of the feasibility and acceptability of an RCT of proactive early palliative care intervention based in primary care with primary care teams and hospital specialists.
- An evaluation of the acceptability, experiences and impact of specific components of the trial intervention including the letter from the oncologist for the patient to take to their GP, anticipatory care planning including completion of a Key Information Summary, and early cancer care reviews in primary care from the perspectives of patients, families/ carers and GPs.

- An evaluation of the use of the new Scottish Anticipatory Care Planning resources from the perspectives of patients, families/ carers and GPs.
- An evaluation of the feasibility of capturing key person-centred outcomes with respect to quality of life, shared decision-making in an RCT, and the impact of proactive care planning on these aspects of patient experience.
- An in-depth understanding of the overall treatment and care experiences of people with poor prognosis oesophageal, gastric or pancreatic cancers and their families.
- A detailed care process map of the patient journey from treatment planning and starting chemotherapy/ radiotherapy to death or 12 month survival.
- An evaluation of the impact of a proactive, anticipatory care planning intervention on participants' treatment choices, service use (including the timing and standardised costs of chemotherapy and/or radiotherapy; oncology treatment within 30 and 90 days of death; and hospital inpatient bed days), care coordination (including use of the Scottish Key Information Summary) and place of death.
- Completion of a Phase 2 RCT that will support refinement of the intervention and inform planning for a subsequent, full RCT in terms of recruitment, retention and qualitative and quantitative data collection, identification of suitable primary and secondary outcomes, and power calculations.

3 STUDY DESIGN

This is a 24-month feasibility randomised controlled trial of a care planning intervention, involving patients starting palliative oncology treatment in a Scottish regional cancer centre. Participants will be patients with a recent diagnosis of a poor prognosis cancer (first diagnosis or relapsed disease) who are being offered palliative chemotherapy or radiotherapy. The study methodology fits with the MRC Framework for evaluating complex healthcare interventions. The design builds on a similar RCT of anticipatory care planning for people with advanced heart disease. As recommended, we are using a mixed-methods approach integrating quantitative and complementary qualitative data collection. The Edinburgh Clinical Trials Unit will provide a customised, online randomisation service and will guide the trial design development, statistical analysis and reporting of the quantitative study data.



Intervention (n=25)		Control (n=25)
Patient sent: • Consent form - Patient; • Allocation letter for participant - Intervention • Intervention letter for patient to hand to GP • Scottish ACP patient leaflets • Participant information booklet	All patients (n=50) receive standard cancer care including palliative radiotherapy/ chemotherapy	Patient sent: • Consent form – Patient • Allocation letter for participant - Control • Participant information sheet (booklet)
GP sent: • Allocation letter for GP – Intervention • Participant information booklet • Scottish ACP leaflets/ guidance • ACP discussion guide	All patients (n=50) receive study questionnaires in booklet by post with SAE at 0, 6, 12, 24, 48 weeks (Researcher telephone support after 1 week)	GP sent: • Allocation letter for GP - Control • Participant information booklet
Qualitative interviews with purposive sample of patients (n=10); family carers and GP at about 6 and 20 weeks	Questionnaire data and service use data (with diagnosis code only) entered into spreadsheets	Qualitative interviews with purposive sample of patients (n=5); family carers and GP at about 6 and 20 weeks

Study setting: The study will be conducted in NHS Lothian and NHS Fife – patients in these Boards are under the care of regional oncology services based at the Edinburgh Cancer Centre. Patents eligible for this study receive surgical care at the Royal Infirmary of Edinburgh (NHS Lothian) and are reviewed at the multi-disciplinary cancer care meetings there. We will identify eligible patients at those twice weekly meetings. Patients who are being offered palliative cancer treatment are then reviewed in oncology outpatient clinics in NHS Lothian and NHS Fife.

Patient recruitment and duration of involvement: The two consultant oncologists and the two clinical nurse specialists who are co-applicants will identify eligible participants, offer them information about the study and with their consent pass their contact details to the researcher who recruits and randomises 2-3 patients per week for 25 weeks using an online randomisation programme. A total number of 50 participants will be randomised to a) intervention: Early Contact group (n=25) b) control: Standard Care group (n=25) using a secure web-based randomisation system with a unique username and password for each researcher. Randomised allocations will be concealed until they are assigned. The randomisation will use computer-generated pseudo-random numbers to create random permuted blocks stratified by diagnostic group (gastrointestinal cancer or pancreatic cancer) and Health Board to ensure balance between the treatment arms in the number of patients with these characteristics.

Patients will remain in the study for up to 12 months unless they withdraw or die.

Trial Intervention: Intervention patients will receive a letter from their oncologist to take to their GP practice to support them in making an appointment with their general practitioner before or soon after starting treatment to discuss their ongoing care and support needs, and a copy of the new Scottish Anticipatory Care Planning (ACP) patient leaflets. A copy of this letter from the oncologist and ACP information for professionals will be sent to the GP practice with a request for the GP to review the patient, start a Key Information Summary (KIS), and offer regular cancer care reviews in primary care.

Quantitative data collection and analysis:

Participants in the intervention arm (n=25) and control arm (n=25) of the trial will be sent two questionnaires at baseline, 6, 12, 24 and 48 weeks after recruitment. Patient experiences and health related quality of life will be evaluated using the EuroQol EQ-5D-5L and the ICECAP Supportive Care Measure questionnaires.

The CollaboRATE measure of shared decision-making will also be completed at these time points to evaluate the most recent oncology consultation as this is a central tenet of high quality cancer care. The three questionnaires will be presented in a booklet that has been reviewed by our PPI advisory group and it will be sent to participating patients by post along with a freepost envelope for their return. The researcher will contact the patient by phone a week after the questionnaire booklet is sent out to help support completion.

Participants in the intervention arm (Early Contact group) will be asked a supplementary question about the value of the Scottish ACP leaflets and whether their GP discussed having an anticipatory care plan or KIS.

The questionnaire data for each participant will be identified by a unique study number and entered into a spreadsheet for analysis by a statistician from the Edinburgh Trials unit. We will obtain data from participants about their reported quality of life and experiences of care including shared decision-making. As this is a feasibility trial, we will also monitor questionnaire completion and return rates along with attrition generally.

Qualitative data generation and analysis

There is also conduct a nested qualitative study. This is best practice to refine the intervention and its evaluation. We will triangulate views of patients, informal carers and GPs to understand how this intervention is perceived and could be improved. Interviews will explore people's views about participating in the trial, and the survey instruments as well as their experiences of treatment and care of people with poor prognosis GI or pancreatic cancers.

The researcher will conduct interviews in the patient's home at about 6 weeks and again at about 20 weeks to provide a longitudinal perspective. We will interview a purposive sample of 15 patients (10 intervention group and 5 control group), their nominated informal/ family carer and their GP (20-30 minute telephone interview). If a patient dies between the interviews, we will seek a carer bereavement interview and interview the GP. Our experience suggests about half of patients and carers prefer a joint interview so patients and carers will be offered this option. Carer perspectives will explore whether the intervention should be extended to highlight carer needs systematically.

Service data

Routine service use data collected for both groups from hospital electronic records and the oncology patient database by the cancer clinicians and the principal investigator. These data will be collected to map the care journey of both intervention (25) and control (25) patients from treatment planning to death or for up to 12 months. Hospital electronic records and the cancer patient database will be used along with primary care and palliative care service data obtained by phone. Includes:

Anonymised service use and questionnaire data will be analysed using descriptive statistics at each follow-up time point and using change from baseline. Interviews will be recorded using an encrypted digital recorder, anonymised, fully transcribed and analysed using a thematic approach together with field notes within and across cases and integrated with the service use and questionnaire data. Standard costings will be applied to service data collected where feasible with support from a health economist in the Clinical Trials Unit, and guided by costs used in a previous study by co-applicant JB.

Project time scale and milestones

Months -3 to 0:

- Preparation and submission of applications for Ethics and R&D review.
- Meetings with the PPI representatives and advisory group to prepare the participant information booklet and the intervention letter from the oncologist for the Early Contact group patients to take to their GP.
- Randomisation process confirmed and set up by the Edinburgh Clinical Trials Unit
- Researcher appointment confirmed and research passport sought.

Months 1-4

- Ethics, R&D approvals and research passport obtained
- Information about study circulated to relevant clinical departments
- Briefing of relevant clinicians about identification and recruitment procedures
- Documentation prepared including patient letters & questionnaires.
- Formats agreed for collecting routine clinical and research data and set up.

Months 4-9

- Oncology nurses (LG and NB who are co-applicants) identify and the researcher recruits and randomises 2 patients per week for 25 weeks (n=50)
- Research team sends all patients (n=50) questionnaires at 0, 6,12, 24 and 48 weeks after recruitment .

- Researcher conducts a nested qualitative study and interviews with 10 intervention and 5 control patients and their linked family carer at about 6 and 20 weeks

Months 4-16

- Research administrator collates and inputs anonymised clinical, questionnaire and service usage data for analysis by Trials Unit statistician.

Months 5-16

- Researcher generates and analyses qualitative data. Research secretary anonymises and transcribes interviews for analysis. Ongoing data analysis to inform second interviews. Regular review of progress and emerging themes by PPI group and steering group members.

Month 10-22

- Research team and cancer clinicians collect routine clinical/ service use data.

Month 21-24

- Complete and integrate quantitative and qualitative data analyses.
- Write report for funder and academic publications. All to contribute, including some PPI group members
- Start wide dissemination through Scottish Research Forum, and oncology networks
- Consider proposal for UK, multi-centre intervention trial.

4 STUDY POPULATION

4.1 NUMBER OF PARTICIPANTS

50 patients with poor prognosis cancers randomised to intervention or control

15 family carers invited for interview (10 intervention 5 control)

15 GP interviews with linked cases (10 intervention 5 control)

4.2 INCLUSION CRITERIA

People aged 18 or over with advanced, inoperable oesophageal, gastric or pancreatic cancers being offered palliative chemotherapy and/or radiotherapy are eligible. Newly diagnosed patients and patients whose cancer has relapsed after radical treatment who choose to have palliative chemotherapy and/or radiotherapy aimed at reducing cancer progression but not cure are eligible. Patients will come from two Health Boards and have diverse demography.

The Lothian interpreter service (used for all translation work with patients/ families NHS practice) may be used for patients/ carers who do not speak English or who communicate through British Sign Language.

4.3 EXCLUSION CRITERIA

•People too ill to participate or give informed consent.

•Patient who are not fit for oncology treatment or who opt for best supportive care.

•People with other life-limiting conditions likely to cause death within 6 months.

•People with moderate to severe cognitive impairment that precludes completions of questionnaires or participation in interviews.

• People unable to give informed consent or communicate by telephone with the researcher.

4.4 CO-ENROLMENT

We are aware of two other trials currently open to similar participants. One is a chemotherapy drug trial recruiting very small number of participants who have gastrointestinal cancers and

specific treatment criteria. The other is a trial of nutritional supplements, self directed exercise and anti-inflammatory medication for which a few of the patients with pancreatic cancer may be eligible

This study does not involve any additional medications, investigations or hospital visits so can be considered 'low burden'. Eligibility is much wider than for the other two studies so we anticipate that there will be many more people able to participate than in the other studies and that there will be no co-enrolment.

5 PARTICIPANT SELECTION AND ENROLMENT

5.1 IDENTIFYING PARTICIPANTS

All patients with a new diagnosis of gastrointestinal or pancreatic cancers or relapsed cancer are reviewed at the weekly cancer multi-disciplinary team meetings at the Royal Infirmary of Edinburgh attended by the two consultant oncologists, the consultant surgeon and the clinical nurse specialists who are co-applicant for this study. These clinicians are those caring for eligible participants. They will identify potential participants and offer them information about the study when the patient is attending their initial or second oncology outpatient clinic.

If an eligible patient is interested in talking with the study researcher about taking part in the study, they will be asked by their cancer clinicians to give written consent for their contact details to be passed to the research team. This information will be recorded on a participant contact information sheet by their cancer clinician, scanned and emailed from a secure NHS account to the study 'nhs.net' account only accessible to the study principal investigator, the researcher and the study administrator.

Participating patients who are selected for the qualitative component of the study will be asked by the researcher for their permission for her to approach their main informal carer and their GP for interview.

Once a patient has consented to take part in the study their GP will be informed by the research team.

5.2 CONSENTING PARTICIPANTS

The study researcher (Marilyn Kendall) will be taking informed consent from all participants.

- Recruitment of patients for randomisation:

The researcher will contact each new potential participant by phone or email (according to their preference) a minimum of two working days after receiving the person's contact details from their cancer clinician. During the telephone contact the researcher will outline the project and answer questions. The potential participant will be asked if they wish to take part, wish to decline or wish further time to consider. It will be made clear that even if they consent to take part at this time that they can change their mind subsequently. The researcher will seek verbal consent to randomise them. She will arrange a convenient time to phone back with the outcome of the randomisation.

- Confirmation of consent and permission to send research packs with questionnaires:

The researcher will complete the randomisation using a customised online programme developed by the Edinburgh Trials Unit which generates a study number and will be set up to stratify participants by diagnosis (GI cancer or pancreatic cancer) and by Health Board to ensure a diverse sample. She will phone back and inform the person if they have been randomised to the intervention or control group and answer any questions about what that

means. She will confirm verbal consent and explain that the participant will be sent their research pack in the post by the study administrator along with a consent form which they are asked to sign and return with the questionnaire booklet. A copy of the consent form for the participant to keep will be enclosed.

- Follow-up and confirmation of consent to remain in the study:

A week before each questionnaire pack is due to be sent (6, 12, 24, 48 weeks), the researcher will contact the participant again by phone to confirm they are able and willing to continue in the study.

- Consent for interview (patient and carer):

For participants sampled for interview at 6 weeks, the researcher will seek verbal consent to interview by phone at the same time as contacting the participant about the 6 week questionnaire pack. If the participant agrees to interview, the researcher will arrange a convenient time to interview the person in their own home. The consent form includes a request that the person agree to interview so any participant who has not consented to interview will not be approached.

At the same time, the participant will also be asked by the researcher if their main family/ informal carer would be willing to take part in an interview as well. An informal carer is close family member or friend who a patient participating in this project has nominated as someone who takes the lead in helping look after them whether or not this person is considered by either party as a "carer." The researcher will ask the participant to invite their carer to contact her by phone or email to talk about the study and taking part. When contacted by the carer, the researcher will verbally outline the project and answer questions. The informal carer will be asked if they wish to take part, wish to decline or wish further time to consider. It will be made clear that even if they consent to take part at this time that they can change their mind subsequently. Verbal consent will be obtained by phone and the interview arranged at a time and place to suit the carer. A carer letter and participant information booklet will be sent to the carer by the researcher.

Our experience in similar studies is that most carers opt for a joint interview with the patient but each carer will be given the option of a shared interview or a separate interview at a convenient time and place for them. Written consent

Each carer will have an opportunity to ask the researcher questions about the study and will be asked to complete a written consent form at the start of their interview.

For the follow-up interviews at about 20 weeks, the researcher will phone the patient and their informal carer about a week beforehand to check they are able and willing to take part and make arrangements to conduct the interview. Consent will be confirmed at the start of each interview. If a patient dies between the first and second interview, their informal carer will be approached 6-8 weeks later and asked to agree to a bereavement interview.

Consent for interview (GP):

The GP of all participants will have been informed by letter at the start of the study that their patient is taking part and the person’s allocation group. The GP will have been sent a copy of the participant information booklet and an explanation that some GPs will be approached for interview at 6 and 12 weeks with the participant’s consent.

If a patient is participating in the interview component of the study, they will be asked for the name of the GP they have had most contact with recently and for permission to approach that GP for an interview about the person’s treatment and care. The researcher will then contact the GP at the practice to invite them to participate in a telephone interview. During the telephone contact the researcher will verbally outline the project and answer questions. The GP will be asked if they wish to take part in an interview, wish to decline or wish further time

to consider. It will be made clear that even if they consent to take part at this time that they can change their mind subsequently. They will be offered another copy of the participant information booklet and given a minimum of two working days to decide if they wish to participate

Written consent will be obtained by emailing the consent form to the practice and asking the GP to return it to the study administrator for secure storage before or after their interview. The telephone interview will be arranged with the GP for a convenient time. The GPs of any patients who die between the first and second interview will still be approached for interview.

5.2.1 Withdrawal of Study Participants

Participants are free to withdraw from this study at any point or a participant can be withdrawn by their cancer clinician or GP if their health deteriorates. If withdrawal occurs, the primary reason for withdrawal will be documented in the participant's case report form.

The participant will be asked for written consent but will always have the option of withdrawal from:

(i) All aspects of the trial but continued use of data collected up to that point

(ii)All aspects of the trial with removal of all previously collected data.

Given that this study involves people with poor prognosis cancers, we expect that there will be a number of withdrawals due to deteriorating health or death.

The cancer clinicians and study principal investigator (an NHS Lothian consultant) will monitor the patient's electronic records to identify if any participating patients have died so that they are withdrawn in a timely manner.

5.3 STUDY ASSESSMENTS

<u>0 weeks (baseline assessments</u>

Completion of booklet containing 3 questionnaires to be returned by post (50 patients)

<u>6-8 weeks</u>

Completion of booklet containing 3 questionnaires to be returned by post (50 patients)

Interview at home of patient with carer or separately by researcher (15)

<u>12 weeks</u>

Completion of booklet containing 3 questionnaires to be returned by post (50 patients)

<u>20-24 weeks</u>

Interview at home of patient with carer or separately by researcher (15)

<u>24 weeks</u>

Completion of booklet containing 3 questionnaires to be returned by post (50 patients)

<u>48 weeks</u>

Completion of booklet containing 3 questionnaires to be returned by post (50 patients)

5.4 LONG TERM FOLLOW UP ASSESSMENTS

Not applicable: there will be no long-term follow-up beyond the 12 months of the study.

6 DATA COLLECTION

Demographic data will be collected by the participants' cancer clinicians.
These data are: name, CHI number, date of birth, contact details, address, postcode (for deprivation score) GP practice name/ number, preferred GP's name.

Clinical data, cancer treatment and service use data will be collected by the participants' cancer clinicians and/or the principal investigator (an NHS Lothian consultant). These data are: gender, cancer diagnosis, new or recurrent disease, disease extent, surgical treatment given (if any), initial oncology treatment plan, social support/ marital status (if available), initial ECOG performance status, major co-morbidities, agreed oncology treatment plan, oncology treatments given, reasons/outcomes of hospital admissions, KIS review, place of death, main underlying cause of death.

Key dates to be recorded for a 'timeline' include:

Initial MDT review meeting, date of 1st oncology clinic visit, date recruited and randomised, dates of oncology clinic visits for review, date of final oncology treatment, dates of GP practice visits, dates of hospital admissions, date of death

Questionnaire data will be collected by post with study packs being sent to the patient's home address by the study administrator. The researcher (Marilyn Kendall) will follow-up the patient by phone a week before sending out the questionnaires and 1 week after the questionnaires have been sent out to offer support and help with completion.

- EuroQol EQ-5D-5L (https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/)
- ICECAP Supportive Care Measure – University of Birmingham (https://www.birmingham.ac.uk/research/activity/mds/projects/HaPS/HE/ICECAP/Evaluation-of-End-of-Life-Care/ICECAP-SCM.aspx)
- CollaboRATE shared decision-making evaluation tool https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3906697/

The researcher will record the patient, carer and GP interviews using an encrypted digital recorder that meets NHS standards. The files will be transferred to a password protected folder on a University of Edinburgh computer and deleted from the recorder before being transcribed with no person identifiable data by the study administrator. The transcriptions will be entered into NVivo (qualitative data analysis package) for subsequent analysis.

6.1 Source Data Documentation

- Patient contact agreement sheet with contact details (secure storage)
- Patient clinical information and service use recording sheet (secure storage)
- Questionnaires EQ-5D, ICE-CAP and CollaboRATE made up as a booklet for participants to complete
- Transcripts of interviews – anonymised for primary analysis and storage for potential future analyses.

6.2 Case Report Forms

Data from the patient clinical record sheets and from the questionnaire booklets to be entered into a spreadsheet (using participant study ID as the identifier) - for analysis by the Edinburgh Clinical Trials Unit statistician.

7 STATISTICS AND DATA ANALYSIS

7.1 SAMPLE SIZE CALCULATION

The number of participants and timing of the data collection is planned expecting that 50% of patients will die by 6 months. The sample size of 50 (25 per group) will provide acceptable precision in estimating feasibility outcomes:

1. Proportion of patients screened for the trial willing to consent and be randomised.
2. Proportion of patients who are still alive retained in the study through all follow-up time points (any difference in retention between intervention and usual care groups).
3. In the intervention group, proportion of patients who do make an appointment with their GP to discuss their ongoing care and support needs.

If the true conversion rate from screening to consent is 50%, then the 95% confidence interval for our estimate of the screening to consent conversion rate will have width +/-9.8%. Similarly, the confidence interval width for the proportion of participants randomised to the intervention who actually make a GP appointment to discuss their ongoing care and support needs will have width ranging from +/-11.8% to +/19.6%.

7.2 PROPOSED ANALYSES

Analysis of the quantitative data will largely consist of descriptive statistics and comparison between the intervention and control groups.

Throughout, continuous variables will be summarised by treatment group and overall using the mean, standard deviation, median, lower quartile, upper quartile, minimum and maximum values. Categorical variables will be reported by treatment group and overall using the frequency and percentage for each category.

Baseline demographic and clinical data will be summarised by treatment arm and overall.

Each of the primary feasibility outcomes (proportion of eligible patients willing to consent and be randomised; proportion of patients randomised to the intervention arm who do make an appointment with their GP to discuss their ongoing care and support needs) will be analysed by calculating the proportion and its exact binomial 95% confidence interval.

The proportion of participants in each treatment arm retained in the study through all follow-up time points will be analysed in the same manner. Furthermore, the difference in retention proportions between treatment arms will be calculated, along with its 95% confidence interval calculated using the normal approximation to the binomial distribution.

Clinical outcomes EQ-5D-5L, ICE-CAP and CollaboRATE will be summarised by treatment arm and overall.

As this is a feasibility study, there will be no imputation of missing data; the missing data rates will be reported by treatment group to inform on trial feasibility. Descriptive summaries of the baseline demographic and clinical data and primary and secondary outcomes will also be provided for the subgroups defined by the randomisation strata: diagnostic group

(gastrointestinal or pancreatic) and Health Board. The intention to treat principle will be followed in all analyses. There are no formal interim analyses planned.

Qualitative data analysis will be supported by use of the data analysis package NVivo. The researcher has extensive experience of using this programme in similar qualitative interview studies. The interviews will be coded and analysed thematically within and across cases and longitudinally in line with established methods for narrative analysis.

8 ADVERSE EVENTS

We consider this study to have a low level of risk to participants. It is possible that some participants may be upset by thinking and talking about their health and wellbeing and the impact of a cancer diagnosis and treatment. They will have standard care support from their cancer nurse specialist and the project researcher will be in regular contact to support participants with the questionnaire completion and any concerns they may have about the study. She is a senior social scientist with extensive experience of conducting potentially sensitive interviews with people living with advanced and life-limiting conditions.

