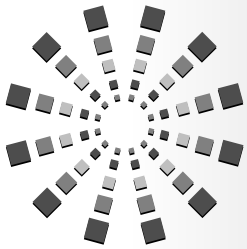

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Development of a Novel Remote Patient Monitoring System

The Advanced Symptom Management System for Radiotherapy to Improve the Symptom Experience of Patients With Lung Cancer Receiving Radiotherapy

KEY WORDS
ASyMS
E-Health
Lung cancer
Radiotherapy
Supportive care
Technology

Background: The use of technology-enhanced patient-reported outcome measures to monitor the symptoms experienced by people with cancer is an effective way to offer timely care. **Objective:** This study aimed to (*a*) explore the feasibility and acceptability of the Advanced Symptom Management System with patients with lung cancer receiving radiotherapy and clinicians involved in their care and (*b*) assess changes in patient outcomes during implementation of the Advanced Symptom Management System with patients with lung cancer receiving radiotherapy in clinical practice. **Methods:** A repeated-measures, single-arm, mixed-methods study design was used involving poststudy interviews and completion of patient-reported outcome measures at baseline and end of treatment with 16 patients with lung cancer and 13 clinicians who used this mobile phone–based symptom monitoring system. **Results:** Only rarely did patients report problems in using the handset and they felt that the system covered all relevant symptoms and helped them to manage their symptoms and

effectively communicate with clinicians. Clinical improvements in patient anxiety, drowsiness, and self-care self-efficacy were also observed. Clinicians perceived the use of ''real-time'' risk algorithms and automated self-care advice provided to patients as positively contributing to clinical care. Reducing the complexity of the system was seen as important to promote its utility. **Conclusions:** Although preliminary, these results suggest that monitoring patient symptoms using mobile technology in the context of radiotherapy for lung cancer is feasible and acceptable in clinical practice. **Implications for practice:** Future research would be most beneficial if the use of this technology was focused on the postradiotherapy phase and expanded the scope of the system to encompass a wider range of supportive care needs.

Lung cancer is the commonest cancer worldwide,[1] with 1.6 million people diagnosed each year. Survival rates are poor, with only 7% to 9% of people in the United Kingdom living 5 years or more.[2–5] Approximately 70% of people with lung cancer receive radiotherapy as a treatment option, with either curative or palliative intent.[6] Radiotherapy is associated with a number of toxicities that occur as acute or late effects which have a negative impact on patient outcomes such as quality of life, symptom burden, and physical functioning.[7–10] People with lung cancer experience a high level of supportive care needs, and many of these needs are unmet.[11–15] Contributing in part to unmet needs is that people with lung cancer tend not to seek help for their supportive care needs, lack awareness of what needs are amenable to intervention, and tend to assume that many of their needs have to be endured.[16] Systematic supportive care is therefore vital in this patient group.[13]

To this end, patient-reported outcome measures (PROMs) can be used to identify the supportive care needs of people with lung cancer throughout the cancer trajectory. Patient-reported outcome measures are defined as ''measurements of an aspect of a patient's health status that come directly from the patient,''[17] and their use has been somewhat instigated by the incongruence between patient and health professional and/or caregiver's perceptions of health and need.[18–20] This has led to the wide scale agreement that patient reporting of their symptoms is the gold standard[21] and that collection of PROMs data in clinical practice has a number of beneficial effects.[22]

Enhancing the utility of PROMs within clinical practice is the use of ''real-time'' health technologies (ie, e-health technologies), which have the ability to collect PROM data and send this information immediately to relevant health/social care professionals, thus providing a prompt to initiate early intervention. Recently, government policy in the United Kingdom has endorsed the use of e-health technologies to support clinical care with the ultimate goal being the promotion of care provided[23] and self-care[24] in people with long-term health conditions, including patients with cancer. With the recent shift from inpatient to ambulatory care, the numbers of patients with cancer receiving treatment on an outpatient basis have increased dramatically; this can be translated to more people having to manage treatment-related toxicities at home without direct supervision from health professionals.[25] The use of e-health technologies such as mobile information and real-time communications technology may be instrumental in overcoming such barriers.[26] In that sense, enhancement of the care provided to people with cancer can be translated into reduction in symptom prevalence and/or burden and, therefore, reduction in unnecessary hospital admissions, inpatient days, or outpatient visits. Alternatively, promotion of self-care, namely, "the ability of individuals, families, and communities to promote health, prevent disease, and maintain health and to cope with illness and disability with or without the support of a health-care provider" (World Health Organization, 2013),[27] can give people with cancer greater confidence and sense of control and consequently enhance perceived well-being and quality of life.[28]

The Advanced Symptom Management System (ASyMS)[29–32] is 1 of the most developed remote patient monitoring systems that enables the real-time collection of PROM data to enhance both provision of structured cancer care and patient self-care. Over the past 10 years, the ASyMS has been tested in several

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patient populations, including adults with breast, colorectal, lung, and hematological cancers receiving chemotherapy[29–31]; teenagers receiving chemotherapy[28]; and people with palliative care needs.[33] These studies have demonstrated positive perceptions by patients and health professionals regarding the utility, acceptability, and feasibility of the system and improvements in symptom outcomes.[30]

Despite the recognition of the wide spectrum of supportive care needs experienced by people with lung cancer during and after radiotherapy,[13] there is a lack of interventions that explore the use of real-time technologies in this patient population. To date, only 1 study has been published on the use of e-health technology to monitor and assess the symptoms experienced by people with lung cancer receiving palliative radiotherapy[34]; however, because of low levels of recruitment, no outcomes were reported and the authors concluded that further research was warranted. Therefore, the primary aim of this study was to develop and explore the feasibility and acceptability of the ASyMS in patients with lung cancer receiving radiotherapy (ASyMS-R) and with clinicians involved in their care. A secondary aim was to explore changes in PROMs during the implementation of ASyMS-R, which could eventually inform the design and primary endpoints of future randomized controlled trials.

Methods

A repeated-measures, single-arm, mixed-methods study design was used in this study, which was conducted in 5 clinical sites in the United Kingdom between 2008 and 2011. The current study was informed by the Medical Research Council (MRC) Complex Interventions Framework.[35] E-health technological interventions are regarded as "complex" because they are built up from a number of components that involve theoretical understanding of how the use of technology benefits patients and require the involvement of multiple agencies. The MRC Framework proposes a cyclical, multimethod process in the evaluation of these components that takes place in partnership with the target population.[35] In addition, the Holistic Framework to improve the Uptake and Impact of e-Health Technologies developed by van Gemert-Pijnen et al[36] was used to inform the current study. According to this framework, 6 fundamental working principles underpin the development of e-health technologies (Table 1). The framework provides comprehensive development strategies that not only can be used in a forward (development) and backward (summative evaluation) process but is also flexible to accommodate for time, policy, and financial challenges in clinical practice.[36]

Sample and Setting

The study aimed to recruit 45 patients with lung cancer receiving a course of thoracic radiotherapy, 18 years or older, and able to provide written, informed consent. This sample size has been advocated as adequate for feasibility/pilot studies.[37] Clinicians involved in the care of people with lung cancer receiving radiotherapy were also recruited at the 5 participating centers after informed consent was obtained. Ethical approval for the study was granted by the Fife and Forth Valley on Medical Research Ethics committee.

Procedures

ADAPTATION OF ASYMS FOR USE IN PEOPLE WITH LUNG CANCER RECEIVING RADIOTHERAPY (MRC FRAMEWORK PRECLINICAL PHASE[35])

The ASyMS is a mobile phone–based, remote patient monitoring system. For this study, it was adapted for use in people with lung cancer receiving radiotherapy via multiple methods, including an e-survey of toxicity assessment tools in the United Kingdom and 3 systematic reviews of the literature (ie, symptoms experienced by people with lung cancer undergoing radiotherapy treatment, toxicity assessment tools, evidence-based self-care; unpublished data). In addition, the protocols from each of the participating sites pertaining to radiotherapy toxicity assessment and self-care advice were also reviewed. Focus groups with clinicians caring for people with lung cancer (n = 2) and people with lung cancer who were currently or had recently received radiotherapy treatment (n = 2) were also conducted. Exploring the perspectives of

Table 1 • Working Principles of the Holistic Framework for the Uptake and Impact of e-Health Technologies[36]

Principle	Concept
e-Health technology development is a participatory process	Stakeholder involvement throughout the entire eHealth technology development process is paramount.
e-Health technology development involves continuous evaluation cycles	e-Health technology development is considered an iterative and dynamic process that involves continuous cycles of evaluation with no fixed end.
e-Health technology development is intertwined with implementation	The conditions for implementation must be considered as soon as development of an eHealth technology begins and evaluated during all subsequent development stages.
e-Health technology development changes the organization of healthcare	e-Health technology development may reshape healthcare as it creates new processes and infrastructures for the delivery of healthcare to patients.
e-Health technology development should involve persuasive design techniques	e-Health technology development should involve persuasive techniques such as user profile matching or rewards for appropriate behavior in order to motivate patients to engage in self-management.
e-Health technology development needs advanced methods to assess impact	Integration of data collected via use of diverse research methods is required to better understand how and why eHealth technologies make a difference or not.

key users is advocated as being a key component in the development and testing of new technologies.[38] This information informed the content and adaptation of the developing ASyMS-R, including (*a*) the selection of the daily electronic PROMs (e-PROMs) completed by patients, which included the Memorial Symptom Assessment Scale–Short Form[39] and the Rotterdam Symptom Checklist–Activity Subscale[40]; (*b*) the risk model for the generation of alerts; and (*c*) the evidence-based self-care advice provided for management of toxicity.

THE ASYMS-R INTERVENTION (MRC FRAMEWORK MODELING PHASE[35])

Participating clinicians notified the study research assistant of a new patient scheduled to receive radiation therapy; the research assistant then checked patient eligibility against inclusion and exclusion criteria, fully informed patients about the study's aims and procedures, discussed issues of confidentiality and anonymity, and invited patients to take part in the study. All consenting patients provided written informed consent.

