

# Effect of exercise on fitness in colorectal cancer survivors

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<b>Registration date</b> 20/01/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/01/2014	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cancer has become a major public health problem in South Korea. Lifestyle factors determine the risk of colorectal cancer and the course of the disease. Studies have shown a strong link between the level of physical activity and the outcomes of colorectal cancer. Although observational studies have shown the link between physical activity and the physical fitness of colorectal cancer patients, there are few interventional studies which have shown these beneficial effects. Therefore, the aims of this study are to investigate the effects of a 6-week home-based exercise intervention on cardiovascular and musculoskeletal fitness and patients' perceived bowel function in stage II-III colorectal cancer survivors.

### Who can participate?

Patients with stage II-III colorectal cancer who have completed all standard cancer-directed therapy at least 4 weeks but no more than 2 years before the study.

### What does the study involve?

Patients are randomly allocated to either the exercise group or the control group. Exercise group patients will be encouraged to walk more than 10,000 steps per day. A pedometer will be provided to count the steps. Patients will be provided with exercise DVDs, which consist of 30 minutes exercise using their own body weight, to be performed at home daily. Following each exercise session, participants will complete their exercise log, recording the daily steps, type of exercise and duration. Exercise group participants will visit the clinic three times during the 6 weeks. They will have two exercise education sessions, and the exercise trainer will make sure that patients are able to perform the exercise properly. Control group patients will be instructed to continue with their usual daily activities. The intervention period will be 6 weeks and assessments will be carried out before the start of the study and at 6 weeks.

### What are the possible benefits and risks of participating?

All participants will receive exercise DVDs, a pedometer, exercise handouts, and the results of the clinical tests. There are no known risks to participants.

### Where is the study run from?

Severance Hospital, Shinchon, Seoul, Korea.

When is the study starting and how long is it expected to run for?  
Patients will be enrolled in the study between August 2011 and October 2014.

Who is funding the study?  
Ministry of Health and Welfare, South Korea.

Who is the main contact?  
Professor Justin Jeon  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
Effect of a 6-week home-based exercise program on fitness in colorectal cancer survivors: a randomized controlled trial

**Study objectives**  
The 6-week exercise intervention program will improve cardiovascular and musculoskeletal fitness and patients perceived bowel function in colorectal cancer survivors.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Institutional Ethics Review Board at Yonsei University College of Medicine

**Study design**

Randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Stage II to III colorectal cancer survivors

**Interventions**

Participants will be randomized into either an exercise or usual care group via minimization method.

1. The exercise group will receive a 6-week home-based exercise program. They will be encouraged to walk more than 10,000 steps per day (pedometer will be provided). In addition, patients will be provided with exercise DVDs, which consisted of 30 minutes exercise using their own body weight, to be performed at home daily. Following each exercise session, participants will complete their exercise log, recording the daily steps, type of exercise and duration. Exercise group participants will visit the clinic three times during 6 weeks. They will have two exercise education sessions, and the exercise trainer will make sure that patients are able to perform the exercise properly.
2. Participants in the control group will be instructed to continue with their usual daily activities.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Cardiovascular and musculoskeletal fitness measured by the 3-minute step test and push up test, respectively
2. Patient perceived bowel function measured by questionnaires

## **Secondary outcome measures**

Quality of life measured by the Functional Assessment of Cancer Therapy - Colorectal (FACT-C) scale

## **Overall study start date**

27/08/2011

## **Completion date**

19/10/2014

# **Eligibility**

## **Key inclusion criteria**

1. Between 18 and 75 years of age
2. Histologically confirmed stage II to III colorectal cancer
3. Completed surgery, radiotherapy, and/or chemotherapy within 4-104 weeks prior to the study
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
5. Not planning extended absences in the 3 months subsequent to enrollment

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

56 patients in each group

## **Key exclusion criteria**

1. Existing evidence of recurrent or metastatic disease
2. Participation in regular physical activity (purposeful activity of at least a moderate intensity of 200 minutes or more a week)
3. Pregnant or planned to be pregnant within 6 months

## **Date of first enrolment**

27/08/2011

## **Date of final enrolment**

19/10/2014

# **Locations**

## **Countries of recruitment**

Korea, South

**Study participating centre**  
**Shinchon-Dong**  
Seoul  
Korea, South  
120-749

## **Sponsor information**

### **Organisation**

Yonsei University College of Medicine (Korea, South )

### **Sponsor details**

c/o Nam Kyu Kim  
Department of Surgery  
250 Seongsan-ro  
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Korea, South  
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### **Sponsor type**

University/education

### **ROR**

<https://ror.org/01wjejq96>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

National Research Foundation of Korea (NRF) (No.2010-0009048)

### **Alternative Name(s)**

, National Research Foundation (South Korea), NRF

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Korea, South

**Funder Name**

Ministry of Health and Welfare, Republic of Korea - National R & D program for Cancer Control (1120230)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration