Evaluation of a mobile phone based, Advanced Symptom Management System (ASyMS©) in the management of chemotherapy related toxicity

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ABSTRACT:

Objectives: To evaluate the impact of a mobile phone based, remote monitoring, advanced symptom management system (ASyMS©) on the incidence, severity and distress of six chemotherapy related symptoms (nausea, vomiting, fatigue, mucositis, hand foot syndrome, diarrhoea) in patients with lung, breast or colorectal cancer.

Design: A two group (intervention and control), by 5 time points (baseline, pre-cycle 2, pre-cycle 3, pre-cycle 4 and pre-cycle 5) randomised controlled trial.

Setting: Seven clinical sites in the UK; 5 specialist cancer centres and 2 local district hospitals.

Participants: One hundred and twelve people with breast, lung or colorectal cancer receiving out patient chemotherapy.

Interventions: A mobile, phone based remote monitoring advanced symptom management system (ASyMS©).

Main outcome measures: Chemotherapy related morbidity of six common chemotherapy related symptoms (nausea, vomiting, fatigue, mucositis, hand foot syndrome and diarhhoea)

Results: There were significantly higher reports of fatigue in the control group compared to the intervention group (odds ratio 2.29, 95% CI 1.04 to 5.05, P=0.040) and reports of hand foot syndrome were on average lower in the control group (odds ratio control: intervention, 0.39, 95% CI to 0.92, P=0.031).

Conclusion: The study demonstrates that ASyMS© can support the management of symptoms in patients with lung, breast and colorectal cancer receiving chemotherapy.

Trial registration ISRCTN 67370244

INTRODUCTION

Chemotherapy is a core component of cancer care and with projected increases in the incidence of cancer[1] and advances in related treatments, its use is likely to increase considerably[2-3]. However, its toxic effects put patients at risk of developing a number of symptoms, which if not identified in the early stages, can be serious and life threatening[4-9]. Of concern, is that it has it has recently been reported that symptoms in patients with cancer are often poorly assessed and managed, with patients continuing to report a high burden of common symptoms[10].

Contributory factors include poor communication between patients and health professionals and inadequate symptom assessment[11]. The restructuring of cancer services[2,12] may also be seen as a potential barrier to the delivery of effective symptom management. With the implementation of new models of care[2,3] designed to deliver services as locally as possible and the shift from in-patient to ambulatory care, means that more patients are receiving treatments on an out-patient basis, resulting in them having to manage the majority of the associated side effects at home without direct supervision from health care personnel[13].

The use of mobile information and communications technology may be seen as a means by which to overcome these barriers[12,14]. With its increasing capabilities and its growing use within healthcare, many have seen it as a solution in the delivery of care in the home and rural setting[3] and other places where medical personnel are not readily accessible[15]. Such systems facilitate the provision of clear lines of 'real time' communication between patients and their health care providers[14,16]. Many of these technologies are patient centred and appear to complement current transitions within health care models, shifting care from the acute hospital setting to the home environment, with technology being used to rationalise and integrate services, where appropriate, based on patient need.

This type of technology has principally been used in the home care of patients with long term conditions such as chronic heart failure, asthma and diabetes[17-21] and to a lesser extent in patients with cancer[22-23]. Improvements in patient outcomes have been reported[22,24] as have reductions in the rate of hospitalisations, emergency room visits and increased cost savings[20].

The use of mobile technology appears to be well suited to the remote monitoring of chemotherapy related toxicity due to the high prevalence of out-patient care and the availability and accessibility of standardised methods of symptom assessment which are commonly used within clinical practice[25-26]. The system reported here is a mobile phone based, remote monitoring, advanced symptom management system (ASyMS©) which has been developed over a period of 5 years to remotely monitor and manage chemotherapy related toxicity in patients with cancer[22,27].

Study objectives

The primary aim of this pilot study was to investigate the viability of the trial design and explore any effect of the advanced symptom management system (ASyMS©) on the incidence, severity and distress of six chemotherapy related symptoms (nausea, vomiting, fatigue, mucositis, hand foot syndrome, diarrhoea) in patients with lung, breast or colorectal cancer.

The hypotheses of the study was that the mobile phone system would provide a more accurate reflection of chemotherapy toxicity and provide a better means of monitoring chemotherapy related morbidity.

METHODS

Study design

The study was a two group (intervention and control), by 5 time points (baseline, pre-cycle 2, pre-cycle 3, pre-cycle 4 and pre-cycle 5) randomised controlled trial.

Sample

Patients with breast, lung or colorectal cancer were selected for involvement in this study due to their high prevalence in the UK [41,42,43,44] and their use of outpatient chemotherapy services. Patients were recruited to the study from March – September 2006. They were eligible to participate in the study if they fulfilled the following criteria: A diagnosis of breast, lung or colorectal cancer; commencing a 'new' course of chemotherapy treatment (defined as those patients commencing a new chemotherapy regime irrespective of stage of disease or line of treatment); receiving out-patient chemotherapy; aged 18 years or over; written informed consent given; able to read and write English and deemed by members of the clinical team as being physically and psychologically fit to participate in the study. Exclusion criteria were patients who are unable to meet the above criteria and who did not agree to give access to their case records.

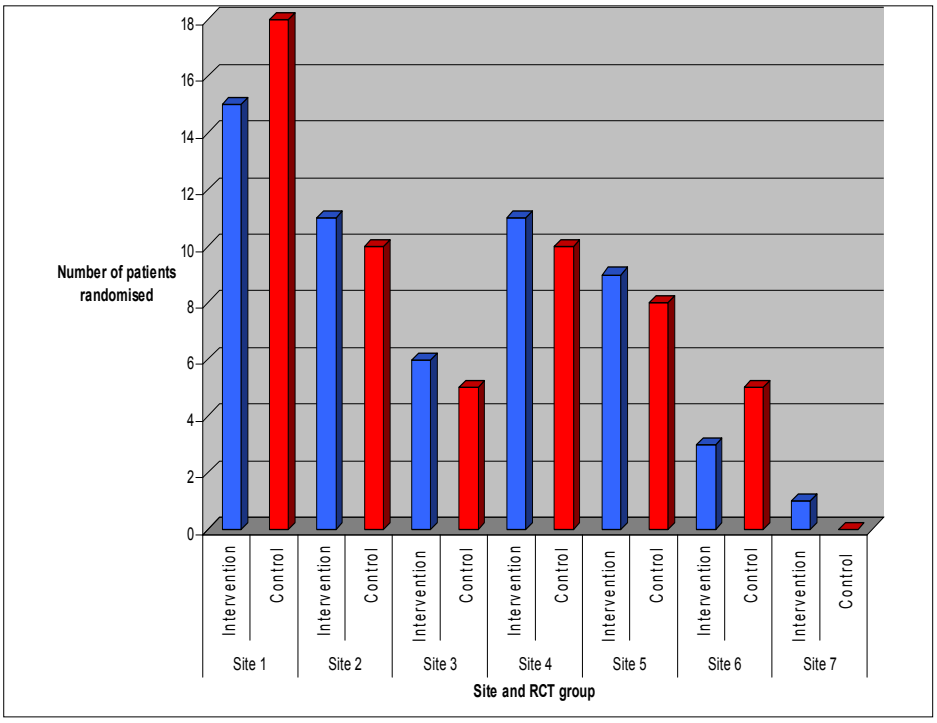
Recruitment

Patients were recruited from 7 clinical sites throughout the UK (6 Scotland/1 Engalnd). Five of the participating sites were specialist cancer centres and the remaining two were local district hospitals. The study was approved by the Fife & Forth Valley Medical Research Ethics Committee as the national approval body and within each local area. All patients provided written informed consent prior to their participation in the study.

Study Randomisation

One hundred and twelve patients were randomised using an automated Interactive Voice Response (IVR) telephone randomisation system at the Centre for Healthcare Randomised Trials Health Services Research Unit, University of Aberdeen. The randomisation used a minimisation algorithm [45] based on centre and tumour type. Figure 1 denotes the randomisation of participants per site.

