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

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## Title Page

### Manuscript title

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

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## Abstract

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

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

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

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

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

### Highlights (for review)

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

## 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  
7 number of people may now live beyond CRC, but still experience the impact of illness and treatment  
8 on several aspects of their lives (Alacacioglu et al., 2010; Arndt et al., 2004; Wu and Snyder, 2011).  
9 The need to provide on-going and comprehensive supportive care to these individuals is therefore  
10 prominent (Jorgensen et al., 2012).

11 Research has shown that people with CRC have multiple unmet supportive care needs (Harrison et  
12 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  
23 facilitates timely management of symptoms, improved communication between patients and health  
24 professionals, increased shared decision-making, and greater patient satisfaction with care  
25 (Donaldson, 2004; Kotronoulas et al., 2014; Valderas and Alonso, 2008). Relevant literature indicates  
26 that nurses are the most appropriate health professionals to assess PROMs as they are more  
27 receptive to, and give greater weight to such information (Greenhalgh et al., 2005). There is also  
28 evidence to suggest that the use of PROMs can be enhanced by taking patients' and clinicians'  
29 **preferences into consideration when selecting such tools as this ensures that clinicians' priorities for**  
30 **care are consistent with those of 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  
34 supportive care needs of people with CRC, and **how this approach can impact** on patient outcomes  
35 and the clinical practice. Thus, we aimed to explore the feasibility and acceptability of the use of  
36 supportive care needs PROMs by colorectal cancer nurse specialists (CNS) in the delivery of  
37 supportive care to people with CRC receiving adjuvant chemotherapy.

38

## 39 Methods

40 After obtaining Research Ethics approval (14/VVS/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  
46 with 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  
12 data and describe response patterns for PROM items. Missing data were replaced using multiple  
13 imputation. To assess sensitivity to change, the mean, standard deviation and median of PROM  
14 subscale scores, and effect sizes of changes thereof were calculated. Effect sizes were calculated as  
15 the difference between a mid-point and baseline score (T1 to T2; T1 to T3) divided by the standard  
16 deviation of the baseline scores. Negative values reflected improvements in the number of standard  
17 deviations of the baseline scores. Effect sizes  $\geq 0.80$  were considered large, 0.50–0.79 moderate,  
18 0.20–0.49 small, and 0.00–0.19 very small (Kazis et al., 1989). Q-Q plots, histograms and Shapiro-  
19 Wilk's tests were used to check the assumption of normality in PROM subscale scores. Due to  
20 deviations from normality, Friedman ANOVA was used to test for statistical significance of changes  
21 in PROM subscale scores over 3 assessment points (with post-hoc comparisons). The level of  
22 significance was set at 0.05.

