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Public title
Study of the public willingness to provide the necessary resuscitation in real situations of out of hospital cardiac arrest after receiving appropriate education and the possible factors that could affect their willingness.

Scientific title
Attitudes and Willingness of Laypersons Towards Applying Basic Life Support in Real Cardiac Arrest Situations: Prospective Observational Multi-Centre Study

Acronym
LayResus 2023

Protocol /serial number: LayResus 2023

Date Applied: 31/03/2023

Date Assigned: 17/04/2023

Last Edited: 31/03/2023

Overall, Trial Status: Ongoing

Recruitment status: Not yet recruiting

Study hypothesis
We hypothesize that the public in middle and low-income communities will demonstrate a lack of willingness to provide resuscitation in real Out Of Hospital Cardiac Arrest (OHCA) situations. We also hypothesize that their low willingness is due to factors possibly related to deficiencies in training, fear of causing harm to the victim, and lack of supportive laws to protect them.

Ethics approval
1.1. Complying with Guideline Principles: The LayResus 2023 Study will comply with the Guideline principles of the World Medical Association Declaration of Helsinki (revised October 2013).

1.2. Preparation and Revision of Documents and Consent Forms: The LayResus 2023 Study Research Office will be responsible for preparing the 'LayResus 2023 Study Information' document, as well as the 'Informed Consent' form for each participant. The local Ethics Committee of participating sites should approve revisions of each document.

1.3. Obtaining Permission at each Participating Site: Since LayResus 2023 Study will be conducted as a multi-center study, the Local Primary Investigator at each participating site will obtain ethical approval from the local Ethics Committee to conduct the Study according to local regulations. This process should take place before the initiation of the Study and in compliance with the applicable national regulatory requirement(s).

1.4. Protection of Personal Information: Participation in the study is voluntary. A written/ digital

online 'Informed Consent' will be obtained from each participant before inclusion in the Study. Data to be collected in the Study will be entered directly into a dedicated online Study database. At that time, a specific identification code will be created using a method that does not have the participant's ID record. No personally identifiable information or pseudonym will be entered into the Study database. Data extracted from the Study database, managed by the LayResus 2023 Study Research Office, will be stored in password-protected files and USB memory devices in the safekeeping of the Research Office. In principle, all persons involved in LayResus 2023 Study are obligated to maintain confidentiality. The scope of those who handle information and data is limited to the Local Primary Investigator at each participating site, and research Co-investigators within the same participating site. In the event of leakage or loss of personal information, local regulations have to be followed.

1.5. Burden and Potential Adverse Effects of Participation in the Study: This international multi-center cross-sectional questionnaire study will be performed without any burden to participants.

1.6. Contact Details of the Lead Ethics Committee: Human Resuscitation Organization:

Study design: This is a multi-center cross-sectional questionnaire-based study on laypersons.

Primary study design: Observational

Secondary study design: Cross sectional study

Study setting(s): Charity/Voluntary sector, Community

Trial type: Screening

Overall trial start date: 01/05/2023

Overall trial end date: 31/12/2023

Reason abandoned (if study stopped) Condition
Effective Basic Life Support (BLS) involving Cardiopulmonary Resuscitation (CPR) with Automated External Defibrillation (AED) doubles the survival from out-of-hospital cardiac arrest (OHCA).

Interventions
This is an observational international multi-center cross-sectional questionnaire study on laypersons, so no intervention will be made.

The Study questionnaire will be composed of five sections:
1.) Demographic information about the participants' age, gender, city and country of residence, level of education, occupation, and socio-economic status in the form of open-response questions.
2.) Level of participants' cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) knowledge utilising the 5 top messages on basic life support (BLS) according to the European Resuscitation Council (ERC) 2021 BLS guidelines. This will cover early signs of cardiac arrest, victim safety position, number to call the Emergency Medical Services (EMS), place of the palm on the victim's thorax, appropriate depth, chest compression rate, and the ratio of compression to rescue breaths, in the form multiple choice questions.
3.) Willingness of the participant to help in real-life out-of-hospital cardiac arrest (OHCA) situations, in the form of the 5-point Likert scale questions, on the following: (1) willingness to help in real-life OHCA situations, (b) participation in local/ national neighborhood resuscitation

response teams, (c) willingness to attend CPR training programs, (d) willingness of the inclusion in a national resuscitator registry, and (e) willingness to be part of the local/ national network of EMS as a first responder to OHCA.
4.) Possible barriers to attending CPR training and for applying resuscitation by the participant, and how it could be overcome, in the form of the closed set of questions.
5) Possible enablers that might help study participants attend CPR training in the form of a closed set of questions.
Open-response questions will be added as appropriate to allow participants to share their ideas/
concerns or suggestions. Cronbach's alpha will be used to measure the internal consistency of the knowledge section questions. A cumulative knowledge score will then be calculated by adding +1 for each correct answer or positive attitude/ willingness answer and a 0 for wrong, missing, or negative attitude/ willingness answer to the sum score which will be converted to a percentage of the expected total positive score. Continuous variables will be expressed in the form of mean ± standard deviation (SD) and will be preliminarily tested for normal distribution.
Categorical data will be reported as percent values, and univariate comparisons between different proportions will be evaluated through a Chi-squared test as a willingness to apply resuscitation with demographic data. Variables with p-value less than 0.05 are then included in a logistic regression model to determine the factors associated with willingness to apply resuscitation and the possible barriers. The results will then be expressed as multivariate Odds Ratio (mOR) and 95% confidence interval (CI). The significance level for all analyses will be set for $p < 0.05$.

