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# Effect of a Real-Time Feedback Smartphone Application (TCPRLink) on the Quality of Layperson Telephone-assisted CPR Performance

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#### Abstract

**Objectives:** To determine the effect of a free smartphone application (TCPRLink) which provides real-time monitoring and audio-visual feedback on chest compressions (CCs) on layperson telephone-assisted CPR (T-CPR) performance.

Design: A manikin-based randomized experimental study.

**Setting:** This study was conducted at a comprehensive university and a community center in China.

**Participants:** One hundred and eighty-six laypeople aged 18-65 years were recruited. Healthcare-related professionals were excluded.

Interventions: Participants were randomized assigned into TCPRLink feedback group and T-CPR group by age stratification. Individuals T-CPR performance were test in both groups.

**Primary and secondary outcome measures:** Primary outcomes were CCs rate and proportion of adequate CCs rate (100-120 min<sup>-1</sup>) during 6-minute compression-only CPR. Secondary outcomes included the proportion of participants counting the CCs rhythm, time to the first CC, CCs depth, hands-off time and CCs fully release ratio.

**Results:** Participants in TCPRLink feedback group (n=94) performed more consistently CCs with higher rate both initially and 3 month later [median 111 (IQR 109-113) vs. 108 (103-112) min<sup>-1</sup>, P=0.002 and 111 (109-113) vs. 108 (105-112) min<sup>-1</sup>, P<0.001, respectively], with less need to count the rhythm [21.3% vs. 41.3%, P=0.003 and 7% vs. 22.6%, P=0.004, respectively] compared with the T-CPR group (n=92). There were no significant differences in hands-off time, CCs fully release ratio and time to the first compression between two groups. Among 55-65 years, CCs depth were deeper in TCPRLink group than control group [47.1 ± 9.6 vs 38.5 ± 8.7 mm, P=0.001, and 44.7 ± 10.1 vs 39.3 ± 10.8 mm, P=0.07, respectively].

**Conclusions:** TCPRLink improved layperson T-CPR quality in terms of CCs rate in simulated scenario. Further investigations are required to confirm its effectiveness in actual resuscitation attempts.

# Strengths and limitations of this study

- This randomized control study evaluated the effect of a novel, digital invention of a combined audio-visual smartphone application and web system (TCPRLink), which provides dispatcher instructions and real-time feedback to ensure CPR quality.
- 2. We compared the quality of telephone CPR (T-CPR) performance by the potential rescuers aged between 18-65 years in a cardiac arrest simulation scenario.
- We invited a senior dispatcher using standardized dispatch instructions to portray T-CPR scenario.
- 4. Outcomes were measured both immediately after T-CPR training and three months later to investigate the long-term effect of the app.

#### Introduction

Bystander provides immediate and adequate cardiopulmonary resuscitation (CPR) directly impact patient outcomes from cardiac arrest [1-3]. The updated American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines state that telephone-assisted CPR (T-CPR) has a positive effect on the entire resuscitation process through getting more callers to start CPR and coaching callers to provide CPR [4 5]. Despite significant advances on the T-CPR instructions during the resuscitation procedures, a blind zone remains between the dispatcher and caller. While the dispatcher is voice connected to the caller by phone, they are unable to see the patient and evaluate bystander CPR quality which suggest a need for new strategies to address this challenge.

The ubiquitous presence and utilization of smartphones suggest a novel opportunity to improve resuscitation care through measurement of bystander CPR metrics [6-12]. In the recent statement from AHA and ERC, the use of digital strategies, such as mobile devices, to provide bystander with an accelerometer to measure CPR metrics were encouraged [13 14]. Adherence to guidelines, an audio-visual smartphone application (TCPRLink) was developed to help the bystander performing high-quality CPR and assist the dispatcher to evaluate the CPR quality real-time [15]. The TCPRLink application utilizes the smartphone front camera to detect the CCs and display the CCs rate to bystanders themselves. Meanwhile, it sends real-time CCs rate and time without no compressions over the internet to a monitor in front of the dispatcher. The aim of this present study was to evaluate the effectiveness of the TCPRLink application with real-time audio-visual feedback under telephone-dispatcher assisted simulated cardiac arrest situation. We hypothesized that this smartphone-based CCs rate feedback application would improve the quality of CPR in the general population compared to use conventional T-CPR instructions.

#### Methods

## 2.1 Study design and ethics

This study was a simulation-based randomized experimental trial carried out from September 1, 2018 to May 30, 2019. We obtained ethics approval from the Joint Research Ethics Board of the Shanghai Jiao Tong University Schools of Public Health and Nursing (SJUPN-201714).

# 2.2 Study population

One hundred and eighty-six participants were randomly recruited from those who participated in the 'WeCan CPR' training program [16], a part of the China Resuscitation Academy. The inclusion criteria for enrolment in the study were college students and laypeople aged 18-65 years who had taken the WeCan CPR training within one week. Physicians, nurses, dispatchers, and other healthcare professionals were excluded from the study. All participants were verbally informed about the intention of the study and gave their written informed consent.

The CPR course is a video-based, one-hour training program applying Dispatcher-Telephone-Guided CPR training in combination with practical, basic CPR training targeted for potential bystanders. In the WeCan CPR training, participants learn how to call the emergency dispatch center, to follow the procedure of the T-CPR instructions, and to perform hands-only CPR. They performed at least 550 chest compressions on instrumented feedback manikins (QCPR Classroom, Laerdal Medical, Norway) during the training.

# 2.3 Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination of our research.

# 2.4 Randomization

Randomization was stratified by age groups (18-24, 25-54, and 55-65 years) and conducted to ensure equal distribution of participants across study arms. Participants were randomized into either the control arm (conventional T-CPR group) or

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intervention arm (T-CPR with TCPRLink group). All participants were informed the purpose of the study to assess the impact of the TCPRLink App on resuscitation performance. They were not blinded to study arm allocation due to the nature of the intervention.

#### 2.5 Study procedures and T-CPR simulation scenario

The study was performed in a quiet, isolated, designated room with a manikin placed on the floor. Individuals were asked to enter the room alone, make an emergency call to an assigned phone number, and try he/her best to rescue the manikin in a cardiac arrest T-CPR simulated scenario. T-CPR instructions were tightly standardized using Medical Priority Dispatch System (MPDS version 12.1, Salt Lake City, US) OHCA dispatch protocol [17]. One dispatcher with six years of T-CPR experience working at the local emergency dispatch center acted as dispatcher.

During T-CPR calls, individuals were asked about the current address, patient's age, gender, patient's consciousness and breathing as per MPDS protocol. Then, individuals were instructed by the dispatcher to activate the speaker, put the phone on the floor by the manikin. Dispatcher followed standard procedure to initiate CPR and let the participant do hands-only CPR for six minutes. For encouragement, the dispatcher counted the CCs rhythm with the participants and said "good job, push harder" every 30 seconds during the simulation.

For the conventional T-CPR group, the participants received no visual feedback from the smartphone and were guided only by the dispatcher instructions. For the TCPRLink group, individuals were asked to call using the TCPRLink app. TCPRLink (University of Stavanger and Laerdal Medical, Norway) is a free, CPR audio-visual feedback smartphone application designed to measure CCs rate and hands-off time and provide feedback both to the bystander and the dispatcher. The accuracy and validation of the TCPRLink app has been demonstrated earlier [18]. During the cardiac arrest simulation scenario, individuals pressed the "call emergency center" button to connect to the dispatcher and to activate the TCPRLink app which captures and analyzes the CPR

movement by the smartphone front-face camera in real-time. Different from the conventional T-CPR instruction, dispatcher reminded the participants to place the phone flat on the floor by the patient and make sure that their head and shoulders were visible by the front camera. When analyzing body movement movements, the individual received real-time objective feedback via a speedometer displayed for CCs rate (indicator in the green range of 100-120 and yellow range of either <100 or >120 compressions/minute). The dispatcher received real-time objective feedback during the emergency call via sliding window from a website presented on a computer screen development CCs showing the and history of the rate (webserver: http://tcprlink.azurewebsites.net/?%20country=china). For the six minutes hands-only CPR, dispatcher guided the individual CCs rate, and direct "push faster" "push slower" guided by the algorithm implemented on the website.

Three months later, subjects were called back to repeat the T-CPR test assigned to the same randomization group. All enrolled participants' behaviors and performance during the cardiac arrest simulation scenario were recorded by a separate video camera face to the manikin located 80 cm above the ground and 1.5 m away for a panorama shot.

#### 2.6 Outcome measures

 The primary outcomes measured were the CCs rate and the percent of the adequate CCs meeting the guideline-recommended rate (100-120 min<sup>-1</sup>) [19 20] during six minutes hands-only CPR. Secondary outcomes were CCs depth, the percent of the adequate CCs depth (5-6 cm), the percent of chest compressions with complete recoil (complete release recoil of the chest between compressions) and the absolute hands-off time (the sum of all periods during which no hand was compression on the chest) during the six minutes hands-only CCs. The above parameters of CCs effectiveness were monitored using software for ResusciAnne<sup>®</sup> QCPR manikin (Laerdal Medical, Norway).

The individual behaviors during the simulation scenario was video recorded, including the communication with the dispatcher (count the CCs rhythms with dispatcher), and time to first CC (time interval from call connected to first CC). We documented age,

sex, education level, self-report body weight and height of all participants.

#### 2.7 Statistical analysis

Differences in outcome for the categorical variables between the two groups were assessed using the Chi-square tests. Normal distribution was confirmed using Kolmogorov-Smirnov test. Independent student *t*-tests were conducted to explore the effect of the intervention for continuous variables with normal distribution, and Mann–Whitney U-test was used for variables with nonparametric distribution between the control and intervention arm. All analyses were conducted using SPSS 22.0. All *P* values were 2-sided, and P < 0.05 was considered to be statistically significant.

#### Results

A total of 186 participants (94 in T-CPR with TCPRLink group and 92 in conventional T-CPR group) were included in this study. The demographic characteristics was shown in **Table 1**. Age, gender, education level, and body mass index (BMI) did not differ between the groups. Eight participants in each study arm were lost between the initial test and the follow up test 3 months later (see consort diagram in Figure 1).

During the six minutes of hands-only CPR, individuals in TCPRLink group performed CCs with higher rate both initially [median 111 (IQR 109-113) vs. 108 (IQR 103-112) min<sup>-1</sup>, P=0.002] and at 3 months [111 (IQR 109-113) vs. 108 (IQR 105-112) min<sup>-1</sup>, P<0.001], compared to conventional T-CPR group, respectively (**Table 2 and Figure 2**). In the TCPRLink group where the CCs rate speedometer was displayed, individuals were less likely to count out the CCs rhythms with the dispatcher [21.3% vs. 41.3%, P=0.003 and 7% vs. 22.6%, P=0.004, respectively] (**Table 2 and Figure 3**). Hands-off times, CCs fully released and time to first compression were not statistically different between the groups neither initially nor at 3 months follow-up.

CCs depth in TCPRLink group was significantly deeper in age group 55-65 [47.1  $\pm$  9.6 vs. 38.5  $\pm$  8.7 mm, *P*=0.001] compared to the control group in the initial cardiac arrest simulation scenarios (**Table 3**). The CCs depth also showed a deeper tendency but not

statistically significant in the simulation 3 months later [44.7  $\pm$  10.1 vs. 39.3  $\pm$  10.8mm, *P*=0.07] (Table 4).

#### Discussion

 This study evaluated a novel, digital invention of a combined audio-visual feedback smartphone app and web system, combining real-time dispatcher instructions and real-time feedback to ensure the quality of CPR. It compared the quality of T-CPR performed by the potential rescuers aged among 18-65 years on a cardiac arrest simulation scenario with or without the smartphone app. The results of the present study showed that real-time, audio-visual feedback using smartphone app and web system in combination with dispatcher instructions augmented the interaction between dispatchers and bystanders resulting in a positive effect on bystander CPR quality.

Although the dispatcher coach callers to do CPR, they rely on audio communication alone to figure out what is happening. Without other means of feedback, dispatcher instruction may lead to lower quality of CCs and more hands-off time [21]. Others have shown that video-instructed T-CPR significantly improved the CCs rate compared to the conventional audio-instructed method [22]. It was noted that guided by the audio-visual feedback app, callers did more consistent CCs than the T-CPR only group.

During dispatch assisted instructions, smartphone has become a promising carrier to improve video resuscitation care with its wide availability and high capabilities. Several diversified, advanced smartphone apps have been developed to fit the links of the chain of survival into a strengthened "Mobile chain of survival" [23]. Previous studies have shown the feasibility of these tools. One kind of app guide users in their CPR procedures via text and pictures or provide video examples of CPR with metronomic guidance that a bystander could watch before or during an actual resuscitation [6 8]. Another kinds of app offers CPR quality measurement and feedback based on motion-sensing which require the user to place the phone on the patient's chest or hold it between rescuer's hands while performing CPR [9-12]. However, those previous smartphone solutions neglected the potency of the dispatcher. They may less suitable

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for real emergencies considering since the phone connection may be accidentally lost while using the phone as a CPR feedback device.

