Title page

Title: Improving cancer preventive behaviors: a randomized trial of tailored lifestyle feedback in colorectal cancer screening

Running title: Improving preventive behavior in colorectal cancer screening

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Abstract:

Background: Cancer screening provides an opportunity to increase awareness of cancer preventive lifestyle behaviors such as non-smoking, physical activity, low alcohol consumption and a healthy diet. We tested the effect of standardized, individually-tailored written feedback and a standard leaflet on one-year lifestyle behaviors in a colorectal cancer (CRC) screening setting.

Methods: Three-thousand-six-hundred-and-forty-two men and women aged 50-74 years invited to sigmoidoscopy screening were randomly assigned to; i) standardized, individually-tailored written feedback (TF); ii) standard leaflet (SL) for cancer preventive lifestyle behaviors; or iii) control. Participants were mailed two self-reported lifestyle questionnaire (LSQ) one year apart. The TF intervention was based on the prescreening LSQ answers. We analyzed differences (with 95% confidence intervals (CI)) by comparing prescreening to one-year follow-up of single cancer preventive factors and the number of cancer preventive lifestyle behaviors (range 0-4) between the groups by multivariable logistic regression and ANCOVA analyses.

Results: One-thousand-and-fifty-four screening participants without neoplastic findings (29% of those invited to screening) were included in the present study. Participants in the TF group increased their number of cancer preventive lifestyle behaviors significantly compared to those in the control group by 0.11 (95% CI 0.02 to 0.19). Overweight/obese individuals in the TF group had a -0.84 kg (95% CI -1.47 to -0.22) larger reduction in body weight compared to the control group.

Conclusions: Individually-tailored written feedback at sigmoidoscopy screening led to small improvements in cancer preventive behaviors.

Impact: CRC screening is a suitable setting for increasing awareness of cancer preventive behavior.

Keyword: lifestyle, behavior, intervention, score, change, prevention, colorectal cancer screening.

Introduction:

The context of cancer screening provides an opportunity for a teachable moment to increase participants' awareness of cancer prevention with a healthy lifestyle (1). Cancer screening programs have not yet fully utilized this opportunity (2,3). It is particularly important to increase lifestyle awareness at screening for cancers that are closely related to lifestyle such as colorectal neoplasia (4-7), as well as recurrent adenomas (8,9). Raising awareness of the importance of a healthy lifestyle at CRC screening is also particularly relevant in light of evidence that CRC screening participation may reduce participants' motivation to make healthy lifestyle choices (10,11).

An automatized written feedback letter delivered in a screening context would be a feasible low-cost strategy for increasing screening participants' awareness of their own lifestyle. Two separate British intervention studies within CRC screening programs have shown beneficial effects of individually-tailored written advice on consumption of fruit and vegetables in screening participants in the short (six weeks) (12) and longer term (six months) (13). Because only long-lasting beneficial lifestyle behaviors may impact chronic disease risk, such intervention effect should be investigated by an extended follow-up.

The present study aimed to investigate the effect of i) standardized, individually-tailored written feedback and ii) a standard leaflet for cancer preventive lifestyle on one-year follow-up of lifestyle behaviors in the context of CRC sigmoidoscopy screening.

Materials and Methods

<u>Study design and participants</u>

The present study is a sub-study within the Bowel Cancer Screening in Norway (BCSN) trial, a randomized trial piloting a national CRC screening program. The BCSN is carried out in two geographically defined areas in south-eastern Norway, Moss representing a more rural area and Bærum representing a more urban area. Men and women aged 50-74 years are included (14). From November 2014 to September 2015, 3642 individuals invited to sigmoidoscopy were additionally invited to complete a two-page lifestyle questionnaire (LSQ). We sent the questionnaire along with the screening invitation to be completed prior to the screening examination (prescreening LSQ). The individuals were randomized (1:1:1) at invitation based on the unique Norwegian social security number to one of the three groups: i) standardized, individually-tailored written feedback (TF); ii) standard leaflet (SL) for cancer preventive lifestyle; or iii) control. A computer program carried out the randomization automatically. This randomization was blinded to the researchers and designed by the IT developer, following the consort guidelines (supplementary material 4). We mailed a second LSQ to the prescreening responders 12 months after the mailing of the prescreening LSQ. The outcome change in lifestyle was assessed by the follow-up LSQ. A paper version of the LSQ was included in the screening invitation letter. It was also possible to complete the LSQs in an online version available by personal login via a link provided in the invitation. No reminder was sent to non-responders of the questionnaire.

