WESTERN SYDNEY
UNIVERSITY

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: Exploring social connections in individuals with clinically severe obesity.
Chief Investigator:
A/Prof Kate McBride
Translational Health Research Institute and School of Medicine
Western Sydney University
Sponsor: Western Syndy University
Principle/Associate Investigators:
Dr Kathryn Williams (Senior Lecturer, Nepean Clinical School)
Associate Professor Milan Piya (WSU School of Medicine and SWS MRBP)
Ghada Alsultany (PhD candidate, WSU Translational Health Research Institute)
Location: [Insert participating site]

Invitation

You are invited to participate in a research study which aims to explore experiences of social connections while living with obesity, including experiences of social isolation and loneliness in order to identify areas of service and community that may be better used to support individuals socially.

The study is being conducted by researchers from Western Sydney University (WSU), and doctors involved with the care of patients at the Nepean Blue Mountains Family Metabolic health service (FMHS) or South Western Sydney Metabolic Rehabilitation and Bariatric Program (SWS MRBP).

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?

The purpose is to explore experiences of social connections, including experiences of social isolation and loneliness, in people living with obesity in the NBM or SWS region to identify areas of service and community that may be better used to support individuals socially.

Who will be invited to enter the study?

You are invited to participate in this study because you are a current or past patient of the FMHS, SWS MRBP or a member of WIN.

Do you have a choice?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. However, it may not be possible to return your samples to you or withdraw your data from the study results if these have already had your identifying details removed.

What will happen on the study?
If you agree to participate in this study, you will be asked to provide online consent. Once you have signed the consent form, you will then be asked to participate in a one-on-one interview which will be approximately 30 minutes to 1 hour long. These interviews will be guided by a short questionnaire which contains open questions about your experiences. We will ask your permission to record the interview. These records will then be transcribed through a transcription service, where any identifying information will be removed. These de-identified transcripts will then be analysed by members of the research team.

Are there any risks?
There is a risk of distress when discussing personal experiences. If this occurs, the interview will stopped until a time you feel you may continue. If you cannot continue due to distress, the interview/focus group will be ceased. There is no penalty for withdrawing from the interview. Clinic participants will be referred back to the clinic should clinical advice be needed or to appropriate counselling services. WIN participants will be referred to the relevant health professional should clinical advice be needed (e.g. GP) or to appropriate mental health services (e.g. lifeline or beyond blue). We will also follow up with a courtesy call to check in with you and answer any questions they may have.

Are there any benefits?
This study aims to further health knowledge and may improve future treatment of obesity, however it may not directly benefit you.

Confidentiality / Privacy
Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results that will be held securely at Western Sydney University.

Will taking part in this study cost me anything, and will I be paid?
Participation in this study will not cost you anything. You will be reimbursed for your time and reasonable travel expenses with a small thank you by way of a $30 gift card.

What happens with the results?
If you give us your permission by signing the consent document, we plan to discuss/publish the results. The results may be published in peer-reviewed journals and presented at conferences. The results from this may also be used to inform future policy

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

decisions and community health strategies. The information in this project will be disclosed only to the investigators mentioned above.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

Who has approved this research?
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 Nepean Blue Mountains Local Health District. The HREC reference number for this study is 2024/ETH01101.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2024). This statement has been developed to protect the interests of people who agree to participate in human research studies. The NBMLHD HREC contact details are via the NBMLHD HREC. Phone: (02) 4734 1988 and Email: NBMLHD-Ethics@health.nsw.gov.au

Contact details
The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project, then you may contact the researcher.

Research contact person

Name	A/Prof Kate McBride
Position	Chief Investigator
Telephone	(02) 4620 3436
Email	k.mcbride@westernsydney.edu.au

Reviewing HREC and HREC executive officer details
If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name/Position	The HREC Executive Officer
Telephone	4734 1998
Email	NBMLHD-Ethics@Health.nsw.gov.au

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.

WESTERN SYDNEY
UNIVERSITY

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

CONSENT TO PARTICIPATE IN RESEARCH

Name of Researcher:

1. I understand that the researcher will conduct this study in a manner conforming to ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

2. I acknowledge that I have read, or have had read to me the Participant Information Sheet relating to this study. I acknowledge that I understand the Participant Information Sheet. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by _____ ("the researcher") and I, being over the age of 16 acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

3. I acknowledge that I have been given time to consider the information and to seek other advice.

4. I acknowledge that refusal to take part in this study will not affect the usual treatment of my condition.

5. I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

6. I acknowledge that this research has been approved by the Nepean Blue Mountains Local Health District Human Research Ethics Committee.

7. I acknowledge that I have received a copy of this form and the Participant Information Sheet, which I have signed.

8. I acknowledge that any regulatory authorities may have access to my medical records to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

9. I acknowledge that I may be contacted for future research related to this project.

10. Do you wish to receive aggregated results from this study? Yes / No

Before signing, please read 'IMPORTANT NOTE' following.
IMPORTANT NOTE:
This consent should only be signed as follows:
1. Where a participant is over the age of 16 years, then by the participant personally.

Name of participant _____ Date of Birth _____

Address of participant _____

Email/phone number of participant _____

Signature of participant _____ Date: _____

Signature of researcher _____ Date: _____

Signature of witness _____ Date: _____