Different from other smartphone apps, TCPRLink utilizes the smartphone frontend camera for continuous quality improvement through real-time feedback for bystander as well as the dispatcher. Dispatcher could monitor the hands-off time and encourage the rescuer when they fatigue. A result of another study evaluates the smartphone APP effectiveness showed the aged over 60 years participants could not persist a long time CPR [9]. As the risk of OHCA increased with age [24 25], seniors are more likely to be bystanders when a cardiac arrest occurs in their spouse or family members. CPR capability of seniors was always a significant concern. Contrast with the previous study, we found TCPRLink App showed an extra stimulation in seniors aged 55-65 years as indicated by subgroup analysis. Quality of CPR by the subjects aged 55-65 years were as good as the younger age subjects during the 6 minutes hands-only CPR in the present study.

Moreover, providing a feasible CPR feedback devices for seniors might be an appropriate approach to increase not only their ability, but also their willingness and confidence to do CPR <sup>[9]</sup>. When guided by TCPRLink app, senior subject's CCs rate and depth were both better and within the guidelines compared to the conventional T-CPR group. Our data suggest that the two-way metric of CPR quality and dispatcher encouragement, seniors performed CPR quality equally well as the young generation.

Counting aloud is the most common method for which dispatcher can ensure proper CCs rate in T-CPR. Without getting feedback from the rescuer, dispatcher' understanding of the rescuer's situation was declined [26]. Interestingly, we found that visual guidance of CCs rate from the speedometer on the smartphone reduced the need to count out loud to maintain proper rate. This means that rescuers could spend more energy on compression and less energy on counting. Alternatively, less need for counting means that the dispatcher protocol can more often coach for compression depth and avoiding leaning. Contrary to common concerns that using mobile devices or smartphone Apps to improve CPR quality might cause time delayed to start CCs [8]

10], time to first CC in TCPRLink group was not prolonged compare with that in conventional T-CPR group in our present study.

Nevertheless, limitations of this study need to be mentioned. On the one hand, our present study was implemented in a simulated environment which may not reflect the real actions. Hawthorn effect could not be excluded under the simulation scenario, resulting in a motivation bias. Hence, our study followed a realistic approach simulating layperson resuscitation in a cardiac arrest situation. We invited a senior dispatcher who was working in the emergency dispatch center to portray the T-CPR scenario. On the other hand, manikin may not represent the diversity of patients' chests and changes in chest resistance during extended CPR. Lastly, we recruited the participants aged between 18-65 years. Elderly aged above 65 years were less likely to participant considering the physical capacity. The mean age of participants was about 40 years old, which might not be the representative age for bystanders in real life.

#### Conclusions

The TCPRLink smartphone application providing real-time feedback to both rescuer and dispatcher could significantly improve the CPR quality of lay rescuers in terms of CCs rate in a simulated cardiac arrest scenario. Further investigations are required to confirm its effectiveness in real resuscitation incidents.

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#### **Authors' contributions**

XJ Dong and L Zhang were contributed equally to this article. L Zhang conceptualized the study. XJ Dong and L Zhang performed the data collection and analysis. XJ Dong and L Zhang contributed to writing the paper. L Zhang, H Myklebust, TS Birkenes and Z-J Zheng provided administrative advices and consultations. H Myklebust, TS

Birkenes and Z-J Zheng critically revised the final version. All authors approved the final version of the manuscript.

#### **Competing interests**

There are no potential conflicts of interest for all authors in this study. H Myklebust and TS Birkenes are employees at Laerdal Medical. The manufacturer (Laerdal Medical, Norway) do not conflict with the trial or in interpreting the results.

#### Data sharing statement

Data are available on reasonable request.

## **Research Ethics Approval**

The study protocol was approved by the Joint Research Ethics Board of the Shanghai Jiao Tong University Schools of Public Health and Nursing under the approval ID of SJUPN-201714.

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#### Patient consent for publication

Not required.

#### Provenance and peer review

Not commissioned; externally peer reviewed.

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	Total	TCPRLink group	T-CPR group	<b>P</b> -
	(N=186)	(n=94)	(n=92)	value
Male (n, %)	83 (44.6)	42 (44.7)	41 (44.6)	1.00
Age				
18-24 years	54 (27.0)	29 (30.9)	25 (27.2)	0.88
25-54 years	75 (37.5)	37 (39.4)	38 (41.3)	
55-65 years	57 (28.5)	28 (29.8)	29 (31.5)	
Education status (n, %)				0.18
≤High school/ Junior college	68 (36.6)	30 (31.9)	38 (41.3)	
College	75 (40.3)	44 (46.8)	31 (33.7)	
Master and Ph.D.	43 (23.1)	20 (21.3)	23 (25.0)	
Height (m, means $\pm$ SD)	$1.68 \pm 0.1$	$1.67 \pm 0.1$	$1.68 \pm 0.1$	0.12
Weight (kg, means $\pm$ SD)	$64.5 \pm 11.4$	$63.3 \pm 10.3$	$65.6 \pm 12.4$	0.17
BMI (kg/m <sup>2</sup> , means $\pm$ SD)	$22.9 \pm 3.1$	$22.7 \pm 2.8$	$23.0 \pm 3.4$	0.48

	Phas	e I (N=186)	Phase II (N=170)			
<b>T-CPR</b> performance	TCPRLink group (n=94)	T-CPR group (n=92)	<i>P</i> -value	TCPRLink group (n=86)	T-CPR group (n=84)	<i>P</i> -value
Counting with the dispatcher (n, %)	20 (21.3)	38 (41.3)	0.003	6 (7.0)	19 (22.6)	0.004
Time from call connected to(seconds, means ±	= SD)					
Cardiac arrest identification	$98.2 \pm 12.8$	$99.1 \pm 16.9$	0.68	$101.7\pm13.0$	$104.2\pm15.0$	0.25
First chest compression	$143.6 \pm 17.8$	$140.0\pm25.8$	0.27	$149.7\pm16.6$	$146.0\pm20.2$	0.19
CPR parameters [M(P <sub>25</sub> -P <sub>75</sub> ) or means ± SD]						
Total number of compressions	661 (643-674)	648 (615-674)	0.035	661 (644-675)	646 (630-667)	0.002
Average compression rate (min <sup>-1</sup> )	111 (109-113)	108 (103-112)	0.002	111 (109-113)	108 (105-112)	< 0.001
Percentage of adequate rate (100-120 min <sup>-1</sup> , %)	96 (89-98)	82 (50-97)	< 0.001	95 (78-98)	93 (67-97)	0.11
Average compression depth (mm)	$45.4 \pm 8.8$	$43.6 \pm 8.8$	0.17	$43.9 \pm 9.1$	$42.9 \pm 11.5$	0.59
Percentage of adequate depth (50-60mm, %)	20 (3-74)	12 (0-51)	0.14	17 (4-54)	13 (0-57)	0.26
Percentage of fully released (%)	97 (72-100)	97 (69-100)	0.79	95 (54-100)	96 (51-100)	0.40
Average hands off time (s)	0 (0-1)	0 (0-1)	0.24	0 (0-1)	0 (0-1)	0.72

Phase I tests were CPR performance and capabilities assessment using Telephone-assistant CPR (T-CPR) simulation scenario among individuals who have taken CPR training with/without TCPRLink APP.

Phase II tests were CPR skill retentions assessment among individuals with/without TCPRLink APP after three months.

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 Table 3 Comparison of Lay rescuers CPR performance between TCPRLink group and T-CPR group by age. (Phase I)

 Age 18 24

 Age 25 54

	A	Age 18-24		Age 25-54			A	Age 55-65		
TCPR performance	TCPRLink group (n=29)	T-CPR group (n=25)	<i>P</i> - value	TCPRLink group (n=37)	T-CPR group (n=38)	<i>P</i> -value	TCPRLink group (n=28)	T-CPR group (n=29)	<i>P</i> - value	
Counting with the dispatcher										
(n, %)	9 (31.0)	12 (48.0)	0.20	7 (18.9)	19 (50.0)	0.005	4 (14.3)	7 (4.1)	0.35	
Time from call connected to	(seconds, mea	ans ± SD)								
Cardiac arrest identification	$98.9 \pm 13.5$	$96.4 \pm 19.5$	0.58	$97.0 \pm 13.2$	$98.2 \pm 14.0$	0.72	$98.9 \pm 12.0$	$102.7\pm17.8$	0.36	
First chest compression	$141.4 \pm 20.2$	$137.8 \pm 26.8$	0.57	143.6 ± 17.7	$135.9 \pm 26.9$	0.14	$145.8 \pm 15.4$	$147.1 \pm 22.5$	0.79	
CPR parameters [M(P <sub>25</sub> -P <sub>75</sub> ) o	r means ± SD	)								
Total number of compression	663(640- 671)	650(608- 666)	0.21	659(653- 677)	652(632-674)	0.29	659(640-676)	640(612-672)	0.14	
Average compression rate (min <sup>-1</sup> )	111(108- 113)	108(101- 112)	0.03	111(109- 114)	109(106-113)	0.12	110(107-113)	107(103-113)	0.06	
Percentage of adequate rate (100-120 min <sup>-1</sup> , %)	95(88-99)	82(50-96)	0.01	97(90-98)	89(51-97)	0.006	95(88-97)	71(48-95)	0.003	
Average compression depth (mm)	$41.8\pm7.8$	$43.1 \pm 6.6$	0.49	$46.9\pm8.2$	47.8 ± 8.1	0.67	47.1 ± 9.6	$38.5 \pm 8.7$	0.001	
Percentage of adequate depth (50-60mm, %)	8(0-28)	12(4-33)	0.37	25(9-84)	37(7-86)	0.92	45(1-99)	1(0-14)	0.002	
Percentage of fully released (%)	100(95- 100)	100(96-100)	0.66	98(79-100)	95(57-99)	0.24	71(5-100)	96(37-100)	0.13	
Average hands off time (s)	0(0-2)	0(0-1)	0.24	0(0-1)	0(0-0)	0.45	0(0-1)	0(0-1)	0.92	
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Phase I tests were CPR performance and capabilities assessment using Telephone-assistant CPR (T-CPR) simulation scenario among individuals who have taken CPR training with/without TCPRLink APP.

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Table 4 Comparison of Lay rescuers CPR performance between TCPRLink group and T-CPR group by age. (Phase II)

	A	ge 18-24		A	ge 25-54			Age 55-65	
TCPR performance	TCPRLink group (n=29)	T-CPR group (n=23)	<i>P</i> - value	TCPRLink group (n=31)	T-CPR group (n=34)	<i>P</i> -value	TCPRLink group (n=26)	T-CPR group (n=27)	<i>P</i> - value
Counting with the dispatcher (n, %)	2 (6.9)	4 (17.4)	0.40	4 (12.9)	12 (35.3)	0.036	0 (0)	3 (11.1)	0.24
Time from call connected to	.(seconds, mea	ns ± SD)							
Cardiac arrest identification	$99.8 \pm 16.0$	$100.4 \pm 16.3$	0.89	$103.8 \pm 13.6$	$103.0 \pm 11.9$	0.82	$101.4 \pm 7.3$	$108.9 \pm 16.7$	0.04
First chest compression	$148.4 \pm 20.1$	$144.2 \pm 25.5$	0.52	$153.2 \pm 17.3$	$143.6 \pm 13.9$	0.018	$146.8 \pm 9.8$	$150.4 \pm 21.9$	0.45
CPR parameters [M(P <sub>25</sub> -P <sub>75</sub> )	or means ± SD]								
Total number of compression	658(643-678)	639(605- 653)	0.004	665(653-675)	648(640- 668)	0.09	663(644- 676)	643(627-680)	0.32
Average compression rate (min <sup>-1</sup> )	111(109-113)	107(101- 110)	< 0.001	112(109-113)	109(107- 112)	0.06	111(107- 114)	109(105-114)	0.28
Percentage of adequate rate (100-120 min <sup>-1</sup> , %)	96(82-99)	82(60-98)	0.08	95(78-98)	95(84-97)	0.64	92(77-98)	90(70-97)	0.61
Average compression depth (mm)	$41.7 \pm 8.2$	$43.7 \pm 14.1$	0.55	$45.2\pm9.0$	$45.4 \pm 9.6$	0.92	$44.7\pm10.1$	$39.3 \pm 10.8$	0.07
Percentage of adequate depth	10(2-32)	10(0-54)	0.92	19(7-55)	22(2-81)	0.97	19(3-68)	2(0-24)	0.04
(50-60mm, %) Percentage of fully released (%)	100(92-100)	99(91-100)	0.52	93(15-100)	90(44-99)	0.65	68(33-100)	89(24-99)	0.84
Average hands off time (s)	0(0-2)	0(0-1)	0.16	0(0-1)	0(0-1)	0.48	0(0-0)	0(0-0)	0.89

Phase II tests were CPR performance and capabilities assessment using Telephone-assistant CPR (T-CPR) simulation scenario among individuals who have taken CPR training with/without TCPRLink APP after three months.