Figure 1: Randomisation of participants per site



Intervention

Patients in the intervention group used ASyMS© throughout 4 cycles of chemotherapy. As ASyMS© was developed to complement standard care, patients using the system were also advised to follow procedures and guidelines related to the monitoring and reporting of chemotherapy related toxicity in their local area. Patients were trained on how to use the system by nurses working in their local area who had received training by the study team on how to use the ASyMS© system.

On days 1-14, in the morning, evening and at any time they felt unwell, patients randomised to the ASyMS© mobile phone group were asked to complete a symptom questionnaire that integrated the Common Toxicity Criteria Adverse Events (CTCAE) grading system[26] and the Chemotherapy Symptom Assessment Scale[25]. Symptoms assessed included nausea, vomiting, mucositis, hand-foot syndrome, diarrhoea and fatigue and were selected in collaboration with a team of cancer chemotherapy specialists and from a review of the related literature. This questionnaire measured the incidence, severity and distress associated with each symptom. The symptom questionnaire was tested for face validity by the project team, two patient advisory groups and by patients and health professionals who were involved in the earlier testing of the system[39]. It was short, simple and relevant with a standardised scoring method and demonstrated high levels of internal reliability (Cronbach's alpha= 0.82).

This symptom information was immediately sent in 'real time' via secure General Packet Radio Services (GPRS) connections to the study server. After completing the electronic symptom questionnaire, patients immediately received written feedback on the mobile phone interface, comprising of tailored self-care advice directly related to the severity of the symptoms they had just reported. This included simple instructions which patients could use to mange their symptoms including advice on pharmacological use, the use of distraction and relaxation techniques and dietary advice where appropriate.

An evidence based risk assessment tool was integrated into the ASyMS© server software. This alerted participants' clinicians, via a dedicated 24-hour pager system, of any incoming symptom reports that were considered to be clinically important. An 'amber alert' was used to indicate to clinicians that a patient was experiencing toxicities at home that were not severe or life threatening but in which early intervention might prevent further symptom progression. This included combinations of mild or moderate symptom reports which resulted in significant symptom burden or for symptoms which were moderate in severity but

had persisted over a period of 48-72 hours. A ‘red alert’ was used to indicate to clinicians that a patient was pyrexial and/or experiencing severe toxicities at home (for example severe diarrhoea). Clinicians were advised to contact patients within one hour of receipt of a red alert. In the event of either amber or a red alert, study clinicians could access secure web pages to view the patients’ symptom reports to assist in their clinical decision making.

Control Group

Patients in the control group received standard care following guidelines and procedures related to the monitoring and reporting of chemotherapy related toxicity in their local area. This included written information as well as verbal information from the nurses administering chemotherapy.

Outcome measure

In order to test the hypotheses of the study patients in both the intervention and control group were asked to complete a paper version of the electronic symptom questionnaire at their pre-chemotherapy assessment (baseline) and before chemotherapy cycles 2, 3 4 and 5. This was completed by both groups at their clinic visit prior to administration of chemotherapy.

Statistical Methods

The study aimed to randomise a total of 150 patients in equal proportion to the two randomised groups (75 in each group), giving approximately 85% power at a 5% level of significance to detect a difference in any of the six individual mean symptom scores between the mobile phone and the control groups of 0.5 standard deviations (an effect size of 0.50). For the binary outcomes of occurrence of the symptoms, and taking the most variable case of an incidence of 50%, the study would have 85% power to detect a halving of this incidence to 25%. The additional information in the serial measurements of these outcomes will have increased the power. Since this was to inform a larger definitive evaluation of the technology, which in part was investigating what the best

outcome would be, we did not declare any of the incidence, severity or distress dimensions of the six individual symptoms as being primary.

All analyses presented here are intention-to-treat. Important baseline characteristics are summarised overall and informally compared for balance between randomised groups in Table 1. We compared the time to drop out using a log rank test, with patients last chemotherapy cycle at which they contributed data recorded, or if still fully participating at study end, they were censored at cycle 4.

