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## Effect of test including feedback and reflection added to standard CPR training on students' practical CPR skills and willingness to act: a cluster randomized study

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6 3 willingness to act: a cluster randomized study  
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## ABSTRACT

**Objectives:** To investigate if two additional interventions, test and reflection, after standard CPR training facilitate learning by comparing 13-year-old students' practical skills and willingness to act.

**Settings:** Seventh grade students in two Swedish municipalities.

**Design:** The classes were randomized to *CPR training only* (O), *CPR training with a practical Test including feedback* (T) or *CPR training with Reflection and a practical Test including feedback* (RT). Outcome measures of practical skills and willingness to act were assessed directly after training and at six months using a PC skill reporting system and a survey. Data on CPR skills were registered in a modified version of the Cardiff test and scores were given in 12 categories (12–48 points). Training and measurements were performed from December 2013 to October 2014, according to European Resuscitation Council guidelines 2010.

**Participants:** Twenty-nine classes or 587 seventh grade students were included in the study.

**Primary and secondary outcome measures:** Primary endpoint was the total score of the modified Cardiff test. The individual variables of the test and self-reported willingness to make a life-saving intervention were secondary endpoints.

**Results:** At six months the T and O group scored 32 (30–35) versus 30 (27–33) points ( $p<0.001$ ), while the RT group scored 31 (29–35) points (not significant when compared with T). There were no significant differences in willingness to act between the groups after six months.

**Conclusions:** A practical test including feedback directly after training improved the students' acquisition of practical CPR skills. Reflection did not increase CPR skills. At six-month follow-up, no intervention effect was found regarding willingness to make a lifesaving effort.

**Keywords:** CPR training; Skill test; Reflection; Willingness; Feedback; Students

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2  
3 49 **Strengths and limitations of this study**

4 50  
5 51 Key concepts in educational science, the effect of test including feedback and reflection as  
6 52 additional interventions after standard CPR training, were evaluated in a cluster randomized  
7 53 trial.  
8 54

9 55 Outcome measures of practical CPR skills and willingness to act were assessed directly after  
10 56 training and at six months follow up.  
11 57

12 58 The intervention was carried out in two major municipalities with schools from all  
13 59 socioeconomic areas.  
14 60

15 61 The study was not designed to explain the cause of any potential differences observed.  
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## 62 INTRODUCTION

63 Sudden unexpected cardiac arrest is one of the most common causes of death in  
64 Europe.<sup>1</sup> Early identification of the cardiac arrest and prompt initiation of bystander  
65 cardiopulmonary resuscitation (CPR) are the cornerstones of resuscitation and crucial for  
66 survival in out-of-hospital cardiac arrest (OHCA),[2]. Early CPR increases the chance of  
67 survival two to three times,[3-4]. If all students receive practical CPR training in school, a  
68 large proportion of the population will have basic skills within a few decades. Such a situation  
69 could potentially increase the lay resuscitation rate,[2, 5-7].

70 Education in CPR can be delivered in different formats. There is a knowledge gap  
71 regarding what is the optimal method of CPR training to acquire CPR skills,[8]. Participants'  
72 CPR skills after training are limited and decrease within months after training,[2, 9-10].

73 Learning is a complex process, influenced by several factors,[11-12]. Key concepts in  
74 educational science are e.g. test, feedback and reflection. Studies show that tests in various  
75 formats can increase learning outcomes,[13-15]. Feedback has a powerful influence on  
76 performance,[16]. According to the Swedish school curriculum, students are expected to  
77 reflect on different situations and events and on their learning,[11]. A core content in CPR  
78 training for the public is practical training; reflection and discussion with the other  
79 participants are limited.

80 The aim of this study was to investigate if two additional interventions, test and  
81 reflection, after standard CPR training facilitate learning by comparing 13-year-old students'  
82 practical skills and willingness to act. We hypothesized that both the test and the reflection  
83 would provide an additional learning session and contribute to improved knowledge,[12-13].