Page 21 of 24

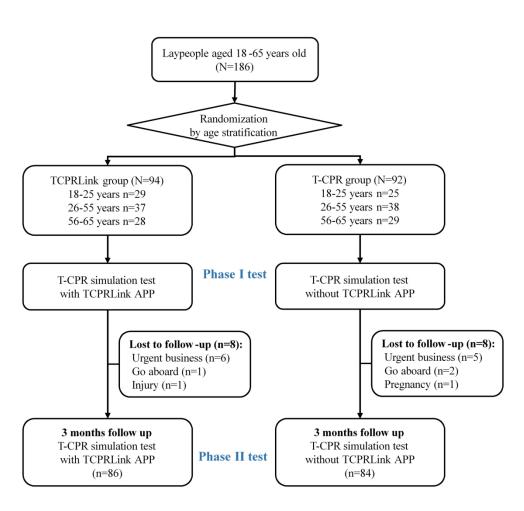
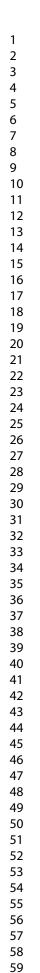
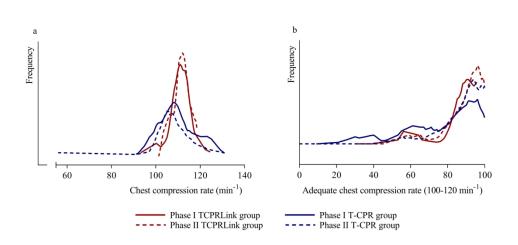


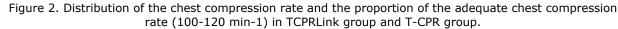
Figure 1. Flow diagram of the participants.

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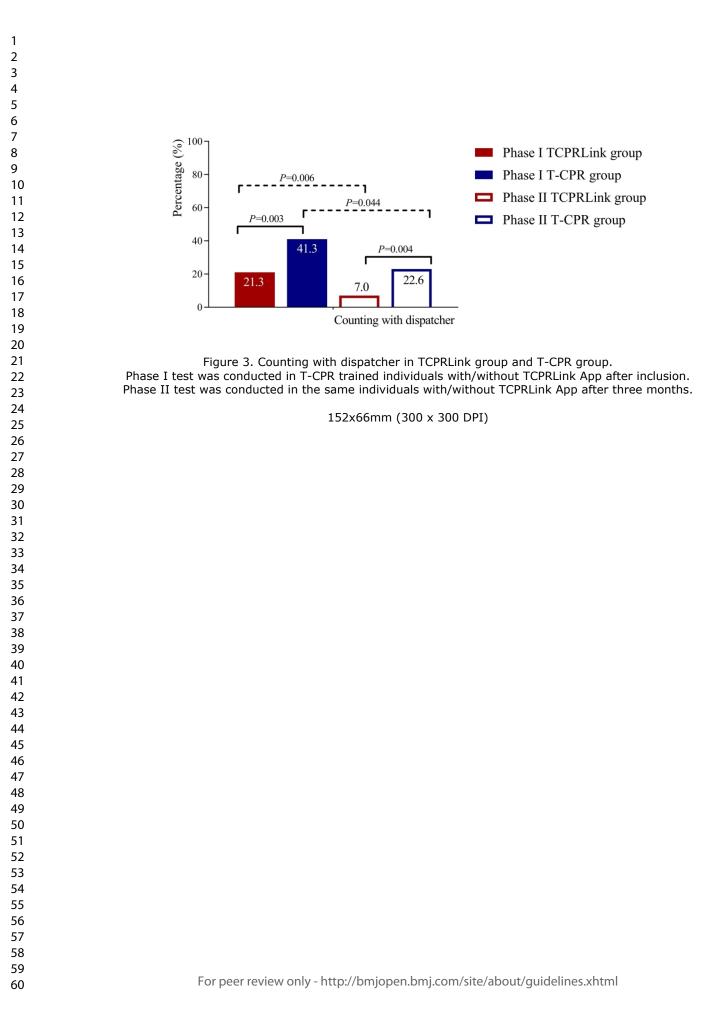
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Phase I test was conducted in T-CPR trained individuals with/without TCPRLink App after inclusion. Phase II test was conducted in the same individuals with/without TCPRLink App after three months.

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# CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	ltem No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and	2a	Scientific background and explanation of rationale	2
objectives	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
-	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	\
Sample size	7a	How sample size was determined	5
-	7b	When applicable, explanation of any interim analyses and stopping guidelines	١
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	5
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	١
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	
CONSORT 2010 checklist		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	Page

 BMJ Open

1		assessing outcomes) and how	
2	11b	If relevant, description of the similarity of interventions	١
3 Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
4 5	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
6 <b>Results</b>			
7 Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	8, Figure 1
<sup>3</sup> diagram is strongly		were analysed for the primary outcome	-
, recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
1 Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
2	14b	Why the trial ended or was stopped	\
<sup>3</sup> <sub>4</sub> Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	15
5 Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	15
6		by original assigned groups	
<sup>7</sup> Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	16
9 estimation		precision (such as 95% confidence interval)	
0	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	\
1 Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	17,18
3 4 Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	\
$_{7}^{6}$ Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10
, 8 Generalisability	21	Generalisability (external validity, applicability) of the trial findings	8-10
<sup>9</sup> Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8-10
0 Other information			
2 Registration	23	Registration number and name of trial registry	١
<sup>3</sup> Protocol	24	Where the full trial protocol can be accessed, if available	\
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist

# **BMJ Open**

# Effect of a Real-Time Feedback Smartphone Application (TCPRLink) on the Quality of Telephone-assisted CPR Performed by trained laypeople in China: A manikin-based randomized controlled study

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<b>Primary Subject Heading</b> :	Emergency medicine
Secondary Subject Heading:	Public health
Keywords:	ACCIDENT & EMERGENCY MEDICINE, PUBLIC HEALTH, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS

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3	1	Effect of a Real-Time Feedback Smartphone Application (TCPRLink) on the
5 6 7	2	Quality of Telephone-assisted CPR Performed by trained laypeople in China: A
8 9	3	manikin-based randomized controlled study
	4	Xuejie Dong <sup>1#</sup> , Lin Zhang <sup>1*#</sup> , Helge Myklebust <sup>2</sup> , Tonje Soraas Birkenes <sup>2</sup> , Zhi-Jie
12 13 14	5	Zheng <sup>3</sup>
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	7	2. Laerdal Medical, Norway
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35	16	Word count: 3210
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**BMJ** Open

# 20 ABSTRACT

Objectives: To determine the effect of a free smartphone application (TCPRLink) that
provides real-time monitoring and audiovisual feedback on chest compressions (CC)
on trained layperson telephone-assisted cardiopulmonary resuscitation (T-CPR)
performance.

**Design:** A manikin-based randomized controlled study.

26 Setting: This study was conducted at a multidisciplinary university and a community27 center in China.

**28 Participants:** One hundred and eighty-six adult participants (age 18-65 years) with T-

29 CPR training experience were randomly assigned to the TCPRLink (n=94) and T-CPR
30 (n=92) groups with age stratification.

31 Interventions: We compared the participants' performance for 6-minutes of CC in a
32 simulated T-CPR scenario both at the baseline and after 3 months.

Primary and secondary outcome measures: The primary outcomes were the CC rate
and proportion of adequate CC rate (100–120 min<sup>-1</sup>). The secondary outcomes included
the proportion of participants counting the CC rhythm, time to first CC, CC depth,
hands-off time, and CC full-release ratio.

Results: Participants in the TCPRLink feedback group more consistently performed CC with higher rate, both initially and 3 month later [median 111 (IQR 109–113) vs. 108 (103–112) min<sup>-1</sup>, P=0.002 and 111 (109–113) vs. 108 (105–112) min<sup>-1</sup>, P<0.001, respectively], with less need to count the rhythm [21.3% vs. 41.3%, P=0.003 and 7% vs. 22.6%, P=0.004, respectively] compared with the T-CPR group. There were no significant differences in time to the first CC, hands-off time, or CC full-release ratio. Among 55-65 year group, the CC depth was deeper in the TCPRLink group than in the TCPR group  $(47.1\pm9.6 \text{ vs } 38.5\pm8.7 \text{ mm}, P=0.001, \text{ and } 44.7\pm10.1 \text{ vs } 39.3\pm10.8 \text{ mm},$ P=0.07, respectively).

46 Conclusions: The TCPRLink application improved T-CPR quality in trained
47 laypersons to provide more effective CCs and lighten the load of counting out the CC
48 with the dispatcher in a simulated T-CPR scenario. Further investigations are required
49 to confirm this effectiveness in real-life resuscitation attempts.

52 Strengths and limitations of this study

- The effectiveness of a real-time feedback smartphone application (TCPRLink) was evaluated in a telephone-assisted CPR (T-CPR) simulation among participants from the Chinese general population.
- Trained adult laypersons (age range 18–65 years) participated in this study to facilitate the identification of discrepancies in T-CPR performance among different age groups.
- The study included a 3-month follow-up T-CPR performance test to investigate the participants' skill retention.
- The Hawthorn effect could not be excluded in the simulation scenario, with the possibility of a motivation bias.

#### 64 INTRODUCTION

Bystander-provided immediate and adequate cardiopulmonary resuscitation (CPR) can directly impact patient outcomes following an out-of-hospital cardiac arrest.[1-3] The updated guidelines of the American Heart Association (AHA) and European Resuscitation Council (ERC) state that telephone-assisted CPR (T-CPR) has a positive effect on the entire resuscitation process by getting more callers to start CPR and through coaching the callers to provide effective CPR.[4, 5] Despite significant advances in the T-CPR instructions during the resuscitation procedures, here exists a blind zone between the dispatcher and caller. The dispatcher is voice connected to the caller via the phone, but is unable to see the patient and evaluate the quality of bystander CPR. Therefore, new strategies to address this challenge are needed.

The ubiquitous presence and utilization of smartphones suggest a novel opportunity to improve resuscitation care through the measurement of bystander CPR metrics.[6-12] In a recent statement from the AHA and ERC, the use of digital strategies, such as mobile devices, were encouraged to provide bystanders with an accelerometer to measure CPR metrics.[13, 14] In adherence to these guidelines, an audiovisual smartphone application (TCPRLink) was developed to facilitate high-quality bystander-provided CPR and assist the dispatcher to evaluate the CPR quality in real time.[15] The TCPRLink application utilizes the smartphone front camera to detect chest compressions (CC) and displays the CC rate to the bystanders and simultaneously sends the real-time CC rate and the time without compressions via the internet to a monitor that is in front of the dispatcher.

This study was conducted to evaluate the effectiveness of the TCPRLink application with real-time audiovisual feedback in dispatcher-assisted CPR during a cardiac arrest simulation. We hypothesized that this smartphone-based CC rate feedback application would improve the quality of CPR in the general population compared to the use of conventional T-CPR instructions.

91 METHODS

#### 92 Study design and ethics

93 This study was a simulation-based randomized experimental trial that was carried out
94 from September 1, 2018 to May 30, 2019. We obtained ethical approval from the Joint
95 Research Ethics Board of the Shanghai Jiao Tong University Schools of Public Health
96 and Nursing (approval no. SJUPN-201714) for study conduct. All participants were
97 verbally informed about the purpose of the study and provided written informed consent.
98 They were informed that their T-CPR performance would be tested and video-recorded
99 in a simulated scenario after training and, again, 3 months later.

#### 100 Study population

We randomly recruited 186 participants from those who participated in the "WeCan
CPR" training program [16] an initiative of the China Resuscitation Academy. College
students and adult laypersons (age range 18–65 years) who had completed the training
program within one week were eligible for study enrolment. Physicians, nurses,
dispatchers, and other healthcare professionals were excluded from the study.

106 The WeCan CPR course is a video-based, 1-hour training program on applying 107 dispatcher-telephone-guided CPR training in combination with practical and basic CPR 108 training that is targeted at potential bystanders. Participants learn how to call the 109 emergency dispatch center, follow the procedure of the T-CPR instructions, and 110 perform hands-only CPR. All trainees performed at least 550 CC on instrumented 111 feedback manikins (QCPR Classroom, Laerdal Medical, Norway) during the training.

# **Patient and public involvement**

113 Patients or the public were not involved in the design, or conduct, or reporting, or 114 dissemination of our research.

### 115 Randomization

116 Randomization was stratified by age groups (18–24, 25–54, and 55–65 years) and 117 conducted to ensure equal distribution of participants across study arms. Participants 118 were randomized into either the control arm (conventional T-CPR group) or 119 interventional arm (T-CPR with the TCPRLink group). All participants were informed 120 the purpose of the study, which was to assess the impact of the TCPRLink App on 121 resuscitation performance, and were not blinded to the study-arm allocation due to the 122 nature of the intervention.

# 123 TCPRLink application

TCPRLink (University of Stavanger and Laerdal Medical, Norway) is a free, CPR
audiovisual feedback smartphone application that was designed to measure the CC rate
and hands-off time and to provide feedback to the *bystander* and the *dispatcher*. The
accuracy and validation of the TCPRLink app has been demonstrated earlier. [17]

The illustration of the application in use is presented in **Figure 1**. By clicking the "Press to start TCPR Link" button, the application activates the speaker, establishes a telephone connection with the dispatcher, activates the TCPRLink app which captures and analyzes the CPR movement via the front facing camera of the smartphone in real time, and simultaneously sends the location and real-time compression data to a web server which is available for the dispatcher (web server: http://tcprlink.azurewebsites.net/?%20 country=china). 

At the bystander interface, a speedometer displayed on the smartphone screen next to a
preview frame allows the bystander to keep track of the CC rate, which is obtained by
analyzing body movement. Thus, the individual receives real-time objective feedback
via the speedometer (with the indicator in the green or yellow range of 100–120 and
<100 or >120 compressions/minute, respectively).

