

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 ward and intensive care units of two cardiac centres 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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Name of organization / entity

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Recruitment status

Recruitment complete

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 oximetry before and after breathing exercises

Intervention groups

1

Description

Intervention group: Acapella (oscillatory 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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Full name of responsible person

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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
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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 manuscript 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.