

## Title page

Employing patient-reported outcome (PRO) measures to support newly diagnosed patients with melanoma: Feasibility and acceptability of a holistic needs assessment intervention

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## Abstract

**Purpose:** Living with a melanoma diagnosis can be challenging. We aimed to assess the feasibility, acceptability, and perceived value of a nurse-led intervention that utilised patient-reported outcome (PRO) measures to identify and address the supportive care needs of newly diagnosed patients with Stage I/II melanoma over the first 4 months post-diagnosis.

**Methods:** We conducted an exploratory, repeated-measures, single-arm, feasibility trial. One baseline (4 weeks post-diagnosis; T1) and one follow-up intervention session (4 weeks after wide local excision; T3) took place, two months apart. Patient survey data were collected monthly, at four assessment points (T1-T4), followed by exit interviews.

**Results:** A recruitment rate of 55% (10/18) was achieved. The skin cancer nurse specialist (CNS) performed 19 in-clinic patient assessments within 6 months. One patient missed their follow-up intervention session (90% retention rate). Three participants (30%) were lost to follow-up at T4. Patients endorsed the standardised use of easy-to-use PRO measures as a means to help them shortlist, report and prioritise their needs. The CNS viewed the intervention as a highly structured activity that allowed tailoring support priority needs. A sizeable reduction in information needs was found from T1 to T4 (Standardised Response Mean [SRM] change=-0.99;  $p<0.05$ ). From T1 to T2, significant reductions in psychological (SRM change=-1.18;  $p<0.001$ ), practical (SRM change=-0.67;  $p<0.05$ ) and sexuality needs (SRM change=-0.78;  $p<0.05$ ) were observed.

**Conclusions:** The intervention appears to be feasible in clinical practice and acceptable to both patients with newly diagnosed melanoma and clinicians. Future research is warranted to test its effectiveness against standard care.

**Keywords:** Melanoma; supportive care needs; patient-reported outcome measures; cancer nurse specialist; feasibility; acceptability

### Highlights (for review)

- Nurse-led, PRO measure-driven consultations to identify and address the supportive care needs of newly diagnosed patients with melanoma are feasible and acceptable in clinical practice.
- Patients endorsed the standardised use of easy-to-use PRO measures as a means to help them shortlist, report and prioritise their needs.
- The skin CNS viewed the intervention as a highly structured activity that allowed tailoring support priority needs.
- The intervention could be associated with (a) reduction in information needs from the point of diagnosis throughout the first four months post-diagnosis, and (b) reduction in psychological, patient care and support and sexuality needs in the month following the baseline intervention session.

## Background

The past decades have seen a steady increase in annual rates of melanoma within the UK (Arnold et al., 2014). In 2012, 14,445 people in the UK (4.4% of all cancer cases) were diagnosed with melanoma (International Agency for Research on Cancer, 2012), which is now ranked fifth behind the leading cancers of breast, lung, colon/rectum and prostate (International Agency for Research on Cancer, 2012). Living with and living beyond melanoma can be challenging (Hajdarevic et al., 2014); yet, little is known about the specific healthcare needs of this patient population. Recent evidence suggests that up to 25% of patients may have unmet needs in the mid- to long-term after primary treatment (Molassiotis et al., 2014). Negative psychosocial effects of a melanoma diagnosis may include emotional hardship due to altered body image, adverse effects on relationships, fear of the sun, uncertainty about the future, and on-going symptoms such as pain and lymphedema (Stamatakis et al., 2015). Effectively supporting people with melanoma means offering nursing care that takes their healthcare needs into consideration (Hansen, 2014).

Comprehensive needs assessments are now considered an important component of cancer care practice (National Cancer Action Team, 2013; Young et al., 2012). Key government initiatives and policy guidelines advocate for the needs of people with cancer (Department of Health, 2007; National Cancer Action Team, 2013; National Institute for Clinical Excellence, 2004; NHS Scotland, 2008; Scottish Government, 2016) and skin cancer (Hansen, 2014) being addressed to minimise distress, improve the experience of care, and reduce healthcare costs through effective self-management. Such needs assessments are often facilitated through use of self-report questionnaires –known as patient-reported outcome (PRO) measures (Valderas and Alonso, 2008)– that collect information from care recipients about their perceived healthcare needs or concerns (Richardson et al., 2007). Clinicians can use this information to offer care that is tailored to a person's unique needs (Kotronoulas et al., 2017; Kotronoulas et al., 2017b; Kotronoulas et al., 2014).

There is evidence, however, suggesting that clinicians in busy clinical settings often fail to assess patients' needs and make appropriate and timely referrals (Kasparian, 2013). One reason may be the fiscal and human resource challenges that healthcare systems currently face, which could deter clinical teams from implementing novel care interventions. Another reason may be that clinicians do not systematically use tools into their current workflows that can help them identify one's unmet needs. Enhancing care in busy clinical settings means meeting end users' (be it care recipients or clinicians) requirements, priorities and expectations for care interventions that are low-cost/maintenance and easy to learn/deliver (Evans-Lacko et al., 2010; Francke et al., 2008; Mair et al., 2012; Scottish Intercollegiate Guidelines Network, 2015).

Given the afore-mentioned gaps, we aimed to test a nurse-led, PRO measures-driven intervention to enhance identification and management of the supportive care needs of people with newly diagnosed melanoma. Nurses are considered to be the most appropriate health professionals to assess PRO measures as they are more receptive to and give greater weight to such information (Greenhalgh et al., 2005). Therefore, the aim of this study was to assess the feasibility, acceptability and perceived value of a needs assessment intervention for newly diagnosed patients with Stage I or II melanoma over the first four months post-diagnosis. Secondary objectives included exploration of (a) the prevalence and intensity of reported supportive care needs and (b) patterns of change in patients' supportive care needs over time.

In accordance to the objectives above, the primary research questions were as follows:

1. What is the feasibility of a PRO measure-driven, nurse-led needs assessment/management intervention for newly diagnosed patients with melanoma in terms of patient availability/recruitment, time and resource requirements, missing data, and patient retention?
2. What is the acceptability of the intervention for newly diagnosed patients with melanoma in terms of adherence, perceived burden, and timing?
3. What is the perceived value of the intervention in supporting patients with melanoma and enhancing health care services offered?

Secondary research questions included the following:

4. What is the prevalence of supportive care needs of newly diagnosed patients with melanoma within the first 4 months after initial diagnosis?

5. How do supportive care needs of patients with melanoma change within the first 4 months after initial diagnosis when participating in the intervention? What is the extent of any change?

## **Methods**

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement was employed to guide reporting of this study (von Elm et al., 2007). The study received a favourable ethical opinion from the West of Scotland REC 3 (15/WS/0226).

