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

Submission date
01/07/2021

Recruitment status
No longer recruiting

Registration date
05/07/2021

Overall study status
Completed

Last Edited
02/02/2022

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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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

Primary study design
Interventional

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

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^2)

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 ≥90cm for males or ≥80cm for females
1.2. Triglycerides ≥150mg/dl
1.3. High-density lipoprotein cholesterol <40mg/dl for males or <50mg/dl for females
1.4. Blood pressure ≥130/85 mmHg
1.5. Fasting glucose ≥100mg/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

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
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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