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Advance care planning in primary care for cancer patients

Feasibility randomised trial

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Advance care planning in primary care for cancer patients: Feasibility randomised trial

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Title

Advance care planning in primary care for cancer patients: Feasibility randomised trial.

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Abstract

Background

Advance (anticipatory) care planning (ACP) requires discussions between patients and healthcare professionals about planning for future deterioration in health. ACP improves care coordination but uptake is limited and often deferred.

Aim

We assessed feasibility and acceptability to patients, carers and general practitioners (GPs) of a primary care ACP intervention for people with incurable oesophageal, gastric or pancreatic cancer.

Design and Setting

12-month feasibility randomised controlled trial in a Scottish Cancer Network.

Method

Patients aged 18 or over starting palliative oncology treatment were randomised 1:1 to an ACP intervention or standard care. Intervention patients received an oncologist letter supporting them to request a GP review and ACP public information. Pre-specified analyses with blinding included trial recruitment and retention, ACP completion, and quality of life questionnaires (EQ-5D-5L, ICECAP-SCM) at baseline, 6, 12, 24 and 48 weeks. Qualitative interviews with purposive sampling explored patient, carer and GP experiences.

Results

Of 99 eligible participants (269 screened), 46% were recruited (n=46) and randomised; 25 to intervention and 21 to control. By 12 weeks, 45% (9/20) intervention patients and 59% (10/17) controls had a documented ACP. Quality of life was maintained at 24 weeks except for physical symptoms but 30% had died. Social norms associating ACP with dying were prevalent among 23 participants interviewed. No psychological or clinical harms were identified.

Conclusion

An RCT of ACP for people with incurable cancer in primary care is feasible. Patient, carer and GPs attitudes and behaviours determined acceptability and timing of care planning.

ClinicalTrials.gov Identifier: NCT03719716. Funder: Macmillan

Keywords

Advance care planning, anticipatory care planning, primary health care, cancer, general practice, mixed methods.

How this fits in

- Advance care planning (ACP) has established benefits for patients with cancer and other serious illnesses but uptake remains low in many countries including the UK.
- Offering opportunities for people to discuss their priorities and preferences and have these recorded informs future care and reduces inappropriate interventions.
- Patients and families prefer ACP conversations with known community professionals and when not acutely ill.
- Identifying and responding to people's preferred care planning style can facilitate early support and meaningful conversations about ACP in primary care.

Introduction

Advance care planning (ACP) is an internationally recommended approach to care of patients with deteriorating health.⁽¹⁾ ACP involves hospital clinicians, GPs and primary care teams talking with patients and families about the future, and making plans for when their health changes.⁽²⁻⁴⁾ Uncertainties are acknowledged and addressed, and proactive care plans agreed for potential health and care crises and to prevent avoidable acute hospital admissions.⁽⁵⁾ ACP is particularly relevant for people with life-limiting illnesses such as incurable cancer as well as those with progressive long-term conditions.

In the UK, cancer patients have an average of five emergency admissions to hospital in the last year of life and the highest per person use of unscheduled care.^(6,7) Unplanned admissions disrupt continuity of care in the community and may lead to inappropriate investigations and interventions.⁽⁸⁾ People with incurable cancers risk such admissions due to illness severity, complexity and complications.⁽⁹⁾ Growing evidence shows this group of cancer patients value and benefit from early support in primary care as well as from oncology soon after diagnosis to improve quality of life, symptom management and care coordination.⁽¹⁰⁻¹³⁾ Integration of oncology, specialist palliative care and primary care has been recommended.⁽¹⁴⁾

Aims

This study aimed to evaluate the feasibility and acceptability of an early ACP intervention in primary care designed to trigger proactive discussions between patients and their GP leading to a documented care plan in the Scottish primary care electronic record (Key Information Summary – KIS). A secondary objective was to empower and encourage patients and their family/carers to engage in an ACP process soon after starting palliative oncology treatment.

