ISRCTN13653455 https://doi.org/10.1186/ISRCTN13653455

Web-based nursing support for patients recovering from bypass surgery

Submission date
21/11/2023

Recruitment status
No longer recruiting

Registration date
23/11/2023

Overall study status
Completed

Last Edited
14/03/2024

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 Morishy'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

ClinicalTrials.gov (NCT)
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).

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