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The use of digital media in patient education for the secondary prevention of coronary heart disease

Submission date
27/08/2025

Recruitment status
No longer recruiting

Registration date
01/09/2025

Overall study status
Completed

Last Edited
01/09/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Acute coronary syndrome is often the first manifestation of cardiovascular disease. While advances in its treatment in the acute phase have improved survival, secondary prevention is essential to prevent the recurrence of serious cardiac events, as these are more frequent in patients with established coronary artery disease. The goals of secondary prevention, through pharmacotherapy, medical monitoring, risk factor management and lifestyle optimization, are to reduce premature illness and death, reduce rising healthcare costs, avoid disability and improve quality of life and, therefore, should be initiated as soon as possible after acute coronary syndrome. Patient education is essential, as a large proportion of patients have low health literacy, which negatively affects their ability to understand, seek, evaluate and apply health information for their self-care. The aim of the study is to evaluate the effect of a secondary prevention educational program, based on an educational video and individual counseling in patients with acute coronary syndrome, on adherence to the treatment regimen and quality of life.

Who can participate?
Patients over 18 years of age who have had a recent episode of acute coronary syndrome and have undergone percutaneous coronary intervention (angioplasty) and stent placement at the Larissa University Hospital. In addition, participants must speak and write in Greek and must provide informed written consent for participation in the study.

What does the study involve?
For all participants, the intervention consists of one individual educational session in the first month after discharge and one follow-up session to record the results 6 months after the educational intervention. For the convenience of both participants and the principal investigator, the sessions take place on the same day and before the scheduled cardiologist follow-up appointments at the Outpatient Cardiology Clinic of the University Hospital of Larissa. In the first session, participants are equally allocated into two groups based on their demographic and clinical characteristics: the intervention group and the control group. The education in the intervention group includes topics related to coronary heart disease, its

etiology, risk factors and secondary prevention, using an educational video. The principal researcher then provides individual counseling with emphasis on the required lifestyle changes, such as regular exercise, diet, and smoking cessation. Additionally, the study information brochure is given to read at home. The control group receives the usual brief information regarding the general objectives of secondary prevention and the study information leaflet. Participants in both groups complete the study forms in person before the intervention and during the 6-month follow-up.

What are the possible benefits and risks of participating?
It is expected that education will contribute to changing the patients' behavior, increasing their compliance with treatment and adopting a healthier lifestyle, aiming to achieve the goals of secondary prevention and improving their quality of life. In addition, the study aims to evaluate the effectiveness of this easily implemented educational program on the participants' quality of life and to monitor health behavior after ACS. There are no risks involved.

Where is the study run from?
University of Thessaly (Greece)

When is the study starting and how long is it expected to run for?
July 2021 to March 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dimitra Anagnostopoulou, danagnostop@uth.gr

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
The effectiveness of Patient Education with Coronary heart disease after angioplasty on Adherence to Treatment and quality of life (PEduCAT): a non-randomised clinical trial

Acronym
PEduCAT

Study objectives
The educational program will improve patients' adherence to treatment and quality of life more in the intervention group compared to the control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 17/01/2022, Ethics Committee of the University of Thessaly Department of Nursing (Gaiopolis Campus, Larissa-Trikala Ring-Road, Larissa, 415 00, Greece; +30 (0)2410 684489, +30 (0)2410 684251; g-nurs@uth.gr), ref: 76/17-01-2022

2. approved 28/01/2022, The Scientific Council of University General Hospital of Larissa (Mezourlo Larissa, Larissa, 41110, Greece; +30 (0)2413501000; uhosplar@uhl.gr), ref: 3675/28-01-2022

Study design
Prospective single-centre interventional non-randomized controlled single-blind two-parallel-group study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Acute coronary syndrome

Interventions
The intervention is carried out in person, 1 month after being discharged from acute coronary syndrome, at the outpatient Cardiology Clinic, before each patient's scheduled appointment with their Cardiologist. Initially, a clinical examination is performed by the nurses of the cardiology clinic, which includes an electrocardiogram, weight, height and waist circumference measurement. After providing informed consent, participants are equally allocated to the intervention or control group, based on demographic and clinical characteristics (matched allocation). Participants are blinded of their allocation on the educational program. The nurse-researcher, due to the nature of the intervention, cannot be blinded to the allocation of participants. Participants complete demographic information and self-reported study questionnaires, and the researcher completes the questionnaire with clinical data (obtained from the medical record of the Clinic and clinical examination during the appointment).