## 84 METHODS

### 85 Study population and design

86 All council schools with seventh grade students (13 years of age) in two Swedish  
87 municipalities were invited to participate in the study. Four schools did not respond and two  
88 had CPR education only in grade 9. In the framework of this study, the intervention methods  
89 have been applied in 13 schools. Before study participation, students and their guardians  
90 received a letter with study information. Participation of individual students was voluntary  
91 and all participants gave oral informed consent.

92  
93 Seventh grade students in participating schools were eligible for inclusion. Students  
94 were excluded if they did not want to participate or had a physical handicap that limited their  
95 physical performance; classes of students with development disabilities (these classes are age-  
96 integrated with fewer students per class) were also excluded.

97 The study used a cluster randomized design,[17], where each school class were  
98 allocated to one of three groups using a randomization list generated by an independent  
99 statistician. The interventions of the groups were based on core concepts in pedagogy; test,  
100 feedback and reflection. To evaluate the effect of test including feedback and reflection, the  
101 groups were as follows:

- 102 • CPR training only (O)
- 103 • CPR training with a practical skill test including feedback (T)
- 104 • CPR training with reflection and a practical skill test including feedback (RT).

105 It was important that the design of the interventions facilitated implementation, that  
 106 the education was brief enough to fit into one lesson, could be given to the whole class at the  
 107 same time and that training could be provided by teachers at the school (less costly, facilitates  
 108 scheduling),[6, 9, 18-19]. Outcome, were assessed directly after training and at six months.  
 109 Training and measurements were performed from December 2013 to October 2014.

### 110 **Standard CPR training applied in all groups**

111 All intervention groups (O, T and RT) received standardized practical CPR training  
 112 and the participants used an individual training manikin, MiniAnne, during training. The CPR  
 113 education was performed in accordance with the European Resuscitation Council guidelines  
 114 2010,[20]. Training was given to the entire class. Classes consisted of 14–29 students.  
 115 Teachers at the schools, who all were CPR instructors, were responsible for the CPR  
 116 training,[6, 9, 18]. All teachers obtained individual oral and written information to ensure that  
 117 they were up to date with the present interventions. The training was either mobile application  
 118 or DVD-based,[21], evenly distributed in the intervention groups (Table 1). The teachers  
 119 acted as facilitators; they introduced the lesson, gave advice on the fly, answered questions  
 120 and completed the course. After the standardized practical CPR training, the additional  
 121 interventions, test and reflection, were performed.

122  
 123 **Table 1.** Characteristics of the students.  
 124

	CPR only (O) (n=171)	CPR + test and feedback (T) (n=224)	O vs T p-value	CPR + reflection + test and feedback (RT) (n=192)	T vs RT p-value
Male	88 (52)	116 (52)	NS	79 (41)	0.03
Previous compression training	49 (29)	54 (24)	NS	49 (26)	NS
Previous ventilation training	34 (20)	41 (18)	NS	39 (20)	NS
DVD method	99 (58)	111 (50)	NS	97 (50)	NS
App method	72 (42)	113 (50)	NS	95 (50)	NS
Number of schools in which methods were applied	8	7		9	

125 A total of 587 participants were included in the analyses, distributed in three groups. Values are presented as *n* (%).

126 Differences in proportions between groups were analysed by Pearson's  $\chi^2$  test. NS, not significant.

### 127 128 **Additional intervention with a practical test including feedback**

129 To compare learning outcomes, the students performed a practical test for three  
 130 minutes directly after the CPR training. Tests can increase learning outcomes, therefore we  
 131 chose to investigate if the test contributed to the learning session,[13-15]. All tests were  
 132 conducted at the schools, one student at a time. The student was introduced to the test by the  
 133 following story: 'You see an adult, someone you know, who collapsed in front of you. There  
 134 is no one more on site. Show how you would act in a real life situation'. The test leader  
 135 answered questions about the victim's condition only if relevant actions had already been  
 136 carried out. The optimal conduct was 30 seconds to check responsiveness, check respiration  
 137 and call for help, followed by 2.5 minutes of CPR. During the CPR, participants' were  
 138 expected to perform at least five cycles of 30 compressions and two ventilations.  
 139