Methods

Design

This was a 12-month feasibility randomised controlled trial (RCT) with integration of quantitative and qualitative data collected and analysed in parallel. Reporting is in line with the CONSORT extension for randomised pilot and feasibility trials.^(15,16) Primary feasibility outcomes were the proportion of eligible patients recruited and randomised, and number of intervention patients who had an ACP review by their GP documented in a new or updated electronic record within 12 weeks. Health-related quality of life was the main patient-reported outcome measured at baseline, 6, 12, 24 and 48 weeks. Mapping patient journeys from diagnosis to 12-month survival or death, and service use were secondary clinical outcomes. Qualitative interviews with purposive sampling explored patient, carer and GP experiences. (Supplementary Box 1)

Sample size

We planned to include 50 participants (25 per group) to provide acceptable precision in estimating feasibility outcomes. If the true conversion rate from screening to consent were 50%, a 95% confidence interval for the rate estimate would have width +/-9.8%. The confidence interval width for the proportion of participants randomised to the intervention who made a GP appointment would lie between +/-11.8% and +/-19.6% across a range of true

proportions (10% to 90%). Qualitative practice relies upon the core principle of data saturation rather than the number of participants recruited.⁽¹⁷⁾ Purposive sampling was utilised to give sufficient range and depth of patient, carer and GP perspectives until no new codes or themes emerged.⁽¹⁸⁾

Setting/patients

Patients over 18 years starting palliative oncology treatment for newly diagnosed incurable pancreatic or upper gastrointestinal (oesophageal or gastric) cancer at a Scottish regional cancer centre were eligible to participate. Exclusion criteria included people who were unfit for oncology treatment, chose supportive care, had another life-limiting condition or suffered from cognitive impairment that precluded informed consent, communication by telephone, questionnaire completion or interview.

Initial eligibility screening happened at weekly multidisciplinary cancer team meetings. Oncology clinicians offered study information to eligible patients at their clinics. Interested patients consented to transfer their contact details to the research team. Participants gave informed consent before being recruited and randomised to either early support (intervention) or standard care (control) in a 1:1 ratio. Randomisation was stratified by diagnostic group (pancreatic or gastrointestinal cancer) and Health Board. The allocation sequence was created by a database programmer at Edinburgh Clinical Trials Unit using computer-generated pseudo-random numbers with random permuted blocks and was concealed by use of a centralised web-based randomisation system (REDCap).

Intervention

Participants in the intervention arm received a personal letter developed with a patient-public involvement (PPI) group and signed by their oncologist to help them make an appointment to discuss ACP with their GP. The Healthcare Improvement Scotland (HIS) patient information leaflet on ACP (known as Anticipatory Care Planning in Scotland) was enclosed with this letter and the study information booklet.⁽¹⁹⁾ GP practices received the same documents plus professional information about ACP⁽²⁰⁾, a copy of the NHS Scotland 'RED-MAP' communication framework (2019)⁽²¹⁾ and a request to consider starting ACP and complete an electronic ACP. Control group participants received standard care.

Quantitative instruments and data analysis

Research team clinicians screened electronic health records for all patients reviewed at the cancer meetings and records of patients subsequently assessed in oncology clinics to document exclusion reasons. All patients agreeing to speak to a researcher were consented and randomised. Study clinicians recorded key events including withdrawal due to poor health or death. GP practices provided service use data including dates of GP contacts. All participants completed validated quality of life measurements at baseline, 6, 12, 24 and 48 weeks: EuroQol EQ-5D-5L and ICECAP-SCM.^(22,23) The ICECAP-SCM has seven wellbeing domains but our PPI group recommended removal of the final question referring to preparation for death as potentially distressing for people starting cancer treatment. Scores for individual domains were reported as summative scores could not be calculated. CollaboRATE is a simple measure of shared decision-making suited to primary care.⁽²⁴⁾ Intervention group questionnaire booklets had two supplementary questions asking if the letter helped obtain a GP appointment within 12 weeks that led to discussion about ACP. The researcher collated all data for analysis into spreadsheets using unique participant identifiers.

Two clinical researchers, who were blinded to trial arm, extracted and graded (high, medium or low) ACP content in the electronic urgent care records (KIS) for participants in one Health Board each. A similarly blinded, academic clinician completed an independent review of all KIS records from both the Health Boards. A high quality KIS had a timely record of key events, informative treatment and care plans, and documented CPR status.

Quantitative data analysis followed a pre-specified analysis plan (Supplementary Box 2) by the trial statistician using SAS version 9.4 with participants identified solely by study code number to maintain blinding. Analysis consisted of descriptive statistics with baseline demographic and clinical data summarised overall and by treatment arm. Feasibility outcomes were calculated as a proportion with exact 95% confidence intervals (CIs). Overall study retention rates and differences between intervention/control groups with 95% CIs were estimated. Baseline data and feasibility outcomes were analysed by stratification factor. Patient-reported outcomes (EuroQol EQ-5D-5L, ICECAP-SCM; CollaboRATE), service use, and time to event outcomes were summarised by randomised group and overall at each time point. These data were stored in a secure University server.