Lifestyle questionnaire (LSQ)

The LSQ consisted of questions used in previous national surveys (15,16) and the Norwegian Colorectal Cancer Prevention study (11,17). The participants were asked about demographic factors as well as lifestyle behaviors.

Demographic factors included ethnicity - dichotomized as native (Norway) or non-native (any other country), marital status - dichotomized as married/cohabiting or non-married/non-

cohabiting (or single), education length (primary school, high school, or a minimum of two years at university/college) and working status - dichotomized as working or not working (including retired, unemployed, homemakers and disabled/on rehabilitation).

Height was assessed by whole centimeters and weight as whole kilograms.

The lifestyle behaviors included smoking status, dichotomized into current smokers (daily and occasional) and non-smoker (former or never smokers). Physical activity (times/week of 30 min of activity) was calculated by adding the responses on frequency to the two questions on physical activity "without sweating or shortness of breath" and "with sweating or getting short of breath". Frequency ranged from 'never' to 'more than seven times/week'. Consumption of alcoholic beverages (glasses/week) was calculated by frequency of intake multiplied by the number of glasses usually consumed. Consumption of fruit, berries and vegetables was calculated as a sum of reported consumption of 1) fruits and berries, 2) raw vegetables, and 3) boiled vegetables (portions/day). Consumption of red and processed meat for dinner was calculated as a sum of reported frequency consumption of 1) steak, pork chops or similar, 2) hamburgers or other dishes with minced meat, and 3) sausages (portions/week). Six frequency alternatives ranging from 'seldom/never' to 'more than three portions/day' were provided as response options for the dietary questions.

Based on the following factors: smoking habits, physical activity, and consumption of alcoholic beverages, fruit, berries and vegetables we created a scale for the number of cancer preventive lifestyle behaviors (Table 1). The number of cancer preventive lifestyle behaviors ranged from zero to four. Each of the single lifestyle factors was dichotomized to reflect adherence to health recommendations (18-20). Change in weight was used as a separate outcome and not included in the scale for number of cancer preventive lifestyle behaviors. Body mass Index (BMI, kg/m^2)

was calculated to identify individuals who were not following the health recommendations on weight (≥25 kg/m^2).

Intervention

The *control* group did not receive any intervention or information on CRC prevention.

One to four weeks after completion of the prescreening LSQ, responders in the *SL* group received the Norwegian Cancer Society's one-page leaflet, "Good habits for a healthier life" with lifestyle advice for low cancer risk (supplementary material 1) by mail. The leaflet was mailed either before or after the screening examination.

Similarly, one to four weeks after completion of the prescreening LSQ, responders in the *TF* group received a two-to-three-page letter by mail from the research team with a standardized, individually-tailored written feedback letter based on their answers to the prescreening LSQ. The letter addressed five lifestyle factors; smoking, consumption of alcoholic beverages, consumption of fruit, berries and vegetables, physical activity and body weight. The behaviors reported by the participant were compared to health recommendations. The participant was praised if meeting the recommendations. If the reported behaviors did not meet the recommendations, the individual was encouraged to change their behavior to meet the recommended levels. This could be; "You answered that you rarely or never eat fruit, berries and vegetables. This is less than recommended. The recommendation is to eat at least five servings/day. One serving is approximately 100g. This equals e.g. a small bowl of salad, a carrot or a medium sized fruit". All participants in the TF group also received the Norwegian Cancer Society's one-page leaflet (Supplementary material 1 and 2). Subjects in both the TF and SL groups who reported current smoking additionally received the Norwegian Cancer Society's leaflet "Stop smoking without gaining weight" (supplementary material 3).

