



Kotronoulas, Grigorios and O'Brien, Fran and Simpson, Mhairi F. and Maguire, Roma (2017) Feasibility and acceptability of the use of patient-reported outcome measures in the delivery of nurse-led, supportive care to women with cervical cancer. *Clinical Nurse Specialist*, 31 (4). E1-E10. ISSN 1538-9782 , <http://dx.doi.org/10.1097/NUR.0000000000000306>

This version is available at <https://strathprints.strath.ac.uk/60963/>

Strathprints is designed to allow users to access the research output of the University of Strathclyde. Unless otherwise explicitly stated on the manuscript, Copyright © and Moral Rights for the papers on this site are retained by the individual authors and/or other copyright owners. Please check the manuscript for details of any other licences that may have been applied. You may not engage in further distribution of the material for any profitmaking activities or any commercial gain. You may freely distribute both the url (<https://strathprints.strath.ac.uk/>) and the content of this paper for research or private study, educational, or not-for-profit purposes without prior permission or charge.

Any correspondence concerning this service should be sent to the Strathprints administrator: strathprints@strath.ac.uk

The Strathprints institutional repository (<https://strathprints.strath.ac.uk>) is a digital archive of University of Strathclyde research outputs. It has been developed to disseminate open access research outputs, expose data about those outputs, and enable the management and persistent access to Strathclyde's intellectual output.

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 women with cervical cancer

Author names:

Grigorios Kotronoulas, PhD, MSc, BSN, RN, Research Fellow in Cancer Care

Fran O'Brien, DipHE, BA (Nurs), RN, Cancer Nurse Specialist

Mhairi F Simpson, MN, BSc, RN, Nurse Consultant Cancer Care

Roma Maguire, PhD, MSc, BN, RGN, Professor of eHealth

Affiliations:

Dr Kotronoulas, (see details for corresponding author)

Ms Fran O'Brien, Wishaw General Hospital, NHS Lanarkshire, 50 Netherton St, Wishaw ML2 0DP,
Lanarkshire, UK (Fran.O'Brien@lanarkshire.scot.nhs.uk);

Dr Simpson, NHS Lanarkshire, Lanarkshire, UK (Mhairi.Simpson@lanarkshire.scot.nhs.uk).

Prof Maguire, School of Health Sciences, University of Surrey, Standard Buildings, 94 Hope Street,
Glasgow, G2 6PH, UK (r.maguire@surrey.ac.uk);

Corresponding author:

Grigorios Kotronoulas

School of Health Sciences, Faculty of Health & Medical Sciences, University of Surrey

Standard Buildings, 94 Hope Street, Glasgow, G2 6PH

T: +44 (0) 141 249 0922

E: g.kotronoulas@surrey.ac.uk

Disclosures:

The present work was supported through a grant awarded by NHS Lanarkshire. The views presented in this article are those of the authors not of the funding body.

Conflict of interest statement:

The authors declare that there are no personal or financial conflicts of interest to disclose.

ABSTRACT

Purpose/Aims: Patient-reported outcome measures (PROMs) can be effectively utilised to uncover the unmet needs of women with cervical cancer for supportive care. Our aim was to explore the feasibility and acceptability of PROMs-driven, nurse-led consultations to enhance delivery of supportive care to women with cervical cancer during active anti-cancer treatment.

Design: A two-phase, mixed-methods, prospective study was conducted. Main research variables included feasibility and acceptability parameters of the trialled intervention.

Methods: Pre-consultation PROM data were collected during three consecutive, monthly consultations, and used by the Gynaecology cancers nurse specialist (CNS) to deliver personalised supportive care. The Problem Checklist and Cervical Cancer Concerns Questionnaire were used to aid data collection.

Findings: Due to considerable recruitment challenges, a recruitment rate of 27% (3/11 patients) was achieved. Two patients completed all three study assessments. Seven in-clinic patient assessments were performed over 6 months. Study participants praised the opportunity for dedicated time for patients to raise concerns and for the CNS to provide sensitive and personalised support.

Conclusion: Women with cervical cancer perceive important benefits from participating in PROMs-driven, time-protected sessions with their CNS. Our findings provide tentative evidence to support the feasibility and acceptability of this intervention model, and warrant future confirmation.

Keywords: Patient-reported outcome measures; unmet needs; supportive care; cervical cancer; cancer nurse specialists

Implications for practice:

- Use of PROMs to identify the unmet needs of women with cervical cancer is acceptable, and must be implemented from the point of diagnosis.

- Cancer nurse specialists (CNS) are receptive to and able to act upon PROM information, rendering them key professionals in addressing the supportive care needs of people with cancer.
- Women with cervical cancer perceive important benefits from participating in PROM-driven, time-protected and private sessions with their CNS.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

INTRODUCTION

1
2 There were close to 528,000 new cases of cervical cancer worldwide in 2012,¹ but incidence rates
3
4 have decreased by over 40% since the late 1970s.² Advances in both diagnostic tests and treatments
5
6 for gynaecological cancers have also led to improved survival rates, with over 60% of women now
7
8 surviving to ≥ 10 years after diagnosis.² This also means that the number of women set to deal with the
9
10 aftermath consequences of cervical cancer is on the rise.^{3,4}

11
12
13 Negative effects of cervical cancer may emerge soon after diagnosis and treatment, whilst some
14
15 women may continue to deal with the adverse physical, psychological and social difficulties for up to
16
17 twelve months after diagnosis, and beyond.⁵⁻⁸ The requirement to provide on-going and
18
19 comprehensive supportive care to these individuals is therefore prominent.^{9,10}