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

## 29 **Results**

### 30 **Phase 1**

#### 31 *Systematic literature review*

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

40 Based on the above findings and drawing on our database of needs assessment PROMs, we  
41 concluded that the following six PROMs would be discussed in subsequent focus groups: Supportive  
42 Care Needs Survey – Short Form 34 (SCNS-SF34) (Boyes et al., 2009); Problems Checklist (Cull et  
43 al., 1995); Cancer Needs Questionnaire – Short Form (Cossich et al., 2004); Psychosocial Needs  
44 Inventory (McIlmurray et al., 2001); Cancer Survivors Unmet Needs (Hodgkinson et al., 2007);  
45 Functional Assessment of Cancer Therapy-Colorectal concerns subscale (FACT-C) (Ward et al.,  
46 1999). These PROMs were selected for their brevity and comprehensiveness in assessing patients'  
47 supportive care 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.  
10 The group talked about the supportive role of their families and friends was in helping them to keep  
11 a positive outlook. One participant explained: "A sympathetic ear, that's really what I needed at the  
12 time". Others admitted trying to 'protect' their families, thereby avoiding communication although  
13 they may have needed it. When queried, participants revealed that their social needs had not been  
14 thoroughly assessed. Nonetheless, the group spoke about the need to return to normal, to find new  
15 meaning in 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  
18 treatment and then to follow-up, but stressed the need for on-going support for patients who are in  
19 the post-treatment phase. The group agreed that people with CRC need to have a clinician  
20 responsible for their care, one that they know they can contact if any issues arise. The group did see  
21 themselves as this front-line clinician. One CNS spoke about variability in the information needs of  
22 this patient population, but acknowledged that such information must be clear, appropriate, accurate  
23 and consistent. The group described how patients strive to know more about their illness and about  
24 the care plan for them: they want to know what happens next and how they can be supported (e.g.  
25 with dietary changes, with coping with a stoma or with stoma care). Echoing patients' views, nurses  
26 asserted that patients need help with psychological and emotional issues, family support, and  
27 practical issues, including getting help with finances, work or child support. The group agreed that  
28 use of a needs assessment PROM would allow them to structure their assessments and better  
29 understand what needs 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  
32 agreed that they would prefer using an even more comprehensive tool, such as the original 59-item  
33 SCNS (Bonevski et al., 2000; Sanson-Fisher et al., 2000). This was regarded a better option than  
34 combining the SCNS-SF34 with another PROM from the pool. After consensus was reached, a 60<sup>th</sup>  
35 item was also developed to assess patients' cognitive needs ("Not being able to remember things  
36 and/or not being 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  
38 perceived unmet needs of cancer patients (Bonevski et al., 2000; Sanson-Fisher et al., 2000).  
39 Respondents are asked to indicate their level of need for help over the last month on a 1-5 scale  
40 (1=not applicable, 2=satisfied, 3=low need, 4=moderate need, 5=high need). Items are classified into  
41 five (factor-analysis-derived) domains of need: (1) psychological (22 items); (2) health system and  
42 information (15 items); (3) physical and daily living (7 items); (4) patient care and support (8 items);  
43 and (5) sexuality (3 items). Four additional items are not incorporated within any domain, but are  
44 included as clinically important. In our study, internal consistency reliability was very good  
45 (Cronbach's alpha  $\geq 0.80$ ) for almost all domains and time-points (Suppl.1).

## 46 **Phase 2**

### 47 *Feasibility and acceptability estimates*

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



1 Fourteen patients provided written informed consent. A recruitment rate of 56% (14/25) and an  
2 average recruitment pace of 2 participants per month were achieved. Thirteen patients (93%)  
3 completed all 3 study assessments, with one patient withdrawing soon after baseline assessment due  
4 to declining health 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  
21 need') for individual patients, confirming high variability in this sample. At T1, a median 15.5 (range 0-  
22 40) unmet needs per patient were reported, accounting for a total of 219 reported needs across the  
23 study sample. These figures slightly dropped to a median 14.5 (range 0-30) unmet needs per patient  
24 at T2 (total 173; 21% reduction from T1), with a further decline at T3 (median 5.5, range 0-38; total  
25 148; 32% reduction from T1).

26 Following two consecutive consultations, the prevalence of unmet needs dropped at or below 50%  
27 at 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  
31 steadily from T2 to T3. Concerns about the family, concerns about financial issues, and anxiety and  
32 depressed mood were also prevalent needs at baseline. From T2 to T3, a rise in 'rehabilitation'  
33 needs was also noted, whereby patients indicated their need to accommodate changes in usual  
34 routine and lifestyle, feel in control of their situation, deal with concerns about losing their  
35 independence, keep a positive outlook, and find ways to become 'useful' again. From baseline to T3,  
36 an upward trend in the prevalence of patients' need to get help with depressed mood was noted (a  
37 rise of two places in the relevant ranking). Conversely, patients' need to get help with financial issues  
38 was less prevalent at T2 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  
42 of physical/daily living needs and psychological needs from T1 to T3. No particular trends were  
43 found for information needs or patient care/support needs. Mean scores of the sexuality needs  
44 domain declined 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  
46 magnitude of needs), but overall very small (Table 4). Small effect sizes were found for the change in  
47 physical/daily living needs scores from T1 to T3 (-0.33), the change in psychological needs scores  
48 from T1 to T3 (-0.29), and the change in patient care/support needs scores from T1 to T2 (-0.21).  
49 The only moderate effect size was found for the change in sexuality needs scores from T1 to T2 (-

1 0.51). No statistically significant over-time changes were found for any of the SCNS domains of need  
2 (all  $p > 0.05$ ; **Suppl.3**).

### 3 *End-of-study interviews: Patients*

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

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

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

### 39 *End-of-study interviews: Colorectal CNS*

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

42 Within the '*using PROMs in practice*' theme, the CNS estimated that on average consultations lasted  
43 30-40 minutes, noting how the intervention became easier to deliver after a few consultations and as  
44 they got more confident with the process. All CNS agreed that, in most instances, they were able to  
45 deal with the issues raised either by using their own resources or by referring to other services. The  
46 CNS expressed how helpful it was to use the tool to tease out more issues with the patients than  
47 they would normally: "*[it] initiates conversations that are deeper*" [N3]; "*It was certainly good to have a*  
48 *prompt...*" [N5]. They also commented on how they were made aware of more patient needs: "*[he*  
49 *was] on chemotherapy and he couldn't have sexual contact with his wife... he's an older gentleman, so you*  
50 *don't kind of think about these things. And I thought well that's quite interesting, cos it's certainly not the kind*

1 of thing that comes up during a kind of normal clinic consultation” [N4]; “One lady actually [said] it was  
2 more her family that was the issue ...which she never had spoken about before” [N6]. Eventually, the  
3 intervention was regarded as educative and worthwhile: “I do think that [it] has been a learning  
4 experience to me” [N3]; “I found it [the time spent with the patient] really therapeutic... it really enhanced  
5 the relationship [with the patient]... and it was quite an eye opener” [N6].

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

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

## 26 Discussion

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

42 Although the target goal of 30 participants in Phase 2 was not met, we were nevertheless able to  
43 confirm availability and recruitment estimates for future use. Fluctuations in the numbers of patients  
44 diagnosed/treated are a known factor to influence availability of research participants. We purposely  
45 opted for inclusive eligibility criteria: this was translated into 4 eligible patients per month about to  
46 enter the penultimate chemotherapy cycle. Broadening the scope of the intervention to involve  
47 newly diagnosed patients and/or CRC survivors, could reliably increase patient availability. A modest  
48 recruitment rate of 56% may have been the result of a challenging treatment period, illness  
49 progression, competing research projects and/or the requirement for in-person attendance that  
50 possibly deterred some patients from considering participation. The few studies that have evaluated

1 interventions to reduce unmet supportive care needs generally achieved higher recruitment rates  
2 (>80%) (Harrison et al., 2011a, 2011b; Young et al., 2010), but the timing (post-operatively) and  
3 design (telephone consultations) employed were different and might have been more appealing to  
4 forthcoming participants. Conversely, retention rate was near perfect (93%), which is comparably  
5 higher than rates reported in similar intervention studies. Potential reasons may include the  
6 relatively short follow-up and relevant timing of the intervention. In the study by (Young et al.,  
7 2010), it was research nurses who delivered a supportive care needs intervention for post-operative  
8 patients with CRC as an adjunct to current services. In contrast, we relied on actual members of the  
9 clinical team to incorporate the intervention as part of their clinical practice. This approach renders  
10 our findings on retention rates and in-clinic assessment performance even more compelling and  
11 relevant to clinical practice, thus further supporting feasibility and acceptability of the intervention. In  
12 Phase 2, six highly experienced CNS were involved, thus increasing the odds for seamless delivery of  
13 the intervention. It is acknowledged that this may not reflect the situation in other clinical settings,  
14 where staff shortages may hinder intervention testing and implementation. However, we believe  
15 that, by applying the intervention in real-life clinical circumstances and by keeping research support  
16 to a minimum, we were able to establish a realistic view of the facilitators and barriers of  
17 implementing this intervention.

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

44 Our preliminary analyses also indicated that this type of intervention could be associated with (a) a  
45 sizeable reduction in the total number of reported unmet needs, and (b) a small decrease in the  
46 magnitude of expressed physical/daily living and psychosocial needs at the initial post-chemotherapy  
47 period. The apparent reduction in the total number of expressed unmet needs over time could be  
48 the result of either patients gradually recovering from chemotherapy or actual intervention effects  
49 taking place, or both. It is reasonable to hypothesise that, to a certain extent, some patient needs  
50 were likely to increase due to patients facing new challenges in the initial post-chemotherapy period.  
51 Thus, simply relying on the natural course of patient recovery cannot provide a complete  
52 explanation for our observations. It seems reasonable to presume that intervention effects have also  
53 taken place, in that those new and/or re-emerging needs were identified and addressed during the

1 first and second consultation in preparation for patients' transition to the post-chemotherapy  
2 period. From T1 to T3, at least 3 or 4 patients fewer (around 20%-30%) reported unmet needs,  
3 including fear of a cancer metastasis, uncertainty about the future, financial concerns or concerns  
4 about their family coping with the situation. One explanation could be that the intervention did  
5 work, in that CNS offered effective help and support with such needs. Alternatively, at T3, some of  
6 the previously identified needs may have not been relevant anymore. These preliminary estimates of  
7 intervention effectiveness will need confirmation in a subsequent controlled trial.

