Health
South Western Sydney
Local Health District

Participant Information Sheet – Health Professionals

Health/Social Science Research - *Adult providing own consent*

South Western Sydney Local Health District

Title	Experiences of odour in chronic wounds: A qualitative investigation from the perspectives of patients, caregivers, and clinicians
Short Title	Wound odour qualitative study
Protocol Number	*1.0*
Project Sponsor	University of Technology Sydney
Coordinating Principal Investigator/ Principal Investigator	*Yinyin Phyo / Emma Bergamin*
Location	*South Western Sydney Local Health District*

Part 1 What does my participation involve?

1 Introduction

You have been invited to take part in this research project because you are **a health care professional working with, or have previously worked with, people with a chronic malodorous wound** including, but not limited to, diabetic foot ulcers, venous leg ulcers, pressure ulcers, arterial ulcers, and malignant or cancerous wounds.

This Participant Information Sheet tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, your consent will be implied by ticking a box on the online registration form before continuing with the registration questionnaire. By doing so, you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to be involved in the research described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

2 What is the purpose of this research?

Over 450,000 Australians live with a chronic wound, causing a huge burden to the healthcare system, patients and carers. There is an annual cost of $3 billion, with each patient spending over $4000 on out-of-pocket expenses. These wounds are commonly associated with various symptoms such as pain, itching, exudate, and unpleasant odour (malodour).

Malodour from wounds have been described as a significant issue, and a highly distressing symptom impacting the wellbeing and quality of life of patients, their family, friends and carers. However it is often overlooked in research and inadequately managed in clinical practice.

There is little understanding on how wound odour affects individuals in the Australian context, as well as the unique factors that may influence their experiences, such as environmental or cultural aspects. This study aims to understand the experiences and impacts of chronic malodorous wounds, and how local factors influence care and outcomes from the perspectives of patients, caregivers, and clinicians.

The study is being initiated by Professor Meera Agar at the University of Technology Sydney (UTS). The results of this research will be used by the researcher, Ms Yinyin Phyo to obtain a Doctor of Philosophy (Health) degree at UTS.

3 What does participation in this research involve?

This is a qualitative study involving focus groups. Your participation will involve the following:

Consent:
Consent will be obtained prior to commencing any discussions and collection of data. If you decide to take part in the research project, you will be provided with a study link which directs you to a registration page on a secure web platform, Qualtrics. To proceed with the registration process, participants will be required to provide their name, contact information, acknowledge they have read this Participant Information Sheet, and provide consent for their participation. Consent will be implied by confirming and ticking a box to continue to the next page. The data and time of consent will be noted by the system.

Registration and questionnaire:
Once you have consented to the study, you will be asked to choose the preferred date and time for a focus group session. We will also ask you questions related to you, your experience and care for wounds. Completing this questionnaire and registration should take no longer than 5-10 minutes.

Focus group session:
The focus group session will be held online via Zoom, hosted by the University of Technology Sydney, on your chosen date and time. These focus groups will be held for duration of 60 minutes maximum. The focus group will be recorded (audio only) and transcribed. There is no follow up interview or sessions.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

There are no costs associated with participating in this research project, nor will you be paid. You will not be reimbursed for your time in this study.

4 Other relevant information about the research project

There are three groups involved in this study. From each group, there will be up to 10 participants recruited to the study.

The first group involve individuals with a chronic malodorous wound. The second group involve individuals that care for a person with a chronic malodorous wound. These two groups will participate via interviews.

The third group will involve health care professionals that work with, or have previously worked with, people living with a chronic malodourous wound. Members of relevant professional organisations will be invited to take part in the study via email. These participants will be involved in a focus group discussion.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given a copy of this Participant Information Sheet to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship or membership with the professional organisation you are a part of.

6 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. The study will provide valuable insights into the experiences and perspectives of wound odour and may inform future studies and contribute to evidence based clinical practice.

7 What are the possible risks and disadvantages of taking part?

This research involves minimal risks, and we do not expect this study to cause any major harms or discomfort.

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately, or withdraw from the study without any consequences.

There is also a potential inconvenience related to the time commitment required. To minimise this, focus group sessions will adhere to the planned schedule and will not exceed the allocated time. We also eliminate the need for travel by conducting these sessions virtually via Zoom.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

9 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as time constraints, low numbers of participation, data saturation, and decisions made by local regulatory/health authorities.

10 What happens when the research project ends?

There will be no follow up assessments. When the project ends, the results may be published and/or presented in a variety of forums and conferences. If you wish to know the results, we will send a general letter that tells you what we found. The results will be about the total group of people who participated in this study and not individual results.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By consenting to the study, you consent to the research team collecting and using personal information about you for the research project.

Any information obtained in connection with this research project that can identify you will remain confidential. Only members of the investigator team will have access to all study data including demographic information, recordings, and transcription documents. Relevant Human Research Ethics Committees will have access to data for any auditing purposes.

Registration data and demographic information will be stored in Qualtrics. Access to this project on Qualtrics is password-protected and can only be accessed if shared by the investigator team. The Qualtrics platform and Data Centre have several security measures and certifications in place and are independently audited using the SSAE-18 method which is an industry standard.

Field notes, recordings, and transcriptions will be securely stored electronically, in a password-protected folder with restricted access. Once the recordings are transcribed, all participant identifying information will be removed and the transcripts will be labelled with unique study codes. To further protect participant privacy, the recordings will be permanently deleted once transcription is complete. Study records will be retained for five years after publication. After this period, all study data and electronic records, including those stored in Qualtrics, will be securely disposed of.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. There will be no identifying participation information distributed. Any data collected will only be reported in aggregate form.

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the study team if you would like to access your information.

12 Compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

13 Who is organising and funding the research?

This research project is being initiated and conducted by Professor Meera Agar, and Ms Yinyin Phyo, who is currently undertaking this project as part of a Doctor of Philosophy (Health) degree.

The research is sponsored by University of Technology Sydney.

There is no personal financial benefits or money paid directly to any member of the research team. There is also no funding involved for this project.

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).
The ethical aspects of this research project have been approved by the HREC of South Western Sydney Local Health District.
This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the researcher via email yinyin.phyo@uts.edu.au or any of the following people:

Contact person(s)

Name	Emma Bergamin
Position	Research Podiatrist
Telephone	02 8738 8296
Email	emma.bergamin@health.nsw.gov.au

16. Complaints contact person

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research and Ethics Office, Locked Bag 7103, LIVERPOOL BC NSW 1871 on 02 8738 8304 / fax 02 8738 8310 / email SWSLHD-ethics@health.nsw.gov.au, website: http://www.swslhd.nsw.gov.au/ethics/default.html and quote [2025/STE00483].

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.