The ASyMS©-YG Study: Final Report

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An evaluation of an advanced symptom management system (ASyMS©) to monitor and manage chemotherapy related toxicity with young people: The ASyMS©-YG Study

End of study report for Teenage Cancer Trust
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## ABBREVIATIONS

<table>
<thead>
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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ASyMS©</td>
<td>Advanced Symptom Management System (generic term)</td>
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<td>ASyMS©-YG</td>
<td>Advanced Symptom Management System designed for use with young people with cancer</td>
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<tr>
<td>GPRS</td>
<td>General Packet Radio Service</td>
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<tr>
<td>LSS-A</td>
<td>Life Situation Scale for Adolescents</td>
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<td>MRC</td>
<td>Medical Research Council</td>
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<td>PDA</td>
<td>Pocket Digital Assistant</td>
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<tr>
<td>PTQv1</td>
<td>Perceptions of Technology Questionnaire version 1</td>
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<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
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<td>STAI</td>
<td>Stait Trait Anxiety Inventory</td>
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INTRODUCTION

The ASyMS©-YG study involved a complex intervention, developing and evaluating an advanced symptom management system (ASyMS©) for use with young people to monitor and manage chemotherapy related toxicity using mobile phone technology. The system involved young people recording and sending symptom reports to the hospital and receiving tailored self-care advice. Health professionals could view symptom reports online and were alerted when severe symptoms occurred. This was a 4-phase development study. The first phase of the study involved young people identifying the symptoms that should be assessed. The second phase involved assessing the feasibility and acceptability of using this technology. Perceptions about the system were sought using questionnaires and interviews. In phase 3, young people and health professionals were involved in developing self-care advice, which is automatically generated in response to reported symptoms. The nurse alert system was put in place in the pilot testing phase, prior to the main RCT. This report outlines the progress and completion of phase 4, the evaluation of ASyMS©-YG through a randomised controlled trial.

METHODS

Young people were eligible to participate if they were aged 13 to 24 years; diagnosed with soft tissue sarcoma, bone tumour, lymphoma or germ cell tumour; and were receiving chemotherapy. The aim was to recruit 150 young people from six cancer units. Young people were randomised to receive ASyMS©-YG or standard care. The primary outcome was anxiety, which was measured using a standardised questionnaire. Young people in both arms of the study completed the questionnaire at the beginning of study, at the end of treatment and six months after treatment. They all completed a paper symptom questionnaire before every cycle of chemotherapy and the ASyMS©-YG group were asked to complete the ASyMS©-YG questionnaire daily, or whenever they felt unwell, until treatment was complete.
RESULTS

Recruitment into the study was problematic, mainly due to the time required by clinicians to recruit and administer the questionnaires. Despite numerous changes to the protocol, including: increasing the age; broadening the diagnostic groups; altering the paging system; and reducing the number of sites recruitment was based at to enable the study coordinator to facilitate recruitment, we were still unable to recruit sufficient numbers to enable meaningful evaluation. The symptom data generated through ASyMS©-YG and paper reports of symptoms are currently being analysed. The results will be available later in the year. Interviews were also conducted with key health professional involved in the study to explore the context of communication within each health care setting and to understand professional’s perceptions of using technology to support young people undergoing treatment for cancer. These data are currently under analysis and will be available later in the year. Our intention is to submit two final publications that will present these remaining findings: symptom data; and professional’s views about technology.

CONCLUSION

While the ASyMS©-YG study was not as successful as we would have hoped, feedback from young people indicates they are receptive to the use of technology to support them while they are undergoing treatment. This is reflected in other diseases where technology is used to promote and support self-care. Since study conception the framework for developing and evaluating complex interventions has changed and more novel study designs have been developed specifically for complex intervention evaluation. We are currently exploring other options in view to taking this forward in the New Year.
BACKGROUND

YOUNG PEOPLE WITH CANCER

Cancer remains relatively rare in young people. Annually about 1,500 to 2,000 young people aged 15 – 24 years are diagnosed with cancer (1). Leukaemia and central nervous system tumours predominate 10 – 14 year olds, but during mid and late adolescence lymphomas become the main single tumour group and epithelial cancers become increasingly common (2). However, it is not only the patterns of cancer occurrence that differ in young people; the biology of a cancer in a young person may be quite different from that of the same disease in an adult or child (3). Furthermore, it is increasingly recognised that young people are a distinct and particularly vulnerable group, with specific and complex needs (4-6). The seriousness of their diagnosis and the nature of its treatment create an increased and unwelcome dependence on parents. In addition, identity and self-esteem are undermined by the cancer experience such as the side-effects of chemotherapy and radiotherapy, weight gain from steroids and scarring from surgery (7). Young people undergoing treatment for cancer experience accompanying physical side-effects (8) and ‘being tired’ and ‘unable to get around’ causes them significant distress (9). They consider the physical side-effects of treatment as the worst aspect of the disease, significantly affecting their quality of life (10).

Few studies have addressed the measurement of physical symptoms in young people with cancer (11). However, research has been hindered by the limited number of symptom assessment instruments validated in this population. Instruments developed to date have tended to concentrate upon the measurement of single symptoms such as nausea and vomiting (12;13) and fatigue (14) or focused upon young people receiving particular treatments such as a bone marrow transplant (15). The Memorial Symptom Assessment Scale (16) is one instrument which has looked at the global assessment of symptoms in young people with cancer. This 30-item instrument assesses both physical and psychological cancer-related symptoms. This scale has yielded relevant and highly consistent information about children’s multiple symptoms. It was however derived from adult’s conceptualisation of symptoms and not originally grounded in children’s experiences (17). A further criticism of the Memorial Symptom Assessment Scale is the number of questions it contains that may be burdensome and time consuming to complete (18). The shortage of appropriate, rapid and efficient instrument available to comprehensively measure symptoms has resulted in the epidemiology of symptoms in young people remaining poorly characterised with few symptom intervention trials being undertaken. In addition, a meaning-centred approach in which researchers seek to understand young people’s experiences as they are lived is missing (19). Consequently a complete picture of the cancer symptom trajectory in young people is lacking.
WISECARE+ was a system enabling patients to record their symptom experience and communicate that experience through the medium of information technology, to healthcare professionals. While this approach to symptom management was shown to be effective in improving symptoms within adult cancer care (20), how far this approach would be feasible and acceptable to young people needed to be explored. The findings of an exploratory study suggested that young people appeared to gain from their participation in the project especially in relation to completing the questionnaire as they were able to see a change in symptoms over time that was encouraging, particularly in situations where the young person had been quite ill. Comments from young people suggested that although they found it more burdensome to complete the questionnaires when symptomatic, it was most helpful during this time. Variation in symptom experiences also appeared to have a positive effect on young people’s motivation to complete the questionnaires. In a subsequent pilot study, patients, parents and nursing staff found WISECARE+ to be useful and effective (21). Nurses noted that involving young people in decisions about their care was the most useful part of the pilot project. This pilot project highlighted that there was interest from young people in participating in a study to monitor and communicate their symptoms to health professionals. This preliminary work that involved collaboration with the WISECARE+ team at University of Stirling provided the impetus for further and more innovative development of a process to record and influence self-care management of symptoms following chemotherapy.