Patients used the ASyMS-R at home during working hours (9 AM–5 PM), 7 days a week, for the duration of their radiotherapy treatment and for 1 month after treatment and were instructed to follow local procedures regarding out-of-hours care. After completing the daily questionnaire on the mobile phone, patient daily symptom data were sent in real time to a central study server, where an integrated risk model analyzed the symptom reports. Successful receipt and analysis of symptom data were followed by 2 actions (Figure 1). First, patients immediately received self-care advice on their mobile phone that was directly related to the severity of their symptoms. Second, for those symptoms that were of clinical concern, the server generated alerts to a pager held by a health professional at the clinical site. The ASyMS-R generated 2 types of alerts. An "amber alert" was generated when the patient was experiencing symptoms that were not severe or life-threatening but where early intervention may have prevented progression of the symptom or minimized it. A "red alert" denoted that the patient was experiencing symptoms that were severe. Table 2 provides examples of symptoms and conditions used in the ASyMS-R risk models to generate amber or red alerts. For amber alerts, clinicians were required to contact the patient within 8 hours after an alert had been received; for red alerts, health professionals were required to contact patients as soon as possible to initiate appropriate management. Upon receipt of a new incoming alert, health professionals were required to log into a secure Web page to access the patient's symptom history in the format of symptom reports and graphs of symptoms to inform any clinical decisions and subsequent interventions. The health professional then contacted the patient over the phone to conduct a clinical assessment and offer timely advice and support. Any interventions initiated as a result of the alert were documented in the patient's medical record and on the secure Web page. No standardized clinical intervention protocols were used in this study; instead, health professionals were asked to make use of clinical intervention protocols available at their clinical site. An example scenario of a clinical intervention following receipt of a red alert is presented in Figure 2.

Data Collection

Perceptions of patients and health professionals of the feasibility and acceptability of ASyMS-R were explored using a combination of semistructured questionnaires and semistructured interviews successfully used in previous ASyMS studies.[29,31] Semistructured questionnaires were completed before and after intervention, and interviews were conducted at the end of the study. The content of the questionnaires and interviews focused on the following predetermined themes that were relevant to both patients and health professionals: experience of using the technology, expectations of being involved in the ASyMS-R study (prestudy only), perceptions of the training received on how to use the ASyMS R system, and experience of using the system in clinical practice (including the e-PROMs used, the alerts generated, and the evidence-based self-care advice provided). Participants were also asked about their perceptions on changes in clinical care as a result of using the ASyMS-R, including perceived changes in symptom management, suggestions for improving the system, and their overall experiences of being involved in the study. Health professionals were also asked to grade the appropriateness of all clinical alerts received.

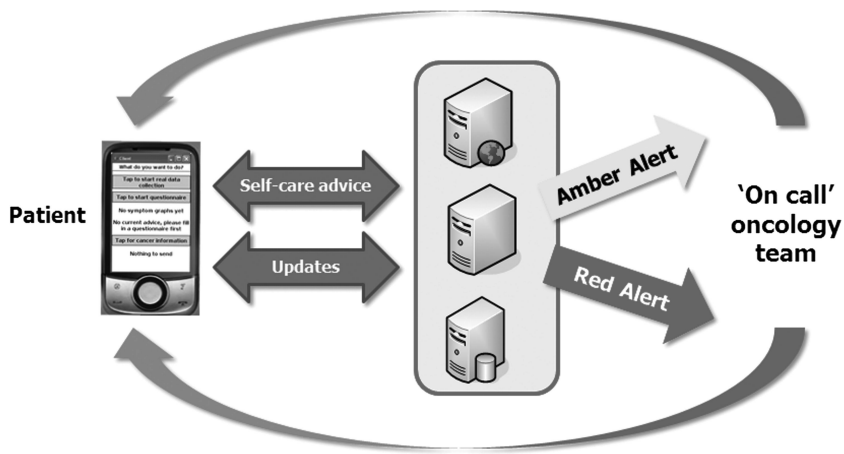

Figure 1 ■ Conceptual diagram of the Advanced Symptom Management System intervention for patients with lung cancer receiving radiotherapy (ASyMS-R).

Table 2 • Examples of Alerts Generated by the Advanced Symptom Management System for Patients With Lung Cancer Receiving Radiotherapy for Different Memorial Symptom Assessment Scale–Short Form and Rotterdam Symptom Checklist–Activity Symptom Items Based on Grading of Symptom Frequency/Severity/Distress

Symptom	Graded as/at	Condition for Alert to Be Triggered	Type of Alert to Be Triggered
Coughing up blood	"Not happened before" AND "more than a few teaspoons of blood"	Always triggered	Red
Pain	"Quite a bit" OR "Very much"	Always triggered	Red
Shortness of breath	"Quite a bit" OR "Very much"	Always triggered	Red
Flu-like symptoms	"Quite a bit" OR "Very much"	Always triggered	Red
Coughing up blood	"Not happened before"	Always triggered	Amber
Coughing up blood	"Happened before" AND "more than two teaspoons of blood"	Always triggered	Amber
Pain	"Somewhat"	Always triggered	Amber
Shortness of breath	"Somewhat"	Always triggered	Amber
Flu-like symptoms	"Somewhat"	Always triggered	Amber
Other symptoms (eg, cough, nausea, lack of appetite, sore throat)	"Quite a bit" OR "Very much"	Always triggered	Amber
Feeling anxious	"Somewhat"	72 hours or more	Amber
Heartburn	"Somewhat"	48 hours or more	Amber
Any "new" symptom	"Quite a bit" OR "Very much"	Always triggered	Amber

However, how fast any incoming alerts were handled by health professionals or the time required for a clinician to fully investigate and respond to an alert was not recorded in this early version of the ASyMS-R.

