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# Effectiveness of Innovation Basic Life Support Training Devices to Layperson: A Randomized Controlled Trial

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## Abstract:

**Objectives:** The use of a cardiopulmonary resuscitation feedback device and automated external defibrillator trainer is beneficial in basic life support (BLS) training. Nevertheless, Thailand lacks these devices in BLS support training. This study aimed to compare the efficacy of the Chiang Mai BLS training devices with conventional training devices in BLS training for laypeople.

**Material and Methods:** A randomized controlled trial was conducted to compare the efficacy of the Chiang Mai device group with the conventional device group, by assessing the theory and practical examination scores of the participants; who were adult, laypeople attending the BLS provider course endorsed by the Thai Resuscitation Council. Evaluating instructors were blinded from both groups of participants.

**Results:** A total of 60 adult, laypeople participants were divided into two groups: 32 and 28 participants of the Chiang Mai device group and conventional device group, respectively. Overall examination scores of included participants were very high. The participants in the Chiang Mai device group had a higher median score of multiple-choice question assessment [9.0/9.0 (8.5-9.0) vs 8.5/9.0 (8.0-9.0) points, p-value=0.134] as well as a higher median score of practical examination [26.0/26.0 (24.3-26.0) vs 25.0/26.0 (24.0-26.0) points, p-value=0.278] when compared to those using conventional BLS training devices. However, there was no statistical significance between both groups.

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**Conclusion:** The effectiveness of the Chiang Mai BLS training device in basic life support training for adult laypeople is comparable to conventional BLS training devices.

**Keywords:** automated external defibrillator, basic life support, cardiopulmonary resuscitation, innovation, training

## Introduction

Sudden cardiac arrest is a severe condition, causing out-of-hospital deaths internationally. In the United States, only ten percent of cardiac arrest patients who receive resuscitation survive hospital discharge.[1] Basic life support (BLS) consists of cardiopulmonary resuscitation (CPR), with the use of automated external defibrillators (AEDs) as the standard of care. The chain of survival is the currently accepted life support system for patients suffering from sudden out-of-hospital cardiac arrest; the first three links signify the detection of cardiac arrest and early initiation of BLS by bystanders; therefore, laypeople should know BLS.[1–5] In Asia, 60.6% of the reported 66,786 non-traumatic out-of-hospital cardiac arrests in adults are due to presumed cardiac etiology, as according to data collected in seven Asian countries including Thailand, by the Pan Asian Resuscitation Outcomes Study (PAROS).[6] In addition, ischemic heart disease and stroke have always been the leading causes of death in Thailand.[7] The survival rate of out-of-hospital cardiac arrest in Thailand is only 2.0-10.0%[8] when compared to 7.4-27.0% for in-hospital cardiac arrest patients.[9] Moreover, previous studies reported six factors associated with sustained Return of Spontaneous Circulation in emergency departments after CPR. These included: event location, cause of cardiac arrest, initial cardiac rhythm, defibrillated shockable rhythm, time spent till chest compression, and CPR quality and duration.[10] Even though over 5.4 million people have been trained in cardiopulmonary resuscitation around the world[11], there is no information on the number of trained laypeople in Thailand. Many public health projects are being organized with the goal of teaching at least 10 million individuals life-saving CPR skills by 2023.[12] In 2015 the Royal Thai Government Gazette stated that the use of AEDs was a part of first aid; thereby, increasing awareness of the importance of BLS training within the general population.[13] Educating laypeople in BLS significantly improved survival rates, and reduced morbidity in patients with out-of-hospital sudden cardiac arrest.[2,14–16] However many resources for the training CPR in Thailand are limited.

An effective model in BLS teaching consists of hands-on training, using CPR quality feedback devices, and AED training to develop both trainee skills and confidence; even though laypeople can use AED without any prior training.[14] Studies have shown that CPR quality feedback devices improved skills in performing rescue breathing as well as chest compressions; furthermore, feedback devices have been found to improve assessment accuracy compared to assessments scored solely by instructors.[14,17–23] Additionally, AED training devices increased skills, short term retention of CPR skills, confidence, and safety in trainees.[14,24–27]

Life support training devices with feedback on CPR quality and AED trainers are of limited availability in Thailand, as such devices need to be imported; and thus costly. This poses obstacles and limitations in implementing training sessions aimed to increase certified laypeoplersons in addition to improving the quality of BLS training. Moreover, conventional feedback devices display only certain aspects of effective life support, and lack a system that ties in CPR quality feedback with the AED trainer; complicating the use for the instructor. The

Faculty of Medicine and Faculty of Engineering, Chiang Mai University, cooperated in developing a life support trainer device. This consisted of a visual feedback device on CPR quality incorporated into manikin itself, and an AED trainer with a program controlling and linking the devices wirelessly.[28] The aims were to develop the device so that it could display feedback on multiple facets of BLS; more than what current devices are able to give feedback on, and at lower production costs. A pilot study, testing the efficacy of the trainer device conducted in BLS training for first-year medical students, found that the effectiveness of the BLS training device was comparable to conventional training devices.[29] However, the goal of developing this BLS training device was for use in training laypeople; thus, further studies in laypeople training were conducted. This study aimed to compare the efficacy of new BLS training devices with conventional training devices in BLS training for laypeople.

## Material and Methods

A randomized controlled trial was conducted to study the efficacy of BLS training using a Chiang Mai training device compared to the conventional training device. We randomly assigned participants, with a computer-generated number, into blocks of four. The student then selected numbers 1 or 2 in a sealed envelope: 1) the intervention group, would be trained using the Chiang Mai BLS training device (Chiang Mai device group), and 2) the control group, would be trained using the conventional BLS training device (conventional device group). Participants were allocated based on the sequence of consent forms submitted. Examiners were blinded from the participants, and from the device group that participants were allocated into. The participants then underwent an examination using another AED trainner that was not used for the training part. Due to the difference appearances of the AED training devices, we could not conceal these from the trainer or instructor. The study protocol was approved by the Research Ethics Committee, Faculty of Medicine, Chiang Mai University (Study Code: 481/2016).

This study used BLS training designed for laypeople, following the standards set by the Thai Resuscitation Council (TRC); under The Heart Association of Thailand under the Royal Patronage H.M. The King, and the American Heart Association (AHA), which comprised of both theory and hands-on training. Instructors and examiners were certified by the TRC. All instructors had an identical instructor manual, and were expected to teach following the manual. The BLS training conducted by this study was held on 16 September 2017, with a total of two sessions; composing of a 1-hour lecture and a 3-hour skill practicing class. The researchers did not participate as instructors or examiners in this study. All participants were evaluated for BLS competency at the end of the course training.

The Chiang Mai BLS training equipment set consists of a Chiang Mai CPR feedback device incorporated into a CPR manikin, Ambu SAM®; a Chiang Mai Thai-language AED trainer device; and a program controlling and providing feedback on the quality of CPR and AED use; as shown in Figure 1, and demonstrated on the video at https://youtu.be/w0KG5T1329E.[28] The training equipment has a unique feature that allows it to automatically activate when used with an AED, and has prompt reporting of CPR quality. Moreover, this device was previously validated in other studies.[29–31] The quality of CPR was focused on 5 aspects; including: 1) a depth of chest compression of more than 5 cm 2) frequency of chest compressions between 100-120 times per min 3) full chest recoil 4) minimizing chest compression interruption 5) correct breathing assistance. The conventional device group used the CPR manikin Laerdal Little Anne in conjunction with the feedback device, Laerdal CPRmeter®, and the Thai-language version of the Zoll AED trainer. The set of devices used for examination consisted of the CPR manikin Laerdal Little Anne, and the Thai-language version of the AED trainer Heartsine®; wherein, the examiners would also score the effectiveness of the training. Primary endpoints included theory and practical examination scores; secondary endpoints included examination results of CPR theory, CPR practice, AED usage theory, and AED usage practice. Results would be analyzed using intention-to-treat analysis.

