Author's response to reviews

Title: The effect of changing stool collection processes on compliance in nationwide organized screening using a fecal occult blood test (FOBT) in Korea: study protocol for a randomized controlled trial

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Version: 3 Date: 5 November 2014

Author's response to reviews: see over
November 5, 2014

Editor-in-Chief, *BMC Trials*

Dear Editor-in-Chief,

We would like to thank you for considering our manuscript “The effect of changing stool collection processes on compliance in nationwide organized screening using a fecal occult blood test (FOBT) in Korea: study protocol for a randomized controlled trial” for publication in *BMC Trials*. We would also like to thank the reviewers for the thorough examination of our manuscript and their excellent comments.

We have addressed all of the reviewers’ comments. In the pages below we provide a detailed description of the modifications introduced to the text in response to the reviewers’ comments. We have uploaded a revised version of the manuscript with marked changes as well as a clean copy. We believe that the manuscript has been improved substantially in the process and we hope that it will be acceptable for the journal. We look forward to your final positive decision on the paper.

Sincerely yours,

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Point-by-Point Responses to the Reviewers’ Comments

1. The "sampling bottle" condition is contaminated with an interpersonal intervention. The manuscript reports that this condition, sampling bottles, also receives more detailed explanation, in the form of an interpersonal exchange, either f2f or via telephone. Hence, this is not just a different device/bottle, but also a personal assistance and contact (see p. 6). "Participants who receive sampling bottles are given more detailed instructions for stool collection via telephone or face to face by research staff, since participants are unfamiliar with the stool devices" – please clarify if there is also a conversation with the "stool container" condition, and if so, conduct time measurement in a subsample of participants. The interpersonal contact or its length may act as a contaminator or a moderator.

Response: Thank you for your valuable comment. Yes, the instruction time given to participants receiving stool containers might be shorter than that given to those receiving sampling bottles. However, we will instruct both groups in methods of stool collection so that their understanding of the use of both devices is similar. We have attached the leaflet to be used for this instruction at the end of this paper. We have revised the text to avoid confusion: “Interventions: All participants who receive stool devices will be instructed in methods of stool collection via telephone or face-to-face by research staff.” (page 6, lines 20-22)

2. The authors present a sound rationale for an expected difference in the primary outcome due to study's conditions. No hypotheses or rationale for expected difference between the study conditions in the secondary and tertiary outcome and are presented. It's most striking for the tertiary outcome (p. 7) of test's results (positive/negative). I wonder: do the authors expect that more healthy (or sick) people will respond more to one of the conditions?
Response: Thank you for your valuable comment. We have revised and added the following text:

“*Background:* Through these interventions, this study will determine the most effective strategy to increase compliance and satisfaction in FOBT screening. This determination is based on the assumption that changing the stool-collection process (especially as regards the type of stool-collection device) will not affect the results of FOBTs, but may affect compliance and satisfaction. We will therefore compare the rates of positive FOBT results between the two stool devices to validate our assumptions.” (page 4, line 25; page 5, lines 1-5)

3. The results of the satisfaction and intention to re-screen can be analyzed by ANOVA, as the dependent variables are continuous. No need to collapse it into 2 or 3 categories, as data will be lost.

Response: Thank you for your valuable comment. We have changed the text as follows:

“**Statistical Analysis:** The satisfaction and intent to rescreen using a FOBT will be assessed by ANOVA.” (page 8, lines 23).

We have also deleted the sentence regarding outcome measures: “This questionnaire is categorized into three dimensions.”

The author can be trusted to make these:

There is inconsistency in the tense used. Sometimes the report is in the future tense, and sometimes in the past tense.

Response: Thank you for your valuable comment. We have made the tense consistent throughout the paper.
The authors may consider:

Think about the idea of pre-stamped envelopes for returning the test.

**Response:** Thank you for your valuable comment. We are planning to include your recommendation in future studies if this study is completed successfully.

Handling editor comments:

1. The manuscript refers to two techniques that are being compared: ?stool bottle? and? stool container?. These terms are not sufficiently distinctive, and the difference is unclear. It would be useful to use somewhat more distinctive terms? e.g. the conventional container versus newer bottle etc.

