

# Web-based nursing support for patients recovering from bypass surgery

<b>Submission date</b> 21/11/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/03/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Coronary artery disease (CAD) patients who have undergone coronary artery bypass grafting (CABG) post-operation always suffer a long-term rehabilitative period accompanied by diverse psychological disorders, which negatively affect their prognosis. Therefore, this study aimed to evaluate the effect of a web-based Information-Knowledge-Attitude-Practice (WIKAP) continuous intervention on the psychological status, medical compliance, and quality of life (QoL) in CAD patients after CABG surgery.

### Who can participate?

Coronary artery disease patients above the age of 18 years who have underwent coronary artery bypass grafting (CABG).

### What does the study involve?

Coronary artery disease (CAD) patients undergone coronary artery bypass grafting (CABG) post-operation will be randomly divided into the Control and WIKAP group, and received conventional routine nursing care and web-based Information-Knowledge-Attitude-Practice (WIKAP) continuous nursing intervention for 12 months, respectively. During the 12-months intervention period, the anxiety and depression rates is measured by Hospital Anxiety and Depression Scale (HADS-A and HADS-D), the medical compliance is detected by Morisky's medication adherence scale (MMAS-8), and the QoL is assessed by using 12-Item Short-Form Health Survey (SF-12) at the first day after discharge (M0), at 3rd-month (M3), 6th-month (M6), 9th-month (M9) and 12th-month (M12) follow-up time points. Besides the 12-months interventional period, the occurrence of major adverse cardiac and cerebrovascular events (MACCE) is analyzed by the Kaplan-Meier curve for another 24-month follow-up period without intervention.

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

The participants who receive the web-based Information-Knowledge-Attitude-Practice (WIKAP) continuous nursing intervention may experience an improvement on their psychological health, medical compliance, quality of life, and a reduction of the occurrence of major adverse cardiac

and cerebrovascular events (MACCE). However, these benefits are not guaranteed and may differ to a great extent depending on personal and social characteristics. Participation in the study does not have any potential risk.

Where is the study run from?

Shengjing Hospital Affiliated to China Medical University (China)

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

January 2018 to June 2023

Who is funding the study?

Liaoning Provincial Natural Science Foundation Program Project (China)

Who is the main contact?

Yan Jiang, yanjiangicu@163.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Yan Jiang

### ORCID ID

<https://orcid.org/0009-0003-9829-7390>

### Contact details

No.36 Sanhao Street, Heping District

Shenyang

China

110004

+86-024-83955555

yanjiangicu@163.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

2018PS110K

## Study information

### Scientific Title

Web-based continuous nursing intervention on the rehabilitation in patients with bypass grafting surgery

### Acronym

WIKAP

### **Study objectives**

Web-based Information-Knowledge-Attitude-Practice continuous intervention would effectively improve the psychological health, medical compliance, and quality of life in patients undergone coronary artery bypass grafting operation.

### **Ethics approval required**

Ethics approval required

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

approved 04/01/2018, Research Ethics Committee of Shengjing Hospital Affiliated to China Medical University (36 Sanhao Rd, Heping District, Shenyang, 110004, China; +86-024-96615-10027 ; Meid\_Zhang@163.com), ref: No.EC-2018-HS-117

### **Study design**

Interventional randomized parallel trial

### **Primary study design**

Interventional

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

Quality of life, Efficacy

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

Outcomes in patients that have undergone coronary artery bypass grafting operation.

### **Interventions**

Randomization Process:

#### 1. Participant List Creation:

- Developed a comprehensive list encompassing all eligible cardiovascular disease patients who had undergone coronary artery bypass grafting, each assigned a distinct and unique identifier or number.

#### 2. Random Selection Method:

- Employed a computer-generated random number generator to ensure an unbiased and impartial selection of participants for the study.

#### 3. Group Assignment:

- Executed the allocation of participants into distinct groups based on the outcomes of the random assignment process.