### ***Study Design and Setting***

An exploratory, repeated-measures, single-arm, feasibility trial was conducted at out-patient clinics within one NHS board in Scotland. The adopted study design is particularly suitable for early-phase exploration of an intervention's feasibility and acceptability.

### ***Sample***

**Patients:** A convenience sample of newly diagnosed patients with melanoma was identified by members of the melanoma multidisciplinary team and recruited during weekly meetings. Patients were invited to take part if they were: (a) Diagnosed with melanoma Stage I or II regardless of tumour thickness. (b) Within 1 month post-initial diagnosis following a multidisciplinary team meeting. (c) Aged 18 years or over. (d) Deemed by a member of the multidisciplinary team to be physically and psychologically fit to participate. (e) Able to read and write English. (f) Able to provide written informed consent. Patients not meeting the afore-mentioned criteria were excluded.

**Health Professionals:** The skin cancer nurse specialist employed within the participating NHS board was invited to the study and asked to provide written informed consent.

### ***The intervention***

The intervention consisted of (a) a pack of "intervention PRO measures" that aimed to identify the supportive care needs of study participants, and (b) face-to-face patient consultations with the skin cancer nurse specialist that were driven by information gleaned from the intervention PRO measures. The intervention PRO measures pack comprised the National Comprehensive Cancer Network's (NCCN) Distress Thermometer and Problem Checklist (DT&PC) (National Comprehensive Cancer Network, 2012), and the Supportive Care Needs Survey-Melanoma module (SCNS-Melanoma) (McElduff et al., 2004). Combining these validated and brief tools into an 'intervention PRO measure' ensured that both generic and melanoma-specific needs can be identified quickly during consultations.

At the time of each intervention session, participants were asked to complete the intervention PRO measures in a quiet room in the hospital immediately prior to their consultation with the nurse specialist. Completed intervention PRO measures were then passed on to the nurse specialist for review. The subsequent consultation was based on information collected on priority supportive care needs that was used to direct nursing actions, provide tailored support and intervene accordingly. At the end of the consultation, the nurse specialist documented all interventions initiated and actions taken in a case report form. The nurse specialist was given no specific advice about how to respond to patient needs.

Implementation of this person-centred model was further enhanced by working with people with melanoma throughout the study in an attempt to ensure that the intervention met their preferences and priorities (Carr et al., 2003; Kotronoulas et al., 2017; 2017b; Ruland, 1998; Ruland et al., 1997).

### ***Procedures***

All eligible patients were thoroughly informed about the purposes and procedures of the study, and provided written informed consent. Patients participated in the study over four, equally spaced (monthly) time-points. This timeline was chosen to allow sufficient time for feasibility testing, whilst minimising the attrition rate. Each patient received the intervention twice. Each intervention session

was followed by a follow-up assessment that enabled investigation of changes in supportive care needs and associated outcomes to be examined over time.

- **Baseline/Intervention Session 1 (T1):** One month after the multidisciplinary team meeting, when melanoma diagnosis had been confirmed following pathological assessment of the excised lesion, participants were asked to attend the clinic to receive the intervention. They completed the intervention PRO measures and the Supportive Care Needs Survey-Short Form 34 (SCNS-SF34) (Boyes et al., 2009) prior to their consultation with the nurse specialist.
- **Follow-up Assessment 1 (T2):** Two months after the multidisciplinary team meeting, participants were sent the SCNS-SF34 to complete at home and return via pre-paid post.
- **Intervention Session 2 (T3):** Three months after the multidisciplinary team meeting, participants attended the clinic for a second intervention session. This visit coincided with the standard review appointment as scheduled for patients with melanoma within the participating NHS board, which is set around the time of wide local excision and possibly lymph node removal. Patients completed the intervention PRO measures and the SCNS-SF34 prior to their consultation with the nurse specialist.
- **Follow-up assessment 2 (T4):** Four months after the multidisciplinary team meeting, participants were sent a final SCNS-SF34 to complete at home and return via pre-paid post.

At the end of the study, the nurse specialist and a subset of study participants were invited to one-to-one, semi-structured, exit interviews to explore their opinions/views about the intervention and its perceived value in clinical practice and cancer care.

### **Instrumentation**

To address the primary aim of the study (Research Questions 1-3), a combination of different sources were employed including clinical audit data, patient survey data (via an author-developed form), and interview data from patients and/or health professionals. Feasibility, acceptability and perceived value parameters included the following: recruitment/refusal rates; reasons for refusal; attrition rates and reasons for attrition; feasibility of eligibility criteria; number of eligible patients; required time and resources to recruit; missing data due to non-response (overall and per time-point); missing data within returned PRO measures; time to complete PRO measures; patient perceived burden; feasibility of time-points/timing of intervention; acceptability of time-points/timing of intervention; acceptability of PRO measures; estimated duration of intervention sessions; perceived usefulness/value of intervention; implementation of intervention; adherence to intervention; and number of delays in consultation appointments/cancellation of consultation appointments. A demographic and clinical characteristics form was used to collect baseline demographic/clinical data for each participant.

The NCCN's DT&PC (National Comprehensive Cancer Network, 2012) consists of a visual analogue scale (thermometer) that measures patient distress (0-10) and a 21-item problem checklist that identifies specific etiologies of distress, including practical, spiritual, physical, emotional, and family problems.

The SCNS-SF34 consists of 34 items, each of which asks respondents to indicate their level of need for help during the preceding month (Boyes et al., 2009). Items are scaled from 1 to 5 (1="not applicable"; 2="satisfied"; 3="low need"; 4="moderate need"; 5="high need"). Each item was considered to represent "some unmet need" if a score of 3, 4, or 5 was obtained. Items on the SCNS-SF34 are grouped into 5 domains of need: health systems and information (11 items), psychological (10 items), physical and daily living (5 items), patient care and support (5 items), and sexuality (3 items). The SCNS supplementary melanoma-specific module comprises 12 items, with wording and response format similar to the SCNS-SF34, that examine needs specific to people with melanoma (McElduff et al., 2004).

### **Sample size**

Sample sizes of 24-50 participants have been recommended for early feasibility testing (Julious, 2005; Sim and Lewis, 2012). Taking into consideration overall patient admissions and resource availability, we considered a sample size of ≤30 patients with melanoma adequate to explore feasibility of our intervention. In addition, ≤10 of all patients recruited were planned to be invited to

participate in exit interviews. This sample size was regarded adequate based on the principles of data saturation and variability for thematic content analysis (Guest et al., 2006).