Qualitative data generation and analysis

A purposive sub-sample of participants and their carers/family members from both groups based on diagnosis, demography, Health Board and treatment arm participated in semi-structured interviews at week 6-8 and week 20-22. Participants chose a joint or individual interview in their own home or at their local cancer clinic. A pre-specified topic guide facilitated exploration of treatment and care experiences, views about the intervention and survey instruments and perceptions about trial participation. With patient consent, their GP gave a 20-30 minute telephone interview with the outline sent in advance. Interviews covered professional perceptions of the intervention and ACP processes in primary care including possible improvements. Interviews with patients and carers/family members were analysed as dyads and addition of a GP interview constituted a triad. Interviews were recorded with an encrypted digital recorder, transcribed and anonymised with a unique code. Transcripts were uploaded to NVivo 12© then coded with a framework based on the interview topic guides. Data were analysed using a thematic approach, within and across cases, and longitudinally in line with established narrative analysis methods.⁽²⁵⁾

Data integration and interpretation

Quantitative and qualitative datasets were analysed separately then integrated to generate a more comprehensive understanding of ACP in primary care for people with incurable cancers.⁽²⁶⁾ Expert steering group meetings and research team discussions considered and managed areas of conflict, agreement or enrichment in these data. Study findings were informed by the Theory of Planned Behaviour (TPB) to help describe and interpret ACP processes from patient/carer and GP perspectives.⁽²⁷⁾ The TPB model has been applied extensively in health care contexts including hospice care and cancer screening.^(28,29)

Results

Participants were recruited from 1st January 2019 to 3rd March 2020 and followed for up to 12 months until 31st August 2020. Recruitment stopped due to COVID-19 and the study end date. Of 269 screened patients, many (170/269; 63%) had advanced disease and/or poor health at diagnosis so did not start oncology treatment or opted for palliative care. Of the 99 eligible participants, 46 were recruited (46%) with 25 randomised to intervention and 21 to

control arm (Figure 1). Relatively few eligible patients and recruitment delays meant 22 participants enrolled too late to reach the 48 week data point. Nine participants remained in the study and six completed the final questionnaires. The main feasibility outcome (a new or updated KIS-ACP) was measured at week 12 and assessed for all 46 participants.

Recruited patients were younger having a median age of 65 (59-71). Fewer had pancreatic cancer 12/46 (26%) due to its poorer prognosis and co-recruitment to another study. Table 1 shows the baseline characteristics of all screened patients. Participants were keen to participate despite their diagnosis and debilitating symptoms or treatment side effects. Many wanted to share their experiences and improve care for future patients. Study retention was high in both groups with most withdrawals due to death or deteriorating health (Figure 1). By 24 weeks, 30% (n=14) had died. At week 6, 64% (28/44) returned their postal questionnaires. The researcher changed to collecting questionnaire responses by telephone in the final eight months due to COVID-19 restrictions with a 66% (21/32) overall completion rate at week 24.

A total of 23 patients participated in semi-structured interviews, often with a carer. Ten case-linked GPs were interviewed. Table 2 shows the individual, dyad and triad interviews. Whilst completing questionnaires by telephone, participants often talked about their experiences. With verbal consent, 21 of these storied accounts were recorded as field notes, providing further rich data for integration with formal interview data.

Feasibility outcomes

Feasibility outcomes from patient clinical data found a new or updated KIS for 83% (20/24) intervention group and 85% (17/20) control group patients by week 12. An ACP was included in the KIS summaries of 45% (9/20) of intervention and 59% (10/17) of control patients. (Table 3). The overall KIS-ACP quality was similar between groups, but almost half of the ACPs were rated as poor by experienced clinicians. Medium to high quality ACPs were mostly completed in the last 2-3 months of life. The letter helped 65% of participants answering the question about obtaining a GP appointment do so. All 13 intervention patients interviewed took the letter to their GP practice. Relationships between GPs and patients, perceived busyness of the practice, and appointment systems impacted both groups. GPs thought the intervention letter a useful prompt to consider earlier engagement with patients. Documented future care plans were valuable but required a difficult, delicate balance between encouraging patients to engage in challenging conversations and respecting individual wishes.

Attitudes and perceptions of individual patients, carers and GPs determined subsequent ACP outcomes and the interviews revealed four styles of care planning behaviour:

- Early patient/carers planners started making future care planning decisions around the time of diagnosis, and GPs were proactive in initiating ACP conversations.
- Evolving patient/carers planners began planning ahead as the disease progressed, and GPs initiated ACP when prompted by patients/carers, oncology clinicians or district nurses.
- Late patient/carers planners only made plans towards the terminal phase of illness, and GPs initiated ACP late in the disease trajectory.
- Non-planners did not make care plans.

Early patient planners were uncommon and most had worked in healthcare. Many participants had not engaged in ACP by second interview. From ten GPs interviewed, three intervention and one control group GP were early planners. Interactions between people with different planning styles emerged as more important than the intervention in determining outcomes; shown here and in Supplementary Box 3.

Interview triad – Early planner patient, carer and GP.

'Our GP took the bull by the horns right from the start. She asked me about end of life and if I wanted resuscitated as soon as I was diagnosed, and I said no.

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

'Some patients find it very difficult to engage with us as GPs or our primary health care team if they are very much fixated on what can oncology offer. Sometimes, we as GPs feel that patients actually haven't got to that stage. There is a small group who cling on for that last bit of hope. So, that is led by the patient, unfortunately.'

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

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

'It's hard to say what he said. Something about this is about what you want towards the end of your life. But we're just no feeling at that stage yet. I'll sort of cross that bridge when I come to it.'

43P, intervention patient, 1st interview, 10/04/2020.

'He has a KIS, yes. We discussed ACP and he was meant to get back to me about it, but he hasn't yet. And that was when all the COVID stuff came up, so that's been disrupted.'

43P, intervention GP, interview, 26/06/2020.

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

'I handed it into the receptionist. And I'll be honest with you, I did'nae (didn't) really need the doctor, 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. Mine's no (not) malignant, and it's no (not) spread. If I get another ten years, I'll be quite happy.'

26P, patient, intervention, 1st interview, 06/12/2019.

'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 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 are very well and have a full active, unrestricted life.'

26P, intervention GP, interview, 03/03/2020.

Attitudes towards ACP and strongly held beliefs about its association with cardiopulmonary resuscitation and planning for the end of life conflicted with living well in the present,

maintaining normality and perceived harms of planning ahead too soon. Public and professional information about ACP being an ongoing process of preparing for the future well before the last phase of life had little impact on prevailing social norms about fighting cancer and maintaining hope. With few exceptions, ACP was reactive and triggered by changes in the patient's health or cancer treatment plan. Pressure of time and the drive to complete resuscitation forms (DNACPR) affected perceived behavioural control among GPs. Figure 2 illustrates factors underlying these ACP behaviours.

Patient-reported outcomes - quality of life

Patients in both groups maintained a good quality of life despite their poor prognosis and the impact of treatment side effects. Baseline EuroQol EQ-5D-5L had a median Health Index score of 0.72 (Q1-Q3, 0.66-0.81) and visual analogue scale (VAS, 0-100) a median of 75/100 (Q1-Q3, 65.0-85.0). Scores remained stable to week 24 where median Health Index was 0.71 (Q1-Q3, 0.55-0.77) and VAS score 70 (Q1-Q3, 60.0-85.0). (Supplementary Box 4, Table 4.2) Patients recorded high scores on five ICECAP-SCM wellbeing measures up to 24 weeks: 'Having a say most of the time' (88%-100%); 'Being with people who care about you most of the time' (80%-79%); 'Emotional suffering sometimes or rarely' (85%-100%) 'Able to maintain dignity most of the time' (92%-100%); 'Being supported most of the time' (93%-100%). ICECAP-SCM domain 'Experiencing physical discomfort' suggested most patients suffered increasing physical symptoms over time. (Supplementary Box 4, Tables 4.3a, 4.3b, 4.3c, 4.3d, 4.3e, 4.3f)

Interviewed patients shared experiences of living with cancer and felt well supported with cancer treatment and involved in all aspects of decision-making reflected in CollaboRATE scores from both groups. Patients recorded a top score (every effort was made to involve me): baseline (65%), week 6 (59%), week 12 (48%) and week 24 (59%). (Supplementary Box 4, Table 4.1b). Trying to maintain normality and balance being pain free while minimising analgesic use and side effects were important considerations.

'It's amazing because these are all pretty serious things and yet I've felt good and I've felt healthy enough and I'm eating well. I feel quite positive although there are the odd days where I feel a bit anxious and things.'

42P, control patient, fieldnotes, 31/07/2020.

'Well, if I could just get to the bottom of this back pain that makes me feel sick, I'd be absolutely fine. I can take the immediate release (opioid) anytime I feel it coming on. It's trial and error.'

38P, intervention patient, 2nd interview, 23/07/2020.

Clinical and service use outcomes

Service use by both groups appeared broadly similar. Intervention patients spent more days in hospital (median 14.0 days [5.0-24.0] v 6.0 days [3.0-11.0]) although home deaths appeared higher (53% v 29%) (Supplementary Box 4, table 4.4). The COVID-19 pandemic and small sample sizes limit generalisability of these findings. Median time from multidisciplinary cancer meeting to first GP contact was shorter in the intervention group but there was substantial overlap between groups indicating diversity of experiences among participants (7.3 weeks [Q1-Q3, 3.6-8.9] v 13.1 weeks [Q1-Q3, 2.6-19.4]) (Supplementary Box 4, Table 4.5a). GP visits or contacts were similar; median [8.0, [Q1-Q3, 3.0-11.0] through to the last week of life (Supplementary Box 4, Table 4.4). Cancer treatment stopped around three months before death in both groups (Supplementary Box 4, table 4.5a). Of 46 participants, 37% received

specialist palliative care, with later referral in the intervention group (26.4 weeks [Q1-Q3, 9.1-48.4] v 11.6 weeks [Q1-Q3, 3.7-22.4]). (Supplementary Box 4, Table 4.4) Other time to event data were similar for all participants. Median survival from cancer review meeting was 30.6 weeks (Q1-Q3, 17.0-42.9), and a KIS was started or updated after a median of 18.6 weeks (Q1-Q3, 7.6-42.9). (Supplementary Box 4, Table 4.5a) A total of 29 (63%) patients died during the study, all from cancer or its complications. (Supplementary Box 4, Table 4.4) No psychological or clinical harms were identified.

Discussion

Summary

This study found patients with incurable oesophageal, gastric or pancreatic cancers starting palliative oncology treatment can be recruited to an ACP trial in primary care with good retention rates even though a third died within six months. An intervention letter from oncology was acceptable to patients but did not trigger more advance care planning discussions leading to documentation of a clinically relevant ACP. Our findings offer insights into how people navigate incurable cancer and cancer treatment by maintaining normality; reflected in high quality of life scores and personal accounts. Interview dyads/triads illuminated an evolving dialogue between patients, family carers and GPs about care planning as the patient's health deteriorated. Where care planning styles aligned or GPs could broach thinking about the future linked to clinical events, meaningful conversations often followed.

Strengths and limitations

The study had several strengths. A feasibility trial evaluated an ACP intervention designed with local cancer clinicians, general practitioners and public-patient representatives and its implementation in routine clinical practice successfully.⁽³⁰⁾ Retention was good, with death or deterioration the main withdrawal reasons. Validated questionnaires with good response rates measured quality of life and decision-making about palliative cancer treatments. Health service use and time to event data mapped care pathways of a rapidly deteriorating patient group. Qualitative interview data generated in parallel were integrated with quantitative data for reporting.⁽³¹⁾ We used longitudinal, multi-perspective interviewing to generate rich data about underlying attitudes, beliefs, social norms and external factors making earlier ACP discussions in primary care possible but complex and individual.⁽³²⁾

There were limitations. Many ineligible patients who were not fit for cancer treatment or palliative care slowed recruitment follow-up to week 48 for later participants. COVID-19 exacerbated difficulties recruiting GPs and obtaining primary care service use data. The pandemic may have impacted KIS completion and ACP quality through pressure to complete more plans that directed care in the event of COVID-19 infection. Excluding the final ICECAP-SCM wellbeing question on PPI advice prevented summative scoring across all domains. This study took place in a single cancer centre serving two Scottish Health Boards and participants did not represent ethnically diverse backgrounds limiting generalisability.

Comparison with existing literature

GPs have an important, valued role in providing care coordination for people with incurable cancers along with general palliative care support as a patient deteriorates.^(13,33) In this study, such care was evident particularly in the final phase of illness. Patients appreciated their cancer care and felt involved in treatment decision-making but collaborative approaches to

ACP between oncology services and primary care were lacking. Systematic reviews of ACP implementation studies found that effective ACP programmes focused on individualised discussions over time and targeted multiple stakeholders to deliver integrated ACP.⁽³⁴⁾ ACP intervention studies in primary care are underdeveloped compared with other settings and lack cohesive structures.⁽³⁵⁾

Social norms associating ACP with death and dying and fears about consequences of discussing them were almost universal among participants. Research exploring end-of-life communication within families has shown how such normative values create multiple barriers to open dialogue including belief in positive thinking and protective buffering.⁽³⁶⁾ Many people in our study exhibited fluid and oscillating 'dual dialogue' or double awareness; the capacity of individuals to live as normally as possible whilst also being aware of the inevitability of death.^(37,38) This concept underpins successful early palliative care interventions in oncology outpatient services that support patients and family carers to gradually engage and cope with both living life well and acknowledging dying.^(12,37)