To address the study's secondary objective, patients also completed 4 PROMs at baseline and at the end of treatment to investigate changes in anxiety levels (State-Trait Anxiety Inventory Form Y[41]), self-care self-efficacy (Strategies Used by Patients to Promote Health [SUPPH-29[42]]), well-being and quality of life (Functional Assessment of Cancer Therapy–Lung Cancer [FACT-L[43]]), and physical symptom distress (Edmonton Symptom Assessment Scale[44]) during use of the ASyMS-R.

The State-Trait Anxiety Inventory Form Y was used to measure psychological distress. It consists of two 20-item scales for

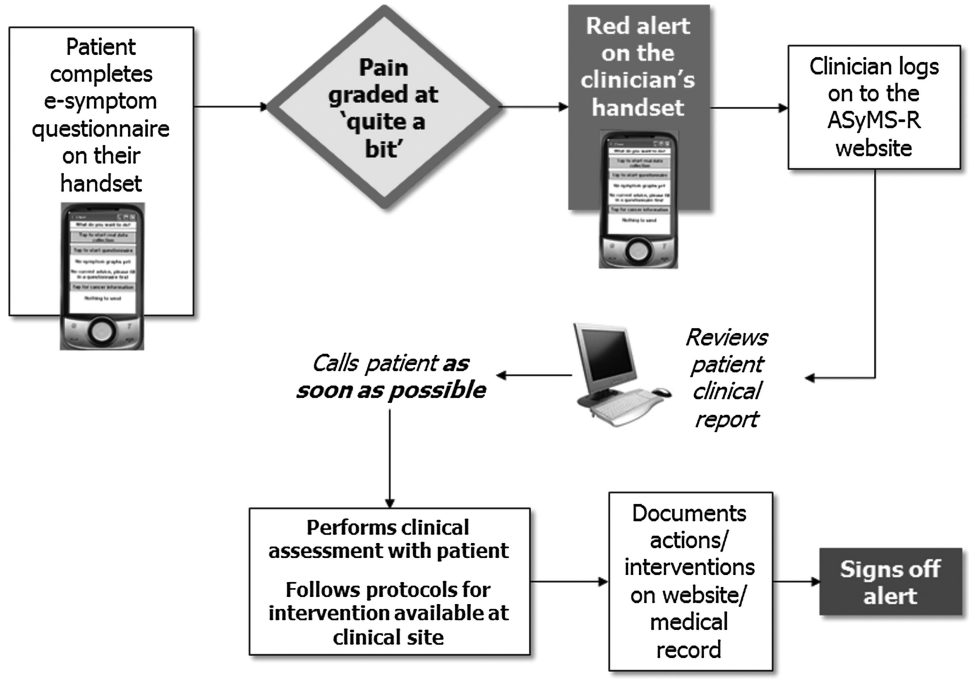

Figure 2 ■ Example scenario of clinician involvement in handling a red alert generated by pain graded at "quite a bit." Abbreviation: Advanced Symptom Management System for patients with lung cancer receiving radiotherapy (ASyMS-R).

measuring state (ie, a transitory emotional response to a stressful situation) and trait anxiety (ie, personality-related predisposition to anxiety).[41] Higher scores indicate more anxiety. The SUPPH-29 was used to measure perceived self-care self-efficacy. It consists of 29 items measuring individuals' belief in the strategies they use to improve their health. Three subscales (stress reduction, making decisions, and positive attitude) and a total score can be calculated.[42] An increase in score shows an increase in level of self-efficacy related to self-care behaviors. Disease-specific quality of life was assessed using the FACT-L scale. The FACT-L scale consists of 5 subscales: 4 general subscales (ie, physical well-being, social/family well-being, emotional well-being, and functional well-being [FWB]) and a 7-item lung cancer subscale that assesses symptoms commonly reported by patients with lung cancer.[43] Along with a total FACT-L score, a trial outcome index is derived by adding scores on the physical well-being and FWB subscales to the lung cancer subscale. Higher scores represent better functioning and better quality of life. Finally, the Edmonton Symptom Assessment Scale measures the presence and severity of 10 common symptoms (pain, fatigue, nausea, depression, anxiety, drowsiness, shortness of breath, lack of appetite, sleep disorders, and impaired feeling of well-being) in patients with cancer.[44] Patients are asked to rate the intensity of symptoms over the past 24 hours using an 11-point numeric rating scale from 0 (no symptoms) to 10 (worst possible symptoms).

Data Analysis

Patient and professional interviews were audio-recorded and transcribed verbatim. Data were analyzed using thematic analysis.[45] Thematic content analysis[45] 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 version 8 was used to aid the organization of the data. Themed categories were identified by 2 researchers on the basis of the research objectives and questions following a deductive approach. Analysis of the data focused on points of convergence or divergence on issues raised by participants. For reliability and validity purposes, 2 researchers coded interviews independently. After this preliminary stage of analysis, the 2 coders cross-checked the codes to ensure that the interpretations were appropriately grounded in the data. Intercoder agreement was achieved for the entire data set.

