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Title: Assessing the sensitivity and acceptability of the Royal Marsden Palliative Care Referral "Triggers" Tool for out-patients with cancer.

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Author Contribution:

All authors contributed to the study conception and design. Material preparation and data collection were performed by LK and YK. Data analysis was carried out by LK, YK, KM, AMS and NP. All authors were involved in interpretation of the data. The first draft of the manuscript was written by LK and JD and all authors commented on, contributed to and approved the final manuscript.

Abstract

Purpose:
To evaluate the use, acceptability, and experience of a seven-item palliative care referral screening tool in an outpatient oncology setting.

Methods:

A two-phase convergent parallel mixed methods study. Patient participants who met any of the "Royal Marsden Triggers Tool" criteria were compared with those who did not in terms of demographic data, palliative care needs (Integrated Palliative Outcome Scale, IPOS) and quality of life indicators (EORTC-QLQ-C30).

In-depth interviews were carried out with patients and oncology staff about their views and experience of the "Royal Marsden Triggers tool". Qualitative and quantitative data were triangulated at data interpretation.

Results:

348 patients were recruited to the quantitative phase of the study of whom 53% met at least one of the Triggers tool palliative care referral criteria. When compared with patients who were negative using the Triggers tool, "Royal Marsden Triggers tool" positive patients had a lower quality of life (EORTC QLQ-C30 Global Health Status scale ($p<0.01$)) and a higher proportion had severe or overwhelming physical needs on IPOS (38% versus 20%, $p<0.001$). Median survival of "Royal Marsden Triggers tool" positive patients was 11.7 months.

16 staff and 19 patients participated in qualitative interviews. The use of the tool normalized palliative care involvement, supporting individualized care and access to appropriate expertise.

Conclusion

The use of a palliative care referral tool streamlines palliative care within oncology outpatient services and supports teams working together to provide an early holistic patient-centered service. Further research is needed to evaluate the effectiveness and feasibility of this approach.

Key Words:

Normalisation

Holistic

Integrated Palliative Outcome Scale (IPOS)

EORTC-QLQ-C30

Early Palliative Care

Palliative Care Referral Tool

Introduction

The outpatient oncology setting provides an ideal opportunity to deliver early integrated palliative care through the proactive identification of needs, timely intervention and crisis prevention.(1,2)

A major challenge faced by palliative care as a specialty is how to address the increased resource requirements as palliative care is no longer confined to end of life care.(3,4) There is a need to prioritize the availability of existing specialist palliative care resources for those who would benefit most.(5–7)

International bodies have called for the development of sustainable systems to streamline palliative care referrals, to normalise palliative care involvement alongside oncology intervention and to ensure proactive rather than reactive identification of patients with or at risk of unmet palliative care needs.(8,9)·The use of defined palliative care referral criteria has the potential to support standardized care pathways, reduce inequitable access and triage patients who are most likely to benefit.(7,10)

Several referral criteria or palliative care screening tools have been developed for use in oncology outpatient clinics (11–14) but none have been implemented widely in clinical practice. We have been using a locally developed set of criteria, the “Royal Marsden Triggers Tool” in the oncology outpatient setting since 2017.This seven-item checklist includes patient and disease-related factors which may indicate progressive disease and increased palliative care needs. (15,16)It was originally devised through literature review and expert consensus.(17) In retrospective evaluations, this tool has been shown to appropriately identify patients who may have benefited from palliative care before inpatient hospital death. A similar set of 11 major palliative care referral criteria were identified through a Delphi process by a panel of international palliative care experts.(18) Although these “Delphi Study Criteria” criteria have not been validated, in a retrospective study, this approachhas been shown to appropriately identify patients who were referred to a supportive care clinic. (19)

The aims of this study were to 1) evaluate the sensitivity of the “Royal Marsden Triggers tool” in identifying patients with palliative care needs in an outpatient oncology setting, 2) explore the acceptability of the “Royal Marsden Triggers tool” to oncology staff and 3) to examine the staff and patient experience of the early palliative care service based on the use of the “Royal Marsden Triggers tool” tool. To add context to this study, we also included descriptive metrics to evaluate the operationalization of the “Delphi Study Criteria” as a secondary outcome in the study.

Methods

Study design and participants:

This was a two-phase convergent parallel mixed methods study in which quantitative and qualitative data were equally prioritized, collected independently and analysed separately prior to integration and interpretation.(20) Phase one quantitative cross-sectional data were collected at a single time point. Phase two involved qualitative in-depth interviews with patients and oncology health care professionals. Reporting followed GRAMMS criteria for mixed-methods studies.(21)

Participants to this study were recruited from a single tertiary referral cancer center situated across two sites in a large metropolitan setting.

Eligibility for Quantitative Phase 1: Adults attending an oncology clinic with a primary diagnosis of lung or upper gastro-intestinal (UGI) cancers, or sarcoma, who had not been seen by a palliative care service within the previous three months.

Eligibility for Qualitative Phase 2: Oncology healthcare professionals (doctors and nurses) working in the lung, UGI or sarcoma clinics where the “Royal Marsden Triggers Tool” was used in clinical practice. Patients who were attending these oncology clinics and who met at least one of the “Royal Marsden Triggers Tool” palliative care referral criteria were invited to participate in semi-structured interviews.

Patients with communication / language needs were offered the use of interpreters, with the IPOS translated into other languages (where available and validated). However inclusion in the in-depth interviews was limited by patients’ fluency in English.

Outcome Measurements and Data Collection

Quantitative Phase 1:

Demographic data were collected from the electronic hospital medical record including clinical and patient specific data, age, gender, co-morbidities, tumour diagnosis, and presence of metastases. Date of death was also recorded for those who had died within the time-period between recruitment and 12 months after the last participant was recruited.

Study Measures completed by the oncology clinical team based on their usual oncology clinic review included:

- Performance status (ECOG (Eastern Co-operative Oncology Group) and Australia-modified Karnofsky Performance status (AKPS)
- The “Royal Marsden Triggers Tool” (15,16) (Table 2).
- The “Delphi Study Criteria”(18) (Table 2).

Staff recorded which criteria on each tool were met during that clinic visit.

Patient participants completed:

- Integrated Palliative Outcome Scale (IPOS): a validated holistic needs assessment tool used widely in clinical practice to determine patients' palliative care needs and priorities of care which are scored using a Likert scale 0-4 with numerical and descriptive response anchors. (22)

- EORTC-QLQ-C30 quality of life measures: a 30-item validated questionnaire developed to assess the quality of life of cancer patients.(23)

Qualitative Phase 2:

The qualitative semi-structured interviews were carried out by a researcher trained in this approach (LK), face to face or over the phone, as per participant preference / relevant social distancing guidelines. An interview topic guide (Supplementary tables 1 and 2) was developed with public and patient involvement (see section at end of manuscript) based on available literature and revised as the study progressed to allow exploration of new and emerging themes.

Staff participants were interviewed about their experience of using the "Royal Marsden Triggers tool" and the palliative care service embedded within the oncology clinic based on the tool.

Patient participants were interviewed about their views and experience of the embedded palliative care service in the oncology clinics where the "Royal Marsden Triggers Tool" was used.

Data analysis and sample size

Quantitative Phase 1:

The demographics of the total study population were described. Patient participants were categorized into cohorts according to whether they met the criteria for palliative care referral. Participants who scored positive on any item on the "Royal Marsden Triggers Tool" or "Delphi Study Criteria" were defined as being "Royal Marsden Triggers Tool positive" or "Delphi Study Criteria positive". Patients scoring positive and negative using each of the tools were compared in terms of demographic data, performance status; palliative care needs (IPOS) and quality of life indicators (EORTC-QLQ-C30).

Descriptive analysis methods were used to summarize the study data including mean/median and standard deviation / interquartile range for continuous data and frequency with percentages for categorical data. Data were compared between referral tool positive and negative cohorts using t-test / Mann-Whitney and Chi-square / Fishers exact test as appropriate. Data from participants who were still alive when the death data were collected (12 months after last participant recruited) were censored at this date. Survival time (between recruitment and death) was compared between cohorts using the log-rank test method.

Missing IPOS data items were excluded from IPOS item analysis of palliative care needs. All study participants with both clinician assessment using the “Royal Marsden Triggers Tool” and completed IPOS study questionnaire were included in the primary endpoint analysis of the sensitivity of the “Royal Marsden Triggers tool” in identifying cancer patients with palliative care needs. In this study, in the absence of validated method of how to define a patient with palliative care needs, the predetermined reference standard for patients with palliative care needs was defined as an IPOS score of 2 (moderate), 3 (severe) or 4 (overwhelming/always) on any item. (24) Binary tables were devised to calculate the sensitivity, specificity, positive and negative predictive values, and overall accuracy of the “Royal Marsden Triggers Tool”.

The proportion of participants scoring 3 or 4 on each IPOS item was calculated to define those with “severe” or “overwhelming” needs.

To observe a target “Royal Marsden Triggers Tool” sensitivity of 80% (alternative hypothesis H_a) from an unacceptable 60% (null hypothesis H_0) sensitivity, based on two-sided 5% alpha and 80% power, and an estimated prevalence of palliative care needs ranging from 40% to 90%, a minimum of 112 patients were required from each tumour group, with a total estimated minimum required sample size of 336 (Supplementary Table 3)(25).

Secondary objectives included evaluation of how the “Delphi Study Criteria” performed in clinical practice in terms of identifying patients with palliative care needs and association of both the referral tools with measures of quality-of-life (EORTC-QLQ-C30). This study was not designed or powered for direct comparative analyses between the “Royal Marsden Triggers Tool” and “Delphi Study Criteria”.

The EORTC-QLQ-C30 functional and Global Health Status Scales were calculated and described according to the scoring manual using mean and standard deviation and median and interquartile range.(26)

Qualitative Phase 2:

A purposive, theoretical sampling technique was adopted, ensuring that not only a range of ages/tumour variations/gender/clinical experience and professions were reflected but could also test emerging theory and sample accordingly until reaching data saturation.

In keeping with a modified Grounded Theory approach,(27) data collection and analysis occurred simultaneously. Digitally recorded and verbatim interview transcripts were analysed alongside original recordings and coded independently by 2 researchers (LK and AMS). Coding followed an iterative open, axial, selective coding structure, with constant comparative technique. Deeper analyses of the interview data and the development and refinement of the codes into themes and subthemes were discussed in regular study management group meetings (LK, AMS and JD with input from TW, MP, and NP) and were tested in an iterative process in subsequent interviews. Data saturation was reached when no new themes were generated.

After both the quantitative and qualitative data were analysed separately, the findings were triangulated during interpretation of the overall study findings. The data were examined together to identify areas of agreement (convergence), dissonance (contradiction) and complementarity. (28)

Results

Quantitative Phase 1:

A total of 578 patients were screened between 3rd December 2018 and 20th August 2020, of whom, 436 patients were eligible and invited to participate in the study. Of these 348 patients were recruited.

Participant characteristics

The clinical characteristics and demographics for the study cohort are presented in Table 1. The mean age was 66 years, and 98% (341/348) patients had an ECOG performance status between 0 and 2, reflecting their ability for self-care. 81% (282/348) patients had metastatic disease and 59% (205/348) had one or more comorbidities.

There was no difference between “Royal Marsden Triggers Tool” positive and negative cohorts in terms of age, comorbidities, or performance status. A higher proportion of “Royal Marsden Triggers Tool” positive participants had metastatic disease compared with negative participants (89.1% versus 72.1%, $p< 0.0001$). The results were similar when the “Delphi Study Criteria” positive and negative cohorts were compared.

Patients who scored positive on either the “Royal Marsden Triggers Tool” or the “Delphi Study Criteria” had a lower median survival (log rank <0.001).

Table 1 Demographics, clinical characteristics, and death data

		"Royal Marsden Triggers Tool"		"Delphi Study Criteria"	
	Total study population N=348	Trigger negative N=165	Trigger positive N=183	Delphi negative N=215	Delphi positive N=133
Age (years), Mean (Standard Deviation)	66.0 (11.4)	66.9 (10.7)	65.2 (12.0)	66.3 (11.4)	65.6 (11.6)
First oncology clinic to recruitment (months), Median (Range)	1.7 (0-170.3)	1.4 (0-153.7)	1.97 (0-170.3)	1.6(0-153.7)	1.7 (0-170.3)
Diagnosis to recruitment[¥] (Months), Median (Range)	11.4 (0.07-443.2)	5.5 (0.07-443.2)***	16.5 (0.07-201.9)***	11.3 (0.07-179.9)	11.5 (0.07-443.2)
Comorbidities N(%)	205 (59)	102 (61.8)	103 (56.3)	126 (58.6)	79 (59.4)
WHO Performance Status[¥¥] 0,1,2 N(%)	341 (98)	163 (99)	178 (97)	214 (99.6)	127 (95.5)
Australian Karnofsky Performance Status ≥ 70 N(%)	341 (98)	164 (99.4)	177 (96.7)	214 (99.5)	127 (95.5)
Presence of metastases N(%)	282 (81)	119 (72.1)***	163 (89.1)***	164 (76.3)*	118 (88.7)*
Median survival months (95% CI)	17.1 (16-18.7)	20.8 (18.9-NR)**	11.7 (9.7-15.6)**	20.5 (17.9-NR)**	10.4 (8.8-13.8)**

