

1 Feasibility and acceptability of the use of patient-reported outcome 2 measures (PROMs) in the delivery of nurse-led supportive care to 3 people with colorectal cancer

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26 27 28 **Highlights (for review)**

- 29 ▪ Nurse-led, PROMs-driven consultations to identify and address the supportive care needs of
30 patients with CRC who transition from active chemotherapy to the initial follow-up period
31 appear to be feasible and acceptable to both patients and CNS
- 32 ▪ Patients appreciated the opportunity for dedicated time with the CNS as it allowed them to
33 raise concerns and get sensitive and personalised help and advice.
- 34 ▪ CNS perceived engagement in the collection and use of patient-reported data as an
35 enlightening and educative activity, enabling them to see beyond just side-effects, assess over
36 time, and investigate issues deeper
- 37 ▪ This type of intervention could be associated with (a) a sizeable reduction in the total
38 number of reported unmet needs, and (b) a small decrease in the magnitude of expressed
39 physical/daily living and psychosocial needs at the initial post-chemotherapy period.

40 **Abstract**

1 **Purpose:** Logistical issues pertinent to the use of patient-reported outcome measures (PROMs) by
2 colorectal cancer nurse specialists (CNS) to identify the needs of people with colorectal cancer (CRC)
3 in acute care remain unknown. We explored the feasibility and acceptability of PROMs-driven, CNS-
4 led consultations to enhance delivery of supportive care to people with CRC completing adjuvant
5 chemotherapy.

6 **Methods:** A systematic literature review and focus groups with patients and CNS (Phase 1) were
7 followed by a repeated-measures, exploratory study (Phase 2), whereby pre-consultation PROM data
8 were collected during three consecutive, monthly consultations, and used by the CNS to enable
9 delivery of personalised supportive care.

10 **Results:** Based on Phase 1 data, the Supportive Care Needs Survey was selected for use in Phase 2.
11 Fourteen patients were recruited (recruitment rate: 56%); thirteen (93%) completed all study
12 assessments. Forty in-clinic patient-clinician consultations took place. At baseline, 219 unmet needs
13 were reported in total, with a notable 21% (T2) and 32% (T3) over-time reduction. Physical/daily living
14 and psychological domain scores declined from T1 to T3, yet not statistically significantly. In exit
15 interviews, patients described how using the PROM helped them shortlist and prioritise their needs.
16 CNS stressed how the PROM helped them tease out more issues with patients than they would
17 normally.

18 **Conclusions:** Nurse-led, PROMs-driven needs assessments with patients with CRC appear to be
19 feasible and acceptable in clinical practice, possibly associated with a sizeable reduction in the frequency
20 of unmet needs, and smaller decreases in physical/daily living and psychosocial needs in the immediate
21 post-chemotherapy period.

22

23 **Keywords:** Patient-reported outcome measures; unmet needs; supportive care; colorectal cancer;
24 cancer nurse specialist; feasibility; acceptability; nurse led

1 Background

2 Colorectal cancer (CRC) is the third most common cancer worldwide and second most common
3 cancer in Europe, accounting for 9.7% and 13.0% of all cancer cases, respectively (Ferlay et al., 2013).
4 As a result of advances in both diagnostic tests and treatments for CRC, mortality has declined over
5 the past decades (Ait Ouakrim et al., 2015), with nearly 60% of patients now surviving to five years
6 after diagnosis (The Scottish Public Health Observatory, 2015). This means that an increasing number
7 of people may now live beyond CRC, but still experience the impact of illness and treatment on several
8 aspects of their lives (Alacacioglu et al., 2010; Arndt et al., 2004; Wu and Snyder, 2011). The need to
9 provide on-going and comprehensive supportive care to these individuals is therefore prominent
10 (Jorgensen et al., 2012).

11 Research has shown that people with CRC may have multiple unmet supportive care needs (Harrison
12 et al., 2011a; Ho et al., 2016) that may well interfere with quality of life (Santin et al., 2015). Long-term
13 recovery may be more prolonged specifically for patients receiving adjuvant chemotherapy and/or
14 radiotherapy, due to persistent physical symptoms and an altered body image, often associated with
15 daily living challenges, anxiety and/or depression, and complicated psychosocial adjustment (Ho et al.,
16 2016; Russell et al., 2015).

17 The development of new clinical supportive care services for people with CRC should identify ways
18 to feasibly assess and effectively address patients' needs. One such service is the use of patient-
19 reported outcome measures (PROMs) to identify the supportive care needs of people with CRC
20 throughout the illness trajectory. Relying on patients' own reports of their health status, needs,
21 priorities and expectations means that care can be personalised. This allows the identification of bio-
22 psychosocial issues that may otherwise be overlooked in standard clinical consultations, and facilitates
23 timely management of symptoms, improved communication between patients and health professionals,
24 increased shared decision-making, and greater patient satisfaction with care (Donaldson, 2004;
25 Kotronoulas et al., 2014; Valderas and Alonso, 2008). Relevant literature indicates that nurses are the
26 most appropriate health professionals to assess PROMs as they are more receptive to, and give greater
27 weight to such information (Greenhalgh et al., 2005). There is also evidence to suggest that the use of
28 PROMs can be enhanced by taking patients' and clinicians' preferences into consideration when
29 selecting such tools as this ensures that clinicians' priorities for care are consistent with those of
30 patients (Carr et al., 2003; Ruland, 1998; Ruland et al., 1997).

31 It is therefore reasonable to hypothesise that PROMs can be used to transform the supportive care
32 offered to people with CRC. However, additional research is needed to explore how the use of
33 PROMs can be implemented in everyday practice to enable nurses to assess and address the supportive
34 care needs of people with CRC, and how this approach can impact on patient outcomes and the
35 clinical practice. Thus, we aimed to explore the feasibility and acceptability of the use of supportive
36 care needs PROMs by colorectal cancer nurse specialists (CNS) in the delivery of supportive care to
37 people with CRC receiving adjuvant chemotherapy.