140 Laerdal PC skill reporting system version 2.4, linked to resuscitation manikin  
 141 ResusciAnne, was used to automatically measure quantitative data; compression/ventilation  
 142 ratio, hand-position, compression depth, total number of compressions and ventilations,  
 143 ventilation volume and hands-off time. The participants' actions regarding checking



144 responsiveness, checking respiration and calling for help were assessed by direct observation.  
145 Data were recorded directly into a scoring sheet, a modified version of the validated Cardiff  
146 test,[22]. A score was given in each category and added up to a total score of 12–48 points.  
147 All categories on the scoring sheet are described in detail in Supplementary File 1.

148 After the test, the investigator gave individual feedback for two minutes. The feedback  
149 was partly based on Hattie and Timperley’s model, which addresses the following questions:  
150 “where am I going” (the goals), “how am I going?” (feedback) and “where to next?” (advice  
151 on progress),[24].

### 152 **Additional intervention with reflection**

153 After the CPR training, the students discussed three reflective questions for 15  
154 minutes. The teacher asked one question at a time. The students discussed and reflected on  
155 each question pairwise. The pairs then shared what they had discussed with the whole class.  
156 The teacher summarized the answers and asked the next question. In the present study, the  
157 aim of the reflection was afterthought,[25-26]. Reflections were based on the students'  
158 experience, understanding and knowledge and could be enriched with interpretations from a  
159 person with more experience,[27]. The three questions were (1) Imagine yourself in a  
160 situation where you see a person suffering from a cardiac arrest. Reflect on which factors  
161 influence if you would intervene in a real situation? Remember that your actions may be the  
162 difference between life and death. (2) You are alone when a person suffers from a cardiac  
163 arrest. According to the guidelines, you should first call 112 and then start CPR, why this  
164 order? (3) Place your hands on the correct compression position on yourself. Reflect on the  
165 compression position. Why should the heel of the hand be placed in the centre of the victims'  
166 chest? The selection of questions were based on the following: we wanted the students to  
167 think about performing a lifesaving intervention so that during the training they would  
168 consider how they would act in a real-life situation; in a pre-study, most students failed to call  
169 112; and previous studies have shown that a large proportion of participants apply an  
170 incorrect hand position during chest compression,[23, 28-29].

### 171 **Assessment**

172 Directly after training and after six months, all students in all intervention groups  
173 answered a fixed-response questionnaire, which included questions on background factors  
174 and willingness to act (Supplementary File 2). Before our study, comprehension of the  
175 questionnaire was tested and found satisfactory in a separate cohort of 175 students.

176 At the six-month follow-up, all participants in all intervention groups individually  
177 performed a practical CPR test (retention test). The retention test was carried out without  
178 prior notice and was conducted in same way as the “additional intervention with a practical  
179 test including feedback “. All measurements were carried out by one investigator (AN)  
180 experienced in the modified Cardiff test and blinded to the training method of the students.

### 181 **Study outcome measures**

182 The primary endpoint was the total score for the modified Cardiff test. The  
183 scores in the individual test categories and self-reported willingness to make a lifesaving  
184 intervention were secondary endpoints.

### 185 **Statistical plan and analyses**

186 Sample size calculations were based on data from a pre-study,[28]. In order to detect a  
187 two-point difference in the total score of the modified Cardiff test, at a significance level of  
188 0.05, an effective sample size of 76 students was needed to test for superiority with a power

of 80%. The intraclass correlation coefficient (95% CI) was 0.26 (0.24, 0.29), [17, 30]. The design effect, caused by the cluster randomization, was 5.99. A total of 587 and 549 students performed the first and the second test, respectively. This corresponds to an effective sample size of 98 and 92, respectively, which is above the 76 needed to reach a power of 80%.

