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eSMART STUDY (PART 2): PARTICIPANT INFORMATION SHEET – Patient
Version 7; 10/09/18

Study title: eSMART: Randomised controlled trial to evaluate electronic Symptom Management using the Advanced Symptom Management System (ASyMS) Remote Technology for patients with cancers

Invitation

You are being invited to participate in the above research study. Before you decide, it is important for you to understand why this research is being done and what it will involve. Take time to read the following information carefully and discuss it with others if you so wish. Please contact us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

Chemotherapy is a common treatment for people with cancer. It can be associated with a number of side effects and symptoms, which if not adequately managed can have a negative impact on the lives of people living with cancer. Chemotherapy is often delivered on an outpatient basis and most people have to manage the side effects of their treatment at home, with limited input from health professionals. Therefore, it is important to look at ways of supporting people receiving chemotherapy to manage their symptoms during periods when they are at home. We are conducting a large study called eSMART to evaluate the impact of mobile phones in the management of symptoms and side effects of people with Breast or Colorectal or Haematological Cancer (Hodgkin Disease or non-Hodgkin Lymphoma) during their chemotherapy and for one year following completion of their treatment. The study is being conducted in two parts.

You are being asked to participate in **Part 2** of the study **only**. The aim of Part 2 is to determine whether the use of the mobile phone system is better or worse than current care in the reporting and management of chemotherapy related symptoms during the first 6 cycles of chemotherapy treatment and for up to one year following this. Not all patients will take part in the Follow Up Phase for one year – the length of time that you take part in the Follow Up depends on when you join the study and the person who gave you this information sheet will be able to tell you roughly how long your involvement in the study would be.

Why have I been invited to participate?

A member of your clinical care team has approached and invited you to participate because you are due to receive chemotherapy for a diagnosis of Breast, Colorectal or Haematological Cancer (Hodgkin Disease or non-Hodgkin Lymphoma). A total of 1,108 patients from different hospitals within a number of European countries will participate in this study.

Do I have to participate?
No. It is your decision whether or not you wish to participate. If you do decide to take part, you will be given this Participant Information Sheet to keep and you will be asked to sign a Consent Form. You are free to withdraw from the study at any time, which will in no way affect the standard care you receive. However, any study data that you will have provided up until withdrawal may be retained and used for analysis purposes.

What will happen if I take part?
In this study, patients will be randomly allocated into two groups. One group will report their symptoms using a mobile phone, whilst the other group will receive care that is normally provided at their hospital. Patients will participate in the study for up to a maximum of 6 cycles of chemotherapy and then for up to one year following this. The person who gave you this information sheet will be able to tell you how long you would be expected to take part after receiving a maximum of 6 cycles of chemotherapy.

The groups that patients will be allocated into will be selected by a computer, which has no information about the individual, so people will be selected by chance. Patients in both groups will have their symptoms and other outcomes (including quality of life, supportive care needs, work limitations, confidence in ability to complete tasks and anxiety) compared. Details of the two groups are given below:

Mobile phone group

If you are allocated to the 'mobile phone' group, you will be given a mobile phone and an ear thermometer for taking your temperature. A health professional involved in your chemotherapy treatment or a researcher/research nurse working on this study will show you how to use both the phone and the thermometer. A booklet for the mobile phone containing instructions and helpful contact numbers will also be supplied.

During your chemotherapy treatment (up to 6 cycles), you will be asked to complete a short symptom questionnaire on the mobile phone once a day and anytime you feel unwell. This questionnaire will ask you whether or not you are in hospital and questions about symptoms you may experience at this time. Every time you complete the questionnaire, you will be asked to record your temperature on the thermometer provided and enter your temperature recording on the mobile phone. It is estimated that each time you complete the questionnaire and take your temperature will take you no longer than 5 minutes.

This symptom information will then be sent to a computer system which will analyse your symptom reports and trigger an alert to healthcare professionals at your hospital if you experience moderate or severe symptoms. Reporting your symptoms using the symptom questionnaire on your mobile phone will trigger the following actions:

- If you are experiencing ***moderate symptoms***, an amber alert will be sent to health professionals at your hospital to inform them that you are experiencing symptoms that

may require some advice and/or treatment. For an amber alert, a health professional will review your symptom report within **8** hours of receiving it and, depending on your symptoms, may decide to call you at home to offer you advice.