[¥] As a tertiary referral cancer centre, many patients are diagnosed elsewhere before starting treatment at the centre

[¥¥] No patients had a ECOG Performance status of 0

*p<0.01

**p<0.001

*** p<0.0001

NR not reached (median survival)

The “Royal Marsden Triggers Tool” and “Delphi Study Criteria”

52.6% (183/348) and 38.2% (133/348) of the total study participants met at least one of the referral criteria according to the “Royal Marsden Triggers Tool” and “Delphi Study Criteria” respectively (Table 2).

Table 2 Palliative Care referral criteria

	Total N(%) N=348
“Royal Marsden Triggers Tool”	
Metastatic cancer progressing after first line treatment	115 (33)
Performance status ECOG 2 and deteriorating	32 (9.2)
Acute oncology or unplanned admission	17 (4.9)
Severe or overwhelming symptoms	29 (8.3)
Anorexia, hypercalcaemia or any effusion	39 (11.2)
Moderate or severe psychological or existential distress	20 (5.7)
Complex social issues	15 (4.3)
Royal Marsden Triggers Tool Positive for at least 1 item	**183 (53)**
“Delphi Study Criteria”	
Severe physical symptoms	35 (10.1)
Severe emotional symptoms	13 (3.7)
Request for hastened death	0
Spiritual or existential crisis	1 (0.3)
Assistance with decision making/care plan	4 (1.1)
Patient request	2 (0.6)
Delirium	0
Brain/leptomeningeal metastases	14 (4)
Spinal cord compression/cauda equina	2 (0.6)
≤ 3 months diagnosis of advanced/incurable cancer with median survival ≤ 1 year.	57 (16.4)

Diagnosis of advanced cancer with progressive disease despite 2nd line systemic therapy (incurable)	43 (12.4)
Delphi Study Criteria positive for at least 1 item	**133 (38.2)**

Palliative Care Needs of study population

Of the 348 patients recruited to the study, 9 patients did not complete the IPOS assessment. Of the remaining 339 patients, 0.3% of IPOS data were missing.

91% (308/339) total participants scored 2 (moderate), 3 (severe) or 4 (overwhelming/always) on at least one IPOS item. There was no difference between "Royal Marsden Triggers tool" positive and negative patients (91% and 90% respectively). The sensitivity of the "Royal Marsden Triggers tool", i.e., the ability to correctly identify patients with palliative care needs *as defined in this way* was 54% (95% CI 48-61%). The sensitivity of the "Delphi Study Criteria" to identify patients with at least one IPOS item of 2,3 or 4 in severity was 42% (95% CI 36-47%). (Supplementary Table 4).

Many participants (76.1% (258/339)) had at least one IPOS item which scored either 3 (severe) or 4 (overwhelming / always), (Table 3). A higher proportion of patients who were positive for the "Royal Marsden Triggers tool" had at least one severe or overwhelming *physical* need (38% (69/182) versus 20% (32/157) for those who were negative, Chi^2 12.4, $p<0.001$, sensitivity 68% (95% CI 58-77%). A higher proportion of these had pain, shortness of breath, weakness/lack of energy, constipation, poor appetite, and poor mobility. "Royal Marsden Triggers Tool" positive participants had a lower quality of life on the EORTC QLQ-C30 Global Health Status scale than those who were negative ($P<0.01$). They also had lower levels of physical, role and social functioning. A similar pattern of difference was seen with the "Delphi Study Criteria". (Table 3).

Table 3: Patient Reported Concerns and Issues using IPOS and EORTC QLQ-C30¥ scores					
	Total (N=339), **N (%)**	"Royal Marsden Triggers Tool" negative (N=157), **N (%)**	"Royal Marsden Triggers Tool" positive (N=182), **N (%)**	"Delphi Study Criteria" negative (N=206), **N (%)**	"Delphi Study Criteria" positive (N=133), **N (%)**
IPOS scores of 3 or 4 in severity					
Physical symptoms					
Pain	26 (7.7)	6 (3.8)*	20 (11)*	8 (3.9)**	18 (13.5)**
Shortness of Breath	21 (6.2)	3 (1.9)*	18 (9.9)*	7 (3.4)**	14 (10.5)**
Weakness / Lack of energy	38 (11.3)	10 (6.5)**	28 (15.5)**	15 (7.4)**	23 (17.4)**
Nausea	10 (2.9)	3 (1.9)	7 (3.8)	5 (2.4)	5 (3.8)
Vomiting	3 (0.9)	1 (0.6)	2 (1.1)	1 (0.5)	2 (1.5)
Poor Appetite	29 (8.6)	7 (4.5)*	22 (12.1)*	12 (5.8)*	17 (12.8)*
Constipation	23 (6.8)	6 (3.8)*	17 (9.3)*	8 (3.9)**	15 (11.3)**
Sore or Dry Mouth	15 (4.4)	4 (2.6)	11 (6)	5 (2.4)*	10 (7.5)*
Drowsiness	12 (3.6)	4 (2.6)	8 (4.4)	7 (3.4)	5 (3.8)
Poor Mobility	26 (7.7)	7 (4.5)*	19 (10.4)*	11 (5.4)*	15 (11.3)*
Emotional symptoms					
Patient anxiety	78 (23.1)	35 (22.3)	43 (23.8)	40 (19.4)	38 (28.8)
Family anxiety	132 (39.1)	64 (40.8)	68 (37.6)	72 (35)	60 (45.5)
Depression	28 (8.3)	12 (7.7)	16 (8.8)	14 (6.8)	14 (10.6)
Feeling at peace	71 (21.1)	37 (23.7)	34 (18.8)	48 (23.4)	23 (17.4)
Communication / practical issues					
Sharing feelings	112 (33.2)	51 (32.7)	61 (33.7)	60 (29.3)	52 (39.4)
Information	136 (40.2)	69 (43.9)	67 (37)	78 (37.9)	58 (43.9)