To evaluate the effect of test including feedback, group O was compared to group T. To assess the effect of reflection, group T was compared to group RT. Data were presented as proportions (percent) or median (interquartile range). Differences in proportions were analysed with Pearson's  $\chi^2$  test. Differences in median total score between the intervention groups were assessed using Mann-Whitney U test. By calculating the  $(\text{individual total score} - 12) / (\text{maximum total score} - 12) \times 100$ , we obtained a measure of CPR quality in relation to optimal CPR.  $p < 0.05$  was considered statistically significant. Analyses were performed using IBM SPSS version 21 and STATA version 13.1.

## RESULTS

Twenty-nine classes involving 587 students were included in the measurements directly after training; 549 (94%) of these students completed the retest at six months (Fig. 1). The students' characteristics are summarized in Table 1.

### CPR only (O) versus CPR with a practical test including feedback (T)

At six months, group T ( $n=224$ ) performed better than group O ( $n=171$ ) in terms of total score: 32 (30–35) points (56% of maximum score) versus 30 (27–33) points (50% of maximum score),  $p < 0.001$ . For the individual variables, group T performed significantly better in eight of 12 variables. Results of the modified Cardiff test are summarized in Table 2.

**Table 2.** Assessment of CPR skills at the 6-month follow-up.

	CPR only (O) ( $n=152$ )	CPR + test and feedback (T) ( $n=213$ )	<i>p</i> -value
<i>Checks responsiveness by talking</i>			
2: Yes	23 (15)	53 (25)	0.024
1: No	129 (85)	160 (75)	
<i>Checks responsiveness by shaking</i>			
3: Yes	25 (16)	59 (28)	0.012
2: No	127 (84)	154 (72)	
3: Potentially dangerous	0	0	
<i>Open airway – chin lift, head tilt</i>			
5: Perfect	0	1 (1)	NS
4: Acceptable	2 (1)	6 (3)	
3: Attempted other	0	0	
<i>Only one element</i>			
2: Only one element	8 (5)	21 (10)	
1: No	142 (94)	185 (87)	
<i>Checks respiration – see, listen, feel</i>			
2: Yes	49 (32)	97 (46)	0.011
1: No	103 (68)	116 (54)	
<i>Call 112</i>			
2: Yes	80 (53)	171 (80)	<0.001
1: No	72 (47)	42 (20)	
<i>Compression/ventilation ratio</i>			
4: 30:2 (28-32:2)	28 (18)	67 (32)	0.011
3: Other ratio	104 (68)	129 (61)	
2: Compressions only	20 (13)	17 (8)	
1: Ventilations only	0	0	
<i>Hand position during compression</i>			
4: Correct	8 (5)	7 (3)	NS
3: Other wrong	59 (39)	107 (50)	
2: Too low	85 (56)	99 (46)	



1: Not attempted	0	0	
<i>Average compression depth</i>			
6: 50–59 mm	55 (36)	79 (37)	0.030
5: ≥ 60 mm	0	6 (3)	
4: 35–49 mm	61 (40)	97 (46)	
2: 1–34 mm	36 (24)	31 (15)	
1: Not attempted	0	0	
<i>Total compression counted</i>			
6: 140–190	52 (34)	75 (35)	NS
5: ≥191	62 (41)	100 (47)	
4: 121–139	11 (7)	19 (9)	
3: 81–120	21 (14)	14 (7)	
2: 1–80	6 (4)	5 (2)	
1: Not attempted	0	0	
<i>Average ventilation volume</i>			
5: 500–600 ml	5 (3)	7 (3)	<0.001
4: 1–499 ml	11 (7)	21 (10)	
3: ≥601 ml	27 (18)	91 (43)	
2: 0 ml	87 (57)	77 (36)	
1: Not attempted	22 (14)	17 (8)	
<i>Total ventilation counted</i>			
5: 8–12	15 (10)	34 (16)	<0.001
4: 1–7	13 (9)	44 (21)	
3: ≥13	15 (10)	41 (19)	
2: 0	87 (57)	77 (36)	
1: Not attempted	22 (14)	17 (8)	
<i>Total hands-off time</i>			
4: 0–60 s	55 (36)	62 (29)	0.024
3: 61–90 s	62 (41)	120 (56)	
2: 91–135 s	33 (22)	30 (14)	
1: 136–180 s	2 (1)	1 (1)	
<i>Total score</i>	30 (27–33)	32 (30–35)	<0.001