- If you report ***severe symptoms***, a red alert will be sent to healthcare professionals at your hospital and they will call you **within 30 minutes** from the time that you completed and sent your symptom questionnaire to discuss your symptoms and offer advice/treatment as appropriate.

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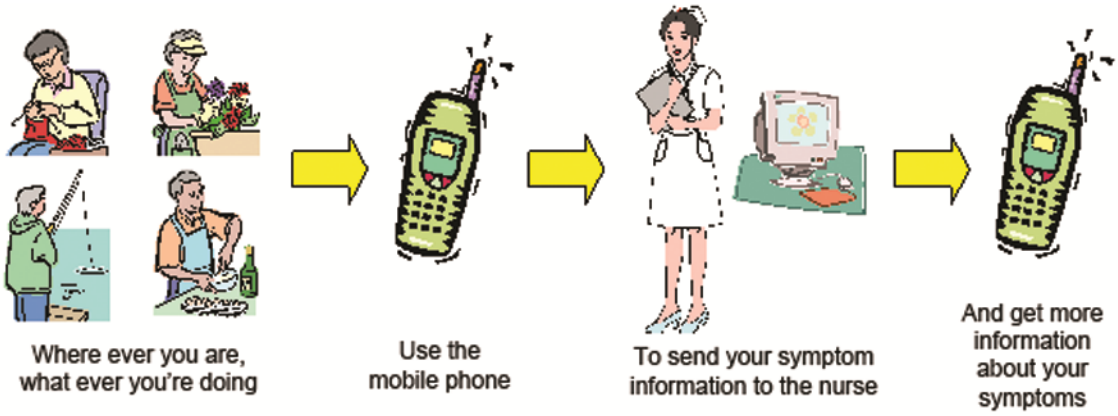
If you answer that you are 'in hospital' on your mobile phone, your symptom information will be sent to the study server, however **no alerts** will be sent to your health professionals.

You will also receive **self-care advice** on the mobile phone on how to manage any symptoms you may be experiencing. You will be able to view graphs of your symptoms on your mobile phone at any time. In addition, your doctor or nurse will have the option to print off graphs of your symptom reports that may be included in your hospital notes for review by your clinical team. If you experience any problems with the mobile phone system, you will be advised to follow the standard procedures for reporting symptoms/problems at your clinical site. You will be asked to inform health professionals at your hospital about any problems with the mobile phone system that you may be experiencing. You will also be supplied with a booklet for the mobile phone containing instructions and helpful contact numbers.



At the beginning of your chemotherapy treatment and before the start of each subsequent chemotherapy cycle (up to 6 cycles) you will also be asked to complete a set of eight questionnaires on a computer tablet or PC. Completing these questionnaires should take between 40 to 60 minutes of your time. These questionnaires will explore issues regarding your quality of life, confidence in ability to complete tasks, anxiety, work-related issues, use of health care services and any other symptoms you are experiencing.

A sub-set of patients (30% of the total patient sample) will also be randomly selected and asked to complete a symptom questionnaire midway through each chemotherapy cycle (up to

a 6 cycles). If you are selected for this assessment, a research assistant/nurse/designated health professional participating in the study will call you via telephone at this time and ask you to provide answers to the symptom questionnaire over the phone. You will not be provided with any advice on how to manage your symptoms during this call.

At the end of your 6th cycle of chemotherapy treatment (or earlier if you finish your chemotherapy before this), you will be asked to return the mobile phone and the thermometer provided to you at the start of the study. If you continue to receive chemotherapy treatment after you have returned the mobile phone, you should follow the normal standard care procedures of your clinical site.

Finally, following completion of your 6th cycle of chemotherapy treatment (or earlier if you finish your chemotherapy before this), you will be asked to complete the same set of questionnaires within a week of finishing chemotherapy and then every 3 months for up to one year. With your permission, before contacting you on any of these occasions, the researcher/research nurse working on this study will first contact your GP/oncology consultant/family doctor [*equivalent to be substituted*] to check with him/her your health status so that the researcher/research nurse does not disturb you if you feel too unwell to take part. On any of these occasions, you will be offered the option to complete the questionnaires either in person at your hospital using a tablet computer, PC or via the internet at home or via telephone at home. The person who gave you this information sheet will able to tell you for how long you would take part in this Follow Up Phase.