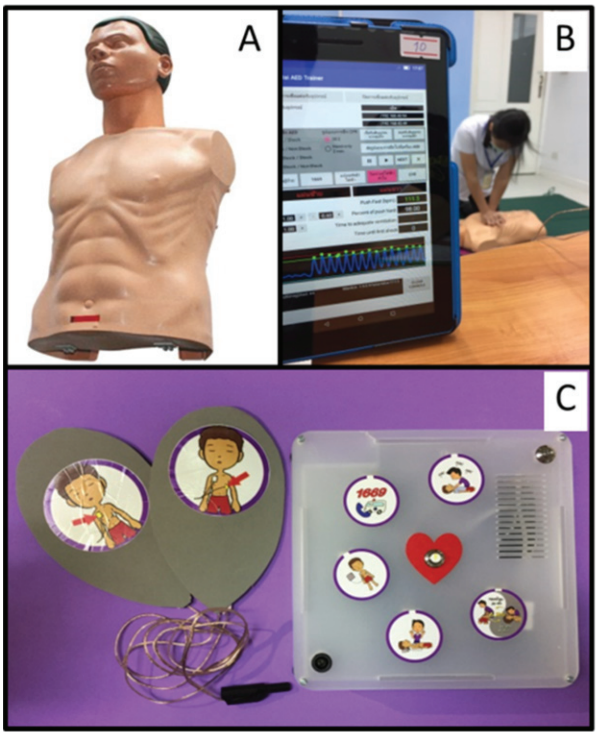



**Figure 1** Chiang Mai basic life support training device set
(A) Manikin for basic life support, consisting of chest compression, maintaining an open airway, and rescue breathing. This manikin is the Ambu SAM model, fitted with a CPR feedback device internally.
(B) Program controlling and showing feedback on CPR quality and AED use
(C) Chiang Mai AED trainer, Thai-language model

The sample population was laypeople, not health care professionals, with an interest in learning BLS, who paid to participate in the BLS training course by themselves. The inclusion criteria were participants aged 18 and above, and consented to be part of the study. The exclusion criteria were participants unable to communicate in Thai; either by listening or reading, participants with a physical illness which may pose an obstacle in learning BLS; such as, visual or auditory problems, conditions preventing exertion of the arms and wrist, and uncontrolled underlying medical conditions; such as, severe asthma or cardiac conditions; and participants with previous BLS or AED training, or prior experience in performing BLS on real patients.

General sample population demographic data collected included: gender, age, level of education, underlying medical conditions, previous experience in BLS training, and previous experience in performing BLS on real patients. Next, participants were allocated into the two groups as mentioned in the study methods. After training was completed, both groups would undergo an examination to be certified BLS providers, according to TRC standards, consisting of a theory exam and a practical exam. The theory exam had 20 questions, each question being worth 1.0 point; wherein, the minimum passing level is 16.0 points (80.0%). Nine questions were selected and used in this study: 5 questions on CPR and 4 questions on AED use. The practical examination had 20 items, each item with 3 levels of evaluation: "correctly performed", "incorrectly performed" and "not performed"; wherein, the passing requirement was the overall performance evaluation, as marked by the examiner. This study utilized 13 items, consisting of 7 items on CPR and 6 items on AED use; wherein, items marked as "correctly performed" were given 2.0 points, "incorrectly performed" 1.0 point, and "not performed" 0 points. Thus, the practical examination had a total score of 26.0 points. Scores would be used to compare the efficacy of the two device groups, as numeric scores can demonstrate more accurate results and statistical analyses compared to using pass or fail scores.