**Response:** Thank you for your valuable comment. We have changed the terms in the manuscript from 'stool container' to 'conventional container', and from 'sampling bottle' to 'sampling kit'.

2. The authors indicate that the new bottle allows sampling from multiple places in stool. The method for this is unclear. Some more details may be provided.

**Response:** Thank you for your valuable comment. We have added a detailed explanation and a diagram to Figure 2.

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Background: The second is to provide a stool sampling kit consisting of a small test tube including a longer, thinner sampling probe that is easier to poke into the stool to collect stool specimens.” (page 4, lines 23-25)

Intervention: Compared to the currently used conventional container, the new sampling kit is thinner and smaller, with a thin (4.2 cm long) sampling probe attached to the cap that
allows easier insertion into the stool. The tip of the sampling probe has a spiral groove to collect stool specimens (Figure 2). The sampling probe with the collected stool (~10 mg) may then be reinserted into the kit. These stool specimens are analyzed in an OC-SENSOR DIANA machine (Eiken Chemical Co., Ltd., Tokyo, Japan) designed for quantitative immunochemical FOBTs and the sampling kits fit this equipment. Stool specimens in conventional containers are transferred to sampling kits for immunochemical FOBTs at the laboratory because the conventional containers do not fit the analyzer.” (page 6, lines 11-19)

3. Is there difference in the amount of stool sampled in the two methods? This may be indicated."

**Response:** There is no difference because stool specimens in conventional containers must be transferred to the sampling kit for analysis. This information has been added as described above.

**Editorial requests:**

1. Please include all author affiliations on the title page.

**Response:** This information has been added.

2 Please include the date your study was registered with the trial registration number at the end of the Abstract.

**Response:** We have added the date at the end of the Abstract.

3. Please include a list of abbreviations used and their meanings, after the Trial Status.

**Response:** We have added a list of the abbreviations used and their meanings. (page 11, lines 4-8)
The English in this document has been checked by at least two professional editors, both native speakers of English. For a certificate, please see:

http://www.textcheck.com/certificate/yzfETn
< Leaflet for sampling kit>

키트 사용 설명서

1. 구성품
   체변용지 1장, 검사키트 1개, 라벨지 1개, 설명서 1장

2. 주의사항
   - 체변용지는 꼭 바른 수송을 제한 하므로 체변이후 체변 후에 소독
   - 체변이전 3일부터 야간피린이나 소형제, 피로한 음주를 지양합니다.
   - 체변이전 3일부터 식사음료가 많은 식사지리가, 알코올, 복수, 술, 사
   - 젖을 피합니다.
   - 체변이전 3일부터 식사음료가 많은 식사지리가, 알코올, 복수, 술, 사
   - 젖을 피합니다.

3. 체변채취
   - 체변채취는 체변이후, 체변이전 3일부터 식사음료가 많은 식사지리가, 알코올, 복수, 술, 사
   - 젖을 피합니다.
   - 체변채취는 체변이후, 체변이전 3일부터 식사음료가 많은 식사지리가, 알코올, 복수, 술, 사
   - 젖을 피합니다.

4. 제출처
   국립암센터로 방문 제출해주시기 바랍니다.
<Leaflet for conventional container>

채변통 사용 설명서

1. 구성품
   채변통 1개, 라벨지 1개, 설명서 1장

2. 주의사항
   - 김치 전 3일부터 아스파르가이나 소염제, 과도한 음주는 피합니다.
   - 김치 전 3일부터 식품첨가물, 백미(식물성, 감칠맛, 음주안, 초과, 황동)를 권장합니다.
   - 생리기간 중 및 체온 전후, 손이 충혈을 동반한 상처가 있을 때, 혈뇨가 있을 때, 체력을 저하한 환자, 약물, 정맥, 정맥 펌브 등이 있을 때는 응급사상 시사된 후 재변합 수시로 바람니다.

3. 제출처
   국영면센터로 방문 제출해주시기 바랍니다.

4. 채변 막대의 전단이 있는 부분으로 반의 표면을 도해 물질가 제변험이요.
   전단의 눈금이 파돌림 정도

재년용 바닥을 감히 아래 주십시오.

제출용 비닐 포장자에 넣고 확인하여 제출하시 주십시오.