Information and communication technologies have opened up new possibilities in the field of health care (22;23). Mobile phone technology provides a creative medium for the development of a system to monitor and support young people receiving chemotherapy. The team at the University of Stirling (now the University of Dundee) have led on this development in adult cancer care (24-32). They have developed and evaluated a personal digital assistant (PDA) based advanced symptom management system (ASyMS©) to remote monitor chemotherapy related toxicity. Their work forms the central component of this development process, with collaborators in other specialities being guided and supported to use and evaluate the technology to their own particular field of cancer care. These systems offer creative ways for health professionals to expand upon and deliver patient-centred care. The system stores real-or near-real time information on patients’ symptom experiences and has the potential to improve the accuracy and completeness of reporting, increase health professionals understanding of patients’ symptom experience, influence the effectiveness of symptom management strategies, and may ultimately improve the cost-effectiveness of healthcare (25).

The ASyMS©-YG study was underpinned by the Medical Research Council (MRC) complex intervention evaluation framework (33). Complex interventions are built up from a number of components or ‘ingredients’, which may act both independently and inter-dependently.
The MRC framework is concerned with evaluating the ‘active ingredients’ in a complex intervention. The work underpinning ASyMS©-YG began in 2007. Following the pathway of the MRC framework (Figure 1), each phase has told a different part of the ‘story’. The end product was intended to be an interactive symptom support system for young people to use while they were receiving chemotherapy that would support communication between young people and their health care team (Appendix 1). Similar to colleagues outside of the United Kingdom (UK), we are testing innovative computer technology for collecting symptom data and offering supportive feedback (34;35). The development phases of ASyMS©-YG are summarised below:

Fig 1: Framework for the development and evaluation of complex interventions

PHASE 1

In Phase 1, five young people selected their five most important symptoms from the Memorial Symptom Assessment Scale (16). Limiting the number of symptoms assessed was important as this scale is long and could influence successful and timely completion if considered by young people to be asking inappropriate questions (36). The top five symptoms selected were mouth sores, vomiting, weight loss, nausea and diarrhoea. These symptoms formed the basis of the phone questionnaire with software developed by KelvinConnect Ltd (37;38).
PHASE 2

In Phase 2, twenty-five young people were recruited from two clinical sites in London, University College London Hospitals NHS Foundation Trust and The Royal Marsden Hospital Foundation Trust. Young people used the PDAs to report the occurrence and severity of symptoms on days one to 14 of a course of chemotherapy. In addition to reporting on five symptoms (listed above), they also recorded their temperature and had the opportunity to report any additional bothersome symptoms. Perceptions and experiences of young people, parents and health professionals were recorded using questionnaires and semi-structured interviews. Young people using the system commented on the potential of ASyMS©-YG to: offer reassurance through being monitored; reduce worry about symptoms; and facilitate communication about their symptoms with health professionals when attending hospital. Gaining self-care of symptoms was just one potential outcome for young people using this system that could improve both physical and psychosocial outcomes and influence quality of life (39-41). Health professionals thought that young people would have more control over symptoms and the system would result in the implementation of more timely interventions (38;42). Advice about symptoms, what to do when symptoms occur and when to refer to professionals for help, as elements of timely and effective interventions, have only recently begun to be explored within the field of cancer care in young people (40).

PHASE 3

Phase 3 involved further developments working with young people and health professionals. This included: developing self-care guidelines and a risk modelling system for alerts; testing all the procedures and technical systems in using the PDA in the home monitoring, symptom management and detection of indicators of infection in young people through a pilot randomised controlled trial (RCT); and finally, education and training of clinical staff to use the system (38).
PHASE 4: PATIENTS & METHODS

AIMS

Phase 4 was the evaluation phase of ASyMS©-YG, which was being conducted as a multi-centre RCT. The study involved randomising young people to either using the ASyMS©-YG PDA (intervention group) or to receive standard care (control group). The aims of the study were:

1. To determine changes in chemotherapy toxicity and symptom distress associated with the use of a remote PDA monitoring system for managing symptoms associated with chemotherapy.
2. To determine changes in quality of life, anxiety and self-efficacy associated with the use of a remote PDA monitoring system for managing symptoms associated with chemotherapy.
3. To determine usefulness of information fed back to the patient under alert conditions.
4. To determine the use of self-management strategies as a result of self-care advice.
5. To determine changes in patient management as a result of generated alerts.
6. To evaluate the cost effectiveness of the ASyMS©-YG system.

PARTICIPANTS

Young people were eligible to participate in the study if they were:

- Aged 13 - 24 years old;
- Diagnosed with lymphoma, bone tumour, soft tissue sarcoma or germ cell tumours;
- Being treated with chemotherapy.