### **Data analysis**

**Feasibility evaluation:** Descriptive statistics and graphs were used to analyse data relating to primary outcomes. Continuous and/or interval-ratio variables are presented as means, standard deviation (or medians, interquartile range depending on normality) and range. Categorical variables will be presented as frequencies and percentages.

**Outcomes evaluation:** SCNS-SF34 data were analysed using descriptive statistics and graphs. Frequency counts for each response were generated to describe response patterns for all measures, and quantify missing data. Missing data within returned PRO measures were treated with mean substitution. Three missingness dummy variables were created (1=missing, 0=not missing) to examine whether significant differences between responders and non-responders at T2, T3 and T4 existed on demographic, clinical and baseline SCNS-SF34 data. No skewed patterns of missing data due to non-response/attrition were found. Hence, data were considered to be missing at random, and regression imputation was used to replace them. Total and subscale scores were calculated where appropriate. Q-Q plots, histograms and Shapiro-Wilk's tests were used to check the assumption of normality in total scores. Deviations from normality were noted, therefore non-parametric tests were performed. Wilcoxon signed rank tests were used to investigate change in SCNS-SF34 domain scores from baseline (T1) to T2 and T4, and from T3 to T4. The extent of intervention-related change over time in patient supportive care needs was explored through calculation of Standardised Response Means (SRM) (Stratford and Riddle, 2005). SRM were calculated as the ratio of individual change to the standard deviation of that change (Crosby et al., 2003), after change scores (T2-T1, T4-T3, T4-T1) had been calculated. SRM were interpreted as 'trivial' (<0.20), 'small' ( $\geq 0.20$  to <0.50), 'moderate' ( $\geq 0.50$  to <0.80), or large ( $\geq 0.80$ ) (Cohen, 1988). To avoid misinterpretation of SRM, the correlation between repeated measurements (baseline and follow-up) was used to determine the SRM and then Cohen's thresholds were applied. SRM\* was standardised by a value  $\sqrt{2(1-r)}$ , where r was the correlation between baseline and any follow-up measurement ( $SRM^* = SRM / \sqrt{2(1-r)}$ ) (Middel and van Sonderen, 2002). All tests were two-tailed at the 0.05 level of significance. IBM SPSS statistical software was utilised to aid analyses.

**Qualitative analysis of exit interviews:** Interviews were audio-recorded and transcribed verbatim. Themed categories were identified by one researcher based on the research objectives. Thematic content analysis (Braun and Clarke, 2014, 2006) is a useful approach for answering questions about the salient issues for a particular group of respondents or for identifying typical responses. The software analysis package QSR NVivo was used to aid the organisation of the data.

### **Results**

Between March 2016 and June 2016, 18 patients with melanoma were considered eligible and invited to the study. Eight patients declined participation. Reasons for refusal were lack of time (n=4), additional health issues (n=2), or lack of interest (n=2). The final sample consisted of 10 participants (55.6%).

Participants were typically women (80%), aged 52 years, married or partnered (75%), employed (62.5%) and with college/university education (80%). Most participants resided 6-20 miles away from the hospital (**Table 1**).

Melanoma diagnosis had been confirmed a median of 33 days before participation in the study. Eight out of ten participants had a stage I disease, and for seven out of ten the tumour was <1 mm thick (Breslow). Nine patients had undergone surgery, whilst six patients had also undergone wide local excision. ECOG performance status was assessed as very good (40%) to excellent (60%).

#### **Estimates of intervention feasibility (RQ 1)**

A recruitment rate of 55% (10/18) and an average recruitment pace of 2-3 participants per month were achieved. Four patients (40%) completed all 4 PRO measure assessments.

The nurse specialist performed a total of 19 in-clinic patient assessments within a period of 6 months.

Only one patient missed their follow-up intervention session, which had to be cancelled. A retention rate of 90% was therefore achieved. None of the other nine patients asked to re-schedule their appointment for the follow-up intervention session. Intervention sessions were not time recorded, but in their majority they lasted 10-30 minutes depending on the issues identified and discussed. Full documentation records (case report form data) were received for all 19 in-clinic assessments. Completeness of background data reached 96%.

Participation rates during the study were variable (T2 60%; T3 80% of expected PRO measure packs returned). Three participants were lost to follow-up, but that was only at T4 (attrition rate 30%). No contact was made possible with these individuals, thus no reasons for attrition were recorded. An overall participation rate of 77.5% was achieved, with 31 PRO measure packs returned out of a maximum theoretical of 40 (Table 2). Completeness of intervention PRO measures reached 100% at baseline, and remained high at the time of intervention session 2 (98.8-100%).

### **Intervention acceptability and perceived value (RQ 2 and 3)**

Exit interviews were conducted with the nurse specialist and a subsample of patients (n=6). Main themes included experiences of the intervention, needs raised during consultations, and experiences of involvement in research.

All of the patients found the intervention PRO measures quick and easy to complete and understand:

*"...very quickly actually, I was quite surprised, it was quicker than I was expecting [...] I found it very easy to answer." [P1] "Oh, it was easy [to complete], no, it didn't take any time at all..." [P3]*

*"They were absolutely fine. [They took] about ten minutes or so [to fill out]... it was clear and, you know, very well laid out" [P4]*

Two patients also agreed that having a space for any additional comments at the end of the intervention PRO measures would be useful for people to log any more thoughts: *"Jot it down, yes, that would have been, probably be more helpful" [P6].*

Patients agreed that the questions asked in the intervention PRO measures were *"...the basis for the start of a conversation" [P8].* Albeit relevant overall, question relevance was felt to be dependent on the individual's circumstances and timing of completion:

*"...and one day I can experience three and four different types o' feelings [...] so a lot depends on just what part o' the, time o' the day it is or how you're feeling." [P1]*

*"...where I said there was nothing, I didn't feel anxious and I didn't feel any, that I needed any help, it then, then changed..." [P3]*

Patients found that completing the PRO measures was useful in that it provided a record of their concerns, thereby overcoming the common and frustrating problem of forgetting to raise all their needs during a consultation, and only realising this at some later point after the consultation:

*"...because sometimes you're, you're intimidated or you're distracted or what have you, and you come out and you think aww, I meant to ask... so and so, and I think the concept is good because it does help to focus on all the areas..." [P6]*

For other patients the questions allowed them to think about issues that they might not otherwise have raised:

*"Maybe I wouldn't have thought about it if, if I hadn't had those questionnaires [...] but when you see it written down on paper you think oh no I, I do need more information on that" [P3]*

*"It really helped me because it made me sit down and think of the things that were affecting me and I may not have if I hadn't had the questionnaire" [P8]*

One patient also noted that being able to complete the questionnaire in a quiet room away from the bustle of the waiting area was very helpful in allowing them to gather their thoughts: *"doing it in a quiet environment I could sit and think..." [P8]*