39 Methods

40 After obtaining Research Ethics approval (14/WVS/0070), we conducted a two-phase, mixed-methods
41 exploratory study within one NHS board (3 hospitals) in Scotland. In Phase 1, we aimed to identify
42 what outcomes are important to patients with CRC and colorectal CNS involved in their care. This
43 information determined selection of a PROM for use in Phase 2. Phase 2 addressed the following
44 objectives:

- 45 • Explore parameters of feasibility and acceptability pertinent to use of a PROM by patients with
46 CRC and their CNS in the delivery of supportive care.
- 47 • Describe the supportive care needs of patients with CRC, receiving adjuvant chemotherapy.
- 48 • Determine whether the PROM is sensitive to change over time.

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Phase 1

In Phase 1, we combined evidence from a systematic literature review with data from subsequent focus groups interviews with patients with CRC and colorectal CNS.

Systematic literature review

We conducted our review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009). The review aimed to appraise the empirical evidence on the supportive care needs of people with CRC. Full methodological details of this review have been published separately (Kotronoulas et al., 2017). The review also aided in the identification of supportive care needs PROMs that were used as part of the included studies. The identified PROMs were added to the pool of supportive care needs PROMs already known to us from previous reviews (Carlson et al., 2012; Maguire et al., 2013; Richardson et al., 2007). All PROMs were considered for use in Phase 2.

Stakeholder interviews

Two focus group interviews – one with patients and one with nurses – each consisting of no more than ten participants were conducted. The interviews aimed to provide information on supportive care outcomes considered important by people with CRC and by CNS involved in their care. All colorectal CNS, registered within the participating NHS board, were invited to participate and identify eligible patients. Patients with CRC were identified through outpatient lists at the participating hospitals. Eligible patients were those (a) receiving adjuvant chemotherapy for early-stage CRC; (b) deemed as physically and psychologically fit for participation; (c) able to read and write English; (d) able to provide written informed consent; (e) aged 18 years or over; and (f) able to provide consent for members of the research team to access their case notes.

The two focus groups were conducted separately, on different dates, and in a meeting room at one of the participating hospitals. All consenting patients and CNS provided written informed consent. Interview guides were used to facilitate discussion. Focus groups were planned to last for no more than one hour to minimise participant burden. At the end of each focus group, we involved participants in a 10-minute exercise. Copies of the previously author-selected PROMs were distributed to each group. We asked participants to review the PROMs and select, in order of descending preference, the three ‘most appropriate’ for use with people with CRC. Participants were asked to focus on such aspects as overall presentation, length, wording, and comprehensiveness as indicators of PROM appropriateness.

Phase 2

Phase 2 entailed a prospective, repeated-measures study that aimed to involve up to 30 patients with CRC as per current available guidance for early feasibility testing (Lancaster et al., 2004). Participation of the CNS was re-confirmed for Phase 2. Patient eligibility criteria were identical to those used in Phase 1. All consenting patients provided written informed consent. None of the patients who were involved in Phase 1 participated in Phase 2.

Procedures

Patients participated in Phase 2 over three, equally-spaced (monthly) time-points: penultimate chemotherapy cycle (T1); last chemotherapy cycle (T2); and approximately one month after the last chemotherapy cycle (T3). Timing of the intervention was selected in consultation with CNS participants. Patient transition from active treatment to the initial follow-up period was perceived as an important period for the provision of effective supportive care. This timeline was also thought to allow sufficient time for feasibility testing, whilst minimising the attrition rate.

1 At each time-point, participating patients were booked on an appointment with their CNS. Whilst in
2 the clinic and prior to their consultation, patients were asked to complete the selected needs
3 assessment PROM in a quiet room. Subsequently, the CNS met with the patient and used the
4 information collected via the PROM to identify the patient's supportive care needs, direct
5 consultations, and intervene accordingly. The CNS documented any needs they identified and any
6 resulting interventions in author-developed case-report forms. Finally, up to ten patients and all CNS
7 were planned to participate in one-to-one, end-of-study, semi-structured interviews to explore their
8 perceptions on the intervention in greater depth.

9 *Data analysis*

10 PROM data were analysed using SPSS (IBM SPSS Inc., Chicago, IL, USA) descriptive statistics
11 functionality and graphs. Frequency counts for each response were generated to quantify missing data
12 and describe response patterns for PROM items. Missing data were replaced using multiple imputation.
13 To assess sensitivity to change, the mean, standard deviation and median of PROM subscale scores,
14 and effect sizes of changes thereof were calculated. Effect sizes were calculated as the difference
15 between a mid-point and baseline score (T1 to T2; T1 to T3) divided by the standard deviation of the
16 baseline scores. Negative values reflected improvements in the number of standard deviations of the
17 baseline scores. Effect sizes ≥ 0.80 were considered large, 0.50–0.79 moderate, 0.20–0.49 small, and
18 0.00–0.19 very small (Kazis et al., 1989). Q-Q plots, histograms and Shapiro-Wilk's tests were used
19 to check the assumption of normality in PROM subscale scores. Due to deviations from normality,
20 Friedman ANOVA was used to test for statistical significance of changes in PROM subscale scores
21 over 3 assessment points (with post-hoc comparisons). The level of significance was set at 0.05.

22 Focus group and end-of-study interviews were audio-recorded and transcribed verbatim. NVivo 9
23 (QSR International) was used to aid the organisation of data. Thematic content analysis (Braun and
24 Clarke, 2006) was used to help answering questions about the salient issues for a particular group of
25 respondents or for identifying typical responses. Whilst analysis of the data was thematic, it also
26 focussed on whether and how participants agreed or disagreed about each topic on our topic guides.

28 **Results**

29 **Phase 1**

30 *Systematic literature review*

31 After initial screening of 3709 references, 54 unique studies were retained and included in a narrative
32 synthesis of evidence (Kotronoulas et al., 2017). Emotional support and reassurance when trying to
33 deal with fear of the cancer returning or spreading featured as the most prominent need regardless of
34 clinical stage or phase of treatment. A top-10 of most prominent needs also included more information
35 about diet/nutrition and about long-term self-management of symptoms and complications at home;
36 tackling issues relating to the quality and mode of delivery of health-related information; help with
37 controlling fatigue; and on-going contact with a trustworthy health professional (Kotronoulas et al.,
38 2017).

39 Based on the above findings and drawing on our database of needs assessment PROMs, we concluded
40 that the following six PROMs would be discussed in subsequent focus groups: Supportive Care Needs
41 Survey – Short Form 34 (SCNS-SF34) (Boyes et al., 2009); Problems Checklist (Cull et al., 1995);
42 Cancer Needs Questionnaire – Short Form (Cossich et al., 2004); Psychosocial Needs Inventory
43 (McIlmurray et al., 2001); Cancer Survivors Unmet Needs (Hodgkinson et al., 2007); Functional
44 Assessment of Cancer Therapy-Colorectal concerns subscale (FACT-C) (Ward et al., 1999). These
45 PROMs were selected for their brevity and comprehensiveness in assessing patients' supportive care
46 needs.

1 *Stakeholder focus group interviews*

2 The focus groups were conducted in October 2014. Eleven patients with CRC were invited to take
3 part, but three refused due to lack of time. Thus, the first focus group involved eight patients with
4 CRC. Participants' accounts mainly revolved around issues of information sharing, navigation through
5 the health service, and patient-clinician communication. The group described their need to receive
6 comprehensive information about the illness and its treatment (surgery, stoma, recovery, symptoms
7 and management thereof), and how important it is for this information to be communicated in a
8 sensitive way. Participants would welcome a more swift reply to their needs, too. Those who had a
9 stoma also spoke about the "shock" of getting one, and the need to receive psychological support. The
10 group talked about the supportive role of their families and friends was in helping them to keep a
11 positive outlook. One participant explained: "A sympathetic ear, that's really what I needed at the time".
12 Others admitted trying to 'protect' their families, thereby avoiding communication although they may
13 have needed it. When queried, participants revealed that their social needs had not been thoroughly
14 assessed. Nonetheless, the group spoke about the need to return to normal, to find new meaning in
15 life, and to resume work or get help if returning to work was not an option anymore.

16 The second focus group involved all seven colorectal CNS registered within the participating NHS
17 board. The CNS spoke of the ever changing nature of one's needs from cancer diagnosis to treatment
18 and then to follow-up, but stressed the need for on-going support for patients who are in the post-
19 treatment phase. The group agreed that people with CRC need to have a clinician responsible for
20 their care, one that they know they can contact if any issues arise. The group did see themselves as
21 this front-line clinician. One CNS spoke about variability in the information needs of this patient
22 population, but acknowledged that such information must be clear, appropriate, accurate and
23 consistent. The group described how patients strive to know more about their illness and about the
24 care plan for them: they want to know what happens next and how they can be supported (e.g. with
25 dietary changes, with coping with a stoma or with stoma care). Echoing patients' views, nurses asserted
26 that patients need help with psychological and emotional issues, family support, and practical issues,
27 including getting help with finances, work or child support. The group agreed that use of a needs
28 assessment PROM would allow them to structure their assessments and better understand what needs
29 are priority for patients.

30 Both groups regarded the SCNS-SF34 as the most appropriate PROM in terms of presentation and
31 wording. However, CNS commented on the lack of comprehensiveness of the SCNS-SF34 and agreed
32 that they would prefer using an even more comprehensive tool, such as the original 59-item SCNS
33 (Bonevski et al., 2000; Sanson-Fisher et al., 2000). This was regarded a better option than combining
34 the SCNS-SF34 with another PROM from the pool. After consensus was reached, a 60th item was also
35 developed to assess patients' cognitive needs ("Not being able to remember things and/or not being
36 able to concentrate") and further increase comprehensiveness of the SCNS.

37 The SCNS is a well-established and thoroughly validated, self-reported tool for assessing the perceived
38 unmet needs of cancer patients (Bonevski et al., 2000; Sanson-Fisher et al., 2000). Respondents are
39 asked to indicate their level of need for help over the last month on a 1-5 scale (1=not applicable,
40 2=satisfied, 3=low need, 4=moderate need, 5=high need). Items are classified into five (factor-analysis-
41 derived) domains of need: (1) psychological (22 items); (2) health system and information (15 items);
42 (3) physical and daily living (7 items); (4) patient care and support (8 items); and (5) sexuality (3 items)
43 Four additional items are not incorporated within any domain, but are included as clinically important.
44 In our study, internal consistency reliability was very good (Cronbach's alpha ≥ 0.80) for almost all
45 domains and time-points (Suppl.1).

46 **Phase 2**

47 *Feasibility and acceptability estimates*

48 Between January and July 2015, 25 eligible patients with CRC were invited to Phase 2. Eleven patients
49 refused participation due to lack of time or interest, or challenging personal circumstances. Fourteen
50

1 patients provided written informed consent. A recruitment rate of 56% (14/25) and an average
2 recruitment pace of 2 participants per month were achieved. Thirteen patients (93%) completed all 3
3 study assessments, with one patient withdrawing soon after baseline assessment due to declining health
4 status.

5 Six CNS performed a total of 40 in-clinic patient assessments within a period of 9 months (i.e. the
6 period when the study was 'open' for recruitment and follow-up). Five CNS had at least 6 years of
7 experience in the care of people with CRC. Full documentation records (case-report forms) were
8 received for each in-clinic assessment. Reflection questions were filled out for all 40 in-clinic
9 assessments. Completeness of background data reached 98.2%.