20
21
22 Developing new clinical supportive care services for women with cervical cancer means
23
24 identifying ways to feasibly assess and effectively address patients' needs. The use of patient-reported
25
26 outcome measures (PROMs) may prove useful to this end. PROMs are defined as measurements of an
27
28 aspect of a patient's health status that come directly from the patient.¹¹ The collection of PROM data
29
30 in clinical practice has been reported to have a number of benefits on patient, clinical process and
31
32 health service outcomes.¹¹⁻¹³ As a result, PROMs are high on political agendas,¹⁴ as their use in
33
34 informing care delivery and organisation of health services becomes apparent. Nurses' prime position
35
36 in the healthcare system means that they have a direct influence on patient experiences and outcomes
37
38 of care,¹⁵ while their overall positive attitude towards collecting and utilising patient-reported health
39
40 data has led to them being regarded as the most appropriate health professionals to lead on use of
41
42 PROMs in clinical practice.^{16,17}

43
44
45
46
47 Currently, additional research is needed to explore feasibility/acceptability parameters around
48
49 the use of PROMs by Gynaecology cancers nurse specialists (CNS) to assess and address the
50
51 supportive care needs of women with cervical cancer in the acute care setting, and to evaluate how
52
53 use of PROMs impacts on patient outcomes and clinical practice.¹⁸ The current study aimed to
54
55 generate evidence to address this gap.
56
57
58
59
60
61
62
63
64
65

METHODS

After obtaining Research Ethics approval (13/ES/0056), we conducted a two-phase, mixed-methods exploratory study within one NHS board in Scotland.

Phase 1

Phase 1 aimed to identify what outcomes are important to women with cervical cancer and health professionals involved in their care. We therefore combined evidence from a systematic literature review with data from subsequent focus groups interviews with women with cervical cancer and health professionals involved in their care.

Systematic literature review

A systematic review of the literature aimed to appraise the empirical evidence on the supportive care needs of women with cervical cancer.¹⁹ In addition, the review aided in the identification of PROMs, developed to assess the supportive care needs of this patient population, and used in the reviewed studies. The identified PROMs were added to the pool of validated supportive care needs PROMs already known to the research group from previous reviews.^{20–22} They were all considered for use in Phase 2 of this project.

Stakeholder interviews

Two focus group interviews – one with patients and one with health professionals – were planned, each consisting of no more than ten participants. In focus groups, participants are guided via a facilitated discussion to express their attitudes and opinions towards a defined concept/topic, by building on each other's ideas.²³ As such, focus groups have become very useful for needs assessment and project evaluation purposes.²⁴ Eligible patients were (a) diagnosed with cervical cancer (of any stage) within the past 12 months; (b) deemed by a member of the health team to be physically and psychologically fit to participate in the study; (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. Members of the multidisciplinary team were also invited to participate in the focus group, including the Gynaecology CNS, who identified eligible patients and delivered the intervention in Phase 2.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

At the end of each focus group, we involved participants in a 10-minute exercise. Copies of the previously selected PROMs were distributed to each group. We asked all participants to review the PROMs and select, in order of descending preference, the two ‘most appropriate’ for use with women with cervical cancer. 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 women with cervical cancer as per current available guidance for early feasibility testing.²⁵ 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 were planned to participate in Phase 2 over three, equally-spaced (monthly) time-points: baseline (within 12 months post-diagnosis) (T1); 1 month following entry into the study (T2); and 2 months following entry into the study (T3). This timeline was chosen together with focus groups participants to allow sufficient time for feasibility testing, whilst minimising the attrition rate.

All eligible patients were thoroughly informed about the purposes and procedures of the study, and provided written informed consent. At each time-point, participating patients were booked on an appointment with their Gynaecology CNS. Whilst in the clinic and prior to their consultation with the CNS, patients were asked to complete the set of selected PROMs selected in a quiet room. Subsequently, the Gynaecology CNS met with the patient and used the information collected via the PROMs to direct consultations, identify the patient’s supportive care needs, and intervene accordingly. The CNS documented the supportive care needs she identified during the consultation and any resulting interventions in author-developed case-report forms. Up to ten participating patients and the Gynaecology CNS were planned to participate in one-to-one, end-of-study interviews to explore their perceptions on the use of PROMs in clinical practice.

Data analysis

In light of poor recruitment in Phase 2 (see Results), the initial analysis plan was revised and a case-report analysis approach was pursued. Pseudonyms were used for presentation purposes. PROM data were entered in Microsoft Excel spread-sheets and analysed using descriptive statistics and graphs/radar plots for each case report. Frequency counts for each response were generated to describe response patterns for PROM domain and domain scores, and quantify missing data. Focus groups and end-of-study interviews were audio-recorded and transcribed verbatim. Thematic analysis was used to identify, analyse and report patterns within interview data.²⁶

RESULTS

Phase 1

Structured literature review

Dealing with fear of cancer recurrence, concerns about appearance/body image, lack of sexual desire, requiring more sexuality-related information, dealing with pain, and dealing with difficulties in relationship with partner were the most frequently cited individual needs (≥ 4 studies).¹⁹ Based on this evidence and drawing on our database of supportive care needs PROMs, we concluded that the following eight supportive care needs PROMs would be discussed in subsequent focus groups: Supportive Care Needs Survey – Short Form 34 (SCNS-SF34);²⁷ Problems Checklist;²⁸ Cancer Needs Questionnaire – Short Form;²⁹ Psychosocial Needs Inventory;³⁰ Comprehensive Needs Assessment Tool in Cancer (CNAT);³¹ Cervical Cancer Concerns Questionnaire (CCCQ);³² Cancer Rehabilitation Evaluation System – Short Form;³³ and Cancer Needs Distress Inventory.³⁴ These PROMs were selected because they are relevant, brief and, in combination, cover the needs of women with cervical cancer. Only one of them was specifically developed/adapted for use with this patient population.