Practical problems	36 (10.7)	23 (14.6)*	13 (7.2)*	22 (10.7)	14 (10.6)
EOTRC QLQ-C30 scores					
Global health status / Quality of Life Mean (SD) 95% CI		67.2 (21.4)** (63.8 – 70.6)	60.3 (23.8)** (56.9 – 63.9)	67 (21.6)*** (64 – 69.9)	58.2 (24)*** (54.1 – 62.3)
Physical functioning Mean (SD) 95% CI		78.8 (17.7)*** (76 – 81.6)	69.8 (25.3)*** (66.1 – 73.5)	78.2 (20.1)*** (75.5 –81)	67.5 (24.6)*** (63.2 – 71.7)
Role functioning Mean (SD) 95% CI		75 (26.93)*** (70.7 – 79.2)	61.6 (31.90)*** (56.8 – 66.3)	75.1 (26.4)*** (71.5 –78.7)	56.8 (33)*** (51.1 – 62.5)
Emotional functioning Mean (SD) 95% CI		75.8 (21.15) (72.45 – 79.16)	74.4 (23.48) (71 – 77.9)	77 (21.3) (74.1 –80)	72.20 (23.9) (68.1 – 76.3)
Cognitive functioning Mean (SD) 95% CI		82.9 (19.11) (79.9 – 85.9)	78.9 (22.27) (75.7 – 82.2)	83.2 (18.4)** (80.6 –85.7)	77 (23.9)** (72.9 – 81.1)
Social functioning Mean (SD) 95% CI		77.5 (24.7)** (73.6 – 81.4)	68.2 (29.1)** (65 – 72.5)	78.2 (23.9)***	63.89 (30.5)*** (58.64 – 69.14)

				(45.88 – 81.43)	

* p<0.05

**p<0.01

***P<0.001

¥ A high score for the functional scales represents a high / healthy level of functioning and a high score for the global health status / Quality of Life scale represents a high quality of life.

Qualitative Phase 2:

25 staff and 255 patients were screened across the three oncology groups. 16 staff (consultants (n=8), oncology trainee doctors (n=2) and Clinical Nurse Specialists (n=6)) working in lung (n=9), UGI (n=5) and sarcoma (n=2) clinics and 19 patients (11 men, 8 women, 10 with lung cancer, 7 with UGI cancer and 2 with sarcoma) consented to participation in the interviews between December 2018 and May 2021 (Supplementary Table 5 Qualitative participant characteristics).

Healthcare professional data then patient/family data were analysed. We then undertook further constant comparative analysis to consider the data across both staff and patients. Nine themes were derived across three categories. These are drawn together in Table 5 with a selection of representative quotes.

Category 1. Staff Acceptability of the "Royal Marsden Triggers Tool": Oncology staff using the "Royal Marsden Triggers Tool" felt that it was more than a palliative care referral tool because it helped reduce bias about palliative care and opened up natural discussions about palliative care (theme 1). Limitations were identified: even with a tool, limited palliative care resources, especially in the community setting, means that not every patient would be able to access palliative care services (theme 2).

Category 2. Staff experience of the palliative care service based on the "Royal Marsden Triggers Tool": For oncology staff, the use of the tool 1) normalized palliative care for both staff and patients (theme 3) and provided an opportunity to access immediate palliative care expertise in the form of communication, symptom control and practical solutions (theme 4). They acknowledged the importance of individualizing care according to the needs of the patients in terms of timing and input rather than having a blanket standardized approach (theme 5) and that there may be potential organizational barriers to palliative care service delivery in terms of resources available (theme 6).

Category 3: Patient experience of the palliative care service based on "Royal Marsden Triggers Tool": Patients described how the palliative care service based on the "Royal Marsden Triggers Tool" facilitated the integration of care between the oncology and palliative care teams which normalized palliative care (theme 7). Like the staff, patients also recognized the importance of an individualized approach in terms of the timing of their introduction to palliative care and information provision and care provision (theme 8). Patients also described their experience of how being seen by the palliative care service based on the "Royal Marsden Triggers Tool" resulted in a change in their preconceived ideas from palliative care being associated with death and dying to being more about support for living well (theme 9).

Triangulation of the quantitative and qualitative data is summarized in Figure 1. Agreement was demonstrated between the data sources about the multidimensional needs of patients and how a palliative care referral tool enables proactive identification of patients who might benefit from access to address these needs. All data sources supported the use of such a tool to enable early palliative care involvement and reinforced the idea that palliative care is not just for end-of-life care. There were no identified areas of dissonance. There was some overlap between the emerging themes from both patients and staff which were not evaluated in the quantitative data. These synergies centered on how perception of palliative care had shifted and how the tool enabled normalization of palliative care and supported communication and closer team working between the palliative care and oncology teams.