Screening

The sigmoidoscopy screening result was defined as positive if one of the following was detected or suspected: 1) any polyp ≥ 10 mm in diameter, 2) any adenoma with villous histology or high-grade dysplasia, 3) ≥ 3 adenomas or 4) cancer. Participants with a positive screening were referred to a follow-up colonoscopy. The final screening result in the present study was one of the following: 1) negative screening, 2) other findings or 3) neoplasia based on the sigmoidoscopy and colonoscopy.

Exclusion criteria

Participants were excluded from screening due to medical reasons (e.g., severe heart, lung or liver diseases, cancer with life expectancy less than one year), previous CRC, relocating out of the screening municipalities or previous colonoscopy in the last 12 months. Furthermore, participants were excluded from the present study if not completing the prescreening LSQ or if the completion date was not possible to determine. Participants who completed the prescreening LSQ after the screening examination, or who completed the one-year follow-up LSQ <10 or >14 months after prescreening LSQ were also excluded. Individuals with any adenomas or cancer findings at screening were excluded from the present study (Figure 1) to minimize potential bias of lifestyle change caused by being diagnosed with adenomas or CRC. This adds comparability between the present and earlier studies, e.g. Robb *et at.* 2010

Statistical analyses

We used t-tests to evaluate the changes in lifestyle between prescreening and one-year follow-up within each group. McNemar's test was used similarly for changes in smoking status. When examining differences in changes in lifestyle variables between the intervention groups and the

control group at follow-up, we used an analysis of covariance for the continuous variables, and a multivariable logistic regression model for smoking. The 95% confidence interval (CI) was also calculated The statistical models were adjusted for sex, age at invitation, education length, working status, ethnicity, marital status, screening center (Moss or Bærum Hospital), and time between completion of prescreening and follow-up questionnaires. The models were additionally adjusted for the prescreening value of the examined variable and prescreening values for weight, and the lifestyle variables; smoking status, level of physical activity, consumption of alcoholic beverages, fruit and vegetables, and red and processed meat and fish. Self-reported chronic disease was not included in the final model, because the preliminary models adjusting for this variable did not differ from the presented results. We conducted analyses stratified by gender. We also compared change in lifestyle between the TF and SL -groups. Furthermore, we completed statistical analyses including only individuals who did not adhere to single health recommendations or who had a number of cancer preventive lifestyle behaviors ≤ 2 at prescreening.

Sample size estimates: We based the power calculation on predicted difference in self-reported one year change in intake of fruit, berries and vegetables between the standardized, individually-tailored written feedback and the control group, which we expected to be 0.26 (SD 1.53) portions/day (80% power, P=0.05) (21). We estimated 540 subjects in each of the three groups to be an adequate number for analyses. We invited 3642 subjects to participate.

The primary analyses were based on intention-to-treat, where if missing the one-year follow-up LSQ the values in the prescreening LSQ was carried forward. Similarly, if answered the one-year follow-up LSQ but values were missing, the baseline values were carried forward. Secondary

191 analyses were based on complete case analyses, meaning that individuals with missing one-year
192 follow-up LSQ or missing values in one or several variables were excluded from the analyses.

193 The analyses were carried out using STATA software, version 14.1 (Stata Corp., College
194 Station, Texas, USA).

195 **Results**

196 Overall, 3642 individuals were invited, and 1433 (39%) participated in sigmoidoscopy screening
197 and completed the prescreening LSQ. Of these, 1054 (75%) completed the prescreening LSQ
198 before the screening and had no neoplastic findings: 308 in the TF, 392 in the SL and 354 in the
199 control group (Figure 1). These were used for the primary analyses based on intention to treat.

200 The demographic characteristics of the three groups at prescreening are shown in Table 2. More
201 individuals in the SL group had a high-level education compared to the TF and control group.