The range of needs set out in the DT&PC and SCNS Melanoma module (they *"covered everything likely to be a problem"* [P6]) gave patients permission and the confidence to discuss issues with the nurse specialist:



*"...to be fair, obviously there was things in there that, I mean I did'nae know you could o' got help for..." [P4]*

*"I can understand how those questions, you know, if people, if they asked them it would make them think about what they needed and what they were going through..." [P3]*

Patients praised the protected time with the **nurse specialist**, who could review their responses and provide immediate support: *"The thing I liked about it was she was able to speak to me immediately..." [P8]*. As an example, one participant discussed the effect of the diagnosis on her family and how best to convey this information to her young children: *"Family, family was a problem [...] for them to realise the seriousness of the illness..." [P7]* The **nurse specialist** acknowledged that this was a challenging topic, but was able to signpost services available to the patient. Another patient discussed their underlying difficulties with anxiety and depression. In this instance, the **nurse specialist** was able to direct the patient toward suitable resources and contacted the patient's GP to provide early medical intervention.

Consistently and most frequently, patients requested support with queries about the tumour, recurrence, skin surveillance, and sun protection. Addressing such and other needs during the consultation was a positive experience for most patients *"was very helpful"* [P1] and patients were generally very happy with the support offered:

*"[the nurse] gave me leaflets home to read, which helped me understand it [the cancer], so I was pretty happy with everything she offered or [...] answer[ed] for me." [P1]*

*"...if there was anything on the questionnaire that was out, you know, she asked me about it and, you know, how did I feel about this, or did I need any more help..." [P3]*

Patients expressed the view that the information offered during consultations provided them with reassurance about their situation:

*"...and she was so reassuring and, and I said to her 'how do I know if, if this is going to come back?' and she said 'but I'll check'." [P4]*

*"I mean it gives you peace o' mind..." [P4]*

*"She [the **nurse specialist**] did put my mind at rest..." [P7]*

As a result, the experience of taking active part in the consultation with the **nurse specialist** was seen as very positive by most patients:

*"Oh, absolutely, definitely, because there's things I said to her or things she looked, you know, for me like checking my whole body for all my, the other moles that I had, nobody, there's nobody else would have done that really, none o' the doctors would have done that really..." [P3]*

*"I think the concept is very good... and I do think that it will help patients to zone in on the areas that there are problems, and I think that is needed..." [P6]*

*"Meeting the nurse was [...] really very, very helpful, 'cause she was able to identify straightaway what I was thinking and feeling [...] and I felt really happy once I had left [her] [...] and I think the questionnaire opened that out to enable that" [P8]*

Timing of consultations was seen as important, too. The nearer to treatment the more relevant the questions on the PRO measures were:

*"There were some questions [...] skin soreness [...] that probably would have been more, more applicable shortly after I had the procedure done and not like a few months after it." [P1]*

*"[The questions] were relevant because it was at very early stages of my melanoma, so there were lots of different things that were relevant to how I was feeling at that time" [P8]*

The **nurse specialist** agreed that seeing patients too soon (e.g. on the day of their diagnosis) was not useful as the diagnosis had still not sunk in. **She also** felt that one month post-diagnosis was the best time to see patients, but no later than six weeks.

*"...probably the month down the line where they've had time to think about it... perhaps give them a, a phone to say that I'm here and that I will be sending an appointment, if you've any questions write them down..." [N1]*

This was borne out by one patient, who due to a number of unfortunate circumstances, did not receive her consultation until 10 weeks after treatment. She felt that this was far too late to address her needs: "...by the time I was seen there was no need for anything." [P6]

The **nurse specialist** described how the PRO measures were useful in directing the patients to express their actual needs and her to offer support relevant to those needs.

*"...and I think as a healthcare professional we are a bit paternalistic and we think this is what they [the patients] need to know, or what we think they need to know, so for me it, it, it directed to be relevant to the patient [...] so I found it directed my consultation pretty well"* [N1]

The **nurse specialist** noted that what she considered important clinically and what was important to the patient did not always tally. This was evident among patients with thin melanomas and thick melanomas. Whereas, she as a health professional would not consider the issue of cancer recurrence a high priority with people with thin melanomas, worry about recurrence was raised by all of the patients that took part in the study. This finding led the **nurse specialist** to re-examine her practice and "...it has made me look at people as individuals and not just as a diagnosis." [N1]

Being given the PRO measure to review prior to consultation allowed the **nurse specialist** time to consider her response rather than the consultation being "...all reaction" [N1]. Use of the PRO measures also gave the **nurse specialist** the opportunity to suggest resources that patients could utilise to address any priority needs.

*"I think it's given me an opportunity to signpost to Maggie's or signpost to The Haven, or even MASScot as well"* [N1]

Overall, the **nurse specialist** felt that using the PRO measures in her consultations **was useful, but the biggest challenge she faced was the** time and effort to recruit patients into the study:

*"I would say the hardest thing for me was trying to get it within my normal working week, that was the hard thing, and I think [...] one of the hardest things was the recruiting"* [N1]

#### **Prevalence of supportive care needs (RQ 4)**

During intervention session 1, an average of 8 needs per patient (range 2-18) were reported via the intervention PRO measures (3.6 needs per patient on the **DT&PC**; 4.4 needs per patient on the SCNS-Melanoma), accounting for a total of 79 reported needs across the study sample. Two (20%) participants reported 0-5 needs, 7 (70%) participants reported 6-10 needs, and 1 (10%) participant reported more than 10 needs. These figures slightly dropped to an average of 7.5 needs per patient (0-20) at the follow-up intervention session (4.5 needs per patient on the **DT&PC**; 3 needs per patient on the SCNS-Melanoma; total 60 needs; overall 25% reduction from T1 to T3). Three (37.5%) participants reported 0-5 needs, 3 (37.5%) participants reported 6-10 needs, and 2 (25%) participants reported more than 10 needs.

During intervention session 1, the most prevalent supportive care needs were information, practical (treatment decisions), emotional (fears, nervousness, worry) or physical (fatigue, pain, sleep) needs (**Table 3**). Participants indicated a need for more information on a variety of health- and disease-related topics, but mainly information about the risk of recurrence and possible outcomes when melanoma spreads from the skin (70%), and how and when to perform skin examinations (60%).

During the follow-up intervention session, a shift towards more emotional needs (worry, nervousness) was noted. Interestingly, additional emotional issues, not previously reported, were reported by 25% of the sample (**Table 3**). These included fears, sadness and loss of interest in usual activities. Some physical needs (fatigue, pain/skin soreness) and information needs (recurrence, spread, surgical removal of lymph nodes) were also evident (reported by 37.5% of the sample).