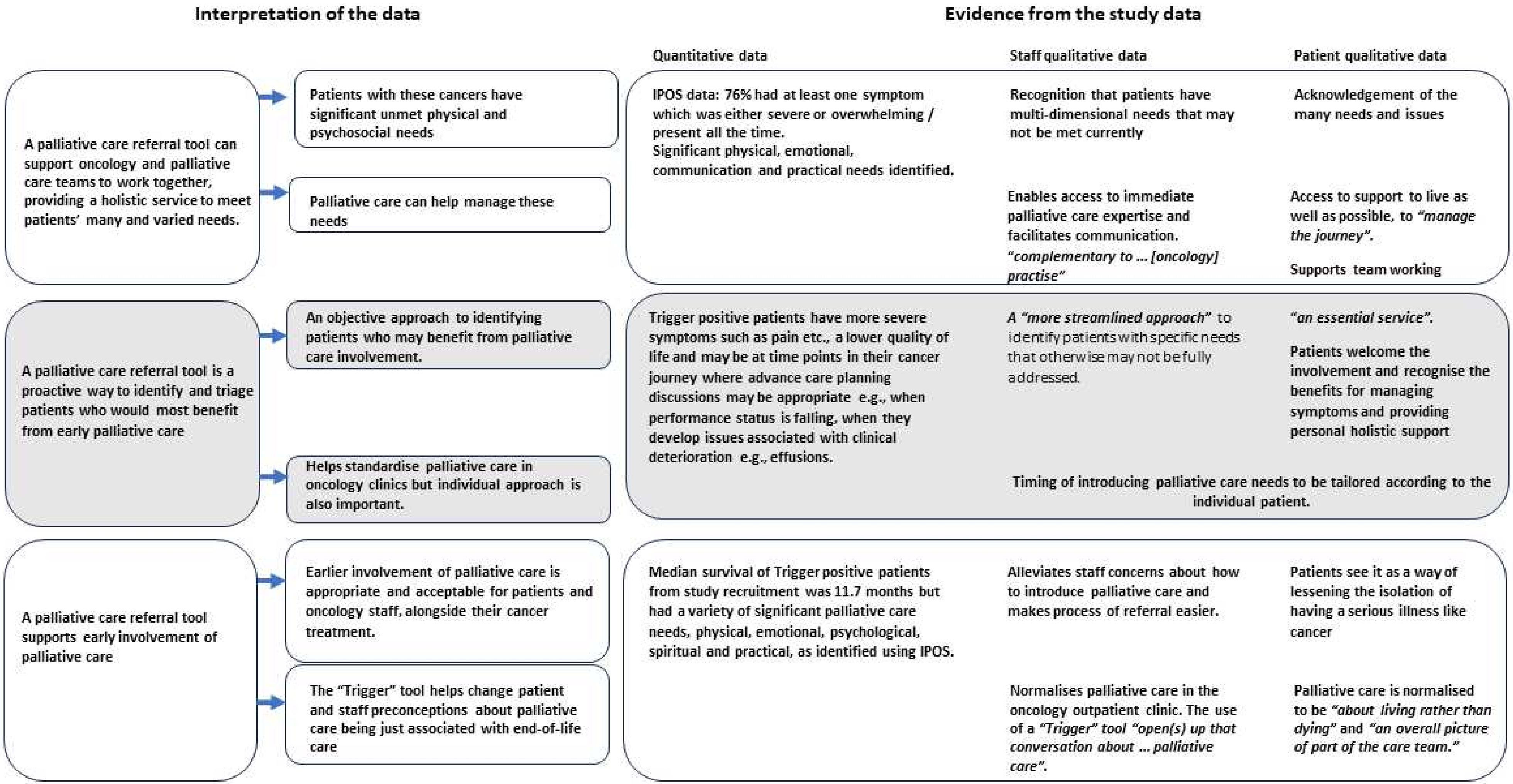
Table 5: Results of qualitative data analysis from patients and staff about the "Royal Marsden Triggers Tool": Themes, subthemes and illustrative quotes

Category	Themes	Quotes
Category 1. Staff Acceptability of the "Royal Marsden Triggers Tool"	**Theme 1: More than a tool….**	"It helps triage doesn't it… it helps triage and gives them a sort of an objective idea of what's going on… so I think they can be of value… because it helps to focus the mind on what the problems are." (TCI0005)
	Theme 2: Perceived limitations	"…availability of the palliative care service is probably a bigger, has a bigger influence than the Trigger tool itself because if we have just someone in clinic with a tool up on the wall and ticking okay do a palliative care referral, in some of those cases they will go off to the community teams and the community teams just won't have the capacity to usefully benefit them" (TSI0004)
Category 2. Staff experience of the palliative care service based on the "Royal Marsden Triggers Tool"	**Theme 3: Normalises palliative care for professionals**	"so with Triggers obviously in lung,… I think it has really opened up that conversation about, um, palliative care" (TCI0002)
	Theme 4: Access to immediate expertise…and more	"….it is a more streamlined approach to flag a patient who has a specific… symptom control needs, that may or may not be being fully met, and then… fast track them into a quick review process with… the expert team" (TCI0006) "….a lot of communication skills…that you can even help the patient explore… some difficulties that they are having either with family, either

		with social support… so definitely its complementary to our practise” (TCI0001) “it’s about symptom management and obviously trying to get people to live a great, as good a quality of life as possible with their symptoms…advance care planning…. end of life, supporting home, hospice, other options” (TSI0005)
	Theme 5: Supporting individualised needs	“…it may not be right for everyone to do it at (the) first meeting but then it is right for a large amount of patients and there is not going to be a right time for everyone….” (TCI0004) ….so there’s a group that should have first contact and then they know that there is somebody there and then there’s a group that probably need a bit more active engagement…” (TSI0001)
	Theme 6: Perceived organisational barriers	“….I think the tricky bit about clinics….the clinic room is quite small….so there’s often a lot of people then, in and out of clinic.” (TCI0003) “the problem is there ain’t enough of you for this hospital so we need more.” (TCI0005)
Category 3: Patient experience of the palliative care service based on “Royal Marsden Triggers Tool”.	**Theme 1:** **Integrating care between Oncology and Palliative Care**	“one of the things I see in the hospital is that it’s not a different department, all of you are a team. All of you are a team, the doctors, the nurses, the palliative care, everybody work together. All of you work together. And it’s about the patient, it’s not about getting the best part

		of the department or anything like that, no its about the patients" (TCIP010) "the cancer it is isolating and having someone that understands, er, the journey, er, and has the compassion … I'm sure (Triggers CNS) deals with many, many patients but whenever she actually sees me or actually sees me in the corridor, er, she actually remembers me as well and she actually remembers my name…. I felt that I wasn't being treated as like a patient, but I was treated as a person like a friend" (TCIP009) "the more that palliative care is integrated into oncology and other hospital fields the more normalised it is… it's about living rather than dying and I think the more integrated it is the less shock you have for the family that are going through a hard time….
	Theme 2: Individualising needs	"so it's a good, er, way to navigate through how, er, cancer affects you as a person, and it's not just from a clinical point of view, I think it's very useful to have some things like how does it affect you spiritually, physically, mentally er, which you don't really touch upon with your clinical team." (TCIP009)
	Theme 3: Perception and understanding of Integrated Palliative Care Service	"it's not just about end of life and it's all about managing the journey actually. I think that's what needs to be communicated better is the management of the journey and quality of life and actually define quality of life as well" (TCIP009) "I do feel it's changed because the words then, I can remember my mum completely panicking and all of us panicking when they said palliative

		care. But I don't really panic anymore like when you say that because I see it as just an overall picture of part of the care team now." (TSIP006) "I would have to say the palliative care service in my mind it's a large umbrella that, er, covers, er, the other small, the other sort of clinical things that we deal with. It's a very good way of ensuring that you are giving yourself the best chance of survival, er, from all aspects, not just physically." (TCIP009)



