

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

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| Submission date 01/07/2021 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 05/07/2021 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 02/02/2022 | Condition category 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised parallel trial

Study setting(s)

Internet/virtual

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

At baseline, week 6, and week 12:

1. Body weight (kg)
2. Waist circumference (cm)
3. Body mass index (kg/m²)

Secondary outcome measures

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)

Overall study start date

14/10/2016

Completion date

05/10/2018

Eligibility

Key inclusion criteria

1. Metabolic syndrome with three or more of the following conditions:
 - 1.1. Waist circumference ≥ 90 cm for males or ≥ 80 cm for females
 - 1.2. Triglycerides ≥ 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 ≥ 100 mg/dl
2. Age ≥ 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

Age group

Adult

Sex

Both

Target number of participants

30

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

Sponsor details

No.901

Zhonghua Rd.

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71101

+886(6)2812811#52652

cmh4000@mail.chimei.org.tw

Sponsor type

Hospital/treatment centre

Website

https://www.chimei.org.tw/main/cmh_department/top/54000_index.html

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/12/2022

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