ISRCTN16157091 https://doi.org/10.1186/ISRCTN16157091

The effect of the cloud-based health education mode on the anxiety, fatigue and self-care of women undergoing gynecological laparotomy

Submission date
22/01/2018

Recruitment status
No longer recruiting

Registration date
19/02/2018

Overall study status
Completed

Last Edited
12/02/2018

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It has been well known that good preoperative care guide (health education) and postoperative recovery and self-care ability is closely related, it is also an essential part of holistic care. However, the shortcomings of traditional health education methods often affect their effect. Based on this, this study adopts the popularity of network systems to combine patient instruction with cloud technology, which could get rid of the limitation of time and space. It is not only increasing the initiative of participating self-care for patients, but also helping to improve the continuity of care, proximity and timeliness as well. Furthermore, it can be environmentally friendly. The aim of this study is to see if a cloud based education programme and increase the postoperative recovery and self-care.

Who can participate?
Women over the age of 20-60-year-old who are undergoing the surgery.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the cloud-based health education. This includes watching videos and health education. Those in the second group receive the routine health education. Participants undergo their planned surgery. Participants are assessed before and after the programme to examine their recovery after their surgery and to assess their ability to care for themselves.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. There are still lack of similar study, if confirmed its effectiveness, in addition to help to improve the nursing quality of gynecological surgery, it can also add the evidence-based nursing intervention.

Where is the study run from?
The study is being run by the China Medical University Hospital (China)

When is the study starting and how long is it expected to run for?
March 2017 to January 2018

Who is funding the study?
China Medical University Hospital (Taiwan)

Who is the main contact?
Professor Ya-Ling Tzeng (Scientific)
tyaling@mail.cmu.edu.tw

Contact information

Type(s)
Scientific

Contact name
Prof Ya-Ling Tzeng

Contact details
China Medical University, Taiwan
No.91, Hsueh-Shih Road
Taichung
Taiwan
40402

Additional identifiers

Protocol serial number
CMUH105-REC1-145

Study information

Scientific Title
Cloud-based health education mode, gynecological surgery, hospital anxiety and depression, fatigue continuum form, satisfaction, self-care knowledge and behavior

Study objectives
The aim of this study is to develop the cloud platform for gynecological surgery self photo guard representing without the constraints, in addition to increasing patient participation in self-care initiative, but also can improve care continuity, accessible, timeliness and save on paper, to achieve environmental protection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
China Medical University & Hospital Research Ethics Committee, 02/03/2017, ref: NA / CMUH105-REC1-145 (AR-1)

Study design

Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Gynecological surgery

Interventions
Participants are randomly allocated to either the intervention or the control group. The researcher explains the research purpose, procedures and rights to the participants, and once the participants agree to sign the consent book they are then randomly assigned to the regular health education group, cloud-based education model group.

Those in the intervention group receive the cloud-based health education program. This was developed as a gynecological surgery education content so that participants can read the QR code (quick response code) on paper from their mobile phone or tablet, then connect to the Youtube platform and the digital learning materials in the cloud through the Internet. The main content of the video includes: ward environment, preoperative education, early mobilization, diaphragmatic breathing, postoperative education, food education, home care, wound dressing steps, physical and mental changes, nine sections of the film, a total length of 24 minutes 45 seconds; It also provides digital learning materials and an online learning manual (brochure, photos and pictures) for women who have undergone radical abdominal hysterectomy. Since participants who have obtained QR code can watch the video, we can know the number of people who attend the video on the Internet according to the statistics on the Internet. The researchers also provide an online questionnaire and suggestion field on one month later.

Those in the control group undergo the standard level of care.

In both groups, pretest and physiological index measurement are conducted with structured questionnaire (basic attributes, emotional state scale, fatigue scale, self-care knowledge and behavior scale of gynecologic laparotomy). After the former test, in the group, nurses used the traditional way of using the health education model, and the nursing staff used the traditional way of education to give oral health education to accompany the leaflet. The time for both education and health education was about 15-20 minutes. Minutes after the first post-test, fill in the questionnaire (emotional state scale, fatigue scale, gynecologic laparotomy self-care knowledge and behavior scale) and physical measurements; and a month after the visit to track the second postoperative After the test (emotional state scale, fatigue scale, gynecologic laparotomy self-care knowledge and behavior scale and health education Satisfaction Scale), fill in the questionnaire time about 20 minutes.

Intervention Type
Behavioural

Primary outcome(s)
Self-care behavior and knowledge is measured using the structured questionnaire at pretest(on the day of admitted), posttest (first post-test was given 60 minutes after the health education, second posttest is in the one month later).

Key secondary outcome(s))
1. Anxiety and Depression are measured using Profile of Mood State (POMS) at pretest (on the day of admitted), post test (first post-test was given 60 minutes after the health education, second post test is in the one month later)
2. Fatigue is measured using Fatigue Continuum Form (FCF) at pretest(on the day of admitted), post test (first post-test was two days after surgery, second post test is in the one month later)
3. Physiological measured using sphygmomanometer at pretest (on the day of admitted), post test (after health education)

Completion date
22/01/2018

Eligibility

Key inclusion criteria
1. The doctor established the diagnosis of need for laparotomy gynecological patients
2. Age 20-60 years old (inclusive) or more
3. Literate, conscious and able to communicate in Mandarin or Taiwanese
4. Agree to participate in this study and sign the research consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Have a history of mental illness or other diseases that affect cognitive function
2. Emergency surgery by the day of surgery
3. Laparoscopic surgery patients

Date of first enrolment
07/03/2017

Date of final enrolment
19/09/2017

Locations

Countries of recruitment
Taiwan

Study participating centre
China Medical University Hospital
No. 2, Yude Road
North District
Taichung City
Taiwan
40447

Sponsor information

Organisation
China Medical University Hospital

ROR
https://ror.org/0368s4g32

Funder(s)

Funder type
Government

Funder Name
China Medical University Hospital

Alternative Name(s)
CMUH

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes