

	HP2C	Version no.: 01.3
	Protocol	Date: 26 June 2021

**Comparison of two chest compression techniques on a training manikin: a pilot, single-centre, randomised cross-over study.
HP2C protocol**



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This protocol belongs to Angers University Hospital. It should be used only to conduct this study. The protocol should not be shared with any persons not involved with the study or for any other purpose without the prior written consent of Angers University Hospital.

(According to version 3 dated 12/16/2019 of the framework protocol of Angers University Hospital)

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List of abbreviations:

RNIPH: Research Not Involving Human Subjects (Recherche N’Impliquant pas la Personne Humaine)
CA: Cardiac arrest
CC: Chest compression
BPM: Beats per minute
CPR: Cardiopulmonary resuscitation
ILCOR: International Liaison Committee on Resuscitation
SAMU: Emergency Medical Service (Service d’Aide Médicale d’Urgence)
SMUR: Emergency and Intensive Care Mobile Services (Service Mobile d’Urgence et de Réanimation)
SDIS: French Departmental Fire and Rescue Service (Service Départemental d’Incendie et de Secours)
AFGSU: Certificate of Training in Emergency First-Aid (Attestation de Formation aux Gestes et Soins d’Urgence)
QCPR: Quality Cardiopulmonary Resuscitation
CPR: Cardiopulmonary Resuscitation
AHA: American Heart Association
HR: Heart rate
CESU: Centre for Emergency Care Teaching (Centre d’Enseignement des Soins d’Urgence)
CNIL: French National Data Protection Authority (Commission Nationale Informatique et Libertés)

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Comparison of two chest compression techniques on a training manikin: a pilot, single-centre, randomised cross-over study. HP2C protocol

SUMMARY

Study classification	Research Not Involving Human Subjects (RNIPH).
Context and scientific grounds for research:	<p>Cardiac arrest (CA) is a severe medical emergency. It is estimated that there are between 40,000 and 50,000 out-of-hospital cardiac arrests per year in France. Its very low survival rate of 4.6% to 8% justifies the rapid implementation of an improved chain of survival. Resuscitation techniques have continued to evolve, thus improving overall survival. Chest compressions (CC) are essential to maintain 25% to 30% normal cerebral perfusion. Optimising compression techniques is therefore essential and the positioning of the hands in relation to each other plays a role in their effectiveness. While it appears that interlocking hands play an important role in the effectiveness of these compressions (90% of compressions are within the recommended criteria), there is another hand position commonly used in practice.</p> <p>This pilot study will compare the overall effectiveness of these two methods according to the latest international recommendations and will evaluate the rescuer's fatigue when using each technique.</p>
Objectives and endpoints	<p>Primary objective:</p> <ul style="list-style-type: none"> - Compare the effectiveness of two chest compression techniques (overlapping or interlocking hands) on a <i>Laerdal Resusci Anne QCPR</i> (Laerdal Company, Stavanger, Norway) adult training manikin. <p>Primary endpoint:</p> <ul style="list-style-type: none"> - Overall score for successful chest compressions, according to the <i>International Liaison Committee on Resuscitation (ILCOR)</i> guidelines. This combined score is generated by the training manikin's software. <p>Secondary objectives:</p> <ol style="list-style-type: none"> 1 - Compare the quality of chest release between the two hand positioning techniques. 2 - Compare the quality of the chest compression between the two hand position techniques. 3 - Compare the chest compression depth

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	<p>between the two hand position techniques.</p> <p>4 - Compare the chest compressions at an appropriate rate between the two hand positioning techniques.</p> <p>5 - Compare the objective physical intensity of the effort exerted by the rescuer during the procedure.</p> <p>6 - Compare the subjective physical intensity perceived by the rescuer during the procedure.</p> <p>Secondary endpoints:</p> <p>1° - The chest relaxation quality score (expressed as a percentage) <i>and</i> automatically monitored on a tablet via the Laerdal QCPR Training app.</p> <p>2° - The chest compression quality score (expressed as a percentage) <i>and</i> automatically monitored on a tablet via the Laerdal QCPR Training app.</p> <p>3° - The average chest compression depth (in millimetres), automatically monitored on a tablet via the Laerdal QCPR Training app.</p> <p>4° - The chest compression score at an appropriate rate (between 100 and 120 per minute and expressed as a percentage), monitored on a tablet via the Laerdal QCPR Training app.</p> <p>5° - Maximum heart rate (HR) measured using a frontal pulse oximetry sensor.</p> <p>6° - Measuring the subjective intensity of the perceived exertion by the rescuer using the modified Borg scale.</p>
Study design and conduct	<p>Single-centre, randomised cross-over study.</p> <p>Eligible participants will be made aware of the study by advertising it in the participating hospital and rescue centres. Afterwards, a briefing will be organised at the work location with a PowerPoint document presented by the coordinating investigator. Afterwards, the participant will be contacted again to make an appointment with the coordinating investigator for performing the CC. The participant will be included in the study on arrival at the study centre and will be allocated the order of the CC sequences by randomisation (A then B or B then A, see flow chart in Appendix 1). They will start with the technique that was assigned to them first, for 2 minutes. A 10-minute wash-out period will be observed, which is required to physically recover before performing the second technique for 2 minutes.</p>

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Inclusion criteria	<ul style="list-style-type: none"> - Hospital carers (nursing assistants, paramedics, nurses, nurse anaesthetists) working in the adult emergency services, SAMU-SMUR49, adult anaesthesia and intensive care units, or professional and/or volunteer firefighters from the Maine-et-Loire Departmental Fire and Rescue Service (SDIS 49). - Adults (age ≥ 18 years). - Professionally active.
Exclusion criteria	<ul style="list-style-type: none"> - Professional who objects to the collection of data for the research or to participate in the study. - Caregivers or firefighters being treated with beta-blockers.
Data flow and collection	<p>The data is collected on an Ennov Clinical® electronic case report form. The data comes from measuring devices (Laerdal Resusci QCPR® manikin via the Laerdal QCPR Training® application, oximetry monitor) and the modified Borg rating scale. Data is collected in coded form. Study participants are identified by:</p> <ul style="list-style-type: none"> - Inclusion order number. - Sex. - Age. - Type of professional (nursing assistants, paramedics, nurses, nurse anaesthetists or firefighters). - Experience in years - Weight - Size - Resting HR
Number of people included in the study	<p>This is a pilot study. As we do not have estimates of the distribution of overall percentages of successful chest compressions for either technique, we will set a target of 100 subjects to be recruited over a four-month period.</p>
Study duration	<p>Duration of inclusion period: 4 months. Study participation duration for a participant: 30 minutes maximum.</p> <p>Total study duration: The total duration of the study including inclusion and</p>

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	participation is 4 months.
Expected outcomes and perspectives	<p>In addition to evaluating techniques, this research will allow all participants to benefit from training in chest compressions on a manikin.</p> <p>If we obtain positive results in favour of a genuine superiority of the interlocking hands technique (according to the 2015 international recommendations), this will still constitute a strong argument for standardising the teaching practices of the hand position technique within the first aid training centres.</p>

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APPENDIX 1: STUDY CONDUCT FLOW CHART 18

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1. Context and scientific grounds for research

1.1. Current state of knowledge

Cardiac arrest is a medical emergency caused by the sudden cessation of blood circulation and breathing. It is estimated that there are between 40,000 and 50,000 out-of-hospital cardiac arrests per year in France (1,2). Its very low survival rate of 4.6 to 8% justifies the rapid implementation of an improved chain of survival and total control of the links in the chain (3). In fact, since 1960, when basic cardiopulmonary resuscitation was first defined, resuscitation techniques have continued to evolve and thus improve overall survival (4). However, while these “basic-life-support (BLS)” techniques are very well codified, they are not implemented by witnesses often enough (32.5%) (3).

Performing chest compressions (CC) is fundamental and helps maintain 25-30% of normal cerebral perfusion (5,6). They can be performed by anyone, including older rescuers (7), which makes optimising the technique essential. The 2015 *European Resuscitation Council Guidelines for Resuscitation* (8) recommend a compression technique based on the following steps: 1: kneel down close to the victim; 2: place the palm of one hand on the centre of the sternum; 3: place the palm of the second hand on top of the previous one; 4: interlock the fingers of both hands and lift the fingers of the lower hand from the plane of the chest; 5: position yourself vertically above the chest and compress with your arms extended; 6: press the sternum about 5 cm deep and at a rate of 100-120 beats per minute (bpm). This technique is intended to be easy and understandable so everyone can learn it (9).