For the binary outcomes (did symptom occur? Y/N) and the continuous outcomes of severity and distress (scores 0-3) of the six individual symptoms, repeated measures generalised linear models with autoregressive correlation structure AR[1] was assumed, using an error structure appropriate for the distribution of the outcome – Binomial for binary outcomes and Gaussian for the assumed continuous outcomes [46]. The 4 on-treatment (post randomisation) cycles were used, and the model adjusted for age and tumour type, and the baseline version of the outcome being modelled and included an indicator for the randomised group to estimate the treatment effect. Subject was included as a random effect.

The severity scores were 1 (mild), 2 (moderate) and 3 (severe) – for a patient who did not have the symptom, a score of zero (no symptom) was imputed. Likewise, for distress, the scores were 0 (not at all), 1 (a little), 2 (quite a bit), and 3 (very much), so 0 (no symptom) was imputed if they did not have the symptom. A secondary analysis was conducted without imputation of these zero scores, to assess whether in the subgroup of patients with symptoms, there were any differences in severity or distress. All analyses were conducted in SAS 9.1 for Windows. No adjustment has been made for multiple comparisons.

RESULTS

A total of 112 patients met the eligibility criteria and were recruited to the study over a 7 month period from March – September 2006 and participated in the study over 4 cycles of chemotherapy (12-16 weeks). Figures on the number of patients approached to take part in the study are not provided due to incomplete data from the participating clinical sites. Fifty six patients were randomly assigned to each study arm (intervention and control). This was 75% of the original target of 150, and so the study power fell to 74%, or 80% to detect a slightly larger effect size of 0.53. Given the feasibility nature (limited funds and time) of the study, there was no opportunity to either extend the recruitment window or recruit additional centres to achieve the full target.

There was a steady decline in participants contributing data to the study, from 100% in both groups at baseline (total n=112, n=56 in each randomised group) to 80% (n=45) in the control group and 73% (n=41) in the intervention group (log rank test comparing time to drop out P=0.33). For full details see the CONSORT flow diagram (Figure 2). One participant withdrew before contributing any data, 3 died before any post randomisation data could be completed, and 2 withdrew because they did not like the mobile phone.

Demographics

At baseline both groups were similar (Table 1) with more women than men recruited as breast cancer was the most common tumour type. The Carstairs social deprivation score ("DepCat") is exclusively a Scottish measure[29] and is used as a measure of socioeconomic deprivation or affluence in different localities across Scotland (a score of 1 indicates the most affluent community and 7 the most deprived). This was not available to the 17 patients randomised in England and therefore this information could not be presented for this group of patients.

Chemotherapy related toxicity

The aim of this study was to evaluate if the mobile phone advanced symptom management system (ASyMS©) would provide a more accurate reflection of chemotherapy related toxicity and would provide a better means of monitoring toxicity, resulting in a decrease in chemotherapy related morbidity on six chemotherapy related symptoms in patients with lung, breast or colorectal cancer. Two of the six symptoms measured, (fatigue and hand foot syndrome), showed statistical significance between the two randomised groups (Table 2).

There was significantly higher reports of fatigue in the control group compared with the intervention group (odds ratio 2.29, 95% CI 1.04 to 5.05, P=0.040) and reports of hand/foot syndrome were on average lower in the control group (odds ratio control: intervention, 0.39, 95% CI 0.17 to 0.92, P=0.031).

Exploring the severity and distress of the individual symptoms demonstrated that there were no significant differences between the randomised groups in the symptoms except for hand/foot syndrome (Table 3) for which both severity and distress were reported as being significantly higher in the mobile phone group than the control group. Whilst not reaching statistical significance, there was a trend for patients in the control group to be more distressed by their fatigue (p=0.081) and for patients in the intervention group, to report greater severity (p=0.18) and distress (p=0.13) from their mucositis.

DISCUSSION

The results of this study indicate that the use of information and communications technology may be seen as a means of supporting symptom management in patients receiving chemotherapy. This supports earlier work which demonstrates the value of technology in the home care of patients with cancer or other chronic diseases[17-21].