The diagnostic groups were selected as these are among the most common malignancies experienced by young people (43) and current treatment protocols for these cancers involve young people receiving chemotherapy on an outpatient basis or during a short inpatient stay, thus these young people would have to manage side-effects at home. Potential recruits were identified by the clinical team at each site. A designated health professional would approach young people and give them information, both verbal and written, about their participation, using the same tested process as in the pilot RCT. Young people were recruited at any point during their treatment to accommodate inclusion in other studies (treatment trials), life events (e.g. exams) and emotional state. In some cases the approach was soon after diagnosis and for others it was further during the treatment period.
young people with lymphoma, bone tumour, soft tissue sarcoma or germ cell tumour, treatment is usually given over a two month to one year period.

SAMPLE SIZE CALCULATION

The comparison of Stait Trait Anxiety Inventory (STAI) total anxiety score after the end of treatment between the two groups was the primary endpoint that the sample size calculation was based upon, comparing the mean score between the control and treatment group. Current literature suggests that there is not equal variance for these groups and as such the sample size calculations were conducted using the 2-sample t-test for unequal variance. The estimates of the group means and standard deviations were taken from current literature and alpha was set to 5%. Assuming a mean STAI anxiety score after completing the study of 44.5 for the control group and 38.5 for the treatment group, a standard deviation of 4.5 for the control group, a variance ratio of 5.1378 and an alpha of 5%; then 80 subjects in total randomised to control ($n_c = 40$) and treatment ($n_t = 40$) were needed to show a difference in the mean STAI anxiety score at the end of the study of 6 with 95% power on a one-sided two sample t-test for unequal variance. This design also enabled a drop-out rate of 35% before the power falls below 85%.

ETHICS

The study was approved by South East Research Ethics Committee on 22nd October 2008 (reference number 08/H1102/66). Trust approval was obtained from each individual R&D between October 2008 and May 2009. The time lines for gaining regulatory approval are summarised in Figure 2. Written consent to participate was obtained from parents and young people over 16 years. Written assent was gained from young people under 16 years in addition to written consent from parents. MRC Guidelines for Good Clinical Practice in Clinical Trials will be followed throughout the entire process of recruitment (44).

STUDY SITES

The aim was to run the study in centres where young people were treated in different settings, including: Teenage Cancer Trust (TCT) specialist TYA units, adult and paediatric units. The aim was to involve six centres: three centres with TCT units and three centres without a specific unit for young people. To look at the potential additional benefit for young people living far from the cancer centre we also aimed to include a centre where patients were spread over a large geographical area which included remote areas. We were able to involve five Trusts in participating initially: University College London Hospitals NHS Foundation Trust, The Royal Marsden NHS Foundation Trust, Oxford Children’s Hospital, The Christie Manchester, and St James’ University Hospitals NHS Foundation Trust. However, as detailed later in the report, recruitment was concentrated on the two London Trusts.
Fig 2: Time taken to gain regulatory approval

*At the time of study approval it was necessary to gain ethics approval from each local committee after approval from a main committee.
METHODS

RANDOMISATION

The study used block randomisation. Random blocks of 4 were used to allocate individuals into the 2 groups (A = intervention group and B = control group). Study subjects were allocated to either control or treatment according to a randomised block design, with 10 blocks of size 8 with 4 replications per block. A block was chosen at random with equal probability from all possible permutations of blocks size 8 with 4 replications and the subjects allocated the next available treatment, this would have been repeated until sample accrual.

INTERVENTION GROUP

When recruited to the study, young people randomised to the intervention group were provided with a PDA pre-loaded with the ASyMS©-YG programme. Loading the programme disabled any other function on the PDA. Young people were instructed on how to use the PDA, how to enter symptom data in the ASyMS©-YG questionnaire and receive self-care information. The symptoms assessed on the PDA questionnaire were determined by symptoms reported by young people receiving the same chemotherapy drugs in earlier phases of this study. A booklet for the PDA containing instructions and contact numbers was also given to young people at this time (Appendix 2). Young people were encouraged to contact relevant study personnel if they experienced any difficulties in using the PDA. Further training was given as necessary to ensure that the young person felt comfortable using ASyMS©-YG and they were able to successfully transmit their symptom information from their home to the study server.

Young people in the intervention group completed ASyMS©-YG on the PDA and entered their temperature daily until chemotherapy treatment end. They were asked to complete the questionnaire once a day and at any time that they feel unwell. This ‘real time’ symptom information was automatically sent via a secured GPRS connection to the study server. Young people were informed when their symptom data had successfully been sent to the study server. If the symptom profiles young people submitted were cause for concern, for example, indicating a developing infection, software on the server alerted a health professional at the patient’s clinical site. S/he would then be able to access the patient's data, stored on the server via a secure web page, enabling him or her to check the patient's condition at any time with up-to-date, accurate and reliable data. In this way, severe, urgent or life threatening symptoms were be promptly identified and appropriately managed. After completing the symptom questionnaire, young people were provided with tailored self-care information directly relating to the severity of the symptoms reported. They were also able to view their symptom history on symptom graphs on their PDA at any time.
Outcome of ASyMS©-YG was measured using a number of questionnaires (see below) that were administered to young people before using the PDA, at the end of treatment and 6 months after treatment had ended. Young people were asked at the start and the end of treatment (when they started and finish using the ASyMS©-YG PDA) to complete a semi-structured questionnaire regarding their perceptions and experiences of mobile technology and the ASyMS©-YG system. Young people also completed a paper version of the ASyMS©-YG symptom questionnaire at baseline and before each cycle of chemotherapy, to report on symptoms experienced during their previous cycle. This was to enable comparison of symptom occurrence, severity and how bothersome symptoms are between intervention and control groups. A purposeful sample of young people were approached to participate in a semi-structured interview to explore their experiences of using ASyMS©-YG.

CONTROL GROUP

Young people in the control group received standard care and a paper copy of the self-care guidance (45). They were asked to complete the paper version of the electronic symptom questionnaire at baseline and at the end of each chemotherapy cycle prior to receiving their next chemotherapy treatment. Case notes were reviewed to reveal communication between young people and health care professional’s in-between courses of chemotherapy, as well as significant events. Young people in the control group were asked to complete the outcome measures at the same time points as the intervention group.