The inter-individual anatomical chest variation and the lack of effect of the change in compression point on haemodynamics and end-tidal CO₂ concentration (EtCO₂) make a small positional difference acceptable (10,11). The major prognostic element is therefore the mechanics of compression and more particularly the chest compression depth, the rate and the relaxation of the chest (12). The positioning of the hands in relation to each other and interlocking them, as recommended, most likely plays a key role in the depth of these compressions (8). Until recently, the first aid practice guidelines recommended an alternative hand positioning technique from the 2015 guidelines, i.e. hands overlapping each other but not interlocked. The withdrawal of this recommendation has simplified practices. However, these two techniques are still used in current practice but have never really been compared.

The aim of this pilot study is to compare the effectiveness of these two chest compression techniques on a low-fidelity simulator adult CPR manikin.

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1.2. Study hypotheses

The hypothesis of this study is that the recommended interlocking hand technique allows caregivers to achieve better efficiency than the overlapping hand technique.

2. Study objectives and endpoints

2.1. Primary objective and endpoint

Primary objective:

Compare the effectiveness of two chest compression techniques (overlapping or interlocking hands) on an adult training manikin.

Primary endpoint:

The overall score for successful chest compressions (expressed as a percentage), according to the *International Liaison Committee on Resuscitation (ILCOR)* guidelines. This score takes into account several parameters:

- 1 - The percentage of compressions at an appropriate depth.
- 2 - The percentage of fully released compressions.
- 3 - The appropriate chest compression rate percentage.

This score will be displayed automatically on a tablet via the *Laerdal QCPR Training®* app associated with the Laerdal Resusci ANNE QCPR® manikin.

As this study did not aim to assess the positioning of the hands on the chest, we chose to stick an adhesive marker on the chest of the manikin indicating the optimal topographic positioning of the hands.

2.2. Secondary objective(s) and endpoint(s)

Secondary objectives:

- 1- Compare the quality of chest release between the two CC techniques.
- 2- Compare the quality of chest compression between the two CC techniques.
- 3- Compare the depth (in mm) of chest compression between the two CC techniques.
- 4- Compare the percentage of chest compressions at an appropriate rate between the two hand positioning techniques.
- 5- Compare the objective physical intensity of the effort exerted by the rescuer during CPR between the two CC techniques.
- 6- Compare the subjective physical intensity perceived by the rescuer between the two CC techniques.

Secondary endpoints:

We chose to collect each CC success criterion independently according to the

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ILCOR recommendations. These scores will highlight the differences in the effectiveness of release, chest compression and CC rhythm between the two CC techniques.

1- The chest relaxation quality score (expressed as a percentage) evaluated *and* automatically monitored on a tablet via the Laerdal QCPR Training® app.

2- The chest compression quality score (expressed as a percentage) evaluated *and* automatically monitored on a tablet via the Laerdal QCPR Training® app.

3- The average chest compression measurement in millimetres (between 50 and 60 mm), automatically monitored on a tablet via the Laerdal QCPR Training® app.

4- The CC score at an appropriate rate (between 100 and 120/min) expressed as a percentage and monitored on a tablet via the Laerdal QCPR Training® app.

5- The objective physical intensity between the two hand positioning techniques per chest compression will be evaluated using rescuer physiological parameters. In this respect, the intensity of a physical activity is directly related to the heart rate (HR) of the person performing the physical effort (13). As cardiopulmonary resuscitation requires an intense physical effort, we will measure the maximum HR recorded during each CC round. We will use a Masimo Radical 7 Pulse CO-Oximeter® with a Masimo LNC TF-I® forehead sensor to effectively monitor the heart rate of each participant performing CC.

6- The subjective intensity of the perceived exertion by the rescuer will be measured using the modified Borg Rating of Perceived Exertion scale in the immediate post-exertion period (15 sec post-exertion) (14,15).

3. Study design

3.1. Study type

This is a single-centre, randomised, open-label, cross-over study conducted by the Centre for Emergency Care Teaching (CESU 49) of Angers University Hospital.

3.2. Justification of the number of people to be included in the study

This is a pilot study. As we do not have estimates of the distribution of overall percentages of successful chest compressions for either technique, we will set a target of 100 subjects to be recruited over a four-month period.