Results are presented as *n* (%) or median (25th–75th percentile). Differences in proportions between groups were analysed by Pearson's  $\chi^2$  test. Differences in total score between intervention groups were analysed by Mann-Whitney U test. *P*-values <0.05 were considered statistically significant. NS, not significant. The table lists the variable's best option at the top. All numbers are rounded to the nearest whole number.

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### 216 CPR with a practical test including feedback (T) versus CPR with reflection and a 217 practical test including feedback (RT)

218 Directly after training and at the six-month follow-up, there were no significant differences  
219 between group RT (*n*=192) and group T (*n*=224) with regard to the total score of the modified  
220 Cardiff test, calling 112 or hand-position during compressions (Table 3). Directly after CPR  
221 training, both groups scored 34 (31–37) points (61% of maximum score); and at the six-  
222 month follow-up, group RT scored 31 (29–35) points (53% of maximum score) and group T  
223 scored 32 (30–35) points (56% of maximum score). Table 3 includes the variables of the  
224 practical test that are direct linked to the intervention of reflection as well as the total score of  
225 the test. All other variables of the test showed no significant differences between the two  
226 groups (T versus RT) and have not been included in the table.

228 **Table 3.** Assessment of CPR skills directly after training and at 6 months.

	CPR + test and feedback (T), directly after ( <i>n</i> =224)	CPR + reflection + test and feedback (RT), directly after ( <i>n</i> =192)	<i>p</i> - value	CPR + test and feedback (T), 6 months ( <i>n</i> =213)	CPR + reflection + test and feedback (RT), 6 months ( <i>n</i> =184)	<i>p</i> -value
<i>Call 112</i>						
2: Yes	161 (72)	152 (79)	NS	171 (80)	147 (80)	NS

1: No	63 (28)	40 (21)		42 (20)	37 (20)	
<i>Hand position during compression</i>						
4: Correct	21 (9)	15 (8)	NS	7 (3)	7 (4)	NS
3: Other wrong	130 (58)	115 (60)		107 (50)	95 (52)	
2: Too low	73 (33)	62 (32)		99 (46)	82 (45)	
1: Not attempted	0	0		0	0	
Total score	34 (31–37)	34 (31–37)	NS	32 (30–35)	31 (29–35)	NS
<i>How to act if at friend suffer cardiac arrest?</i>						
Compression and ventilation	178 (80)	155 (81)	NS	155 (73)	143 (78)	NS
Compressions only	35 (16)	33 (17)		41 (19)	37 (20)	
Ventilations only	2 (1)	1 (1)		1 (<1)	0	
Not dare to act	9 (4)	2 (1)		14 (7)	4 (2)	
Missing	0	1 (1)		2 (1)	0	
<i>How to act if at stranger suffer cardiac arrest?</i>						
Compression and ventilation	71 (32)	67 (35)	0.006	66 (31)	53 (29)	NS
Compressions only	116 (52)	113 (59)		111 (52)	106 (58)	
Ventilations only	3 (1)	0		0	1 (1)	
Not dare to act	34 (15)	11 (6)		34 (16)	24 (13)	
Missing	0	1 (1)		2 (1)	0	

Results are presented as *n* (%) or median (25th–75th percentile). Differences in proportions between groups were analysed by Pearson's  $\chi^2$  test. Differences in total score between intervention groups were analysed by Mann-Whitney U test. *p* values <0.05 were considered statistically significant. NS, not significant. All numbers are rounded to the nearest whole number.

