Curtin University

PARTICIPANT INFORMATION STATEMENT

Improving diet quality of patients living with obesity.

Name of Investigators: Professor Deborah Kerr will lead the research.

What is the project about?

There are very few publicly available weight management services led by dietitians who are the experts in dietary advice. This leaves many Australians without access to dietitians.

The study is testing a new weight management (chat2) program led by dietitians, to support people living with overweight and obesity in building healthy habits. The aim of this study is to see if providing people with access to a dietitian through telehealth by video can help people improve the quality of their diet and generally feel better about themselves.

The study will run for one year and aims to recruit 430 people. Half the people who volunteer for the study will be given the chat2 program, and half will be asked to continue with current best care for obesity with their doctor. You will not be able to choose which group you are in as this is decided randomly, like tossing a coin. If you are asked to be part of the "chat2 dietitian program", you will be asked to attend 8 online telehealth appointments by video over 12 months to support you to change your diet. This is in addition to your visits to Curtin University at the beginning, at 6 months and 12 months (see below for more details about the study visits to Curtin). The study will also use an app on your mobile telephone to help you record your diet through taking pictures of your meals that will help the dietitian give you feedback on your diet.

Who is doing the research?

The project is being conducted by Prof Deborah Kerr as part of a Medical Research Future Fund Research in Primary Care project at Curtin University.

All volunteers in both groups, will be provided with vouchers to the value of $80 ($20 per visit) for participating in this project. Everyone who volunteers will also receive information about their diet and health once they have finished all 4 visits, completed 3 food records, and 3 surveys for the study.

Who can participate in the research?

Participating in this study is likely to be suitable for:

- People living with obesity (body mass index ≥ 30 and ≤ 45). You can check your body mass index here: https://www.healthdirect.gov.au/bmi-calculator
- Aged between 18 and 65 years and in reasonably good health.
- Access to a smartphone (iPhone 7 or above or Android)
- Able to take part in telehealth video conferencing calls.

Participating in this research is **not** suitable if:

- You are on insulin.
- You have had or plan to have surgery for weight loss.
- You are taking medications for weight loss.
- You have been diagnosed with an eating disorder.
- You are pregnant or breastfeeding.
- You are receiving counselling from a dietitian.

What will I have to do if I decide to take part?

Once you have read the information statement and the terms and conditions and agree you will be directed to an online screening survey. If you are eligible, you will be asked to provide contact details and your consent online prior to commencing.

You will be asked to do the following:

1. Complete online questionnaires on your background (including ethnicity, education, employment, postcode), height, weight, alcohol use, smoking, physical activity, eating and dietary habits, motivation, and weight loss history. It is estimated the questionnaires will take approximately 30 minutes to complete.
2. Attend Curtin University's School of Population Health on four separate occasions (2 at the beginning, then at 6 months and 12 months) to have your blood tested, height, weight and body composition measured.
3. For your first visit, you will need to attend a one-hour morning appointment at the School of Population Health, Curtin University in Bentley in building 400 room 101 – Bentley campus. You will be asked to do the following:
   a) fast overnight and undertake a blood test at the Curtin pathology clinic to test for blood fats and glucose. You will be provided with the forms to do this.
   b) you will be trained in how to record your diet using an App designed by the investigators, known as a mobile Food Record for four days.
   c) you will also undertake an assessment of your whole-body composition using dual X-ray absorptiometry (DXA, pronounced dec-sa). For all participants you must wear clothing that does not contain any metal (e.g., zips or underwire) as this will affect the results obtained in the DXA scan. A hospital gown will be available to wear. You will also be asked to remove any jewellery or piercings for the scan. We will take you through a pre-scan questionnaire that will check off these factors ahead of your scan. In total the session will take approximately 1 hour.
4. You will be asked to return approximately one week later to review your mobile food record and blood test results. You will be randomly (by chance) allocated to one of two groups: standard care (control) group or intervention group. There will be 215 people in each group (total 430 people). All participants will be asked to complete some on-line surveys about your health, activity and dietary habits and have your height and weight measured on three occasions (at the beginning at 6 and 12 months). The group receiving the CHAT2 program will receive telehealth (online) consultation sessions with a dietitian for 12 months. The Standard Care group will receive feedback on their diet when the study has finished.

Post-study Interview

A few people will be asked to take part in a longer conversation to understand how they felt about the chat2 program and how it helped or did not help. A researcher will contact you and arrange a convenient time. This part of the study is optional. If you are invited and decide to take part in this conversation, we will audio-record and transcribe the conversation.

What are the benefits to being in the research project?

Sometimes, people like having the chance to think about their health. We hope that what we find out during this research will help us to improve services available for people trying to live a healthier lifestyle.

Additionally, all participants will receive:

- Blood test results,
- Body composition scan and reports,

- Vouchers for attending,
- Use of the app to record your food intake.

Are there any risks, side-effects, discomforts or inconveniences from being in the research project?

The DXA body composition tests involve the use of low dose x-rays about equal to one thousandth of the background radiation you would receive in one full year living in Perth. This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts each year. The dose from this study is about 12.6 microsieverts, which is equivalent to about three days of background radiation exposure. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal. You will complete a DXA pre-scan safety questionnaire to assess your suitability to be involved in this project and will be excluded from participating if you do not meet these safety requirements.