The COVID-19 pandemic highlighted harms associated with policy drives to record advance treatment plans, including CPR status, at the expense of meaningful conversations about what matters to people at risk of deteriorating health.⁽³⁹⁾ Shifting professional and public understanding away from 'planning for dying' towards broader, values-based concepts of ACP in the UK and internationally is accepted increasingly as best practice.^(1, 40, 41) Patient-public information and education about ACP is becoming more widely available and aims to normalise ACP by empowering people to have these important conversations with their family, friends and clinicians.⁽⁴²⁻⁴⁴⁾ Primary care teams can be supported better to embed ACP in routine care, and start earlier conversations about serious illness, coping with uncertainty, and preparing for future changes in a person's health by resources developed by primary care leads.^(35, 45) Electronic care coordination systems for ACP in primary and secondary care are being developed to be accessible, readily updated by all key professionals and clinically relevant.⁽⁴⁶⁾

Implications for research and/or practice

Progression to a full trial of early ACP in primary care with people with incurable cancers is feasible in terms of patient recruitment and retention, and this study suggested a 24-week intervention may be sufficient. Longer follow-up remains valuable for secondary outcomes like quality of life and health service use. People living with the challenges of incurable cancer and palliative oncology treatments were keen to participate in research and improve care for others. Timing and acceptability of ACP depended on perceptions and attitudes of patients, carers and GPs. Understanding these behaviours is already informing future ACP research and clinical practice through the 2021 national toolkit for ACP in Scotland and development of a new digital platform that addresses current limitations of the KIS system. Primary care has a central role in ACP but collaborative models with oncology merit investigation. Public engagement campaigns should continue to promote wider discussions about future care and highlight benefits of planning for changes in health to help patients and carers navigate health and care crises. Values-based healthcare prioritises talking about what matters to a person; reflected in recent professional education on meaningful conversations about ACP.

Supplementary data (separate PDF)

Funder

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Ethical approval

Ethical approval was obtained from the West of Scotland Research Ethics Committee 4, Integrated Research Application System (IRAS) No: 18/WS/1035, project ID: 243938. Local R&D approvals for the two Health Boards and Caldicott Guardian approval to access health service use data were obtained.

Competing interests

The authors have declared no competing interests.