232

### 233 Willingness to act

234 Directly after training, a lower proportion of the students in group O versus group T  
 235 stated that they felt more confident about acting compared with before training (73% versus  
 236 88%;  $p=0.002$ ) and at retest (73% versus 82%;  $p=0.025$ ). There were also differences in how  
 237 the students considered that they had enough knowledge to do chest compressions, 60% (O)  
 238 versus 81% (T,  $p<0.001$ ), and to do rescue breathing, 57% versus 75% ( $p<0.001$ ). At six  
 239 months, 84% (O) versus 91% (T, not significant) considered they had enough knowledge to  
 240 do chest compressions and 59% (O) versus 74% (T,  $p=0.007$ ) to do rescue breathing. There  
 241 were no significant differences between group T and group RT regarding confidence about  
 242 acting or self-rated knowledge either after training or at six months.

243 Directly after training, most students responded that they would do both compressions  
 244 and ventilations if a friend suffered OHCA; 72% (O), 80% (T) and 81% (RT). If a stranger  
 245 suffered OHCA, there was a significant difference between group T and group RT in how the  
 246 students would act, with a more positive attitude in group RT (Table 3) but there was no  
 247 significant difference between groups O and T.

248 At six-month follow-up, there were no significant differences between the three  
 249 intervention groups with regard to how they would act in OHCA situations; 76% (O), 73%  
 250 (T) and 78% (RT) would do both compressions and ventilations if a friend suffered a cardiac  
 251 arrest. Only 31% (O and T) versus 29% (RT) were prepared to do compressions and  
 252 ventilations if a stranger suffered a cardiac arrest.

### 253 DISCUSSION

254 The main findings of the present study are threefold. First, adding a practical test with  
 255 feedback after CPR training resulted in significantly improved practical skills at the six-month  
 256 follow-up. Second, reflection added to CPR training did not influence the practical skills.  
 257 Third, adding a practical test with feedback or reflection to CPR training did not affect long-  
 258 term willingness to make a lifesaving effort. The study was carried out in schools from all

259 socioeconomic areas and each intervention was applied in 7–9 different schools,  
260 strengthening the generalizability of our findings.

261 The group with a practical test including feedback (T) added after CPR training  
262 showed superior practical skills at six months compared with the group with CPR training  
263 only (O). However, the clinical relevance of the two-point difference in the total score for the  
264 modified Cardiff test is unclear. We discuss possible reasons for the outcome linked to  
265 learning theories. The result may be due to a further three minutes of hands-on training under  
266 the supervision of the investigator, or due to the individual feedback the students received  
267 after the test,[14]. Previous studies indicate that testing can increase learning outcome  
268 compared with an equal amount of time spent on training,[13, 15]. The test was not only a  
269 tool to assess skills but also an opportunity to give the students feedback,[31]. The feedback  
270 aimed to reduce discrepancies between present understanding and the goal,[24]. Qi et al,[16]  
271 indicate that a pre-test and feedback can inspire learners to develop strategies to minimize  
272 their dependence on feedback from the instructors, which improve skill acquisition and skill  
273 retention. At feedback, the question “where to next?” was assumed to be the most important  
274 question, while praise for a task seems to be less effective,[24, 32]. A limitation is that the  
275 feedback to the students was given when the training was completed. In a pre-study, some  
276 students indicated that feedback helped to strengthen their self-esteem,[28]. According to  
277 Bandura,[33] and social cognitive theory, an individual's self-efficacy may affect a person's  
278 performance. Self-efficacy is about a person's confidence in their own ability (not actual  
279 ability) in a given situation. Self-efficacy can be affected by verbal persuasion,[34]. Further  
280 studies are needed to elucidate whether the results were caused by the additional training  
281 during supervision or by the feedback given to the students. Use of a feedback device is  
282 another form of feedback that may improve skill acquisition,[2]. A feedback device was not  
283 tested in this study.