We will monitor the study patients carefully so that any change in their condition including deteriorating health or death is identified and addressed. This will include proactive checks made by the clinical team as part of routine monitoring and care. The clinical team will update the research team if there are any changes that might impact on a participant continuing in the study as well as if they die. The researcher will talk with participants about contacting them before each study pack of questionnaires is posted out to check that they are still able and consent to receive it. In our previous longitudinal studies, having a single researcher in regular contact with participants enables rapport to be established such that people feel supported by regular contacts and able to withdraw at any time without difficulty.

9 OVERSIGHT ARRANGEMENTS

9.1 INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, REC review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation. Consent for this access will be obtained from participants.

9.2 RISK ASSESSMENT

A study specific risk assessment has been performed by ACCORD in accordance with ACCORD governance arrangements and the study has been designated as low risk not requiring planned monitoring although some monitoring may occur.

9.3 STUDY MONITORING AND AUDIT

The ACCORD Sponsor Representative has assessed the study and decided that no independent risk assessment is required.

10 GOOD CLINICAL PRACTICE

10.1 ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

10.2 INVESTIGATOR RESPONSIBILITIES

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

10.2.1 Informed Consent

The Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information – appropriate Participant Information and Informed Consent Forms will be provided. The oral explanation to the participant will be performed by the Investigator or qualified delegated person, and must cover all the elements specified in the Participant Information Sheet and Consent Form.

The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant must be given sufficient time to consider the information provided. It should be emphasised that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant will be informed and agree to their medical records being inspected by regulatory authorities and representatives of the sponsor(s).

The Investigator or delegated member of the trial team and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The participant will receive a copy of this document and a copy filed in the Investigator Site File (ISF) and participant's medical notes (if applicable).

10.2.2 Study Site Staff

The Investigator must be familiar with the protocol and the study requirements. It is the Investigator's responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

10.2.3 Data Recording

The Principal Investigator is responsible for the quality of the data recorded in the CRF at each Investigator Site.

10.2.4 Investigator Documentation

The Principal Investigator will ensure that the required documentation is available in local Investigator Site files ISFs.

10.2.5 GCP Training

For non-CTIMP (i.e. non-drug) studies all researchers are encouraged to undertake GCP training in order to understand the principles of GCP. However, this is not a mandatory requirement unless deemed so by the sponsor. GCP training status for all investigators should be indicated in their respective CVs.

Professor Weir (Edinburgh Trials Unit) has GCP training, as indicated in his CV and the study researcher and PI will complete this before recruitment starts.

10.2.6 Confidentiality

All laboratory specimens, evaluation forms, reports, and other records must be identified in a manner designed to maintain participant confidentiality. All records must be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The Investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

10.2.7 Data Protection

All Investigators and study site staff involved with this study must comply with the requirements of the General Data Protection Regulation (2018) with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Access to collated participant data will be restricted to individuals from the research team treating the participants, representatives of the sponsor(s) and representatives of regulatory authorities.

Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data that could allow identification of individual participants.

11 STUDY CONDUCT RESPONSIBILITIES

11.1 PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D for approval prior to participants being enrolled into an amended protocol.

11.2 MANAGEMENT OF PROTOCOL NON COMPLIANCE

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsors and therefore will not be implemented, except where necessary to eliminate an immediate

hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the REC, and local R&D for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsors every 3 months. Each protocol violation will be reported to the sponsor within 3 days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multi-centre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

11.3 SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or

(b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the co-sponsors (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the co-sponsors to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

11.4 STUDY RECORD RETENTION

All study documentation will be kept for a minimum of 3 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

11.5 END OF STUDY

The end of study is defined as the last participant's end of follow-up period – that is up to 12 months from study entry or to withdrawal or death if sooner.

The Investigators or the co-sponsor(s) have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, and R+D Office(s) and co-sponsors within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. End of study notification will be reported to the co-sponsors via email to resgov@accord.scot.

A summary report of the study will be provided to the REC within 1 year of the end of the study.

11.6 INSURANCE AND INDEMNITY

The co-sponsors are responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the co-sponsors' responsibilities:

- The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.
- Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The co-sponsors require individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.
- Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.
- Sites out with the United Kingdom will be responsible for arranging their own indemnity or insurance for their participation in the study, as well as for compliance with local law applicable to their participation in the study.

12 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

12.1 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team.

13 REFERENCES

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Supplementary Appendix S2: Statistical analysis plan

Early support in primary care for people starting treatment for cancer: GI-ACP

Version No	1.0
Date Finalised	19th Feb 2020
Author(s)	Jacqueline Stephen
CI Name	Dr Kirsty Boyd
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Signatures	
Trial Statistician: **Dr Jacqueline Stephen**	**Date:** **20th Feb 2020**
Chief Investigator: **Dr Kirsty Boyd**	**Date:** **20th Feb 2020**

Document Control		
Version No	**Date**	**Summary of Revisions**
1.0	26th June 2019	Initial Creation

Table of Contents

List of Abbreviations

Abbreviation	Full name
ACP	Anticipatory care planning
CI	Confidence interval
ECTU	Edinburgh Clinical Trials Unit
GI	Gastrointestinal
ITT	Intention to treat
IQR	Inter-quartile range
KIS	Key information summary
MDT	Multidisciplinary team
SOP	Standard operating procedure
SPCC	Specialist palliative care contact
VAS	Visual analogue scale

1. Introduction

This document details the criteria to be used for the definition of the analysis populations and the statistical methodology for analysis of the GI-ACP trial, a feasibility randomised controlled trial of a care planning intervention involving patients starting palliative oncology treatment in a Scottish regional cancer centre.

The aim of the trial is to randomise 50 patients using a secure web-based randomisation system stratified by diagnostic group and health board with 1:1 allocation to either intervention: Early Contact or control: Standard care, to determine the feasibility and acceptability to patients and carers of a person-centred, care planning intervention.

This document has been compiled according to the Edinburgh Clinical Trials Unit (ECTU) standard operating procedure (SOP) "Statistical Analysis Plans v4.0" and has been written based on information contained in the study protocol version 2.0, dated 5th July 2019. Analysis of the qualitative data from the trial is not within the scope of this analysis plan and will be handled separately.

The results will be submitted for publication and reported according to the CONSORT 2010 extension to randomised pilot and feasibility trials (Eldridge et al., 2016).

2. Statistical Methods section from the protocol

Analysis of the quantitative data will largely consist of descriptive statistics and comparison between the intervention and control groups.

Throughout, continuous variables will be summarised by treatment group and overall using the mean, standard deviation, median, lower quartile, upper quartile, minimum and maximum values. Categorical variables will be reported by treatment group and overall using the frequency and percentage for each category.

Baseline demographic and clinical data will be summarised by treatment arm and overall. Each of the primary feasibility outcomes (proportion of eligible patients willing to consent and be randomised; proportion of patients randomised to the intervention arm who do make an appointment with their GP to discuss their ongoing care and support needs) will be analysed by calculating the proportion and its exact binomial 95% confidence interval.

The proportion of participants in each treatment arm retained in the study through all follow-up time points will be analysed in the same manner. Furthermore, the difference in retention proportions between treatment arms will be calculated, along with its 95% confidence interval calculated using the normal approximation to the binomial distribution.

Clinical outcomes EQ-5D-5L, ICE-CAP and CollaboRATE will be summarised by treatment arm and overall.

As this is a feasibility study, there will be no imputation of missing data; the missing data rates will be reported by treatment group to inform on trial feasibility. Descriptive summaries of the baseline demographic and clinical data and primary and secondary outcomes will also be provided for the subgroups defined by the randomisation strata: diagnostic group (gastrointestinal or pancreatic) and

Health Board. The intention to treat principle will be followed in all analyses. There are no formal interim analyses planned.

3. Overall Statistical Principles

All analyses will follow the intention to treat (ITT) principle. The ITT analysis population will include all patients who have been randomised into the GI-ACP study. Patients will be analysed in the group to which they were randomised, regardless of intervention received.

In general terms, categorical data will be presented using counts and percentages, whilst continuous variables will be presented using the mean, median, standard deviation (SD), minimum, maximum, inter quartile range (IQR) and number of patients with an observation (n).

Where there is missing data for a variable, those records will be removed from any statistical analysis relating to that variable, unless otherwise specified. There will be no imputation of missing data.

There will be no formal statistical hypothesis tests. 95% (2-sided) confidence intervals (CIs) will be presented where specified.

Distributional assumptions underlying the statistical analyses will be assessed by visual inspection of residual plots. Normality will be examined by normal probability plots. If the distributional assumptions for the parametric approach are not satisfied, further data transformation (to alleviate substantial skewness (i.e. normalizing) or to stabilise the variance), or other suitable methods will be considered. This will be documented in the statistical results report together with the reasoning supporting the action taken, if applicable.

All analyses and data manipulations will be carried out using SAS software, Version 9.4 or later. Copyright (c) 2002-2012 by SAS Institute Inc., Cary, NC, USA.

4. List of Analyses

4.1 Participant Flow

Participant recruitment and retention will be reported as recommended by CONSORT 2010 extension to randomised pilot and feasibility trials (Eldridge et al., 2016). This will include the number (1) screened, (2) eligible, and (3) randomly assigned. Losses, exclusions and withdrawals after randomisation will be described, together with reasons.

4.2 Baseline characteristics

Baseline characteristics of patients will be summarised using descriptive statistics for (1) eligible but not randomised versus eligible and randomised, (2) randomised group (early contact or standard care), (3) diagnostic group (gastrointestinal or pancreatic), and (4) health board.

4.3 Feasibility outcomes

Feasibility outcomes (proportion of eligible patients who were randomised; proportion of patients randomised to the intervention arm who received at least one anticipatory care planning review at their GP practice documented in a new or updated key information summary (KIS); had at least one care planning review by GP, by phone or face to face; a clear ACP in those with a KIS) will be analysed by calculating the proportion and its exact binomial 95% confidence interval.

The proportion of participants in each treatment arm who are still alive and retained in the study through all follow-up time points will be analysed in the same manner. Furthermore, the difference in retention proportions between treatment arms will be calculated, along with its 95% confidence interval calculated using the normal approximation to the binomial distribution.

The number of deaths in the study through all follow-up time points will be reported descriptively.

The feasibility outcomes will also be presented by stratification factors: diagnostic group and health board.

4.3 Clinical outcomes

Clinical outcomes EQ-5D-5L, ICECAP and CollaboRATE will be summarised using descriptive statistics by randomised group and overall at each time point (baseline, 6,12, 24 and 48 weeks after recruitment).

The EQ-5D-5L summary will include the health index (5 health states converted into single index value) and the visual analogue scale (VAS).

The 7 ICECAP questions will be converted into a single score using the simple tariff values without interactions published by Huynh et al (Huynh et al., 2017).

The CollaboRATE summary will present both scoring methods (CollaboRATE mean and CollaboRATE top score). For CollaboRATE mean, participant's scores on the 3 items are summed and multiplied by 3.704, transforming to a scale from 0 to 100. For CollaboRATE top score, participants will be coded as 1 (yes) when they recorded the highest response on the scale for all 3 items and as 0 (no) in all other situations.

Service use data (total hospital admissions, total bed days, total GP/practice contacts, total oncology clinic treatments, specialist palliative care contact (SPCC)), the number, place and cause of death will also be summarised by randomised group using descriptive statistics.

The following time-to-event outcomes will be reported by randomised group using descriptive statistics: multidisciplinary team (MDT) review meeting to first GP contact; last GP contact to death; last oncology treatment to death; MDT review meeting to death; MDT review meeting to updated KIS; MDT review meeting to first SPCC; last SPCC to death.

