

Web-based nursing support for patients recovering from bypass surgery

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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised parallel trial

Study setting(s)

Home, Telephone

Study type(s)

Quality of life, Efficacy

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 Morisky'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 measure

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.

Secondary outcome measures

The medication compliance is measured using a Chinese version of Morisky'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.

Overall study start date

04/01/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

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

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Funder(s)

Funder type

Government

Funder Name

Liaoning Provincial Natural Science Foundation Program Project (China)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

15/12/2023

Individual participant data (IPD) sharing plan

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

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/03/2024	14/03/2024	Yes	No