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CONSORT

TRANSPARENT REPORTING of TRIALS

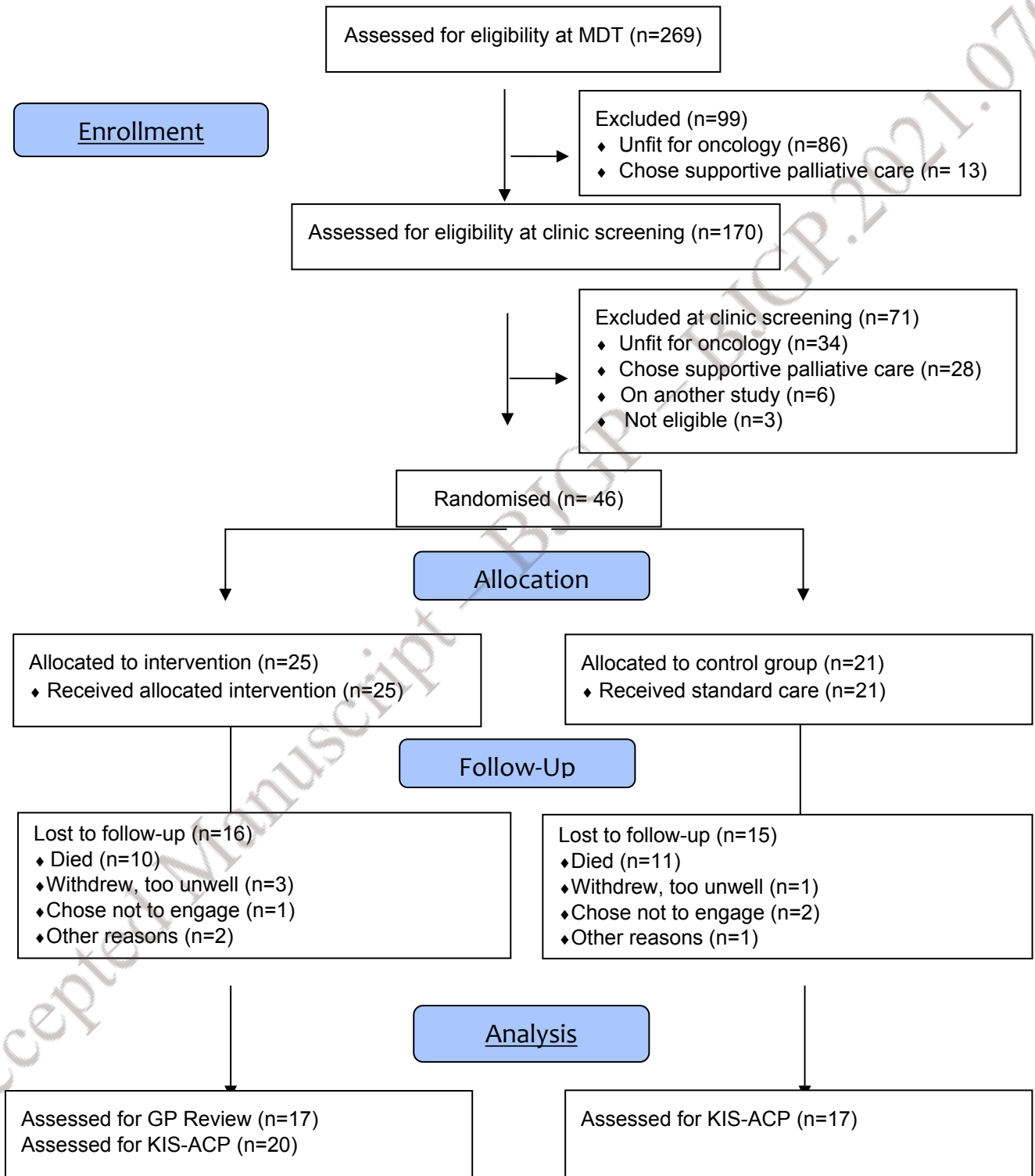


Figure 1. Consort (2010) diagram of study participant flow, adapted for this study. (16)