OUTCOME MEASURES

Study outcomes included: perceptions and experiences of using the ASyMS©-YG system; the experience, occurrence and management of symptoms; and how symptoms change over time. These were evaluated using a combination of qualitative and quantitative methods (Table 1). These included questionnaires with young people, a purposeful sample of young people were also invited to participate in a semi-structured interview. Other data collected included daily recording of temperature and ASyMS©-YG system log data. Health professionals were asked to keep a log of alerts, considering their appropriateness and timeliness. Interviews with health professionals explored communication patterns and significant events.
### Table 1: Outcomes and measures

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<td><strong>Primary outcome:</strong></td>
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<tr>
<td>1. Does the use of ASyMS©-YG influence changes in a young person’s behaviour and reduce their anxiety?</td>
<td>• State-Trait Anxiety Inventory (STAI; (46)</td>
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<tr>
<td></td>
<td>• Self-Efficacy Scale (47)</td>
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<tr>
<td><strong>Secondary outcome measures:</strong></td>
<td></td>
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<tr>
<td>1. Does the use of ASyMS©-YG reduce the severity of chemotherapy related symptoms and improve quality of life for young people with cancer?</td>
<td>• Symptom questionnaire on the mobile phone</td>
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<td></td>
<td>• Life situation Scale for Adolescents (LSS-A; (48)</td>
</tr>
<tr>
<td></td>
<td>• PedsQL™ – Cancer Module (49)</td>
</tr>
<tr>
<td>2. Does the availability of real-time information about young people’s symptoms influence the timeliness of interventions and improve communication between young people and professionals?</td>
<td>• Health care professional log of alerts for intervention group and interventions for control and intervention groups.</td>
</tr>
<tr>
<td></td>
<td>• Interviews with young people and health care professionals.</td>
</tr>
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<td></td>
<td>• Investigator led perceptions and experiences of using technology questionnaire</td>
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<tr>
<td>3. How acceptable is ASyMS©-YG to young people and health care professionals?</td>
<td>• Investigator led perceptions and experiences of using technology questionnaire (PTQv1)</td>
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</table>

**The State-Trait Anxiety Inventory (STAI)**

The STAI consists of 2 scales, each with 20 items. One scale looks at the long standing quality of ‘trait’ anxiety. The other scale measures ‘state’ anxiety a more temporary condition, involving apprehension, tension, nervousness and worry. The STAI takes 10 minutes to complete and normative data is available for young people (46).

**Self-efficacy scale**

A measurement of self-efficacy based on Bandura’s Theory of Self-Efficacy (47) was developed during previous work on the ASyMS©-YG study.
Life Situation Scale for Adolescents (LSS-A)
This is a condition specific 45-item instrument listing problems, symptoms, and inconveniences related to cancer and its treatment. The instrument is validated for use with young people aged 13-18 years (48).

The Paediatric Quality of Life Inventory™ (Peds-QL™)
The Cancer Module Teen Report Form was used as a measure of cancer specific quality of life (49). It contains 27 items on 8 scales including pain and hurt, worry, communication and perceived physical appearance. It is validated for use with young people aged 13-18 years.

Perceptions of Technology Questionnaire (PTQv1)
Young people’s perceptions and experiences of using technology questionnaire was an investigator developed questionnaire specific for this project. It was developed from earlier phases of the study and was completed by young people in the intervention group only. The PTQv1 includes questions relating to perceptions of the ASyMS©-YG, experiences of using the system, satisfaction with the system and any difficulties encountered. Attitudes towards technology will be assessed using a ‘semantic differential tool’ (50) consisting of bipolar adjectives (e.g. useful, useless) each being rated on a 7 point scale; this section of the questionnaire will also be completed by the control group.

Background information was collected from participants when they were recruited to the study. This information included age and ethnicity. Data were also recorded on distance from home to the hospital as there may be an extra benefit for young people who live far from the cancer centre. Stage of disease was also recorded as this was thought likely to impact on symptoms experienced.

HEALTH PROFESSIONALS

Prior to the start of the study, health professionals involved in the project attended a one day training session on using ASyMS. They were provided with a booklet (similar to Appendix 2) which contained instructions on how to use the device, how to deal with common problems that may arise and relevant contact numbers. Each clinical team was asked to identify a named person who the project team linked with and who other members of their team could refer to for guidance. The named link person was encouraged to contact relevant study personnel if they experienced any difficulties. Link professionals were asked to keep a log of all generated alerts, subsequent interventions and hospitalisations, and grade the appropriateness of interventions. They were also asked to record relevant interventions and associated hospitalisation of young people in the control arm of the study.
Health professionals, who were significantly involved in the trial, were asked to participate in a semi-structured interview/focus group at the end. Understanding the effect the system had on clinical care was an important finding in this study.

DATA ANALYSIS

One of the aims of this study was to determine changes in symptom outcomes and symptom distress as a result of the use of the ASyMS©-YG PDA compared to the control group. The two randomised groups will be compared on an intention to treat basis. The primary outcomes will be compared between the two randomised groups using linear models to adjust for the stratification factors and possibly additional pre-specified baseline covariates felt to be of prognostic importance. Pre-specified subgroup analyses to explore differential treatment effects within some of these covariates will also be considered. Our second aim is to evaluate the short and long-term effect the intervention has on young people. Through the use of validated questionnaires differences between the control and intervention group participants’ scores will be analysed. Semi-structured interviews will be analysed using thematic analysis (51).
RESULTS

RECRUITMENT

Recruitment into the trial is summarised in Table 2. Reasons for non-participation include: too much going on already (n = 4); parents not wanting the young person to take part (n = 2); just not wanting to take part (n = 2); unknown (n = 1).

