UiO : Faculty of Medicine
University of Oslo

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Invitation to participate in the research project

"Nutrition and Medication" part II, (Øvre Eiker)

This is an invitation were we ask if you may be willing to be a participant in a research project concerning nutritional status and medication use among elderly persons receiving home nurse services.
Many older adults are unable to eat adequately and are at risk of developing malnutrition. Adverse medication effects, as reduced appetite, nausea or dry mouth can contribute to malnutrition. The aim of the project is to investigate if an individual tailored nutritional plan and medication review can contribute to a better nutritional status, increased quality of life and functioning in daily living activity, and if these interventions can reduce the need for admissions to hospital and nursing home. The study is a part of a Ph.D.-project, and the implementation in collaboration with the Health and Care Services in your home municipality.

What does participation in the project imply for you?
If you accept to participate, a qualified nurse from the Home Nurse Service will visit you at home four times during a period of six months. In the first visit, the Ph.D. – candidate, and nursing home physician Mari Fiske, will participate. In this first visit, we will ask questions about your life situation, health, medication use, nutritional habits, activity of daily living and quality of life. You will got a clinical examination and a time for blood tests. We will recommend that your next to kin can participate in this meeting.

When we make a medication review, we will need some more information about your diseases and we will ask for permission to contact your General Practitioner. From your physician we also want information about eventually hospital admissions during the last six months and in the project period. If relevant, we will ask the Health and Care Service in your municipality about admission to short- time ward in a nursing home in the same period.

During the medication review, we will investigate if you use drugs considered to be inappropriate or potentially harmful in particular with respect to their possible ability to

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impair your nutritional status. This will be undertaken cooperation with your General Practitioner who will hold the final decision to recommend and implement any changes in your medication list. Based on our findings and what you have told us, we will propose measures which may improve your nutritional situation. Together with you, and possibly with a close relative of yours, we will design a tailored nutrition plan for you.

Possible benefits and risks by participation

We assume that the measures in this project will be of benefit to you. We will follow the Norwegian guideline for prevention and treatment of malnutrition, and recommendations for medication reviews. Participating in this project does not imply any risks for you, but we will use your time, approximately 60 minutes for the first visit, and 15-30 minutes for each of the following visits. If symptoms or findings will be disclosed which should be assessed by your general practitioner, we will with your permission, contact your General Practitioner for an appointment for following up.

Voluntary participation and the possibility to withdraw consent

Participation in the project is voluntary. If you want to participate, you will need to sign the declaration of consent (last page in this letter). At any given time and without need for giving reasons, you are free to withdraw your consent. This will not have any consequences for future provision of health care. If you decide to withdraw participation in the project, you are also free to demand that your data file in in this project can be deleted, unless if your anonymized data have already been analysed or used in scientific publications.

If you at a later point, wish to withdraw your consent or have any questions regarding the project, you can contact Ph.D. -candidate and nursing home physician Mari Fiske, University of Oslo, mari.fiske@medisin.uio.no, telephone 926 67 311.

What will happen to your personal data concerning health?

Any personal data concerning health that has been recorded about you, will only be used as described in the purpose of the project. You have the right to access the information that we have recorded for you and also to control that any error(s) in the recorded data is/ are corrected. You also have the right to know which security measures that have been/will be taken when personal data concerning health is processed.

All information will be processed and used without names or personal identification numbers, or any other information that may identify the participants as persons. Linkage between you and your health data, will only be possible via a separate identifier list. Only the researchers, professors Jørund Straand, Anne Moen and Ph. D. - candidate and nursing home physician Mari Fiske will have access to that list.

Funding

The project is funded by The Norwegian Research Fund for General Practice and the County Governor in Buskerud, Norway.

Approval

The Regional Committee for Medical and Health Research Ethics has reviewed and approved the Research Project. Reference number 2018/1045.
In accordance with the General Data Protection Regulation, the University of Oslo and the project manager, Professor Jørund Straand, is independently responsible for ensuring that the processing of your personal health data has a legal foundation. This project has a legal foundation in accordance with the EUs General Data Protection Regulation, article 6 no. 1a, Article 9 no. 2a and with your consent. You have the right to submit a complaint on the processing of personal health data to the Norwegian Data Inspectorate.

Contact information

If you have any questions regarding the research project, you can get in touch with
Mari Fiske, University of Oslo, Email: telephone: 926 67 311
Jørund Straand, University of Oslo, Email: jorund.staand@medisin.uio.no, telephone: 928 52 523
Anne Moen, University of Oslo, Email: anne.moen@medisin.uio.no

I consent to participating in the research project and that my personal data concerning health can be used as described above

City/Town and date	Participant's Signature
	Participant's Name (in BLOCK LETTERS)

I confirm that I have given information about the research project

City/Town and date	Signature

Role in the research project