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To cite this article: Anne Miles , Ruth E. C. Evans & Stuart A. Taylor (2020): Predictors of distress among patients undergoing staging investigations for suspected colorectal and lung cancer, Psychology, Health & Medicine, DOI: [10.1080/13548506.2020.1852477](https://doi.org/10.1080/13548506.2020.1852477)

To link to this article: <https://doi.org/10.1080/13548506.2020.1852477>



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Published online: 24 Nov 2020.



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Predictors of distress among patients undergoing staging investigations for suspected colorectal and lung cancer

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ABSTRACT

People undergoing investigations for suspected cancer have to undergo a number of investigations before they know their full diagnosis and treatment plan. We examined predictors of distress among patients undergoing staging investigations for suspected colorectal or lung cancer. Patients were prospectively recruited to two multi-centre trials comparing WB-MRI with standard scans. Patients completed a questionnaire, administered at trial recruitment, measuring demographic and psychological variables ($n = 129$, 66 colorectal, 63 lung; median age 66.4, range: 31–89). Predictors of distress were analysed using logistic regression. Forty percent of patients reported high distress (a score of 4 or higher on the GHQ-12). Higher deprivation and greater intolerance of uncertainty (IU) predicted high distress in both unadjusted (low deprivation: OR 0.352, 95% CIs 0.144 to 0.860, $p = 0.022$; IU: OR 1.972, 95% CIs: 1.357 to 2.865, $p < 0.001$) and adjusted analyses (low deprivation: OR 0.243, 95% CIs 0.083 to 0.714, $p = 0.010$; IU: OR 2.231, 95% CIs 1.429 to 3.485, $p < 0.001$). Age, gender, presence of comorbid illness, cancer type, probable knowledge of cancer diagnosis, and a final diagnosis of cancer did not predict high distress. Future research should examine how to reduce distress in patients undergoing investigations for cancer, particularly among those who find uncertainty difficult to manage.

ARTICLE HISTORY

Received 10 March 2020
Accepted 11 November 2020

KEYWORDS

Cancer; diagnosis; distress; diagnostic tests; uncertainty

Introduction

Considerable research has examined the psychological impact of having a confirmed diagnosis of cancer (Abbey et al., 2015; Dunn et al., 2013; Mitchell et al., 2013), but relatively little has looked at distress during the diagnostic phase. People undergoing investigations for suspected cancer face the threat of serious illness while having to undergo a number of investigations before they know their full diagnosis and treatment plan. Cancer diagnostic and staging scans often require injections, some involving radioactive ligand (e.g. PET-CT) which may promote fears about radiation risk; while others, such as MRI, are noisy and require full body immersion into a relatively narrow tube, causing anxiety and claustrophobia in a substantial proportion of patients (Katz et al., 1994; Melendez & McCrank, 1993). While a high level of distress is of concern in its own right, it is also a predictor of patients' perceived 'burden' whilst undergoing

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investigative tests such as WB-MRI (Evans et al., 2018), exacerbating the challenges patients face during the diagnostic phase.

In their review, Brocken et al. (2012) reported that between 33% and 60% of patients undergoing investigations for cancer reported anxiety prior to diagnosis at levels which reach the clinical threshold. However, the majority of studies included patients with suspected breast cancer. Lung and colorectal cancer are the first and third most common cancers worldwide (Bray et al., 2018) yet Brocken et al.'s review included only one study on anxiety in patients with suspected lung malignancy and none on patients with suspected colorectal cancer (Brocken et al., 2012). Indeed there is evidence that distress may vary by cancer site, as higher rates of distress have been reported among people with lung cancer than other cancer sites (Zabora et al., 2001) and it is possible that similar disparities may be observed in the diagnostic phase.