During intervention session 1, the **nurse specialist** discussed on average 2 topics (range 1-5; total 23) of supportive care needs with patients. Information **gleaned** from the **case report form** indicated that at this time the main topics of discussion in patient-**nurse specialist** interactions revolved around risk of recurrence, information, skin protection, and emotional issues (**Table 4**). On average, 2 topics (range 1-2; total 12) per intervention session were discussed at follow-up, mainly focussing on emotional issues and pain management, although advice on skin examination/protection and the possibility of recurrence and spread of the tumour was also requested and offered.

### **Over-time changes in supportive care needs (RQ 5)**

A downward trend in SCNS-SF34 domain scores was noted over time (**Figure 1**). The only exception was psychological needs. After an initial decrease at T2, psychological needs steadily increased from T3 to T4, reaching baseline levels at T4.

From T1 to T2, a statistically significant reduction in all domain scores, except physical needs, was noted (**Table 5**). The greatest reduction (large SRM) was in domain scores for psychological and sexuality needs.

From T3 to T4, non-statistically significant reductions in domain scores were found for information (small SRM) and physical needs (trivial SRM), whereas scores remain unchanged for patient care and support and sexuality needs (trivial SRM).

Overall, a sizable reduction from T1 to T4 was observed in domain scores for information needs (large SRM;  $p < 0.05$ ). A moderate, yet not significant, reduction in domain scores for sexuality needs was also found. To a smaller extent, non-statistically significant reductions were also seen in patient care and support and sexuality needs (small SRM;  $p > 0.05$ ) (**Table 5**).

### **Discussion**

This study recognised the importance of understanding the patient perspective of living with a diagnosis of melanoma, and ensuring that patient preferences and priorities are effectively incorporated in the delivery of supportive care services (National Cancer Action Team, 2013). To this effect, we introduced nurse-led and PRO-measures-driven consultations in routine clinical practice to identify and address the supportive care needs of people with newly diagnosed melanoma. We anticipated that this model would be of benefit in the following areas: (a) identification of previously undetermined issues; (b) enhancement of person-centred, supportive care; (c) quicker and more comprehensive management of supportive care needs; and (d) adoption of a shared model of care and partnership working between patients and health care professionals. In practice, we evidenced that the consultations appeared to be feasible and highly acceptable to both patients and clinicians, whilst there was preliminary evidence that this type of intervention could be associated with:

- A sizeable reduction in the extent of information needs from the point of initial diagnosis throughout the first four months post-diagnosis, and
- Reduction in the extent of psychological, patient care and support and sexuality needs in the month following the baseline intervention session.

A modest recruitment rate of 56% may have been the result of a challenging period that deterred some patients from considering participation. Variable recruitment rates (ranging from >25% to >80%) have been reported in the few studies that have evaluated interventions to meet the supportive care needs of people with different types of cancer (Harrison et al., 2011; Kotronoulas et al., 2017; 2017b; Young et al., 2010), and the timing of intervention delivery does seem to play a role. Although the face-to-face nature of the intervention sessions was highly regarded, alternative options (e.g. telephone or video calls) could have allowed for easier patient access (Cox et al., 2017). In contrast, retention rate was near perfect, reaching 90% for intervention attendance, which is also higher than similar rates reported in other supportive care intervention studies (Harrison et al., 2011; Young et al., 2010). Moreover, attrition was kept below 25%. Potential reasons may include the relatively short follow-up and the timing of the intervention, which was endorsed by participants as highly relevant in exit interviews.

Session delivery, in-clinic performance, and data completeness were highly satisfactory. Given the minimal research support offered to the skin **cancer nurse specialist**, such performance estimates have greater significance and applicability to clinical practice. That said, it also became apparent that single-handedly delivering a time-intensive intervention may challenge adequate testing and implementation. With increased patient volumes and advanced nursing roles in force (e.g. skin surveillance, lymph node checks, skin protection and self-examination education) (Skripnik Lucas et al., 2016), reviewing and attending to individual patient healthcare needs had to be limited to priority needs only and concluded within a short time space. It is thus important to identify ways to either bring the intervention down to a delivery schedule that is more manageable for lone providers or ensure that adequate resources for nursing support are available. For instance, use of automated

reports/summaries/graphs of expressed needs as part of an electronic platform could provide for a less time-consuming and more comprehensive means of PRO data interpretation and patient-clinician communication (Jensen et al., 2014). We believe that, by applying the intervention in real-life clinical circumstances and by keeping research support to a minimum, we were able to establish a realistic view of the facilitators and barriers of implementing this intervention within the participating NHS board.

The intervention was highly acceptable to both patients and clinicians. Completeness of PRO and **case report form** data exceeded 90% both within and across time-points. In exit interviews, patients and the **nurse specialist** expressed positive opinions about the intervention. Patients endorsed the standardised use of an easy-to-use pack of supportive care need PRO measures as a means to help them shortlist, report and prioritise their needs, also confirming that no need is too unimportant to be discussed with the **nurse specialist**. The timing of the intervention was also perceived as appropriate and relevant. The **nurse specialist** viewed engagement in the PRO-measures-drive consultations as a highly structured and patient-centred activity that allowed her to get more detailed information about patients' experiences, prepare herself to respond rather than "react" to expressed needs, and tailor support to tackle these needs according to patients' preferences. Notably, the use of the PRO measures helped the **nurse specialist** to see how preconceptions about the level of need of certain patient groups could lead to suboptimal delivery of care. Consistent with current evidence (Hetz and Tomasone, 2012), people with thin melanomas (and for this reason, with better prognosis) expressed fears of recurrence at the same frequency and intensity as those with thicker tumours. When we statistically compared these two groups, this same pattern emerged: on average, patients had the same anxieties, concerns and needs regardless of prognosis. From a training point of view, this realisation helped the **nurse specialist** to change her "thought pattern" to focus more on the patients' expressed needs than her own beliefs about what these needs must be.

As with similar research, no specific clinical algorithms, guidelines or training were given to the **nurse specialist** about how to deal with patients' needs (Kotronoulas et al., 2014). Nonetheless, the **nurse specialist** drew on her clinical expertise and was able to use her own resources or make appropriate referrals to support organisations such as Macmillan Cancer Support (<https://www.maggiescentres.org/>) or Melanoma Action and Support Scotland (MASScot; <https://masscotcharity.wordpress.com/>). Signposting patients to appropriate services after an initial assessment was particularly helpful when the **nurse specialist** was faced with the more sensitive, demanding and challenging needs of patients, such as patients' need for help to explain cancer to their children. Bringing up cancer diagnosis with the family (especially at school or under school age children) is a well-known concern and potentially distressful act for patients regardless of type of cancer (Asbury et al., 2014; Ewing et al., 2016), and one that professionals in the medical and nursing sciences may struggle to help with (Banerjee et al., 2016). Expert support provided by the aforementioned services (in the form of one-to-one counselling or peer support, or via group therapy) is indispensable at the community level. Nonetheless, supporting hospital nursing staff (especially those more junior ones) with formal training and a toolkit of available resources, and/or deploying in-hospital counselling services to out-patient clinics could further promote intervention applicability and acceptability.

In absolute terms, the number of expressed needs per participant at baseline intervention session was moderate, with only a slight reduction at the follow-up session. Both intervention sessions were purposely planned to be delivered at two critical time-points, which people with a new diagnosis of melanoma find challenging, perhaps for different reasons. The baseline intervention session was set around 4 weeks post-melanoma diagnosis, a period when patients struggle to make sense of a life-disrupting situation (Hajdarevic et al., 2014). Similar to previous research (Beesley et al., 2015; Bonevski et al., 1999), our participants did express a need for more information about a great deal of issues surrounding their diagnosis and requested support with making treatment decisions. Whilst emotional needs were also evident (Kasparian et al., 2009), they were far more prominent at the follow-up intervention session, which was set around the time of wide local excision. It was interesting to see how participants focussed more on their fears and anxieties that preceded and/or followed surgery, as well as their physical symptoms (skin soreness, fatigue, sleeplessness) that manifested in relation to the operation. In contrast, information needs abated. This could be due to an actual shift in priorities as well as intervention effects taking place, whereby information needs were sufficiently addressed by the **nurse specialist**. These observations support our conclusion that the timing of the intervention was indeed appropriate, and allowed the **nurse specialist** to tailor nursing actions to patients' unique needs at a period of time where increased clinician support was critical.

The large effect size in the reduction in psychological/emotional needs from T1 to T2 could well mean that introducing the intervention at the immediate post-diagnosis period is of utmost benefit. This is supported by similar findings on other needs domains, symptom severity and satisfaction with care. In terms of emotional support, by providing reassurance and reliable information, our intervention possibly helped patients' to control their anxiety and fear of the unknown as they awaited removal of the tumour (Hajdarevic et al., 2014). However, the overall curvilinear pattern of change in psychological/emotional needs may suggest that if any sustainable effects were to take place, ongoing emotional support by **the multidisciplinary team** is required in the period surrounding wide local excision. Of note, participants' information needs significantly decreased from T1 to T4. This potentially means that any emotional issues were related more to the overall hardship experienced living with a melanoma diagnosis than to lack of information. Patients' needs in the physical, patient care support and sexuality domains also showed a gradual decline over time, but especially from T1 to T2. From T3 to T4 (follow-up intervention session), scores on the latter two domains of need remained unchanged, which could be interpreted as no added effect of the intervention at T3.

### ***Strengths and limitations***

In this feasibility study, we followed a collaborative approach, engaging in early discussions with patient representatives and members of the clinical team that enabled us to customise and refine aspects of the intervention in an attempt to meet users' preferences, expectations and priorities. Moreover, we employed different sources of information to comprehensively investigate feasibility and acceptability of the intervention, including observation, questionnaire and interview data. Finally, evaluation of the intervention with minimal research support and clinical practice assimilation conditions allowed for a realistic intervention evaluation within the participating NHS board.

A number of key limitations warrant comment. Neither PRO measure completion nor consultation appointments were formally timed, but we only relied on retrospective accounts of duration. However, none of our participants reported the intervention as time-consuming. With a small sample size like this, the reliability of feasibility estimates may be questioned. Relatedly, although we were able to provide estimates of responsiveness to change for all PRO measures, SRMs may be artificially low or high given the small sample size that has limited heterogeneity in demographic/clinical characteristics. Finally, this was a single-centre study, thus reflecting current facilitators and barriers in the implementation of the intervention within this particular NHS board. Whether feasibility and acceptability of the intervention is similar in diverse clinical contexts remains unknown and generalizability is limited.

### ***Implications***

Implementing nurse-led, PRO-measure-driven consultations may be helpful in addressing the supportive care needs of people with newly diagnosed melanoma in clinical practice. If regularly audited, PRO data can provide important insight into priority supportive care needs of people treated for newly diagnosed melanoma. Special attention should be given to salient patient needs, including help to deal with fear of recurrence, need for more information, advice and guidance around skin protection, help to deal with emotional issues such as sadness and anxiety, and help with pain management.

A number of actions could enhance feasibility and applicability of this model. These include (a) formal clinician training in the management of supportive care needs and a toolkit for signposting to available resources; (b) technology solutions to collect, synthesise and deliver PRO data to clinicians; (c) employing phone or Skype calls for consultation delivery; (d) revised intervention delivery schedules that allow for flexibility for lone providers (e.g. combine in-clinic with home-based sessions, increase the time interval between consecutive sessions, or investigate a single-session model); and (e) availability of adequate resources for nursing support.

A pilot randomised controlled trial is warranted to provide preliminary evidence on the effectiveness of this intervention in relation to important patient behaviours (e.g. regularity of self-examination; adherence to skin protection recommendations) and patient outcomes (e.g. supportive care needs, self-efficacy, psychosocial adjustment, anxiety, relapse/survival). In addition, the feasibility and acceptability of the use of automated reports/summaries/graphs of expressed needs based on the use of electronic platforms to administer PRO measures should be explored as a less time-consuming

and more comprehensive means of data interpretation and patient-clinician communication.

## **Conclusions**

The use of PRO measures in nurse-led consultations to identify and address the supportive care needs of people with newly diagnosed melanoma appear to be feasible in clinical practice and acceptable to both patients and clinicians. This study re-confirms that **nurse specialists** are key professionals in the delivery of supportive care. It also suggests that, when structured through systematic use of PRO measures, nursing care can be tailored to a person's unique supportive care needs. This can tentatively be followed by sizable reductions in said needs, also increasing patient satisfaction with care. Whilst our findings do provide evidence to support the future use of PRO measures in this area, the results of this study are still tentative and warrant confirmation in a larger study.

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## **Conflict of interest**

The authors declare that there are no conflicts of interest in relation to this work.

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## Figure legends

**Figure 1.** Over-time change in supportive care needs based on SCNS-SF34 domain scores (Notes: PSYCH – Psychological needs; INFO – Information needs; PHYS – Physical needs; PCS – Patient care and support needs; SEX – Sexuality needs).