The sample size was calculated using the formula for testing two independent means.[32,33] Using an alpha error of 0.05, beta error of 0.2, expected difference between means of 2.5, and standard deviation of 3.3[29], a sample size of 28 was calculated per group (56 in total). With a 20 percent sample size for missing and incomplete data, the total sample size for this study was 70. As a protocol for BLS training by the TRC, the researchers allocated 6 participants to 1 instructor and 1 set of training equipment. Consequently, this study included participants of up to 72, with 36 in each group.

Demographic data and examination results of the sample population were demonstrated using descriptive statistics as percentages, averages, medians, and interquartile based on data distribution. Pearson chi-square and independent-samples T-test were used to compare demographic data between the two groups; wherein, statistical significance was defined at p-value<0.050. Independent-samples Mann-Whitney U test was used to analyze the efficacy of BLS training; wherein, statistical significance was defined as p-value<0.050. All analyses were performed using SPSS Statistics software version 23.0.

## Results

A total of 240 laypeople participated in this BLS training session; 42 were excluded from the study due to having previous training in BLS or AED use, and 12 were excluded due to having previous experience in performing in BLS in a real situation. The sample population was then selected by the sequence of registration and consent forms handed in, until a total number of 72 participants were reached. After training was complete, two participants were less than 18 years of age, and results from ten participants were missing. Hence, a sample size of 60 participants was used in the analysis: 32 participants in the Chiang Mai device group and 28 participants in the conventional device group. As shown in Figure 2, statistical analysis was conducted using per-protocol analysis rather than intention-to-treat analysis as specified in the methodology, due to the presence of missing data. This included examination scores of varying numerical values, which may have skewed the results, and would be difficult to analyze using intention-to-treat analysis. Regarding demographics, there were more male participants allocated to the Chiang Mai device group compared to the conventional device group; however, other demographic characteristics did not differ between the two groups; as shown in Table 1.

Participants in both groups passed the examination with very good scores, consequently results from both groups did not have normal distributions. Thus, median values were used to show data results. Statistical analysis, using independent-samples Mann-Whitney U test, found that examination scores of the Chiang Mai device group did not differ from the conventional device group. The primary endpoint results show that out of the total 9.0 points for the theory exam, the median scores of the Chiang Mai device group and conventional device group were 9.0 vs 8.5 points, respectively (p-value=0.134), and that out of the total 26.0 points for the practical exam, the median scores of the Chiang Mai device group and conventional device group were 26.0 vs 25.0 points, respectively (p-value=0.278). The primary and secondary endpoint measures are shown in Table 2.

**Table 1** Sample population demographic characteristics

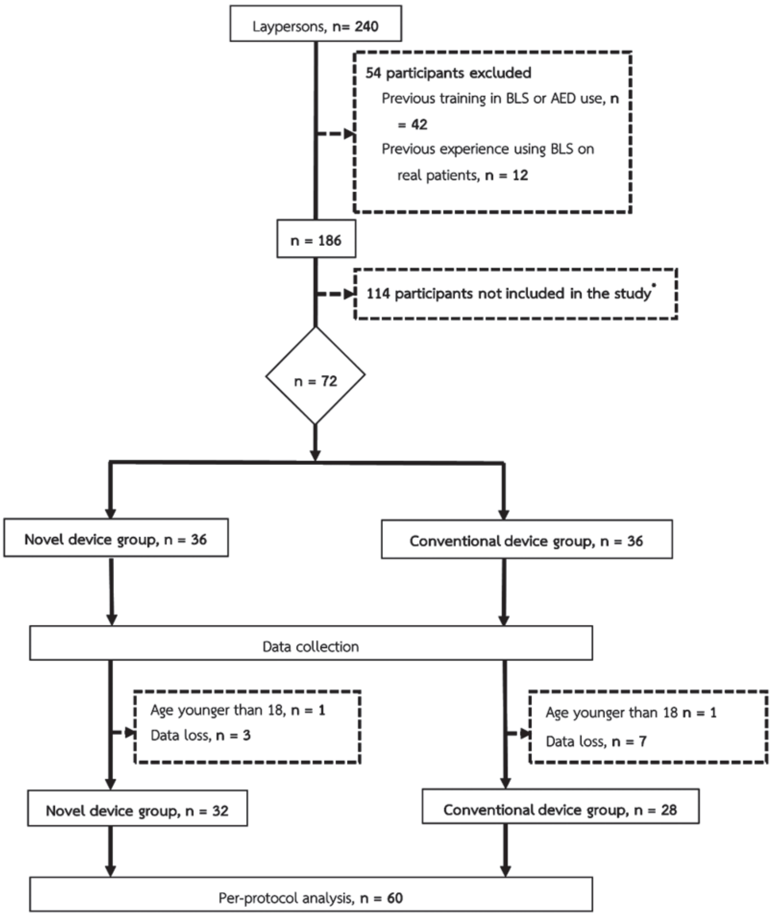
| Demographic parameters | Novel device group (n=32) | Conventional device group (n=28) | p-value |
|---|---|---|---|
| Male (percentage) | 20 (74.1) | 7 (25.9) | <0.004[c] |
| Age[a]; mean number of years (S.D.) | 28 (2.2) | 33 (2.4) | 0.111[d] |
| Level of education | | | 0.725[d] |
| Secondary school | 4 (26.7) | 5 (29.4) | |
| Bachelor's degree | 8 (53.3) | 7 (41.2) | |
| Master's degree | 3 (20.0) | 3 (17.6) | |
| Doctorate | 0 (0.0) | 1 (5.9) | |
| Others | 0 (0.0) | 1 (5.9) | |
| No underlying medical condition (percentage) | 32 (100) | 28 (100) | - |
| No prior BLS training (percentage) | 32 (100) | 28 (100) | - |
| No prior experience in performing BLS in real situations (percentage) | 32 (100) | 28 (100) | - |

Novel device group: group trained using the novel set of basic life support training equipment; conventional device group: group trained using the conventional set of life support training equipmen
n=number of participants (persons), BLS=basic life support
[a]Missing data on participants age in the novel device group and the conventional device group of participants 18 and 11, respectively;
[b]Missing data on the level of education in the novel device group and the conventional device group of participants 17 and 11, respectively
[c]Pearson chi-square: p-value<0.050
[d]Independent-samples T-test: p-value<0.050

**Table 2** Median (IQR) scores of participant groups

| Module | Novel device group (n=32) | Conventional device group (n=28) | p-value* |
|---|---|---|---|
| Primary endpoints: | | | |
| Theory examination (Total of 9.0 points) | 9.0 (8.0, 9.0) | 8.5 (8.0, 9.0) | 0.134 |
| Practical examination (Total of 26.0 points) | 26.0 (24.3, 26.0) | 25.0 (24.0, 26.0) | 0.278 |
| Secondary endpoints: | | | |
| Theory examination on CPR (Total of 5.0 points) | 5.0 (5.0, 5.0) | 5.0 (4.0, 5.0) | 0.046 |
| Theory examination on AEDs (Total of 4.0 points) | 4.0 (4.0, 4.0) | 4.0 (4.0, 4.0) | 0.831 |
| Practical examination on CPR (Total of 14.0 points) | 14.0 (14.0, 14.0) | 14.0 (13.0, 14.0) | 0.482 |
| Practical examination on AEDs (Total of 12.0 points) | 12.0 (11.0, 12.0) | 11.5 (10.3, 12.0) | 0.162 |

Novel device group: group trained using the novel set of basic life support training equipment; conventional device group, group trained using the conventional set of basic life support training equipment:
IQR=interquatile range, n=number of participants (persons), CPR=cardiopulmonary resuscitation, AED=automated external defibrillator
*Independent-samples Mann-Whitney U test: p-value<0.050




n=number of sample population (persons), AED=automated external defibrillator
Chiang Mai device group: group which trained using the Chiang Mai set of basic life support training equipment; conventional group, group which trained using the conventional set of basic life support training equipment

**Figure 2** Study flow chart

## Discussion

This study aimed to examine the efficacy of the Chiang Mai BLS trainer device in laypeople and to expand on the results from the previous pilot study conducted in the first-year medical students.[29] The sample population in this study was found to be able to represent the general population. Moreover, the number of participants in the study exceeded that of the initial calculated sample size; thereby, increasing the power of the test of this study. From the demographic data, we found that the Chiang Mai device group had a statistically significantly higher number of male participants compared to the conventional device group, which may affect CPR. The previous study shows that the percentage of correct chest compressions is higher in males, but the percentage of full recoil is higher in females[34]; therefore, the evidence on the effect of gender on overall quality of CPR is inconclusive.

Participants of both groups passed both the theory and practical exams, so statistical analyses on efficacy comparisons between the two groups, using examination scores, were carried out as outlined in the methodology. Examination scores of both types of exams in the Chiang Mai device group were found to not differ from the conventional device group. This finding was in line with the researchers' initial hypothesis, as both groups received standardized training from certified instructors, and BLS training equipment sets used by both study groups have similar operating systems as well as basic characteristics; although there are differences in the external appearance and method of use.

The training results of CPR, in both the theory and practical sessions, of the two study groups were found to be very good. These results agreed with studies by Wee et al. and Lynch et al., which found that training equipment with audiovisual feedback on the quality of CPR was able to improve the quality of CPR in training.[19,22] Furthermore, a randomized clinical trial by Cheng et al., found that devices with visual feedback on CPR quality[20]; either real-time or one where participants were able to see visual feedback at intervals, improved the quality of CPR.

Practical examinations using AED Heartsine® were not analyzed in this study to reduce bias, and to ensure that participants have the confidence to use other AED models; even after training. Our study found that practical examination scores on AED use in both study groups were very good. A study by Younas et al. reported concordant results; participants who received AED training were able to use the AED correctly with more confidence and safety compared to those who did not receive training, despite being able to use the AED correctly.[15]

The researchers hope to develop this Chiang Mai device as an innovation of Thailand; thereby, reducing production costs: one of the main obstacles in BLS training in Thailand. International AED trainers and basic manikins cost about 2,000 USD; whereas, the prototype Chiang Mai device costs 120 USD for production; which would be cheaper when manufacturing as an industrial product. Thus, further research needs to be conducted on the efficacy of the other modalities of the device; such as, utilizing the Chiang Mai device in evaluations to help elevate the assessment standards and ensure improved accuracy; student and instructor satisfaction; evaluating the cost-effectiveness of the device, and testing the efficacy in advanced life support training for health care providers in the future.

Firstly, practical examination passing requirements utilized evaluations solely from examiners, which may result in some personal bias. A study by Lynch et al. found that using CPR quality feedback devices to aid evaluations can augment student assessment accuracy compared to subjective assessments made by examiners alone.[22] Secondly, this study only looked into short-term results after training, and lacks data on long-term retention after training. Thirdly, both the multiple choice question examination and the checklist were derived from the TRC standard examination; therefore, the test reliability and validity were not measured. Fourthly, we did not collect anthropometric variables that may affect the quality of CPR.[34] Lastly, while this study aimed to examine the efficacy of devices in BLS training, the Chiang Mai BLS training device was created with the following aims: improving and advancing training devices; demonstrating the efficacy in other modes of training; such as, accuracy in electrical pad placement and time intervals in successful decisions to use the AED in addition to increasing ease of use for both students and instructors.

## Conclusion

This training devices effect outcome of learning was the as same as a conventional CPR device. The effectiveness of the Chiang Mai training device in BLS training is comparable to conventional training devices in laypeople.

## Conflict of interest

The research team received funding solely from the Faculty of Medicine, Chiang Mai University. This novel training device is still in its improvement and development stages and has not as of yet been sold.

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