Participant Information and Consent Form

Study Title: *Norwegian Mental Illness Heart Health Study (NORMI-Heart)*
Official Title: *Dietary Counselling and Exercise to Combat Cardiovascular Disease Risk in Norwegian Patients With a Severe Mental Illness*
NCT Number: NCTXXXXXXX
Document Date: 4 June 2025
Principal Investigator: Professor Kjetil Retterstøl
Study administrator: Madeleine E Angelsen
Study Location:
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UNIVERSITY OF OSLO

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CAN A HEALTHY LIFESTYLE REDUCE CARDIOVASCULAR RISK IN PEOPLE WITH SEVERE MENTAL ILLNESS?

PURPOSE OF THE STUDY AND WHY YOU ARE INVITED

You are invited to participate in this research study because you are currently receiving treatment for a severe mental illness. Research shows that individuals with severe mental illness have a higher risk of cardiovascular disease, partly due to lifestyle factors and side effects of medications. The purpose of this study is to investigate whether a structured lifestyle program including dietary counseling and physical activity can improve health outcomes in this population.

WHAT DOES PARTICIPATION INVOLVE?

Participation includes an initial health and lifestyle assessment, after which you will be randomly assigned to either an intervention group receiving lifestyle support or a control group receiving treatment as usual for the first six months. After this period, the control group will also be offered the same lifestyle program, ensuring that all participants receive equal access to health-promoting support.

Participation involves:

1. Initial health assessment:

At baseline, your weight, height, waist circumference, blood pressure, body composition (via BIA), and physical activity (using an accelerometer) will be measured. Blood samples will be taken. You will complete questionnaires about your diet, physical activity, and mental health. Relevant information will be collected from your medical records or healthcare provider, including diagnosis, medications, previous weight and medical history, and family history of cardiovascular disease. These assessments will be repeated at 3 months and after the intervention period.

After initial assessment, you are randomly assigned to either group A (intervention) or the group B (control)

2A) Intervention Group:

If assigned to the intervention group, you will participate in a six-month lifestyle program in addition to your usual treatment. The goal is to support you in eating healthier, being more active, and losing weight if desired. You will meet with a clinical dietitian once a month (six sessions total) for dietary counseling and follow-up. At each session, weight, blood pressure, waist circumference, and body composition will be measured. You will keep a food diary during parts of the program.

You will receive a physical activity plan to follow twice a week and will meet with a fitness instructor twice during the six-month period. One group training session per month (six total) will also be offered. The program will be tailored to your needs, and support will be provided to help you get started. At three months (midway), the same assessments as at baseline will be repeated.

2B) Control Group:

If assigned to the control group, you will continue your usual treatment for six months. You will be asked to attend follow-up assessments at 3 and 6 months. After this period, you will be offered the same lifestyle program as the intervention group, without further measurements during that phase.

3. Final health assessment:

All measurements from baseline will be repeated at six months to evaluate any changes.

By participating, you consent that your healthcare provider at Oslo University Hospital / Lovisenberg Diaconal Hospital / Diakonhjemmet Hospital (correct institution selected) or your general practitioner may be contacted if any unexpected severe mental or physical reactions occur during the study period, even though such reactions are not expected.

POTENTIAL BENEFITS AND RISKS

Participation may increase your awareness of your own health and lifestyle and give access to personalized support from qualified professionals. All participants will be offered the lifestyle program, either immediately or after six months. However, no guarantee of health improvement can be given. Lifestyle changes require personal effort, and it may be challenging to maintain physical activity or dietary changes. Blood sampling may cause mild and brief discomfort. You will also be asked to complete questionnaires on mental health and discuss lifestyle topics, which some may find sensitive or emotionally difficult. If participation raises any issues for you, your project contact can refer this to your healthcare provider for follow-up.

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

Participation is voluntary. If you choose to participate, you will sign the consent form on the last page. You may withdraw your consent at any time without giving any reason. This will not affect your treatment. If you withdraw, your data and biological samples will no longer be used in the study. You can request access to your data within 30 days and request that they be deleted, and that biological samples be destroyed. This right does not apply if your data has been anonymized or published, or if it has been incorporated into completed analyses or biological products.

WHAT HAPPENS TO YOUR DATA?

The data collected about you will only be used for the purposes described in this document and will be used until 2030 to ensure that key findings are analyzed and shared with relevant health authorities and academic institutions. Any extension of storage or use will require further approval by the Regional Ethics Committee and other relevant authorities. You have the right to access the information stored about you, request correction of any errors, and gain insight into the security measures used in processing your data. You may also file a complaint with the Norwegian Data Protection Authority or the institutional data protection officer.

All information will be stored without name or personal ID number (= pseudonymized data). A code will link your identity to your data. Only the project leader and relevant staff have access to this key. All personnel are bound by confidentiality.

After the study ends, data will be stored for five years for audit purposes. If stored elsewhere than the responsible institution, this will be specified.

LEGAL BASIS FOR DATA PROCESSING

We process your data for scientific research purposes, and because the study is considered to be in the public interest. On behalf of the University of Oslo, the Data Protection Services at Sikt – the Norwegian Agency for Shared Services in Education and Research – have reviewed the study and determined that the data processing is in accordance with applicable privacy regulations.

YOUR RIGHTS

As long as you can be identified in the research data, you have the right to object, access, correct, and delete your data. You will receive a response within one month. If we believe you cannot be identified or the rights cannot be exercised, you will receive a justification. You also have the right to complain to the Data Protection Authority.

RESPONSIBLE PARTIES

The study is conducted by the University of Oslo (UiO) in collaboration with the Norwegian School of Sport Sciences, Diakonhjemmet Hospital, Oslo University Hospital, and Lovisenberg Diaconal Hospital. Professor Kjetil Retterstøl is the principal investigator at UiO, and PhD candidate Madeleine Angelsen is responsible for

conducting the study and communicating with participants. Your current treatment provider remains responsible for your regular care during the study period.

APPROVALS

The study was approved by the Regional Committee for Medical and Health Research Ethics on 04.06.2025, ref. no. 865976. UiO, represented by Professor Kjetil Retterstøl and PhD candidate Madeleine Angelsen, is responsible for ensuring data protection in this project.

CONTACT INFORMATION

If you have questions about the project, please contact:

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If you have questions about privacy or wish to file a complaint, contact the UiO Data Protection Officer at: **personvernombud@uio.no**

I CONSENT TO PARTICIPATE IN THE PROJECT AND THAT MY PERSONAL DATA AND BIOLOGICAL MATERIAL IS UTILIZED AS DESCRIBED

Place and date	Participants signature
	Participants name in block letters

I confirm to have provided information about the project

Place and date	Signature
	Role in the project