Table 2: Recruitment into the ASyMS©-YG study by site

<table>
<thead>
<tr>
<th>Participating centre</th>
<th>Intervention</th>
<th>Control</th>
<th>Refusals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leeds</td>
<td>1</td>
<td>0</td>
<td>a</td>
</tr>
<tr>
<td>Manchester</td>
<td>2</td>
<td>3</td>
<td>a</td>
</tr>
<tr>
<td>Oxford¹</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Royal Marsden Hospital</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>University College London Hospitals</td>
<td>3</td>
<td>6</td>
<td>8</td>
</tr>
</tbody>
</table>

¹Unable participate due to no mobile phone reception at the hospital
²Information not available

PATIENTS

Of the 20 patients recruited into the study, documents were returned for 17. Two patients were recruited but no paper data were collected (ASyMS©-YG PDA data only) and data were missing for the other. Patient characteristics are summarised in Table 3. There were no complete data sets collected for any participant. In view of the abundance of missing data and the limited sample, no evaluation of the benefits of ASyMS©-YG will be possible. However, ASyMS©-YG symptom data is available for 8 young people (ranging from up to day 15 to day 160 of treatment) and paper symptom reports were returned by 10 for 1 – 7 cycles. These data are currently being analysed and will be available by the end of the year.
Table 3: Young person characteristics

<table>
<thead>
<tr>
<th></th>
<th>All patients (n = 16&lt;sup&gt;1&lt;/sup&gt;)</th>
<th>ASyMS©-YG (n = 6)</th>
<th>Control (n = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)&lt;sup&gt;2&lt;/sup&gt;</strong></td>
<td>17 [14 – 23]</td>
<td>17 [14 – 21]</td>
<td>16.5 [15 – 23]</td>
</tr>
<tr>
<td><strong>Gender (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8 (53)</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Female</td>
<td>7 (47)</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td><strong>Ethnic group (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>12 (80)</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>White &amp; Asian</td>
<td>1 (7)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>African</td>
<td>1 (7)</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>1 (7)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Diagnosis (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone tumour</td>
<td>4 (24)</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Hodgkin’s disease</td>
<td>5 (29)</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Soft tissue sarcoma</td>
<td>6 (35)</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

<sup>a</sup>Numbers do not equal ‘n’ because of missing data

<sup>1</sup>No demographic data provided for patient 104/01

<sup>2</sup>Median [range]

INTERVIEWS WITH YOUNG PEOPLE

Permission to approach young people to participate in the interview was attached to the end of treatment questionnaire. As this was not administered to any young people we were unable to conduct any interviews with young people.

INTERVIEWS WITH HEALTH PROFESSIONALS

Interviews were conducted with six health professionals from three of the participating sites. The transcripts of these interviews are currently being analysed and will be available by the end of the year.
CHALLENGES

This study encountered a number of challenges and despite amending the protocol on five occasions (Table 4); it was not possible to increase recruitment. The original plan was to recruit patients from six cancer units in England. We had interest and gained permission for recruitment in five. ASyMS©-YG was unable to be introduced to Oxford Children’s Hospital as they were unable to receive a mobile phone signal and therefore the pager system would not work. In the remaining four, the plan was for recruitment to be conducted by health professionals working within each unit. However, this was problematic because of the requirements of conducting an RCT (regulatory paperwork). This was found to be too time consuming and burdensome for professionals on top of their existing clinical workload. A pragmatic decision was therefore made to withdraw the study from Manchester and Leeds and concentrate recruitment in the London sites where the ASyMS©-YG team could provide more support.

Table 4: Changes to the protocol to maximise recruitment

<table>
<thead>
<tr>
<th>Amendment*</th>
<th>What professionals told us...</th>
<th>What we did...</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 21/01/09</td>
<td>A cycle of chemotherapy could be over a number of weeks so completing ASyMS©-YG from days 1 – 14 was not practicable.</td>
<td>Changed the system so young people complete ASyMS©-YG daily until treatment ends.</td>
</tr>
<tr>
<td>2. 15/06/09</td>
<td>Teenage &amp; young adult units take up to 24 years.</td>
<td>Changed the recruitment range from 13 – 24 years.</td>
</tr>
<tr>
<td>3. 24/09/09</td>
<td>Increasing the age then involves other cancer types.</td>
<td>Germ cell tumours were added to the inclusion criteria.</td>
</tr>
<tr>
<td>4. 04/05/10</td>
<td>Majority of young people were being randomised to the control arm.</td>
<td>Randomisation method was changed from minimisation to block.</td>
</tr>
<tr>
<td>5. 14/07/10</td>
<td>There were difficulties recruiting after diagnosis: young person’s mental state and the volume of studies they were being approached with at this time.</td>
<td>Recruitment can be at any time during the treatment trajectory.</td>
</tr>
</tbody>
</table>

*date refers to the date the amendment was submitted to the ethics committee, not the date approved
STRATEGIES FOR STUDY SUCCESS AND IMPLICATIONS FOR FUTURE RESEARCH

The measures that were taken to try and ensure the ASyMS©-YG study was completed and the subsequent outcomes of these measures are discussed below. We have learnt from this experience and the text in italics indicates the strategies we will employ in future to ensure this does not impact on the success of future research.

1. Broadening the age to reflect both teenagers and young adults. This also necessitated the inclusion of germ cell tumours as a diagnosis, which is common in the 20 – 24 age groups. One suggestion we did not make any action on was the inclusion of young people with leukaemia. Due to the duration of treatment and anecdotal evidence that their symptom profile was different we made the decision to continue excluding this population.

It is important to have an in-depth understanding of the population under study prior to commencing a project. As leukaemia was deemed to represent a sizable proportion of the population in the participating units, more work could have been conducted in the development phases with this diagnostic group. Preparation for future studies will involve broader scoping of the population and setting; and more active discussion with health professionals.

2. Centralising recruitment in the two London units so more direct support could be provided by the ASyMS©-YG project team.

Conducting a clinical trial requires a lot of staff time as non-clinical trials of medicinal products need to be conducted with the same rigor as drug trials. Relying on clinicians to run the study was erroneous on two accounts. First, they were unable to allocate the required time to identify young people, ensure consent was informed and to administer questionnaires in a timely manner. Second, health professionals are rarely trained in trial research conduct and few receive Good Clinical Practice training (which ensures the conduct of research follows Research Governance). We will ensure that all future projects will include funding for appropriate personnel, and in discussions with grant awarding bodies emphasise the importance of supporting this cost.