Research into predictors of distress in the diagnostic phase is also scant, although studies on anxiety or depression post-diagnosis suggest certain sectors of the population may be more vulnerable; for example, people with a family or personal history of psychiatric disorder, people with low socio-economic status, women, and those of a younger age (Cardoso et al., 2016; Moseholm et al., 2016; Strong et al., 2007; Walker et al., 2014). Intolerance of uncertainty (IU), defined by Dugas et al. (2001) as 'the excessive tendency of an individual to consider it unacceptable that a negative event may occur, however small the probability of its occurrence' is associated with higher levels of negative affect such as fear and worry in the short term, and is also a risk factor for the development of pathological anxiety (Einstein, 2014). A review of its role in health and health-care related outcomes, found poorer tolerance to uncertainty was consistently associated with higher distress and a greater tendency to use avoidant coping behaviours (Strout et al., 2018). IU has been conceptualised as the 'filter' through which events are perceived, while worry relates to 'mental acts' reflecting a person's thoughts about a situation and its potential outcomes, with worry seen as a product of IU (Buhr & Dugas, 2002). People high on IU have been described as lacking the cognitive flexibility needed to cope with a potentially life-threatening illness, which among other things, challenges people's fundamental assumptions about themselves and the world (Eisenberg et al., 2015).

Among people diagnosed with cancer, intolerance of uncertainty has been associated with higher anxiety among men with low-risk prostate cancer, undergoing active surveillance of their condition (Tan et al., 2016), greater cancer-related distress among prostate cancer survivors (Eisenberg et al., 2015), as well as higher depression and poorer emotional wellbeing among lung cancer patients (Kurita et al., 2013). Among people at higher risk for cancer, low tolerance for ambiguity (one source of uncertainty, Hillen et al., 2017) has been associated with high post-counselling distress among people undergoing genetic counselling for hereditary colorectal cancer risk (Codori et al., 2005) and higher cancer-related and general distress in women receiving uninformative BRCA1/2 test results (O'Neill et al., 2006). Collectively this previous research suggests that the diagnostic phase may be particularly challenging for people who find uncertainty difficult to manage.

The aims of this study were to examine: i) rates of distress among patients undergoing staging investigations for suspected colorectal or lung cancer, and ii) predictors of distress. We hypothesized distress would be higher among younger people, women, those with higher deprivation, lung cancer, and higher intolerance of uncertainty.

Materials and methods

Patients were recruited to two parallel multi-centre clinical trials, comparing the diagnostic accuracy and cost-effectiveness of WB-MRI with standard tests for staging colorectal (Streamline C) and lung cancer (Streamline L). The trials received ethical approval from the Camden and Islington National Research Ethics Service (NRES) on 03/10/2012, project numbers: 12/LO/1176 (Streamline C) and 12/LO/1177 (Streamline L). Eligible patients had known or suspected colorectal or lung cancer and were due to undergo staging. The full protocols can be found at (Taylor et al., 2017) and the main outcomes have been reported (Taylor, Mallett, Ball et al., 2019; Taylor, Mallett, Beare et al., 2019). As part of the main trials, patients underwent WB-MRI in addition to all standard staging tests, and were also invited to complete postal questionnaires before and after staging.

Participants were recruited to the Streamline trials from 22 hospitals in the UK, and consented to participate in either an interview or one of the two questionnaire studies, to gauge their experience of staging and the influence of scan attributes on scan preference. The results of the interview study (Evans et al., 2017) and a discrete choice experiment assessing the influence of scan attributes on patient preferences (Miles et al., 2019) have been reported elsewhere, as has data from the present cohort on the perceived burden of WB-MRI vs. standard staging scans (Evans et al., 2018). This current report describes predictors of distress assessed in the baseline questionnaire.

Questionnaires

Patients were mailed the baseline questionnaire by the UCL Cancer Trials Centre within 1 to 2 days after consenting to participate, and while they were still undergoing staging investigations. Patients were also invited to complete a post-staging questionnaire (not reported here) in order to assess patient experience of and preferences for the different staging scans. The study was originally powered to assess the comparative patient perceived burden of WB-MRI and standard staging tests (Evans et al., 2018).

Emotional distress

The 12 item General Health Questionnaire (GHQ-12) was used to assess probable emotional distress. An example item is, *'In the last three months have you ...been able to face up to your problems?'* Using the GHQ-12 binary coding method (0,0,1,1), a mean sum score (if at least 50% of items were answered) was created ranging from 0 to 12 (Goldberg et al., 1997). A score of 4 or more is considered indicative of high distress levels (Knott, 2013).