Demographic, clinical, and perception questionnaires were calculated as frequencies (percent), means, standard deviations, and range. Pairwise deletion approach was used to effectively deal with missing data. Data were examined for normality (Shapiro-Wilk test for samples <50) to select between parametric and nonparametric tests. Statistical analyses for 2 (t test or Mann-Whitney U) or more independent groups (1-way analysis of variance or Kruskal-Wallis test) were performed to identify significant associations between demographic or clinical variables and items on the perceptions questionnaire. Because of the small sample size, Fisher exact tests were performed to examine differences between categorical/nominal variables. Paired-samples t tests (or Wilcoxon signed ranks tests) and McNemar tests were performed to test for significant differences between prestudy and poststudy data. IBM SPSS 17.0 for Windows was used to aid statistical analyses. Given that this was an exploratory study, no adjustment for multiple statistical tests was applied. All tests were conducted with a 2-tailed level of significance of .05.

Results

A total of 57 patients across the 5 sites were approached to take part in the study. Of these, 41 patients declined and 16 patients (response rate, 28.1%) consented and participated in the study. Reasons for refusal included poor health status, patients feeling that they were being adequately managed by their clinical team and therefore perceived no need for additional supportive care interventions, and lack of familiarity with the use of technology. Such low rates of participation are common among people with lung cancer, those with advanced disease, and those approaching the end of life.[46–48] No comparisons between patients who consented and those who refused participation could be conducted as we did not have permission to collect sociodemographic data from nonparticipants.

Participants were predominantly women (n = 11), with a mean (SD) age of 63.6 (12.9) years, ranging between 42 and 85 years. Three of 4 patients (n = 12) had a good performance status (Eastern Cooperative Oncology Group Performance Status 0 or 1), with most (n = 5) scheduled to receive 5 fractions of radiotherapy for lung cancer. Because of the progressive nature of the disease, 5 patients died before poststudy assessment; thus, information was collected only from the remaining 11 patients at this point. Because also of missing data, actual numbers of patients commenting on the different components of the ASyMS-R vary.

A total of 13 health professionals also participated in the study. Most of the health professionals identified themselves as lung cancer nurse specialists (n = 4), consultant oncologists (n = 2), nursing research fellows (n = 2) or other (staff nurse; radiographer; charge nurse; consultant nurse; n = 4). One health professional did not fill out the respective question.

Primary Aim: Feasibility and Acceptability of ASyMS-R

Over a 12-month period, a total of 182 alerts were generated by the ASyMS-R during the study (138 amber alerts/44 red alerts). Health professionals graded 51% of amber alerts and 43% of red alerts generated by ASyMS-R as being appropriate. Reasons for alerts being deemed as inappropriate included no change from the patient's baseline measurements, patients being seen on a daily basis by health professionals involved in their care, symptoms preexisting before radiotherapy treatment, other health professionals dealing with symptoms, and symptoms improving from previous measurement. However, a few health professionals also spoke about the difficulties in labeling the alerts as appropriate or inappropriate as they perceived all alerts generated by the patient to be appropriate.

During poststudy interviews, 9 patients indicated that they had received enough training to use the ASyMS-R handset. Furthermore, all or almost all reported that they never or very rarely

encountered problems in using the handset (n = 10; 100%), answering and submitting questionnaires (n = 9; 90%), reading the self-care information after submitting a questionnaire or again at a later date (n = 10; 100%), or finding cancer information pages (n = 8; 89%).

> I had no hassle with it at all, and as I say having, you know I'm no(t) great on computers and things but I have some knowledge so I was able to do it. [ID18]

Seventy-eight percent of patients (n = 7) felt that the ASyMS-R questionnaire covered all relevant symptoms, and all (n = 9) agreed that the handset helped them to both manage their symptoms and communicate with the physicians and nurses responsible for their care, irrespective of phase of treatment.

> Well as far as I am concerned yes, because it was very helpful because I had this bad cough and 1 or 2 alerts came up and the nursing staff at the other end were immediately onto it…the fact that we were in contact with the hospital very much quicker than we would be if we'd waited and maybe even phoned. [ID51]

Irrespective of phase of treatment, most health professionals (n = 10; 83%) also felt that the use of ASyMS-R resulted in earlier detection of problematic symptoms and timely interventions more often than with usual practice.

Patients also expressed feelings of reassurance offered by ASyMS-R and the rapid feedback by health professionals in response to reported symptoms.

> I think it's a necessity almost, it just keeps your morale up and I think it's a great little gadget. I'm glad, let me say I'm glad I had it and I'm glad I used it. [ID31]

Comments were also made on the way that ASyMS-R reduced the uncertainty experienced by the patients, particularly at times when they were at home and were unsure as to whether they should contact health professionals or not.