5. Validation and QC

The statistical report will be read and sense-checked by a second statistician.

The derivation of the clinical trial outcomes (EuroQol EQ-5D-5l, CollaboRATE scores and the ICECAP Supportive Care Measure) will be validated by a second statistician.

6. References

ELDRIDGE, S. M., CHAN, C. L., CAMPBELL, M. J., BOND, C. M., HOPEWELL, S., THABANE, L. & LANCASTER, G. A. 2016. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *Bmj,* 355**,** i5239.

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CONFIDENTIAL

Supplementary Appendix S3: Final statistical analysis report

Early support in primary care for people starting treatment for cancer

GI-ACP Final Analysis Report

Version Number 1.0 : 25NOV2020: Author JS

Dataset analysed as it was on: 30.10.2020

S3.1:

1. Trial Recruitment

Table 1.1 Summary of Screening Data.

		N (%)
Screened		269

Excluded at MDT screening		99 (37%)
	Unfit for oncology treatment	86 (87%)
	Patient chose supportive/palliative care	13 (13%)
Excluded at clinic screening		71 (26%)
	Unfit for oncology treatment	34 (48%)
	Chose palliative care	28 (39%)
	On other study	6 (8%)
	Not eligible	3 (4%)
Eligible		99 (37%)

Not randomised		53 (54%)
	Not discussed	36 (68%)
	Other	8 (15%)
	Unknown	5 (9%)
	Declined offer	4 (8%)
Randomised		46 (46%)

Withdrawals		10 (22%)
	Too unwell	4 (40%)
	Participant chose not to engage	3 (30%)
	Opt out	2 (20%)
	Alcohol issues prevented engagement	1 (10%)
	(Withdraw followed by death)	8 (80%)
Deaths		21 (46%)

Numbers are n (%).
Abbreviations: MDT = multidisciplinary team

S3.2:

2. Baseline Characteristics

Table 2.1: Summary of baseline characteristics for all screened patients - not eligible, eligible and not randomised, and randomised.

	All N=269	*Not eligible N=170*	*Eligible but not randomised N=53*	*Randomised N=46*
Age				
N	269	170	53	46
Mean (SD)	71 (11)	74 (11)	68 (10)	65 (9)
Median [Q1-Q3]	72 [64-79]	76 [68-83]	68 [62-74]	65 [59-71]
Min, Max	42,98	42,98	45,92	45,80
Gender				
Female	94 (35%)	57 (34%)	22 (42%)	15 (33%)
Male	175 (65%)	113 (66%)	31 (58%)	31 (67%)
Cancer Diagnosis				
Oesophagus/ Junctional	119 (44%)	68 (40%)	24 (45%)	27 (59%)
Pancreas	106 (39%)	70 (41%)	24 (45%)	12 (26%)
Stomach	44 (16%)	32 (19%)	5 (9%)	7 (15%)
First Diagnosis				
No - relapsed disease	8 (3%)	4 (2%)	3 (6%)	1 (2%)
Yes	261 (97%)	166 (98%)	50 (94%)	45 (98%)
Disease Extent - Locally Advanced Only				
No	169 (63%)	100 (59%)	35 (66%)	34 (74%)
Yes	100 (37%)	70 (41%)	18 (34%)	12 (26%)
Disease Extent - Metastatic				
No	100 (37%)	70 (41%)	18 (34%)	12 (26%)
Yes	169 (63%)	100 (59%)	35 (66%)	34 (74%)
Surgical Treatment - Surgery				
No	40 (74%)	0 (0%)	0 (0%)	40 (89%)
Yes	14 (26%)	6 (100%)	3 (100%)	5 (11%)
Missing	215 ()	164 ()	50 ()	1 ()
Surgery Type				
Bypass surgery	3 (25%)	1 (20%)	0 (0%)	2 (50%)
Gastrectomy	1 (8%)	0 (0%)	0 (0%)	1 (25%)
Oesophagectomy	3 (25%)	2 (40%)	1 (33%)	0 (0%)
Whipples'	5 (42%)	2 (40%)	2 (67%)	1 (25%)
Missing	2 ()	1 ()	0 ()	1 ()
Initial Oncology Treatment Plan made at MDT review				

S3.2 continued:

2. Baseline Characteristics

Table 2.1: Summary of baseline characteristics for all screened patients - not eligible, eligible and not randomised, and randomised.

	All N=269	*Not eligible N=170*	*Eligible but not randomised N=53*	*Randomised N=46*
Chemotherapy	156 (58%)	68 (40%)	44 (83%)	44 (96%)
Other	101 (38%)	100 (59%)	1 (2%)	0 (0%)
Radiotherapy	12 (4%)	2 (1%)	8 (15%)	2 (4%)
Main Disease Group				
Pancreas	106 (39%)	70 (41%)	24 (45%)	12 (26%)
Upper GI	163 (61%)	100 (59%)	29 (55%)	34 (74%)

Numbers are n (%) or n, mean (SD), median (Q1, Q3).
Abbreviations: GI, gastrointestinal; MDT, multidisciplinary team; N, number; Q, quartile; SD, standard deviation.

S3.3:

2. Baseline Characteristics

Table 2.2: Summary of baseline characteristics by randomised group.

	All N=46	*Intervention N=25*	*Control N=21*
Age			
N	46	25	21
Mean (SD)	65 (9)	65 (9)	64 (8)
Median [Q1-Q3]	65 [59-71]	66 [61-71]	64 [58-71]
Min, Max	45,80	45,80	46,79
Gender			
Female	15 (33%)	8 (32%)	7 (33%)
Male	31 (67%)	17 (68%)	14 (67%)
Cancer Diagnosis			
Oesophagus/ Junctional	27 (59%)	15 (60%)	12 (57%)
Pancreas	12 (26%)	7 (28%)	5 (24%)
Stomach	7 (15%)	3 (12%)	4 (19%)
First Diagnosis			
No - relapsed disease	1 (2%)	1 (4%)	0 (0%)
Yes	45 (98%)	24 (96%)	21 (100%)
Disease Extent - Locally Advanced Only			
No	34 (74%)	19 (76%)	15 (71%)
Yes	12 (26%)	6 (24%)	6 (29%)
Disease Extent - Metastatic			
No	12 (26%)	6 (24%)	6 (29%)
Yes	34 (74%)	19 (76%)	15 (71%)
Surgical Treatment - Stented			
No	38 (83%)	21 (84%)	17 (81%)
Yes	8 (17%)	4 (16%)	4 (19%)
Surgical Treatment - Surgery			
No	40 (89%)	22 (92%)	18 (86%)
Yes	5 (11%)	2 (8%)	3 (14%)
Missing	1 ()	1 ()	0 ()
Surgery Type			
Bypass surgery	2 (50%)	1 (50%)	1 (50%)
Gastrectomy	1 (25%)	1 (50%)	0 (0%)
Whipples'	1 (25%)	0 (0%)	1 (50%)
Missing	1 ()	0 ()	1 ()

S3.3 continued:

2. Baseline Characteristics

Table 2.2: Summary of baseline characteristics by randomised group.

	All N=46	*Intervention N=25*	*Control N=21*
Initial Oncology Treatment Plan made at MDT review			
Chemotherapy	44 (96%)	23 (92%)	21 (100%)
Radiotherapy	2 (4%)	2 (8%)	0 (0%)
Main Disease Group			
Pancreas	12 (26%)	7 (28%)	5 (24%)
Upper GI	34 (74%)	18 (72%)	16 (76%)
Social Support			
Lives alone	10 (22%)	3 (12%)	7 (33%)
Lives with other	3 (7%)	1 (4%)	2 (10%)
Lives with partner	33 (72%)	21 (84%)	12 (57%)
Comorbidities			
Diabetes	5 (26%)	3 (27%)	2 (25%)
None	2 (11%)	1 (9%)	1 (13%)
Other	12 (63%)	7 (64%)	5 (63%)
Missing	27 ()	14 ()	13 ()
Agreed Oncology Treatment Plan			
Chemotherapy	43 (93%)	22 (88%)	21 (100%)
Radiotherapy	3 (7%)	3 (12%)	0 (0%)

Numbers are n (%) or n, mean (SD), median (Q1, Q3).
Abbreviations: GI, gastrointestinal; MDT, multidisciplinary team; N, number; Q, quartile; SD, standard deviation.

S3.4:

2. Baseline Characteristics

Table 2.3: Summary of baseline characteristics by stratification factors.

		Disease Group		*Health Board*	
	All N=46	***Pancreas N=12***	***Upper GI N=34***	***Lothian N=29***	***Fife N=17***
Age					
N	46	12	34	29	17
Mean (SD)	65 (9)	65 (9)	65 (9)	64 (9)	66 (9)
Median [Q1-Q3]	65 [59-71]	67 [59-72]	64 [60-71]	64 [59-71]	67 [62-71]
Min, Max	45,80	45,75	46,80	46,80	45,79
Gender					
Female	15 (33%)	7 (58%)	8 (24%)	9 (31%)	6 (35%)
Male	31 (67%)	5 (42%)	26 (76%)	20 (69%)	11 (65%)
Cancer Diagnosis					
Oesophagus/ Junctional	27 (59%)	0 (0%)	27 (79%)	18 (62%)	9 (53%)
Pancreas	12 (26%)	12 (100%)	0 (0%)	8 (28%)	4 (24%)
Stomach	7 (15%)	0 (0%)	7 (21%)	3 (10%)	4 (24%)
First Diagnosis					
No - relapsed disease	1 (2%)	0 (0%)	1 (3%)	1 (3%)	0 (0%)
Yes	45 (98%)	12 (100%)	33 (97%)	28 (97%)	17 (100%)
Disease Extent - Locally Advanced Only					
No	34 (74%)	8 (67%)	26 (76%)	18 (62%)	16 (94%)
Yes	12 (26%)	4 (33%)	8 (24%)	11 (38%)	1 (6%)
Disease Extent - Metastatic					
No	12 (26%)	4 (33%)	8 (24%)	11 (38%)	1 (6%)
Yes	34 (74%)	8 (67%)	26 (76%)	18 (62%)	16 (94%)
Surgical Treatment - Stented					
No	38 (83%)	8 (67%)	30 (88%)	24 (83%)	14 (82%)
Yes	8 (17%)	4 (33%)	4 (12%)	5 (17%)	3 (18%)
Surgical Treatment - Surgery					
No	40 (89%)	8 (73%)	32 (94%)	24 (83%)	16 (100%)
Yes	5 (11%)	3 (27%)	2 (6%)	5 (17%)	0 (0%)
Missing	1 ()	1 ()	0 ()	0 ()	1 ()
Surgery Type					
Bypass surgery	2 (50%)	2 (67%)	0 (0%)	2 (50%)	0 (0%)
Gastrectomy	1 (25%)	0 (0%)	1 (100%)	1 (25%)	0 (0%)
Whipples'	1 (25%)	1 (33%)	0 (0%)	1 (25%)	0 (0%)

S3.4 continued:

2. Baseline Characteristics

Table 2.3: Summary of baseline characteristics by stratification factors.