202 Table 3 shows lifestyle characteristics at prescreening and one-year changes in the TF, SL and
203 control groups and adjusted differences in lifestyle changes during follow-up. There were no
204 differences in lifestyle factors at prescreening between the groups. Individuals in the SL group
205 reduced their alcohol consumption significantly by -0.54 glasses/week (95%CI -0.94 to -0.14)
206 compared to the control group. Individuals in the TF group increased their number of cancer
207 preventive lifestyle behaviors significantly by 0.11 (95% CI 0.02 to 0.19) compared to the control
208 group (Table 3). Analyses stratified by gender showed that only men in the SL group
209 significantly decreased their consumption of alcoholic beverages compared to controls -0.91
210 glasses/week, (95% CI -1.56 to -0.26). Women in the TF group significantly increased their
211 physical activity by 0.51 times/week (95% CI (0.05 to 1.98) compared to controls. Only men in

212 the SL group significantly increased their number of cancer preventive lifestyle behaviors by 0.13
213 (95% CI 0.01 to 0.24) compared to controls (See supplementary material 5, table 1).

214 Lifestyle characteristics and one-year changes for individuals who did not adhere to single health
215 recommendations and those with a number of cancer preventive lifestyle behavior ≤ 2 at
216 prescreening are shown in Table 4. Among participants with a BMI ≥25 kg/m^2, individuals in the
217 TF group reduced their weight significantly by -0.84 kg (95% CI -1.47 to -0.22) compared to the
218 controls at one-year follow-up. In the SL group, participants with an alcohol consumption higher
219 than recommended had a significant decrease in consumption by
220 -4.98 glasses/week (95% CI -7.83 to -2.13) compared to the controls at one-year follow-up (Table
221 4).

222 When comparing the TF with the SL group, a significantly higher increase in fruit and vegetable
223 intake was observed in the TF group; 0.18 portions/day (95% CI 0.01 to 0.34) (See
224 supplementary material 5, table 2).

225 The proportion of non-responders to the one-year follow-up LSQ differed between the three
226 groups, being 100/308 (32%) in the TF, 90/392 (22%) in the SL and 85/354 (24%) in the control
227 group (Figure 1). Non-responders to the follow-up LSQ were younger (mean age 62.8, 63.9 and
228 62.8 years) compared to the responders (mean age 65.9, 65.2 and 64.7 years) in the TF, SL and
229 control groups, respectively. Prescreening lifestyle variables and screening result did not differ
230 between the follow-up LSQ responders and non-responders. The secondary results by complete
231 case analyses, based on the 779 participants who completed both the prescreening LSQ and the
232 one-year follow-up LSQ showed similar trends as the primary intention-to-treat analyses. The
233 improvement in the number of cancer preventive lifestyle behaviors was some larger in the
234 complete case analyses than in the intention-to-treat analyses (see supplementary material, 5,

table 3 and 4). The improvement in fruit and vegetables intake in the TF compared to the control group was significant only in the complete case analyses.

Discussion

In this randomized trial in a CRC screening setting, we found that standardized, individually-tailored written feedback (TF) led to small improvements at one-year follow-up for cancer preventive behaviors among participants with no neoplastic findings. There was a low overall questionnaire response rate at prescreening (39%).The non-response rate to the one-year follow-up LSQ was higher in the TF group (32%) compared to the SL (22%) and control (24%) –groups. However, similar trends were observed for the intention-to-treat analyses (including non-responders to one-year follow-up LSQ) and complete-case analyses (excluding non-responders to one-year follow-up LSQ).

To the best of our knowledge, this is the first letter-based lifestyle intervention study with follow-up time longer than six months in a population-based CRC screening context. The few studies on lifestyle intervention in a CRC screening setting have suggested that an individually tailored approach is more effective than delivery of standard leaflets (12,13,22,23). This has been observed as increased consumption of fruit and vegetables in both short (six weeks) (12) and longer term (six months) (13). The short-term trial (six weeks) intervened on fruit and vegetable intake only. That study differed from the present study by including individuals who voluntarily signed up to receive more information about healthy diet (12), while the present study included a random sample of sigmoidoscopy invitees. The six-month-follow-up trial (13) showed that the individually tailored intervention had an effect on fruit and vegetable consumption similar to our study. An intervention trial including only individuals diagnosed with colorectal adenomas at CRC screening found personalized advice letters and face-to-face contact to increase fiber intake

after three months (23). Also in a non-screening setting, eight months of telephone counseling and a tailored letter intervention after removal of adenomatous polyps increased physical activity level, reduced intake of red meat and increased an overall score on lifestyle (22). These studies may indicate a higher success of lifestyle interventions in high-risk individuals compared to our population, as earlier suggested (24), although the interventions used were also more intense (face-to-face contact, telephone counseling) than the present study.