Relative to chemotherapy related toxicity, patients in the intervention group reported significantly lower levels of fatigue and there is a trend, albeit non-significant, for these episodes of fatigue to be less severe and less distressing. It may be postulated that patients in the intervention group reported lower levels of this symptom for a number of reasons. The inclusion of descriptors of this symptom from the Common Toxicity Criteria[26] in the patient questionnaire may have facilitated measurement of this subjective symptom and hence any subsequent intervention. This may be supported by other studies which have found that health professionals do not screen for fatigue in patients with cancer because they are uncertain on how to assess and treat the condition[31] despite the high prevalence of this symptom in patients with cancer[32].

In relation to the differences in hand foot syndrome and mucositis between both groups, there is either significantly more (or a trend to more) being reported in the mobile phone group, and for these episodes to be characterised as both more severe and causing more distress. Once again this may be partly attributed to the inclusion of clinically meaningful descriptors within the patient questionnaire to facilitate assessment and management of this symptom. The mobile phone may also have facilitated improved assessment of these symptoms which are known to be poorly assessed in routine clinical practice[33-35] and it is hypothesised that allowing patients the opportunity to report on these symptoms in real time allows more accurate measurement of this toxicity which should result in more appropriate management.

Taken together these preliminary findings suggest that ASyMS© provides a more accurate reflection of chemotherapy toxicity offers a better means of monitoring chemotherapy related toxicity and has the potential to reduce chemotherapy related morbidity as the significant reduction in fatigue, suggests more timely and effective management of debilitating symptoms. The use of the RCT has allowed comparisons to be made between both groups and had also provided

information of sample sizes and methods of measurement which will be used in a later, definitive evaluation of the ASyMS© system in the remote monitoring of chemotherapy related toxicity. The perceptions of patients and health professionals using the ASyMS© system are reported elsewhere in the literature[38, 39]. The ASyMS© system has also been developed for use in teenagers with cancer[36] and patients with palliative care needs[40] and future developments include its use in people with lung cancer receiving radiotherapy.

Strengths and Limitations

Whilst acknowledging limitations, this is an innovative study that pragmatically tests the use of technology within cancer care. The 75% recruitment rate does limit the effect size identified within the study and suggests the need for a larger trial and plans are underway begin this. The attrition of patients over the course of the study which was comparable for both groups suggests that use of the mobile phone was not a factor, however it may indicate either worsening symptoms or fatigue with the data collection process. Exploration of the reasons for attrition will be closely monitored in future studies.

In relation to the completion of the symptom questionnaire, patients within the intervention arm were reporting the symptoms twice daily within the mobile phone and so may have reported their symptoms differently on the paper based questionnaire following each cycle of chemotherapy as they were more familiar with the questions. Also, as the same questionnaire was used as an intervention on the mobile phone and as an outcome measure, the differences observed between the intervention and control groups may be due to the learning effect of the intervention group in completing the same questionnaire. Furthermore, whilst we assessed the impact of the ASyMS© system on chemotherapy related toxicity, we did not measure additional parameters such as quality of life or the impact of the system on self care behaviour, which are pertinent issues relative to the use of such technology in this patient group and its utility within clinical practice. In addition use of the DepCat" an exclusively Scottish measure[29] limited analysis of

the total sample and this will be rectified in future studies. Future work will consider all these issues and will include an economic evaluation to assess cost benefit of such technology within cancer care.

CONCLUSIONS

The study demonstrates that the ASyMS© system can support the management of symptoms in patients with breast, lung and colorectal cancer receiving chemotherapy. It has demonstrated that the ASyMS© system could provide a more accurate reflection of chemotherapy related toxicity and could provide a better means of monitoring toxicity in clinical practice with the potential to decrease chemotherapy related morbidity. In addition it offers a systematic approach to symptom assessment which in the future could afford comparison of chemotherapy related toxicity and facilitate a more accurate picture of the real time morbidity experience of patients receiving chemotherapy.