Stakeholder interviews

The first focus group involved four women with cervical cancer. Two women were in their 30s and two in their 50s (age range 35-55). Three women were in full-time employment, whereas one was unemployed. None of the women was married or partnered. Initially, the discussion focussed on the diagnosis of cervical cancer and how different people react to the diagnosis. One woman indicated that she took in all the cancer information she could, whereas another one did not want as much

1
2 information. All women felt it was the manner in which health professionals conveyed information to
3 them (i.e. “very matter of fact”, “not sugar-coated”) that was of particular importance.

4
5 The group also discussed their experiences of chemotherapy, revealing a range of symptoms
6 that included constipation, fatigue, pins and needles, sleep disruption and flatulence. Notably, all
7 women felt that during treatment it was good to be among people, who were experiencing the same
8 thing as they were. This was in contrast to their family and friends “who do not really know what it is
9 like”. These women did not feel the need for spiritual or pastoral care, but they admitted to not being
10 particularly religious. The suggestion of discussing spiritual needs was initially interpreted by one
11 patient as dealing with death, for which there was an obvious fear. Finally, when discussing if their
12 needs had been covered during consultations, one woman noted that she was never asked if she
13 wanted to preserve her ovaries, and stressed the importance of fertility concerns being identified and
14 addressed.
15
16
17
18
19
20
21
22
23
24
25

26
27 The second focus group involved three health professionals (1 Gynaecology CNS and 2
28 consultant oncologists). Two health professionals had over 10 years of experience working with
29 women with cervical cancer. The main message from the health professional focus group was the
30 need to have individualised assessments, given the mix of patients health professionals normally deal
31 with. Various demographic and clinical characteristics (e.g. patients’ age, where they are in their
32 reproductive cycle, stage of cancer, and type of treatment) have to be taken into account.
33
34
35
36
37
38
39

40
41 The health professionals indicated that, although they would normally suggest to women with
42 cervical cancer to make use of available community services to get additional information and
43 support, one-to-one meetings were felt as more protective of patients’ privacy and conducive to open
44 discussions about the effects of cervical cancer. The group felt that no set of needs should be given
45 priority over any other for, if it is truly patient-centred care, then it should be guided by each patient’s
46 own priorities.
47
48
49
50
51
52

53
54 Finally, when asked if they would like a formal way to assess to supportive care needs, one
55 consultant was somewhat sceptical. In contrast, the other two health professionals seemed more open
56 to introducing formal needs assessments in clinical practice. The CNS reported that she had used the
57 Distress Thermometer in the past and found it “very valuable”. The second consultant highlighted
58
59
60
61
62
63
64
65

1
2 how important it would be to have a CNS in the consultation room every time there is a new or a
3 recurring diagnosis to ensure that women's needs are identified and addressed.

4 **Decisions made prior to Phase 2**

5
6 The health professionals chose the Problem Checklist as the most acceptable PROM in terms of
7 presentation and wording, whereas patient participants selected the CCCQ. Taking both perspectives
8 into consideration as well as the need for comprehensive assessments, a final decision was made to
9 use both the CCCQ and the Problem Checklist in Phase 2. One item was added to the Problem
10 Checklist, pertaining women's concerns about their ability to have children/become pregnant in the
11 future, in line with findings from Phase 1.
12
13
14
15
16
17
18

19
20 The CCCQ is a 37-item questionnaire that aims to assess women's concerns in relation to
21 cervical cancer and its treatment.³² A combination of Likert-type or numerical scales, and open-ended
22 questions are employed. Thirty-two items are used to categorised into seven domains of concern,
23 including (1) communication with the treatment team, (2) treatment issues, (3) sexuality, (4)
24 prognosis, (5) cause/transmission risk, (6) partner relationship, and (7) relationship with others. Each
25 item is rated for level of concern during the past week on a seven-point Likert scale, ranging from 1
26 "not very much" to 7 "very much".
27
28
29
30
31
32
33
34

35
36 The Problem Checklist assesses the extent of patients' concerns or difficulties in each of 16
37 aspects of their lives as a result of cancer and/or its treatment.²⁸ Items are scored on a four-point scale
38 (1 "no difficulty" – 3 "severe difficulty"). In our study, a 17-item checklist was used.
39
40
41

42 **Phase 2**

43 **Feasibility and acceptability estimates**

44
45 Between July 2014 and July 2015, recruitment in Phase 2 had to be postponed twice due to
46 considerable challenges with patient availability for a focus group, and a period of clinician absence
47 from work. In the limited amount of time left (July to October 2015), 11 eligible women with cervical
48 cancer were invited to the study. Four women declined participation, due to lack of time, deteriorating
49 physical condition, or lack of interest. In addition, four women never contacted the CNS or attended
50 the clinic after being invited, thus lack of interest was also assumed. The final sample consisted of 3
51 women, who provided written informed consent.
52
53
54
55
56
57
58
59
60
61
62
63
64
65

1 A recruitment rate of 27% (3/11) and an average recruitment pace of 1 participant per month
2 were achieved. Two patients (67%) completed all 3 study assessments, with one patient withdrawing
3 soon after baseline assessment due to declining health status.
4
5

6 The Gynaecology CNS performed a total of 7 in-clinic patient assessments within a period of 6
7 months (i.e. the period when the study was 'open' for recruitment and follow-up). Full documentation
8 records were received for each in-clinic assessment. Reflection questions were filled out for all 7 in-
9 clinic assessments. Completeness of background data was 95%.
10
11

12 In terms of data collection, 7 questionnaire packs were returned (100%), one for each-clinic
13 assessment. Data completeness analysis indicated that across 378 actual questionnaire data, only 0.8%
14 were missing across 3 assessment points. Questionnaire completeness reached 99.5% at baseline, and
15 remained high at T2 and T3 (99.6% and 99.8%, respectively).
16
17