		Disease Group		*Health Board*	
	All N=46	***Pancreas N=12***	***Upper GI N=34***	***Lothian N=29***	***Fife N=17***
Missing	1 ()	0 ()	1 ()	1 ()	0 ()
Initial Oncology Treatment Plan made at MDT review					
Chemotherapy	44 (96%)	12 (100%)	32 (94%)	27 (93%)	17 (100%)
Radiotherapy	2 (4%)	0 (0%)	2 (6%)	2 (7%)	0 (0%)
Main Disease Group					
Pancreas	12 (26%)	12 (100%)	0 (0%)	8 (28%)	4 (24%)
Upper GI	34 (74%)	0 (0%)	34 (100%)	21 (72%)	13 (76%)
Social Support					
Lives alone	10 (22%)	2 (17%)	8 (24%)	8 (28%)	2 (12%)
Lives with other	3 (7%)	1 (8%)	2 (6%)	2 (7%)	1 (6%)
Lives with partner	33 (72%)	9 (75%)	24 (71%)	19 (66%)	14 (82%)
Comorbidities					
Diabetes	5 (26%)	2 (29%)	3 (25%)	3 (25%)	2 (29%)
None	2 (11%)	1 (14%)	1 (8%)	1 (8%)	1 (14%)
Other	12 (63%)	4 (57%)	8 (67%)	8 (67%)	4 (57%)
Missing	27 ()	5 ()	22 ()	17 ()	10 ()
Agreed Oncology Treatment Plan					
Chemotherapy	43 (93%)	12 (100%)	31 (91%)	26 (90%)	17 (100%)
Radiotherapy	3 (7%)	0 (0%)	3 (9%)	3 (10%)	0 (0%)

Numbers are n (%) or n, mean (SD), median (Q1, Q3).
Abbreviations: GI, gastrointestinal; MDT, multidisciplinary team;
N, number; Q, quartile; SD, standard deviation.

S3.5:

3. Feasibility Outcomes

Table 3.1. Deaths and study retention

	All N=46		*Intervention N=25*		*Control N=21*		
	N	***n (%)***	***N***	***n (%)***	***N***	***n (%)***	***Difference (95% CI)***
Deaths*							
Week 6	46	2 (4%)	25	1 (4%)	21	1 (5%)	-
Week 12	46	6 (13%)	25	3 (12%)	21	3 (14%)	-
Week 24	46	14 (30%)	25	7 (28%)	21	7 (33%)	-
Week 48	25	16 (64%)	12	7 (58%)	13	9 (69%)	-
Retained in the study**							
Week 6	44	28 (64%)	24	16 (67%)	20	12 (60%)	6.7% (-21.9% to 35.2%)
Week 12	40	25 (63%)	22	13 (59%)	18	12 (67%)	-7.6% (-37.5% to 22.4%)
Week 24	32	21 (66%)	18	9 (50%)	14	12 (86%)	-35.7% (-65.2% to -6.2%)
Week 48	9	6 (67%)	5	4 (80%)	4	2 (50%)	30.0% (-30.3% to 90.3%)

*Cumulative number of deaths at each time point.
**Defined as those who returned a questionnaire at the respective time period. The Denominator (N) includes only those who were alive.
Note. Week 48 represents a subset of the participants who were randomised and due their follow-up prior to the study end (31 Aug 2020).
Difference is for Intervention minus Control.
Abbreviations: CI, confidence interval; N, number.

S3.6:

3. Feasibility Outcomes

Table 3.2. Deaths and study retention by Stratification Factors

	Disease Group				*Health Board*			
	Pancreas		*Upper GI*		*Lothian*		*Fife*	
	N	***n (%)***	***N***	***n (%)***	***N***	***n (%)***	***N***	***n (%)***
Deaths*								
Week 6	12	0 (0%)	34	2 (6%)	29	1 (3%)	17	1 (6%)
Week 12	12	2 (17%)	34	4 (12%)	29	3 (10%)	17	3 (18%)
Week 24	12	6 (50%)	34	8 (24%)	29	8 (28%)	17	6 (35%)
Week 48	7	7 (100%)	18	9 (50%)	15	10 (67%)	10	6 (60%)
Retained in the study**								
Week 6	12	6 (50%)	32	22 (69%)	28	17 (61%)	16	11 (69%)
Week 12	10	5 (50%)	30	20 (67%)	26	15 (58%)	14	10 (71%)
Week 24	6	3 (50%)	26	18 (69%)	21	14 (67%)	11	7 (64%)
Week 48	0	0 (0%)	9	6 (67%)	5	4 (80%)	4	2 (50%)

*Cumulative number of deaths at each time point.
**Defined as those who returned a questionnaire at the respective time period. The Denominator (N) includes only those who were alive.
Note. Week 48 represents a subset of the participants who were randomised and due their follow-up prior to the study end (31 Aug 2020).
Abbreviations: GI, gastrointestinal; N, number.

S3.7:

3. Feasibility Outcomes

Table 3.3. Feasibility Outcomes

		All N=46			*Intervention N=25*			*Control N=21*		
		N	***n (%)***	***95% CI***	***N***	***n (%)***	***95% CI***	***N***	***n (%)***	***95% CI***
Feasibility										
Eligible patients who were randomised		99	46 (46%)	(36.4% to 56.8%)	-	-	-	-	-	-
New or updated KIS		44	37 (84%)	(69.9% to 93.4%)	24	20 (83%)	(62.6% to 95.3%)	20	17 (85%)	(62.1% to 96.8%)
KIS Quality	Low		17 (47%)			12 (60%)			5 (31%)	
	Med		12 (33%)			6 (30%)			6 (38%)	
	High		7 (19%)			2 (10%)			5 (31%)	
	Missing		1 ()			0 ()			1 ()	
Clear ACP in those with a KIS		37	19 (51%)	(34.4% to 68.1%)	20	9 (45%)	(23.1% to 68.5%)	17	10 (59%)	(32.9% to 81.6%)
Letter helped get an appointment to see your GP*		-	-	-	17	11 (65%)	(38.3% to 85.8%)	-	-	-

*Included in denominator if participants had provided any response (yes/no) to the question at either the 6 or 12 week questionnaire follow-up.
Abbreviations: ACP, Anticipatory care planning; CI, confidence interval
KIS, Key information summary; N, number; -, not applicable.

S3.8:

3. Feasibility Outcomes

Table 3.4. Feasibility Outcomes by Stratification Factors

		Disease Group				Health Board			
		Pancreas		Upper GI		Lothian		Fife	
		N	n (%)	N	n (%)	N	n (%)	N	n (%)
Feasibility									
New or updated KIS		12	9 (75%)	32	28 (88%)	28	22 (79%)	16	15 (94%)
KIS Quality	Low		4 (50%)		13 (46%)		10 (48%)		7 (47%)
	Med		2 (25%)		10 (36%)		8 (38%)		4 (27%)
	High		2 (25%)		5 (18%)		3 (14%)		4 (27%)
	Missing		1 ()		0 ()		1 ()		0 ()
Clear ACP		9	5 (56%)	28	14 (50%)	22	12 (55%)	15	7 (47%)
Letter helped get an appointment to see your GP*		4	2 (50%)	13	9 (69%)	11	8 (73%)	6	3 (50%)

*Included in denominator if participants had provided any response (yes/no) to the question at either the 6 or 12 week questionnaire follow-up.
Abbreviations: ACP, Anticipatory care planning; GI, gastrointestinal; KIS, Key information summary; N, number.

Supplementary Appendix S4: Additional qualitative data from interviews

S4.1: Exemplar quotations showing different planning styles.

Just one out of eighteen patients interviewed had engaged proactively in ACP with their GP at the time of diagnosis (23P, control group). Patient, carer and GP were firm advocates of future care planning which was discussed, agreed and incorporated into the patient's KIS/ACP. ACP conversations continued throughout first and second interview data supported in field notes over the one-year study timeline. These patient/carer views may have related to their personal experiences of working in healthcare environments. The vast majority of patient-carer-GP triads did not follow this planning style and often delayed discussing ACP.

Interview triad – Early planner patient, carer and GP.

'The GP did that as soon as she heard (diagnosis), she did that. I was quite pleased that it was asked (ACP). Yes, because I don't want to be the vegetable. If I can't wash and dress myself and feed myself then I don't think it's right to drag anybody down to make them do that. Even my wife who's a nurse would be able to do it, but I don't think that's fair. (wife interjects), "I mean, I'm not ill like you, but I would be the same. We do talk about things like that".'

23P, patient and carer, control, 1st interview, 15/11/2019.

'She guided me to go and see the hospice, see what the facilities were, have a chat she said, they're nice folk. The nurses said that as well. Our GP took the bull by the horns right from the start. She took the initiative, (name of doctor) asked me about end of life and asked if I wanted to be resuscitated as soon as I was diagnosed, and I said no.'

23P, patient, control, 2nd interview, 06/02/2020.

The couple praised their GP, the cancer centre and NHS in general and were full of admiration of the 'sterling work' carried out by all. The GP talked about her patient with confidence and one got the impressions she knew him well which was also demonstrated by the patient.

'He does, he has that set up, it was set up on the 19th September, giving a brief outline of his metastatic gastric cancer. He has a just in case box available for him in his home. It's viewed that this patient is for active medical management including hospital admission if required. It includes that he is on chemotherapy and at risk of infection and sepsis and that it due to be updated very shortly. I would say that he is extremely understanding of his illness. We have a DNR form in place as well.'

23P, GP, control, interview, 06/01/2020.

Although pre-emptive, the doctor talked about her experiences as a GP during this interview. She remembered resistance from some patients when attempting to initiate ACP conversations. Her recollections seem to indicate, that no matter how pro-active a GP may prove, sometimes patients are just not open to these emotive discussions.

'If a patient has cancer, we try to have one particular doctor who looks over and manages their care. So, he is actually on my list. I am aware of his cancer diagnosis and have been following him up with consultations. Some patients find it very difficult to engage with us as GP's or our primary health care team if they are very much fixated on what can oncology offer me. And sometimes, we as GPs feel that patients actually haven't got to that stage that it would be far better for them to come to terms with the fact that nothing more can be done for them. But there is a small patient group who cling on for that last bit of hope. And sometimes they are continued to be given that hope. And we find it difficult sometimes to step in as GPs and say, actually, maybe we should be looking at not having all this intensive treatment. Why don't we look at you know, going to the day hospice or trying to get some more enjoyment out of the time that you have. So, some of that is led by the patient, unfortunately.'

Interview triad – Early planner GP, evolving planner patient/carer.

'At this point I don't want to know anything more. That might put the fear in me. So, at this point I'm quite happy with the information that I've got.'
38P, intervention patient, 1st interview, 05/03/2020.

'The KIS was started on 4th February. I discussed the KIS with her. I think the ACP was incorporated in the KIS, let me see, (pause, looking at screen) 17th February. Yes, ACP. I don't see any updates for that. I don't think she's in touch with the palliative care team.'
38P, intervention GP, interview, 24/06/2020.

'We've been down for a care plan. What she said was we'll maybe pick up again at some point.'
38P, intervention patient, 2nd interview, 23/07/2020.

Interview triad – Early planner patient and carer. Evolving planner GP.

3P was disappointed to recall the GP being conspicuous by his absence, having had no contact for five months since diagnosis.

'*The GP, I've had no contact since he referred me to get the endoscopy.'*
3P, patient, control 1st interview, 25/04/2019

Due to their need to arrange future care, the patient's carer spoke to oncology at their next clinic appointment and through this, oncology staff prompted the GP.

'We had an appointment with the oncologist days after the last interview and we spoke to him about it (lack of communication from GP). And I don't know if he spoke to the GP or not, but things improved greatly. GP turned out to be very good at getting things done immediately and that's what we needed. And he was absolutely brilliant with me when (name of patient) passed. The GP came into his own.'
3P, carer, control, bereavement interview, 29/01/2020.

GP actions facilitated patient 3P's wish to remain at home. Social work carers and district nurses swiftly became involved as a result of oncology mediation, resulting in all patient needs being met.

