UiO : Faculty of Medicine
University of Oslo

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Clinical Trial unique protocol ID 2017/12883-2

Invitation to participate in a research project

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

This is an invitation where we ask if you may be willing consent that your next of kin can be a participant in a research project concerning undernutrition 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 this 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 this intervention 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 the municipality.

**What does participation in the project imply?**
If you accept participation, a nurse from the Home Nursing Service will visit your next of kin 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 visits, we will ask questions about life situation, health, medication use, nutritional habits, activity of daily living and quality of life. At the first visit, the participant will got a clinical examination and a time for blood tests. As next of kin to the participant, we will recommend you to participate in this meeting.

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

During medication review, we will investigate use of drugs considered inappropriate or potentially harmful in particular with respect to their possible ability to impair nutritional status. This will be undertaken cooperation with the General Practitioner, who will hold the decision to implement any changes in the medication list. Based on our findings, and what the participant and you told us, we will propose measures, which may improve the

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nutritional situation. Together with the participant and you, as a next of kin, we will design a tailored nutrition plan.

**Possible benefits and risks by participation**

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

**Voluntary participation and the possibility to withdraw consent**

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

If you at a later point, wish to withdraw the consent or have 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 recorded data concerning health?**

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

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 the participant and the 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 this list.

**Finance**

The project is fund 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 to ensure that the processing of your personal data concerning health has a legal basis. This project has legal basis in accordance with the EUs General Data Protection Regulation, article 6 no. 1a, Article 9 no. 2a and your consent. You have the right to submit a complaint on the processing of personal health data concerning health 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: mari.fiske@medisin.uio.no, 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

**Consent to participating in the research project and that personal data concerning health can be used as described above**

As next of kin for _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ (Full name) I hereby consent to that he/she can participate in the research project.

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|---|---|
| Town / City and date | Next of kin signature |
| | Next of kin name (IN BLOCK LETTERS) |

I confirm that I have given information about the research project

| | |
|---|---|
| Town/City and date | Signature |
| | Role in the research project |