Demographics

Patients were asked their age and gender. Missing demographic data on age and gender as well as zip code data were supplied via the central trial database (with patient consent). Zip code data were used to calculate an area-based deprivation score for each individual using the 2010 IMD scale (McLennan et al., 2011), categorised into quintiles from 1 (highest levels of deprivation) to 5 (lowest).

Co-morbidity

Patients were asked about their current and recent physical health and mental well-being. Patients were asked to report ('yes' or 'no') whether they had any of the following diseases: heart or vascular disease, diabetes, epilepsy, stroke, arthritis, asthma, mental or emotional disorder. There was also an option to provide details of other illnesses. A response of 'yes' to any illness was coded and summed to form a dichotomous 'co-morbidity' variable ('present' or 'absent'), excluding mental or emotional disorder as this was captured in the GHQ-12.

Aware of diagnosis at the time of completing the baseline questionnaire

Knowledge of confirmed cancer diagnosis was not asked directly, but was estimated based on date of primary biopsy and date of registration to the trials, which were both recorded by the central trial database. Patients whose date of primary biopsy was equivalent to or earlier than their date of registration to the trial were categorised as probably knowing their cancer diagnosis at the time of completing the baseline questionnaire. Those whose date of primary biopsy was later were categorised as probably not knowing their cancer diagnosis at the time of questionnaire completion. The majority of patients had a date of primary biopsy ($n = 100, 77.5\%$). In cases where there was no primary biopsy, other dates were used in the following order of priority: date of biopsy of spread (e.g. lymph nodes) ($n = 6, 4.7\%$), date of surgical resection ($n = 10, 7.8\%$), date of withdrawal from the trial due to a non-cancer diagnosis ($n = 9, 7.0\%$), and date of MDT ($n = 3, 2.3\%$). One person had no date recorded of their recruitment to the trial and were later then deemed ineligible (as the cancer was a recurrence, not a primary).

Final diagnosis

This was recorded by the central trial database (cancer, not cancer). One person did not have the WB-MRI scan so their diagnosis was unknown.

Intolerance of uncertainty

This was measured using the four highest loadings items on the subscale 'Uncertainty is stressful and upsetting' of the Intolerance of uncertainty measure (Buhr & Dugas, 2002) (loadings 0.53–0.74). ('My mind can't be relaxed if I don't know what will happen tomorrow', 'Uncertainty makes life intolerable', 'Uncertainty makes me uneasy, anxious or stressed', 'Uncertainty keeps me from sleeping soundly'). Participants were given the following instructions: 'You will find below a series of statements which describe how people may react to the uncertainties of life. Please use the scale below to describe to what extent each item is characteristic of you. Please circle a number (1 to 5) that describes you best.' Response options 1–5 with 1 anchored 'not at all characteristic of me,' and 5 anchored 'entirely characteristic of me' with the mid-point (3) labelled 'somewhat characteristic of me'. Internal reliability of the scale was good (Cronbach's $\alpha = 0.903$). (Only one person answered fewer than half – 2 – of the items).

Statistical analysis

Data were analysed using SPSS version 24. Demographics of responders and non-responders, and of participants recruited to Streamline C and Streamline L, were

analysed using independent t-tests or Mann-Whitney U for continuous variables, and chi-square or Fisher's exact for categorical variables.

Logistic regression was used to identify predictors of high levels of emotional distress (yes, no). Predictors (age, gender, deprivation, cancer type, presence of comorbidities, awareness of diagnosis, final diagnosis, and intolerance to uncertainty) were entered individually in an unadjusted analysis, and altogether in an adjusted analysis.

Age and deprivation levels were collapsed into three groups. For age, this was to check for non-linear associations with distress (categories were: 30–49, 50–69, 70–89). For deprivation, it was to increase the sample size in each category (categories were: groups 1 and 2 – highest deprivation, group 3, and groups 4 and 5 – lowest deprivation).