Some limitations have to be acknowledged in interpreting the present results. We did not have information about the participants' pre-study awareness of lifestyle recommendations or their knowledge of the association between lifestyle and risk of CRC at prescreening. However, this might be a minor problem, as previous studies have not observed any effect of awareness of lifestyle recommendations on change in lifestyle (13). Attitudes to lifestyle change were not assessed in the present study and could be a confounding variable. The findings are only generalizable to those attending CRC screening and completing a LSQ. People attending cancer screening willing to complete questionnaires might be more motivated towards cancer preventive behavior or lifestyle changes than the general population and non-participants. The sample size was smaller than estimated by the power calculations, which resulted in the study being underpowered. We were unable to analyze the independent effect of the standardized, individually-tailored written feedback without the standard leaflet for cancer preventive lifestyle, because these were both sent to the TF and SL group. Furthermore, chance findings cannot be ruled out as a large number of statistical tests were carried out. The results should be interpreted with caution and as indicative findings that should be tested in a fully powered trial.

A strength of the present study was the relatively long-term follow-up period. The intervention with a multiple risk factor approach may be more effective on overall lifestyle change compared

to an approach with one or two individual lifestyle factors (25,26). Furthermore, being a population-based randomized trial increases the generalizability of the results to population based screening programs.

A minimal intervention such as the TF or SL in this study might not be adequate to enhance lifestyle behaviors or reinforce motivation to change lifestyle behaviors over time. However, it may increase awareness of the importance of lifestyle behavior to lower CRC risk when delivered at CRC screening (27). To have an impact on population health, the lifestyle improvement has to be long lasting. To date, there are no intervention trials with longer than one-year follow-up within CRC-screening. Future trials should therefore test the effect of repeated reminders of lifestyle recommendations on lifestyle behavior e.g. by standard leaflets or a smartphone app. Furthermore, it should be investigated if intervention materials should be tailored to gender and educational level. A previous Norwegian study showed that CRC screening increased the occurrences of lifestyle related diseases among individuals with low educational levels but not for people with higher levels of education (28). The present study indicates that the effect of giving a leaflet on healthy behaviors at CRC screening may be almost as effective as standardized, individually-tailored written feedback in promoting favorable lifestyle changes. Future studies are necessary to separate the impact of individual and general feedback.

Conclusion

A low-cost, minimal intervention using standardized, individually-tailored written feedback and a standard leaflet for cancer preventive behaviors given in a CRC screening context led to small improvement in cancer preventive behaviors. The intervention appeared to be most effective in over weight individuals.

Abbreviations:
Bowel Cancer Screening in Norway (BCSN), Confidence Intervals (CI), Colorectal Cancer (CRC), standardized, written individually-tailored feedback (TF), lifestyle questionnaire (LSQ), standard leaflet (SL)

Declarations

Ethics:
The Regional Ethics Committee of South-East Norway approved the study protocol (approval no. 2011/1272). Trial registration: http://www.clinicaltrials.gov, identifier: NCT 03396029, retrospectively registered 10 of January 2018). The invited, randomized subjects gave their consent for participation by returning the filled prescreening questionnaire.

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Authors' contributions:

MDK generated the standardized, individually-tailored written feedback letter, collected and analyzed the data and drafted the manuscript. PB participated in collecting data. PB, GH, TdL, KR and AH provided supervision in generating the standardized, individually-tailored written feedback letter and helped to draft the manuscript. MDK, PB, GH, TdL, KR and AH read and approved the final manuscript.

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Table 1. Number of cancer preventive lifestyle behaviors and cutoff for each cancer preventive behavior		
	Prescreening	Follow-up
Smoking		
Non-smoking	1	1
Smoking	0	0
Physical activity,		
≥ 30 min times/week	1	1
< 30 min times/week	0	0
Alcoholic beverages, mean glasses/week		
≤ 14 for ♂, ≤ 7 for ♀)	1	1
> 14 for ♂, > 7 for ♀)	0	0
Fruits & vegetables, mean portions/day		
≥5 a day	1	1
< 5 a day	0	0
Number of cancer preventive lifestyle behaviors	1-4	1-4

420

Table 2. Demographic characteristic.
A randomized trial of tailored lifestyle feedback in a sub study of the sigmoidoscopy arm of the bowel cancer screening in Norway: a pilot study. TF = standardized, individually-tailored written feedback, SL= standard leaflet and controls N=1054.(Intention-to-treat analyses),

	TF (n=308)	**SL (n=392)**	**Controls (n=354)**
Age			
Mean (SD), years	64.1 (6.9)	64.9 (7.0)	63.8 (6.8)
Time between sigmoidoscopy and one-year follow-up LSQ			
Mean (SD), days	345,6 (29.4)	341.4 (25.6)	346.6 (33.9)
Sex (%)			
Female	53	50	52
Center (%)			
Moss	72	39	74
Bærum	28	61	26
Working status (%)*			
Working	48	47	49
Not working	48	49	49
Marital status (%)*			
Non-married/ non-cohabiting (or single)	19	20	18
Married/cohabiting	79	77	80
Education length (%)*			
Primary school	18	12	16
High school	39	39	43
University/≥2 years at college	41	46	37
Ethnicity (%)*			
Norwegian	92	92	95
Not Norwegian	5	7	3

N=1054, who answered the lifestyle questionnaire at prescreening before sigmoidoscopy and without neoplasia. *The percent might not add up to 100% due to missing data.

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Table 3. Changes in cancer preventive factors.
A randomized trial of tailored lifestyle feedback in a sub study of the sigmoidoscopy arm of the bowel cancer screening in Norway: a pilot study. TF standardized, individually-tailored written feedback, SL= standard leaflet and control**s.** N=1,054 (Intention-to-treat analyses)

	TF (n=308)	**SL (n=392)**	**Control (n=354)**
Non-smoker (%)			
Prescreening	83.4	87.5	83.3
one-year follow up	86.6	88.5	86.8
Change¤	ns	ns	ns
Adjusted one-year outcome compared to the controls, odds ratio (95% confidence interval (CI))	2.38 (0.56 to 10.2)	1.85 (0.41 to 8.28)	1.00 (ref)
Weight, mean (kg)			
Prescreening, (S.D)	79.6 (14.7)	78.7 (14.9)	80.8 (15.1)
one-year follow-up, (S.D)	79.6 (14.8)	78.6 (15.0)	80.8 (15.2)
Change, (95% CI)	-0.08 (-0.37 to 0.22)	-0.03 (-0.28 to 0.22)	0.17(-0.07 to 0.41)
Adjusted one-year outcome compared to the controls, (95%CI)	-0.27 (-0.73 to 0.19)	-0.39 (-0.83 to 0.06)	(ref)
Physical activity, mean 30 min times/week			
Prescreening, (S.D)	4.2 (2.8)	4.7 (3.0)	4.1 (2.9)
one-year follow-up, (S.D)	4.2 (2.7)	4.7 (3.0)	4.0 (2.8)
Change, (95% CI)	-0.01 (-0.22 to 0.21)	-0.06 (-0.27 to 0.14)	-0.05 (-0.26 to 0.16)
Adjusted one-year outcome compared to the controls, (95%CI)	0.14 (-0.19 to 0.48)	0.04 (-0.29 to 0.37)	(ref)
Alcoholic beverages, mean glasses/week			
Prescreening, (S.D)	4.2 (15.4)	4.4 (9.1)	3.8 (5.0)
one-year follow-up, (S.D)	4.4 (15.6)	4.0 (5.7)	4.0 (5.2)
Change, (95% CI)	0.23 (-0.12 to 0.57)	-0.41 (-1.18 to 0.35)	0.18 (-0.09 to 0.44)
Adjusted one-year outcome compared to the controls, (95%CI)	-0.27 (-0.68 to 0.14)	-0.54 (-0.94 to -0.14)	(ref)
Fruits & vegetables, mean portions/day			
Prescreening, (S.D)	2.3 (1.3)	2.3 (1.3)	2.2 (1.4)
one-year follow-up, (S.D)	2.4 (1.5)	2.3 (1.3)	2.2 (1.4)
Change, (95% CI)	0.11 (0.00 to 0.23)	-0.04 (-0.12 to 0.05)	0.02 (-0.11 to -0.14)
Adjusted one-year outcome compared to the controls, (95%CI)	0.12 (-0.05 to 0.28)	-0.01 (-0.16 to 0.15)	(ref)
╬ Number of cancer preventive lifestyle behaviors, mean number			
Prescreening (S.D)	2.0 (0.7)	2.1 (0.7)	2.0 (0.7)
one-year follow-up (S.D)	2.1 (0.7)	2.1 (0.6)	2.0 (0.7)
Change (95% CI)	0.02 (-0.04 to 0.09)	-0.03 (-0.08 to 0.03)	-0.04 (-0.10 to 0.02)
Adjusted one-year outcome compared to the controls, (95%CI)	0.11 (0.02 to 0.19)	0.06 (-0.02 to 0.14)	(ref)