At the end of the 6th cycle of chemotherapy (or earlier if chemotherapy finishes before this) a small number of patients from the mobile phone group in each country will be invited to take part in an interview or a focus group to discuss their experiences of taking part in the study and using the technology. If you agree to this, you may be contacted and asked to take part in a telephone/face-to-face interview or focus group. It is anticipated that this would not last longer than one hour. The interview/focus group would be recorded to allow it to be analysed later. Anything discussed in the interview would be kept confidential and you would not be able to be identified from any comments as all the information gathered during interviews will be anonymised.

Normal care group

If you are allocated to the 'normal care' group, you will report your symptoms according to normal local practice as employed by your hospital.

At the beginning of your chemotherapy treatment and before the start of each subsequent chemotherapy cycle (up to 6 cycles) you will also be asked to complete a set of eight questionnaires on a computer tablet or PC. Completing these questionnaires should take between 40 to 60 minutes of your time. These questionnaires will explore issues regarding

your quality of life, confidence in ability to complete tasks, anxiety, work-related issues, use of health care services and any other symptoms you are experiencing.

A sub-set of patients (30% of the total patient sample) will also be randomly selected and asked to complete a symptom questionnaire midway through each chemotherapy cycle (up to 6 cycles). If you are selected for this assessment, a research assistant/nurse/designated health professional participating in the study will call you via telephone at this time and ask you to provide answers to the symptom questionnaire over the phone. You will not be provided with any advice on how to manage your symptoms during this call.

Following completion of your 6th cycle of chemotherapy treatment (or earlier if you finish your chemotherapy before this), you will be asked to complete the same set of questionnaires within a week of finishing chemotherapy and then every months up to one year. With your permission, before contacting you on any of these occasions, the researcher/research nurse working on this study will first contact your GP/oncology consultant/family doctor [*equivalent to be substituted*] to check with him/her your health status so that the researcher/research nurse does not disturb you if you feel too unwell to take part. On any of these occasions, you will be offered the option to complete the questionnaires either in person at your hospital using a tablet computer, PC or via the internet at home or via telephone at home. The person who gave you this information sheet will able to tell you for how long you would take part in this Follow Up Phase.

What is the procedure being tested?

Overall, the study is testing the impact of a mobile phone system to manage the symptoms and side effects of people with Breast, Colorectal, or Haematological cancer (Hodgkin Disease and non-Hodgkin Lymphoma) during their chemotherapy and for up to one year after the end of it.

What are the side-effects or disadvantages of taking part in the study?

As this study does not affect the treatment and care that you are receiving, there are no real side-effects of taking part. However, if you are allocated to the 'mobile phone' group, as you will be completing a daily symptom questionnaire you may be thinking about your symptoms more than you might if you were not asked to complete the questionnaire. Some people may find it upsetting to focus on their symptoms, whilst others find this helpful or do not notice any difference. If you did feel that taking part in the study was making you think too much about your symptoms, then you can withdraw from the study without having any effect on your future treatment and care. You should discuss these feelings or concerns with your doctor or nurse. [*Local contact details will be inserted here*].

In addition, you might find completing the study questionnaires a burden. You will be given adequate time to complete the questionnaires at your own pace, and a research assistant/nurse will always be available should you need any help. However, if you find

completing these questionnaires overly tiring or frustrating, then you can withdraw from the study without this having any effect on your future treatment and care.

What are the possible benefits of taking part?

If you are allocated to the 'mobile phone' group, the possible benefits of participating are that during periods after chemotherapy, whilst you are at home, the symptoms that you may experience will be remotely monitored and health professionals will be alerted if you are experiencing moderate or severe symptoms that require treatment and/or advice. Furthermore, each time you enter your symptoms on the mobile phone, you will receive self-care advice linked to the symptoms that you are experiencing, which may assist you to manage your symptoms at home. In addition, on the mobile phone there is a library of helpful information for people undergoing chemotherapy such as advice on feelings and emotions and living with and beyond cancer. You will also have a list of important contacts on your mobile phone, such as numbers of care teams and patient support organisations available in your country. Finally, your nurse will have the option to print your reported symptoms from the computer and file these in your hospital notes. This may help you to remember and discuss the symptoms you experienced at home for when you visit your doctor or nurse at the hospital.