3.3. Randomisation

The order in which the two techniques are performed is defined by a balanced randomisation list (1:1 ratio). The patients were randomised by the Biostatistics and Methodology Department of Angers University Hospital.

Participants are randomised upon inclusion in the study by the investigator using the randomisation module in Ennov Clinical®.

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4. Screening of study participants

4.1. Inclusion criteria

- Hospital carers (nursing assistants, paramedics, nurses, nurse anaesthetists) working in the adult emergency services, SAMU-SMUR49, adult anaesthesia and intensive care units, or professional and/or volunteer firefighters from the Maine-et-Loire Departmental Fire and Rescue Service (SDIS 49).
- Adults (age ≥ 18 years).
- Professionally active.

4.2. Exclusion criteria

- Professional who objects to the collection of data for the research or to participate in the study.
- Caregivers or firefighters being treated with beta-blockers.

5. Study conduct / Data collection

5.1. Recruitment and inclusion procedure

Recruitment:

- The study will be advertised in the break rooms of the participating hospital and rescue centres.
- The coordinating investigator will then present the study using a PowerPoint during a meeting at their workplace. The coordinating investigator will be able to answer any questions participants may have. Following this meeting, a dedicated form will be used to collect personal information (surname, first name, e-mail address, telephone number), so that the volunteers can be contacted again.
- Afterwards, the coordinating investigator will contact the participant to make an appointment to perform the CC in the study. A confirmation email will be sent to the participant with the date, time and place of participation.
- For this study, the carers will come to the teaching centre (CESU 49) at Angers University Hospital where the manikin used for this study is located. In order to facilitate the participation of firefighters in this research, the investigator will be able to travel to the participating fire stations with the necessary equipment for the study.

Inclusion:

- The participant will be included in the study on arrival at the study centre.

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Randomisation:

- Before performing both compression techniques, the participant will be randomised after inclusion at the study centre.

Information to participants on the study conduct:

- The investigator will ensure that the hands are applied correctly to the chest (interlocking or overlapping hands) according to the technique allocated by the randomisation.

Information to participants on the equipment used:

- The modified Borg scale will be explained and described before each subject participates. It will be printed in colour and displayed on the floor near the resuscitation manikin in full view of the rescuer as they perform the CC round so that they can correlate their perceived effort and the corresponding figure. The investigator will speak to the participant to collect the data (modified Borg scale figure) for a maximum of 15 seconds after each round.
- The Laerdal Resusci Anne QCPR manikin will be shown to each participant before the start of the compressions, as well as the means of data collection via the tablet and the app.
- The participants will also be shown the pulse oximetry monitor as well as forehead sensor and how it is set up.

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Flow chart illustrating the timeline: (see chart in Appendix 1).

For each rescuer, the procedure will be as follows:

- Placement of the forehead oximetry sensor for recording HR during the procedure.
- Chest compressions with the first technique allocated for 2 minutes uninterrupted.
 - o At the same time, the rescuer's HR is continuously recorded using a forehead oximetry monitor (collection of max HR during exertion).
 - o Collection of the overall chest compression score, the % compression and release efficiency scores, the average depth in mm and the average rate at the end of the CC session. All this data on the Laerdal manikin.
 - o Self-assessment of the intensity of the exertion using the modified Borg scale.
- Ten-minute break with data collection in the first minute:
- Chest compressions using the second technique. For 2 minutes uninterrupted.
 - o At the same time, the rescuer's HR is continuously recorded using a forehead oximetry monitor (collection of max HR during exertion).
 - o Collection of the overall chest compression score, the % compression and release efficiency scores, the average depth in mm and the average rate at the end of the CC round. All this data on the Laerdal manikin.
 - o Self-assessment of the intensity of the exertion using the modified Borg scale.
- End of study for the rescuer with data collection in the first minute.

5.2. List of data collected

The data collected is as follows:

- Sex, age, type of professional (nursing assistants, paramedics, nurses, nurse anaesthetists or firefighters), years of experience, weight, height and resting HR.
- The following are collected at the end of the round for each technique:
 - o The overall CPR score (expressed as a percentage).
 - o The chest compression quality score (expressed as a percentage).
 - o The measurement of the average chest compression during CC (in millimetres).
 - o The CC score at an appropriate rate (between 100 and 120/min).
 - o The chest relaxation quality score (expressed as a percentage).
 - o Maximum HR of the rescuer.
 - o The modified Borg scale score.