Paired t-test was used to test mean changes and 95% confidence intervals (95% CI), ¤McNemar test was used to test for changes in smoking status, within the groups (TP, SL, control), ns =nonsignificant. Intention-to-treat analyses used.
In the adjusted models differences in change of lifestyle between TP vs. control and SL vs. control were tested.

A logistic regression model was used for smoking and ANCOVA for the other lifestyle variables. The adjusted models were controlled for: age, sex, screening center, ethnicity, marital status, working status, education length, prescreening weight and prescreening value of the dependent variable along with prescreening value of the other lifestyle variables.
╬ the number of cancer preventive lifestyle behaviors were adjusted for age, sex, screening center, ethnicity, working status, education length, prescreening weight and the prescreening number of cancer preventive lifestyle behaviors.

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Table 4. Changes in cancer preventive factors for individuals who did not adhere to health recommendations at prescreening. A randomized trial of tailored lifestyle feedback in a sub study of the sigmoidoscopy arm of the bowel cancer screening in Norway: a pilot study. TF = standardized, individually-tailored written feedback SL= standard leaflet and controls. (Intention-to-treat analyses)

	TF	SL	Controls
Smokers prescreening, N=156	n=51	n=49	n=56
Non-smokers, prescreening, n	0	0	0
Non-smokers, one-year follow-up, n	7	4	6
Change	p=0.02	p=0.13	p=0.03
Adjusted one-year outcome compared to the controls, by logistic regression, odds ratio (95% confides interval (CI))	2.33 (0.31-17.5)	0.50 (0.03-7.55)	1.00 (ref)
Weight, mean (kg), N=620	n=178	n=217	n=225
prescreening, (S.D)	87.5 (12.6)	87.0 (12.1)	88.0 (12.5)
one-year follow-up, (S.D)	87.1 (12.8)	86.9 (12.5)	88.1 (12.6)
Change	-0.40 (-0.85 to 0.04)	-0.14 (-0.51 to 0.23)	0.12 (-0.17 to 0.40)
Adjusted one-year outcome compared to the controls (95% CI)	-0.84 (-1.47 to -0.22)	-0.61 (-1.22 to 0.00)	(ref)
Physical activity, mean 30 min times/week, N=743	n=229	n=257	n=257
prescreening, (S.D)	3.1 (1.7)	3.2 (1.6)	2.8 (1.7)
one-year follow-up, (S.D)	3.5 (2.3)	3.5 (2.2)	3.2 (2.2)
Change	0.38 (0.17 to 0.59)	0.32 (0.10 to 0.54)	0.38 (0.19 to 0.58)
Adjusted one-year outcome compared to the controls (95% CI)	0.03 (-0.33 to 0.39)	-0.11 (-0.47 to 0.25)	(ref)
Alcoholic beverages, mean glasses/week, N=77	n=22	n=29	n=26
prescreening, (S.D)	11.8 (3.9)	12.7 (5.2)	15.9 (7.8)
one-year follow-up, (S.D)	10.3 (4.3)	9.5 (5.2)	15.6 (8.5)
Change	-1.52 (-3.44 to 0.40)	-3.20 (-5.40 to -1.00)	-0.27 (-1.29 to 0.75)
Adjusted one-year outcome compared to the controls (95% CI)	-0.83 (-3.82 to 2.16)	-4.98 (-7.83 to -2.13)	(ref)
Fruits & vegetables, mean portions/day, N=941	n=275	n=350	n=316
prescreening, (S.D)	2.2 (1.1)	2.2 (1.1)	2.1 (1.1)