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FIGURE 2: CONSORT FLOW DIAGRAM

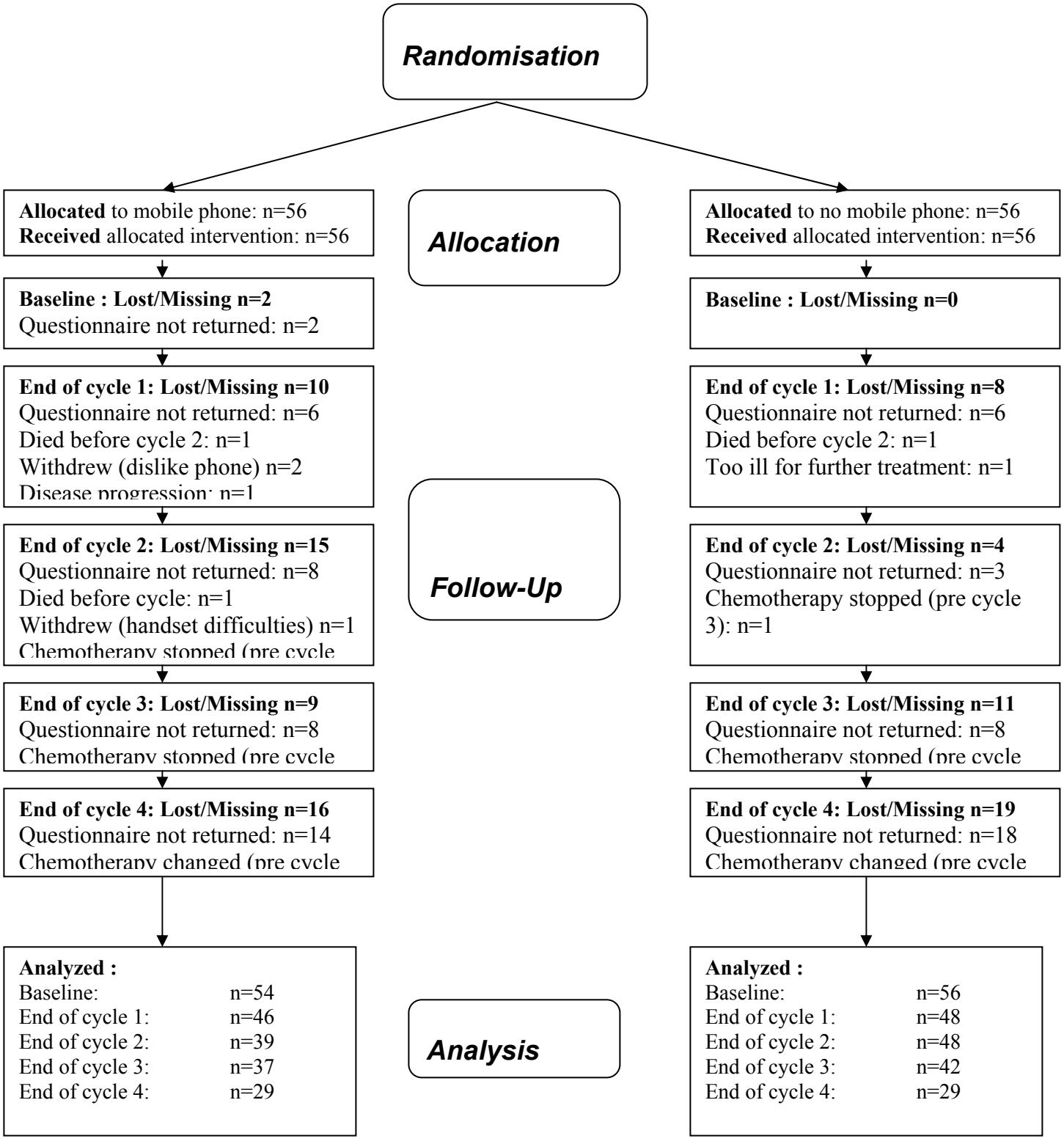

Table 1: Baseline characteristics for all participants and for patients assigned to the intervention and control groups. DEPCAT scores reported only for Scottish site patients. Values are in numbers (percentages) unless stated otherwise.