Similarly, at the dispatcher's interface, real-time objective feedback is presented during
the emergency call via a sliding window from a website presented on a computer screen
that shows the history and progression of the CC rate. Guided by the indicator on web
server, the dispatcher can further guided the bystander-rendered CC rate through direct
instructions to "push faster", "push slower", or "don't stop".

145 Study procedures

The T-CPR performance of all participants were evaluated twice. The first evaluation
(Phase I test) was conducted within one week of WeCanCPR training in a cardiac arrest
T-CPR simulated scenario, and the second occurred 3 months later (Phase II test) and
corresponded to the same setting as the initial test.

The simulations were performed in a quiet, isolated, designated room with a manikin
placed on the floor. Individuals were asked to enter the room alone, make an emergency
call to an assigned phone number, and try their best to rescue the manikin in a cardiac

arrest T-CPR simulated scenario. T-CPR instructions were strictly standardized using
the Medical Priority Dispatch System (MPDS version 12.1, Salt Lake City, US) OHCA
dispatch protocol.[18] One dispatcher who had 6 years of T-CPR experience from
working at the local emergency dispatch center acted as dispatcher in the simulation.

During T-CPR calls, individuals were asked for their current address, patient's age and gender, patient's consciousness level, and breathing status in accordance with the MPDS protocol. Then, individuals were instructed by the dispatcher to activate the speaker and place their phone on the floor by the manikin. The dispatcher followed a standard procedure to initiate CPR and let the participant perform hands-only CPR for 6 minutes. For encouragement, the dispatcher counted the CC rhythm with the participants and said "good job, push harder" every 30 seconds during the simulation.

For the conventional T-CPR group, the participants received no visual feedback from the smartphone and were guided only by the dispatcher instructions. For the TCPRLink group, individuals were asked to call for help using the TCPRLink app. The participants' behavior and performance during the simulation exercise were recorded by a separate video camera that faced toward the manikin and was located 80 cm above the ground and 1.5 m away for a panoramic shot.

#### **Outcome measures**

The primary outcomes measured were the CC rate and the proportion of the adequate CC meeting the guideline-recommended rate  $(100-120 \text{ min}^{-1})$  [19, 20] during 6 minutes of hands-only CPR. The secondary outcomes were CC depth, the proportion of CC with the adequate CC depth (5–6 cm), the proportion of CC with complete recoil (complete release recoil of the chest between compressions), and the absolute hands-off time (the sum of all periods during which there was no hand compression of the chest) during the 6 minutes of hands-only CC. The abovementioned parameters of CCs effectiveness were monitored using the proprietary software for the ResusciAnne® QCPR manikin (Laerdal Medical, Norway).

180 The video recording of the simulation scenario was used to evaluate individual
181 participant behaviors, including the communication with the dispatcher (counting the
182 CC rhythms with the dispatcher) and time to first CC (time interval from call connection
183 to first CC). We documented the age, sex, education level, self-reported body weight,

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184 and height of all participants.

## 185 Sample size estimation

The sample size calculation was followed to sequentially recruit 68 participants (34 in the TCPRLink group with 12, 11, and 11 participants in the 18-24, 25-54, and 55-65 years age range, respectively, and 34 in the T-CPR group with 11, 12, and 11 participants in the 18–24, 25–54, and 55–65 years age range, respectively) in the Phase I test. A change in the proportion of adequate CC by >5% was considered to be a relevant difference. With a statistical power of 90% and two-sided alpha level of 0.05, the minimum numbers of participants required in the TCPRLink/T-CPR group among the different age groups were 20 (18–24 years), 26 (25–54 years), and 18 (55–65 years), respectively. Considering the possibility of 20% loss to follow-up and the participants' availability, we recruited 54, 75, and 57 participants in the age ranges of 18–24, 25–54, and 55–65 years, respectively. 

## 197 Statistical analysis

Data are presented as frequencies with percentages for categorical variables and mean  $\pm$  standard deviation or median (interquartile range, IQR; M [P<sub>25</sub>-P<sub>75</sub>]) for continuous variables. Normal distribution was confirmed using the Kolmogorov-Smirnov test. Intergroup differences in the outcomes for the categorical variables were assessed using the chi-square or Fisher's exact test. Independent Student *t*-tests were conducted to explore the effect of the intervention for continuous variables with normal distribution, and Mann-Whitney U-test was used for variables with nonparametric distribution between the control and intervention arm. All analyses were conducted using SPSS 22.0. All P-values were 2-sided, and P < 0.05 was considered to be statistically significant.

## 208 RESULTS

A total of 186 participants (94 in T-CPR with TCPRLink group and 92 in conventional
T-CPR group) were included in this study. The demographic characteristics are shown
in Table 1. Age, gender, education level, and body mass index (BMI) did not differ
between the groups. Eight participants in each study arm were lost to follow-up after
the initial test (Figure 2).

During the 6 minutes of hands-only CPR, individuals in the TCPRLink group performed CC with a higher rate, both initially [median 111 (IQR 109–113) vs. 108  $(103-112) \text{ min}^{-1}$ , P=0.002] and at the 3-month re-test [111 (109-113) vs. 108 (105-112)] min<sup>-1</sup>, P < 0.001], compared to the conventional T-CPR group, respectively (Table 2 and Figure 3). In the TCPRLink group where the CC rate speedometer was displayed, individuals were less likely to count out the CC rhythms with the dispatcher (21.3% vs. 41.3%, P=0.003 and 7% vs. 22.6%, P=0.004, respectively) (Table 2 and Figure 4). Hands-off times, CC full-release ratio, and time to first CC did not statistically differ between the study groups either initially or at 3 months follow-up.

The depth of CCs in the TCPRLink group was significantly deeper in the age group of 55–65 years (47.1  $\pm$  9.6 vs. 38.5  $\pm$  8.7 mm, *P*=0.001) than in the control group in the Phase I test (**Table 3**). However, the CC depth showed a tendency to be deeper in TCPRLink group but the difference was not statistically significant in the Phase II test conducted 3 months later (44.7  $\pm$  10.1 vs. 39.3  $\pm$  10.8 mm, *P*=0.07; **Table 4**).

#### 228 DISCUSSION

This study evaluated a novel, digital invention that integrated an audiovisual feedback smartphone application and a web-based system, thereby combining real-time dispatcher instructions and real-time feedback to ensure the appropriate quality of CPR. We compared the quality of T-CPR performed by potential bystander-rescuers in the age range of 18–65 years in a cardiac arrest simulation scenario with or without the smartphone application. The results of this study showed that real-time, audiovisual feedback using a smartphone application and web-based system in combination with dispatcher instructions augmented the interaction between dispatchers and bystanders with a resultant positive effect on the quality of bystander-rendered CPR.

Dispatchers may coach callers to perform CPR, although they rely on audio communication alone to understand what is happening. With no other means of feedback, depending on the dispatcher's instructions may lead to lower quality CC and more hands-off time.[21] Several experimental manikin studies have demonstrated the potential benefits and drawbacks of video-assisted communication between rescuers and dispatchers compared to that of the conventional audio-instructed practice with regard to the CC rate and hand position.[22-26] In a recent study that compared the

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real-world effects of video- or audio-instructed T-CPR on the resuscitation outcomes,
video-instructed T-CPR caused no delay in initiating CC although it was not associated
with improvement in the survival rates.[27]

In dispatch-assisted instructions, the smartphone has secured a role as a promising carrier to improve video resuscitation care with its wide availability and high communication capabilities. Several diversified, advanced smartphone applications have been developed for integration into the links of the chain of survival and have feasibly created a strengthened "Mobile chain of survival" [28] as shown previously. One kind of application guides users in their CPR procedures via text and pictures or provides video examples of CPR with metronomic guidance that a bystander could watch before or during an actual resuscitation.[6, 8] Another application provides measurement of CPR quality and feedback based on motion-sensing which require the user to place the phone on the patient's chest or hold it between the rescuer's hands while performing CPR.[9-12] However, these previous smartphone solutions have neglected the potential to leverage the dispatcher's involvement and, therefore, may be less suitable for real-life emergencies as the phone connection may be accidentally lost when using the phone as a CPR feedback device.

Given its salient differences with regard to the other smartphone applications, the TCPRLink application could improve the effectiveness of T-CPR, both on the dispatcher instruction and bystander operation aspects. The TCPRLink application utilizes the smartphone front facing camera for continuous quality improvement through real-time feedback for the bystander and the dispatcher. Dispatcher could monitor the hands-off time and encourage the bystander to continue CPR when they experience fatigue. Therefore, this application may be suitable for real-world emergencies when considering the prolonged time to call the dispatch center and start CC, and that phone connection may be accidentally lost when using the phone as a CPR feedback device. [29]

As the risk of OHCA increases with age, [30, 31] older adults are more likely to be bystanders when their spouse or a family member experiences a cardiac arrest. The CPR capability of older adults has always been a significant concern. Another study that evaluated the effectiveness of a smartphone CPR application showed that

participants aged over 60 years could not sustain long-duration CPR. [9] However, in contrast with the results of that study, our study showed that TCPR Link app used with dispatcher assistance caused extra stimulus among seniors aged 55-65 as indicated by the subgroup analysis, with comparable quality of CPR with that of the younger participants during the 6 minutes of hands-only CPR. Moreover, providing a feasible CPR feedback devices for seniors might be an appropriate approach to increase not only their ability, but also their willingness and confidence to do CPR. [9] When guided by the TCPRLink application, the CC rate and depth of CPR performed by older participants were both better and in adherence to the guidelines when compared with that in the conventional T-CPR group. These data suggest that, with the two-way metric of CPR quality and dispatcher encouragement, older participants performed CPR equally well as did the younger generation.

Counting aloud is the commonest method by which the dispatcher can ensure an appropriate CC rate in T-CPR. Without feedback from the rescuer, the dispatcher's understanding of the rescuer's situation is poor. [32] Interestingly, we found that visual guidance of the CC rate from the speedometer on the smartphone reduced the need to count the number of CC aloud to maintain an appropriate rate. Thus, rescuers could expend more energy on compression and less on counting. Furthermore, a lesser need for counting in the dispatcher's protocol leaves more time to coach for compression depth and avoiding leaning. Contrary to the common concern that the use of mobile devices or smartphone applications to improve CPR quality might cause a delay in the initiation of CCs, [8, 10] the time to the first CC in the TCPRLink group was not prolonged as compared with that in the conventional T-CPR group in this study.

Nevertheless, some limitations of this study need to be mentioned. On the one hand, this study was implemented in a simulated environment which may not reflect the real-world scenario. The Hawthorn effect could not be excluded under the simulation scenario, and could result in a motivation bias. Therefore, this study followed a realistic approach to the simulation of bystander CPR in a cardiac arrest scenario. We invited a senior dispatcher who worked in the emergency dispatch center to portray the T-CPR scenario. On the other hand, a manikin may not represent the diversity of patients' chests and the changes in chest resistance during extended CPR. Lastly, we recruited voluntary participants aged between 18 and 65 years who attended the "WeCan CPR" 

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training project. Therefore, the participants of this study might have had a selection bias
as they had a positive willingness and knowledge of CPR training. We found that
elderly individuals older than 65 years were less likely to participate, considering their
physical capacity. The mean age of participants was nearly 40 years, which might not
be the representative age for bystanders in real life.

313 Conclusions

The TCPRLink smartphone application provides real-time feedback to both rescuer and dispatcher to enable more effective CC and lighten the load of counting out the CC with the dispatcher in a simulated T-CPR scenario. Further investigations are required to confirm the effectiveness of this application in the real-life resuscitation scenario.

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and analysis. XJ Dong and L Zhang contributed to manuscript writing. L Zhang, H
Myklebust, TS Birkenes, and Z-J Zheng provided administrative advice and
consultation. H Myklebust, TS Birkenes, and Z-J Zheng critically revised the final
version. All authors approved the final version of the manuscript.

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331 with regard to the trial or in the interpretation of the results.

