

# Effects of evidence-based exercise on body composition, physical fitness, and recovery-related parameters in Hematopoietic Stem Cell Transplantation Patients

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<b>Registration date</b> 03/04/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/09/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Hematologic cancers are cancers of the blood. Hematopoietic stem cell transplantation (HSCT) is the primary treatment for hematologic cancers which involves replacing the patient's own immune cells with donated healthy stem cells taken from the bone marrow or blood. Patients who undergo HSCT are at risk of suffering from treatment-related problems. Patients are required to be isolated in a bio-clean room (a room without any bacteria), and this can cause patients to be limited in their mobility in these small rooms. This can result in the loss of physical function, fatigue, psychological problems, and decrease of quality of life (QOL). These problems lead to delays in recovery, which can cause delays in being discharged from hospital. Exercise is known to improve physical function, fatigue, depression, QOL, and immune function. The aim of this study is to examine the effect of evidence-based exercise on the body composition and physical fitness, and recovery in HSCT patients.

### Who can participate?

Adults aged 18 and older who have blood cancers who are receiving HSCT.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive a non-supervised daily exercise plan during their hospital stay. The programme is developed for participants so that they can do it in their hospital room. It includes bed stretching and strengthening exercises. Those in the second group receive their usual care. Participants are assessed for their body composition, physical fitness levels.

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

Participants may benefit from improvements in muscle mass and physical fitness. There are no notable risks with participating.

Where is the study run from?  
Yonsei Severance Hospital (South Korea)

When is the study starting and how long is it expected to run for?  
February 2017 to September 2017

Who is funding the study?  
Yonsei Severance Hospital (South Korea)

Who is the main contact?  
1. Dr June Won Cheong (Scientific)  
2. Professor Justin Jeon (Scientific)

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

Effects of evidence-based exercise on body composition, physical fitness, and recovery-related parameters in Hematopoietic Stem Cell Transplantation Patients: A randomized controlled trial

**Study objectives**

Evidence-based exercise will improve muscle mass, physical fitness, and recovery-related parameters in Hematopoietic stem cell transplantation patients.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Institutional Ethics Review Board at Yonsei University College of Medicine, 16/03/2017, ref: 4-2017-0058

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Other

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

Hematopoietic Stem Cell Transplantation Patients

**Interventions**

Participants are randomly allocated to either the exercise group or to the control group. Randomisation is done using stratified randomisation according to gender and transplanting.

Exercise group: Participants in this group conduct a non-supervised exercise intervention programme at least one time per day during hospitalization in addition to their usual care. The exercise program is divided into three types according to patients' daily condition. The exercise program is divided into two types according to hospital room type. The exercise program includes bed stretching, resistance exercise, and joint strengthening exercise. Participants in exercise group are educated exercise program by exercise instructor at admission and record daily exercise log book during hospitalization.

Control group: Participants in control group will receive only usual care including chemotherapy, medication, blood count monitoring, and managing side effects like general patients.

Participants are assessed for their body composition and physical fitness using various tests at baseline, after entering the bio-clean room and when they are discharged from the hospital.

**Intervention Type**

Other

**Primary outcome(s)**

1. Body composition (muscle mass) is measured using the BIA machine (Inbody IH-U070R, Biospace, Korea) at baseline and after entering a bio-clean room, and discharge from hospital

2. Physical fitness is measured using the six min-walking test (or 2 minute walking), step test, hand-grip strength, sit and reach, 8 foot up and go test, and chair stand at baseline and after entering a bio-clean room, and discharge from hospital

### **Key secondary outcome(s)**

Current secondary outcome measures as of 08/04/2019:

1. Time to platelet engraftment is measured using hospital charts daily during hospital stay
2. Absolute neutrophil count is measured using hospital charts daily during hospital stay
3. Amount of blood transfusion is measured using hospital charts daily during hospital stay
4. Length of hospital stay is measured using hospital charts daily during hospital stay
5. Symptoms are measured using the Korean version of the M. D. Anderson symptom inventory (MDASI) at baseline and after entering a bio-clean room, and discharge from hospital

Previous secondary outcome measures:

1. Time to platelet engraftment is measured using hospital charts daily during hospital stay
2. Absolute neutrophil count is measured using hospital charts daily during hospital stay
3. Amount of blood transfusion is measured using hospital charts daily during hospital stay
4. Amount of meal intake is measured using hospital charts daily during hospital stay
5. Length of hospital stay is measured using hospital charts daily during hospital stay
6. Symptoms are measured using the Korean version of the M. D. Anderson symptom inventory (MDASI) at baseline and after entering a bio-clean room, and discharge from hospital
7. Satisfaction in exercise program is measured using Satisfaction with Life Scale (SLS) at discharge from hospital

### **Completion date**

15/09/2017

## **Eligibility**

### **Key inclusion criteria**

1. Patients with leukemia, lymphoma, or multiple myeloma who are scheduled to receive autologous or allogeneic HSCT
2. Aged between 18 and 65 years
3. Ability to understand and provide written informed consent in Korea
4. No evidence of cardiac or pulmonary failure associated with treatment
5. Ability to conduct low and moderate intensity exercise program

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Existing evidence of recurrent or metastatic disease
2. Pregnant or planned to be pregnant within six month
3. Any condition unsuitable for participation in the study

### **Date of first enrolment**

16/03/2017

### **Date of final enrolment**

15/08/2017

## **Locations**

### **Countries of recruitment**

Korea, South

### **Study participating centre**

**Yonsei Severance Hospital**

50 Yonsei-ro

Seodaemun-gu

Seoul

Korea, South

120-752

## **Sponsor information**

### **Organisation**

Yonsei Severance Hospital

### **ROR**

<https://ror.org/044kjp413>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Yonsei University

## Alternative Name(s)

YONSEI University, Seoul, Korea, Yonsei University in South Korea

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Universities (academic only)

## Location

Korea, South

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available due to confidentiality reasons.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	qualitative study results	16/09/2020	21/09/2020	Yes	No
<a href="#">Basic results</a>		03/04/2019	08/04/2019	No	No