18 **Prevalence and over-time change in patients' needs**

19 **Case #1: Kristie** – Kristie was a single woman in her 40s when she was diagnosed with stage 2b
20 cervical cancer. She was employed, but on sick leave. She reported no comorbid illnesses. At the time
21 of her baseline assessment, she was receiving a combination of chemo-radiation treatment with
22 brachytherapy. Her performance status was assessed as moderate, meaning that she was ambulatory
23 and capable of all self-care, but unable to carry out any work activities.
24
25

26 At baseline, Kristie's concerns revolved around receiving clear information about her diagnosis
27 and treatment, coping with chemotherapy and related fatigue, surviving cervical cancer, and dealing
28 with the possibility of a cancer recurrence and the effects of cancer on her family and friends. The
29 latter issues seemed to abate during the second assessment (T2), but the same treatment-related
30 concerns were still prominent as she went through full cycles of active anticancer treatment, and her
31 physical functioning deteriorated. At T3, when Kristie was close to finishing with treatment, her
32 concerns were considerably lower and she appeared to be in control of even the most consistent ones,
33 i.e. surviving cancer and fearing of cancer recurrence. The radar plot of CCCQ domains of concern
34 supports this trend (Figure 1a).
35
36

37 Answers on the Problem Checklist also revealed moderate to severe difficulty with dealing with
38 work-related and financial matters throughout the study, but mainly at T2 (Figure 1b). During her
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

1 appointments with the CNS, Kristie specifically requested advice about symptom management,
2 information about brachytherapy, and help to deal with feelings of isolation, fears of cancer
3 recurrence, financial concerns, an altered body image, relationships, menopause, and current and
4 future work issues.
5
6
7

8 **Case #2: Anna** – Anna was a young, married woman and a mother of two. She was a full-time
9 employee, currently on sick leave. She was diagnosed with stage 1b cervical cancer and planned to
10 receive post-surgery chemo-radiation therapy combined with brachytherapy. She reported no
11 comorbid medical conditions. Her baseline performance status was assessed as moderate.
12
13
14
15
16

17 Regardless of time-point of assessment, Anna appeared to be overly distressed and in need for
18 on-going help and support. Her responses on the CCCQ (scoring ‘7’ for 99% of all items and
19 assessments) were indicative of a person overwhelmed by the diagnosis of cancer – especially at this
20 very young age – that struggled to come to terms with the illness and its treatment, and the effects of
21 cancer on her, her family and their future (Figure 2a).
22
23
24
25
26
27

28 A similar picture was obtained from reviewing Anna’s responses on the Problem Checklist.
29 Practical, daily living and social needs were evident especially as Anna moved on with her treatment
30 (Figure 2b). The only area that was of no concern for her was her ability to have children in the future.
31 During consultations, Anna was able to ask for help to deal with the “information overload” about her
32 diagnosis and treatment. In addition, she felt the need to discuss issues around the effects of cancer on
33 her relationship with her husband, her fears about dying and about the cancer returning, her feelings
34 of being abandoned by friends and family, financial difficulties, and her efforts to accept that she
35 could not be her children’s caregiver anymore and had to rely on her own parents.
36
37
38
39
40
41
42
43
44
45

46 **Case #3: Ruth** – Our third participant, Ruth, was a 30-year-old married woman, on extended
47 sick leave after her diagnosis. Ruth reported no comorbid illnesses, while her baseline functional
48 status was good. Of note, Ruth was diagnosed at an advanced stage and the aggressiveness of her
49 tumour increased her odds for a poorer clinical outcome. Ruth was put on a combination of chemo-
50 radiation therapy with brachytherapy, but eventually, her rapidly deteriorating condition prevented her
51 from completing the study. She dropped out soon after her first consultation.
52
53
54
55
56
57
58
59
60
61
62
63
64
65

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

Although a comparative, over-time analysis of Ruth's data was not possible, her baseline assessment revealed a multitude of concerns and needs (Figure 3a). This was particularly in relation to the short- and long-term effects of treatment, survival, sexuality and intimacy issues, the impact of cancer on her relationship with her husband and her family and friends, and even the possibility of her being stigmatised for having a cervical cancer diagnosis. Ruth's Problem Checklist also confirmed her difficulty to come to terms with her illness and deal with such issues as relationships and sexuality. Additional areas of concern included work, finances, managing at home, and keeping up with her interests (Figure 3b). However, Ruth's primary difficulty was that of coming to terms with the possibility of her not being able to have children in the future. In her questionnaire, she scored this as a severe difficulty, underlined the relevant item twice, and wrote: "Side effects on young women with no children. Losing the right to become parents (support)!!" Her consultation appointment focussed on these areas.

End-of-study interviews: Kristie

In her exit interview, Kristie focussed on how the PROM intervention helped her flag needs or concerns that were initially less obvious to her: "*Well when I was filling it [the questionnaire] in, it was things that I never really thought of... you think, "I probably did need more information."* During the PROM-driven consultation, Kristie got clearer and more personalised information on a number of pertinent issues, predominantly those practical, daily living and family-related ones. The secured time with the CNS was perceived as beneficial; a useful adjunct to the support she was getting from her family: "*...cause it's somebody [the CNS] there to sit and listen to your problems. Somebody that was out [with] the family.*" During her consultations, Kristie opted for a family member to attend, too, possibly as a way to feel more comfortable and secure.