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5.3. Study duration

Duration of inclusion period: 4 months.

Study participation duration for a participant: 30 minutes maximum.

Total study duration (inclusion time + follow-up time): 4 months.

6. Statistics

Qualitative data will be described in numbers, percentages and 95% confidence intervals. Quantitative data will be described as means and standard deviations (or medians and interquartile ranges if necessary).

The means of the following variables correspond to the primary and secondary endpoints, namely:

- the overall percentage of successful chest compressions,
- the percentage of chest compressions with appropriate chest compression quality,
- the average chest compression depth,
- the percentage of chest compressions at an appropriate rate,
- the percentage of chest compressions with appropriate chest release quality,
- the maximum heart rate recorded during the procedure.
- the subjective intensity of exertion score measured using the modified Borg scale.

They will be compared between each technique using the paired sample t-test (or Wilcoxon test if necessary).

For the primary and secondary endpoints, the “order” effect of the techniques will be studied as well as the possible

“order x technique” interaction to take into account the design of the cross-over study. If there is a significant “order x technique” interaction for one of the criteria, we will compare the two techniques for this criterion on the data of the technique allocated first.

The significance threshold of the tests is set at 5%.

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7. Data management

7.1. Data collection methods

All the data collected for conducting the research is then entered by the coordinating investigator into an Ennov Clinical® electronic case report form set up by the data management unit of Angers University Hospital.

7.2. Data circuit and confidentiality

Individuals who have direct access to the data take all the necessary precautions to ensure the confidentiality of information relating to study participants, and particularly their identity and health data. These individuals are bound by professional confidentiality (according to the terms defined by Articles 226-13 and 226-14 of the French Penal Code).

Data is collected in coded form. Study participants are identified by a number made up of the centre number and their inclusion order number used at the centre. Only the first letters of the study participant's name and last name are collected, along with the month and year of their birth.

The coordinating investigator is responsible for keeping a mailing list. This list is kept for the prescribed duration for this type of study.

7.3. Right to access data and source documents In Accordance with Good Clinical Practice:

- the sponsor ensures that each study participant gives their written consent to access to their personal data, which is strictly necessary for quality control purposes.
- investigators ensure that the documents and individual data strictly necessary for this control are available to the individuals responsible for follow-up, quality control, study auditing and, where necessary, inspections by relevant authorities.

7.4. Archiving

The investigator and the sponsor ensure that study documents and data are stored in accordance with current regulations. The methods used to store these essential documents must ensure that the documents remain complete and legible for the entire period for which their storage is required.

The investigator is responsible for the storage of key study documents at the study site. If the investigator leaves the institution, they must inform the sponsor and delegate responsible for the continuity of written records.

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8. Ethical considerations and regulations

8.1. Study classification

This is a practice evaluation study on chest compressions in adults that does not involve human subjects.

8.2. Ethics committee

This study does not require the opinion of an Institutional Review Board but the study protocol was submitted to and validated by the Ethics Committee of Angers University Hospital on 7 July, 2021 under the registration number 2021-138 before selecting the eligible patients for this study and starting the data collection and sample analysis.

8.3. Processing of personal data

Data processing for this study will be recorded in the register of processing activities in accordance with the provisions of the French Data Protection Act (Law No. 78-17), as amended, of 6 January, 1978 and the EU general data protection regulation (GDPR).

9. Regulations relating to publication

The papers and scientific reports corresponding to this study will be drafted under the responsibility of the study's coordinating investigator, together with the chief co-investigators and associated scientists. The co-authors of the report and publications are the investigators and clinicians involved, on a pro-rata basis according to their contribution to the study, as well as the methodologist and/or biostatistician and associated researchers.

The main findings of the study are to be published in a separate publication. Unless specifically authorised, no study phases may be the subject of an oral presentation or poster before the corresponding manuscript is accepted by a referenced journal.

Angers University Hospital is mentioned in all publications regarding this study.

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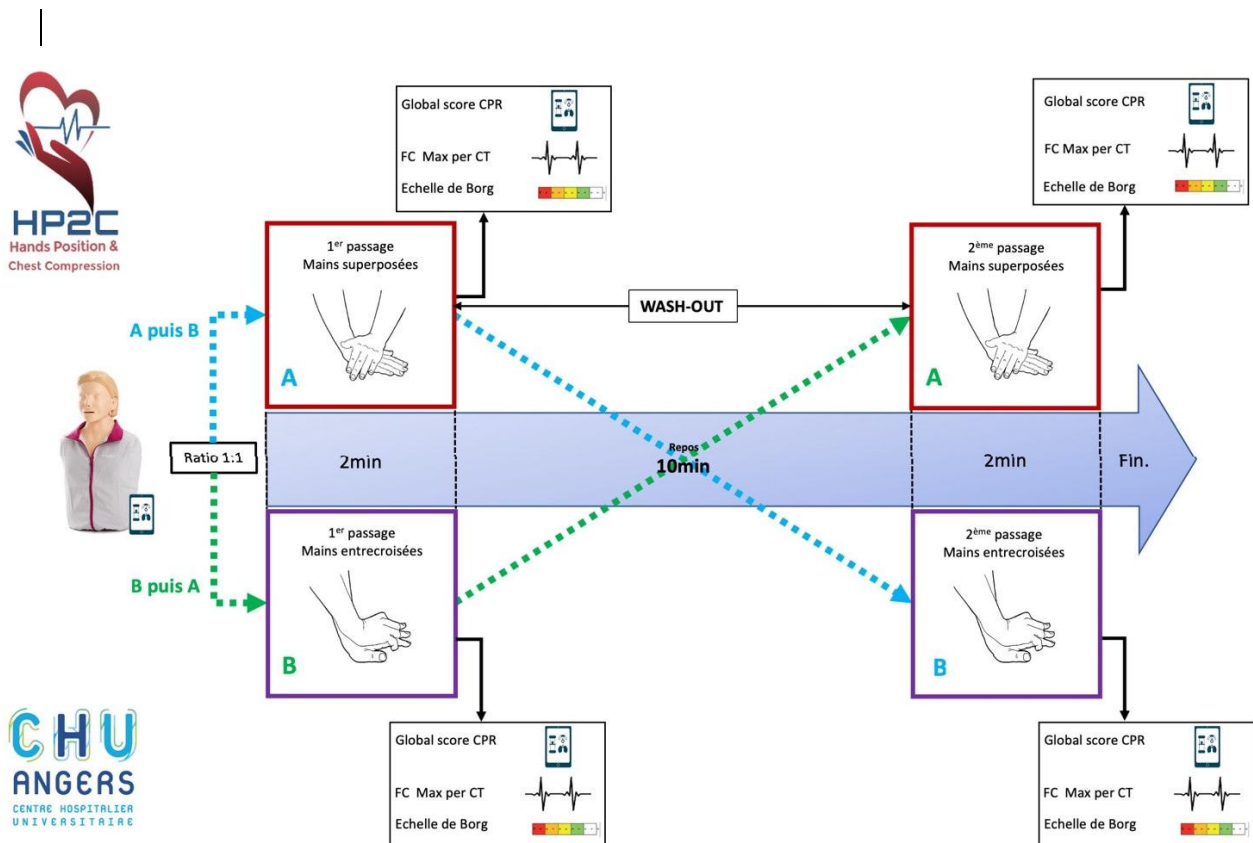
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11. Liste des annexes

Annexe 1 : schématisation du déroulé de l'étude



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Annexe 2 : échelle de Borg de perception de l'intensité d'un effort physique

Échelle de perception de l'effort (Échelle de Borg modifiée)

	0. Aucun effort	Je dors
	1. Très très facile	Je regarde la TV en mangeant des chips
	2. Très facile	Je suis bien et je peux maintenir ce rythme toute la journée
	3. Facile	Je suis toujours bien mais je respire un peu plus difficilement
	4. Effort modéré	Je transpire un peu mais je me sens bien et je peux tenir une conversation sans problème
	5. Moyen	Légèrement fatigant, je transpire un peu plus mais je peux toujours parler facilement
	6. Un peu difficile	Je peux toujours parler mais je suis un peu essoufflé et j'ai du mal à finir mes phrases. Je transpire vraiment.
	7. Difficile	Je peux toujours parler mais je n'en ai pas envie et je transpire abondamment.
	8. Très difficile	Je peux grogner pour répondre aux questions et je ne peux tenir ce rythme que pour une courte période
	9. Très très difficile	Je vais probablement tomber d'épuisement bientôt !
	10. Maximal	Je suis tombé !!!