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# The effect of a dietary intervention with rice bran on intestinal health among adults at high risk of colorectal cancer

**Submission date**
29/10/2020

**Recruitment status**
No longer recruiting

**Registration date**
25/11/2020

**Overall study status**
Completed

**Last Edited**
23/11/2021

**Condition category**
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Colorectal cancer (CRC) is one of the most commoncancers among humans worldwide. Recent studies demonstrated that the composition of the bacterial community in the human gut, as well as inflammation occurring in the gut, are some of the factors that modify the risk of an individual to develop CRC. The human gut is home to more than 1000 bacterial species, including health-promoting species and disease-causing species.
The consumption of rice bran, a by-product of rice milling, was previously shown to positively modify bacterial composition in the gut among healthy adults. The protective effect of a long-term rice bran consumption against CRC among individuals known to have higher risk of CRC, such as older individuals who are regular smokers and having a family history of CRC, needs to be established.
This study aims to investigate whether the implementation of a 24-week dietary programme involving rice bran consumption among adults at high risk of CRC is feasible, and whether it has any effect in inducing a health-promoting modification of the bacterial community, as well as a reduction of inflammation, in the gut of these individuals.

Who can participate?
Chinese adults of either gender, who are aged 50 or above and are categorised to be in the high risk CRC group by the Asian-Pacific Colorectal Screening tool, in which classification is based on age, smoking status and family history of CRC.

What does the study involve?
After the recruited subjects were screened for eligibility of study participation and written informed consent had been obtained from them, they were randomly assigned into either Group A or Group B. Participants in Group A were given packets of rice bran and were asked to consume 30 grams of the rice bran at 24-hour intervals for 24 weeks. Participants in Group B were given packets of rice powder that has similar appearance and colour as the rice bran, and were asked to consume 30 grams of the rice powder, also at 24-hour intervals for 24 weeks. All participants were asked to provide a stool sample and blood sample at various time points during the study, namely just before rice bran consumption, as well as 6 weeks, 12 weeks and 24

weeks after the start of rice bran consumption. Laboratory tests were conducted on these samples. All participants were also instructed to complete a log book, detailing the date and time of rice bran or rice powder intake each day, and the amount consumed. The participants also completed a faecal diary where they documented the frequency of egestion, and the shape and amount of stool egested each day, as well as the occurrence of any abdominal discomfort or pain.

What are the possible benefits and risks of participating?
Benefits: Rice bran and rice powder consumed by the participants are known to be nutritious dietary supplements, which may promote health. There is a small potential risk of choking as rice bran and rice powder are available in powder form.
Risks: There are no known health risks or side effects upon consumption of rice bran or rice powder as these are commercially available dietary supplements. Moreover, a blood sample was taken from each participant at various points during the study, and bruising at the site of blood collection may occur among some participants.

Where is the study run from?
Centre for Digestive Health, The Chinese University of Hong Kong

When is the study starting and how long is it expected to run for?

Who is funding the study?
The Chinese University of Hong Kong

Who is the main contact?
Prof. Winnie K.W. So
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Winnie K.W. So

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# Additional identifiers

# Study information

### Scientific Title
Modulations of gut microbiota and metabolites by dietary intervention with heat-stabilised rice bran in adults of high risk colorectal cancer - a double blinded randomized controlled study

### Study objectives
1. The 24-week dietary rice bran intervention is feasible among adults at high risk of CRC.
2. Intervention participants exhibit a significantly greater extent of increase in bacterial diversity in the gut microbiota, as well as a significantly greater increase in the intestinal abundance of health-promoting bacteria and greater decrease in that of pathogenic bacteria, compared to control participants after the intervention.
3. Intervention participants exhibit a significantly greater extent of reduction in the serum level of molecular biomarkers for intestinal inflammation, namely high-sensitivity C-reactive protein and calprotectin, compared to control participants after the intervention.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 23/10/2019, Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee (8/F Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, The New Territories, Hong Kong SAR; +852 35053935; crec@cuhk.edu.hk), ref: 2019.482

### Primary study design
Interventional

### Study design
Double-blind randomized controlled trial

### Study type(s)
Prevention

### Health condition(s) or problem(s) studied
Digestive health in healthy adults at high risk of colorectal cancer

### Interventions
Forty participants were randomised into either the intervention or control group, with each group having 20 participants. Randomisation was performed by an independent statistician on a 1:1 allocation ratio, using computer-generated randomisation scheme with a block size of 10. Allocation concealment was achieved with the use of sealed opaque envelopes.