Primary outcome measure

The primary outcome measure is laypersons' willingness to perform resuscitation in real cardiac arrest situations to further improve the outcome of out-of-hospital cardiac arrest (OHCA).

Secondary outcome measures

The secondary outcome measures are barriers and enablers that might hinder or improve the willingness of laypersons to apply their learned resuscitation skills after cardiopulmonary resuscitation (CPR) training.

Trial website: https://humansresus.org/training-%26-research

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Participant inclusion criteria

All laypersons of both genders, aged eighteen and above, who were educated on any kind of resuscitation training, either on cardiopulmonary resuscitation (CPR) or basic life support (BLS), within the last 2 years in the involved countries of Egypt, Libya, Sudan, and Tunisia.

Participant type: Healthy volunteer

Age group: Adult

Sex: Both

Target number of participants: 800

Total final enrolment: 800

Participant exclusion criteria:
1. All laypersons of both genders, who are younger than 18 years, and were educated on any kind of resuscitation training, either on cardiopulmonary resuscitation (CPR) or basic life support (BLS), within the last 2 years in the involved countries of Egypt, Libya, Sudan, and Tunisia
2. All healthcare professionals who were educated on any kind of resuscitation training, either on CPR or BLS, within the last 2 years in the involved countries of Egypt, Libya, Sudan, and Tunisia
3. Participants who have expressed their refusal to have their responses used in research

Recruitment start date: 01/05/2023

Recruitment end date: 31/12/2023

Recruitment status override

Countries of recruitment
Egypt, Sudan, Tunisia

Trial participating centers

Trial Centre Name: Human Resuscitation Council

Address: AlSteen St. AlRiyadh District
P.O. Box 7216
Sudanese Postal Service Co. Ltd. (SudaPost) Khartoum, Sudan

Trial Centre Name: Egyptian Resuscitation Council

Address: 170 Ahmed Shawki Street
Roushdy, Alexandria, Egypt

Trial Centre Name: Tunisian Resuscitation Council

Address: Service SAMU 03
CHU Sahloul
Sousse Jouahara, Sousse, Tunisia

Plain English Summary

Background and Study aims: Ischaemic heart disease resulting in sudden cardiac arrest is the leading cause of death worldwide. Early start of effective Basic Life Support (BLS) involving Cardiopulmonary Resuscitation (CPR) with Automated External Defibrillation (AED) doubles the survival from out-of-hospital cardiac arrest (OHCA). The 2021 Consensus of Science and Treatment Recommendation (CoSTR) of the International Liaison Committee on Resuscitation (ILCOR) and the 2021 guidelines of the European Resuscitation Council (ERC) stressed the important role of the trained bystanders or laypersons in initiating early CPR in OHCA situations. CPR should be started immediately in

any unresponsive person with absent or abnormal breathing. The implementation of frequent BLS training that enables as many people as possible to quickly identify OHCA, call for help, perform high-quality CPR and initiate early defibrillation is crucial for the improvement of OHCA survival. Training of laypersons on BLS is established in many countries using different training modalities. The different training modalities for laypersons have focused mainly on achieving the needed competency to perform resuscitation when required. The 2021 ERC guidelines on Education identified enhancing willingness to perform CPR by laypersons as one of five key points in resuscitation education for laypersons and first responders. Growing evidence shows that decreased willingness to start CPR by laypersons are an additional factor that hinders immediate resuscitation in OHCA situations. Some factors, such as the age and level of education of the laypersons, relationship with the cardiac arrest victim, and fear of causing more harm to the victim, were reported to alter the degree of willingness by laypersons to start resuscitation in OHCA situations. However, investigating the willingness to perform CPR in middle and low-resource settings hasn't been reported in the literature to date. The primary study aim is to investigate laypersons' willingness to perform resuscitation in real cardiac arrest situations to further improve the outcome of OHCA. The secondary study aims to build local scientific evidence on the possible reasons for the lack of willingness to perform resuscitation by laypersons which could be used to encourage local stakeholders and lawmakers to support resuscitation training and practice through community involvement in public well-being.

Who can participate? All laypersons of both genders, aged eighteen and above, who were educated on any kind of resuscitation training, either on CPR or BLS, within the last 2 years in the involved countries of Egypt, Libya, Sudan, and Tunisia can participate in the Study.

What does the study involve? This is an observational international multi-center cross-sectional questionnaire study on laypersons, so no intervention will be made.

What are the possible benefits and risks of participating? Participation in LayResus 2023 Study will provide insight into the layperson's willingness to provide resuscitation in real Out of Hospital Cardiac Arrest (OHCA) situations. Identifying the independent possible barriers and enablers that might hinder or improve the willingness of laypersons to apply their learned resuscitation skills after CPR training may be used to encourage local stakeholders and lawmakers to support resuscitation training and practice through community involvement in public wellbeing. This international multi-center cross-sectional questionnaire study will be performed without any burden to participants.

Where is the study run from? The Study will run from Khartoum (Sudan),

When is the study starting and how long is it expected to run for? The Study will start on the 01st of May 2023 and is expected to run for 6 months.

Who is funding the study? The Study will be self-financed by local study centers.

Who is the main contact? Prof. Ayman O. Nasr (email address: aomnasr@hotmail.com).

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

The Intention to publish date: 01/05/2024

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Funder(s)

Funder Name: Human Resuscitation Organization
Alternative Name(s) Funding Body Type Funding Body Subtype Location

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