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Table 1.	. Demographic	characteristics	of the	participants

	Total	TCPRLink group	T-CPR group
	(N=186)	(n=94)	(n=92)
Male (n, %)	83 (44.6)	42 (44.7)	41 (44.6)
Age, years			
18–24	54 (27.0)	29 (30.9)	25 (27.2)
25–54	75 (37.5)	37 (39.4)	38 (41.3)
55–65	57 (28.5)	28 (29.8)	29 (31.5)
Education status (n, %)			
≤High school/junior college	68 (36.6)	30 (31.9)	38 (41.3)
College	75 (40.3)	44 (46.8)	31 (33.7)
Masters and PhD	43 (23.1)	20 (21.3)	23 (25.0)
Height, m, means $\pm$ SD	$1.68 \pm 0.1$	$1.67 \pm 0.1$	$1.68 \pm 0.1$
Weight, kg, means $\pm$ SD	$64.5 \pm 11.4$	$63.3 \pm 10.3$	$65.6 \pm 12.4$
BMI, kg/m <sup>2</sup> , means $\pm$ SD	$22.9 \pm 3.1$	$22.7 \pm 2.8$	$23.0 \pm 3.4$

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	Phas	e I (N=186)	Phase II (N=170)			
<b>T-CPR performance</b>	TCPRLink group (n=94)	T-CPR group (n=92)	<i>P</i> -value	TCPRLink group (n=86)	T-CPR group (n=84)	<i>P</i> -value
Counting with the dispatcher (n, %)	20 (21.3)	38 (41.3)	0.003	6 (7.0)	19 (22.6)	0.004
Time from call connected to: (seconds	s, mean ± SD)					
Cardiac arrest identification	$98.2 \pm 12.8$	$99.1 \pm 16.9$	0.68	$101.7 \pm 13.0$	$104.2 \pm 15.0$	0.25
First chest compression	$143.6 \pm 17.8$	$140.0\pm25.8$	0.27	$149.7 \pm 16.6$	$146.0\pm20.2$	0.19
CPR parameters [M (P <sub>25</sub> -P <sub>75</sub> ) or mean	$n \pm SD$ ]					
Total number of compressions	661 (643–674)	648 (615–674)	0.035	661 (644–675)	646 (630–667)	0.002
Average compression rate (min <sup>-1</sup> )	111 (109–113)	108 (103–112)	0.002	111 (109–113)	108 (105–112)	< 0.001
Percentage of adequate rate (100– 120 min <sup>-1</sup> , %)	96 (89–98)	82 (50–97)	< 0.001	95 (78-98)	93 (67-97)	0.11
Average compression depth (mm)	$45.4\pm8.8$	$43.6\pm8.8$	0.17	$43.9 \pm 9.1$	$42.9 \pm 11.5$	0.59
Percentage of adequate depth (50– 60 mm, %)	20 (3–74)	12 (0–51)	0.14	17 (4–54)	13 (0–57)	0.26
Percentage of fully released (%)	97 (72–100)	97 (69–100)	0.79	95 (54–100)	96 (51-100)	0.40
Average hands-off time (s)	0 (0–1)	0 (0–1)	0.24	0 (0–1)	0 (0–1)	0.72

Phase I tests were cardiopulmonary resuscitation (CPR) performance and capabilities assessment using the telephone-assisted CPR (T-CPR) simulation scenario among individuals who have undergone CPR training with/without the TCPRLink application.

Phase II tests were CPR skill retention assessments among individuals with/without TCPRLink application after 3 months.

	Age	e 18–24 years		Age 2	5–54 years		Age 55–65 years			
TCPR performance	TCPRLink group (n=29)	T-CPR group (n=25)	<i>P</i> - value	TCPRLink group (n=37)	T-CPR group (n=38)	<i>P</i> - value	TCPRLink group (n=28)	T-CPR group (n=29)	<i>P</i> - value	
Counting with the				X	· · · · · · ·		<i>x x</i>			
dispatcher (n, %)	9 (31.0)	12 (48.0)	0.20	7 (18.9)	19 (50.0)	0.005	4 (14.3)	7 (4.1)	0.35	
Time from call connection to	: (seconds, me	ean ± SD)								
Cardiac arrest identification	98.9 ± 13.5	96.4 ± 19.5	0.58	97.0 ± 13.2	$98.2 \pm 14.0$	0.72	$98.9 \pm 12.0$	$102.7 \pm 17.8$	0.36	
First chest compression	$141.4 \pm 20.2$	$137.8 \pm 26.8$	0.57	$143.6 \pm 17.7$	$\begin{array}{r} 135.9 \pm \\ 26.9 \end{array}$	0.14	$145.8 \pm 15.4$	$147.1 \pm 22.5$	0.79	
CPR parameters [M (P <sub>25</sub> -P <sub>75</sub>	) or mean ± S	D]								
Total number of compression	663 (640– 671)	650 (608–666)	0.21	659 (653–677)	652 (632– 674)	0.29	659 (640– 676)	640 (612– 672)	0.14	
Average compression rate, (min <sup>-1</sup> )	111 (108– 113)	108 (101–112)	0.03	111 (109–114)	109 (106– 113)	0.12	110 (107– 113)	107 (103– 113)	0.06	
Percentage of adequate rate, (100–120 min <sup>-1</sup> , %)	95 (88–99)	82 (50–96)	0.01	97 (90–98)	89 (51–97)	0.006	95 (88–97)	71 (48–95)	0.003	
Average compression depth (mm)	$41.8 \pm 7.8$	$43.1\pm6.6$	0.49	$46.9\pm8.2$	47.8 ± 8.1	0.67	47.1 ± 9.6	$38.5 \pm 8.7$	0.001	
Percentage of adequate depth (50–60 mm, %)	8 (0–28)	12 (4–33)	0.37	25 (9-84)	37 (7–86)	0.92	45 (1–99)	1 (0–14)	0.002	
Percentage of fully released (%)	100 (95–100)	100 (96–100)	0.66	98 (79–100)	95 (57–99)	0.24	71 (5–100)	96 (37–100)	0.13	
Average hands-off time (s)	0 (0–2)	0 (0–1)	0.24	0 (0–1)	0 (0–0)	0.45	0 (0–1)	0 (0–1)	0.92	

**Table 3** Age-stratified comparison of the participants' CPR performance in the TCPRLink and T-CPR groups (Phase I)

 Phase I tests were conducted for the evaluation of CPR performance and capabilities assessment using a telephone-assisted CPR (T-CPR) simulation scenario among individuals who have undergone CPR training with/without the TCPRLink application.

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	Ag	e 18–24 years		Age 2	5–54 years		Age	55–65 years	
TCPR performance	TCPRLink group (n=29)	T-CPR group (n=23)	<i>P</i> - value	TCPRLink group (n=31)	T-CPR group (n=34)	<i>P</i> - value	TCPRLink group (n=26)	T-CPR group (n=27)	<i>P</i> - valu
Counting with the dispatcher (n, %)	2 (6.9)	4 (17.4)	0.40	4 (12.9)	12 (35.3)	0.036	0 (0)	3 (11.1)	0.24
Time from call connected to:	(seconds, me	an ± SD)							
Cardiac arrest identification	$99.8 \pm 16.0$	$100.4 \pm 16.3$	0.89	$103.8 \pm 13.6$	$103.0 \pm 11.9$	0.82	$101.4\pm7.3$	$108.9 \pm 16.7$	0.04
First chest compression	$148.4 \pm 20.1$	$144.2 \pm 25.5$	0.52	$153.2 \pm 17.3$	$143.6 \pm 13.9$	0.018	$146.8 \pm 9.8$	$150.4 \pm 21.9$	0.45
CPR parameters [M(P <sub>25</sub> -P <sub>75</sub> )	or mean ± Sl	D]							
Total number of compressions	658 (643– 678)	639 (605–653)	0.004	665 (653–675)	648 (640– 668)	0.09	663 (644– 676)	643 (627– 680)	0.32
Average compression rate (min <sup>-1</sup> )	111 (109– 113)	107 (101–110)	< 0.001	112 (109–113)	109 (107– 112)	0.06	111 (107– 114)	109 (105– 114)	0.28
Percentage of adequate rate (100-120 min <sup>-1</sup> , %)	96 (82–99)	82 (60–98)	0.08	95 (78–98)	95 (84–97)	0.64	92 (77–98)	90 (70–97)	0.61
Average compression depth (mm)	41.7 ± 8.2	$43.7 \pm 14.1$	0.55	$45.2 \pm 9.0$	$45.4 \pm 9.6$	0.92	44.7 ± 10.1	39.3 ± 10.8	0.07
Percentage of adequate depth (50–60 mm, %)	10 (2–32)	10 (0–54)	0.92	19 (7–55)	22 (2-81)	0.97	19 (3–68)	2 (0-24)	0.04
Percentage of fully released compressions (%)	100 (92– 100)	99 (91–100)	0.52	93 (15–100)	90 (44–99)	0.65	68 (33–100)	89 (24–99)	0.84
Average hands-off time (s)	0 (0-2)	0 (0–1)	0.16	0 (0-1)	0 (0–1)	0.48	0 (0–0)	0 (0-0)	0.89

Phase II tests were conducted for the evaluation of CPR performance and capabilities assessment using telephone-assisted CPR (T-CPR) simulation scenario among individuals who have received CPR training with/without a TCPRLink application at 3 months after the training.

## **Figure Legends**

Figure 1 The illustration of TCPRLink application in use.

(a) Illustration photo of TCPRLink in use in a simulated T-CPR situation. (b) Screenshots of TCPRLink. Front page to the left and bystander feedback example to the right. (c) Screenshot of the web server available for the dispatcher.

Figure 2 Flow diagram of the participants.

**Figure 3** Distribution of the chest compression rate and the proportion of the adequate chest compression rate (100-120 min-1) in TCPRLink group and T-CPR group.

Phase I test was conducted in T-CPR trained individuals with/without TCPRLink App after inclusion.

Phase II test was conducted in the same individuals with/without TCPRLink App after three months.

Figure 4 Counting with dispatcher in TCPRLink group and T-CPR group.

Phase I test was conducted in T-CPR trained individuals with/without TCPRLink App after inclusion.

Phase II test was conducted in the same individuals with/without TCPRLink App after three months.

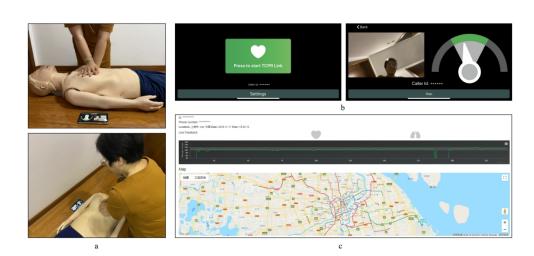


Figure 1 The illustration of TCPRLink application in use.

(a) Illustration photo of TCPRLink in use in a simulated T-CPR situation. (b) Screenshots of TCPRLink. Front page to the left and bystander feedback example to the right. (c) Screenshot of the web server available for the dispatcher.

225x111mm (300 x 300 DPI)

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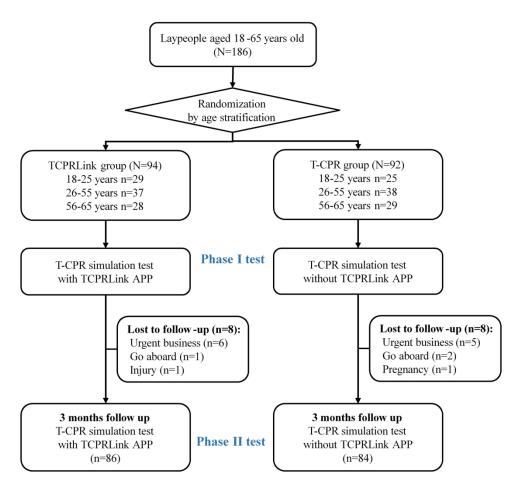
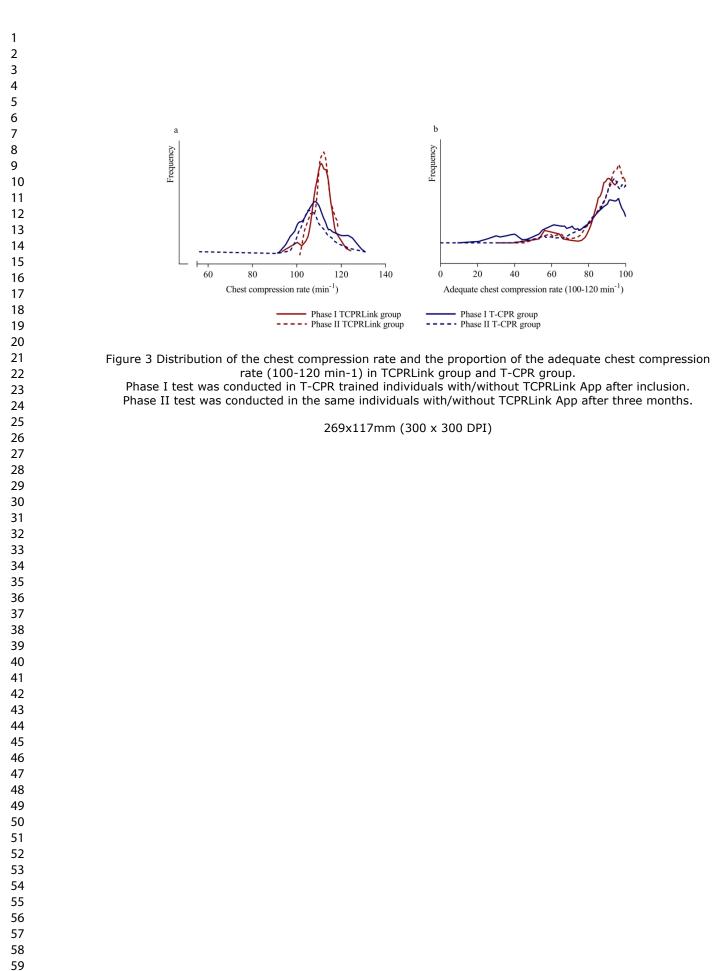


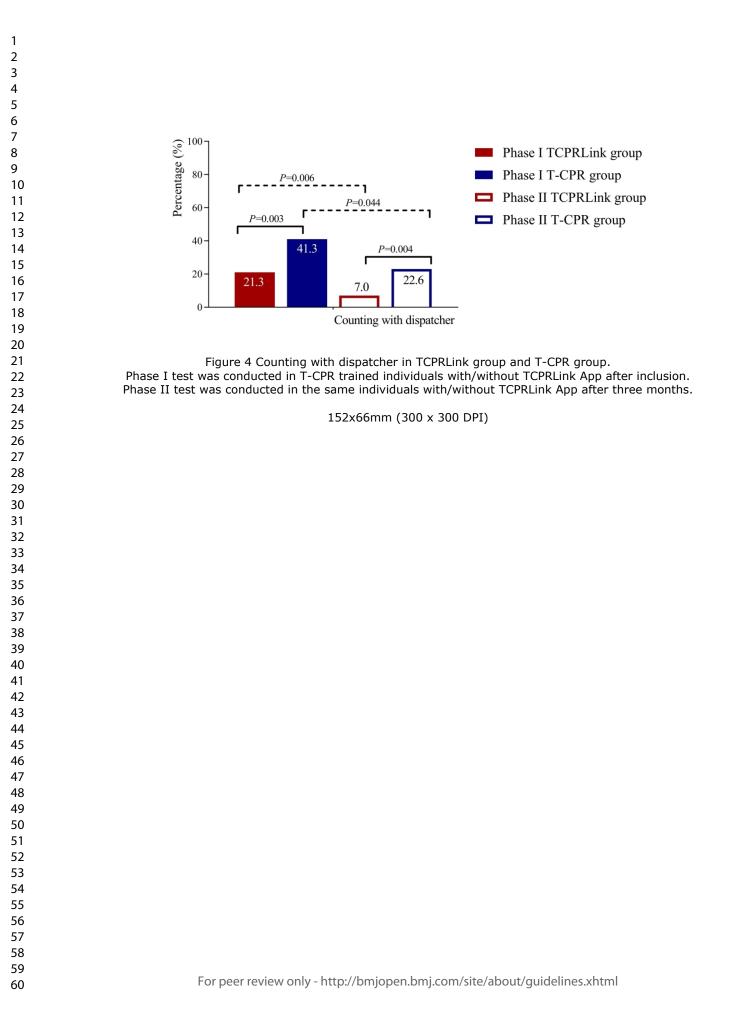
Figure 2 Flow diagram of the participants.