> I was very pleased because once you're away from the hospital and you needed contact with them you're out on a limb sort of thing…and you do tend to think "oh well perhaps this isn't anything" and at least when you're in contact with them (via ASyMS) they can, they know whether it is anything that's necessary or not. So yes I quite agree with it, I'm glad that they were (there). [ID51]

Corroborating these findings, health professionals also viewed positively having real-time access to the patient's symptom reports on the ASyMS-R Web site after an alert, while having this information at hand before calling the patient enabled them to be better prepared:

> …em, I think you, even in any situation so that you're, like a bit more prepared, em seeing what their, their issues are em, because they might have kind of forgotten what they put in to their questionnaire when you, when you phone them, em so it's just kind of saying you phoned and it makes them feel that you've actually… it's very individual to them you've taken the time to look, you've taken the time to prepare before you phone so you've got the knowledge, and they don't need to go through everything again with you cause they might no [not] be feeling up to that. [SHP2]

Another area where patients provided positive feedback was the automated self-care advice generated by the ASyMS-R; 89% of them (n = 8) perceived the self-care advice offered easy to understand and user-friendly:

> Oh it was helpful, yes…yes, that was helpful. Aye well the, the coughing and just to, reminding you to lie upright upright, that was the thing you're inclined to forget…you know to sort of eh, even sit up, up in bed…pillows up and eh coughing, and what was the other thing…? Breathless, breathless, instead of panicking, sometimes you could be inclined to, if you just let it get on top of you, and being reassured there that just, to do your breathing exercises which I had got in the hospital… and just relax, so that, that, that was good. [ID1]

Similarly, most health professionals (n = 9) also perceived the self-care advice as being a positive aspect that could help patients feel more empowered:

> The best thing I think was the self-care advice because it's encouraging patients with their own health and to try things first cause that's what we would do for them anyway…so I think it is putting the ball back in their court for their health em and you know trying that first and if they feel better after a self-help tip that they've done themselves, it gives them a bit of kind of encouragement to. [SHP2]

However, 6 patients admitted to never or only sometimes having read the self-care information pages, either during or after treatment. In the poststudy interviews, some of the participants commented on how they were not trained on using this component of the system. Others commented on how they did not use the self-care information because of having received similar information from their healthcare professionals:

> Aye, I'll be honest about that, I scanned over it [self-care] because I was getting, I, I was getting the treatment for it, do you know I was doing, what I should have been doing kind of thing it wis'nae [was not] anything that was new to me. [ID18]

Importantly, professionals perceived the system to have most potential during the posttreatment phase, when patients had to deal with the toxicities of their treatment with limited input from healthcare personnel:

> I think there's quite good contact during radiotherapy. But where it falls down and this is where this device would be useful, I think, is after treatment; if patients are at home by themselves, nobody's is really asking them every day how they are feeling, what their symptoms are…I think that would be something to think about for the future. [PI2]

Despite seeing the utility of ASyMS-R in the delivery of timely interventions to people with lung cancer, half of the health professional sample (n = 6) were unsure of the utility of ASyMS-R or considered it as definitely unhelpful. One health

professional spoke about how she found the system cumbersome because of having to use different pieces of equipment:

> It takes the patient to key in something and then for a nurse to respond to an additional piece of equipment that they have to carry apart from the equipment they already carry. It then depends on them picking that that alert up and then physically logging into another system in addition to the system they will always be logging into and then phoning the patient. So compared to the system that I'm used to, it seems cumbersome, it adds in too many other things to do to actually get to the patient. [CNS1]

Secondary Aim: Change in Patient Outcomes

Patients reported moderate levels of anxiety both at baseline and at follow-up (Table 3). No differences in anxiety levels were found according to clinical or demographic variables at either prestudy or poststudy (all P values > .05). In addition, no significant between–time point differences were found for either state ($Z = -0.42$; $P = .68$) or trait anxiety ($Z = -0.25$; $P = .80$) before and after using the handset.

Mean SUPPH-29 scores also indicated that patients were "somewhat confident" in handling the effects of their disease and treatment at each time point. Again, no associations with demographic or clinical variables emerged (all P values > .05). Moreover, no significant differences were found between prestudy and poststudy data (all P values > .05); however, a slight improvement in mean scores was noted for "positive attitude" and "making decisions" subscales after use of the handset.

Patient well-being was reported as overall good, especially the physical, social, and emotional components, at either point of assessment; only scores on the FWB scale were relatively low.

Table 3 • Baseline and Posttreatment Outcome Scores and Between–Time-Point Associations

