Pressure UlceR Programme Of ReSEarch

The Pressure Ulcer Risk Assessment Framework (PURAF) Pre-Test Study

NURSE PARTICIPANT INFORMATION SHEET

You have been invited to take part in the study detailed above. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and ask us if anything is unclear, or if you would like more information.

What is the purpose of the study?

The clinical guidelines and policies in place in the NHS focus on risk assessment as being the key to prevention of PUs but risk assessment tools have not been updated for decades. While existing tools offer some structure to PU risk assessment they were developed in the 1970-80s through expert opinion and outdated literature reviewing methods when the evidence was limited. The preliminary PURAF (Pressure Ulcer Risk Assessment Framework) was developed following a systematic review of pressure ulcer risk factors and a consensus study involving international experts in the pressure ulcer field to establish what elements need to be included in pressure ulcer risk assessment. The purpose of this study is to assess the acceptability of the preliminary PURAF amongst nurses in relation its clarity and ease of use.

Why have I been chosen?

You have been invited to participate in this study as you are a practising Registered Nurse who is involved with the planning and delivery of pressure area care.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide after reading this information sheet and asking any questions you may

have. If you wish to participate you will be asked to provide informed written consent. You will be able to retain a copy of this for your records and one will be held by the researcher. You will be free to withdraw from the study at any time including before, during or after the PURAF training, focus group or one-to-one interview, without giving a reason. Data collected from you prior to withdrawal will be used in the final study analysis.

What does the study involve?

If you agree to take part in the study, you will be required attend a 4 hour PURAF session. The session will incorporate training in the use of the PURAF which will be followed by your participation in either a focus group meeting or one-to-one interview. It will involve you travelling to the venue in Leeds and standard rate travel expenses will be reimbursed.

The training will involve 8-12 other nurses in similar roles to yourself and will involve the researcher explaining how to use the PURAF and demonstrating this with a simulated patient (an actor taking on the role of a patient). You will then be asked to practice using the PURAF with a training case study relevant to your area of practice and photographs of pressure ulcers/areas, noting any areas of confusion on the PURAF form.

Following training you will then participate in either the focus group with approximately 4-8 other nurses or a one-to-one interview with the researcher. Allocation to the focus group and one-to-one interview will be done using randomisation in advance of the session.

If you are assigned to the focus group you will be asked to complete the PURAF again using another case study before the focus group meeting; you will be encouraged to highlight any areas which you find confusing on the PURAF documentation form which will inform the discussions of the focus group meeting. This is not a test and there are no 'right or wrong' answers. At the focus group meeting you will be invited to discuss your thoughts about using the PURAF in a group setting. It is anticipated that working in a group may spark further discussion and highlight any issues you found difficult or unclear when using the PURAF. The focus group will be led by a trained facilitator and will be audio-taped.

If you are assigned to the one-to-one interview you will be asked to complete the PURAF again using another case study. The researcher will ask you to 'think out loud' as you complete the PURAF. This is not a test and there are no 'right or wrong' answers; it will

allow the researcher to get a better understanding of areas of the PURAF which nurses find confusing to complete. The interview will be audio-recorded.

The audio-tapes from the interview and the focus group will be transcribed to allow thematic analysis of the issues relating to PURAF. At the session you will also be asked to provide anonymous demographic data including: age, gender, nationality, role and sector i.e. community or acute hospital to allow the group characteristics to be described.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time and this will involve you travelling to the session.

What are the possible benefits of taking part?

You will be contributing to the development of a PURAF which could lead to more useful nurse assessment and improvements in patient care. You would also be involved in research which would help you to develop your professional portfolio in relation to being involved in research to enhance patient care. As this is dedicated research activity outside of clinical hours, the payment of £105 (subject to deductions for national insurance and tax) will be made to participants to attend the session.

Will my taking part be kept confidential?

As part of the PURAF session your identity would be apparent to other group members due to the face to face nature of the session. Focus group and individual interview responses would not be revealed by the Clinical Trials Research Unit (CTRU).