187x175mm (300 x 300 DPI)

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## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	ltem No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and	2a	Scientific background and explanation of rationale	
objectives	2b	Specific objectives or hypotheses	
•			
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	\
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5, 6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	\
Sample size	7a	How sample size was determined	7, 8
·	7b	When applicable, explanation of any interim analyses and stopping guidelines	\
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	5
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	\
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	5
Blinding	11a	interventions If done, who was blinded after assignment to interventions (for example, participants, care providers, those	\
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		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	١
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8, Figure 2
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	1
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	Figure 2
		by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	\
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Table 3-4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	9-11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	9-11
Other information			
Registration	23	Registration number and name of trial registry	١
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1, 12

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see <u>www.consort-statement.org</u>.

CONSORT 2010 checklist

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## Effect of a Real-Time Feedback Smartphone Application (TCPRLink) on the Quality of Telephone-assisted CPR Performed by trained laypeople in China: A manikin-based randomized controlled study

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Keywords:	ACCIDENT & EMERGENCY MEDICINE, PUBLIC HEALTH, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS

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3	1	Effect of a Real-Time Feedback Smartphone Application (TCPRLink) on the
5 6 7	2	Quality of Telephone-assisted CPR Performed by trained laypeople in China: A
8 9	3	manikin-based randomized controlled study
10 11	4	Xuejie Dong <sup>1#</sup> , Lin Zhang <sup>1*#</sup> , Helge Myklebust <sup>2</sup> , Tonje Soraas Birkenes <sup>2</sup> , Zhi-Jie
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35 36 37	16	Word count: 3210
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## 20 ABSTRACT

Objectives: To determine the effect of a free smartphone application (TCPRLink) that
provides real-time monitoring and audiovisual feedback on chest compressions (CC)
on trained layperson telephone-assisted cardiopulmonary resuscitation (T-CPR)
performance.

**Design:** A manikin-based randomized controlled study.

26 Setting: This study was conducted at a multidisciplinary university and a community27 center in China.

**28 Participants:** One hundred and eighty-six adult participants (age 18-65 years) with T-

29 CPR training experience were randomly assigned to the TCPRLink (n=94) and T-CPR
30 (n=92) groups with age stratification.

31 Interventions: We compared the participants' performance for 6-minutes of CC in a
32 simulated T-CPR scenario both at the baseline and after 3 months.

Primary and secondary outcome measures: The primary outcomes were the CC rate
and proportion of adequate CC rate (100–120 min<sup>-1</sup>). The secondary outcomes included
the proportion of participants counting the CC rhythm, time to first CC, CC depth,
hands-off time, and CC full-release ratio.

Results: Participants in the TCPRLink feedback group more consistently performed CC with higher rate, both initially and 3 month later [median 111 (IQR 109–113) vs. 108 (103–112) min<sup>-1</sup>, P=0.002 and 111 (109–113) vs. 108 (105–112) min<sup>-1</sup>, P<0.001, respectively], with less need to count the rhythm [21.3% vs. 41.3%, P=0.003 and 7% vs. 22.6%, P=0.004, respectively] compared with the T-CPR group. There were no significant differences in time to the first CC, hands-off time, or CC full-release ratio. Among 55-65 year group, the CC depth was deeper in the TCPRLink group than in the TCPR group  $(47.1\pm9.6 \text{ vs } 38.5\pm8.7 \text{ mm}, P=0.001, \text{ and } 44.7\pm10.1 \text{ vs } 39.3\pm10.8 \text{ mm},$ P=0.07, respectively).

46 Conclusions: The TCPRLink application improved T-CPR quality in trained
47 laypersons to provide more effective CCs and lighten the load of counting out the CC
48 with the dispatcher in a simulated T-CPR scenario. Further investigations are required
49 to confirm this effectiveness in real-life resuscitation attempts.

52 Strengths and limitations of this study

- The effectiveness of a real-time feedback smartphone application (TCPRLink) was evaluated in a telephone-assisted CPR (T-CPR) simulation among participants from the Chinese general population.
- Trained adult laypersons (age range 18–65 years) participated in this study to facilitate the identification of discrepancies in T-CPR performance among different age groups.
- The study included a 3-month follow-up T-CPR performance test to investigate the participants' skill retention.
- The Hawthorn effect could not be excluded in the simulation scenario, with the possibility of a motivation bias.

#### 64 INTRODUCTION

Bystander-provided immediate and adequate cardiopulmonary resuscitation (CPR) can directly impact patient outcomes following an out-of-hospital cardiac arrest.[1-3] The updated guidelines of the American Heart Association (AHA) and European Resuscitation Council (ERC) state that telephone-assisted CPR (T-CPR) has a positive effect on the entire resuscitation process by getting more callers to start CPR and through coaching the callers to provide effective CPR.[4, 5] Despite significant advances in the T-CPR instructions during the resuscitation procedures, here exists a blind zone between the dispatcher and caller. The dispatcher is voice connected to the caller via the phone, but is unable to see the patient and evaluate the quality of bystander CPR. Therefore, new strategies to address this challenge are needed.

The ubiquitous presence and utilization of smartphones suggest a novel opportunity to improve resuscitation care through the measurement of bystander CPR metrics.[6-12] In a recent statement from the AHA and ERC, the use of digital strategies, such as mobile devices, were encouraged to provide bystanders with an accelerometer to measure CPR metrics.[13, 14] In adherence to these guidelines, an audiovisual smartphone application (TCPRLink) was developed to facilitate high-quality bystander-provided CPR and assist the dispatcher to evaluate the CPR quality in real time.[15] The TCPRLink application utilizes the smartphone front camera to detect chest compressions (CC) and displays the CC rate to the bystanders and simultaneously sends the real-time CC rate and the time without compressions via the internet to a monitor that is in front of the dispatcher.

This study was conducted to evaluate the effectiveness of the TCPRLink application with real-time audiovisual feedback in dispatcher-assisted CPR during a cardiac arrest simulation. We hypothesized that this smartphone-based CC rate feedback application would improve the quality of CPR in the general population compared to the use of conventional T-CPR instructions.

91 METHODS

#### 92 Study design and ethics

93 This study was a simulation-based randomized experimental trial that was carried out
94 from September 1, 2018 to May 30, 2019. We obtained ethical approval from the Joint
95 Research Ethics Board of the Shanghai Jiao Tong University Schools of Public Health
96 and Nursing (approval no. SJUPN-201714) for study conduct. All participants were
97 verbally informed about the purpose of the study and provided written informed consent.
98 They were informed that their T-CPR performance would be tested and video-recorded
99 in a simulated scenario after training and, again, 3 months later.

#### 100 Study population

We randomly recruited 186 participants from those who participated in the "WeCan
CPR" training program [16] an initiative of the China Resuscitation Academy. College
students and adult laypersons (age range 18–65 years) who had completed the training
program within one week were eligible for study enrolment. Physicians, nurses,
dispatchers, and other healthcare professionals were excluded from the study.

106 The WeCan CPR course is a video-based, 1-hour training program on applying 107 dispatcher-telephone-guided CPR training in combination with practical and basic CPR 108 training that is targeted at potential bystanders. Participants learn how to call the 109 emergency dispatch center, follow the procedure of the T-CPR instructions, and 110 perform hands-only CPR. All trainees performed at least 550 CC on instrumented 111 feedback manikins (QCPR Classroom, Laerdal Medical, Norway) during the training.

## **Patient and public involvement**

113 Patients or the public were not involved in the design, or conduct, or reporting, or 114 dissemination of our research.

### 115 Randomization

116 Randomization was stratified by age groups (18–24, 25–54, and 55–65 years) and 117 conducted to ensure equal distribution of participants across study arms. Participants 118 were randomized into either the control arm (conventional T-CPR group) or 119 interventional arm (T-CPR with the TCPRLink group). All participants were informed 120 the purpose of the study, which was to assess the impact of the TCPRLink App on 121 resuscitation performance, and were not blinded to the study-arm allocation due to the 122 nature of the intervention.

## 123 TCPRLink application

TCPRLink (University of Stavanger and Laerdal Medical, Norway) is a free, CPR
audiovisual feedback smartphone application that was designed to measure the CC rate
and hands-off time and to provide feedback to the *bystander* and the *dispatcher*. The
accuracy and validation of the TCPRLink app has been demonstrated earlier. [17]

The illustration of the application in use is presented in **Figure 1**. By clicking the "Press to start TCPR Link" button, the application activates the speaker, establishes a telephone connection with the dispatcher, activates the TCPRLink app which captures and analyzes the CPR movement via the front facing camera of the smartphone in real time, and simultaneously sends the location and real-time compression data to a web server which is available for the dispatcher (web server: http://tcprlink.azurewebsites.net/?%20 country=china). 

At the bystander interface, a speedometer displayed on the smartphone screen next to a
preview frame allows the bystander to keep track of the CC rate, which is obtained by
analyzing body movement. Thus, the individual receives real-time objective feedback
via the speedometer (with the indicator in the green or yellow range of 100–120 and
<100 or >120 compressions/minute, respectively).

Similarly, at the dispatcher's interface, real-time objective feedback is presented during
the emergency call via a sliding window from a website presented on a computer screen
that shows the history and progression of the CC rate. Guided by the indicator on web
server, the dispatcher can further guided the bystander-rendered CC rate through direct
instructions to "push faster", "push slower", or "don't stop".

145 Study procedures

The T-CPR performance of all participants were evaluated twice. The first evaluation
(Phase I test) was conducted within one week of WeCanCPR training in a cardiac arrest
T-CPR simulated scenario, and the second occurred 3 months later (Phase II test) and
corresponded to the same setting as the initial test.

The simulations were performed in a quiet, isolated, designated room with a manikin
placed on the floor. Individuals were asked to enter the room alone, make an emergency
call to an assigned phone number, and try their best to rescue the manikin in a cardiac

arrest T-CPR simulated scenario. T-CPR instructions were strictly standardized using
the Medical Priority Dispatch System (MPDS version 12.1, Salt Lake City, US) OHCA
dispatch protocol.[18] One dispatcher who had 6 years of T-CPR experience from
working at the local emergency dispatch center acted as dispatcher in the simulation.

During T-CPR calls, individuals were asked for their current address, patient's age and gender, patient's consciousness level, and breathing status in accordance with the MPDS protocol. Then, individuals were instructed by the dispatcher to activate the speaker and place their phone on the floor by the manikin. The dispatcher followed a standard procedure to initiate CPR and let the participant perform hands-only CPR for 6 minutes. For encouragement, the dispatcher counted the CC rhythm with the participants and said "good job, push harder" every 30 seconds during the simulation.

For the conventional T-CPR group, the participants received no visual feedback from the smartphone and were guided only by the dispatcher instructions. For the TCPRLink group, individuals were asked to call for help using the TCPRLink app. The participants' behavior and performance during the simulation exercise were recorded by a separate video camera that faced toward the manikin and was located 80 cm above the ground and 1.5 m away for a panoramic shot.

#### **Outcome measures**

The primary outcomes measured were the CC rate and the proportion of the adequate CC meeting the guideline-recommended rate  $(100-120 \text{ min}^{-1})$  [19, 20] during 6 minutes of hands-only CPR. The secondary outcomes were CC depth, the proportion of CC with the adequate CC depth (5–6 cm), the proportion of CC with complete recoil (complete release recoil of the chest between compressions), and the absolute hands-off time (the sum of all periods during which there was no hand compression of the chest) during the 6 minutes of hands-only CC. The abovementioned parameters of CCs effectiveness were monitored using the proprietary software for the ResusciAnne® QCPR manikin (Laerdal Medical, Norway).