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

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

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

49



## 1 Strengths and limitations

2 In this study, we adopted a phased approach, whereby we thoroughly reviewed the existent  
3 literature and subsequently engaged patients and health professionals as research collaborators. This  
4 technique helped us to customise and refine aspects of the intervention in an attempt to meet users'  
5 preferences, expectations and priorities, and increase the intervention's feasibility and acceptability.  
6 Second, we relied on a widely used and well-validated PROM to collect information in a reliable and  
7 comprehensive way. Third, we employed different sources of information to comprehensively  
8 investigate the study's feasibility and acceptability, including observation, questionnaire and interview  
9 data. Last, evaluation of the intervention with minimal research support and in clinical practice  
10 assimilation conditions increases our confidence that implementation of such an intervention can be  
11 a realistic and achievable goal within NHS.

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

## 32 Implications for clinical practice and research

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

47 A pilot randomised controlled trial is warranted to provide preliminary evidence on the effectiveness  
48 and cost-effectiveness of this PROMs-driven, nurse-led supportive care needs intervention. The  
49 feasibility and acceptability of the use of electronic needs assessment PROMs (e.g. available via the  
50 Internet or on tablet PCs) should be explored as an alternative means of administration and data

1 collection. The feasibility and acceptability of the use of automated reports/summaries/graphs of  
2 expressed needs based on the use of electronic platforms to administer PROMs should be explored  
3 as a less time-consuming means of data interpretation and communication between patients and  
4 health professionals. Finally, the impact of PROMs-driven supportive care on important patient  
5 outcomes (e.g. quality of life, self-efficacy, psychosocial adjustment, work presenteeism, and/or  
6 routine non-work-related activities, survival) and health service utilisation outcomes (e.g. emergency  
7 presentation, hospital re-admissions) should be established.

8

## 9 **Conclusions**

10 **The use of** PROMs by CNS in the delivery of supportive care to people with CRC **appears to be**  
11 feasible and acceptable. Congruent with the literature, this study illustrates that CNS are key  
12 professionals in the delivery of supportive care, and able to act upon information gleaned from needs  
13 assessment PROMs used in clinical practice. Whilst the findings do provide some evidence to  
14 support the future use of PROMs in this area, the results of this study are still tentative and warrant  
15 confirmation in a larger randomised controlled trial in order to demonstrate the positive impact of  
16 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		
<b>Age (years)</b>	Mean (SD)	64.1(8.2)
	Median	65.5
	Range	51-75
	<b>n (%)</b>	
<b>Age (years)</b>	50-59	5 (35.7)
	60-69	4 (28.6)
	70+	5 (35.7)
<b>Gender</b>	Male	9 (64.3)
	Female	5 (35.7)
<b>Educational attainment</b>	High School	12 (85.8)
	Some college	1 (7.1)
	University	1 (7.1)
<b>Employment</b>	Employed	5 (35.7)
	Unemployed	2 (14.3)
	Retired	7 (50.0)
<b>Marital status</b>	Married/partnered	12 (85.8)
	Widowed	2 (14.3)
<b>Cancer type</b>	Colon	12 (85.8)
	Rectum	2 (14.3)
<b>Cancer staging</b>	I	2 (14.3)
	II (A or B)	2 (14.3)
	III (A, B, or C)	8 (57.1)
	IV	2 (14.3)
<b>Surgery</b>	Yes	9 (64.3)
<b>Chemotherapy</b>	Yes	14 (100.0)
<b>Radiotherapy</b>	Yes	4 (28.6)
<b>Supportive care</b>	Yes	0 (0.0)
<b>Any comorbidities</b>	Yes	0 (0.0)
<b>ECOG PS</b>	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
<b>Physical/daily living</b>						
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
<b>Psychological</b>						
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
<b>Sexuality</b>						
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
<b>Health system and information</b>						
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
<b>Patient care and support</b>						
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