one-year follow-up, (S.D)	2.3 (1.4)	2.2 (1.1)	2.2 (1.3)
Change	0.13 (0.02 to 0.25)	0.00 (-0.08 to 0.08)	0.08 (-0.03 to 0.19)
Adjusted one-year outcome compared to the controls (95% CI)	0.12 (-0.04 to 0.28)	-0.01 (-0.16 to 0.15)	(ref)
Number of cancer preventive lifestyle behaviors ≤ 2, mean ╬ N=641	n=192	n=235	n=214
prescreening (S.D)	1.8 (0.4)	1.8 (0.4)	1.7 (0.5)
one-year follow-up, (S.D)	1.9 (0.5)	1.9 (0.5)	1.8 (0.6)
Change	0.11 (0.05 to 0.17)	0.09 (0.03 to 0.15)	0.08 (0.02 to 0.13)
Adjusted one-year outcome compared to the controls (95% CI)	0.08 (-0.00 to 0.17)	0.03 (-0.06 to 0.11)	(ref)

Paired t-test was used to test mean changes and 95% confidence intervals (95% CI), ¤McNemar test was used to test for changes in smoking status, within the groups (TP, SL, control), ns =nonsignificant. Intention-to-treat analyses used.
In the adjusted models differences in change of lifestyle between TP vs. control and SL vs. control were tested. A logistic regression model was used for smoking and ANCOVA for the other lifestyle variables. The adjusted models were controlled for: age, sex, screening center, ethnicity, marital status, working status, education length, prescreening value of the dependent variable, prescreening weight along with prescreening value of the other lifestyle variables.
╬ the number of cancer lifestyle preventive behaviors were adjusted for age, sex, screening center, ethnicity, working status, education length, prescreening weight and the prescreening number of cancer preventive lifestyle behaviors.

Figure legends

Figure 1. Flow-chart of participant recruitment and randomization.

Assessed for eligibility
Standardized, individually-tailored feedback (TF) (n=1199), Standard Leaflet (SL) (n=1239), controls (n=1204)

dead (n=91), emigrated (n=21), medical reasons (n=42), moved (n=3)
did not respond (n=1670),
did not complete the prescreening LSQ but attended sigmoidoscopy (n=338)
completed the prescreening LSQ but did not attend sigmoidoscopy (n=44)

TF (n=451)

Excluded:
Completed the prescreening LSQ after screening (n=19)
Completed the 1-year follow-up LSQ < 10 month or >14 months after prescreening (n=52)
Diagnosed with neoplasia (n=72)

Intent-to-treat analysis (n=308)

Did not complete 1-year follow-up LSQ (n=100)

Complete case analysis (n=208)

SL (n=503)

Excluded:
Completed the prescreening LSQ after screening (n=16)
Completed the 1-year follow-up LSQ < 10 month or >14 months after prescreening (n=42)
Diagnosed with neoplasia (n=53)

Intent-to-treat analysis (n=392)

Did not complete 1-year follow-up LSQ (n=90)

Complete case analysis (n=302)

Controls (n=479)

Excluded:
Completed the prescreening LSQ after screening (n=12)
Completed the 1-year follow-up LSQ < 10 month or >14 months after prescreening (n=30)
Diagnosed with neoplasia (n=83)

Intent-to-treat analysis (n=354)

Did not complete 1-year follow-up LSQ (n=85)

Complete case analysis (n=269)