3. The sample size calculation was re-calculated. The original estimate was based on a change in perceived symptom severity. However, ASyMS©-YG was not developed to improved symptoms rather to provide a means of support and reduce anxiety. The original calculation estimated 150 young people (75 in each arm) were necessary for a power of 90%. Recalculation using the STAI as the primary outcome
measure, the sample size required for 95% power at a significance of 5% reduced to 80 young people (40 in each arm). A dropout rate was also factored into the calculation so a total of 52 young people would still provide an 85% power. Despite providing evidence to support a smaller sample, we were unable to achieve the required numbers. The study was therefore so under powered that no meaningful statistical analysis can be undertaken.

ASyMS©-YG was evaluated as a randomised controlled trial. It has now been recognised that this may not be the most appropriate design for complex interventions. As such, ‘novel’ trial designs are now being advocated (52). In future evaluation studies we will ensure we include a member of the team who has expertise in these designs.

4. The ASyMS©-YG project team kept regular contact with staff at University College London Hospitals and The Royal Marsden Hospital to try and maximise recruitment. By having a prominent presence it helped to keep the project on health professional’s minds. Originally this was through weekly emails; however this was noted by professional to be annoying and often the emails would be deleted without reading.

Other methods of keeping professionals informed and ‘energised’ about a study need to be identified. There is a dearth of literature in this area and therefore it may be something we wish to explore further in the future.

5. ASyMS©-YG was developed using the technology of the time, i.e., PDA’s and pagers were considered ‘hi-tech’ in 2007. However, since the project conception, technology has advanced ten-fold and therefore certain aspects were considered burdensome in 2009/10. While young people found the ASyMS©-YG PDA amusing because of its out dated style, they knew they would keep it at home and did not have to carry it with them. Similarly, health professionals viewed the pager as out dated, often forgetting to take it with them. To facilitate better communication, the pager was therefore removed and a text messaging system was introduced. This was evaluated as being more acceptable.

The development of interventions using technology needs to reflect the technology of the time. Development phases therefore need to adopt novel study designs so they can be completed in a timely fashion. Our study was ahead of its time in respects to the development phase as it involved users (young people, parents and health professionals) in study conception. Future studies will continue to use this model; however, they will also be adaptable so they can reflect changes in technology through study development and evaluation.
6. Finally, we were unable to recruit young people at the time of diagnosis because of the ‘emotional burden’ of being invited to participate in research or the young person already being involved in a study. Interestingly, young people are invited to take part in drug trials early at the point of diagnosis, where the level of information that is needed to be retained is potentially greater than a non-drug trial. Health professionals perceive the drug trial to be more important and therefore prioritise recruitment to these above other research projects. Similarly, there is the belief among health professionals that inviting young people to participate in more than one project is unethical because they are being overburdened. This contravenes young people’s human right to have information about all aspects of care and to make their own informed choice.

*Researchers working in future projects will be trained in research ethics pertaining to the rights of patients to make a choice.*
CONCLUSIONS

IS ASyMS©-YG VIABLE?

The ASyMS©-YG study did not progress as we had either planned or hoped for. However, current evidence supports the idea of the use of technology in health care, such as ASyMS©. For example, an RCT is currently underway in Australia using video telephones to support young people with cancer living in remote regions (53). Internet-based education and illness management interventions have been shown to improve treatment adherence (54;55), increase children and young people’s illness knowledge (55;56) and improve young people’s self-efficacy (55;57). This suggests therefore that while the ASyMS©-YG system may be of benefit to patients, the way in which it was originally designed to link with the health care team, may need revising.

WHERE WE WENT WRONG

ASyMS©-YG was developed and evaluated using the linear framework suggested by the MRC (58). This has since been shown to be unsuitable for all complex interventions as the process of development is rarely linear (59). The MRC have proposed a new framework (Figure 3) that is non-linear and allows an iterative process between development, feasibility and evaluation (52). Other projects in teenage and young adult cancer care have successfully followed this process (60) as it allows for multiple phases to be conducted concurrently and therefore the time in development is less. At the end of the ASyMS©-YG study, the equipment had become obsolete and ‘apps’ were becoming the new technological trend. More timely methods are therefore welcomed so future studies will be able to reflect and capture the trends of the time.

Fig. 3: Revised version of the framework for the development & evaluation of complex interventions
WHAT NEXT?

As we suggested in the interim report (January 2011), we need to re-think how technology can be used to support young people. We are confident young people enjoy using the system, which is reflected in the large volume of usage in those randomised to the intervention (e.g., participant 501 used ASyMS©-YG for 110 days). Furthermore, we know from the developmental work that young people like it. They have described benefits that relate to seeing changes in their symptoms, helps them better able to communicate with health professionals and they felt in control of managing their symptoms (37). It appears that health professionals are not convinced of the benefits of such systems. Future work will involve looking at methods of supporting young people without the need for health professional input. This would focus more on supporting self-management. It is also timely to consider a re-design of the software to work on a range of platforms so young people can use it freely on their preferred medium. The system of the future may be an application used by young people that could become a place they record their treatment summary and treatment story. We will continue working with young people to ensure the future development of systems, similar to ASyMS, are fit for practice and the evaluation of such systems are less labour intensive and even more inclusive. We already have in place meetings with Teenage Cancer trust and others to explore refining and describing the next ASyMS prototype.
REFERENCES


(26) Kearney N, McCall K, Maguire R. Feasibility study into the use of mobile phone based technology (ASyMS(C)p) in the remote monitoring of symptoms experienced by patients receiving palliative care at home. Cancer Care research Centre: University of Stirling; 2007.