		Baseline (n = 15)			Posttreatment (n = 11)		
Outcome Subscale	Cronbach's α	Mean	SD	Range	Mean	SD	Range
STAI-Y state	.63	43.9	9.0	23–61[a]	46.4[b]	5.1	38–54
STAI-Y trait	.62	43.0[c]	8.3	23–53	44.9[d]	5.3	33.51
SUPPH29 positive attitude	.70	48.1[e]	16.1	17–80[f]	56.1[g]	14.6	31–76
SUPPH29 stress reduction	.65	27.4[c]	10.9	13–50	26.6	9.4	16–42
SUPPH29 making decisions	.72	8.4[c]	4.0	2–15	9.4	3.7	3–14
FACT-L PWB	.74	19.7	6.5	6–27[h]	17.4	6.2	3–25
FACT-L SWB	.69	18.6	4.0	12–24	17.1	4.0	10–22
FACT-L EWB	.70	16.6	6.4	3–24	16.5	6.6	5–24
FACT-L FWB	.73	12.0	7.8	2–26	14.6	6.6	8–25
FACT-L LCS	.72	21.2	6.7	10–32	19.6	7.1	8–32
FACT-L Total	.68	86.2	24.7	36–125	85.1	21.6	53–120
FACT-L TOI	.73	52.1	17.8	18–80	51.6	15.5	20–74
		Baseline (n = 14)			Posttreatment (n = 10)		
	Cronbach's α	Median	Range	>4 (%)[i]	Median	Range	>4 (%)
ESAS pain	.68[j]	1.5	0–7[k]	21.4	4	0–8	20.0
ESAS tiredness		5	1–8	57.1	4	0–9	50.0
ESAS nausea		0	0–8	7.1	2	0–6	20.0
ESAS depression		0	0–8	14.2	0	0–8	10.0
ESAS anxiety		0.5	0–10	28.5	1	0–8	10.0
ESAS drowsiness		3.5	0–9	42.9	3	0–8	20.0
ESAS appetite		5	0–10	57.1	4[l]	0–10	44.4
ESAS well-being		4.5	0–10	50.0	4.5	0–7	50.0
ESAS breathlessness		3.5	0–9	35.7	3	0–9	30.0
ESAS other problem		0[g]	0–6	40.0	0[m]	0–7	16.7

Abbreviations: ESAS, Edmonton Symptom Assessment Scale; EWB, emotional w/b subscale; FACT-L Total, Functional Assessment of Cancer Therapy–Lung Cancer, sum of all 5 subscales; FWB, functional w/b subscale; LCS, lung cancer specific w/b subscale; PWB, physical w/b subscale; STAI-Y, State-Trait Anxiety Inventory Form Y; SUPPH29, Strategies Used by Patients to Promote Health 29; SWB, social w/b subscale; TOI, trial outcome index (sum of PWB, FWB, and LCS); w/b, well-being.
[a]Possible range of scores: 20–80.[b] n = 11.
[c]n = 13.
[d]n = 8.
[e]n = 14.
[f]Possible range of scores: positive attitude, 15–75; stress reduction, 10–50; making decisions, 3–15.
[g]n = 10.
[h]Possible range of scores: PWB, 0–28; SWB, 0–28; EWB, 0–24; FWB, 0–28; LCS, 0–40; FACT-L, 0–148; TOI, 0–96.
[i]A score greater than 4 indicates increased symptom distress and warrants intervention.
[j]Cronbach's α was calculated for the total ESAS.
[k]Possible range for all scales, 0–10.
[l]n = 9.
[m]n = 6.

Patients scheduled to receive fewer radiotherapy fractions had poorer FWB ($F = 17.358$; $P = 0.002$); however, this association disappeared in the poststudy assessment. Only a slight, yet not significant, improvement in patient FWB was noted during use of the ASyMS-R ($t = -1.54$; $P = .12$).

Prevalence rates of moderate to severe symptoms at either point of assessment are shown in Table 3, with decreases found for fatigue, depression, anxiety, drowsiness, appetite, and other problems, which were nevertheless not significant (all P values >. 05). Wilcoxon signed rank tests revealed only a significant increase ($Z = -2.03$; $P = .04$) in the levels of pain at posttreatment compared with baseline.

Discussion

This is the first study of its kind to report patients' and health professionals' perceptions of the feasibility and acceptability of the use of a mobile phone–based symptom monitoring system in patients with lung cancer receiving radiotherapy. Although the study sample is small, the findings suggest that the use of this type of technology is feasible and acceptable to patients with lung cancer. Participating patients perceived the use of ASyMS-R as a positive contribution to their care, particularly the real-time reporting of symptoms, the quick clinician response to alerts, and the reassurance that was evoked by the fact that clinicians were able to closely monitor patient symptoms even from a distance. These findings are supportive of similar positive evidence generated by previous ASyMS studies conducted among various patient populations with cancer.[29,30,49] One issue that emerged during the study related to reduced patient usability of 1 of the components of the ASyMS-R, namely, access and/or use of the automated self-care advice that followed receipt of a patient symptom questionnaire. Apart from the fact that patient training might have been suboptimal in a few cases, a contributing factor to this problematic area could have been the availability of clinical advice to patients receiving active radiotherapy treatment, which might have led to this patient sample feeling that any additional symptom management information was redundant. However, self-care strategies have been advocated as an important concept in cancer care,[50] and past evidence demonstrates positive effects of self-care approaches in controlling symptoms.[51–54] In the context of the current study, prompt self-care advice and strategies can be used immediately after symptoms have been reported and while awaiting for clinician response and intervention, thus ultimately supporting patients' sense of control and independence.