For both groups, the intervention consists of one individual session. A 22-minute animated educational video and an 18-page information brochure, in plain language, have been created for the needs of the study. The content of both materials includes topics related to the disease and its manifestations, warning symptoms, the procedure of angioplasty with endovascular stenting, and the goals of secondary prevention after it, such as adherence to medication, diet, regular exercise, smoking cessation, alcohol abuse, hypertension, weight and blood sugar control, and stress management.

Participants in the intervention group receive the education via a video presentation on a laptop in the presence of the principal investigator and their family. The video presentation is paused whenever participants need further explanation. This is followed by counseling on the management of individual risk factors. To confirm the patient’s understanding of the individual prevention goals, the “teach back” method is used. In addition, the study information brochure is given with the recommendation to study it at home and refer to it when they need to remember a specific topic. The education session, including the completion of the questionnaires, lasts approximately 60 minutes.

The control group receives standardized, brief, oral information about the general goals of secondary prevention and, in addition, the study information brochure. In this way, the allocation to groups is concealed from patients and clinic staff and we are consistent in our commitment to providing education. Thus, we consider this minimal education provided to the control group as the standard care.

Participants in both groups receive standard care from the doctors and nurses of the Cardiology Clinic. Follow-up data collection for both groups is conducted in person and in the same manner, 6 months after the intervention in the cardiology outpatient clinic, before the participants' regular appointment with their cardiologist. If a participant has not scheduled an appointment, a reminder call is made.

Intervention Type
Behavioural

Primary outcome(s)
Health-related quality of life (HRQoL) measured with the self-reported SF-36 questionnaire at baseline, before the intervention, and at the 6-month endpoint.

Key secondary outcome(s))
1. Health behavior outcomes: medication adherence is measured with the Medication Adherence Reasons Scale (MAR Scale), diet, physical activity and smoking cessation are measured using a self-report questionnaire developed for the study, at baseline and 6 months after the intervention.
2. Clinical parameters and somatometric outcomes: blood pressure, weight, waist circumference, LDL cholesterol are measured with standardized methods and equipment, at baseline and at the 6-month follow-up point.
3. Self-reported health beliefs are measured using the Multidimensional Health Control (MHLC) scale, at the 6-month follow-up point.

Completion date
07/03/2025

Eligibility

Key inclusion criteria
1. Patients older than 18 years (range 18-75 years)
2. Both sexes
3. With ACS undergoing treatment with percutaneous coronary intervention (PCI) and stent placement
4. Speak and write in Greek
5. Informed written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
122

Key exclusion criteria
1. Age over 75 years
2. History of psychiatric and cognitive disorders
3. Motor, visual and auditory disabilities
4. Substance abuse
5. Serious comorbidities such as heart failure or cancer with reduced life expectancy

Date of first enrolment
20/07/2022

Date of final enrolment
06/09/2024

Locations

Countries of recruitment
Greece

Study participating centre

University General Hospital of Larissa
Mezourlo Larissa
Larissa
Greece
41110

Sponsor information

Organisation
University of Thessaly

ROR
https://ror.org/04v4g9h31

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality and ethical restrictions regarding the participating patients. Access to the data will be available 1 year after the completion of the doctoral thesis and the publication of the results, upon reasonable request, from the principal investigator Anagnostopoulou Dimitra (danagnostop@uth.gr).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			01/09/2025	No	No