As with any blood sample, there is possibility that you may develop some bruising around the area and some people occasionally faint while the sample is taken.

Some of the questions we ask in the questionnaires are personal and may raise issues for you about your mental health. If you find any of the questions distressing, you have the right to withdraw from the study at any time without penalty. If you are concerned about your mental health or are feeling distressed after completing the questionnaires, it may help to talk with someone about how you have been feeling. There are a number of different ways that you can do this, including the following telephone or online options:

1. Call Lifeline 13 11 14 (24 hour) Website: www.lifeline.org.au/.
2. Call beyondblue 1300 22 4686; Website: www.beyondblue.org.au/.
3. Call the Butterfly Foundation 1800 33 4673 for help with eating disorders; Website: https://butterfly.org.au
4. Your local general practitioner (GP) can refer you to a health practitioner.
5. If you are a Curtin staff or student, you can contact Counselling services on 9266 7850.

Measures to minimise the risks of COVID-19:
To minimise the risks of COVID-19 we will:

- Require staff undertaking the DXA scans to be vaccinated, practise physical distancing and good hygiene (e.g., handwashing before/after each participant, not working while unwell).
- Conduct frequent cleaning of touched surfaces with disinfectant solution before/after each participant (e.g., DXA bed).
- Participants will be offered a surgical mask to wear and asked not to attend when unwell.

Who will have access to my information?

Due to the ionizing radiation, the University is required to keep the data 50 years after the date of publication or completion of project whichever is later. It is a legal requirement (Radiation Safety Act, Section 36: point 2.4) that “records are maintained of the patients examined on the apparatus including their name, age, the type of examination, the date of the examination and the name of the referring medical practitioner and these records shall be available for inspection by officers of the (Radiological) Council.” The Curtin University license has been endorsed to permit densitometry scans for research subjects without medical referral. Therefore, a register of participants scanned will include the study they are participating in instead of the referring Doctor’s name, but a register will be maintained for the Radiological Council. If this arrangement doesn’t suit you, you will be unable to participate in the study.

All the information we collect will be stored securely in the School of Population Health at Curtin University. Only the research team will have access to the data. Any information we collect and use during this research will be treated as confidential. The information collected in this study will be re-identifiable. Your data will have identifiers (e.g., name) removed and replaced by a code. Electronic data will be password-protected on a secure online server and hard copy data will be kept in locked storage. The information we collect in this study will be kept under secure conditions at Curtin University. People will have the right to access, and request correction of information in accordance with relevant privacy laws. People may request access to the research findings by emailing the investigator on d.kerr@curtin.edu.au. The results of this research may be presented at conferences or published in professional journals. People will not be identified in any results that are published or presented.

Will you tell me the results of the research?

At the end of the research, we will let you know your final results by email. This will include a research summary based on all the information we collect and review as part of the research.

Do I have to take part in the research project?

Taking part in this research project is voluntary. It is your choice to take part or not. You do not have to agree if you don't want to. If you do decide to take part and then change your mind, that is okay, you can withdraw from the project at any time by contacting us by telephone or by email. You do not have to give us a reason; just tell us that you want to stop. If you choose to leave the study, we will use any information that is collected unless you tell us not to. Please let us know you want to stop so we can make sure you are aware of any thing that needs to be done so you can withdraw safely.

What happens next and who can I contact about the research?

If you decide to take part in this research, we will ask you to complete the on-line consent form in the questionnaire that pops up when you click "join" on the website. After the information part at the start of the questionnaire (available via the link provided), at the bottom of the consent form there is a checkbox to indicate you have understood the information provided here in the information sheet. By clicking the checkbox, you are telling us that you understand what you have read, that you agree to be in the research project and have your health information used as described.

Please take your time and ask any questions you may have before you decide what to do. We can give you a copy of this information and the consent form to keep.

Ethics approval

Curtin University Human Research Ethics Committee (HREC) (HRE2022-0059) and the Department of Health WA Human Research Ethics Committee (PRN: RGS0000005490) have approved this study. Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au or the Department of Health WA Human Research Ethics Committee (HREC) by conducting the Ethics Officer on (08) 9222 6874.

Who do I contact about the study?

If you have any questions, you can contact the research team leader Prof. Deborah Kerr on 9266 4122 or d.kerr@curtin.edu.au. Your contribution will be greatly appreciated.

Curtin University

CONSENT FORM

I have read the Participant Information Sheet and have had the details and purpose of the study explained to me.

My questions have been answered to my satisfaction, and I understand that I may ask further questions at any time.

- I understand the reason for the research, what I will need to do, and any possible risks of my involvement.
- I have decided to take part in this research project voluntarily.
- My name will not be used and the information I provide will be used only for this study and publications arising from it.
- I have the right to request a copy of this information.
- I understand that this project has been approved by Curtin University Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research 2007 (updated 2018).
- I understand I will receive a copy of this Information Statement and Consent Form.

[online consent]

If you decide to take part in this research, you will be asked if you consent to participating in this study and start answering the survey. By checking this box and completing the survey it is telling us that you understand what you have read. The survey will take about 5 minutes to complete.