180 The video recording of the simulation scenario was used to evaluate individual
181 participant behaviors, including the communication with the dispatcher (counting the
182 CC rhythms with the dispatcher) and time to first CC (time interval from call connection
183 to first CC). We documented the age, sex, education level, self-reported body weight,

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184 and height of all participants.

## 185 Sample size estimation

The sample size calculation was followed to sequentially recruit 68 participants (34 in the TCPRLink group with 12, 11, and 11 participants in the 18-24, 25-54, and 55-65 years age range, respectively, and 34 in the T-CPR group with 11, 12, and 11 participants in the 18–24, 25–54, and 55–65 years age range, respectively) in the Phase I test. A change in the proportion of adequate CC by >5% was considered to be a relevant difference. With a statistical power of 90% and two-sided alpha level of 0.05, the minimum numbers of participants required in the TCPRLink/T-CPR group among the different age groups were 20 (18–24 years), 26 (25–54 years), and 18 (55–65 years), respectively. Considering the possibility of 20% loss to follow-up and the participants' availability, we recruited 54, 75, and 57 participants in the age ranges of 18–24, 25–54, and 55–65 years, respectively. 

## 197 Statistical analysis

Data are presented as frequencies with percentages for categorical variables and mean  $\pm$  standard deviation or median (interquartile range, IQR; M [P<sub>25</sub>-P<sub>75</sub>]) for continuous variables. Normal distribution was confirmed using the Kolmogorov-Smirnov test. Intergroup differences in the outcomes for the categorical variables were assessed using the chi-square or Fisher's exact test. Independent Student *t*-tests were conducted to explore the effect of the intervention for continuous variables with normal distribution, and Mann-Whitney U-test was used for variables with nonparametric distribution between the control and intervention arm. All analyses were conducted using SPSS 22.0. All P-values were 2-sided, and P < 0.05 was considered to be statistically significant.

## 208 RESULTS

A total of 186 participants (94 in T-CPR with TCPRLink group and 92 in conventional
T-CPR group) were included in this study. The demographic characteristics are shown
in Table 1. Age, gender, education level, and body mass index (BMI) did not differ
between the groups. Eight participants in each study arm were lost to follow-up after
the initial test (Figure 2).

During the 6 minutes of hands-only CPR, individuals in the TCPRLink group performed CC with a higher rate, both initially [median 111 (IQR 109–113) vs. 108  $(103-112) \text{ min}^{-1}$ , P=0.002] and at the 3-month re-test [111 (109-113) vs. 108 (105-112)] min<sup>-1</sup>, P < 0.001], compared to the conventional T-CPR group, respectively (Table 2 and Figure 3). In the TCPRLink group where the CC rate speedometer was displayed, individuals were less likely to count out the CC rhythms with the dispatcher (21.3% vs. 41.3%, P=0.003 and 7% vs. 22.6%, P=0.004, respectively) (Table 2 and Figure 4). Hands-off times, CC full-release ratio, and time to first CC did not statistically differ between the study groups either initially or at 3 months follow-up.

The depth of CCs in the TCPRLink group was significantly deeper in the age group of 55–65 years (47.1  $\pm$  9.6 vs. 38.5  $\pm$  8.7 mm, *P*=0.001) than in the control group in the Phase I test (**Table 3**). However, the CC depth showed a tendency to be deeper in TCPRLink group but the difference was not statistically significant in the Phase II test conducted 3 months later (44.7  $\pm$  10.1 vs. 39.3  $\pm$  10.8 mm, *P*=0.07; **Table 4**).

#### 228 DISCUSSION

This study evaluated a novel, digital invention that integrated an audiovisual feedback smartphone application and a web-based system, thereby combining real-time dispatcher instructions and real-time feedback to ensure the appropriate quality of CPR. We compared the quality of T-CPR performed by potential bystander-rescuers in the age range of 18–65 years in a cardiac arrest simulation scenario with or without the smartphone application. The results of this study showed that real-time, audiovisual feedback using a smartphone application and web-based system in combination with dispatcher instructions augmented the interaction between dispatchers and bystanders with a resultant positive effect on the quality of bystander-rendered CPR.

Dispatchers may coach callers to perform CPR, although they rely on audio communication alone to understand what is happening. With no other means of feedback, depending on the dispatcher's instructions may lead to lower quality CC and more hands-off time.[21] Several experimental manikin studies have demonstrated the potential benefits and drawbacks of video-assisted communication between rescuers and dispatchers compared to that of the conventional audio-instructed practice with regard to the CC rate and hand position.[22-26] In a recent study that compared the

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real-world effects of video- or audio-instructed T-CPR on the resuscitation outcomes,
video-instructed T-CPR caused no delay in initiating CC although it was not associated
with improvement in the survival rates.[27]

In dispatch-assisted instructions, the smartphone has secured a role as a promising carrier to improve video resuscitation care with its wide availability and high communication capabilities. Several diversified, advanced smartphone applications have been developed for integration into the links of the chain of survival and have feasibly created a strengthened "Mobile chain of survival" [28] as shown previously. One kind of application guides users in their CPR procedures via text and pictures or provides video examples of CPR with metronomic guidance that a bystander could watch before or during an actual resuscitation.[6, 8] Another application provides measurement of CPR quality and feedback based on motion-sensing which require the user to place the phone on the patient's chest or hold it between the rescuer's hands while performing CPR.[9-12] However, these previous smartphone solutions have neglected the potential to leverage the dispatcher's involvement and, therefore, may be less suitable for real-life emergencies as the phone connection may be accidentally lost when using the phone as a CPR feedback device.

Given its salient differences with regard to the other smartphone applications, the TCPRLink application could improve the effectiveness of T-CPR, both on the dispatcher instruction and bystander operation aspects. The TCPRLink application utilizes the smartphone front facing camera for continuous quality improvement through real-time feedback for the bystander and the dispatcher. Dispatcher could monitor the hands-off time and encourage the bystander to continue CPR when they experience fatigue. Therefore, this application may be suitable for real-world emergencies when considering the prolonged time to call the dispatch center and start CC, and that phone connection may be accidentally lost when using the phone as a CPR feedback device. [29]

As the risk of OHCA increases with age, [30, 31] older adults are more likely to be bystanders when their spouse or a family member experiences a cardiac arrest. The CPR capability of older adults has always been a significant concern. Another study that evaluated the effectiveness of a smartphone CPR application showed that

participants aged over 60 years could not sustain long-duration CPR. [9] However, in contrast with the results of that study, our study showed that TCPR Link app used with dispatcher assistance caused extra stimulus among seniors aged 55-65 as indicated by the subgroup analysis, with comparable quality of CPR with that of the younger participants during the 6 minutes of hands-only CPR. Moreover, providing a feasible CPR feedback devices for seniors might be an appropriate approach to increase not only their ability, but also their willingness and confidence to do CPR. [9] When guided by the TCPRLink application, the CC rate and depth of CPR performed by older participants were both better and in adherence to the guidelines when compared with that in the conventional T-CPR group. These data suggest that, with the two-way metric of CPR quality and dispatcher encouragement, older participants performed CPR equally well as did the younger generation.

Counting aloud is the commonest method by which the dispatcher can ensure an appropriate CC rate in T-CPR. Without feedback from the rescuer, the dispatcher's understanding of the rescuer's situation is poor. [32] Interestingly, we found that visual guidance of the CC rate from the speedometer on the smartphone reduced the need to count the number of CC aloud to maintain an appropriate rate. Thus, rescuers could expend more energy on compression and less on counting. Furthermore, a lesser need for counting in the dispatcher's protocol leaves more time to coach for compression depth and avoiding leaning. Contrary to the common concern that the use of mobile devices or smartphone applications to improve CPR quality might cause a delay in the initiation of CCs, [8, 10] the time to the first CC in the TCPRLink group was not prolonged as compared with that in the conventional T-CPR group in this study.

Nevertheless, some limitations of this study need to be mentioned. On the one hand, this study was implemented in a simulated environment which may not reflect the real-world scenario. The Hawthorn effect could not be excluded under the simulation scenario, and could result in a motivation bias. Therefore, this study followed a realistic approach to the simulation of bystander CPR in a cardiac arrest scenario. We invited a senior dispatcher who worked in the emergency dispatch center to portray the T-CPR scenario. On the other hand, a manikin may not represent the diversity of patients' chests and the changes in chest resistance during extended CPR. Lastly, we recruited voluntary participants aged between 18 and 65 years who attended the "WeCan CPR" 

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training project. Therefore, the participants of this study might have had a selection bias
as they had a positive willingness and knowledge of CPR training. We found that
elderly individuals older than 65 years were less likely to participate, considering their
physical capacity. The mean age of participants was nearly 40 years, which might not
be the representative age for bystanders in real life.

313 Conclusions

The TCPRLink smartphone application provides real-time feedback to both rescuer and dispatcher to enable more effective CC and lighten the load of counting out the CC with the dispatcher in a simulated T-CPR scenario. Further investigations are required to confirm the effectiveness of this application in the real-life resuscitation scenario.

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and analysis. XJ Dong and L Zhang contributed to manuscript writing. L Zhang, H
Myklebust, TS Birkenes, and Z-J Zheng provided administrative advice and
consultation. H Myklebust, TS Birkenes, and Z-J Zheng critically revised the final
version. All authors approved the final version of the manuscript.

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331 with regard to the trial or in the interpretation of the results.

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Table 1.	. Demographic	characteristics	of the	participants

	Total	TCPRLink group	T-CPR group
	(N=186)	(n=94)	(n=92)
Male (n, %)	83 (44.6)	42 (44.7)	41 (44.6)
Age, years			
18–24	54 (27.0)	29 (30.9)	25 (27.2)
25–54	75 (37.5)	37 (39.4)	38 (41.3)
55–65	57 (28.5)	28 (29.8)	29 (31.5)
Education status (n, %)			
≤High school/junior college	68 (36.6)	30 (31.9)	38 (41.3)
College	75 (40.3)	44 (46.8)	31 (33.7)
Masters and PhD	43 (23.1)	20 (21.3)	23 (25.0)
Height, m, means $\pm$ SD	$1.68 \pm 0.1$	$1.67 \pm 0.1$	$1.68 \pm 0.1$
Weight, kg, means $\pm$ SD	$64.5 \pm 11.4$	$63.3 \pm 10.3$	$65.6 \pm 12.4$
BMI, kg/m <sup>2</sup> , means $\pm$ SD	$22.9 \pm 3.1$	$22.7 \pm 2.8$	$23.0 \pm 3.4$

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	Phas	e I (N=186)	Phase II (N=170)			
<b>T-CPR performance</b>	TCPRLink group (n=94)	T-CPR group (n=92)	<i>P</i> -value	TCPRLink group (n=86)	T-CPR group (n=84)	<i>P</i> -value
Counting with the dispatcher (n, %)	20 (21.3)	38 (41.3)	0.003	6 (7.0)	19 (22.6)	0.004
Time from call connected to: (seconds	s, mean ± SD)					
Cardiac arrest identification	$98.2 \pm 12.8$	$99.1 \pm 16.9$	0.68	$101.7 \pm 13.0$	$104.2 \pm 15.0$	0.25
First chest compression	$143.6 \pm 17.8$	$140.0\pm25.8$	0.27	$149.7 \pm 16.6$	$146.0\pm20.2$	0.19
CPR parameters [M (P <sub>25</sub> -P <sub>75</sub> ) or mean	$n \pm SD$ ]					
Total number of compressions	661 (643–674)	648 (615–674)	0.035	661 (644–675)	646 (630–667)	0.002
Average compression rate (min <sup>-1</sup> )	111 (109–113)	108 (103–112)	0.002	111 (109–113)	108 (105–112)	< 0.001
Percentage of adequate rate (100– 120 min <sup>-1</sup> , %)	96 (89–98)	82 (50–97)	< 0.001	95 (78-98)	93 (67-97)	0.11
Average compression depth (mm)	$45.4\pm8.8$	$43.6\pm8.8$	0.17	$43.9 \pm 9.1$	$42.9 \pm 11.5$	0.59
Percentage of adequate depth (50– 60 mm, %)	20 (3–74)	12 (0–51)	0.14	17 (4–54)	13 (0–57)	0.26
Percentage of fully released (%)	97 (72–100)	97 (69–100)	0.79	95 (54–100)	96 (51-100)	0.40
Average hands-off time (s)	0 (0–1)	0 (0–1)	0.24	0 (0–1)	0 (0–1)	0.72

Phase I tests were cardiopulmonary resuscitation (CPR) performance and capabilities assessment using the telephone-assisted CPR (T-CPR) simulation scenario among individuals who have undergone CPR training with/without the TCPRLink application.

Phase II tests were CPR skill retention assessments among individuals with/without TCPRLink application after 3 months.