10 Forty questionnaire packs were returned (100%), one for each-clinic assessment. Data completeness
11 analysis indicated that across 2420 actual data, only 6.1% were missing across 3 assessment points.
12 SCNS completeness reached 97.1% at baseline, and dropped to 92.5% and 91.9% at T2 and T3,
13 respectively. No skewed patterns of missing data were identified. The item with the greatest amount
14 of missing data was the additional cognitive needs question (28.2%).

15 *Prevalence and over-time changes in patients' needs*

16 Patients were typically men (64.3%), aged 66 years, married or partnered (86%), retired (50%) and
17 with high school education (86%) (Table 1). Twelve had a diagnosis of colon cancer. The majority of
18 participants (57%) had stage III disease at the time of diagnosis. At baseline (T1), performance status
19 was very good for 6 patients (ECOG PS 0) and good for 8 patients (ECOG PS 1).

20 Figure 1 shows trajectories of number of unmet needs (i.e. SCNS items reported as at least 'low need')
21 for individual patients, confirming high variability in this sample. At T1, a median 15.5 (range 0-40)
22 unmet needs per patient were reported, accounting for a total of 219 reported needs across the study
23 sample. These figures slightly dropped to a median 14.5 (range 0-30) unmet needs per patient at T2
24 (total 173; 21% reduction from T1), with a further decline at T3 (median 5.5, range 0-38; total 148;
25 32% reduction from T1).

26 Following two consecutive consultations, the prevalence of unmet needs dropped at or below 50% at
27 T3, with T1-to-T3 reductions ranging from 21% to 29% (Suppl.2). At T1, fears about the cancer
28 spreading or returning, lack of energy and not being able to do things they used to do were the most
29 frequent concerns of this patient group, remaining prominent (top-3 needs) at T2 and T3 (Table 2).
30 Uncertainty about the future was also prominent at baseline (64.3%), but its frequency declined steadily
31 from T2 to T3. Concerns about the family, concerns about financial issues, and anxiety and depressed
32 mood were also prevalent needs at baseline. From T2 to T3, a rise in 'rehabilitation' needs was also
33 noted, whereby patients indicated their need to accommodate changes in usual routine and lifestyle,
34 feel in control of their situation, deal with concerns about losing their independence, keep a positive
35 outlook, and find ways to become 'useful' again. From baseline to T3, an upward trend in the
36 prevalence of patients' need to get help with depressed mood was noted (a rise of two places in the
37 relevant ranking). Conversely, patients' need to get help with financial issues was less prevalent at T2
38 and at T3 compared to baseline (Table 2).

39 Patients had a greater need for support with physical/daily living and psychological issues, followed by
40 sexuality needs. Comparably, information needs and patient care/support needs were less prominent
41 (Table 3). Examination of over-time trajectories indicated a slight gradual decline in the mean score of
42 physical/daily living needs and psychological needs from T1 to T3. No particular trends were found for
43 information needs or patient care/support needs. Mean scores of the sexuality needs domain declined
44 from T1 to T2, but increased above baseline levels at T3.

45 Effect sizes of over-time changes were predominantly negative (i.e. showing reduction in the magnitude
46 of needs), but overall very small (Table 4). Small effect sizes were found for the change in physical/daily
47 living needs scores from T1 to T3 (-0.33), the change in psychological needs scores from T1 to T3 (-
48 0.29), and the change in patient care/support needs scores from T1 to T2 (-0.21). The only moderate
49 effect size was found for the change in sexuality needs scores from T1 to T2 (-0.51). No statistically
50 significant over-time changes were found for any of the SCNS domains of need (all $p > 0.05$; Suppl.3).

1 *End-of-study interviews: Patients*

2 Twelve patients initially consented to end-of-study interviews; no contact was made possible for 6 of
3 them. Two additional patients were not interested at the time and declined participation. Four patients
4 re-confirmed participation, but only 3 were actually interviewed. One patient never attended the
5 interview and no further contact with them was made possible.

6 Three main themes emerged from the analysis of patient interview data, namely (a) patients'
7 experiences of the health service, (b) a host of needs raised during consultations, and (c) patients'
8 involvement in the project. Within the '*patient's involvement in the project*' theme, subthemes included:

- 9 • Appropriate need management. Patients were very satisfied with how their needs were dealt
10 with by the nurse specialists ("*I saw value in it for me ...it wasn't just a case of answering questions*
11 *and here's the paper thank you ...the nurse would talk to me about it and you know ask me how I*
12 *felt about it and she would try to explain things*" [P2]; "*And so I left there reasonably happy with the*
13 *advice I was getting...*" [P1]), and how the CNS was able to support them through a challenging
14 period: "*...and for them to take time out to sit and talk to you and explain what's all going to happen,*
15 *what to worry about, what not to worry about you know... the nurses were great*" [P2].
- 16 • Benefits of using the PROM. Use of the PROM was viewed as bringing to the fore issues that
17 the patient might not have remembered otherwise ("*sometimes you experience feelings [...]*" *and*
18 *by the time you come to see the nurses, you've maybe forgot bits and pieces*" [P2]), as well as issues
19 that the patient might not have raised had they not seen it written down: "*I think this*
20 *questionnaire is a good thing [...]*" *it brings up things that maybe you hadn't thought of and you think*
21 *oh that's right enough*" [P2].
- 22 • Experiences of using the PROM, attending the consultation, and being involved in research.
23 The SCNS was easy to understand ("*...the questions were all quite straight forward*" [P2]) and
24 complete in 10-20 minutes ("*I didn't find it too long*" [P3]), the duration of the consultation
25 appropriate ("*I wouldn't have minded if it went on a wee bit longer actually*" [P2], and patients
26 were willing to take part in research: "*I was quite willing to participate... anything that kind of*
27 *way helps*" [P1]; "*...quite happy to go through it. You're looking at first and say "oh, boy" but then*
28 *when you start to read, then you know what you want to say*" [P3].
- 29 • Timing of the intervention. Having the intervention towards the end of chemotherapy was
30 seen as useful; during that time the psycho-emotional needs become more evident: "*towards*
31 *the end when you're starting to feel better physically, it's the mental thing that kicks in*" [P2].
32 However, the patients expressed the view that introduction of this intervention near the
33 beginning of the journey would also be beneficial, when patients face the fear of the unknown:
34 "*I wouldn't mind if it had started a wee bit earlier you know... when your fear kicks in*" [P2].