'He had easy access to us, district nurses in, syringe driver went up early, his symptoms were well controlled. You know, the wife was happy and comfortable with things. He was getting best treatment. You know, his pain was under control, he had no pain. We'd assess his pain, bowel, nausea symptoms. He had all the things for weight loss. The dietitian had been in. He'd had all these ENSURE® things, he'd bowel treatment and you know, nurses coming in, keep an eye on how things were going.'
3P, GP, control, interview, 29/01/2020.

Interview triad – Non-planner patient, evolving planner carer and GP.

This patient was a non-planner and remained so throughout first and second interviews. His wife respected his wishes even though she would have preferred to start planning sooner.

*'Nobody's mentioned anything like that yet (*ACP*). I try not to think about it. I try to keep that to the back of my mind as much as I can whilst I'm still fit. If something changed drastically, my view is that I'll cross that bridge when I come to it.'*
16P, intervention patient, 2nd interview, 10/03/2020.

'Different people obviously think in different ways. I think if that deterioration happens, hopefully a long way down the road, then that's when he would think about it. I've lived with him for 30 odd years, he won't make a decision if he doesn't want to make a decision.'
16P, intervention carer, 2nd interview, 10/03/2020.

The GP took a similar view to the patient of not intervening while treatment continued, but also picked up the carers concerns and desire to start planning.

'He's pretty self-sufficient to be honest. However, seeing him on Friday, there's a definite decline and his wife is starting to get worried about him as well. I think he's been in regular contact with oncology and being reviewed by them. If that tails off, he'll start coming to see me more.'
16P, intervention GP, interview, 13/01/2020.

Interview triad – Non-planner patient, (no carer), late planner GP.

Another patient talked about handing his intervention letter into the GP practice but chose not to acknowledge his terminal diagnosis despite being given clear information at the oncology clinic. He therefore, saw no value in engaging with his GP.

*'I handed it into the receptionist. And I'll be honest with you, I did'nae (*didn't*) really need the doctor at the time, so I've never really bothered him. He's (*GP*) never been in touch about the cancer. Looking ahead with the cancer, I'm nae (*not*) worried about that. Mine's no (*not*) malignant, and it's no (*not*) spread. If I get another ten years, I'll be quite happy with that.*
26P, patient, intervention, 1st interview, 06/12/2019.

When asked about his views of ACP, this man held fixed and clear opinions however, he did not make any attempt to have these wishes formally recorded.

'I've never given that a thought. Well, I'm telling a lie there; I have thought about it and basically, I wouldn't want resuscitated. I wouldn't mind being asked that question, but I've never been asked. I feel that if my quality of life was over, I'd rather just be.'
26P, intervention patient, 2nd interview, 03/03/2020.

The GP explained the patient's palliative care plan pathway and the approach of that GP practice.

'The KIS has been activated but it simply says a new diagnosis of atrial fibrillation. We don't have a standard policy on palliative care. *We are expected to make all of them a KIS with a palliative care summary. In reality, we have a lot of patients who you could call palliative, but who in terms of their day to day functioning are very well and have a full active, unrestricted life.'*
26P, intervention GP, interview, 03/03/2020.

S4.2: Care planning styles among intervention patients, carers and GPs interviewed.

Table S3.2: Care planning styles – Intervention group interviews				
Triad	**Participant**	**1st interview**	**2nd interview**	**GP interview**
	16P	Non-planner	Non-planner (spouse evolving planner)	Evolving planner (prompted by spouse)
	26P	Non- planner	Non-planner	Late planner
	28P	Non-planner	Non-planner (spouse evolving planner)	Early planner
	35P	Non- planner	Non-planner (spouse evolving planner)	Late planner
	38P	Non- planner	Evolving planner	Early planner
	43P	Non- planner	Non-planner	Early planner
Dyad				**Patient view of GP***
	12P	Non-planner	Non-planner	Non-planner
	17P	Non-planner	Non-planner	Non-planner
	19P	Non-planner	Evolving planner	Early planner
	20P	Non-planner	Evolving planner	Evolving planner
	41P	Early planner	Early planner	Evolving planner

* Patient view as GP not interviewed.

S4.3: Care planning styles among control patients, carers and GPs interviewed.

Table S3.3: Care planning styles – Control group interviews				
Triad	**Participant**	**1st interview**	**2nd interview**	**GP interview**
	3P	Early planner	Early planner	Evolving planner (prompted by oncology)
	14P	Non-planner	Non-planner	Late planner
	21P	Non-planner	Evolving planner	Evolving planner
	23P	Early planner	Early planner	Early planner
Dyad				**Patient view of GP***
	29P	Non-planner	Non-planner	Late planner
	34P	Early Planner	Early planner	Late planner
	45P	Non-planner	Non-planner	Evolving planner (prompted by COVID-19)

* Patient view as GP not interviewed.

S5.1:

4. Clinical Outcomes

Table 4.1. EQ5D

	Baseline			Week 6			Week 12			Week 24			Week 48		
	N	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*
EQ5D Health Index															
C	14	0.71 (0.11)	0.70 [0.66-0.75]	11	0.66 (0.17)	0.68 [0.54-0.80]	12	0.77 (0.11)	0.74 [0.68-0.86]	12	0.69 (0.18)	0.75 [0.63-0.81]	2	0.34 (0.56)	0.34 [-0.06-0.74]
I	20	0.72 (0.14)	0.73 [0.66-0.84]	17	0.71 (0.14)	0.72 [0.68-0.75]	13	0.68 (0.28)	0.68 [0.64-0.84]	9	0.57 (0.26)	0.55 [0.53-0.71]	4	0.67 (0.29)	0.69 [0.48-0.86]
Overall	34	0.71 (0.13)	0.72 [0.66-0.81]	28	0.69 (0.15)	0.72 [0.64-0.77]	25	0.73 (0.22)	0.73 [0.65-0.84]	21	0.64 (0.22)	0.71 [0.55-0.77]	6	0.56 (0.38)	0.69 [0.30-0.74]
EQ5D VAS															
C	14	69.50 (14.77)	72.5 [65.0-80.0]	12	70.83 (18.57)	72.5 [67.5-80.0]	12	70.67 (19.84)	75.0 [57.5-85.0]	12	72.33 (15.28)	72.5 [60.0-82.5]	2	55.00 (63.64)	55.0 [10.0-100.0]
I	20	71.90 (19.00)	75.0 [65.0-85.0]	17	72.24 (15.91)	75.0 [60.0-85.0]	13	74.08 (14.84)	75.0 [65.0-80.0]	9	70.00 (14.79)	65.0 [60.0-85.0]	4	73.75 (16.52)	75.0 [60.0-87.5]
Overall	34	70.91 (17.18)	75.0 [65.0-85.0]	29	71.66 (16.75)	75.0 [60.0-80.0]	25	72.44 (17.13)	75.0 [65.0-80.0]	21	71.33 (14.74)	70.0 [60.0-85.0]	6	67.50 (32.67)	75.0 [55.0-90.0]

Abbreviations: C, control; I, intervention; IQR, interquartile range; N, number; SD, standard deviation.

S5.2:

4. Clinical Outcomes

Table 4.2a. ICE-CAP - Having a say.

	All N=46	*Intervention N=25*	*Control N=21*
Baseline			
1, I am never able to make decisions that I need to make about my life and care	0 (0%)	0 (0%)	0 (0%)
2, I am able to make decisions that I need to make about my life and care only a little of the time	0 (0%)	0 (0%)	0 (0%)
3, I am able to make decisions that I need to make about my life and care some of the time	0 (0%)	0 (0%)	0 (0%)
4, I am able to make decisions that I need to make about my life and care most of the time	34 (100%)	20 (100%)	14 (100%)
Missing	12 ()	5 ()	7 ()
Week 6			
1, I am never able to make decisions that I need to make about my life and care	0 (0%)	0 (0%)	0 (0%)
2, I am able to make decisions that I need to make about my life and care only a little of the time	0 (0%)	0 (0%)	0 (0%)
3, I am able to make decisions that I need to make about my life and care some of the time	0 (0%)	0 (0%)	0 (0%)
4, I am able to make decisions that I need to make about my life and care most of the time	29 (100%)	17 (100%)	12 (100%)
Missing	17 ()	8 ()	9 ()
Week 12			
1, I am never able to make decisions that I need to make about my life and care	0 (0%)	0 (0%)	0 (0%)
2, I am able to make decisions that I need to make about my life and care only a little of the time	0 (0%)	0 (0%)	0 (0%)
3, I am able to make decisions that I need to make about my life and care some of the time	3 (12%)	1 (8%)	2 (17%)
4, I am able to make decisions that I need to make about my life and care most of the time	22 (88%)	12 (92%)	10 (83%)
Missing	21 ()	12 ()	9 ()
Week 24			
1, I am never able to make decisions that I need to make about my life and care	0 (0%)	0 (0%)	0 (0%)
2, I am able to make decisions that I need to make about my life and care only a little of the time	0 (0%)	0 (0%)	0 (0%)
3, I am able to make decisions that I need to make about my life and care some of the time	0 (0%)	0 (0%)	0 (0%)
4, I am able to make decisions that I need to make about my life and care most of the time	22 (100%)	10 (100%)	12 (100%)
Missing	24 ()	15 ()	9 ()

S5.2 continued:

4. Clinical Outcomes

Table 4.2a. ICE-CAP - Having a say.

	All N=46	*Intervention N=25*	*Control N=21*
Week 48			
1, I am never able to make decisions that I need to make about my life and care	0 (0%)	0 (0%)	0 (0%)
2, I am able to make decisions that I need to make about my life and care only a little of the time	0 (0%)	0 (0%)	0 (0%)
3, I am able to make decisions that I need to make about my life and care some of the time	0 (0%)	0 (0%)	0 (0%)
4, I am able to make decisions that I need to make about my life and care most of the time	6 (100%)	4 (100%)	2 (100%)
Missing	40 ()	21 ()	19 ()

Numbers are n (%).

S5.2 continued:

4. Clinical Outcomes

Table 4.2b. ICE-CAP - being with people who care.

	All N=46	*Intervention N=25*	*Control N=21*
Baseline			
1, If I want to, I am never able to be with people who care about me	0 (0%)	0 (0%)	0 (0%)
2, If I want to, I am able to be with people who care about me only a little of	0 (0%)	0 (0%)	0 (0%)
3, If I want to, I am able to be with people who care about me some of the time	2 (6%)	1 (5%)	1 (7%)
4, If I want to, I am able to be with people who care about me most of the time	32 (94%)	19 (95%)	13 (93%)
Missing	12 ()	5 ()	7 ()
Week 6			
1, If I want to, I am never able to be with people who care about me	0 (0%)	0 (0%)	0 (0%)
2, If I want to, I am able to be with people who care about me only a little of	0 (0%)	0 (0%)	0 (0%)
3, If I want to, I am able to be with people who care about me some of the time	1 (3%)	0 (0%)	1 (8%)
4, If I want to, I am able to be with people who care about me most of the time	28 (97%)	17 (100%)	11 (92%)
Missing	17 ()	8 ()	9 ()
Week 12			
1, If I want to, I am never able to be with people who care about me	1 (4%)	0 (0%)	1 (8%)
2, If I want to, I am able to be with people who care about me only a little of	0 (0%)	0 (0%)	0 (0%)
3, If I want to, I am able to be with people who care about me some of the time	4 (16%)	2 (15%)	2 (17%)
4, If I want to, I am able to be with people who care about me most of the time	20 (80%)	11 (85%)	9 (75%)
Missing	21 ()	12 ()	9 ()
Week 24			
1, If I want to, I am never able to be with people who care about me	0 (0%)	0 (0%)	0 (0%)
2, If I want to, I am able to be with people who care about me only a little of the time	2 (9%)	0 (0%)	2 (17%)
3, If I want to, I am able to be with people who care about me some of the time	2 (9%)	1 (10%)	1 (8%)
4, If I want to, I am able to be with people who care about me most of the time	18 (82%)	9 (90%)	9 (75%)
Missing	24 ()	15 ()	9 ()
Week 48			
1, If I want to, I am never able to be with people who care about me	0 (0%)	0 (0%)	0 (0%)
2, If I want to, I am able to be with people who care about me only a little of the time	1 (17%)	1 (25%)	0 (0%)
3, If I want to, I am able to be with people who care about me some of the time	0 (0%)	0 (0%)	0 (0%)
4, If I want to, I am able to be with people who care about me most of the time	5 (83%)	3 (75%)	2 (100%)
Missing	40 ()	21 ()	19 ()

Numbers are n (%).

