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## Executive summary

Health Council of the Netherlands. Population Screening Act: accelerated repeat screening for bowel cancer. The Hague: Health Council of the Netherlands, 2012; publication no. 2012/01

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The Minister of Health, Welfare and Sport has recently decided to implement a national bowel cancer screening programme starting in 2013. This screening programme involves offering an immunochemical faecal occult blood test (iFOBT) to people aged between 55 and 75 years every two years.

This advice concerns a scientific study that aims to clarify the optimum screening interval. The question is whether repeat iFOBT screening at short intervals for a limited number of times yields equally good results as iFOBT screening every two years for twenty years. In order to study this hypothesis, the Elkerliek Hospital in Helmond and the Comprehensive Cancer Centre South (IKZ) in Eindhoven have submitted a licence application in accordance with the Population Screening Act (WBO). The Population Screening Committee of the Health Council has tested the study described in the licence application against the WBO, as requested by the Minister.

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### The proposed study

The project aims to provide more clarity about the acceptance and yield of repeat iFOBT screening at short intervals (three sets of two tests within one year). The project will also provide information about the implementation of a screening programme in a non-academic setting, about the participation rate of people with a lower socio-economic status (SES) and about the impact of participation in the

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screening programme on the quality of life. The inclusion and screening of participants for the proposed study will take 18 months.

A random group of 5,500 people aged between 55 and 75 years will be selected for the screening trial based on information from the municipal records in Helmond. The investigators will determine the uptake and yield after each round, in order to determine the total participation rate and yield over the three rounds. In three rounds, the investigators expect to detect 95 percent of the bowel cancers and 80 percent of the advanced adenomas that would have been detected by primary colonoscopy – the screening method with the greatest yield.

The investigators will compare the screening results to those of a control group. This control cohort consists of 10,000 German men and women – just across the border with the Netherlands – who participated in the German screening colonoscopy programme.

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### **Testing of the legal criteria**

The Committee has ruled that the proposal meets the legal requirements of ‘scientific validity’ and ‘the interests of public health’. They also deem the principle of the benefit and usefulness of the screening trial weighing favourably against the risks to participants to have been met and that the requirement of ‘agreement with legal stipulations for medical actions’ has been met. In view of the testing of requirements of great meticulousness (proportionality, subsidiarity, the study must deliver new insights), the committee deems it acceptable that the intended project is performed on the basis of pre-randomisation. The Committee agrees with the investigators that this is the only way to obtain a reliable answer to the primary study question.

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### **Conclusion and advice**

According to the Committee, the project described in the licence application meets the legal requirements of the WBO. The Committee advises the minister to grant a licence for the execution of this study.