35 *End-of-study interviews: Colorectal CNS*

36 Six CNS participated in end-of-study interviews. Three main themes were identified, namely (a) using
37 PROMs in practice, (b), challenges of the study and (c) suggestions for future work.

38 Within the '*using PROMs in practice*' theme, the CNS estimated that on average consultations lasted
39 30-40 minutes, noting how the intervention became easier to deliver after a few consultations and as
40 they got more confident with the process. All CNS agreed that, in most instances, they were able to
41 deal with the issues raised either by using their own resources or by referring to other services. The
42 CNS expressed how helpful it was to use the tool to tease out more issues with the patients than
43 they would normally: "*[it] initiates conversations that are deeper*" [N3]; "*It was certainly good to have a*
44 *prompt...*" [N5]. They also commented on how they were made aware of more patient needs: "*[he*
45 *was] on chemotherapy and he couldn't have sexual contact with his wife... he's an older gentleman, so you*
46 *don't kind of think about these things. And I thought well that's quite interesting, cos it's certainly not the kind*
47 *of thing that comes up during a kind of normal clinic consultation*" [N4]; "*One lady actually [said] it was more*
48 *her family that was the issue ...which she never had spoken about before*" [N6]. Eventually, the intervention
49 was regarded as educative and worthwhile: "*I do think that [it] has been a learning experience to me*"
50 [N3]; "*I found it [the time spent with the patient] really therapeutic... it really enhanced the relationship [with*
51 *the patient]... and it was quite an eye opener*" [N6].

1 In terms of ‘challenges of the study’, issues raised included some concerns that the questions were “too
2 many” or too much repetition was involved as the questions were not relevant at all time-points (“I
3 think initially the questions were fine and it certainly picked up a lot of things that needed to be picked up...
4 but I just think it was the second two legs of it that was a wee bit repetitive” [N6]), or that the consultations
5 would take too long because questions would trigger a more general than focussed discussion: “it was
6 very difficult to get them to focus on the last period of time... So there’s a lot of chat probably in between it
7 that wasn’t relevant to the actual study” [N1]. Additional challenges related to more general research
8 activities. For instance, one CNS commented on the time interval between assessments: “the time
9 between each visit could have been a wee bit longer” [N2]. Moreover, the numbers recruited were seen
10 as disappointing: “we all thought oh 10 patients – that’s a doodle, we’ll have no bother with that at all ...
11 and that just wasn’t the case” [N2].

12 ‘Suggestions for future work’ included broadening the intervention out: “...open it up a wee bit because I
13 felt at our clinics we have a lot of metastatic patients, and I felt we were pretty restricted with just the adjuvant”
14 [N3]. In addition, CNS felt the need to follow people for a longer time period: “I think on reflection I
15 would probably have wanted to start it when they started their treatment” [N5]; “I don’t know maybe 3
16 months or 6 months or something like that... after their treatment’s finished” [N4]; “then maybe at a follow-
17 up appointment you know 6 months after that” [N5]. One CNS felt that keeping the consultation face-
18 to-face was important, because of the personal nature of the issues discussed and also because “there’s
19 non-verbal cues that you pick up on as well” [N5].

20

21 Discussion

22 This study has shown that nurse-led, PROMs-driven consultations to identify and address the
23 supportive care needs of patients with CRC who transition from active chemotherapy to the initial
24 follow-up period appear to be feasible and acceptable to both patients and CNS. Our systematic
25 review identified more than 50 studies that demonstrated the variability and extent of unmet needs of
26 people with CRC across different phases of the illness trajectory (Kotronoulas et al., 2017). Young et
27 al. (Harrison et al., 2011b; Young et al., 2010) point out that, in comparison, “there is relatively little
28 interventional research to develop and evaluate strategies to address these needs.” Previous
29 interventions have targeted patients with CRC during either the immediate post-operative period
30 (Young et al., 2010) or survivorship (Macvean et al., 2007; Siegel et al., 1992). Somewhat differently,
31 our study aimed to address the needs of those transitioning from active chemotherapy to post-
32 treatment in line with clinical priorities identified by our study participants. This is an equally important
33 phase, where new or rekindled needs for information and emotional support may arise for patients
34 preparing to start another treatment modality; similarly, psychosocial, rehabilitation and daily living
35 needs may become more prominent for those who enter survivorship. The intervention provides a
36 mechanism by which gaps in clinical care at this transitional point could be identified and addressed
37 promptly.