Overall, the PROMs were found to be clear enough and straightforward. Kristie stressed that the wording of questions that patients are asked to respond to need to be as clear as possible to prevent confusion: "*Don't put like big words in, just put simple questions just to ask them.*" Kristie also mentioned that she would welcome more time with the CNS if that was feasible. Getting access to such a service from the point of diagnosis onwards was also flagged as very important: "*At the beginning. Mhmm. Definitely... To let people know they're no[t] alone... But I think maybe once you*

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

get the first, maybe 6 months maybe a year out you, I think I'd probably feel better. I wouldn't be worrying it as much." Kristie felt that, after treatment, she was struggling to communicate her needs to health professionals, especially those seen at the community (GP or district nurse), who had limited insight in her condition and experiences. Relaying PROM information to GPs or district nurses was seen as an effective way to bridge the gap: *"So they've got a, more understanding of what folk are going through. Cause every time I've went to them, it's like, 'And what is it that's wrong with you?'"*

End-of-study interviews: Anna

Anna spoke about how completing the PROM and discussing flagged needs with the CNS was helpful as she was trying to cope with her diagnosis: *"It's just obviously when I came to complete [the questionnaire] with [the CNS] I could kinda speak to her. And speak over all the, the questions and she would kinda help me kinda answer it."* Using the PROM gave Anna the opportunity to disclose sensitive information and subsequently discuss it with the CNS in a non-judgmental environment, whilst it prompted her to seek help for any issues rather than ignore them: *"I think [it was] just because of the questionnaire [that helped to bring up the issue]. ...I had some bleeding after sex the other day. ...I would [...] just have shrugged that off. But obviously because of what I've been through now, I think 'I need to ask somebody'."*

Anna stressed that the one-to-one and face-to-face approach was an important component of the intervention. She also pointed out that appropriate timing is important, and that the intervention should be placed at the very start of the journey and then during staging, because: *"...it's the times in-between that you need somebody to explain."* Anna suggested that allowing one to write a short paragraph about themselves would help put the needs assessment into perspective and further tailor the advice to the specific person: *"I don't know if you could write a wee bit about yourself. And what, that's happened to you. Kinda would maybe be a bit helpful."* Moreover, involving another person with a similar experience was seen as a way to further improve the quality of the support given: *"I think it would be beneficial to people to kinda maybe speak to somebody who's been through, been through all the treatment. Having somebody there that can relate to what you're going through"*

Finally, Anna agreed that making PROM data available to GPs would be a helpful strategy to enhance receipt of personalised support in the community.

End-of-study interviews: Gynaecology CNS

1
2 The CNS felt that the PROMs helped patients to feel more comfortable and open up, which facilitated
3
4 assessment of a wide range of needs. Using the PROMs gave the consultation structure and improved
5
6 the quality of the discussion: *“I do discuss everything with these women anyway, but I felt that, that*
7
8 *the questionnaire, it was a bit more structured em and it was, like I used it as a guide to me, to keep*
9
10 *me in the track...”* Eventually, the structure that the PROMs instilled facilitated a patient-led
11
12 consultation, which *“was very useful... [and it] gave them the choice... and it was their choice what*
13
14 *they wanted to discuss and what was a priority at that particular time.”* The CNS felt that the PROMs
15
16 were overall *“very comprehensive and there was absolutely nothing at all missing...”*, but there were
17
18 certain areas that appeared more challenging for patients to raise (*“intimacy ...they [the patients]*
19
20 *were a wee bit apprehensive about discussing it”*) or for the CNS to handle (*“there was one [area]*
21
22 *that I found quite challenging; death and dying”*). Did the CNS have adequate resources to respond to
23
24 such patients’ needs? *“I think you know, you, you have to work with the resources that you've got and*
25
26 *if I felt that I couldn't have dealt wi' these women then obviously I would have signposted them to*
27
28 *other agencies.”* Eventually, the CNS seemed clearly satisfied with being involved in the study: *“I*
29
30 *thoroughly enjoyed doing that study... because I think, you know, that the information that we get*
31
32 *from this could generate a change”*.

DISCUSSION

33
34
35
36
37
38
39
40 Our systematic review identified 13 studies, demonstrating the variability and extent of unmet needs
41
42 of women with cervical cancer across different phases of the illness trajectory.¹⁹ Yet, interventional
43
44 research to develop and evaluate strategies to address these needs is lacking.¹⁸ This small study has
45
46 shown that nurse-led, PROMs-driven consultations to identify and address the supportive care needs
47
48 of women with cervical cancer are acceptable to and considered worthwhile by both care recipients
49
50 and care providers. Nonetheless, certain feasibility parameters need to be taken into careful
51
52 consideration before the intervention is deployed in clinical practice. For instance, given the
53
54 unsatisfactory recruitment rates, it remains unclear whether the intervention itself was of no interest to
55
56 possible candidates or whether it was affected by how the intervention was delivered (needs
57
58 assessment sessions on top of normal in-clinic consultations) or how women were approached to
59
60
61
62
63
64
65

1 participate (letters sent to eligible women and a mixed opt-in/opt-out method was applied). With only
2 one new attendee per month, the time-effectiveness of the intervention is also unclear. Adopting a
3 more flexible schedule for delivery of the intervention, whereby PROMs-driven consultations
4 coincide with pre-arranged hospital visits and/or are delivered via telephone or online, could further
5 encourage participation.
6
7
8
9

10 Unlike researcher-supported studies, here we relied on an actual member of the clinical team to
11 incorporate the intervention and research activities in her workload. This approach renders our
12 findings significant and relevant to clinical practice as we were able to establish a realistic view of the
13 facilitators and barriers of implementing this intervention. That said, it was made apparent that single-
14 handedly delivering a time-intensive intervention may hinder adequate testing and implementation. It
15 is thus important to identify ways to either bring the intervention down to delivery schedule that is
16 more manageable for lone providers or ensure adequate nursing support.
17
18
19
20
21
22
23
24
25

