Objectives Screening for cancer intends to provide benefit and it unintentionally entails risk of causing harm. The type of harm most commonly studied is the risk of complications, i.e. physical harms. The risk of physical harm due to colorectal cancer screening has been quantified in systematic reviews. However, the harms of screening tend to be underreported and inadequately studied compared to the benefits of screening. In addition, the recently published PRISMA-harms extension raise concern that systematic reviews compound simplistic definitions, inadequate measurements and poor reporting in clinical studies of the harms of medical interventions. Due to these concerns, this systematic review aims to quantify the risk of physical harms due to colorectal cancer screening, to assess the quality of the evidence and to investigate the usability of guidance in the area, including the recommendations in the PRISMA-harms extension, the GRADE approach and the ROBINS-I bias assessment tool by the Cochrane Collaboration.

Method A detailed account of the methods is available in the PROSPERO protocol (CRD42017058844). The review was conducted in line with the PRISMA harms extension and the Cochrane Handbook. Databases searched include Pubmed, Medline, Embase, Cinahl, PsycInfo and the Cochrane library. There were no restrictions concerning study design, language or date of publication. All types of studies were included if they provided data on physical harms due to screening of asymptomatic individuals in average risk of colorectal cancer by any combination of fecal occult blood testing, sigmoidoscopy and/or colonoscopy. The risk of bias was assessed per outcome via ROBINS-I, a bias assessment tool for non-randomized studies. Prior to bias assessment, the tool was extended and adjusted to increase its applicability for studies reporting harms of screening. The overall quality of the evidence was evaluated using the GRADE criteria and the reporting quality of randomized controlled trials (RCTs) was judged via the CONSORT-harms extension.

Results Analyses are ongoing. Results will be presented at the conference. Preliminary trends: In total, 89 studies were included for review, 20 RCTs and 69 non-randomized studies (NRS) of various design. The majority of studies were conducted in Europe, the United States and in Asia. Both conduct and reporting of physical harms was very heterogeneous across RCTs and NRS. Overall, the risk of physical harms seems to be underreported, narrowly defined and inadequately measured in both RCTs and NRS. There is a trend towards higher estimates of harm in well-conducted studies (low risk of bias) and in studies of ongoing colorectal cancer screening programmes compared to RCTs.

Conclusions Pending analyses, the conclusions will be presented at the conference.

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