Participants in the intervention group consumed 30 grams of rice bran at 24-hour intervals, over a period of 24 weeks.

Participants in the control group consumed 30 grams of rice powder at 24-hour intervals, over a period of 24 weeks.

The rice powder serves as a placebo to the rice bran consumed by the intervention participants as the rice powder and rice bran have similar appearance and colour.

### Intervention Type
Supplement

### Primary outcome(s)
1. Bacterial diversity in the intestinal microbiota of participants, measured by 16S metagenomic sequencing of the stool samples provided by participants, at baseline, 6 weeks, 12 weeks and 24 weeks after start of intervention
2. The Firmicutes/Bacteroidetes ratio of the bacterial community in the intestine of participants, measured by 16S metagenomic sequencing of the stool samples provided by participants, at baseline, 6 weeks, 12 weeks and 24 weeks after start of intervention
3. Serum level of high-sensitivity C-reactive protein of participants, measured by solid-phase enzyme-linked immunosorbent assay using the blood samples provided by participants, at baseline, 6 weeks, 12 weeks and 24 weeks after start of intervention
4. Faecal level of calprotectin of participants, measured by sandwich enzyme-linked immunosorbent assay using the stool samples provided by participants, at baseline, 6 weeks, 12 weeks and 24 weeks after start of intervention

### Key secondary outcome(s)
1. Recruitment rate, measured by the number of subjects recruited over the subject recruitment period, and the proportion of recruited participants in relation to the total number of potential subjects approached during subject recruitment. This was measured at baseline
2. Retention rate, measured by the proportion of subjects having completed the intervention in relation to the total number of recruited subjects. This was measured at 24 weeks after start of intervention
3. Compliance rate, measured by the proportion of the actual number of times of rice bran consumption in relation to the expected number of times of rice bran consumption among the subjects. This was measured at 24 weeks after start of intervention
4. Bowel patterns of participants, measured by the description of the shape and amount of stool egested by the participants and frequency of egestion each day during the intervention. This was measured throughout the 24-week intervention via a log-book provided to each participant
5. Adverse events, measured by the daily reporting on the experience of any abdominal pain and /or abdominal discomfort by the participants during the intervention. This was measured throughout the 24-week intervention via a log-book provided to each participant

### Completion date
30/11/2020

## Eligibility

### Key inclusion criteria
1. Chinese aged 50 or above
2. Categorised as a high risk group for the development of CRC (score 4-7) by the Asian-Pacific Colorectal Screening tool (APCS)
3. No gastrointestinal symptoms suggestive of colorectal cancer
4. Negative fecal occult blood test or negative colonoscopy findings for CRC within 1 year
5. No history of food allergy
6. No dietary restriction

7. Not currently taking cholesterol-lowering medications
8. Not currently taking non-steroidal anti-inflammatory drugs (NSAIDs)
9. No probiotic and prebiotics use for the past 3 months
10. No history of gallstones
11. No Chinese medicine use (except traditional Chinese soup) for the past 3 months
12. No antibiotic taking for the past 3 months

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Total final enrolment
40

### Key exclusion criteria
1. Having lower gastrointestinal symptoms in the past week
2. Currently pregnant unless sterilization was done or in menopause or lactating (self-reported by the participants)
3. Diagnosed to have diabetes mellitus

### Date of first enrolment
07/01/2020

### Date of final enrolment
14/04/2020

## Locations

### Countries of recruitment
China

Hong Kong

### Study participating centre
**The Chinese University of Hong Kong**
Centre for Digestive Health
Lui Che Woo Clinical Sciences Building (Professorial Block)
Ngan Shing Street
Shatin

Hong Kong
China
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# Sponsor information

**Organisation**
Chinese University of Hong Kong

**ROR**
https://ror.org/00t33hh48

# Funder(s)

**Funder type**
University/education

**Funder Name**
Chinese University of Hong Kong

**Alternative Name(s)**
The Chinese University of Hong Kong, , , Hēunggóng Jūngmàhn Daaihhohk, CUHK,

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Hong Kong

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are available from Prof Winnie K.W. So (winnieso@cuhk.edu.hk) by all individuals. Data on all primary and secondary outcomes will be available. Any identifiers of the participants will not be shown in the dataset and only the participant codes will be presented.

**IPD sharing plan summary**
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 06/02/2021 | 23/11/2021 | Yes | No |
| Protocol file | | 04/11/2020 | 02/12/2020 | No | No |