26 The unique nature of the consultations (one-to-one, face-to-face, patient-driven, and time-
27 protected) was highly praised by both intervention recipients and provider as it fostered a secure place
28 for women with cervical cancer to disclose intimate and/or hard-to-verbalise issues. Both Kristie and
29 Anna endorsed the standardised use of an easy-to-understand supportive care need PROM as a means
30 to help them shortlist, report and prioritise their needs. Although we did combine two PROMs,
31 totalling 54 items, we received no complaints regarding time or length of the assessment. It is worth
32 noting that in Phase 1, health professionals opted for brevity in needs assessments, whereas patients
33 focussed more on relevance and comprehensiveness. In Phase 2, we decided to prioritise patients'
34 preferences, but we do appreciate the need to find ways to minimise clinical work overload. If this
35 model is to be implemented in practice, it will be an interesting future step to explore whether use of a
36 bespoke and concise, yet equally comprehensive, needs assessment PROM could be used, and/or
37 additional clinical resources become available.
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52

53 In exit interviews, both women agreed that timing of the intervention was appropriate and
54 relevant, but specifically flagged the post-diagnosis and post-treatment period as the ones where
55 greatest support is necessary.¹⁸ Interestingly, both women also mentioned how helpful it would be if
56 summaries of their needs were also shared with GPs and community nurses in order to increase
57
58
59
60
61
62
63
64
65

1 understanding of their situation and facilitate more tailored discussions in the community. The need to
2 attend to cancer survivors' rehabilitation needs is a known one,³⁵ and major policy documents
3 advocate development of mechanisms to promote clinical continuity and better manage transitions of
4 care.^{36,37} Previous research has shown that while physical concerns are often addressed by the GP
5 and/or community nursing staff, psychosocial aspects (such as fear of relapse or social adjustment) are
6 often under-reported and under-assessed, and thus neglected.³⁸ Our findings pose a clear indication for
7 needs assessment data to be shared with all health professionals involved in the provision of care to
8 (at least) women with cervical cancer in order to enable effective communication that can lead to
9 seamless care.

10
11 From a clinical point of view, the Gynaecology CNS perceived engagement in the collection
12 and use of patient-reported data as an enlightening and educative activity. In Phase 1, it was
13 interesting to see how one consultant argued against the 'mechanistic' nature of PROMs-driven
14 assessments, essentially opting for needs assessments that are based on individual clinical expertise
15 and experience only. Conversely, existing evidence is largely supportive of a combination of
16 structured (PROMs-based) assessments and patient management that is based on clinical expertise
17 and specialised training to ensure that the holistic care that patients expect to receive is indeed
18 provided.^{13,39} PROMs can be the means to unveil unmet needs that can clinical expertise can help to
19 address. It can't be ignored however the possibility for some concerns to be difficult to explore or
20 handle.⁴⁰ In our study, concerns about death and dying proved challenging to address, whilst
21 assessment of intimacy issues was met with apprehension. As part of a needs assessment intervention,
22 nurse specialists could be trained to provide education for possible patient adjustment issues or
23 address women's sexuality needs,⁴¹ whilst clear routes of referral could enable timely and appropriate
24 referral to clinical specialists.

25
26 As yet, we cannot reliably estimate the potential effectiveness of the intervention nor can we
27 claim superiority of consecutive, monthly assessments over one-off, post-diagnosis assessments or
28 assessments timed in line with major patient transitions. Provided that such aspects are clarified in a
29 future replication study, this intervention could be an effective means for Gynaecology CNS to
30 provide comprehensive, nurse-led supportive care to women with cervical cancer.¹⁸

STRENGTHS AND LIMITATIONS

1 We thoroughly reviewed the existent literature and subsequently engaged patients and health
2 professionals in the actual planning of the study. This phased approach helped us to customise and
3
4 refine aspects of the intervention in an attempt to meet users' preferences, expectations and priorities,
5
6 and increase the intervention's feasibility and acceptability. Subsequently, we relied on a set of well-
7
8 validated PROMs to collect information in a reliable and comprehensive way. We then employed
9
10 different sources of information to comprehensively investigate the study's feasibility and
11
12 acceptability, including observation, questionnaire and interview data. Last, evaluation of the
13
14 intervention with minimal research support and clinical practice assimilation conditions allowed for a
15
16 realistic assessment.
17
18
19
20

21
22 The study should nonetheless be interpreted in the context of a number of key limitations.
23
24 Neither PROM completion nor consultation appointments were timed; however, none of the
25
26 participants reported the intervention as time-consuming. With a small sample size like this, whether
27
28 reliable feasibility estimates were obtained is unclear as is the influence of demographic/clinical
29
30 characteristics as moderators of feasibility. Relatedly, we were unable to provide estimates of
31
32 responsiveness to change or effect sizes for any of the intervention PROMs. Finally, this was a single-
33
34 centre study, thus reflecting current facilitators and barriers in the implementation of PROMs-driven
35
36 supportive care intervention for women with cervical cancer within the participating NHS board.
37
38 Whether feasibility and acceptability of the intervention is similar in diverse clinical contexts remains
39
40 unknown.
41
42
43

CONCLUSIONS

44
45
46 Testing the use of PROMs by nurse specialists in the delivery of supportive care to women with
47
48 cervical cancer indicated that this approach appears to be acceptable, but its feasibility requires further
49
50 evaluation. Congruent with the literature, we confirmed that CNS are key professionals in the delivery
51
52 of supportive care, and are receptive to and able to act upon information gleaned from supportive care
53
54 needs PROMs in clinical practice. Women with cervical cancer perceive important benefits from
55
56 participating in PROMs-driven, time-protected and private sessions with their CNS. Nevertheless, our
57
58
59
60
61
62
63
64
65

findings provide only tentative evidence to support the future use of PROMs as part of nurse-led consultations in this area, and warrant further confirmation in the future.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

1
2
3
4
5
6
7
8
9

Acknowledgments

The authors would like to thank all patients and health professionals for their invaluable contribution to this study.

