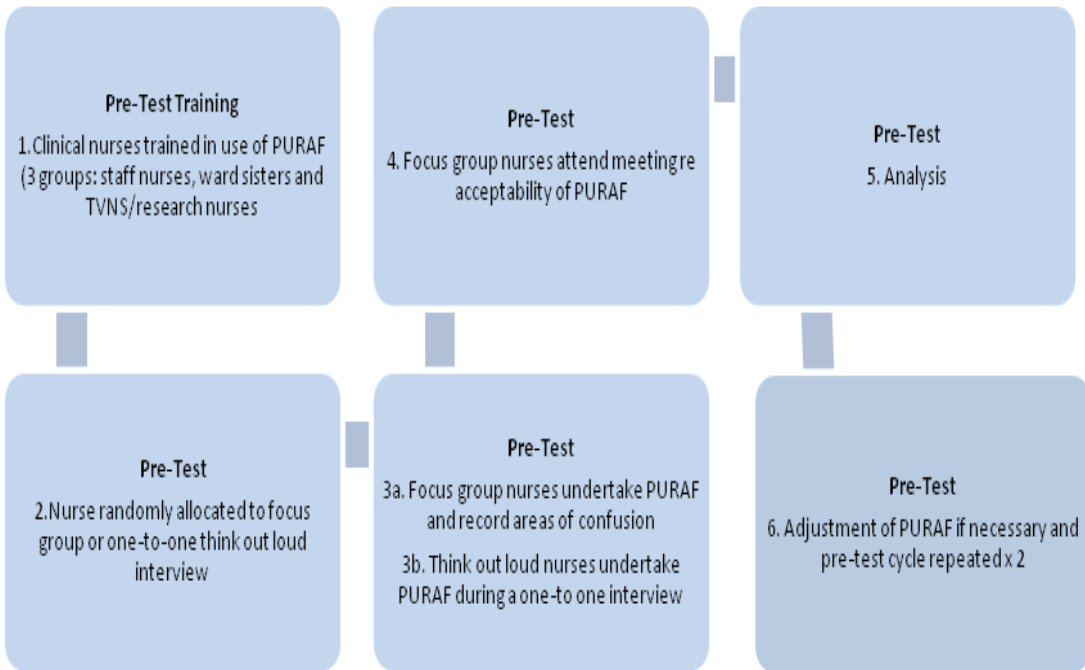
NB: This study protocol (version 1, dated 31 January 2012) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to quality assurance, confidentiality, archiving, statement of indemnity, study organisational structure, funding, and publication policy are available upon request

3 FLOW DIAGRAM PRE-TEST



5.3 PRESSURE ULCER MINIMUM DATA SET (PU-MDS) and PRESSURE ULCER RISK ASSESSMENT FRAMEWORK (PURAF)

Work to review current risk assessment practice has been taken forward as part of the Pressure UlceR Programme Of ReSEarch (PURPOSE) - a programme of research funded by the National Institute for Health Research (RP-PG-0407-10056).

We are developing a Pressure Ulcer Minimum Data Set (PU-MDS) which will be incorporated into a Pressure Ulcer Risk Assessment Framework (PURAF) to support risk assessment in clinical practice. The development stages are detailed in Figure 1.

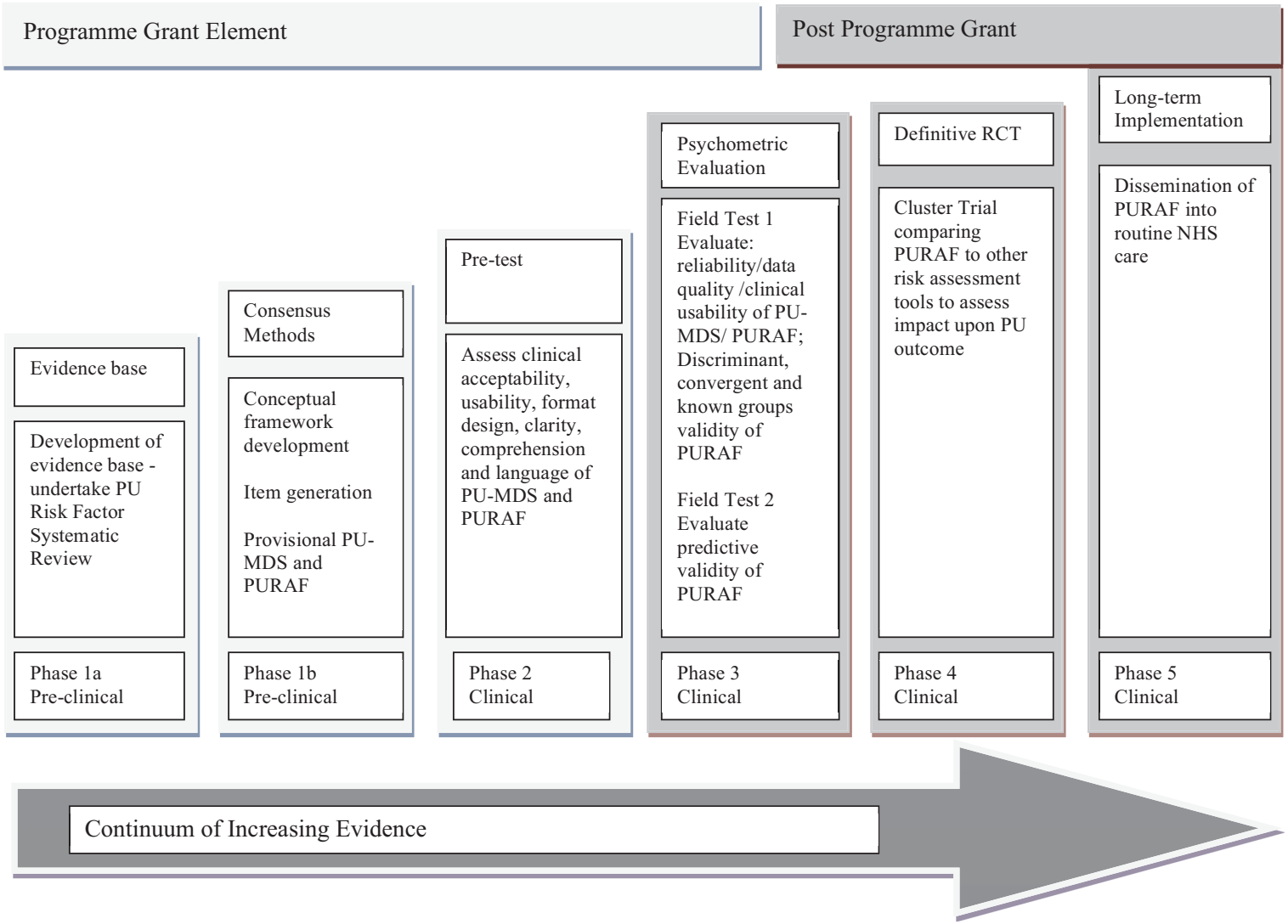


Figure 1: PhD Programme – Based on an Adapted Complex Intervention Framework (MRC 2000)

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of epidemiological studies identifying risk factors associated with PU development (Nixon, Coleman and Gorecki et al unpublished) and a Consensus Study.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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