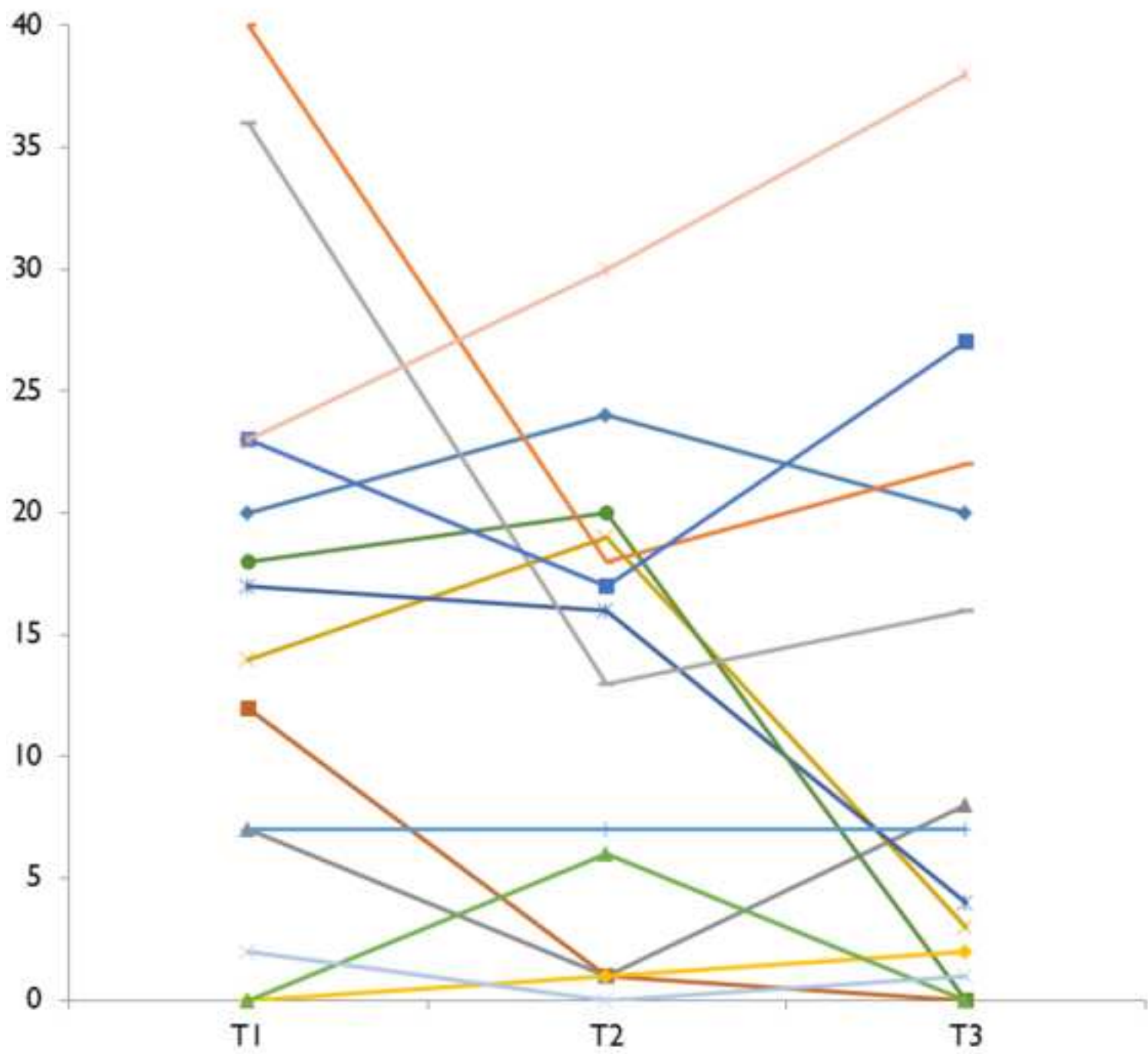
\*Standardised scores are based on unstandardised (original) domain scores, using the following formula:  $(x-m) \cdot [100 / (m(k-1))]$ , where  $x$ =unstandardised domain score;  $m$ =number of items on domain;  $k$ =value of the maximum response for each item. Unstandardised scores have possible values 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.

	<b>ES.T1-T2</b>	<b>ES.T2-T3</b>	<b>ES.T1-T3</b>
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

Figure 1  
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### **Conflict of interest**

None.

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**Supplementary Material (for publication online only)**

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