Characteristics	All Patients (n=112)	Intervention Group (n=56)	Control Group (n=56)
Mean age years (Std.Dev)	56.0 (10.5)	55.1 (10.6)	56.9 (10.5)
Sex n (%)			
Male	26 (23.2)	15 (26.8)	11 (19.6)
Female	86 (76.8)	41 (73.2)	45 (80.4)
Tumour type n (%)			
Breast	70 (62.5)	34 (60.7)	36 (64.3)
Lung	26 (23.2)	13 (23.2)	13 (23.2)
Colorectal	16 (14.3)	9 (16.1)	7 (12.5)
*Dep cat score n (%)	(n=95)	(n=47)	(n=48)
1	9 (9.5)	5 (10.6)	4 (8.3)
2	28 (29.5)	16 (34.0)	12 (25.0)
3	27 (28.4)	13 (27.7)	14 (29.2)
4	11 (11.6)	6 (12.8)	5 (10.4)
5	11 (11.6)	5 (10.6)	6 (12.5)
6	9 (9.5)	2 (4.3)	7 (14.6)

Chemotherapy regime n (%)			
FEC	32 (28)		
AC	23 (20)	15 (27)	17 (30)
Carbo-gem	8 (7)	12 (21)	11 (20)
Cis-gem	6 (5)	5 (9)	3 (5)
Cis-etoposide	5 (5)	3 (5)	3 (5)
CAPOX	8 (7)	2 (4)	3 (5)
Capecitabine	3 (3)	4 (7)	4 (7)
Taxotere	4 (4)	2 (2)	1 (2)
Other	23 (21)	3 (5)	1 (2)
		10 (16)	13 (25)

Table 2 :Estimated intervention effects, non-mobile compared with mobile randomised groups. Primary outcome of symptom scores, and the occurrence of the 6 symptoms that are components of the total symptom score.

Measure	Non-mobile group**	Mobile group**	Non-mobile vs. mobile estimated difference*	95% confidence interval	P-value
Vomiting	21.9%	20.3%	1.23	0.57 to 2.68	0.60
Nausea	61.1%	53.9%	1.55	0.77 to 3.12	0.22
Diarrhoea	30.2%	33.0%	0.97	0.51 to 1.82	0.91
Hand/foot syndrome	12.2%	24.0%	0.39	0.17 to 0.92	0.031
Sore Mouth or Throat	42.1%	53.3%	0.78	0.41 to 1.48	0.44
Fatigue	81.3%	67.3%	2.29	1.04 to 5.05	0.040

* All odds ratios (non-mobile:mobile)

** The average proportion of subjects with the attribute over the 4 post randomisation cycles.

Table 3 : Severity and distress of the six symptoms. The data shown are the raw mean(SD), while the estimated difference, 95% confidence interval and P-value are from the adjusted model.

Measure	Non-mobile group: mean (SD)	Mobile group : mean (SD)	Non-mobile vs.mobile estimated difference*	95% confidence interval	P-value
Severity					
Vomiting	0.50(0.81)	0.51(0.93)	0.04	-0.29 to 0.38	0.80
Nausea	1.43(1.08)	1.23(1.19)	0.25	-0.16 to 0.67	0.23
Diarrhoea	0.56(0.70)	0.60(0.76)	-0.06	-0.32 to 0.20	0.64
Hand/foot syndrome	0.22(0.49)	0.46(0.64)	-0.27	-0.52 to -0.02	0.033
Sore Mouth/Throat	0.78(0.80)	1.05(0.89)	-0.22	-0.54 to 0.10	0.18
Fatigue	1.82(1.09)	1.54(1.11)	0.24	-0.14 to 0.63	0.21
Distress					
Vomiting	0.32(0.51)	0.35(0.65)	-0.02	-0.24 to 0.20	0.87
Nausea	1.06(0.87)	0.93(0.91)	0.13	-0.18 to 0.45	0.40
Diarrhoea	0.40(0.51)	0.40(0.47)	0.03	-0.14 to 0.20	0.77
Hand/foot syndrome	0.16(0.34)	0.30(0.45)	-0.17	-0.33 to -0.02	0.028
Sore Mouth/Throat	0.55(0.54)	0.74(0.62)	-0.17	-0.39 to 0.05	0.13
Fatigue	1.52(0.88)	1.24(0.91)	0.28	-0.03 to 0.59	0.081