10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

Conflicts of interest

The authors declare that there are no conflicts of interest, financial or otherwise.

Statement of Authorship

All authors have equally contributed to the preparation of this manuscript.

References

1. GLOBOCAN. Cervical Cancer: Estimated Incidence, Mortality and Prevalence Worldwide in 2012. International Agency for Research on Cancer.
<http://globocan.iarc.fr/old/FactSheets/cancers/cervix-new.asp>. Published 2012. Accessed July 6, 2016.
2. Cancer Research UK. Cervical cancer statistics. <http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/cervical-cancer#heading-Zero>. Published 2015. Accessed May 10, 2016.
3. Torre LA, Bray F, Siegel RL, Ferlay J, Lortet-Tieulent J, Jemal A. Global cancer statistics, 2012. *CA Cancer J Clin*. 2015;65(2):87-108. doi:10.3322/caac.21262.
4. Westin SN, Sun CC, Tung CS, et al. Survivors of gynecologic malignancies: impact of treatment on health and well-being. *J Cancer Surviv*. 2016;10(2):261-270. doi:10.1007/s11764-015-0472-9.
5. Obama K, Maru M, Maeda R, Kubota T. Cancer-related fatigue and physical activity among premenopausal cervical and endometrial cancer survivors in Japan. *J Med Dent Sci*. 2015;62(3):57-68. <http://www.ncbi.nlm.nih.gov/pubmed/26531173>. Accessed May 10, 2016.
6. Everhov ÅH, Ekberg S, Hirschberg AL, et al. Lost workdays in uterine cervical cancer survivors compared to the general population: impact of treatment and relapse. *J Cancer Surviv*. 2016;10(3):514-523. doi:10.1007/s11764-015-0496-1.
7. Bodurka DC, Sun CC, Frumovitz MM. Quality of life in cervix cancer survivors--what matters the most in the long-term? *Gynecol Oncol*. 2005;97(2):307-309. doi:10.1016/j.ygyno.2005.03.014.
8. Pfaendler KS, Wenzel L, Mechanic MB, Penner KR. Cervical cancer survivorship: long-term quality of life and social support. *Clin Ther*. 2015;37(1):39-48. doi:10.1016/j.clinthera.2014.11.013.
9. Vermeer WM, Bakker RM, Kenter GG, de Kroon CD, Stiggelbout AM, ter Kuile MM. Sexual issues among cervical cancer survivors: how can we help women seek help? *Psychooncology*. 2015;24(4):458-464. doi:10.1002/pon.3663.

10. Toubassi D, Himel D, Winton S, Nyhof-Young J. The informational needs of newly diagnosed cervical cancer patients who will be receiving combined chemoradiation treatment. *J Cancer Educ.* 2006;21(4):263-268. doi:10.1080/08858190701347937.
11. Valderas JM, Alonso J. Patient reported outcome measures: a model-based classification system for research and clinical practice. *Qual Life Res.* 2008;17(9):1125-1135. doi:10.1007/s11136-008-9396-4.
12. Donaldson MS. Taking stock of health-related quality-of-life measurement in oncology practice in the United States. *J Natl Cancer Inst Monogr.* 2004;20892(33):155-167. doi:10.1093/jncimonographs/lgh017.
13. Kotronoulas G, Kearney N, Maguire R, et al. What is the value of the routine use of patient-reported outcome measures toward improvement of patient outcomes, processes of care, and health service outcomes in cancer care? A systematic review of controlled trials. *J Clin Oncol.* 2014;32(14):1480-1501. doi:10.1200/JCO.2013.53.5948.
14. Darzi, Lord. High Quality Care For All. NHS Next Stage Review Final Report. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825. Published 2008. Accessed July 4, 2016.
15. Whiteing N, Cox C. Using patient reported outcome measures to improve patient care. *Gastrointest Nurs.* 2010;8(5):16-19.
16. Greenhalgh J, Long AF, Flynn R. The use of patient reported outcome measures in routine clinical practice: Lack of impact or lack of theory? *Soc Sci Med.* 2005;60(4):833-843. doi:10.1016/j.socscimed.2004.06.022.
17. Meadows KA, Rogers D, Greene T. Attitudes to the use of health outcome questionnaires in the routine care of patients with diabetes: A survey of general practitioners and practice nurses. *Br J Gen Pract.* 1998;48(434):1555-1559.
18. Cook O, Mcintyre M, Recoche K. Exploration of the role of specialist nurses in the care of women with gynaecological cancer: A systematic review. *J Clin Nurs.* 2015;24(5-6):683-695. doi:10.1111/jocn.12675.
19. Maguire R, Kotronoulas G, Simpson M, Paterson C. A systematic review of the supportive