Health professionals' perceptions of feasibility and acceptability of ASyMS-R were similarly positive, mainly in relation to the generation of real-time clinical alerts and the self-care advice provided by the system. However, although most agreed that the alerting system was of clinical benefit and resulted in the timely management of symptoms, half of the clinicians were unsure of its clinical utility. Some of the negative perceptions seem to have occurred as a result of health professionals viewing ASyMS-R as an addition to their workload or perhaps because of perceived "inappropriateness" of the alerts generated. Such perceptions appeared to also stem from health professionals' views on the "appropriateness" of using ASyMS-R during radiotherapy treatment, when patients were in frequent contact with the clinical team. Although this may suggest that the system would be of greater benefit after radiotherapy treatment, such clinician perspectives seem to be contrary to those expressed by patients in this study. A similar comment can be made with regard to alert appropriateness and the observed discrepancy in the views of patients and clinicians. The resource implications of the use of ASyMS-R in clinical practice were also raised, including the time taken to log patients onto the system, train patients in using the system, or deal with incoming alerts. According to the Normalization Process Theory,[55] the identification of factors that promote or inhibit routine embedding of interventions in everyday practice is fundamental to their future implementation. In that sense, the findings of this study provide insight into the future development and use of mobile technologies and key aspects for clinicians that should be considered in future studies.

In terms of patient-reported outcomes, some clinically significant gain emerged, which can be cautiously linked to a hypothesized improved patient symptom management as a result of the use of the ASyMS-R that boosted patients' sense of control and confidence. This seemed to be particularly related to patients' perceptions of their self-care self-efficacy, as well as to clinically significant symptom distress, especially with respect to patient anxiety and drowsiness. Self-efficacy, defined as the confidence in one's ability to execute a course of action, has been regarded as an influential factor of the patients' ability to self-manage their symptoms[56] as it can determine how a person thinks, feels, motivates, and performs. Zhang et al[57] argued that a sense of control and involvement in the treatment are important aspects of patient self-efficacy. Current evidence suggests that higher levels of patient self-efficacy in symptom management may be linked to less psychological distress[58] and better adjustment in the long run.[59] In the current study, the absence of statistically significant changes may have been the result of different factors interfering with the data, including (*a*) population-specific ceiling effects not allowing additional gain to be shown; (*b*) attrition, especially with such a small sample size, that might have been related to the more distressed patients withdrawing from the study; or (*c*) actual positive (eg, dyspnea) or negative (eg, well-being) radiotherapy effects that might have interfered with intervention effects. All of the issues addressed here will need to be reevaluated to inform a future pilot study of a "pragmatic" randomized controlled trial tailored to lung cancer care in line with current recommendations.[60]

Our findings provide useful insight as to how ASyMS-R can be further developed for use in patients receiving radiotherapy. Future studies will need to include audio and visual resources within the self-care component, as this may provide patients with a greater array of self-care information in an interactive, accessible, and easy-to-understand format. The use of these mediums in the delivery of self-care advice is widely reported in the literature, with positive perceptions and improved patient outcomes reported as a consequence of such interventions.[61,62] Moreover, the restricted scope of the ASyMS-R,

focusing only on the toxicities associated with radiotherapy during and immediately after the treatment phase, may have limited its clinical utility. Patients with lung cancer receiving radiotherapy commonly experience toxicities several months after treatment,[63] are increasingly receiving combined modality treatments,[64] and often have several other comorbidities.[65,66] Widening the scope of the system to allow for inclusion of additional time points in the lung cancer treatment continuum, measurement of toxicities associated with combined cancer treatments, recognition and distinction of symptoms relating to comorbidities, and evaluation of the wider supportive care needs of patients with lung cancer could render this system more appealing to health professionals in busy clinical settings. In conjunction with the aforementioned developments, reducing the time that clinicians will be required to spend on using the system possibly through use of adequately sized smartphones that could act as both pagers and computer terminals to allow Web access, as well as standardizing the protocols for clinician intervention following an alert, could further enhance the system's clinical utility.

Strengths and Limitations

Although this study is, to our knowledge, 1 of the first to explore the use of mobile technology in the remote monitoring and reporting of radiotherapy-related toxicity in people with lung cancer, the results should be interpreted with some caution given the small sample size, the observed attrition, and lack of a control group. In addition, our findings may be associated more with the characteristics of this specific sample rather those of the lung cancer patient population. For instance, lack of familiarity with technology might have deterred patients from taking part in this study. Furthermore, it remains to be verified whether the observed fluctuations in patient outcomes reflect true intervention effects or simply the natural course of change after administration of radiation therapy. What is more, the follow-up evaluation included 1 posttreatment measurement only, which may have compromised our sensitivity in documenting changes over time in patient-reported outcomes. Addition of intermediate measurements might have allowed for a more detailed investigation of over-time change and revealed significant intervention effects manifested earlier in the course of radiotherapy.

■ Conclusions

This study demonstrated the potential to provide an accurate and acceptable means of radiotherapy-related toxicity assessment and management in clinical practice, thus effectively responding to the needs of patients with lung cancer and facilitating the delivery of timely interventions. Patients with lung cancer perceived the ASyMS-R to positively impact on their care and promote the timely reporting and management of their symptoms. Health professionals involved in the care of patients with lung cancer perceived the use of "real-time" risk algorithms and automated self-care advice as being positive aspects of such systems. Future research will be required to enhance the properties of the system, expand the use of this technology to the postradiotherapy period, and widen the scope of the system to encompass a wider range of supportive care needs of people with lung cancer.

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