Results

Response rates

During the study period (March 2013 and July 2015) 392 people were recruited to the Streamline trials of whom 350 (89.3%) agreed to participate in the questionnaire or interview study (see [Figure 1](#)). Ninety-one were recruited for the interview study and three were not sent the baseline questionnaire. Of those sent the baseline questionnaire ($n = 256$), 117 did not complete it, and 10 returned it but had not completed the GHQ-12 (total non-response = 127), leaving 129 in the final study cohort.

There were no significant differences between participants and non-responders in terms of median age ($z = 0.184$; $p = 0.854$), cancer type [colorectal or lung] (chi-square = 0.015; $df = 1$; $p = 0.902$), gender (chi-square = 2.544, $df = 1$, $p = 0.111$) or deprivation (chi-square = 4.543; $df = 2$; $p = 0.103$).

Participant characteristics

Median participant age was 66.4 (range: 31–89), with no differences between men and women (66.6 vs 64.9 respectively; $z = 0.730$, $p = 0.466$). Seventy-seven (59.7%) were male, and seventy four (57.4%) reported at least one additional comorbidity (see [Table 1](#)). The majority (89.1%, $n = 115$) were ultimately diagnosed with cancer.

Patients recruited to Streamline C were younger, less likely to report comorbidities, more likely to be diagnosed with cancer at the end of staging, and more likely to be potentially aware of their diagnosis at the time of completing the baseline questionnaire than patients recruited to Streamline L. There were no differences between Streamline C and Streamline L cohorts regarding gender, deprivation, intolerance to uncertainty and presence of high emotional distress (see [Table 1](#)).

Predictors of distress

In unadjusted analyses, high distress was predicted by higher deprivation and greater intolerance of uncertainty. While cancer type alone did not significantly predict high distress ([Table 2](#)), Streamline C patients were more likely to (probably) know their diagnosis at the time of completing the questionnaire ([Table 1](#)). Adjusting for probable knowledge of diagnosis showed Streamline C patients had lower levels of distress than