S5.2 continued:

4. Clinical Outcomes

Table 4.2c. ICE-CAP - physical suffering.

	All N=46	*Intervention N=25*	*Control N=21*
Baseline			
1, I always experience significant discomfort	2 (6%)	2 (10%)	0 (0%)
2, I often experience significant physical discomfort	8 (24%)	4 (20%)	4 (29%)
3, I sometimes experience significant physical discomfort	10 (29%)	7 (35%)	3 (21%)
4, I rarely experience significant physical discomfort	14 (41%)	7 (35%)	7 (50%)
Missing	12 ()	5 ()	7 ()
Week 6			
1, I always experience significant discomfort	2 (7%)	1 (6%)	1 (8%)
2, I often experience significant physical discomfort	6 (21%)	4 (24%)	2 (17%)
3, I sometimes experience significant physical discomfort	10 (34%)	4 (24%)	6 (50%)
4, I rarely experience significant physical discomfort	11 (38%)	8 (47%)	3 (25%)
Missing	17 ()	8 ()	9 ()
Week 12			
1, I always experience significant discomfort	1 (4%)	1 (8%)	0 (0%)
2, I often experience significant physical discomfort	3 (12%)	2 (15%)	1 (8%)
3, I sometimes experience significant physical discomfort	11 (44%)	3 (23%)	8 (67%)
4, I rarely experience significant physical discomfort	10 (40%)	7 (54%)	3 (25%)
Missing	21 ()	12 ()	9 ()
Week 24			
1, I always experience significant discomfort	1 (5%)	1 (10%)	0 (0%)
2, I often experience significant physical discomfort	4 (18%)	3 (30%)	1 (8%)
3, I sometimes experience significant physical discomfort	10 (45%)	4 (40%)	6 (50%)
4, I rarely experience significant physical discomfort	7 (32%)	2 (20%)	5 (42%)
Missing	24 ()	15 ()	9 ()

S5.2 continued:

4. Clinical Outcomes

Table 4.2c. ICE-CAP - physical suffering.

	All N=46	*Intervention N=25*	*Control N=21*
Week 48			
1, I always experience significant discomfort	2 (33%)	1 (25%)	1 (50%)
2, I often experience significant physical discomfort	1 (17%)	1 (25%)	0 (0%)
3, I sometimes experience significant physical discomfort	2 (33%)	1 (25%)	1 (50%)
4, I rarely experience significant physical discomfort	1 (17%)	1 (25%)	0 (0%)
Missing	40 ()	21 ()	19 ()

Numbers are n (%).

S5.2 continued:

4. Clinical Outcomes

Table 4.2d. ICE-CAP - emotional suffering.

	All N=46	*Intervention N=25*	*Control N=21*
Baseline			
1, I always experience emotional suffering	2 (6%)	1 (5%)	1 (7%)
2, I often experience emotional suffering	3 (9%)	3 (15%)	0 (0%)
3, I sometimes experience emotional suffering	19 (56%)	12 (60%)	7 (50%)
4, I rarely experience emotional suffering	10 (29%)	4 (20%)	6 (43%)
Missing	12 ()	5 ()	7 ()
Week 6			
1, I always experience emotional suffering	0 (0%)	0 (0%)	0 (0%)
2, I often experience emotional suffering	2 (7%)	0 (0%)	2 (17%)
3, I sometimes experience emotional suffering	11 (38%)	8 (47%)	3 (25%)
4, I rarely experience emotional suffering	16 (55%)	9 (53%)	7 (58%)
Missing	17 ()	8 ()	9 ()
Week 12			
1, I always experience emotional suffering	0 (0%)	0 (0%)	0 (0%)
2, I often experience emotional suffering	3 (12%)	1 (8%)	2 (17%)
3, I sometimes experience emotional suffering	11 (44%)	6 (46%)	5 (42%)
4, I rarely experience emotional suffering	11 (44%)	6 (46%)	5 (42%)
Missing	21 ()	12 ()	9 ()
Week 24			
1, I always experience emotional suffering	0 (0%)	0 (0%)	0 (0%)
2, I often experience emotional suffering	0 (0%)	0 (0%)	0 (0%)
3, I sometimes experience emotional suffering	10 (45%)	5 (50%)	5 (42%)
4, I rarely experience emotional suffering	12 (55%)	5 (50%)	7 (58%)
Missing	24 ()	15 ()	9 ()
Week 48			
1, I always experience emotional suffering	0 (0%)	0 (0%)	0 (0%)
2, I often experience emotional suffering	0 (0%)	0 (0%)	0 (0%)
3, I sometimes experience emotional suffering	2 (33%)	1 (25%)	1 (50%)
4, I rarely experience emotional suffering	4 (67%)	3 (75%)	1 (50%)
Missing	40 ()	21 ()	19 ()

Numbers are n (%).

S5.2 continued:

4. Clinical Outcomes

Table 4.2e. ICE-CAP - dignity.

	All N=46	*Intervention N=25*	*Control N=21*
Baseline			
1, I am never able to maintain my dignity and self-respect	0 (0%)	0 (0%)	0 (0%)
2, I am able to maintain my dignity and self-respect only a little of	0 (0%)	0 (0%)	0 (0%)
3, I am able to maintain my dignity and self-respect some of the time	0 (0%)	0 (0%)	0 (0%)
4, I am able to maintain my dignity and self-respect most of the time	33 (100%)	20 (100%)	13 (100%)
Missing	13 ()	5 ()	8 ()
Week 6			
1, I am never able to maintain my dignity and self-respect	0 (0%)	0 (0%)	0 (0%)
2, I am able to maintain my dignity and self-respect only a little of	0 (0%)	0 (0%)	0 (0%)
3, I am able to maintain my dignity and self-respect some of the time	1 (3%)	1 (6%)	0 (0%)
4, I am able to maintain my dignity and self-respect most of the time	28 (97%)	16 (94%)	12 (100%)
Missing	17 ()	8 ()	9 ()
Week 12			
1, I am never able to maintain my dignity and self-respect	0 (0%)	0 (0%)	0 (0%)
2, I am able to maintain my dignity and self-respect only a little of	0 (0%)	0 (0%)	0 (0%)
3, I am able to maintain my dignity and self-respect some of the time	2 (8%)	2 (15%)	0 (0%)
4, I am able to maintain my dignity and self-respect most of the time	23 (92%)	11 (85%)	12 (100%)
Missing	21 ()	12 ()	9 ()
Week 24			
1, I am never able to maintain my dignity and self-respect	0 (0%)	0 (0%)	0 (0%)
2, I am able to maintain my dignity and self-respect only a little of	0 (0%)	0 (0%)	0 (0%)
3, I am able to maintain my dignity and self-respect some of the time	0 (0%)	0 (0%)	0 (0%)
4, I am able to maintain my dignity and self-respect most of the time	22 (100%)	10 (100%)	12 (100%)
Missing	24 ()	15 ()	9 ()
Week 48			
1, I am never able to maintain my dignity and self-respect	0 (0%)	0 (0%)	0 (0%)
2, I am able to maintain my dignity and self-respect only a little of	0 (0%)	0 (0%)	0 (0%)

S5.2 continued:

4. Clinical Outcomes

Table 4.2e. ICE-CAP - dignity.

	All N=46	*Intervention N=25*	*Control N=21*
3, I am able to maintain my dignity and self-respect some of the time	0 (0%)	0 (0%)	0 (0%)
4, I am able to maintain my dignity and self-respect most of the time	6 (100%)	4 (100%)	2 (100%)
Missing	40 ()	21 ()	19 ()

Numbers are n (%).

S5.2 continued:

4. Clinical Outcomes

Table 4.2f. ICE-CAP - being supported.

	All N=46	*Intervention N=25*	*Control N=21*
Baseline			
1, I am never able to have the help and support that I need	0 (0%)	0 (0%)	0 (0%)
2, I am able to have the help and support that I need only a little of	0 (0%)	0 (0%)	0 (0%)
3, I am able to have the help and support that I need some of the time	0 (0%)	0 (0%)	0 (0%)
4, I am able to have the help and support that I need most of the time	33 (100%)	20 (100%)	13 (100%)
Missing	13 ()	5 ()	8 ()
Week 6			
1, I am never able to have the help and support that I need	0 (0%)	0 (0%)	0 (0%)
2, I am able to have the help and support that I need only a little of	0 (0%)	0 (0%)	0 (0%)
3, I am able to have the help and support that I need some of the time	2 (7%)	2 (12%)	0 (0%)
4, I am able to have the help and support that I need most of the time	27 (93%)	15 (88%)	12 (100%)
Missing	17 ()	8 ()	9 ()
Week 12			
1, I am never able to have the help and support that I need	0 (0%)	0 (0%)	0 (0%)
2, I am able to have the help and support that I need only a little of	0 (0%)	0 (0%)	0 (0%)
3, I am able to have the help and support that I need some of the time	1 (4%)	1 (8%)	0 (0%)
4, I am able to have the help and support that I need most of the time	24 (96%)	12 (92%)	12 (100%)
Missing	21 ()	12 ()	9 ()
Week 24			
1, I am never able to have the help and support that I need	0 (0%)	0 (0%)	0 (0%)
2, I am able to have the help and support that I need only a little of	0 (0%)	0 (0%)	0 (0%)
3, I am able to have the help and support that I need some of the time	1 (5%)	0 (0%)	1 (8%)
4, I am able to have the help and support that I need most of the time	21 (95%)	10 (100%)	11 (92%)
Missing	24 ()	15 ()	9 ()
Week 48			
1, I am never able to have the help and support that I need	0 (0%)	0 (0%)	0 (0%)
2, I am able to have the help and support that I need only a little of	0 (0%)	0 (0%)	0 (0%)

S5.2 continued:

4. Clinical Outcomes

Table 4.2f. ICE-CAP - being supported.

	All N=46	*Intervention N=25*	*Control N=21*
3, I am able to have the help and support that I need some of the time	0 (0%)	0 (0%)	0 (0%)
4, I am able to have the help and support that I need most of the time	6 (100%)	4 (100%)	2 (100%)
Missing	40 ()	21 ()	19 ()

Numbers are n (%).