Interpretation of the data		Evidence from the study data		
		Quantitative data	Staff qualitative data	Patient qualitative data
A palliative care referral tool can support oncology and palliative care teams to work together, providing a holistic service to meet patients' many and varied needs.	Patients with these cancers have significant unmet physical and psychosocial needs	IPOS data: 76% had at least one symptom which was either severe or overwhelming / present all the time. Significant physical, emotional, communication and practical needs identified.	Recognition that patients have multi-dimensional needs that may not be met currently	Acknowledgement of the many needs and issues
	Palliative care can help manage these needs		Enables access to immediate palliative care expertise and facilitates communication. *"complementary to ... [oncology] practise"*	Access to support to live as well as possible, to *"manage the journey"*. Supports team working
A palliative care referral tool is a proactive way to identify and triage patients who would most benefit from early palliative care	An objective approach to identifying patients who may benefit from palliative care involvement.	Trigger positive patients have more severe symptoms such as pain etc., a lower quality of life and may be at time points in their cancer journey where advance care planning discussions may be appropriate e.g., when performance status is falling, when they develop issues associated with clinical deterioration e.g., effusions.	A *"more streamlined approach"* to identify patients with specific needs that otherwise may not be fully addressed.	*"an essential service"*. Patients welcome the involvement and recognise the benefits for managing symptoms and providing personal holistic support
	Helps standardise palliative care in oncology clinics but individual approach is also important.		Timing of introducing palliative care needs to be tailored according to the individual patient.	
A palliative care referral tool supports early involvement of palliative care	Earlier involvement of palliative care is appropriate and acceptable for patients and oncology staff, alongside their cancer treatment.	Median survival of Trigger positive patients from study recruitment was 11.7 months but had a variety of significant palliative care needs, physical, emotional, psychological, spiritual and practical, as identified using IPOS.	Alleviates staff concerns about how to introduce palliative care and makes process of referral easier.	Patients see it as a way of lessening the isolation of having a serious illness like cancer
	The "Trigger" tool helps change patient and staff preconceptions about palliative care being just associated with end-of-life care		Normalises palliative care in the oncology outpatient clinic. The use of a *"Trigger" tool "open(s) up that conversation about ... palliative care"*.	Palliative care is normalised to be *"about living rather than dying"* and *"an overall picture of part of the care team."*

Figure 1: Triangulation of data evaluating the use, acceptability, and experience of the "Royal Marsden palliative care referral Triggers tool" in an outpatient oncology setting (direct quotations presented in italics)

Discussion

Data from this study demonstrates how the use of standardized palliative care referral criteria can underpin proactive early palliative care provision(7) and how this approach can support integration of palliative care within oncology outpatient clinics. The use of a "Trigger" tool helps triage those who would benefit most and normalises palliative care for patients who are living with, rather than dying from, cancer. The median survival of patients who were positive for the "Royal Marsden Triggers Tool" was 11 months and all were receiving anticancer treatment. Patients and staff identified that opportunities for palliative care for these outpatients was not confined to end of life care but more about proactive involvement to support them alongside cancer treatment.

The use of a palliative care referral tool supported oncology and palliative care teams to work together, providing a service that was "*about the patients*". Oncology patients have significant unmet needs and early, timely, team-based palliative care can help manage these needs.(29) This was recognised by the staff and patients themselves and also recorded through the objective lens of patient reported outcome measure, IPOS. These data demonstrate the multidimensional care needs of cancer outpatients and support the requirements for a team-based multidisciplinary approach (30) to provide holistic "umbrella" support (31) alongside oncology treatment.

(29)(33)(1,2)(33)
In this study we present how palliative care referral criteria may form part of a standardized care pathway to underpin the organization and delivery of integrated working between oncology and palliative care (7) regardless of stage of cancer, prognosis or aim of treatment. Delivery of a service based on standardized referral "Triggers" breaks down some of the motivational, capability and opportunity-related barriers to providing integrated palliative care, including time, space, resource availability and access. (32)
The use of palliative care referral criteria is an alternative and pragmatic approach to the traditional oncologist-driven referral to palliative care, the latter of which may be influenced by personal bias, time, resources, and experience. "Automatic" referral triggers are used to "augment" clinician-based referral rather than being used in isolation.(33) This was reflected in our staff and patient interview data in which the importance of tailoring the involvement of the palliative care team and timing of involvement according to individual patients' needs was highlighted.

Normalization is a key component of successful implementation of complex interventions.(34) Both patients and staff acknowledged the joined up working in the clinics supported by the "Royal Marsden Triggers Tool" and how this approach "normalized" and "opened up" the discussion about palliative care being part of the standard care offered to cancer patients. Patients described how their understanding and perceptions of palliative care changed because of their experience with the palliative care service based on the "Royal Marsden Triggers Tool". They understood palliative care to be "*about living rather than dying*" and being "*an overall picture of part of the care team*". Clear explanation of the role of the palliative care team was regarded as important to normalize involvement, a finding which has mirrors other work in this area.(35)

Using the study definition of palliative care needs, the sensitivity data of both tools suggest that this was a negative study. This is likely to be due to a methodological challenge in the design of this study. There is no validated reference standard to define patients with palliative care needs or patients who would benefit from specialist palliative care.(36,37) In our study we found that 91% of all study participants were experiencing at least one issue that was of at least moderate severity. Referral based on these criteria would overwhelm most specialist palliative care services and suggest that our original study definition of a patient with palliative care needs was, in retrospect, too broad. This impacted negatively on the sensitivity analysis, as originally defined. Prioritizing palliative care referral for those patients with more severe needs may be more efficient, for example IPOS items scoring 3 or 4 (severe or overwhelming) as being indicative of requiring higher attention. (38) In our study both tools identified patients with significant severe or overwhelming physical needs or lower quality of life and functioning, who would benefit from immediate intervention, for example, symptom control. An alternative approach may be to specify severity thresholds depending on the symptom itself, prioritizing those for whom specialist palliative care interventions may be more effective. (39)

