

# Effects of an internet interactive empowerment-based self-management protocol on physiological indicators in adults with metabolic syndrome

<b>Submission date</b> 01/07/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/07/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/02/2022	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Metabolic syndrome is the medical term for a combination of diabetes, high blood pressure (hypertension) and obesity.

Poor control of metabolic syndrome may lead to serious disease, complications, and even life-threatening health problems. The study aims to explore the effects of the internet interactive empowerment-based self-management protocol on adults with metabolic syndrome.

### Who can participate?

Adults aged 18 years or above, with metabolic syndrome.

### What does the study involve?

Participants will be randomly allocated to the experimental group or the control group.

The experimental group received the internet interactive empowerment-based self-management protocol for 6 weeks and usual care. The website consisted of a home page; a system manual; health education, basic information, self-awareness, and self-management pages; participants' personal self-management history records; and a health professional contact page.

The control group received internet self-management health education and usual care for 6 weeks.

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

The possible benefits are the internet interactive empowerment-based self-management protocol can improve the physiological outcomes, and there are no obvious risks.

### Where is the study run from?

Chi-Mei medical center (Taiwan)

When is the study starting and how long is it expected to run for?  
October 2016 to October 2018

Who is funding the study?  
Chi-Mei medical center (Taiwan)

Who is the main contact?  
Chia-Chi Kuo, kuochiachi@yahoo.com.tw

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Chia-Chi Kuo

**ORCID ID**  
<https://orcid.org/0000-0003-2194-9007>

**Contact details**  
No.901  
Zhonghua Rd.  
Yongkang Dist.  
Tainan  
Taiwan  
71101  
+886-0935437462  
kuochiachi@yahoo.com.tw

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
Nil known

## Study information

**Scientific Title**  
Effects of an internet interactive empowerment-based self-management protocol on physiological indicators in adults with metabolic syndrome: Pilot study

**Study objectives**

The internet interactive empowerment-based self-management intervention group can significantly reduce body weight, body mass index, and waist circumference in adults with metabolic syndrome more than the control group.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 14/10/2016, Institutional review board of Chi-Mei medical center (No.901, Zhonghua Rd., Yongkang Dist., Tainan City 710, Taiwan; +886(6)2812811#53720; csr2930@mail.chimei.org.tw), ref: 10502-008

### **Study design**

Two-group pretest-posttest double-blind pilot randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Intervention effects on reduction of body weight, body mass index, and waist circumference in adults with metabolic syndrome.

### **Interventions**

This pilot randomized controlled trial had a two-group, pretest-posttest (at 6th week and 3rd month), double-blind (participants and outcome assessors) design randomized block design. Convenience sampling was used to recruit 16 participants with metabolic syndrome from a medical center in southern Taiwan. A randomized block design was used to assign participants to the experimental and comparison groups (n=8/group) with an allocation ratio of 1:1.

The experimental group received the internet interactive empowerment-based self-management protocol for 6 weeks and usual care. The website consisted of a home page; a system manual; health education, basic information, self-awareness, and self-management pages; participants' personal self-management history records; and a health professional contact page.

The comparison group received internet self-management health education and usual care for 6 weeks.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

At baseline, week 6, and week 12:

1. Body weight (kg)
2. Waist circumference (cm)
3. Body mass index (kg/m<sup>2</sup>)

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

Measured by blood test unless noted at baseline, week 6, and week 12:

1. Fasting glucose
2. Glycated hemoglobin
3. Total cholesterol level
4. Triglyceride level
5. High-density lipoprotein cholesterol levels
6. Blood pressure (mmHG, sphygmomanometer)

### **Completion date**

05/10/2018

## **Eligibility**

### **Key inclusion criteria**

1. Metabolic syndrome with three or more of the following conditions:
  - 1.1. Waist circumference  $\geq 90$ cm for males or  $\geq 80$ cm for females
  - 1.2. Triglycerides  $\geq 150$ mg/dl
  - 1.3. High-density lipoprotein cholesterol  $< 40$ mg/dl for males or  $< 50$ mg/dl for females
  - 1.4. Blood pressure  $\geq 130/85$  mmHg
  - 1.5. Fasting glucose  $\geq 100$ mg/dl
2. Age  $\geq 20$  years
3. No visual or hearing impairment or psychological disorder
4. Conscious state and ability to communicate in Mandarin or Taiwanese
5. Literacy with at least a primary school education
6. Weekly internet browsing at home

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

18

### **Key exclusion criteria**

1. Using medication for hyperlipidemia, hypertension, or diabetes
2. Other serious metabolic complications, such as kidney failure with hemodialysis or heart failure

### **Date of first enrolment**

02/03/2018

**Date of final enrolment**

13/07/2018

**Locations****Countries of recruitment**

Taiwan

**Study participating centre****Chi-Mei medical center**

No.901

Zhonghua Rd.

Yongkang Dist.

Tainan City

Taiwan

710

**Sponsor information****Organisation**

Chi Mei Medical Center

**ROR**

<https://ror.org/02y2htg06>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Chi Mei Medical Center

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Taiwan

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

### IPD sharing plan summary

Other