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The effect of a dynamic overlay mattress on chest compression quality during cardiopulmonary resuscitation

Submission date	Recruitment status	[X] Prospectively registered
15/09/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/09/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/11/2021	Circulatory System	

Plain English summary of protocol

Background and study aims
Adult cardiac arrest both in- and out-of-hospital is common and associated with high mortality and morbidity. High-quality cardiopulmonary resuscitation (CPR) is important for patient survival and for a decent neurological outcome after a cardiac arrest. Therefore, It is important to identify factors that can affect CPR quality.

This study investigates the effect of a dynamic mattress overlay on the quality of cardiac massage during resuscitation as the certainty of the available evidence is still very low.

Who can participate?
Students enrolled in one of the nursing education programs (offered by the participating centres) who have completed basic CPR training and their first year of nursing education.

What does the study involve?
Students have to complete a 2-minute cardiac arrest CPR scenario on a manikin. For a random sample of half of the students, the manikin will be on a bed with a memory foam mattress alone, and for the other half, the manikin will be on a bed with a memory foam mattress and dynamic overlay mattress combination.

What are the possible benefits and risks of participating?
Participation in this study offers a chance to participate in the development of evidence-based nursing. No risks are anticipated.

Where is the study run from?
Odisee University College and TI Sint-Carolus (Belgium)

When is the study starting and how long is it expected to run for?
From September 2020 to November 2020

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Tim Torsy
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
BPWD1920

Study information

Scientific Title
The effect of a dynamic overlay mattress on chest compression quality during cardiopulmonary resuscitation: A randomised controlled trial

Study objectives
A dynamic overlay mattress has a negative impact on chest compression quality during CPR

Ethics approval required

Old ethics approval format

Ethics approval(s)
Following external advice, the approval of the study by a medical ethics review committee was waived as this is manikin-based simulation research.

Study design
Single-blinded, two-arm, parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Chest compression quality in patients who had a cardiac arrest

Interventions
In this manikin-based simulation study, participants (students from two nursing education programs) are going to be allocated to one arm of the two-arm parallel-group design using block randomisation. The students will be blinded to the allocation. Student body height (in cm), body weight (in kg) will be collected.

The students will be assessed for the quality of chest compressions during adult cardiopulmonary resuscitation (CPR), in a 2-minutes cardiac arrest CPR scenario, on either:
1. A manikin in bed on a memory foam mattress (control group)
2. A manikin in bed on a dynamic overlay mattress on top of a memory foam mattress (intervention group)

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CPR simulation feedback device

Primary outcome measure
1. Chest compression rate is measured in the total number of compressions per min using a feedback device

2. Sternum-to-spine chest compression depth is measured in mm using a feedback device
3. Hand positioning is measured in scores out of 100 using a feedback device

Secondary outcome measures
1. The predictive effect of body height (cm), body weight (kg), hand positioning (scores out of 100), and mattress type (dynamic overlay mattress or not) on depth and frequency of chest compressions measured using a feedback device

Overall study start date
01/09/2020

Completion date
30/11/2020

Eligibility

Key inclusion criteria
1. Enrolled as a student in one of the two selected nursing education programs
2. Aged ≥18 years
3. Successfully completed a basic CPR training
4. Successfully completed first year of nursing education

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Total final enrolment
70

Key exclusion criteria
Inability to use normal muscle strength in arms and trunk at the time of data collection due to an injury

Date of first enrolment
28/09/2020

Date of final enrolment
02/10/2020

Locations

Countries of recruitment
Belgium

Study participating centre
Odisee University College
Hospitaalstraat 23
Sint-Niklaas
Belgium
9100

Study participating centre
TI Sint-Carolus
Hospitaalstraat 23
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Sponsor information

Organisation
University College Odisee

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Sponsor type
University/education

Website
https://www.odisee.be/

ROR
https://ror.org/02c89h825

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/11/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available as an SPSS dataset at any time upon request from the researchers (Tim Torsy - tim.torsy@odisee.be). Datasets are anonymized, are not intended for IPD sharing and wil only made available based on a good, well-founded motivation. Datasets will only be made available until the next major update of the ERC guidelines for adult basic life support and automated external defibrillation.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		16/09/2020	08/10/2020	No	Yes
Results article		21/04/2021	08/11/2021	Yes	No