38 Although the target goal of 30 participants in Phase 2 was not met, we were nevertheless able to
39 confirm availability and recruitment estimates for future use. Fluctuations in the numbers of patients
40 diagnosed/treated are a known factor to influence availability of research participants. We purposely
41 opted for inclusive eligibility criteria: this was translated into 4 eligible patients per month about to
42 enter the penultimate chemotherapy cycle. Broadening the scope of the intervention to involve newly
43 diagnosed patients and/or CRC survivors, could reliably increase patient availability. A modest
44 recruitment rate of 56% may have been the result of a challenging treatment period, illness
45 progression, competing research projects and/or the requirement for in-person attendance that
46 possibly deterred some patients from considering participation. The few studies that have evaluated
47 interventions to reduce unmet supportive care needs generally achieved higher recruitment rates
48 (>80%) (Harrison et al., 2011a, 2011b; Young et al., 2010), but the timing (post-operatively) and design
49 (telephone consultations) employed were different and might have been more appealing to
50 forthcoming participants. Conversely, retention rate was near perfect (93%), which is comparably
51 higher than rates reported in similar intervention studies. Potential reasons may include the relatively

1 short follow-up and relevant timing of the intervention. In the study by (Young et al., 2010), it was
2 research nurses who delivered a supportive care needs intervention for post-operative patients with
3 CRC as an adjunct to current services. In contrast, we relied on actual members of the clinical team
4 to incorporate the intervention as part of their clinical practice. This approach renders our findings
5 on retention rates and in-clinic assessment performance even more compelling and relevant to clinical
6 practice, thus further supporting feasibility and acceptability of the intervention. In Phase 2, six highly
7 experienced CNS were involved, thus increasing the odds for seamless delivery of the intervention. It
8 is acknowledged that this may not reflect the situation in other clinical settings, where staff shortages
9 may hinder intervention testing and implementation. However, we believe that, by applying the
10 intervention in real-life clinical circumstances and by keeping research support to a minimum, we were
11 able to establish a realistic view of the facilitators and barriers of implementing this intervention.

12 Intervention acceptability was also high. Completeness of PROM and case report form data exceeded
13 90% both within and across time-points. It was interesting to see that the item with the greatest
14 amount of missing data was the one about cognitive deficits. Being the last question printed on the
15 back of the SCNS sheet, we can assume that some patients simply missed it. Limited relevance is a
16 less likely possibility based on our review and empirical findings (Kotronoulas et al., 2017). In end-of-
17 study interviews, patients and health professionals expressed very positive opinions about the
18 intervention. Patients appreciated the opportunity for dedicated time with the CNS as it allowed them
19 to raise concerns and get sensitive and personalised help and advice. Patients endorsed the
20 standardised use of an easy-to-understand needs assessment PROM as a means to help them shortlist,
21 report and prioritise their needs, and as a reminder that no need is too unimportant to be discussed
22 with the CNS. Similar to CNS, patients agreed that timing of the intervention was appropriate and
23 relevant, which further underpins the high retention rates documented in the study. Moreover,
24 participating CNS perceived engagement in the collection and use of patient-reported data as an
25 enlightening and educative activity, enabling them to see beyond just side-effects, assess over time, and
26 investigate issues deeper. As with the majority of PROM-related research (Kotronoulas et al., 2014),
27 no specific clinical algorithms, guidelines or training were given to CNS to help them deal with patients'
28 needs. Owing to their clinical expertise, CNS were well prepared to address patients' needs.
29 Consecutive needs assessments were however perceived as repetitive. When used in practice, the
30 SCNS proved to be rather lengthy and incorporated items that CNS viewed as duplicates in repeated
31 measures. We cannot rule out the possibility that some of the CNS might have seen this as a downside
32 of their involvement, which might deter them from use of PROM data outside research. Moreover,
33 some nurses did feel unsure about how best to address concerns that were more complex and touch
34 upon deeper issues than those physical or practical. It is true that supplying CNS with additional
35 information on available resources as well as training in focussed problem-solving techniques could
36 increase intervention applicability and acceptability, also allowing for smoother involvement of the
37 more junior members of staff.

38 Our preliminary analyses also indicated that this type of intervention could be associated with (a) a
39 sizeable reduction in the total number of reported unmet needs, and (b) a small decrease in the
40 magnitude of expressed physical/daily living and psychosocial needs at the initial post-chemotherapy
41 period. The apparent reduction in the total number of expressed unmet needs over time could be the
42 result of either patients gradually recovering from chemotherapy or actual intervention effects taking
43 place, or both. It is reasonable to hypothesise that, to a certain extent, some patient needs were likely
44 to increase due to patients facing new challenges in the initial post-chemotherapy period. Thus, simply
45 relying on the natural course of patient recovery cannot provide a complete explanation for our
46 observations. It seems reasonable to presume that intervention effects have also taken place, in that
47 those new and/or re-emerging needs were identified and addressed during the first and second
48 consultation in preparation for patients' transition to the post-chemotherapy period. From T1 to T3,
49 at least 3 or 4 patients fewer (around 20%-30%) reported unmet needs, including fear of a cancer
50 metastasis, uncertainty about the future, financial concerns or concerns about their family coping with
51 the situation. One explanation could be that the intervention did work, in that CNS offered effective
52 help and support with such needs. Alternatively, at T3, some of the previously identified needs may

1 have not been relevant anymore. These preliminary estimates of intervention effectiveness will need
2 confirmation in a subsequent controlled trial.

3 As with previous longitudinal research (Lam et al., 2016), certain patient needs remained prominent
4 (and to an extent unmet) throughout our study. Dealing with fear of recurrence, lack of energy, and
5 the inability/difficulty to return to normal were ranked as top unmet needs regardless of time-point.
6 It may be that, due to the life-threatening nature of the illness and intensity of treatment, such needs
7 or concerns may be persistent and pervasive, and for that reason less amenable to interventions of
8 this type and/or duration. Bearing in mind that no specific training or additional resources were offered
9 to CNS, incorporating a referral algorithm could enable greater/better use of available resources and
10 more effective management of such patient needs.

11 Equally, it is interesting to see how specific needs became more relevant/prominent at post-
12 chemotherapy. These included changes to one's routine, lifestyle and sexual relationships, fighting
13 depression, getting control of one's situation, maintaining independence, or feeling useful to others
14 and the society. Such issues reveal patients' need for rehabilitation and adjustment. Such spikes in need
15 may counteract the intervention tested here. However, it is also possible that the intervention actually
16 facilitated a safe environment for patients to reflect on these needs and get support in a way that
17 superseded current clinical practice. In other words, one cannot rule out the possibility that the
18 observed prevalence rates related to these needs were suppressed because of intervention effects and
19 in comparison to usual care; this can only be regarded as a positive outcome that nonetheless warrants
20 confirmation in a future trial.

