Executive summary

Health Council of the Netherlands. Population Screening Act: the Maastricht Study. The Hague: Health Council of the Netherlands, 2013; publication no. 2013/10.

In this advisory report, the Committee on Population Screening discusses the assessment of an application for authorisation within the context of the Population Screening Act (WBO) by research institute CARIM, Maastricht UMC+ for the Maastricht Study. On 3 April 2012, the Minister of Health, Welfare and Sport asked the Health Council to advise on this issue. Based on additional questions from the Committee regarding the application, the applicant updated the application and final modifications were received on 3 April 2013. The Committee bases its recommendations on the updated application.

Background, population screening and authorisation requirements

The Maastricht Study is an observational study in which (1) healthy men and women between the ages of 40 and 75 years are invited to participate in population screening for risk factors and conditions that may indicate type two diabetes (diabetes-II). Participants receive modest compensation and (2) tailored health recommendations (unless they do not want this). A number of sub-studies (3) use ionising radiation and/or entail a real risk of discovering tumours and untreatable and/or unpreventable conditions or risk factors, such as vascular anomalies in the brain. This combination of factors means the Maastricht Study requires authorisation for population screening under the WBO.

The Maastricht Study started in 2010, but did not include the sub-studies in question at the time. At the time, the study was considered population screening

under the WBO, but did not require authorisation. With the additional sub-studies, the Maastricht Study requires authorisation and the application must be assessed based on the legal criteria.

Assessment based on legal criteria

The Committee previously concluded that the scientific integrity of population screening not primarily focused on identifying conditions or risk factors must be assessed in the broadest sense. After all, the focus is not on the efficacy of (future) population screening. The Committee chose to follow this approach for the application for authorisation for the new sub-studies in the Maastricht Study. The Committee considers the questions under investigation to be sufficiently well substantiated and the sample size large enough to allow testing with sufficient statistical power. Furthermore, the Committee is particularly interested in the risk-benefit ratio and the treatment of participants.

Individual usefulness is limited

It is important for candidate participants to understand that the study is primarily focused on advancing scientific knowledge, and not on improving the health of participants. Participants may also consider scientific importance relevant when deciding whether to participate or not, but the risks of participation must be acceptable. The risks may be limited by ensuring that the study design and sub-studies are no more intensive than required in order to answer the study questions. The Committee is of the opinion that while the Maastricht Study has an extremely wide scope, the applicant provides an adequate explanation of the purpose, of what is expected from participants and of the potential consequences (discomfort and risks) of the study.

The right to know and the right to not know

There are a large number of sub-studies, so more or less (clinically) relevant (intended and incidental) findings will be observed in a relatively large number of participants. Participants may choose not to take part in certain sub-studies. Participants are informed of intended findings relevant to their health, unless they choose not to be. They decide which incidental findings they will be informed of: (1) anything that may be important to their health, or (2) only matters for which treatment or prevention is available, or (3) none of the above. The distinction between intended findings and incidental findings is not always

clear to participants; after all, they have no indication for the tests performed and therefore do not expect any findings. During the first visit, a study doctor discusses the options and the potential implications of each choice with the participant. For options one and two, the participant must realise that the GP will be informed of the findings unless the participant objects. The Committee recommends that the study doctor point out that, for the first option, findings without direct treatment or prevention options cannot be ruled out.

The Dutch Medical Treatment Act (WGBO) states the following about the right to not know:

> If the patient has made it clear he does not wish to receive information, this information will not be shared, except insofar as the interests the patient has do not outweigh the potential disadvantages for himself or others

The law leaves room for the care provider to choose to ignore the right to not know in the interests of the patient. But only if it may reasonably be assumed, after careful consideration, that the patient's (or a third party's) interest in knowing outweigh the interest in not knowing. In order to support the care provider in this decision, the Maastricht Study provides for a multidisciplinary Clinical Medical Ethics Decision Team, including at least a medical ethicist.

Declaration of informed consent

After the conversation during the first visit, the choices are recorded in the informed consent declaration, which is signed by the participant and the study doctor.

Compensation and health recommendations

Participants are not excessively encouraged to take part. They receive acceptable reimbursement of expenses from the applicant, along with a so-called 'personalised health recommendation'. This health recommendation means that the study doctor discusses the health findings important to health and, if necessary, provides lifestyle recommendations. Should the results necessitate further care, the study doctor will facilitate the necessary referrals (at the latest within 6 weeks of the result). The Committee considers this procedure to be acceptable, but this task could be fulfilled equally well by the GP.

Conclusion

The Maastricht Study can contribute to the scientific knowledge of diabetes-II that is impossible or almost impossible to obtain in another way. The study meets the requirements of the WBO. The Committee recommends that the Minister of Health, Welfare and Sport authorise the study for duration of five years.