All information collected will be handled, processed, stored, and destroyed in accordance with the Data Protection Act 1998. Where personal data is provided this will be stored separately to focus group and interview data and held on the CTRU secure IT system which has restricted password protected access to only the CTRU research team working directly on the study. At the end of the study, data will be securely archived at the CTRU for a minimum of 10 years and arrangements for confidential destruction will then be made.

Who has organised and sponsored the research?

The study is being organised and coordinated by the CTRU at the University of Leeds, who is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, this study has been reviewed by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC).

What will happen to the results of the research study?

When the study is complete the results will be included in a final report and disseminated by publishing in scientific/ health related journals and through conference presentations.

Further information and contact details

If you have any questions please contact:

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What do I do now?

If you wish to participate please provide written consent.

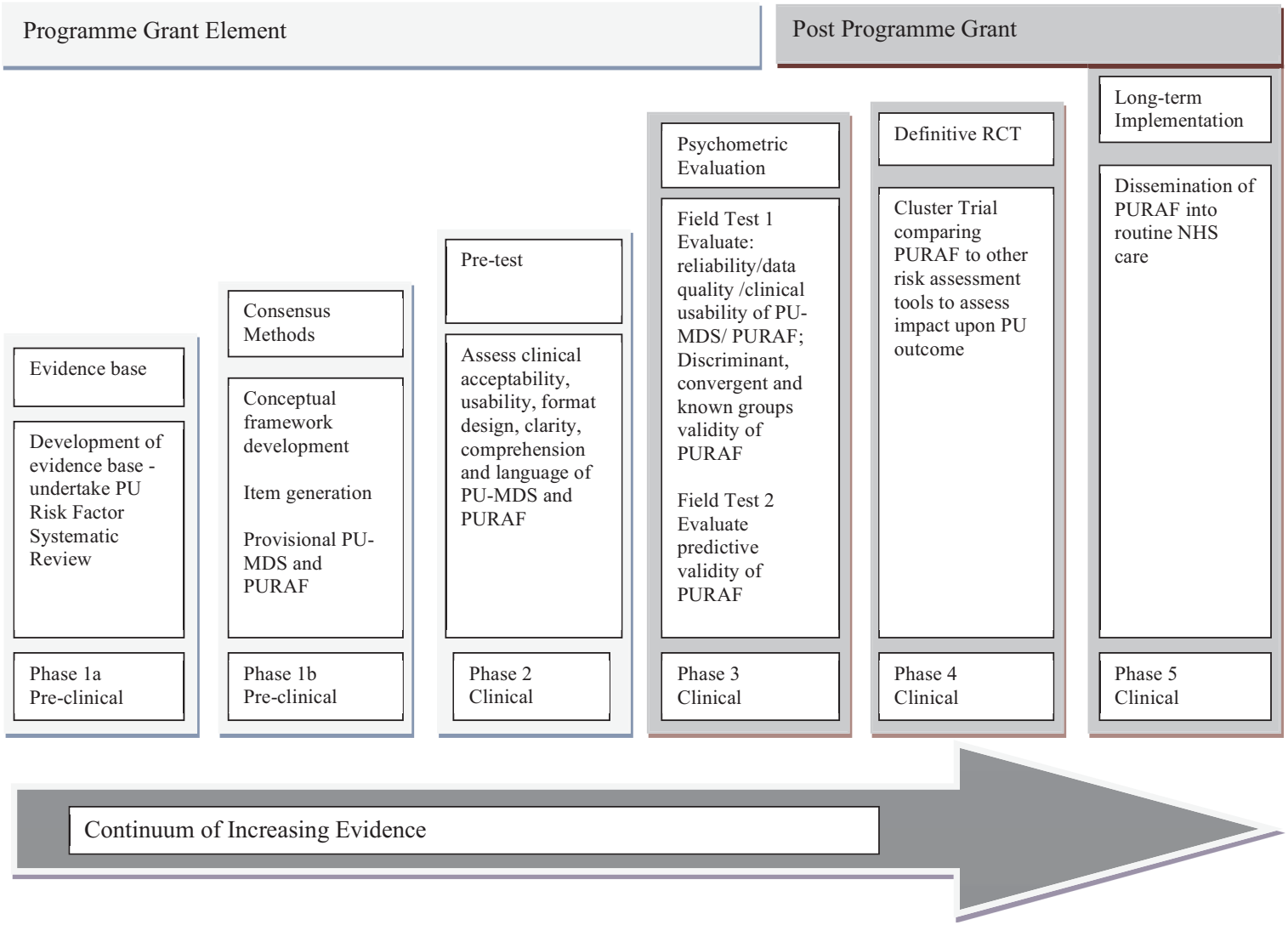

Figure 1: PhD Programme – Based on an Adapted Complex Intervention Framework (MRC 2000)

The development and evaluation of PU-MDS and PURAF has five phases. Phase 1 has involved a systematic review of epidemiological studies identifying risk factors associated with PU development (Nixon, Coleman and Gorecki et al unpublished) and a Consensus Study. The Consensus Study has utilised structured consensus methods involving an international expert nominal group and wider Delphi consultation, drawing upon the systematic review as well as wider scientific evidence, results from other PURPOSE projects (including a pain cohort study, a severe PU study and quality of life work (PU-QOL), and the experience of experts in the field to ensure face and content validity of a conceptual map and provisional PU-MDS and PURAF for use in clinical practice, by March 2012.

Phase 2, the pre-test will assess the acceptability, usability, format, design, clarity, comprehension and language of the preliminary PU-MDS and PURAF. Phase 3 will evaluate the psychometric properties of the final PU-MDS and PURAF, and comprises 2 stages: Field Test 1 will assess the reliability, data completeness, discriminant validity, convergent validity, known groups validity and clinical usability. Field Test 2 will evaluate the predictive validity of the PURAF in a prospective cohort. Phase 4 will assess the effectiveness of PURAF compared to 'standard care' in the prevention of PUs, prior to widespread NHS implementation in Phase 5.

This protocol outlines the methods for the Phase 2 Pre-test.

6 AIM AND OBJECTIVES

The aim of the pre-test is to assess the acceptability, usability, format, design, clarity, comprehension, language and data completeness of the preliminary PU-MDS and PURAF.

7 PRE-TEST METHODS

7.1 Design

Cognitive pre-testing methods will be used to indicate how clinical nurses interpret questions, response categories and instructions relating to using the preliminary PURAF (Colins 2003). The pre-test phase will incorporate PURAF training, focus groups and 'think out loud' interviews. It is anticipated that focus groups of nurses in similar roles would facilitate greater understanding of the usability of the PURAF, and would benefit from the proposed advantages of the method, allowing group members to "spark ideas off one another" which

may lead to greater disclosure (McColl 2005). However, the possible disadvantage of more vocal participants dominating discussions will be carefully counteracted by affective facilitation. Furthermore, some one-to-one think out loud interviews (Willis 2005) will also be undertaken to allow the researcher to identify specific areas where there are problems within the PURAF, which may be resolved by modification.

The Pre-test will involve nurses from a large acute Teaching Hopsital Trust, a District General Hospital and two Primary Care Trusts. We estimate that approximately 3 focus groups and 12 think out loud interviews will be needed to reach saturation (no new issues arising). As this is dedicated research activity outside of clinical hours, payment will be made to participants and this is detailed in the Participant Information Leaflet.

7.2 Eligibility of Nurses

Purposive sampling will be undertaken to ensure that Tissue Viability Nurses and Registered Nurses (Staff Nurses and Sisters) from hospital and community settings are recruited from each of the 4 participating sites. Potential participants will include those who:

- have an interest in tissue viability (for example a link nurse or member of a local PU or wound care working group)
- have commitment to attend the training session and participate in a focus group or one-to-one inteview.

7.3 Recruitment and consent

The Local Principal Investigator or a Tissue Viability Clinical Research Nurse will invite nurses to participate in the study via invitation letters and presentations to their local link nurse/pressure ulcer/wound care groups. For those who express an interest in participating in the study the Local Principle Investigator or Tissue Viability Clinical Research Nurse will explain what the study involves, provide the nurse with the written information sheet and answer any questions regarding the study. Those who fullfill the eligibility criteria and agree to take part will provide informed written consent prior to participation in the study and complete a researcher contact form to allow arrangements for the training and group session to be undertaken.