S5.3:

4. Clinical Outcomes

Table 4.3a.CollaboRATE for patients: Questions about appointment you just had with your oncologist

	Baseline			Week 6			Week 12			Week 24			Week 48		
	N	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*
How much effort was made to help you understand your health issues?															
C	14	8.14 (1.29)	9.0 [8.0-9.0]	12	8.50 (0.90)	9.0 [8.0-9.0]	12	8.25 (0.97)	8.5 [8.0-9.0]	12	8.58 (0.90)	9.0 [8.5-9.0]	2	9.00 (0.00)	9.0 [9.0-9.0]
I	20	8.35 (1.42)	9.0 [8.5-9.0]	16	8.44 (0.89)	9.0 [8.0-9.0]	13	8.62 (0.65)	9.0 [8.0-9.0]	10	8.60 (0.52)	9.0 [8.0-9.0]	4	8.00 (1.15)	8.0 [7.0-9.0]
Overall	34	8.26 (1.36)	9.0 [8.0-9.0]	28	8.46 (0.88)	9.0 [8.0-9.0]	25	8.44 (0.82)	9.0 [8.0-9.0]	22	8.59 (0.73)	9.0 [8.0-9.0]	6	8.33 (1.03)	9.0 [7.0-9.0]
How much effort was made to listen to the things that matter most to you about your health issues?															
C	14	8.29 (1.14)	9.0 [8.0-9.0]	12	8.50 (0.90)	9.0 [8.0-9.0]	12	8.25 (0.87)	8.0 [8.0-9.0]	12	8.33 (1.15)	9.0 [8.0-9.0]	2	9.00 (0.00)	9.0 [9.0-9.0]
I	20	8.40 (1.14)	9.0 [8.0-9.0]	17	8.53 (0.51)	9.0 [8.0-9.0]	13	8.31 (1.70)	9.0 [9.0-9.0]	10	8.70 (0.48)	9.0 [8.0-9.0]	4	8.00 (1.15)	8.0 [7.0-9.0]
Overall	34	8.35 (1.12)	9.0 [8.0-9.0]	29	8.52 (0.69)	9.0 [8.0-9.0]	25	8.28 (1.34)	9.0 [8.0-9.0]	22	8.50 (0.91)	9.0 [8.0-9.0]	6	8.33 (1.03)	9.0 [7.0-9.0]
How much effort was made to include what matters most to you in choosing what to do next?															
C	14	8.21 (1.19)	9.0 [8.0-9.0]	12	8.50 (1.00)	9.0 [8.5-9.0]	12	7.92 (1.08)	8.0 [7.0-9.0]	12	8.33 (1.07)	9.0 [7.5-9.0]	2	9.00 (0.00)	9.0 [9.0-9.0]
I	20	8.30 (1.38)	9.0 [8.0-9.0]	15	8.33 (1.18)	9.0 [8.0-9.0]	13	8.38 (0.87)	9.0 [8.0-9.0]	10	8.70 (0.67)	9.0 [9.0-9.0]	4	8.00 (1.15)	8.0 [7.0-9.0]
Overall	34	8.26 (1.29)	9.0 [8.0-9.0]	27	8.41 (1.08)	9.0 [8.0-9.0]	25	8.16 (0.99)	9.0 [7.0-9.0]	22	8.50 (0.91)	9.0 [8.0-9.0]	6	8.33 (1.03)	9.0 [7.0-9.0]

Abbreviations: C, control; I, intervention; IQR, interquartile range;N, number; SD, standard deviation.
Scores range from 0 (no effort was made) to 9 (every effort was made).

S5.3 continued:

4. Clinical Outcomes

Table 4.3b.CollaboRATE for patients

	Baseline			Week 6			Week 12			Week 24			Week 48		
	N	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*	*N*	*Mean (SD)*	*Median [IQR]*
CollaboRATE Mean Score															
C	14	91.27 (13.20)	100.0 [88.9-100.0]	12	94.44 (10.17)	100.0 [90.7-100.0]	12	90.43 (10.41)	90.7 [85.2-100.0]	12	93.52 (10.37)	100.0 [87.0-100.0]	2	100.0 (0.00)	100.0 [100.0-100.0]
I	20	92.78 (14.19)	100.0 [88.9-100.0]	15	93.58 (8.57)	100.0 [88.9-100.0]	13	93.73 (10.41)	100.0 [92.6-100.0]	10	96.30 (5.52)	100.0 [92.6-100.0]	4	88.89 (12.83)	88.9 [77.8-100.0]
Overall	34	92.16 (13.61)	100.0 [88.9-100.0]	27	93.96 (9.14)	100.0 [88.9-100.0]	25	92.15 (10.33)	96.3 [85.2-100.0]	22	94.78 (8.45)	100.0 [88.9-100.0]	6	92.59 (11.48)	100.0 [77.8-100.0]
CollaboRATE Top Score*															
C	14	8 (57%)	-	12	8 (67%)	-	12	5 (42%)	-	12	7 (58%)	-	2	2 (100%)	-
I	20	14 (70%)	-	15	8 (53%)	-	13	7 (54%)	-	10	6 (60%)	-	4	2 (50%)	-
Overall	34	22 (65%)	-	27	16 (59%)	-	25	12 (48%)	-	22	13 (59%)	-	6	4 (67%)	-

Abbreviations: C, control; I, intervention; IQR, interquartile range; N, number; SD, standard deviation.
CollaboRATE Mean Score: Higher scores represent more shared decision making (range 0-100).
CollaboRATE Top Score: Proportion of patients for whom there was 'gold standard' shared decision making.
*Numbers are n (%).

S5.4:

4. Clinical Outcomes

Table 4.4. Service use.

	All N=46	*Intervention N=25*	*Control N=21*
Total oncology treatments			
N	44	24	20
Mean (SD)	5.2 (5.8)	6.0 (7.1)	4.3 (3.7)
Median [Q1-Q3]	3.5 [2.0-6.0]	4.0 [2.0-6.5]	3.0 [2.0-6.0]
Total hospital admissions			
N	45	24	21
Mean (SD)	2.3 (1.8)	2.7 (2.1)	1.8 (1.2)
Median [Q1-Q3]	2.0 [1.0-3.0]	2.0 [1.0-3.5]	2.0 [1.0-3.0]
Total hospital bed days			
N	44	23	21
Mean (SD)	12.7 (12.7)	16.3 (14.7)	8.8 (8.7)
Median [Q1-Q3]	8.5 [3.5-19.5]	14.0 [5.0-24.0]	6.0 [3.0-11.0]
Total GP practice visits			
N	17	11	6
Mean (SD)	9.8 (11.3)	9.8 (12.6)	9.8 (9.6)
Median [Q1-Q3]	8.0 [3.0-11.0]	8.0 [3.0-11.0]	6.5 [3.0-16.0]
Specialist palliative care contact			
No	29 (63%)	17 (68%)	12 (57%)
Yes	17 (37%)	8 (32%)	9 (43%)
Death			
No	17 (37%)	10 (40%)	7 (33%)
Yes	29 (63%)	15 (60%)	14 (67%)
Place of death			
Home	12 (41%)	8 (53%)	4 (29%)
Hospice	8 (28%)	3 (20%)	5 (36%)
Hospital	9 (31%)	4 (27%)	5 (36%)
Pre UK lockdown* - place of death			
Home	7 (35%)	5 (50%)	2 (20%)
Hospice	6 (30%)	2 (20%)	4 (40%)
Hospital	7 (35%)	3 (30%)	4 (40%)
Post UK lockdown* - place of death			
Home	5 (56%)	3 (60%)	2 (50%)
Hospice	2 (22%)	1 (20%)	1 (25%)

S5.4 continued:

4. Clinical Outcomes

Table 4.4. Service use.

	All N=46	*Intervention N=25*	*Control N=21*
Hospital	2 (22%)	1 (20%)	1 (25%)
Main cause of death			
Cancer	21 (84%)	13 (93%)	8 (73%)
Cancer complication	2 (8%)	0 (0%)	2 (18%)
Haematemesis	1 (4%)	0 (0%)	1 (9%)
Pulmanory Embolism and Pancreatic Cancer	1 (4%)	1 (7%)	0 (0%)
Missing	4 ()	1 ()	3 ()

Numbers are n (%) or n, mean (SD), median [Q1-Q3].
*Date of UK lockdown - 23rd March 2020.
Abbreviations: N, number; Q, quartile; SD, standard deviation.

S5.5:

4. Clinical Outcomes

Table 4.5: Time-to-event data.

Time in weeks	***All N=46***	***Intervention N=25***	***Control N=21***
MDT review meeting to first GP contact			
N	15	9	6
Mean (SD)	9.5 (7.2)	7.6 (5.5)	12.4 (9.1)
Median [Q1-Q3]	7.4 [2.6-14.9]	7.3 [3.6-8.9]	13.1 [2.6-19.4]
Last GP contact to death			
N	10	6	4
Mean (SD)	2.2 (3.0)	2.5 (3.9)	1.8 (1.5)
Median [Q1-Q3]	1.1 [0.3-2.4]	1.0 [0.1-2.4]	1.7 [0.6-3.0]
Last oncology treatment to death			
N	27	15	12
Mean (SD)	17.3 (14.9)	14.5 (12.1)	20.8 (17.7)
Median [Q1-Q3]	12.7 [7.4-20.4]	11.4 [7.4-18.3]	13.2 [9.5-25.0]
MDT review meeting to death			
N	29	15	14
Mean (SD)	31.7 (18.6)	31.4 (18.0)	32.1 (19.9)
Median [Q1-Q3]	30.6 [17.0-42.9]	28.6 [17.0-47.3]	34.5 [12.6-42.9]
MDT review meeting to updated KIS			
N	37	20	17
Mean (SD)	24.4 (19.2)	24.3 (20.0)	24.5 (18.8)
Median [Q1-Q3]	18.6 [7.6-42.9]	16.2 [6.0-44.9]	18.9 [9.6-33.0]
MDT review meeting to SPC referral			
N	17	8	9
Mean (SD)	20.8 (17.4)	27.3 (20.3)	15.0 (12.7)
Median [Q1-Q3]	18.9 [4.4-33.9]	26.4 [9.1-48.4]	11.6 [3.7-22.4]

Numbers are n, mean (SD), median [Q1-Q3].
Abbreviations: MDT, multidisciplinary team; N, number; Q, quartile;
SPC, specialist palliative care ; SD, standard deviation.

S5.5 continued:

Time in weeks	***All N=46***	***Intervention N=25***	***Control N=21***
Date randomised to first oncology treatment			
N	40	22	18
Mean (SD)	1.8 (2.8)	1.5 (2.2)	2.2 (3.5)
Median [Q1-Q3]	1.7 [0.5-2.6]	1.7 [0.4-2.3]	1.7 [0.7-2.7]
Date randomised to first GP practice visit			
N	15	9	6
Mean (SD)	5.2 (6.6)	4.0 (5.9)	6.8 (7.7)
Median [Q1-Q3]	3.0 [0.6-11.4]	3.0 [1.7-7.3]	3.4 [0.6-16.6]
Date randomised to updated KIS			
N	37	20	17
Mean (SD)	20.1 (18.1)	19.7 (18.9)	20.5 (17.7)
Median [Q1-Q3]	15.0 [4.0-38.1]	13.3 [3.2-39.6]	15.0 [7.9-25.9]
Date randomised to last oncology treatment			
N	39	21	18
Mean (SD)	17.3 (18.6)	20.1 (22.1)	14.0 (13.3)
Median [Q1-Q3]	10.1 [6.7-21.6]	10.1 [6.9-28.3]	10.0 [6.7-16.0]
Date randomsied to SPC referral			
N	17	8	9
Mean (SD)	16.0 (15.3)	20.7 (18.2)	11.9 (11.9)
Median [Q1-Q3]	12.1 [3.0-19.9]	17.0 [7.1-37.1]	10.9 [2.9-16.6]
SPC referral to death			
N	16	7	9
Mean (SD)	10.6 (12.4)	9.2 (5.8)	11.8 (16.1)
Median [Q1-Q3]	5.1 [3.5-12.6]	6.7 [4.1-13.4]	3.9 [3.3-8.7]

Numbers are n, mean (SD), median [Q1-Q3].
Abbreviations: MDT, multidisciplinary team; N, number; Q, quartile; SPC, specialist palliative care ; SD, standard deviation.