Not all cancer patients need specialist palliative care at all stages in their illness. (30) Our data show that a palliative care referral tool is an acceptable way of identifying and triaging patients who would most benefit from early palliative care. This study was not designed to directly compare the "Royal Marsden Triggers Tool" and the "Delphi Study Criteria" but in terms of structure and analytical metrics, our data suggest that both tools are similar. The "Royal Marsden Triggers Tool" and the "Delphi Study Criteria" include needs-based criteria relating to significant distress (physical and psychological). Both also include other criteria which are potential markers of a change or deterioration in health status, the beginning of progressive disease and/or functional decline. (40) Involvement of palliative care at times of change in cancer treatment or trajectory has been recently studied within a randomized controlled trial.(41) In our study, by incorporating these other multidimensional markers of palliative care complexity(37) both tools identified patients who may have an uncertain outcome or who are at a significant junction in their illness. These patients who would benefit from palliative care input, even if they don't have immediate physical needs. The benefits of early patient-centered palliative care interventions for this group of patients include future care planning, support for communication and treatment decision making, crisis prevention through proactive identification of problems (rather than reacting only when patients present with severe problems) (1,2) and developing skills to cope with serious illness. (42)

This study demonstrates the acceptability and usefulness of standardized criteria as an approach to targeted palliative care referrals. In clinical practice, the criteria included in a referral tool may need to be locally adapted.(18) The successful implementation and integration of any such tool will be influenced by data collection and communication processes, available resources including staffing and cultural acceptability. More evidence is needed about the best timing and mode of assessment, as well as thresholds for specialist palliative care referral. Routine symptom screening and the use of patient reported outcome measures is being explored as the basis for targeted referrals. (39,41) A better understanding of how to define the complexity of palliative care needs may also be beneficial.(37)

A strength of this study is that a convergent mixed-method approach was adopted with qualitative and quantitative data being used to answer different types of questions. Given the issues with the planned sensitivity analyses, the qualitative data is likely the most important aspect of the study. Triangulation enabled the contextualisation of the findings of both data sources to provide evidence to support the use of a palliative care referral tool to underpin integration of early palliative care as an acceptable and welcome part of the standard oncology service for patients undergoing cancer treatment.

Limitations of this study:

This is a single timepoint, single centre study based in an urban tertiary referral cancer centre with only English-speaking patients included in the interviews. Therefore the findings may not be fully generalizable to other settings, patient cohorts or tumor groups. However, the proportion of "Royal Marsden Triggers Tool" or "Delphi Study Criteria" positive patients was similar to proportions of patients identified for palliative care referral using screening tools in other studies.(14,38,43,44) The staff in our study appreciated the availability of immediate access to specialist palliative care expertise which is facilitated through the geographical proximity of the embedded service but acknowledged the resource and logistical implications associated with proactive identification of patients for referral including issues with space and capacity.(10,43)

Conclusion:

Our data support the use of a palliative care referral tool, in association with usual oncology services, to facilitate streamlined and equitable access to timely palliative care. Additional longitudinal research is needed to evaluate the effectiveness and feasibility of this approach in the delivery of a sustainable integrated service providing patient-centered care. In the absence of evidence to support the use of one tool rather than another, referral criteria may need to be adapted and tailored according to the local patient population, healthcare environment and available health care resources.

Statements and Declarations:

Funding:

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Competing Interests:

The authors have no relevant financial or non-financial interests to disclose.

Ethics approval:

This study was performed in line with the principles of the Declaration of Helsinki. Ethical approval was granted by the London Harrow Research Ethics Committee (date 21st November 20018, REC reference 18/LO/1373).

Consent to participate:

Written informed consent was obtained from all individual participants in the study.

Patient and Public Involvement:

This study was co-produced with input from patients and members of the public.

The study was reviewed by over 30 members of The Royal Marsden Patient and Carer Research Review Panel three times (January and July 2017, October 2019). The Patient and Carer Research Review Panel is a rigorous PPI platform where there is extensive discussion (and transcription of those discussions for subsequent action) and shaping of design. The Triggers project was presented at the ideas stage, where PPI members shaped the project, as described by the addition of the qualitative element. The project was well received, with lengthy discussion and unanimous agreement about the aims of the project; panel members provided feedback and suggestions, which were incorporated into the design. A member of the panel (MP) was involved in the protocol development and submission for REC approval, study design and delivery, qualitative data analysis, review and interpretation of the results and drafting of the manuscript.

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Supplementary Table 1 - CCR4930 Triggers Study Patient Interview schedule

Theme	**General questions**	**Prompt items**
Introduction	• Introduce • Research • Consent	• Introduce self • Explain: confidentiality, length of interview, nature of discussion • Any questions • Obtain consent • Start recording
This study is about understanding the perceptions, expectations and experiences about integration of palliative care in oncology care, and specifically the Integrated Symptom Control and Palliative Care service we offer early on in oncology clinics, alongside your active treatment. This will also explore any needs we may be able to identify. I would like to understand what your experience has been and what kinds of things have been helpful to you and what kinds of things you might have wanted or needed but did not receive.		
Background to diagnosis	• Please can you tell me about your experience of cancer and your treatment • How old are you?	• What type of cancer do you have? • When were you diagnosed? • What treatment have you received? • Are you currently receiving treatment?
Background	• Please can you tell me about your referral to the ISCPC?	• How was the ISCPC service introduced to you? • How was palliative care explained to you? • Were you given any written information? • How did you feel about completing the questionnaires in the assessment? Did they help?
Perceptions	• What did you think when you were offered a referral to ISCPC service?	• How did you feel? • What did you think palliative care was? • What services did you think the ISCPC service could provide? • How did you think ISCPC service would fit with the care you were receiving at the time?
Experience	• I can see that you met with Jone/Lorraine/Julie in clinic. Can you tell me about your experience of meeting with the ISCPC?	• How do you feel about the timing of meeting the ISCPC service in clinic? • How much contact have you had with the ISCPC nurse? F2F?Phone? • What input were you provided with? • What affect has the ISCPC team had on the care you have received?