## Tables

**Table 1.** Demographic/clinical characteristics of the study sample (n=10)

Variable		
Age (years)	M (SD)	51.8 (14.2)
	Median	52.5
	Range	30-70
		<b>n (%)</b>
Age (years)	<40	2 (20.0)
	40-49	2 (20.0)
	50-59	2 (20.0)
	60-69	3 (30.0)
	≥70	1 (10.0)
Gender	Female	8 (80.0)
Educational attainment	High School	2 (20.0)
	Some college	6 (60.0)
	University	2 (20.0)
Employment (n=8)	Employed	5 (62.5)
	Retired	3 (37.5)
Marital status (n=8)	Married/partnered	6 (75.0)
	Divorced	1 (12.5)
	Widowed	1 (12.5)
Distance from hospital	1-5 miles	3 (30.0)
	6-20 miles	7 (70.0)
Cancer staging	I	8 (80.0)
	II	2 (20.0)
Tumour thickness (in Breslow's depth)	≤1 mm	7 (70.0)
	1.01-3.00 mm	3 (30.0)
Surgery	Yes	9 (90.0)
Wide local excision	Yes	6 (60%)
Chemotherapy	Yes	0 (0.0)
Radiotherapy	Yes	0 (0.0)
Supportive care	Yes	1 (10.0)
Any comorbidities	Yes	1 (10.0)
ECOG performance status (baseline)	0 (fully active)	6 (60.0)
	1 (restricted in strenuous physical activity)	4 (40.0)
<i>Notes: ECOG – Eastern Cooperative Oncology Group; M – Arithmetic mean; SD – Standard Deviation</i>		

**Table 2.** Return, completeness and attrition rates for all PRO measures

<b>Parameter</b>	<b>T1</b>	<b>T2</b>	<b>T3</b>	<b>T4</b>	<b>Total</b>
<b><i>Intervention PRO measures</i></b>					
PRO measures packs returned	10/10	6/10	8/10	7/10	31/40
Missing data within returned PRO measures due to non-response out of total number of available data at Tx					
DT&PC	1/210	-	4/168	-	5/378
SCNS-Melanoma	0/120	-	0/96	-	0/216
SCNS-SF34	2/340	0/204	0/272	1/238	3/1054
Missing data due to attrition out of theoretical maximum of available data at Tx	0/770	268/770	134/770	201/770	603/3080
<i>Notes: PRO – Patient-reported outcomes; DT&amp;PC – Distress Thermometer and Problem Checklist; SCNS-Melanoma – Supportive Care Needs Survey-Melanoma module; SCNS-SF34 – Supportive Care Needs Survey-Short Form 34; M – Arithmetic mean; SD – Standard Deviation; Tx – Time-point.</i>					

**Table 3.** Ranking of the most prevalent supportive care needs reported on the DT&PC and SCNS-Melanoma during intervention sessions 1 and 2.

Intervention session 1 (n=10)			Intervention session 2 (n=8)		
DT&PC			DT&PC		
Median distress score 3.5 (range 0-6)			Median distress score 3.0 (0-6)		
Need	Ranking	n (%)	Need	Ranking	n (%)
Treatment decisions (PP)	1	3 (30%)	Worry (EP)	1	5 (62.5%)
Fears (EP)	1	3 (30%)	Nervousness (EP)	2	3 (37.5%)
Nervousness (EP)	1	3 (30%)	Fatigue (PhP)	2	3 (37.5%)
Worry (EP)	1	3 (30%)	Pain (PhP)	2	3 (37.5%)
Fatigue (PhP)	1	3 (30%)	Sleep (PhP)	3	2 (25%)
Pain (PhP)	1	3 (30%)	Indigestion (PhP)	3	2 (25%)
Sleep (PhP)	1	3 (30%)	Treatment decisions (PP)	3	2 (25%)
Indigestion (PhP)	2	2 (20%)	Fears (EP)	3	2 (25%)
Memory/concentration (PhP)	2	2 (20%)	Sadness (EP)	3	2 (25%)
Skin dry/itchy (PhP)	2	2 (20%)	Loss of interest in usual activities (EP)	3	2 (25%)
SCNS-Melanoma			SCNS-Melanoma		
Need (at least "low")	Ranking	n (%)	Need (at least "low")	Ranking	n (%)
More information about the risk of recurrence of melanoma.	1	7 (70%)	Skin soreness.	1	3 (37.5%)
More information about possible outcomes when melanoma has spread from the skin.	1	7 (70%)	More information about the risk of recurrence of melanoma.	1	3 (37.5%)
To be informed about how and when to check your skin for changes.	2	6 (60%)	To be informed about the need for surgical removal of lymph nodes.	1	3 (37.5%)
To be informed about the need for surgical removal of lymph nodes.	3	5 (50%)	More information about possible outcomes when melanoma has spread from the skin.	1	3 (37.5%)
More information about non-surgical treatment of melanoma (chemotherapy, immunotherapy).	3	5 (50%)	To be informed about the need for surgical treatment of melanoma of the skin.	2	2 (25%)
To be informed about things you can do for skin protection.	4	4 (40%)	To be informed about how and when to check your skin for changes.	2	2 (25%)
Skin soreness.	5	3 (30%)	Access to a second opinion about your condition or treatment if you want one.	2	2 (25%)
More information about the unwanted effects of surgical treatment.	5	3 (30%)	More information about the unwanted effects of surgical treatment.	2	2 (25%)

*Notes: DT&PC – Distress Thermometer and Problem Checklist; SCNS-Melanoma – Supportive Care Needs Survey-Melanoma module; PP – Practical problems; EP – Emotional problems; PhP – Physical problems.*

**Table 4.** Topics of discussion between patients and the CNS during intervention sessions 1 and 2

<b>Intervention session 1 (n=10)</b>	<b>Intervention session 2 (n=8)</b>
<ul style="list-style-type: none"> <li>▪ Risk of recurrence (x4)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Anxiety/worry (x3: anxiety about prognosis; worry about skin exposure; anxiety about results of SLNB)</li> </ul>
<ul style="list-style-type: none"> <li>▪ Information (x4) (More information about possible outcomes when melanoma spread; How and when to check for skin changes; Information on melanoma; Lack of information pre-surgery)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pain (x2) (Skin soreness; pain in right chest wall)</li> </ul>
<ul style="list-style-type: none"> <li>▪ Things to do for skin protection (x3)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Risk of recurrence (x2)</li> </ul>
<ul style="list-style-type: none"> <li>▪ Nervousness, anxiety depression (x2)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Skin surveillance/examination</li> </ul>
<ul style="list-style-type: none"> <li>▪ Unwanted effects of surgical treatment</li> </ul>	<ul style="list-style-type: none"> <li>▪ Things to do for skin protection</li> </ul>
<ul style="list-style-type: none"> <li>▪ Loss of interest in usual activities</li> </ul>	<ul style="list-style-type: none"> <li>▪ Removal of lymph nodes</li> </ul>
<ul style="list-style-type: none"> <li>▪ Sleep</li> </ul>	<ul style="list-style-type: none"> <li>▪ Appearance of scar</li> </ul>
<ul style="list-style-type: none"> <li>▪ Cosmetic appearance of scar</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Decisions made: Patient decided not to have SLNB</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Time delay seeing CNS</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Lymphoedema</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Dealing with children</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Skin surveillance</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Pain</li> </ul>	
<p><i>Notes: SLNB – Sentinel lymph node biopsy; CNS – Cancer nurse specialist.</i></p>	

