

# Effect of exercise on insulin resistance and adiponectin in colorectal cancer survivors

<b>Submission date</b> 20/04/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/04/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/10/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Cancer has become a major public health problem in South Korea. The lifestyle factors are important determinants of colorectal cancer risk. Previous studies have shown a strong association between the level of physical activity and the outcomes of colorectal cancer. However, the effects of exercise on insulin resistance and adipocytokines in colorectal cancer patients still need to be investigated. The aim of this study are to assess the effects of a 12-week home-based exercise intervention on insulin resistance and adiponectin (the hormone produced by fat cells which influences the bodys response to insulin) in colorectal cancer survivors.

### Who can participate?

Patients with stage II-III colorectal cancer, who have completed all standard cancer treatment at least 4 weeks earlier but no more than 2 years.

### 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. They will get exercise DVDs, will record their daily activities and will visit the clinic five times during the 12 weeks. Control group patients will be instructed to continue with their usual daily activities.

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

Participants allocated to the exercise group will receive the exercise DVDs, a pedometer, exercise hand outs, and results of clinical tests. There are no known risks to participants.

### Where is the study run from?

Severance Hospital, Shinchon, Seoul (South 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 December 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**  
Effects of 12-week home-based exercise program on insulin resistance and adiponectin in colorectal cancer survivors: a randomized controlled trial

**Study objectives**  
The 12-week exercise intervention program will decrease fasting insulin resistance and increase adiponectin 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)**

Other

**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 12-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. Level of fasting insulin will be measured by a chemiluminescence immunoassay
2. Adiponectin levels will be measured by an enzyme immunoassay kit
3. Insulin resistance will be estimated using the homeostatic model assessment of insulin resistance (HOMA-IR) index

**Secondary outcome measures**

1. hs-CRP will be measured by a latex-enhanced immunoturbidimetric assay using an ADNIA 1650 Chemistry system
2. TNF- $\alpha$  levels will be measured using a commercially available enzyme-linked immunosorbent assay
3. Chemerin levels will be measured by an enzyme immunoassay kit
4. Levels of fasting glucose, AST, ALT, GGT, TC, TG, HDL-C will be measured using an ADVIA 1650

Chemistry system

5. Physical fitness measured by the 30minute step test, 6-min walk test, chair stand and push up test

6. Quality of life measured by the FACT-C questionnaires

**Overall study start date**

27/08/2011

**Completion date**

31/12/2014

## **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. 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

**Upper age limit**

75 Years

**Sex**

Both

**Target number of participants**

56 patients in each group

**Total final enrolment**

123

**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**

31/12/2014

## **Locations**

**Countries of recruitment**

Korea, South

**Study participating centre**

134 Shinchon-Dong, Seodaemun-Gu, Yonsei University

Seoul

Korea, South

120-749

## **Sponsor information**

**Organisation**

Yonsei University College of Medicine (South Korea)

**Sponsor details**

c/o Nam Kyu Kim

Department of Surgery

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Korea, South

120-752

**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 - National R & D program for Cancer Control (Republic of Korea),  
Ref: 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2017	23/10/2020	Yes	No