		• How has the ISCPC service affected the management of your cancer, symptoms and your overall wellbeing
Information needs	• What are your views on information provision about palliative care?	• Is there enough information available about palliative care? • What information do you think patients need to know before being offered a referral or at the time of referral? • How should this information be delivered? • When is the best time to introduce palliative care?
Reflections on palliative care	• Have your views of palliative care changed since you had contact with the service?	• How do you feel about palliative care now you have experienced it? • How would you describe palliative care now you have experienced it? • Are there any advantages or disadvantages of being referred? • Do you think you were referred to the ISCPC service at the right time?
Closing	• Do you have anything else you would like to say? • Thank you for your participation	

<table>
<tr><th colspan="3">Supplementary Table 2 - CCR4930 Triggers Study Healthcare Professional Interview schedule</th></tr>
<tr><th>Theme</th><th>General questions</th><th>Prompt items</th></tr>
<tr><td>Introduction</td><td>• Introduce
• Research
• Consent</td><td>• Introduce self
• Explain: confidentiality, length of interview, nature of discussion
• Any questions
• Obtain consent
• Start recording</td></tr>
<tr><td colspan="3">This study is about understanding the perceptions, expectations and experiences about integration of palliative care in oncology care, and specifically the Integrated Symptom Control and Palliative Care or the Triggers service we offer early on in oncology clinics, alongside patients' active treatment. This will also explore any needs we may be able to identify. I would like you to understand what your experience has been and what kinds of things have been helpful to you and what kinds of things you might have wanted or needed but did not receive.</td></tr>
<tr><td>Background</td><td>First of all, we would like to collect some information about you.</td><td>• What is your role
• How long have you been working in Oncology</td></tr>
<tr><td>Experience of palliative care needs</td><td>• I would like to get more insight about the palliative care needs of patients with cancer. Could you tell me what you see in your practice?</td><td>• What are the most frequently reported symptoms in patients with cancer?
• Do you encounter any difficulties when assessing palliative care needs for your patients?
• What are those difficulties?</td></tr>
<tr><td>Perceptions</td><td>• What do you understand by the term 'palliative care'?</td><td>• How do you feel about palliative care?
• How did you feel about patients meeting the Triggers/Palliative Care team?
• How do you feel about a referral tool for Palliative Care?</td></tr>
<tr><td>Expectations/Preferences</td><td>• What are your expectations from the ISCPC/ triggers service in oncology care?
• What are your preferences for the ISCPC/ Triggers service in oncology care?</td><td>• Do you feel like your patients need palliative care?
• Do you feel that your patients would benefit from early palliative care?
• What do you think the ISCPC service should look like?</td></tr>
</table>

Experiences	• How do you feel about the timing of the patients meeting the ISCPC in clinic? • How did you feel about completing the tools that are part of the study (RMH Triggers and Delphi)? • How did you feel about the patients meeting the ISCPC team? • What do you think your patients' experience is of meeting with the ISCPC team?	• Was there anything good or bad about the Palliative care experience? • Do you think there is anything else we should be doing to improve our integrated palliative care service? • What has your overall experience been with your patients receiving palliative care in general, for their cancer? • Did you notice any benefit from them getting early palliative care?
Closing	• We have discussed a number of things. These are… • Thank you for your help.	• Summarise the issues raised during the interview and identify which issues are the most important. • Out of everything we have talked about today, what would you see as the key priorities for this service going forward? • Is there anything else about early palliative care you would like to add?

Supplementary Table 3 Sample size calculation

The target sample size (N=336) was sufficient for analyses to be stratified according to cancer diagnosis(N=112), as well as analyzing the study population as a whole.

Prevalence	Sensitivity		Power	p-value	Minimum number of sample size for positive palliative care needs	Minimum number of sample size for total study cohort
	H_0	H_a				
40%	60%	80%	0.826	0.034	45	112
50%	60%	80%	0.826	0.034	45	90
60%	60%	80%	0.826	0.034	45	75
70%	60%	80%	0.826	0.034	45	64
80%	60%	80%	0.826	0.034	45	56
90%	60%	80%	0.826	0.034	45	50
Adapted from Bujang M, Adnan T. Requirements for minimum sample size for sensitivity and specificity analysis. Journal of Clinical and Diagnostic Research 2016						

Supplementary Table 4a Sensitivity of “Royal Marsden Triggers Tool” for all participants (N=339)

		Number of patients with Study-defined Palliative Care Needs i.e., scoring 2,3 or 4 on any IPOS item			Test (95% CI)			
		No	Yes	Totals	**Sensitivity** The ability of the “Royal Marsden Triggers Tool” to correctly identify patients scoring ≥2 on at least 1 IPOS item	**Specificity** The ability of the “Royal Marsden Triggers Tool” to correctly identify people not scoring any IPOS item ≥2	**Positive Predictive Value** (True positive) The probability that the “Royal Marsden Triggers Tool” is positive when the patient has scored ≥2 on at least 1 IPOS item	**Negative Predictive Value** (True Negative) The probability that the “Royal Marsden Triggers Tool” is negative when the patient has not scored ≥2 on at least 1 IPOS item
“Royal Marsden Triggers Tool”	Positive	16	166	182	0.54 (0.48-0.6)	0.48 (0.31-0.67)	0.91 (0.86-0.95)	0.1 (0.06-0.16)
	Negative	15	142	157				
	Totals	31	308	339				

Supplementary Table 4b Sensitivity of "Delphi Study Criteria" for all participants (N=339)

		Number of patients with Study-defined Palliative Care Needs i.e., scoring 2,3 or 4 on any IPOS item			Test (95% CI)			
		No	Yes	Totals	**Sensitivity** The ability of the "Delphi Study Criteria" to correctly identify patients scoring ≥2 on at least 1 IPOS item	**Specificity** The ability of the "Delphi Study Criteria" to correctly identify people not scoring any IPOS item ≥2	**Positive Predictive Value** (True positive) The probability that the "Delphi Study Criteria"is positive when the patient has scored ≥2 on at least 1 IPOS item	**Negative Predictive Value** (True Negative) The probability that the "Delphi Study Criteria" is negative when the patient has not scored ≥2 on at least 1 IPOS item
"Delphi Study Criteria"	Positive	5	128	133	0.41 (0.36-0.47)	0.84 (0.66-0.94)	0.96 (0.91-0.99)	0.1 (0.09-0.18)
	Negative	26	180	206				
	Totals	31	308	339				

Supplementary Table 5 Qualitative Participant Characteristics	
Patients	N = 19
Age: M (Range)	64 (31 – 83)
Gender: N (%)	
Male	11 (58%)
Female	8 (42%)
Primary Cancer Diagnosis: N (%)	
Lung Cancer	10 (53%)
Upper GI Cancer	7 (37%)
Sarcoma	2 (10%)
Interview: N (%)	
Face to face	11 (58%)
Telephone	8 (42%)
Staff	N = 16
Gender: N (%)	
Male	4 (25%)
Female	12 (75%)
Professionals: N (%)	
Consultants	8 (50%)
Trainees	2 (12%)
Clinical Nurse Specialists	6 (38%)
Cancer Specialty: N (%)	
Lung Cancer	9 (56%)
Upper GI Cancer	5 (31%)
Sarcoma	2 (13%)