**Table 5.** SCSN-SF34 domain scores and SRM

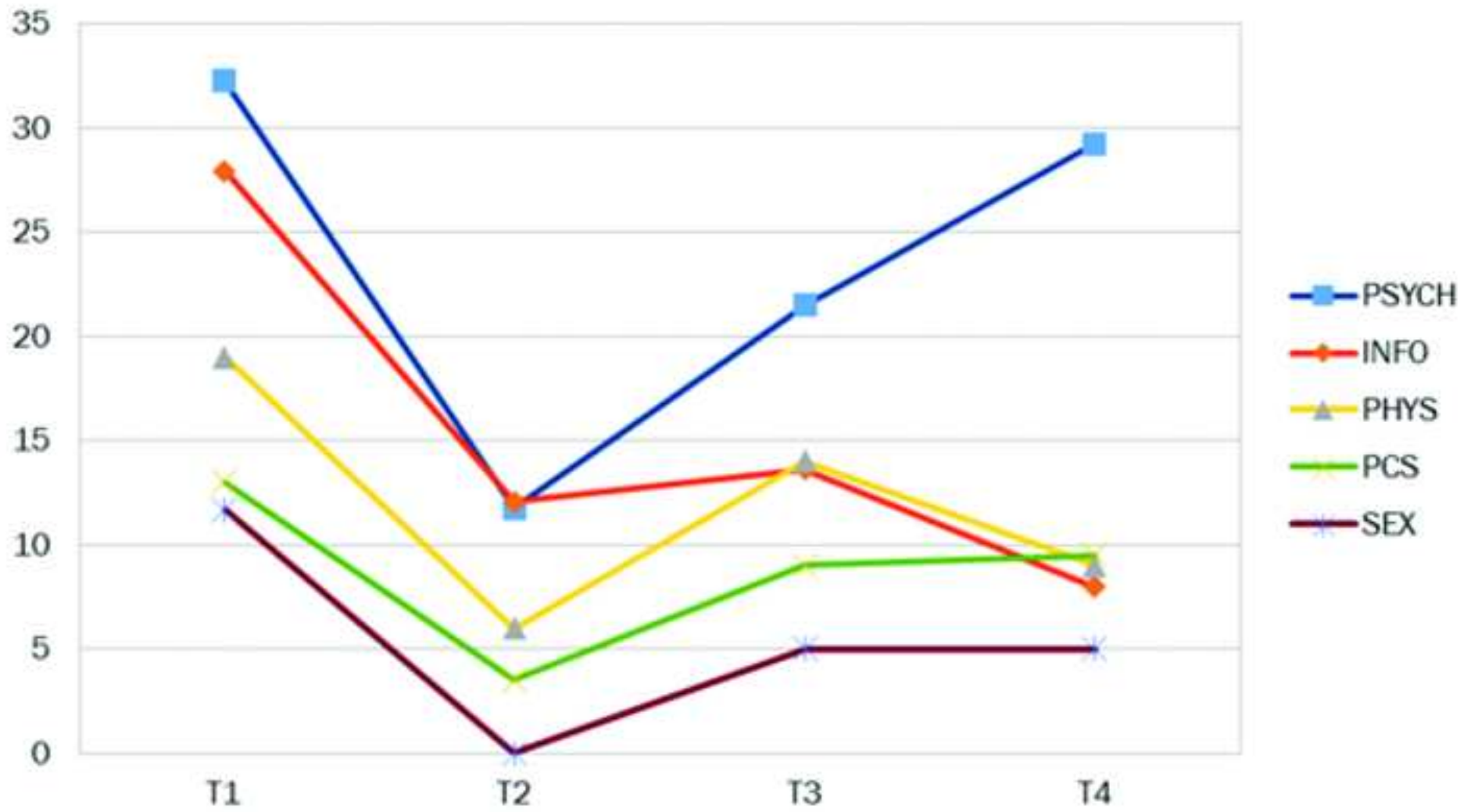
<b>Parameter</b>		<b>PSYCH</b>	<b>INFO</b>	<b>PHYS</b>	<b>PCS</b>	<b>SEX</b>
T1 domain score	M (SD)	32.3 (16.2)	28 (10.3)	19 (20.5)	13 (12.1)	11.7 (10.5)
	Median	33.8	25	12.5	15.0	16.7
	Range	10-55	13.6-45.5	0-70	0-25	0-25
T2 domain score	M (SD)	11.8 (8.3)	12 (5.7)	6 (10.5)	3.5 (6.3)	0 (0)
	Median	8.8	15.1	0	0	0
	Range	0-25	0-45.5	0-30	0-15	0
T3 domain score	M (SD)	21.5 (13.6)	13.7 (11.1)	14 (16)	9 (13.7)	5 (9)
	Median	25	11.4	10	0	0
	Range	2.5-37.5	0-36.4	0-50	0-35	0-25
T4 domain score	M (SD)	29.3 (23)	8 (10.2)	9 (14.7)	9.5 (14.4)	5 (10.5)
	Median	26.3	2.3	0	0	0
	Range	0-67.5	0-25	0-45	0-35	0-25
T1-T2 SRM		-1.18	-0.63	-0.63	-0.67	-0.78
T3-T4 SRM		0.24	-0.27	-0.16	0.05	0.00
T1-T4 SRM		-0.08	-0.99	-0.37	-0.40	-0.60
T1-T2 change <sup>a</sup>		-2.71**	-2.20*	-1.90	-2.00*	-2.27*
T3-T4 change <sup>a</sup>		-0.91	-1.12	-0.93	0	0
T1-T4 change <sup>a</sup>		-0.87	-2.50*	-1.54	-0.81	-1.79

<sup>a</sup>Wilcoxon signed ranks test (Z statistic)  

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001  
Notes: SCNS-SF34 – Supportive Care Needs Survey-Short Form 34; PSYCH – Psychological needs; INFO – Information needs; PHYS – Physical needs; PCS – Patient care and support needs; SEX – Sexuality needs; SRM – Standardised Response Mean; M – Arithmetic mean; SD – Standard Deviation.



Figure  
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