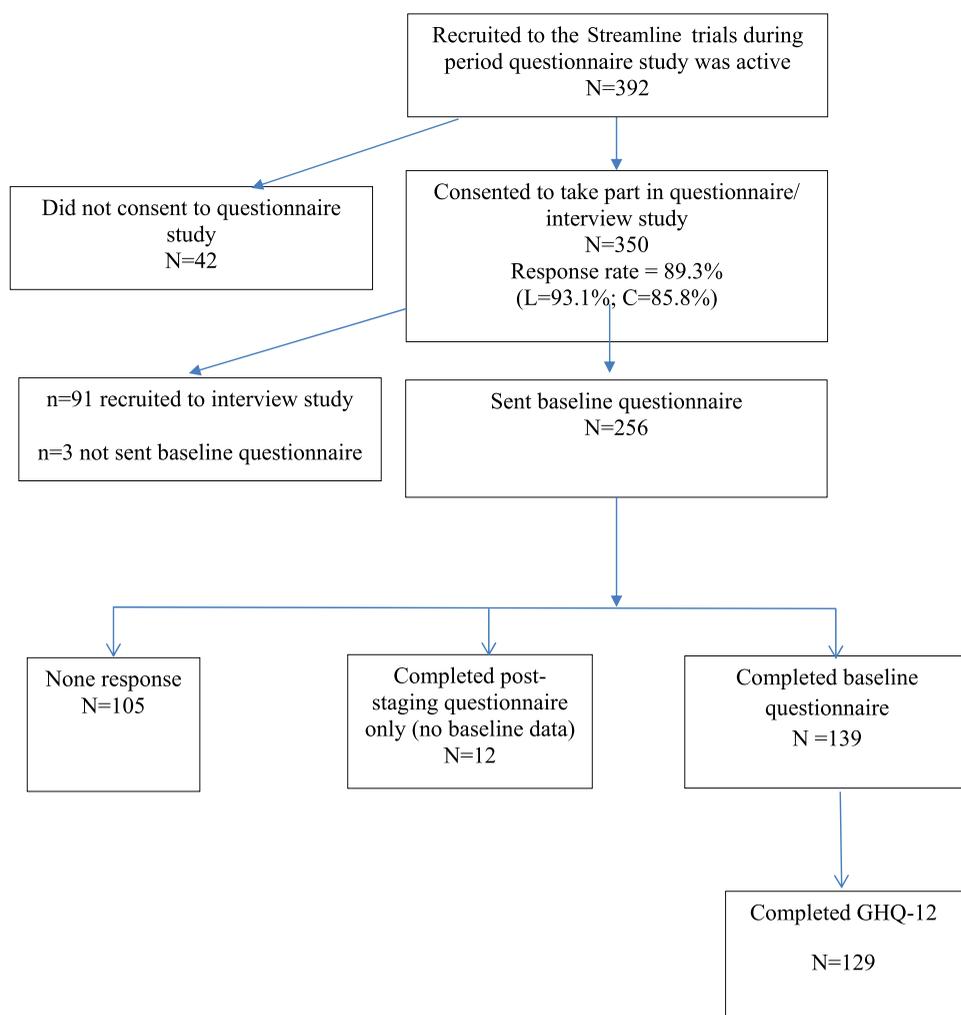


Figure 1. Flow Chart showing flow of participants in study.

Streamline L (OR: 0.410, CIs: 0.179 to 0.938, $p = 0.035$). There was also a non-significant trend towards a greater likelihood of high distress among patients aware of their diagnosis (OR: 2.055, CIs: 0.890 to 4.749, $p = 0.092$). However when all the variables were entered into the analysis together, only higher deprivation and greater intolerance of uncertainty were predictive of high distress, although awareness of diagnosis approached significance. The analysis was repeated separately for people who probably knew vs probably did not know their diagnosis (cancer vs. not cancer) at the time of completing the GHQ-12 and the pattern of significant results was broadly similar (see Supplementary data). In addition, the interaction between intolerance to uncertainty and probably knowledge of diagnosis was not significant (OR: 0.727, 95% CIs: 0.328 to 1.608, $p = 0.431$).

Table 1. Participant characteristics. Numbers are percent (n) unless otherwise specified.

	Overall (N = 129)	Colorectal (N = 66)	Lung (N = 63)	Significance
Age ^a	Median: 66.4	64.2	69.2	$z = 2.313, p = 0.021$
30–49	7.0 (9)	12.1 (8)	1.6 (1)	
50–69	51.2 (66)	53.0 (35)	49.2 (31)	
70–89	41.9 (54)	34.8 (23)	49.2 (31)	
Gender (% male) ^a	59.7 (77)	59.1 (39)	60.3 (38)	Chi-square = 0.020; df = 1; p = 0.887
Deprivation ^a				Chi-square = 2.442; df = 2; p = 0.295
1 & 2	48.8 (63)	43.9 (29)	54.0 (34)	
3	20.9 (27)	19.7 (13)	22.2 (14)	
4 & 5	30.2 (39)	36.4 (24)	23.8 (15)	
Comorbidity ^a	57.4 (74)	47.0 (31)	68.3 (43)	Chi-square = 5.970; df = 1; p = 0.015
Ultimately diagnosed with cancer ^b				Fisher's exact, $p < 0.001$
Yes	89.1 (115)	65 (98.5)	50 (79.4)	
No	10.1 (13)	1 (1.5)	12 (19.0)	
Unknown	0.8 (1)	0 (0)	1 (1.6)	
Potentially aware of cancer diagnosis at time of GHQ-12 completion ^b				Chi-square = 24.470, df = 1, p < 0.001
Probably not	43.8 (56)	22.7 (15)	66.1 (44)	
Possibly yes	56.3 (72)	77.3 (51)	33.9 (21)	
Intolerance of uncertainty ^b (mean, sd)	2.31 (1.06)	2.32 (1.00)	2.31 (1.14)	$t = -0.084; df = 122;$ $p = 0.933$
High emotional distress (GHQ-12 score of 4 or more) ^a	39.5 (51)	33.3 (22)	46.0 (29)	Chi-square = 2.174, df = 1, p = 0.140