21 Finally, diverse over-time trajectories in SCNS domain scores were noted. Despite the absence of
22 statistically significant changes, the magnitude of patient needs in the physical/daily living and
23 psychological domains did show a gradual decline over time. Effect sizes were rather small, but
24 suggestive of satisfactory responsiveness to change. Information needs and needs for patient care and
25 support emerged as the least prominent in this patient group compared to scores on all other domains.
26 This can be explained by the timing of the intervention, whereby patients approaching the end of at
27 least two months of post-operative chemotherapy felt that they had the information necessary to feel
28 in control and confident to make decisions. Due perhaps to this fact, scores on these domains
29 remained stable over time and systematically lower than the scores of other domains. Interestingly,
30 the greatest fluctuation in over-time scores was observed for sexuality needs, with moderate positive
31 and negative effect sizes suggesting high sensitivity to change. We noted a curvilinear pattern of change,
32 whereby sexuality need scores dropped clinically significantly from the first to the second consultation
33 session, but then returned close to baseline levels after the end of chemotherapy. This pattern may
34 suggest a radical change in the nature and intensity of sexuality/intimacy needs from active treatment
35 to post-treatment that rendered nurses' advice and support to patients, though successful from T1 to
36 T2, insufficient to address new sexuality/intimacy challenges that may have been complicated by
37 additional social adjustment and rehabilitation issues. In addition to paying attention to sexuality needs
38 expressed close to the end of chemotherapy, a pro-active approach to management of future
39 'rehabilitation' sexuality/intimacy needs for this patient group may be beneficial. As part of the
40 intervention, nurse specialists could be trained to assess current sexuality needs, but also provide
41 education for anticipated, adjustment issues that involve sexuality, body image and intimacy, and
42 relationships with one's partner or the absence of a romantic relationship (Kotronoulas et al., 2009).

44 **Strengths and limitations**

45 In this study, we adopted a phased approach, whereby we thoroughly reviewed the existent literature
46 and subsequently engaged patients and health professionals as research collaborators. This technique
47 helped us to customise and refine aspects of the intervention in an attempt to meet users' preferences,
48 expectations and priorities, and increase the intervention's feasibility and acceptability. Second, we
49 relied on a widely used and well-validated PROM to collect information in a reliable and comprehensive
50 way. Third, we employed different sources of information to comprehensively investigate the study's

1 feasibility and acceptability, including observation, questionnaire and interview data. Last, evaluation of
2 the intervention with minimal research support and in clinical practice assimilation conditions increases
3 our confidence that implementation of such an intervention can be a realistic and achievable goal within
4 NHS.

5 The study should nonetheless be interpreted in the context of a number of key limitations.
6 Consultation appointments were not timed; therefore, we cannot reliably report the overall and
7 average time commitment for patients and CNS. Nevertheless, none of the participants reported the
8 intervention as time-consuming. To assess patients' cognitive needs, we developed and used an item
9 based on existing questionnaires. Although face validity of this new item was established, its
10 content/construct validity remains unknown. To make use of all available data, we relied on missing
11 values replacement via multiple imputation. Multiple imputation is the method of choice in dealing with
12 missing data, yet the possibility of under- or over-estimation cannot be entirely ruled out. With a
13 smaller than planned sample size, the accuracy of feasibility and/or effect size estimates might have
14 been compromised. This small sample size has also prevented us from testing the influence of
15 demographic/clinical characteristics as moderators of feasibility and unmet needs. Only 3 out of 12
16 consenting patients participated in end-of-study interviews. Although participation was more
17 influenced by patients not being contactable rather than expressly refusing attendance, one might
18 consider the available interview data as skewed towards more positive views and opinions. However,
19 this effect is likely to only be minimal given the high retention and data completeness rates. Finally, this
20 was a single-centre study, thus reflecting current facilitators and barriers in the implementation of
21 PROMs-driven supportive care intervention for people with CRC within one NHS board only.
22 Whether the feasibility and/or acceptability of this intervention are similar in diverse clinical contexts
23 requires further investigation.

25 **Implications for clinical practice and research**

26 PROM data should be regularly audited and assist in the provision of supportive care to people with
27 CRC and should be able to be accessed by all members of the multidisciplinary team. A standardised
28 needs assessment PROM could be implemented within clinical practice at the beginning and the end
29 of treatment, and during long-term follow-up, both for adjuvant and metastatic patients with CRC. In
30 the interest of implementation of this intervention, a concise, yet comprehensive and informative,
31 clinical tool may be more appropriate in busy clinical settings. Special attention should be given to
32 salient patient needs that may be heightened during transition to the post-chemotherapy period. Such
33 needs include dealing with changes to one's routine, lifestyle and sexual relationships, fighting
34 depression, getting control of one's situation, maintaining independence, or feeling useful to others
35 and the society. Colorectal CNS (particularly those junior ones) may benefit from formal education
36 with regard to pervasive concerns of this patient group (e.g. psychosocial adjustment and difficulty to
37 return to normal) and associated management strategies. Employing phone or Skype calls to deliver
38 consultations may facilitate patient attendance for those patients physically or otherwise unable or
39 limited to visit the hospital, and reduce workload associated with face-to-face consultations for CNS.

40 A pilot randomised controlled trial is warranted to provide preliminary evidence on the effectiveness
41 and cost-effectiveness of this PROMs-driven, nurse-led supportive care needs intervention. The
42 feasibility and acceptability of the use of electronic needs assessment PROMs (e.g. available via the
43 Internet or on tablet PCs) should be explored as an alternative means of administration and data
44 collection. The feasibility and acceptability of the use of automated reports/summaries/graphs of
45 expressed needs based on the use of electronic platforms to administer PROMs should be explored
46 as a less time-consuming means of data interpretation and communication between patients and health
47 professionals. Finally, the impact of PROMs-driven supportive care on important patient outcomes
48 (e.g. quality of life, self-efficacy, psychosocial adjustment, work presenteeism, and/or routine non-
49 work-related activities, survival) and health service utilisation outcomes (e.g. emergency presentation,
50 hospital re-admissions) should be established.