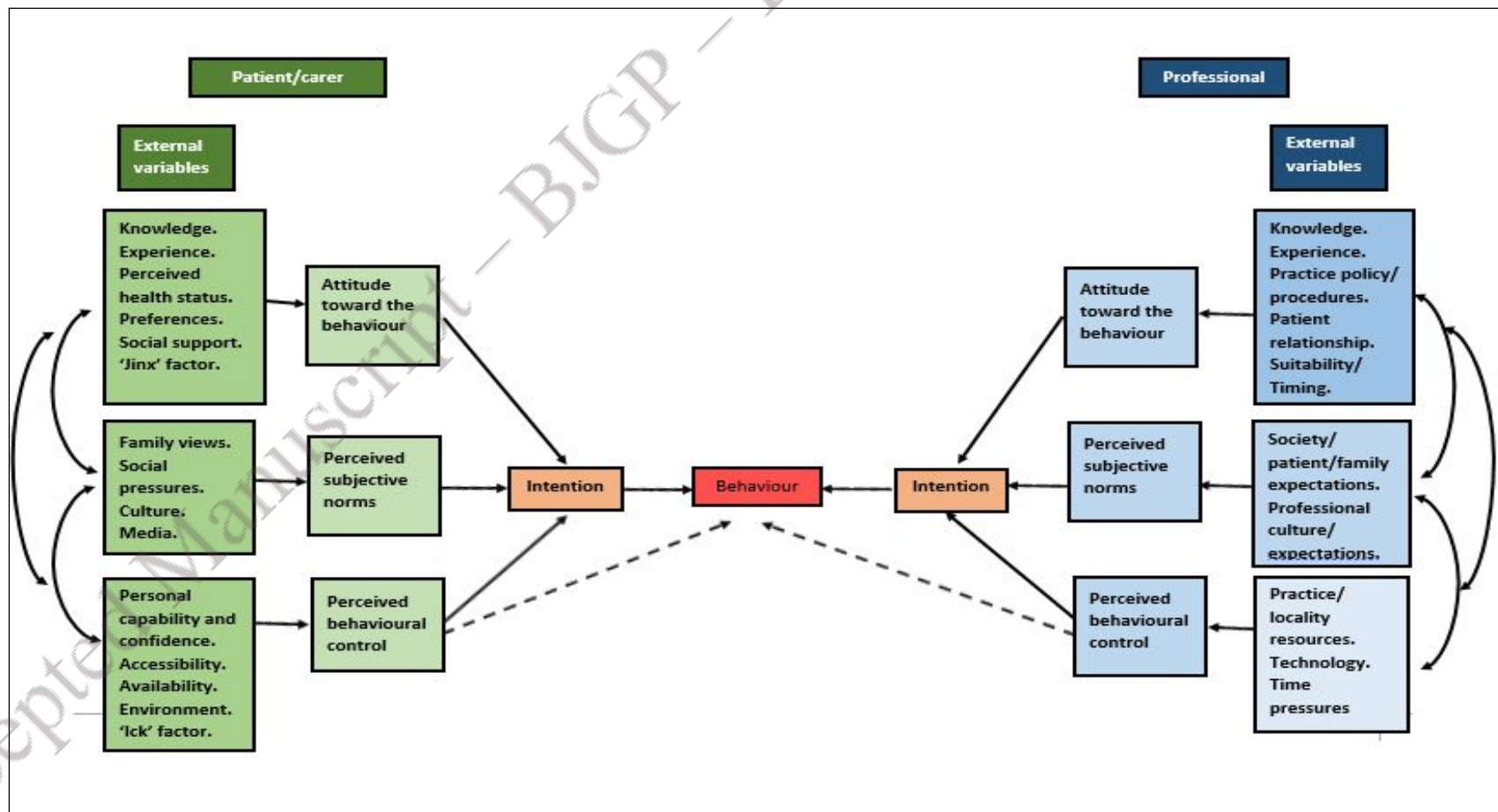


Figure 2. Theory of Planned Behaviour applied to ACP.

Table 1. Baseline characteristics of all screened patients.

	<i>All N=269</i>	<i>Not eligible N=170</i>	<i>Eligible but not randomised N=53</i>	<i>Randomised N=46</i>
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				
Male	175 (65%)	113 (66%)	31 (58%)	31 (67%)
Female	94 (35%)	57 (34%)	22 (42%)	15 (33%)
Cancer diagnosis				
Oesophagus/Junctional	119 (44%)	68 (40%)	24 (45%)	27 (59%)
Stomach	44 (16%)	32 (19%)	5 (9%)	7 (15%)
Pancreas	106 (39%)	70 (41%)	24 (45%)	12 (26%)
Main disease group				
Upper GI	163 (61%)	100 (59%)	29 (55%)	34 (74%)
Pancreas	106 (39%)	70 (41%)	24 (45%)	12 (26%)
First diagnosis				
Yes	261 (97%)	166 (98%)	50 (94%)	45 (98%)
No - relapsed disease	8 (3%)	4 (2%)	3 (6%)	1 (2%)
Disease extent - metastatic				
Yes	169 (63%)	100 (59%)	35 (66%)	34 (74%)
No	100 (37%)	70 (41%)	18 (34%)	12 (26%)
Initial oncology treatment plan made at MDT review				
Chemotherapy	156 (58%)	68 (40%)	44 (83%)	44 (96%)
Radiotherapy	12 (4%)	2 (1%)	8 (15%)	2 (4%)
Other	101 (38%)	100 (59%)	1 (2%)	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.				

Table 2. Number of first, second and dyad/triad interviews.

Category	Patient and carer	Patient alone	Carer alone	GP	Total
First Interview	16	7	1	10	34
Intervention	9	4	1	6	
Control	7	3	-	4	
Second interview	13	3	3	-	19
Intervention	8	2	2*	-	
Control	5	1	1	-	
Total interviews	29	10	4	10	53

* Included one carer in a bereavement interview.

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Table 3. Outcomes analysis of GP urgent care records (KIS), ACP content and quality.

		<i>All N=46</i>			<i>Intervention N=25</i>			<i>Control N=21</i>		
		<i>N</i>	<i>n (%)</i>	<i>95% CI</i>	<i>N</i>	<i>n (%)</i>	<i>95% CI</i>	<i>N</i>	<i>n (%)</i>	<i>95% CI</i>
Intervention feasibility outcomes										
Eligible patients who were randomised		99	46 (46%)	(36.4% to 56.8%)	-	-	-	-	-	-
New or updated KIS in patient clinical record		44	37 (84%)	(69.9% to 93.4%)	24	20 (83%)	(62.6% to 95.3%)	20	17 (85%)	(62.1% to 96.8%)
Clear ACP included in patient 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 me get a GP appointment		-	-	-	17	11 (65%)	(38.3% to 85.8%)	-	-	-
**Clinician assessment of KIS-ACP quality	High		7 (19%)			2 (10%)			5 (29%)	
	Med		12 (32%)			7 (35%)			5 (29%)	
	Low		18 (49%)			11 (55%)			7 (41%)	
* Included in denominator if participants had provided any response (yes/no) to the question.										
** For KIS-ACP quality, post-hoc clinical review changed the grading of KIS-ACP assessments (n=4) after the quantitative analysis report had been issued.										
Abbreviations: ACP, Anticipatory Care Planning; CI, confidence interval; KIS, Key Information Summary; N, number; “-”, not applicable.										