7.4 Pre-test data collection

The pre-test will comprise three sessions. Each session will comprise PURAF training, a focus group and think out loud interviews. Each session will involve 8-12 nurses from participating sites, who will be grouped by job role (Staff Nurse, Sister/Charge Nurse and TVNS/Research Nurse). The sessions will be held away from the clinical setting. Grouping the nurses in relation to their role will ensure that those participating in the focus group are similar in relation to job roles, as heterogeneous groups can lead to inhibition in raising issues that do not seem to be shared by others (McColl 2005) Furthermore, having nurses from different centres will minimise familiarity which can lead to participants relying on 'taken for granted' assumptions (McColl 2005). Each session will include training in the use of the PURAF followed by participants attending either a focus group or a one-to-one think out loud interview. Participants will be randomly allocated to either the focus group or one-to-one think out loud interview, prior to attending the PURAF session.

7.5 PURAF training

The nurses will be trained in the use of the PURAF: this will involve a short presentation and a member of the project team demonstrating how to use PURAF with a simulated patient. Each nurse will then complete the PURAF using a specific case study via vignettes that will be accompanied by photographs of pressure areas and ulcers. The vignettes will be appropriate to the nurses area of practice (i.e. community nurses will use vignettes of community patients). The vignettes will be co-developed by the project lead, the project team and members of PURSUN (Pressure Ulcer Research Service User Network) to ensure they are realistic and clinically relevant. Nurses will be encouraged to ask questions throughout the training session. It is recognised that group training may contaminate the discussions of the focus group and think out loud interviews, therefore detailed field notes of the training session will be recorded by a co-facilitator.

7.6 Focus group

The 4-8 nurses (Kitzinger 1995) assigned to the focus group will be asked to complete the PURAF again, using a vignette relevant to their area of practice prior to the focus group meeting. Nurse participants will be encouraged to highlight any areas which they find confusing on the PURAF documentation form. The co-facilitator will assess data completeness and list areas where data items have not been completed or not completed as required, as well as areas noted by the nurses as confusing.

Following this the focus group meeting will convene to discuss the use of the PURAF. The moderator will promote group interaction and guide discussions around a topic guide which will incorporate the data completeness assessment. This will consider the usability and any areas of confusion regarding the use of the PURAF. The meeting will be moderated by the researcher and a co-facilitator and will be audio-recorded.

7.7 Think out loud interviews

Up to four nurses from each session will be assigned to the one-to-one think out loud interview. Each nurse will be asked to complete the PURAF again using a vignette case study appropriate to their area of practice in the presence of the researcher. The researcher will be present to encourage the nurse to vocalise their thoughts as they complete the PURAF (see topic guide appendix 5). This will allow specific issues relating to difficulty in interpreting or confusion about aspects of the PURAF to be identified. The interview will be audio-recorded.

7.8 Data analysis

The focus group meetings and the think out loud interviews will be audio-recorded and transcribed to allow thematic analysis of issues relating to the PURAF. The emphasis will be on identifying dominant trends across the focus groups and think out loud interviews which impact on the application of the PURAF in clinical practice. Following this, adjustments in relation to the wording and the format of the PURAF may be made informing the next stages of the study. The analysis and adjustments will be made soon after each focus group and think out loud interviews, informing the PURAF used in subsequent groups in an iterative process.

Participant demographics data will be summarised using simple descriptive statistics. Data completeness of the PURAF will be assessed by missing data for data items and risk categories using simple descriptive statistics (computing the percentage of missing data for each item) and areas of confusion will be listed.

8.2 Ethical considerations

This study will recruit Registered Nurses. The related ethical issues are minimal and mainly relate to the time taken to attend the PURAF training and audio-taped focus groups or one-to-one think out loud interviews. There are no other forseen risks to participants. Informed

consent will be obtained prior to participation in the study. The right of a potential participant to refuse without giving reasons will be respected. The patient will remain free to withdraw at any time from the study without giving reasons

The study will be submitted to and approved by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC). The CTRU will provide SHREC with a copy of the final protocol, participant information sheets, consent forms and all other relevant study documentation.

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