1

2 **Conclusions**

3 The use of PROMs by CNS in the delivery of supportive care to people with CRC appears to be
4 feasible and acceptable. Congruent with the literature, this study illustrates that CNS are key
5 professionals in the delivery of supportive care, and able to act upon information gleaned from needs
6 assessment PROMs used in clinical practice. Whilst the findings do provide some evidence to support
7 the future use of PROMs in this area, the results of this study are still tentative and warrant
8 confirmation in a larger randomised controlled trial in order to demonstrate the positive impact of
9 the delivery of PROMs-driven supportive care on patient outcomes.

Figure captions

Figure 1. Individual trajectories in numbers of unmet needs.

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Tables

Table I. Descriptive statistics

Variable		
Age (years)	Mean (SD)	64.1 (8.2)
	Median	65.5
	Range	51-75
	n (%)	
Age (years)	50-59	5 (35.7)
	60-69	4 (28.6)
	70+	5 (35.7)
Gender	Male	9 (64.3)
	Female	5 (35.7)
Educational attainment	High School	12 (85.8)
	Some college	1 (7.1)
	University	1 (7.1)
Employment	Employed	5 (35.7)
	Unemployed	2 (14.3)
	Retired	7 (50.0)
Marital status	Married/partnered	12 (85.8)
	Widowed	2 (14.3)
Cancer type	Colon	12 (85.8)
	Rectum	2 (14.3)
Cancer staging	I	2 (14.3)
	II (A or B)	2 (14.3)
	III (A, B, or C)	8 (57.1)
	IV	2 (14.3)
Surgery	Yes	9 (64.3)
Chemotherapy	Yes	14 (100.0)
Radiotherapy	Yes	4 (28.6)
Supportive care	Yes	0 (0.0)
Any comorbidities	Yes	0 (0.0)
ECOG PS	0 (fully active)	6 (42.9)
	I (restricted in strenuous physical activity)	8 (57.1)

Table 2. Over-time changes in the ranking of the most prevalent unmet needs identified at baseline (T1).

Item	T1 rank	T2 rank	T3 rank
Fears about the cancer spreading	1	2	3
Fears about the cancer returning	1	1	1
Lack of energy and tiredness	2	3	2
Not being able to do the things you used to do	2	3	2
Uncertainty about the future	2	6	5
Concerns about the worries of those close to you	2	4	3
Changes to your usual routine and lifestyle	3	4	1
Worry that the results of treatment are beyond your control	4	7	3
Concerns about the ability of those close to you to cope with caring for you	4	6	5
Concerns about your financial situation	4	8	6
Feeling bored and/or useless	5	5	2
Anxiety	5	8	5
Feeling down or depressed	5	5	3
Keeping a positive outlook	5	5	5
Feelings about death and dying	5	9	6

Table 3. Descriptive statistics of SCNS-LF59 domain scores (unstandardised and standardised scores)

Domains	Unstandardised scores			Standardised scores*		
	T1	T2	T3	T1	T2	T3
Physical/daily living						
Mean (SD)	15.1 (5.7)	14.5 (5.4)	13.3 (5.2)	29.1 (20.2)	26.8 (19.4)	22.4 (18.6)
Median	15.5	14.5	12.5	30.4	26.8	19.7
Range	7-24	7-22	7-25	0-60.7	0-53.6	0-64.3
Psychological						
Mean (SD)	50.0 (17.7)	48.9 (15.8)	44.9 (18.3)	31.8 (20.1)	30.6 (18.0)	26.1 (20.8)
Median	51.0	51.5	35.0	33.0	33.5	14.8
Range	23-77	25-70	25-82	1.1-62.5	3.4-54.5	3.4-68.2
Sexuality						
Mean (SD)	6.0 (1.8)	5.1 (2.6)	6.2 (2.3)	25.0 (15.3)	17.3 (21.8)	26.8 (19.4)
Median	6.0	5.0	6.0	25.0	16.7	25.0
Range	3-9	3-13	3-11	0-50.0	0-83.3	0-66.7
Health system and information						
Mean (SD)	26.9 (7.1)	26.2 (6.6)	26.1 (6.0)	19.9 (11.8)	18.7 (10.9)	18.5 (9.9)
Median	29.0	28.0	28.0	23.3	21.7	21.7
Range	15-37	15-33	15-36	0-36.7	0-30.0	0-35.0
Patient care and support						
Mean (SD)	13.1 (4.3)	12.1 (3.1)	12.9 (3.6)	15.9 (13.3)	12.7 (9.8)	15.2 (11.2)
Median	13.5	12.0	13.5	17.2	12.5	17.2
Range	8-21	8-16	8-17	0-40.6	0-25.0	0-28.1

*Standardised scores are based on unstandardised (original) domain scores, using the following formula: $(x-m) \cdot [100 / (m(k-l))]$, where x =unstandardised domain score; m =number of items on domain; k =value of the maximum response for each item. Unstandardised scores have possible values ranging as follows: physical/daily living=7-35, psychological=22-110, sexuality=3-15, health system and information=15-75; patient care and support=8-40. Standardised scores have possible values ranging from 0 to 100.

Table 4. Effect sizes of over-time changes in domain scores.

	ES.T1-T2	ES.T2-T3	ES.T1-T3
Physical/daily living	-0.11	-0.22	-0.33
Psychological	-0.06	-0.25	-0.29
Sexuality	-0.51	0.44	0.11
Health system and information	-0.10	-0.02	-0.12
Patient care and support	-0.23	0.25	-0.05