If you are allocated to the 'normal care' group, you may not experience any direct benefits of participating in this study. However, the information and feedback you provide may be beneficial for other patients with cancer in the future as it will help us to understand the impact of the mobile phone system as we will compare the symptoms and the information from people in the 'mobile phone' group and the 'normal care' group.

What if new information becomes available?

Sometimes during the course of a research project new information can becomes available regarding the procedures being tested. If this happens, your doctor or nurse will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your doctor or nurse will make arrangements for your treatment and care to continue, and it will not be affected in any way. If you decide to continue in the study you might be asked to sign an updated consent form. Also, on receiving new information, your doctor or nurse may consider it to be in your best interests to withdraw you from the study. They will explain the reasons and arrange for your treatment and care to continue. However, any study data that you will have provided up until withdrawal may be retained and used for analysis purposes.

What happens when the research study stops?

Your participation in the study will continue until up to a maximum of 12 months after either the end of your chemotherapy treatment (if it is fewer than 6 cycles), or up to 6 cycles of chemotherapy. If you received a mobile phone and thermometer to report your symptoms, you will be asked to hand this back following the completion of your chemotherapy treatment (or

up to a maximum of 6 cycles of chemotherapy). At the end of the study, you will receive standard care as is normal at your hospital.

What if you have questions or if something goes wrong?
If you have any comments or complaints about this study, or should you need to get in touch with your clinical site in the event of a problem with your participation in the study, you should contact your doctor or nurse (see contact details below). *Please keep these contact details safe and accessible at all times should you need them.*

Name and contact address/details (including telephone number) of Doctor and Nurse to be inserted.

If you do not get a satisfactory response from them, you are free to contact the sponsor of this study at the address below.

Name and contact address/details (including telephone number) of Sponsor to be inserted.

If you believe that you have been harmed in anyway by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through the University of Strathclyde which is acting as the research sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS but you may have to pay your legal costs.

Will my participation in this project be kept confidential?
All information that is collected about you during this study will be kept strictly confidential. If you decide to take part and are allocated to the mobile phone group, information about you will be stored securely on the study server and will be treated as strictly confidential. This information includes your hospital/identification number, name, gender, age, date of birth, address, contact telephone numbers and clinical information, i.e. details of your diagnosis and treatment/other medical conditions that you have. Storing this information on the study server is appropriate to cross-check your information with your nurse if they need to contact you and to assist in clinical decision making.

In addition, your name, your study identification number and details of your chemotherapy regime will be stored on your mobile phone. This is to ensure you get asked the appropriate questions in the questionnaire and get the correct self-care advice. All the information stored on the study server and the mobile phone is encrypted and securely stored, in line with data protection legislation, meaning it cannot be read by anyone else except health professionals and the researchers involved in the study. Only your name will be displayed on the device.

All non-anonymised information (i.e. personal data that can be used to identify you; e.g. hospital number, name, date of birth, and contact details including your home address and telephone numbers) will be stored securely for 5 years after the last contact between the research team and yourself according to standard Information Governance (ISO 27001) and NHS Information Governance Toolkit safeguards. All anonymised information (e.g. your responses to the study questionnaires) will be stored securely for 10 years according to University of Strathclyde policy. The procedures that will be followed for the collection, storage, protection, retention and destruction of all information comply with national and EU legislation.

Should you require the details of the information held about you in electronic form during the study or this information to be removed from electronic storage during the study, please contact Docobo Ltd by phone on +44 1372 456673, or by email using the address technicalsupport@docobo.co.uk.

For all patients participating in the study (both mobile phone and normal care groups), your medical records may be inspected by the team organising the research for purposes of checking the data. In addition, your medical notes may be looked at by appropriate individuals from the hospital, the University of Strathclyde, from regulatory bodies or from the organisation co-ordinating the study, where it is relevant to your taking part in this research. In addition, data collected during the study may be looked at by responsible representatives from the sponsor (University of Strathclyde) for the purposes of monitoring and auditing to ensure that the study is being conducted properly. If you provide your consent, your General Practitioner (GP) [*please note this term will be updated to reflect appropriate personnel in each participating country*] will be sent a letter, telling him/her that you are taking part in this project.

