Experimental population-based platform to evaluate and monitor the effectiveness of screening colonoscopy: a population-based comparative effectiveness study—summary of co-studies.

1 The sensitivity of the screening episode and screening program for detection of CRC expected to become clinically detectable within 2 years (or 5 years)

The aim of the study is to determine the program and episode sensitivity to detect preclinical cancers that are supposed to be clinically detectable within 2 and 5 years. Individuals aged 55–64 years living in the 68 poviat areas covered by the PCSP in 2012–2014 are eligible for the study. Eligible individuals are drawn from the Population Registry (PESEL Registry) and assigned in a 1:1 ratio to the group invited to screening colonoscopy in the year of draw (screening group) or in 5 years time (control group for this study). The follow-up will be calculated from the date of randomization to the date of CRC diagnosis, death, or the end of follow-up (2 and 5 years from randomization, respectively). The information on 2 years’ (and 5-years) cumulative CRC incidence will be extracted from National Cancer Registries and PESEL Registry by personal linkage. The episode and program sensitivity will be calculated using an incidence-based method [10].

2 The incidence of advanced CRC in the screening and control group within 2 years (or 5 years) from the date of draw

The aim of the study is to determine the incidence of advanced CRC in the screening and control group within 2 and 5 years. Advanced CRC is defined as TNM stage III or IV. Individuals aged 55–64 years living in the 68 poviat areas covered by the PCSP in 2012–2014 are eligible for the study. Eligible individuals are drawn from the PESEL Registry and assigned in a 1:1 ratio to the group invited to screening colonoscopy in the year of draw (screening group) or in 5 years time (control group for this study). The follow-up will be calculated from the date of randomization to the date of CRC diagnosis, death, or the end of follow-up (2 and 5 years from randomization, respectively). The information on 2 years’ (and 5-years) cumulative incidence of advanced CRC will be extracted from National Cancer Registry, hospital records, and the PESEL Registry by personal linkage.

3 A 30-day mortality rate and 30-day hospitalization rate in the screening and control group

The aim of this study is to compare mortality and unplanned hospitalization rate 6 weeks before and 30 days after the date of actual or virtual colonoscopy in the screening and control groups of the PCSP. Individuals aged 55–64 years living in the 34 poviat areas covered by the PCSP in 2015 and randomly assigned to the immediate screening group are eligible for the study. Eligible individuals will be randomly assigned in a 1:1 ratio to the group invited to screening colonoscopy with ANL plus standard invitation vs. those invited by standard invitation only. The primary outcome measure is participation rate in screening colonoscopy, defined as percentage of invitees who undergo screening colonoscopy within 3 months from the time of invitation.

4 The cost-effectiveness of the screening colonoscopy program

The cost-effectiveness of colonoscopy screening vs. no screening will be estimated using a Markov model. The actual data on costs and baseline colonoscopy findings from the PCSP will be used.

5 Participation in screening colonoscopy in response to an advanced notification letter plus standard invitation vs. standard invitation only—a population-based RCT

The primary aim is to evaluate the effect of an ANL on participation in primary screening colonoscopy. The secondary aim is to assess the cost effectiveness of ANLs in a colonoscopy screening program. All individuals aged 55–64 years living in the poviat areas covered by the PCSP in 2015 and randomly assigned to the immediate screening group are eligible for the study. Eligible individuals will be randomly assigned in a 1:1 ratio to the group invited to screening colonoscopy with ANL plus standard invitation vs. those invited by standard invitation only. The primary outcome measure is participation rate in screening colonoscopy, defined as percentage of invitees who undergo screening colonoscopy within 3 months from the time of invitation.
Routine video recording of the colonoscopy examination has been proposed as a simple and easy-to-implement method that could possibly improve the quality of colonoscopy. This study aims to investigate the effect of routine video recording on adenoma detection rate, cecal intubation rate, and screenee pain scores. Screening centers participating in the PCSP that contribute at least 500 screening colonoscopies annually and do not video record them routinely are eligible for the study. The study has three phases: 1) pre-intervention phase in which colonoscopy quality parameters will be extracted from the PCSP database; 2) randomization phase in which eight screening centers (clusters) will be randomly assigned in a 1:1 ratio to the routine video recording group or to the no routine video recording group; and 3) intervention phase in which centers will start interventions, and colonoscopy quality parameters will again be extracted from the PCSP database. The primary outcome measure is adenoma detection rate, defined as the proportion of screened individuals in whom at least one adenoma or cancer is identified. Secondary end points are reported and audited cecal intubation rates, and rates of painful colonoscopies.