^ano missing data^bmissing data less than 5%

Discussion

Research to date shows a substantial proportion of people undergoing investigations for cancer have high levels of distress, with rates similar to people with a confirmed diagnosis of cancer (Brocken et al., 2012). This study examined distress among patients undergoing staging investigations for suspected colorectal or lung cancers. In line with predictions, higher rates of distress were associated with higher deprivation and high intolerance to uncertainty both in unadjusted and adjusted analyses. Rates of distress observed in our study among people with suspected colorectal (33.3%) and lung cancer (46.0%) were comparable to rates observed in people with confirmed diagnoses (colon: 31.6% and lung: 43.4% (Zabora et al., 2001)), and to rates of anxiety observed in the diagnostic phase of between 33% and 60% in other cancer groups (Brocken et al., 2012). Although one study found 40% of patients with colorectal cancer reported high levels of anxiety, it was assessed retrospectively and did not use a validated measure (Wiljer et al., 2013). Distress rates only significantly differed by cancer type once probable knowledge of diagnosis was entered into the model (as people with suspected colorectal cancer were more likely to

Table 2. Predictors of high distress at baseline.

	Proportion with high distress (n)	Unadjusted (n = 129)	Adjusted (all variables entered into the analysis together) (N = 121)
<i>Demographics</i>			
Age ^a			
30–49	55.6 (5)	2.303 (0.552 to 9.608)	3.475 (0.598 to 20.181)
50–69	40.9 (27)	1.275 (0.606 to 2.682)	1.079 (0.443 to 2.629)
[70–89]	35.2 (19)	[1.00]	[1.00]
Gender ^a			
Female	36.5 (19)	[1.00]	[1.00]
Male	41.6 (32)	1.235 (0.599 to 2.547)	1.341 (0.533 to 3.249)
Deprivation ^a			
[1 and 2]	46.0 (29)	[1.00]	[1.00]
3	48.1 (13)	1.089 (0.441 to 2.686)	1.019 (0.360 to 2.883)
4 and 5 (lower deprivation)	23.1 (9)	0.352 (0.144 to 0.860) p = 0.022	0.243 (0.083 to 0.714) p = 0.010
<i>Clinical and psychological variables</i>			
Comorbidity ^a			
No	36.4 (20)	[1.00]	[1.00]
Yes	41.9 (31)	1.262 (0.616 to 2.586)	0.927 (0.375 to 2.291)
Cancer site ^a			
Lung	46.0 (29)	[1.00]	[1.00]
Colorectal	33.3 (22)	0.586 (0.288 to 1.195)	0.459 (0.169 to 1.243)
Aware of diagnosis ^b			
Probably not	35.7 (20)	[1.00]	[1.00]
Probably yes	43.1 (31)	1.361 (0.663 to 2.792)	2.358 (0.885 to 6.286) p = 0.086
Ultimately diagnosed with cancer ^b			
No	38.5 (5)	[1.00]	[1.00]
Yes	39.5 (45)	1.043 (0.321 to 3.392)	0.526 (0.118 to 2.339)
Intolerance of uncertainty ^b			
-	-	1.972 (1.357 to 2.865) p < 0.001	2.231 (1.429 to 3.485) p < 0.001

^ano missing data^bless than 5% missing data

know this). However, once other variables were added into the model, cancer type did not significantly predict distress. Contrary to predictions, we found no association between distress and either age or gender. Only a small number of people were aged under 49, meaning there was reduced statistical power needed to detect age effects in the youngest group, but no differences were observed between those aged 50–69 and 70–89 either. The lack of association between gender and distress is more surprising, although a recent systematic review of predictors of distress one or more years after a cancer diagnosis found little evidence gender or age were predictors (Cook et al., 2018).

Study limitations

The study has a number of limitations. The design was cross-sectional, and the direction of influence of variables is unknown – hence while intolerance of uncertainty may predict high distress, high distress may equally reduce people’s ability to tolerate uncertainty. In addition, the questions used to assess uncertainty intolerance came from a subset of a questionnaire, and assessed people’s views about the negative consequences of uncertainty, and did not ask about positive responses to uncertainty (Hillen et al., 2017). As such, the association between high distress and intolerance of uncertainty could partially

reflect a negative response bias. There is also some conceptual overlap between the items on the GHQ-12 distress scale and the intolerance to uncertainty scale – such as the question assessing uncertainty as causing anxiety and stress, which may have inflated associations between distress and IU. A recent review of the concept of IU called for the development of broader measures, including both positive and negative responses to uncertainty (Hillen et al., 2017), and such measures may show different relationships with distress.