Clinical Study Design:

Eligible patients, having undergone coronary artery bypass grafting, were systematically and randomly assigned to two groups in a 1:1 ratio:

#### 1. Control Group:

- Participants in the control group received conventional routine nursing care over a 12-month period.

#### 2. Experimental Group (WIKAP):

- In addition to routine nursing guidance, patients in the WIKAP group underwent a 12-month continuous nursing intervention focused on Web-based Information-Knowledge-Attitude-Practice (WIKAP).

Intervention Duration: 12 months

Throughout this 12-month intervention phase, various parameters were assessed at specific intervals:

- Anxiety and depression rates were measured using the Hospital Anxiety and Depression Scale (HADS-A and HADS-D).
- Medical compliance was evaluated through Morishy's Medication Adherence Scale (MMAS-8).
- Quality of Life (QoL) was assessed using the 12-Item Short-Form Health Survey (SF-12) at distinct time points: the first day after discharge (M0), 3rd-month (M3), 6th-month (M6), 9th-month (M9), and 12th-month (M12) post-discharge.

Total Follow-up Period: 36 months

Beyond the initial 12-month interventional period, the occurrence of major adverse cardiac and cerebrovascular events (MACCE) was scrutinized using the Kaplan-Meier curve during an additional 24-month follow-up period without intervention.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Measured using self report:

1. Anxiety is measured using the Hospital Anxiety and Depression Scale (HADS)-A on the first day after discharge (M0), at 3rd-month (M3), 6th-month (M6), 9th-month (M9) and 12th-month (M12) after discharge.
2. Depression is measured using the Hospital Anxiety and Depression Scale (HADS)-D on the first day after discharge (M0), at 3rd-month (M3), 6th-month (M6), 9th-month (M9) and 12th-month (M12) after discharge.
3. Quality of life (QoL) is measured using the 12-Item Short-Form Health Survey (SF-12) on the first day after discharge (M0), at 3rd-month (M3), 6th-month (M6), 9th-month (M9) and 12th-month (M12) after discharge.
4. The occurrence of major adverse cardiac and cerebrovascular events (MACCE) is monitored and recorded within the whole 36-month follow-up period among all participants in this study.

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

The medication compliance is measured using a Chinese version of Morishy's Medication Adherence Scale (MMAS-8) on the first day after discharge (M0), at 3rd-month (M3), 6th-month (M6), 9th-month (M9) and 12th-month (M12) after discharge.

## **Completion date**

10/06/2023

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosed with cardiovascular diseases and underwent coronary artery bypass grafting operation surgery for the first time;
2. Patients or their direct caregivers were capable of using web-based social media (such as WeChat and QQ);

3. Age > 18 years old;
4. In good mental conditions and proper communication abilities;
5. Willing the taking part in this study voluntarily and sign the informed consent.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

174

**Key exclusion criteria**

1. Had cognitive or psychiatric disorders;
2. Combined with other severe organ dysfunctional disorders;
3. Unwilling to cooperate with researchers for any reason and refusal of continuing caring;
4. Lack of vision, speaking, reading and writing abilities;
5. The emergency of acute psychological or physical incidents;
6. Death after CABG operation

**Date of first enrolment**

10/01/2018

**Date of final enrolment**

10/12/2019

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

China

**Study participating centre**

**Shengjing Hospital Affiliated to China Medical University**

No.36 Sanhao Street, Heping District

Shenyang

China

110004

# Sponsor information

## Organisation

China Medical University

## ROR

<https://ror.org/032d4f246>

# Funder(s)

## Funder type

Government

## Funder Name

Liaoning Provincial Natural Science Foundation Program Project (China)

# Results and Publications

## Individual participant data (IPD) sharing plan

Dataset will be available upon request from Yan Jiang ([yanjiangicu@163.com](mailto:yanjiangicu@163.com)).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		13/03/2024	14/03/2024	Yes	No