	Age	e 18–24 years		Age 25–54 years			Age 55–65 years		
TCPR performance	TCPRLink group (n=29)	T-CPR group (n=25)	<i>P</i> - value	TCPRLink group (n=37)	T-CPR group (n=38)	<i>P</i> - value	TCPRLink group (n=28)	T-CPR group (n=29)	<i>P</i> - value
Counting with the				X	· · · · · · ·		<i>x x</i>		
dispatcher (n, %)	9 (31.0)	12 (48.0)	0.20	7 (18.9)	19 (50.0)	0.005	4 (14.3)	7 (4.1)	0.35
Time from call connection to	: (seconds, me	ean ± SD)							
Cardiac arrest identification	98.9 ± 13.5	96.4 ± 19.5	0.58	97.0 ± 13.2	$98.2 \pm 14.0$	0.72	$98.9 \pm 12.0$	$102.7 \pm 17.8$	0.36
First chest compression	$141.4 \pm 20.2$	$137.8 \pm 26.8$	0.57	$143.6 \pm 17.7$	$\begin{array}{r} 135.9 \pm \\ 26.9 \end{array}$	0.14	$145.8 \pm 15.4$	$147.1 \pm 22.5$	0.79
CPR parameters [M (P <sub>25</sub> -P <sub>75</sub>	) or mean ± S	D]							
Total number of compression	663 (640– 671)	650 (608–666)	0.21	659 (653–677)	652 (632– 674)	0.29	659 (640– 676)	640 (612– 672)	0.14
Average compression rate, (min <sup>-1</sup> )	111 (108– 113)	108 (101–112)	0.03	111 (109–114)	109 (106– 113)	0.12	110 (107– 113)	107 (103– 113)	0.06
Percentage of adequate rate, (100–120 min <sup>-1</sup> , %)	95 (88–99)	82 (50–96)	0.01	97 (90–98)	89 (51–97)	0.006	95 (88–97)	71 (48–95)	0.003
Average compression depth (mm)	$41.8 \pm 7.8$	$43.1\pm6.6$	0.49	$46.9\pm8.2$	47.8 ± 8.1	0.67	47.1 ± 9.6	$38.5 \pm 8.7$	0.001
Percentage of adequate depth (50–60 mm, %)	8 (0–28)	12 (4–33)	0.37	25 (9-84)	37 (7–86)	0.92	45 (1–99)	1 (0–14)	0.002
Percentage of fully released (%)	100 (95–100)	100 (96–100)	0.66	98 (79–100)	95 (57–99)	0.24	71 (5–100)	96 (37–100)	0.13
Average hands-off time (s)	0 (0–2)	0 (0–1)	0.24	0 (0–1)	0 (0–0)	0.45	0 (0–1)	0 (0–1)	0.92

**Table 3** Age-stratified comparison of the participants' CPR performance in the TCPRLink and T-CPR groups (Phase I)

 Phase I tests were conducted for the evaluation of CPR performance and capabilities assessment using a telephone-assisted CPR (T-CPR) simulation scenario among individuals who have undergone CPR training with/without the TCPRLink application.

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	Age 18–24 years			Age 2	5–54 years		Age	55–65 years	
TCPR performance	TCPRLink group (n=29)	T-CPR group (n=23)	<i>P</i> - value	TCPRLink group (n=31)	T-CPR group (n=34)	<i>P</i> - value	TCPRLink group (n=26)	T-CPR group (n=27)	<i>P</i> - valu
Counting with the dispatcher (n, %)	2 (6.9)	4 (17.4)	0.40	4 (12.9)	12 (35.3)	0.036	0 (0)	3 (11.1)	0.24
Time from call connected to:	(seconds, me	an ± SD)							
Cardiac arrest identification	$99.8 \pm 16.0$	$100.4 \pm 16.3$	0.89	$103.8 \pm 13.6$	$103.0 \pm 11.9$	0.82	$101.4\pm7.3$	$108.9 \pm 16.7$	0.04
First chest compression	$148.4 \pm 20.1$	$144.2 \pm 25.5$	0.52	$153.2 \pm 17.3$	$143.6 \pm 13.9$	0.018	$146.8 \pm 9.8$	$150.4 \pm 21.9$	0.45
CPR parameters [M(P <sub>25</sub> -P <sub>75</sub> )	or mean ± Sl	D]							
Total number of compressions	658 (643– 678)	639 (605–653)	0.004	665 (653–675)	648 (640– 668)	0.09	663 (644– 676)	643 (627– 680)	0.32
Average compression rate (min <sup>-1</sup> )	111 (109– 113)	107 (101–110)	< 0.001	112 (109–113)	109 (107– 112)	0.06	111 (107– 114)	109 (105– 114)	0.28
Percentage of adequate rate (100-120 min <sup>-1</sup> , %)	96 (82–99)	82 (60–98)	0.08	95 (78–98)	95 (84–97)	0.64	92 (77–98)	90 (70–97)	0.61
Average compression depth (mm)	41.7 ± 8.2	$43.7 \pm 14.1$	0.55	$45.2 \pm 9.0$	$45.4 \pm 9.6$	0.92	$44.7 \pm 10.1$	$39.3 \pm 10.8$	0.07
Percentage of adequate depth (50–60 mm, %)	10 (2–32)	10 (0–54)	0.92	19 (7–55)	22 (2-81)	0.97	19 (3–68)	2 (0-24)	0.04
Percentage of fully released compressions (%)	100 (92– 100)	99 (91–100)	0.52	93 (15–100)	90 (44–99)	0.65	68 (33–100)	89 (24–99)	0.84
Average hands-off time (s)	0 (0-2)	0 (0–1)	0.16	0 (0-1)	0 (0–1)	0.48	0 (0–0)	0 (0-0)	0.89

Phase II tests were conducted for the evaluation of CPR performance and capabilities assessment using telephone-assisted CPR (T-CPR) simulation scenario among individuals who have received CPR training with/without a TCPRLink application at 3 months after the training.

## **Figure Legends**

Figure 1 The illustration of TCPRLink application in use.

(a) Illustration photo of TCPRLink in use in a simulated T-CPR situation. (b) Screenshots of TCPRLink. Front page to the left and bystander feedback example to the right. (c) Screenshot of the web server available for the dispatcher.

Figure 2 Flow diagram of the participants.

**Figure 3** Distribution of the chest compression rate and the proportion of the adequate chest compression rate (100-120 min-1) in TCPRLink group and T-CPR group.

Phase I test was conducted in T-CPR trained individuals with/without TCPRLink App after inclusion.

Phase II test was conducted in the same individuals with/without TCPRLink App after three months.

Figure 4 Counting with dispatcher in TCPRLink group and T-CPR group.

Phase I test was conducted in T-CPR trained individuals with/without TCPRLink App after inclusion.

Phase II test was conducted in the same individuals with/without TCPRLink App after three months.

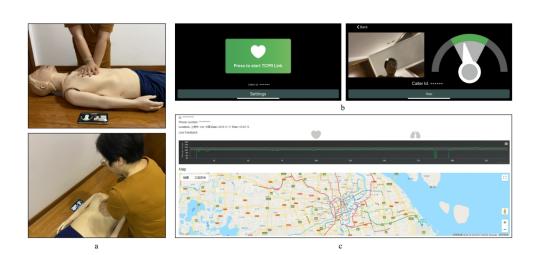


Figure 1 The illustration of TCPRLink application in use.

(a) Illustration photo of TCPRLink in use in a simulated T-CPR situation. (b) Screenshots of TCPRLink. Front page to the left and bystander feedback example to the right. (c) Screenshot of the web server available for the dispatcher.

225x111mm (600 x 600 DPI)

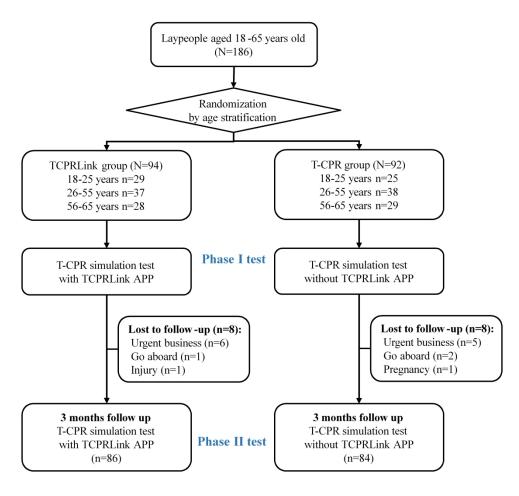
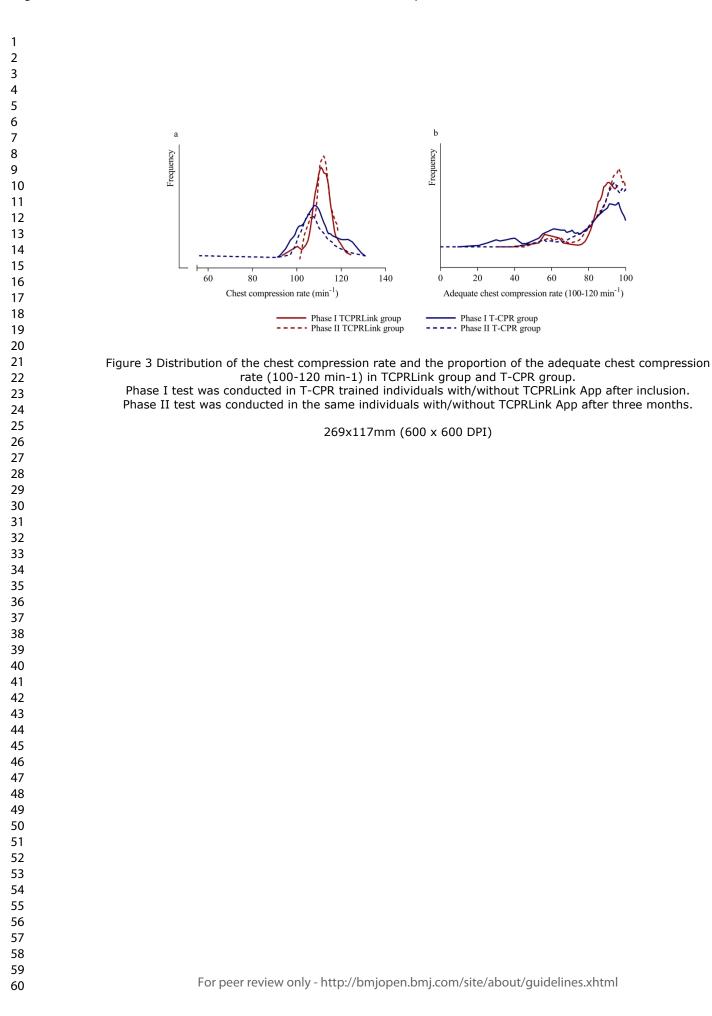
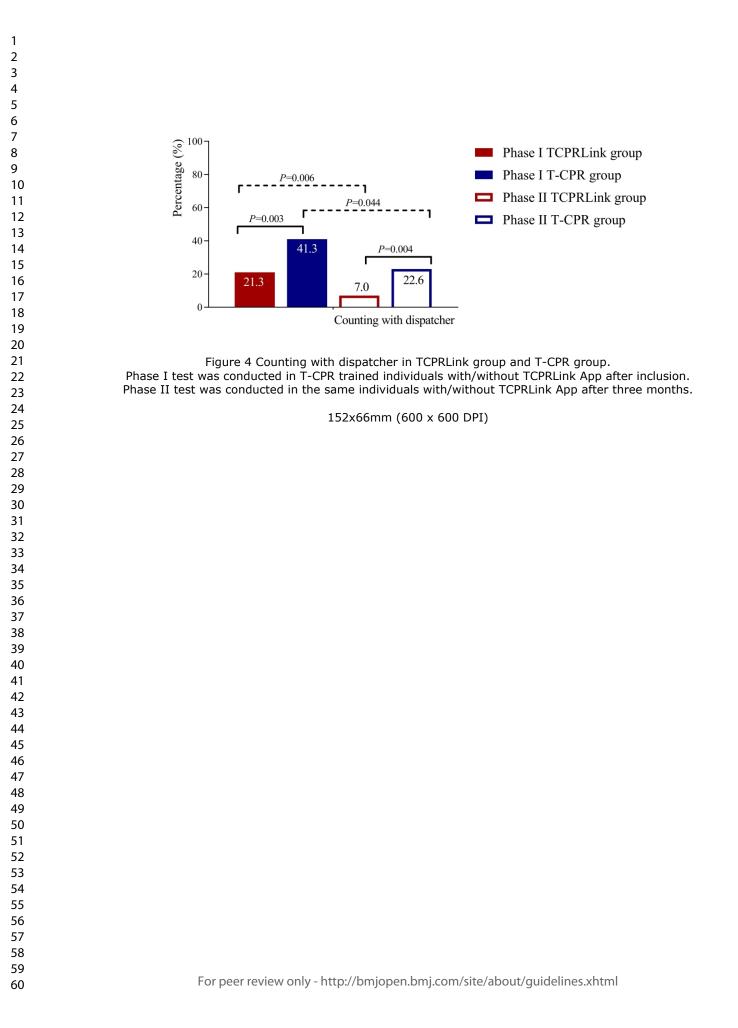


Figure 2 Flow diagram of the participants.

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## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	ltem No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and	2a	Scientific background and explanation of rationale	
objectives	2b	Specific objectives or hypotheses	
•			
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	\
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5, 6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	\
Sample size	7a	How sample size was determined	7, 8
·	7b	When applicable, explanation of any interim analyses and stopping guidelines	\
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	5
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	\
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	5
Blinding	11a	interventions If done, who was blinded after assignment to interventions (for example, participants, care providers, those	\
CONSORT 2010 checklist		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	Pa

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	١
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8, Figure 2
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	1
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	Figure 2
		by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	\
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Table 3-4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	9-11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	9-11
Other information			
Registration	23	Registration number and name of trial registry	١
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1, 12

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see <u>www.consort-statement.org</u>.

CONSORT 2010 checklist