Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Acapella and Incentive Spirometry on Blood Gases and Peak Expiratory Flow Rate after Coronary Artery Bypass Graft: A Randomized Controlled Trial

Protocol summary

Study aim

1. To Evaluate the effect of incentive spirometry on Blood Gases and Peak Expiratory Flow Rate (PEFR) for patients after Coronary Artery Bypass Graft Surgery. 2. To Evaluate the effect of Acapella on Blood Gases and Peak Expiratory Flow Rate (PEFR) for patients after Coronary Artery Bypass Graft Surgery. 3. To compare the effect of incentive spirometry versus Acapella on Peak Expiratory Flow Rate (PEFR) and Blood Gases among patients with coronary artery bypass surgery.

Design

The study design in the present study was a randomized controlled trial (RCT), parallel, single blinded.

Settings and conduct

Surgical word and intensive care units of tow cardiac centrs in Iraq .Baghdad.Single blinded throughout the study

Participants/Inclusion and exclusion criteria

Inclusion Criteria: -A patient who is an adult admitted to the hospital for coronary artery bypass graft surgery after receiving a diagnosis of coronary artery disease. -Been between 33 years and 60 years old. -being open to taking part in the research and giving informed permission. Exclusion Criteria: -individuals having a body mass index (BMI) between 16 and 28 kg/m2. -patients who have asthma or COPD. -patients that need reintubation-patients who have history of respiratory tract infection.

Intervention groups

intervention group (A) will take Acapella for 10-15 minutes per session, two times per a day for 2 days before surgery and 3 days after CABG operation.Intervention group (B) will not be exposed to Acapella and take only Incentive Spirometry for 10-15 minutes per session, 2 times per a day for 2 days before surgery and three consecutive days after CABG Surgery.

Main outcome variables

Peak Expiratory Flow Rate (PEFR) Description: For improvement in expiratory airflow indicating lung function recovery Time Frame: as baseline one day before surgery (pre-intervention) and post intervention in three consecutive days after surgery.

General information

Reason for update

Acronym

A Randomized controlled trial (ARCT),Coronary Artery Bypass Graft (CABG).

IRCT registration information

IRCT registration number: **IRCT20251101067852N1**
Registration date: **2025-11-13, 1404/08/22**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-13, 1404/08/22**
Update count: **0**

Registration date

2025-11-13, 1404/08/22

Registrant information

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-11-10, 1404/08/19

Expected recruitment end date

2026-07-01, 1405/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Acapella and Incentive Spirometry on Blood Gases and Peak Expiratory Flow Rate after Coronary Artery Bypass Graft: A Randomized Controlled Trial

Public title

The Effect of Acapella and Incentive Spirometry on Blood Gases and Peak Expiratory Flow Rate after Coronary Artery Bypass Graft.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A patient who is an adult admitted to the hospital for coronary artery bypass graft surgery after receiving a diagnosis of coronary artery disease.-Been between 33 years and 60 years old.-being open to taking part in the research and giving informed permission.

Exclusion criteria:

-individuals having a body mass index (BMI) between 16 and 28 kg/m2. -patients who have asthma or COPD. patients that need reintubation. patients who have history of respiratory tract infection.

Age

From **33 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

A Randomized Controlled Trial. RCT is a quantitative, true experimental, and comparative study executed under controlled conditions, in which interventions are randomly allocated to different groups in order to minimize bias and determine a cause-effect relationship between an intervention and an outcome. the population was patients from two cardiac centers selected based on eligibility criteria the. This was achieved through a simple random sampling probability method using two cards. The white card represents the participant included in the study group, and the black card represents patients control the study sample. This method provides researchers with the opportunity to select participants for the study randomly and without bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person measuring blood gases

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethical Approval Committee

Street address

College of Nursing/University of Baghdad Bab Al Mua'adham-Baghdad-Iraq P.O.Box:(14149)

City

Baghdad

Postal code

(14149)

Approval date

2025-03-25, 1404/01/05

Ethics committee reference number

37

Health conditions studied

1

Description of health condition studied

patient undergoing Coronary Artery Bypass Graft Surgery

ICD-10 code

I25.10 + Z

ICD-10 code description

This code indicates chronic ischemic heart disease caused by atherosclerosis (plaque buildup) in one or more native coronary arteries.The patient does not experience angina pectoris (chest pain) at the time of diagnosis.

Primary outcomes

1

Description

Peak Expiratory Flow Rate (PEFR) For improvement in expiratory airflow indicating lung function recovery

Timepoint

as baseline one day before surgery (pre-intervention) and post intervention in three consecutive days after surgery.

Method of measurement

Peak flow meter

2

Description
Arterial Blood Gases (ABG) we see the change in Arterial Blood Gases value before and after intervention
Timepoint
as a baseline (pre-intervention) one day before surgery and three consecutive days after surgery and post-intervention.
Method of measurement
Blood Gas Analyzer

Secondary outcomes

1

Description
Peripheral Oxygen Saturation
Timepoint
as baseline one day before surgery (pre-intervention) and post intervention in three consecutive days after surgery.
Method of measurement
Pulse oximetey before and after breathing exercises

Intervention groups

1

Description
Intervention group: Acapella (oscilatory PEP) Experimental group will take Acapella for 10-15 minutes per session, two times per a day for 1 days before surgery and 3 days after CABG operation.
Category
Treatment - Devices

2

Description
Intervention group: Incentive Spirometry Experimental group will not be exposed to Acapella and take only Incentive Spirometry for 10-15 minutes per session, 2 times per a day for 1 days before surgery and three consecutive days after CABG Surgery.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Iraqi Center of Heart Disease, Baghdad,
Full name of responsible person
Bassima Amir Naji
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
College of Nursing /University of Baghdad
Full name of responsible person
Professor.Wissam Jabbar Qasim,PhD.Dean
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The authors of the trial are the funding source
Proportion provided by this source
100
Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

University of Baghdad/College of Nursing

Full name of responsible person

Bassima Amir Naji

Position

Lecturer

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The researcher is acknowledging the scientific community to have verifiable findings of the study. Sharing plan includes making all the related data available through publishing the study report in peer-reviewed reputable journals.

When the data will become available and for how long

once finishing the process of data collection, analysis, and successful publishing of the manuscript, all the related files will become available for 6 months after the publications, after you are approved to register on the Iranian clinical trials website

To whom data/document is available

All the related files will be shared with any scientific interested parties

Under which criteria data/document could be used

All the related files will be shared with any scientific

interested parties

From where data/document is obtainable

The author's professional e-mail that will be available with the published manuscipt can be used to contact the author.E-mail bassima.a@conursing.uobaghdad.edu.iq

What processes are involved for a request to access data/document

The processes involved in accessing this documentation are possible via email

:bassima.a@conursing.uobaghdad.edu.iq, the first and last name of authors, trial' title variable and the trial Id.

Comments

Profound appreciations are due to the IRCT members for their genuine efforts in helping researchers fulfilling their academic endeavors. The three groups were added individually in each field. We hope that the modifications will be appropriate to the design of the experiment. With many thanks and appreciation for your patience.