A further limitation is that patients were not asked directly whether they knew their cancer diagnosis at time of baseline questionnaire completion. Instead, an indicator of probable knowledge was used, based primarily on date of primary biopsy. Equally, although patients were sent the baseline questionnaire on recruitment to the trial, we do not know how many completed it after their staging investigations had been completed.

This study demonstrates that a substantial proportion of patients undergoing staging investigations for suspected lung or colorectal cancer experience significant levels of distress. A Canadian study reporting on patients with a confirmed diagnosis of colorectal cancer attending clinics for follow-up care, found patients retrospectively reported feeling high anxiety levels during the diagnostic phase, with 31.6% reporting informational and 20.3% reporting emotional needs during this time (Wiljer et al., 2013). While the majority (84%) said their needs had been met, a high proportion of patients (77.9%) stated they had not been directed to any sources of help in coping with their anxiety. Together with the current study, such research points to the need for more patient support while undergoing investigations for cancer.

In conclusion, a substantial proportion of patients experience high distress while undergoing staging investigations for a suspected or confirmed cancer diagnosis. Future research should assess distress associated with both waiting for a cancer diagnosis and also waiting for a prognosis (once the diagnosis has been made), and examine how best to reduce distress, particularly among those at higher risk such as people with higher levels of deprivation and uncertainty intolerance.

Collaborators

The authors of this paper are part of a wider group of Streamline trials investigators and include the following collaborators: A Aboagye, L Agoramoorthy, S Ahmed, A Amadi, G Anand, G Atkin, A Austria, S Ball, F Bazari, R Beable, S Beare, H Beedham, T Beeston, N Bharwani, G Bhatnagar, A Bhowmik, L Blakeway, D Blunt, P Boavida, D Boisfer, D Breen, J Bridgewater, S Burke, R Butawan, Y Campbell, E Chang, D Chao, S Chukundah, C S Clarke, B Collins, C Collins, V Conteh, J Couture, J Crosbie, H Curtis, A Daniel, L Davis, K Desai, M Duggan, S Ellis, C Elton, A Engledow, C Everitt, S Ferdous, A Frow, M Furneaux, N Gibbons, R Glynne-Jones, A Gogbashian, V Goh, S Gourtsoyianni, A Green, Laura Green, Liz Green, A Groves, A Guthrie, E Hadley, S Halligan, A Hameeduddin, G Hanid, S Hans, B Hans, A Higginson, L Honeyfield, H Hughes, J Hughes, L Hurl, E Isaac, M Jackson, A Jalloh, SM Janes, R Jannapureddy, A Jayme, A Johnson, E Johnson, P Julka, J Kalasthry, E Karapanagiotou, S Karp, C Kay, J Kellaway, S Khan, D Koh, T Light, P Limbu, S Lock, I Locke, T Loke, A Lowe, N Lucas, S Maheswaran, S Mallett, E Marwood, J McGowan, F Mckirdy, T Mills-Baldock, T Moon, V Morgan, S Morris, A Morton, S Nasser, N Navani, P Nichols, C Norman, E Ntala, A Nunes, A Obichere, J O'Donohue, I Olaleye, A Oliver, A Onajobi, T O'Shaughnessy, A Padhani, H Pardoe, W Partridge, U Patel, K Perry, W Piga, D Prezzi, K Prior, S Punwani, J Pyers, H Rafiee, F Rahman, I Rajanpandian, S Ramesh, S Raouf, K Reczko, A Reinhardt, D Robinson, A

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Disclosure statement

Professor Taylor and Dr Anne Miles report grants from NIHR, during the conduct of the study. Professor Taylor reports personal fees from Robarts, outside the submitted work.

Data sharing statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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