- care needs of women living with and beyond cervical cancer. *Gynecol Oncol.* 2015;136(3):478-490. doi:10.1016/j.ygyno.2014.10.030.
20. Maguire R, Kotronoulas G, Papadopoulou C, Simpson MF, McPhelim J, Irvine L. Patient-reported outcome measures for the identification of supportive care needs in people with lung cancer: Are we there yet? *Cancer Nurs.* 2013;36:E1-E17. doi:10.1097/NCC.0b013e31826f3c8f.
21. Richardson A, Medina J, Brown V, Sitzia J. Patients' needs assessment in cancer care: A review of assessment tools. *Support Care Cancer.* 2007;15(10):1125-1144. doi:10.1007/s00520-006-0205-8.
22. Carlson LE, Waller A, Mitchell AJ. Screening for distress and unmet needs in patients with cancer: review and recommendations. *J Clin Oncol.* 2012;30(11):1160-1177. doi:10.1200/JCO.2011.39.5509.
23. Krueger RA. *Focus Groups: A Practical Guide for Applied Research.* Thousand Oaks, CA: SAGE Publications; 1994.
24. Mansell I, Bennett G, Northway R, Mead D, Moseley L. The learning curve: the advantages and disadvantages in the use of focus groups as a method of data collection. *Nurse Res.* 2004;11(4):79-88. doi:10.7748/nr2004.07.11.4.79.c6217.
25. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: Recommendations for good practice. *J Eval Clin Pract.* 2004;10(2):307-312. doi:10.1111/j..2002.384.doc.x.
26. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol.* 2006;3:77-101. doi:10.1191/1478088706qp063oa.
27. Boyes A, Girgis A, Lecathelinais C. Brief assessment of adult cancer patients' perceived needs: Development and validation of the 34-item supportive care needs survey (SCNS-SF34). *J Eval Clin Pract.* 2009;15(4):602-606. doi:10.1111/j.1365-2753.2008.01057.x.
28. Cull a, Stewart M, Altman DG. Assessment of and intervention for psychosocial problems in routine oncology practice. *Br J Cancer.* 1995;72(1):229-235.
29. Cossich T, Schofield P, McLachlan SA. Validation of the cancer needs questionnaire (CNQ)

- short-form version in an ambulatory cancer setting. *Qual Life Res.* 2004;13(7):1225-1233.
doi:10.1023/B:QURE.0000037496.94640.d9.
- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
30. McIllmurray MB, Thomas C, Francis B, Morris S, Soothill K, Al-Hamad A. The psychosocial needs of cancer patients: Findings from an observational study. *Eur J Cancer Care (Engl)*. 2001;10(4):261-269. doi:10.1046/j.1365-2354.2001.00280.x.
31. Shim EJ, Lee KS, Park JH, Park JH. Comprehensive needs assessment tool in cancer (CNAT): The development and validation. *Support Care Cancer*. 2011;19(12):1957-1968. doi:10.1007/s00520-010-1037-0.
32. De Groot JM, Mah K, Fyles A, et al. The psychosocial impact of cervical cancer among affected women and their partners. *Int J Gynecol Cancer*. 2005;15(5):918-925. doi:10.1111/j.1525-1438.2005.00155.x.
33. Schag CA, Ganz PA, Heinrich RL. Cancer Rehabilitation Evaluation System--short form (CARES-SF). A cancer specific rehabilitation and quality of life instrument. *Cancer*. 1991;68(6):1406-1413. <http://www.ncbi.nlm.nih.gov/pubmed/1873793>. Accessed April 22, 2016.
34. Lowery AE, Greenberg MA, Foster SL, et al. Validation of a needs-based biopsychosocial distress instrument for cancer patients. *Psychooncology*. 2012;21(10):1099-1106. doi:10.1002/pon.2008.
35. Mikkelsen T, Søndergaard J, Jensen A, Olesen F. Cancer rehabilitation: psychosocial rehabilitation needs after discharge from hospital? *Scand J Prim Health Care*. 2008;26(4):216-221. doi:10.1080/02813430802295610.
36. National Institute for Clinical Excellence. Guidance on cancer services: improving supportive and palliative care for adults with cancer. The manual. London: National Institute for Clinical Excellence. <https://www.nice.org.uk/guidance/csg4/resources/improving-supportive-and-palliative-care-for-adults-with-cancer-773375005><https://www.nice.org.uk/guidance/csg4/resources/improving-supportive-and-palliative-care-for-adults-with-cancer-773375005>. Published 2004. Accessed June 27, 2016.
37. Stout NL, Silver JK, Raj VS, et al. Toward a National Initiative in Cancer Rehabilitation:

Recommendations From a Subject Matter Expert Group. Arch Phys Med Rehabil. 2016.

doi:10.1016/j.apmr.2016.05.002.

38. Mikkelsen T, Sondergaard J, Sokolowski I, Jensen A, Olesen F. Cancer survivors' rehabilitation needs in a primary health care context. Fam Pract. 2009;26(3):221-230. doi:10.1093/fampra/cmp004.
39. National Cancer Action Team. Holistic Needs Assessment for people with cancer: A practical guide for healthcare professionals. National Cancer Supportive Initiative, NHS. http://www.ncsi.org.uk/wp-content/uploads/The_holistic_needs_assessment_for_people_with_cancer_A_practical_Guide_NCAT.pdf. Published 2013. Accessed June 21, 2016.
40. Faithfull S, Samuel C, Lemanska A, Warnock C, Greenfield D. Self-reported competence in long term care provision for adult cancer survivors: A cross sectional survey of nursing and allied health care professionals. Int J Nurs Stud. 2016;53:85-94. doi:10.1016/j.ijnurstu.2015.09.001.
41. Kotronoulas G, Papadopoulou C, Patiraki E. Nurses' knowledge, attitudes, and practices regarding provision of sexual health care in patients with cancer: critical review of the evidence. Support Care Cancer. 2009;17(5):479-501. doi:10.1007/s00520-008-0563-5.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

Figure Legends

Figure 1. (A) Kristie’s CCCQ radar plot showing scores on seven domains of concern over three time-points. Higher scores indicate greater concerns. (B) Kristie’s responses on the Problem Checklist over three time-points.

Figure 2. (A) Anna’s CCCQ radar plot showing scores on seven domains of concern over three time-points. Higher scores indicate greater concerns. (B) Anna’s responses on the Problem Checklist over three-time points.

Figure 3. (A) Ruth’s CCCQ radar plot showing scores on seven domains of concern for T1. Higher scores indicate greater concerns. (B) Ruth’s responses on the Problem Checklist at T1.