APPENDIX 1

THE ASyMS©-YG SYSTEM FOR PROVIDING SUPPORT TO YOUNG PEOPLE

The ASyMS© System

Patient completes symptom questionnaire

Data is sent in real time from the mobile phone via the server to the nurse at the clinical site

Problematic symptoms immediately generate alerts on the dedicated pager system nurses carry

Nurse views the patient’s symptom data on the ASyMS-YG© website and contacts patient to offer advice

Patients receive a message with self-care advice in response to reported symptoms

Patients can also view symptom graphs and information at any time
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<td>Two</td>
<td>Your ASyMS-YG handset</td>
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<td>Contact numbers</td>
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</table>
SECTION 1

ASyMS-YG Handset: the Equipment

(i) the handset

(ii) stylus (plastic pen)

(iii) handset cover

(iv) cradle/stand

(v) adapter plug

(vi) charging lead
SECTION 2
The Handset

Front view

1. Screen
2. Ear piece
3. Mouth piece
4. Button to make a call (green telephone)
5. Button to end call (red telephone)
6. On/off button
7. Battery indicator light (flashes green when charged, glows orange when charging)
8. Stylus/plastic pen compartment
9. Charging socket

Top view

Bottom view
The handset **must** be charged for **no less than 3 hours** prior to being given to the young person. When the battery is allowed to go flat, the ASyMS-YG programme is wiped from the handset and will need to be reloaded (hard reset: see section 7)

This can be done in two ways:
1. Using the cradle/stand
2. Using the charging plug

**To use the cradle/stand:**
1. Plug the charging lead into the back of the cradle/stand by inserting the yellow tipped plug into the socket shown
2. Plug this lead into the electricity supply
3. Slide the handset on to the cradle
4. When in place, the battery indicator light will glow orange to show it is charging

**To use the charging lead:**
1. Take the adapter plug, attached to the charging lead and place on the yellow tipped plug at the end of the charging lead
2. As before, plug this lead into the electricity supply
3. Now plug the adaptor socket into the handset charging socket (as shown)
4. **We advise using the cradle for charging the ASyMS-YG handset into it after each use. This will prevent the battery from becoming too low**
SECTION 4
Switching ON/OFF

Press the ON/OFF button once, quickly and the screen will activate. Repeat this quick process to switch the handset off. Holding this button down for a longer period of time will switch the screen light on or off. When not in use the handset will automatically turn off.

SECTION 5
Using the Stylus/Plastic Pen

This makes it easier to use the handset. It slides into a compartment on the side of the handset and is stored there when not in use. Holding it like a pen, you use it to tap on the handset screen. Tapping on the screen with the stylus/plastic pen allows you to enter information into the handset.
The first time you switch on, your screen should show you this list. The list will change once you have symptom graphs and if you have information to send.

To start with you can practice using the handset and fill in test symptom questionnaires until you feel comfortable. The test questionnaires are there for you to practice with until you feel ready to move on to start collecting real data (information).

To fill in a test questionnaire, tap the plastic pen on **Tap to start test questionnaire**.

Please do not start real data collection until:
  a) You feel comfortable using the handset
  b) The day you start your chemotherapy cycle
SECTION 7
Filling in a Practice/Test Questionnaire

Using the plastic pen, tap on ‘**Tap to start test questionnaire**’.

You will first be asked whether you are in hospital, when you move on to collect ‘real data’ if you say you are in hospital no alert messages to the hospital team are sent.

Read the questions and answer by tapping in the **Yes** or **No** response box.

Then tap on **NEXT**.

When you get to the temperature page enter the temperature recorded on your thermometer by tapping on the numbers. If you make a mistake, tap clear and start again.

Then, tap on the **Finish** button.
The handset will ask you to confirm your temperature – if the temperature you entered is correct, tap on the **Yes** button.

After you have entered your temperature you will be asked if you have any symptoms to report.

If you answer **No**, this is the end of the questionnaire and you will not be asked any more questions about symptoms. You will just be asked the final question about who has completed the questionnaire.

If you answer **Yes**, the questionnaire will continue and you will then be asked whether you are experiencing a number of symptoms. For each symptom you say you have, you will be asked to report how bad it is (mild, moderate or severe) and how much it is bothering you (not at all, a little, quite a bit or very much).
On the question about pain, **Have you experienced any pain in the past 24 hours?** If you answer **Yes**, you will be asked to mark where your pain is on a picture of a body.

Use the pen to tap where your pain is. You will only be able to show one place at a time where you have pain. Once you have answered the questions about how bad this pain is and how much it is bothering you, you will then be asked if you have got any pain anywhere else. If you answer, **Yes** you will see the body picture again and you will be able to mark another place you have pain. You can report as many different places where you have pain as you like.

Once you have answered the questions about the main symptoms on the questionnaire you will be given the chance to report any other, extra symptoms that you have.

If you answer **Yes** when asked **Is there any other symptom you would like to report that you have experienced in the past 24 hours?** you will see this screen:

Use the pen to tap on the letters to spell out the symptom. Then tap on **Next**.

Once you have said how bad this symptom is and how much it has been bothering you, you will be asked again if you have any other symptoms to report. You can report as many **other symptoms** as you like.
Once you are happy filling in the questionnaires and you have started your chemotherapy, tap on **Tap to start real data collection**.

Once you have finished the **real data** collection questionnaire, the handset will automatically send the information to the hospital.

If the telephone reception is poor it may not send the information at that time. The handset will save the information until the reception is better. If this happens, you might be asked to send the report the next time you switch on the handset. If you keep having problems sending your information, contact Rachel, Susie or Faith (See page ... for contact numbers).
When you begin to fill in the questionnaires for real, a new set of options should appear on your opening screen.

If you have been unable to send information due to a poor signal the screen will have an option saying Tap to send instead of Nothing to send. Tap on this message and provided the signal has improved, any stored information should be sent to the hospital.

If the telephone reception is still poor it may not send the report, but save it again until reception is improved. You may be prompted to send the report when you switch on again. If you keep having problems sending your information, contact Rachel, Susie or Faith (see page ... for contact numbers).

If you are filling in the real questionnaire, which is unable to be sent because of poor telephone reception, in some cases you will be asked to contact the hospital to tell them your symptoms. A message will come up on your ASyMS-YG handset when you need to do this. You will not need to do this every time there is poor reception but you will need to use a landline telephone to contact the hospital if your ASyMS-YG handset reception is poor.

If you report a high temperature (38 or above) you will also be asked to ring the hospital yourself, rather than waiting for them to contact you.

You will not be charged for sending your information to the hospital or for ringing the hospital using the ASyMS-YG phone.
SECTION 9
Symptom Graphs

These graphs show you in picture form how your symptoms have affected you each day.

SECTION 10
Self-Care Advice

If you have problematic symptoms, the handset stores advice on things you can do to try to make you feel better.

By tapping on Tap for my self care advice you can look at ideas you may find helpful.

To go back to the first page tap on My self care in the top right hand corner of the screen.