However, if at any point during this part of the study you disclose that you are at risk of harm, with your permission, the research team would report this to your clinical team. Your clinical team will discuss with you what type of support may be appropriate for you and who else may need to have this information.

The research team would also like to use anonymised data collected from patients in this study for the purposes of secondary data analysis. You will not be able to be identified from any of the data used for this purpose. However, this data may be sent to other European countries or the United States of America, where Data Protection regulations may not be as stringent as in the UK. This data will be used primarily for the purposes of symptom management and supportive care research. It is anticipated that this data will contribute to research that has the impact to improve the patient experience of cancer, improve patient outcomes and inform cancer service delivery.

As part of the study, we have also been requested to share your anonymised responses regarding your work status and productivity with the developer of the questionnaire (i.e. Work Limitations Questionnaire). The developer (i.e. Tufts Medical Centre), who is based in the

United States of America, aims to use this data to further refine the questionnaire. Your responses will be anonymised and treated with confidentiality based on an official agreement with the developer. Your anonymised responses will be linked to a random patient ID before being provided to Tufts Medical Centre. The data will be treated, processed and protected as personal data. It is up to you whether or not you agree to your questionnaire responses being sent to the developer, but your decision will have no effect on your rights or the standard of care you receive. If you do not want your questionnaire responses to be sent to the developer, then you have the option to opt out by leaving the box on your consent form relevant to this matter blank; your treatment and care will not be affected in any way.

Finally, we may contact you in the future to invite you to participate in follow-up studies to this project, or in future studies of a similar nature. In order to contact you, we will need to access your contact details, which we will store securely as part of this study. We may also use your contact details to check with your hospital and/or GP/oncology consultant/family doctor [*equivalent to be substituted*] your health status so that we do not disturb you if you feel too unwell to take part. Your contact details will be used with strict confidentiality. It is up to you whether or not you agree to us accessing your information and contacting you in the future, but your decision will have no effect on your rights or the standard of care you receive. If you agree to us accessing your contact details and wish to be contacted in the future, you can mark the relevant box on your consent form. If you do not agree to us accessing your contact details and do not wish to be contacted in the future, then you have the option to opt out by placing a cross in the box on your consent form relevant to this matter; your treatment and care will not be affected in any way.

What will happen to the results of the study?

The overall results of the study will be used to provide information to determine whether the use of the mobile phone system is better or worse than current care in the reporting and management of chemotherapy related symptoms during and for up to one year following treatment.

Who is organising and funding the research?

This study is being led by a team of researchers in the University of Strathclyde. It is being funded by the European Commission under the Seventh Framework Programme. Hospitals involved in this study may be provided with some funding to cover the additional costs incurred in facilitating the study.

Who has reviewed this study?

The *[insert]*, which has the responsibility for scrutinising proposals for medical research on humans in *[xxxx]* area has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in the research, together with any relevant records, be made available for scrutiny by monitors from the University of Strathclyde and NHS *[insert Health board area]*, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

[insert NHS logo here]

Contact for further information?
Should you wish any further information about the project, please contact:

Insert name of 2 local contacts here: medical and nursing

If you would like to report a problem or a complaint about this study to someone out with the research team, please contact:

Dr Katriina Whitaker

Senior Lecturer and Lead in Cancer Care

School of Health Sciences, Faculty of Health & Medical Sciences

University of Surrey

Guildford, Surrey, United Kingdom

GU2 7XH

T:+44 (0)1483 68 4622

Email : k.whitaker@surrey.ac.uk

Thank you very much for taking time to read this information sheet.

[insert NHS logo here]

Addendum to comply with updated GDPR guidelines

The University of Strathclyde is the sponsor for this study based in the United Kingdom and other countries in Europe. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Strathclyde will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the Data Protection Officer at dataprotection@strath.ac.uk.

[NHS/other site] will collect information from you and/or your medical records for this research study in accordance with our instructions.

[NHS/other site] will keep your name, hospital/identification number, gender, age, date of birth, and contact details confidential and will not pass this information to the University of Strathclyde [NHS/other site] will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from the University of Strathclyde and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The University of Strathclyde will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, hospital/identification number, gender, age, date of birth, or contact details.

[NHS/ other site] will keep identifiable information about you from this study for 5 years after the study has finished.