<table>
<thead>
<tr>
<th>Nausea</th>
<th>My Self Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Avoid fatty, fried, very spicy or very sweet foods</td>
<td></td>
</tr>
<tr>
<td>- Drink small sips of clear fluids frequently</td>
<td></td>
</tr>
<tr>
<td>- Distract yourself by chatting with friends and family, reading, listening to music or watching TV</td>
<td></td>
</tr>
<tr>
<td>- Have someone else make the meals if you're feeling sick</td>
<td></td>
</tr>
</tbody>
</table>

(1 of 3)
SECTION 11
Useful Websites

Under ‘Tap for cancer information’ you will find a list of websites you might find useful to have a look at to find out information about cancer, symptoms, support available and general health.

Note: You cannot access the actual websites listed using your ASyMS-YG handset.

You have four choices of lists to view.

Tap on Close when you are ready to return to the main menu screen.
SECTION 12
Contacting the Hospital

If you need to contact the hospital you can use the telephone in your handset. **You will not be charged for calling the hospital.**

This can be done by tapping on the **Call hospital** button from the menu page. The number is pre-programmed into the handset. During working hours the number dialed is ... and out of hours the number dialed is .... You can only use the handset to phone the pre-programmed numbers.

Once you tap this button, you’ll be asked to confirm you want to make the call.

If you tap on **Yes**, you will be taken to the dialing box. To make the call, tap on **Dial** and to end the call tap on **Exit**.

Tapping on **Exit** will then take you back to the ASyMS-YG Menu.
1. **The handset will not switch on.**

Check the battery is charged. The green light on the top right hand side of the handset should be flashing.

Check you are pressing the ON/OFF switch on the top right hand side of the handset. Do this once, quickly.

If it still will not turn on, contact the ASyMS-YG team.

2. **I have difficulty using the plastic pen.**

If you find the plastic pen too difficult to use or have problems getting it out from the handset, it is possible to use the blunt end of a pen instead. **Do not use the ink end.**

3. **The orange light does not appear when the handset is charging.**

Make sure the handset is properly attached to either the cradle/stand or the plug, as shown.

Make sure the electricity supply is switched on.

If it still is not flashing, contact the ASyMS-YG team.

4. **When should I start the real questionnaires?**

We would like you start filling in real questionnaires as soon as possible after starting chemotherapy. If you feel uncomfortable using the handset please contact the ASyMS-YG team.

5. **My questionnaires will not send.**

This may be because the signal in your area is poor. Try moving to a different area within the house if you are able or perhaps the garden if you have one.

If you still have difficulty sending the questionnaires, contact the ASyMS-YG team.

6. **I have no graphs.**

Your graphs will not appear unless you have entered symptoms that have troubled you. If you have kept well, you will not see any graphs.
7. There is no self-care advice.

If you have not been troubled by any symptoms, no self-care advice will be shown on the handset.

8. I’ve just turned my handset on, but I’ve not been taken straight to the ASyMS menu.

If you have turned your handset on and it is showing the main O2 menu like this:

![Main O2 menu image]

Press either of the two buttons above the screen on the handset

9. The handset has been lost or stolen

Please contact the ASyMS-YG team as soon as possible. We will then be able to stop the handset from working.
CONTACT NUMBERS

ASyMS-YG Headquarters Team:

Rachel Taylor
Research Associate

Faith Gibson
Senior Lecturer in Children’s Cancer Nursing

Dedicated mobile number: 0770 760 4063

ASyMS-YG local team:

If you have a problem relating to using your handset please try to contact Rachel Taylor or Faith Gibson. If you cannot get in touch with Rachel/Faith or it is outside their working hours (usually 9am to 5pm Monday to Friday), please leave a message on the answer phone and they will get back to you as soon as possible.

IMPORTANT: If you have any worries about your health or symptoms please do what you would normally, this may involve contacting your hospital or GP.
APPENDIX 3

DISSEMINATION

Dissemination has been on going in a number of formats, including peer reviewed publication, presentation (oral and poster) at conferences and through comprehensive reports.

MANUSCRIPTS IN PREPARATION

Taylor RM, Aldiss S, Donachie P, Maguire R, Soanes L, Whelan J, Gibson F. The real time symptom experience of teenage and young adults receiving cancer chemotherapy. Supportive Care in Cancer
Taylor RM, Aldiss S, Maguire R, Gibson F. Health professionals perceptions of technology as supportive care for young people with cancer. International Journal of Nursing Studies

PEER REVIEWED MANUSCRIPTS

REPORTS


PRESENTATIONS


Gibson F, Taylor RM (2009) Development of an advanced symptom management system for monitoring and managing chemotherapy using mobile phone technology. Teenagers and Young Adults with Cancer: Royal Marsden Hospital, London


Gibson F, Taylor RM (2009) Developing and evaluating a complex intervention: engaging users throughout the process. RCN Research Society Annual Conference, Cardiff, March

Stevenson L, Gibson F, Taylor R (2008) Using the technology of the day: the mobile phone study. ‘Find your sense of tumour’ conference, Centr Parcs, Nottingham, October
Gibson F (2008) Using a mobile phone to monitor and manage chemotherapy related symptoms. 5th International Conference on Teenage and Young Adult Cancer Medicine, London, June

Gibson F, Aldiss S, McCann L, Maguire R, Miller M, Kearney N (2007) Using a mobile phone based advanced symptom management system to monitor and manage chemotherapy related toxicity. Pediatric Blood and Cancer 49 (4) 408 (Abstract 0.035 oral) 39th Annual Conference of the International Society of Paediatric Oncology (SIOP), Mumbai, India

POSTERS

Gibson F, Aldiss S, Taylor RM, Maguire R, Sage M, Kearney N. Involving young people and health professionals in the development of a supportive care system to be used on a PDA. (poster presentation) Association of Pediatric Hematology and Oncology Nurses 34th Annual Conference, Minneapolis, USA, October 2010

Taylor RM (2009) Using a mobile phone with young people to monitor and manage chemotherapy related symptoms. Cancer and Young People: Age Matters Conference, Glasgow, Scotland (awarded the poster prize)