284 According to the Swedish school curriculum, knowledge “can be expressed in a  
285 variety of forms, as facts, understanding, skills, familiarity and accumulated experience”,[11].  
286 Reflection and practical training are two teaching methods that can contribute to  
287 understanding, skills and familiarity. There are many definitions of reflection, which implies  
288 that there are many different models,[26-27]. In this study, the aim of the reflection was  
289 afterthought,[25-26]. Adding reflection to CPR training did not influence the students’  
290 practical skills. In particular, reflection did not improve calling 112 and hand positioning  
291 during compressions, despite both being included in the reflective questions. Directly after  
292 training, a higher proportion of students in the reflection group were willing to intervene if a  
293 stranger suffered a cardiac arrest, but this difference could not be observed at six months. This  
294 result might, at least in part, be explained by the content and the framing of the reflective  
295 questions. The first question, concerning how the students would act in an OHCA situation, is  
296 based on ethical considerations, which may provoke emotions and empathy in students,[35].  
297 These emotions might have affected the participants close to the training but not in the long  
298 term. Question two (calling 112) and question three (hand positioning during compressions)  
299 were a cognitive complement to the practical training. Thus, the students might have  
300 discussed and answered these questions as knowledge questions, rather than questions to  
301 reflect upon. Perhaps the outcome would have been different if these reflective questions had  
302 been asked when the action was practiced, so-called reflection on action,[27]. Mann et al,[26]  
303 stated that there is no evidence to support or refute the assumption that reflection will enhance  
304 competence. Ixer,[36] stated that we do not know enough about reflection or how it can  
305 enhance learning. Further research is needed to clarify whether and how reflection can be  
306 used as a successful teaching tool in CPR training.

307 Practical training increases willingness to intervene in a real situation,[2, 37]. At the  
308 six-month follow-up, the three intervention groups did not differ with regard to willingness to  
309 make a lifesaving effort. Regardless of the intervention method, we found, in accordance with  
310 previous studies, a huge difference in willingness to intervene in an OHCA situation  
311 involving a friend compared with a situation involving a stranger,[37-39].

### 312 **Study limitations**

313 First, we cannot exclude that students who performed a test directly after training were  
314 more familiar with the test manikin at the retention test at six months. However, during the  
315 test the participants do not take part of the technical feedback received from the full-body  
316 Resusci-Anne and should thus not have any advantage. The same design has also been used in  
317 other studies,[14, 23].

318 Second, it is a risk that the instructors' experience and/or enthusiasm affect learning.  
319 Therefore, the methods were standardized to ensure equivalent education; the teacher only  
320 had a role as a facilitator and the practical exercises were based on instructions from the app  
321 and the DVD.

322 Third, the intervention was carried out in two major municipalities. We do not know  
323 how applicable the results are for other locations, but a strength of the present study is that  
324 schools from all socioeconomic areas were included.

### 325 **CONCLUSIONS**

326 This study contributes to knowledge on the efficiency of two additional CPR training  
327 interventions. A practical test with feedback in connection with CPR training is an efficient  
328 strategy to increase learning outcome, both practical skills and self-rated knowledge, when  
329 teaching seventh grade students. Further studies are needed to find alternative methods for  
330 testing and feedback, and to elucidate how feedback works most effectively in the CPR  
331 learning process. Reflective questions, in the format applied in this study, did not increase the  
332 participants' practical CPR skills. Most students, regardless of the intervention applied,  
333 indicated they would intervene in an OHCA situation.

### 334 **Competing interests**

335 None declared.

### 336 **Acknowledgments**

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338 study.

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3 339 **Contributors**

4 340 AN contributed to the study design, developed the modified Cardiff test and the  
5 341 questionnaire, conducted all measurements, analysed results and wrote the initial draft of the  
6 342 manuscript. LS and JH contributed to the study design, developed the modified Cardiff test  
7 343 and revised the manuscript. HH and SKS contributed to the study design and revised the  
8 344 manuscript. LN contributed to the study design, developed the modified Cardiff test and the  
9 345 questionnaire, analysed results and revision of the manuscript.

11  
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16 350 data analysis, decision to publish, or preparation of manuscript.

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19 351 **Ethics approval**

20 352 The study was approved by the Regional Ethical Review Board of Linköping, Sweden  
21 353 (2013/358-31).

22  
23 354 **Data sharing statement**

24 355 No additional unpublished data is available.  
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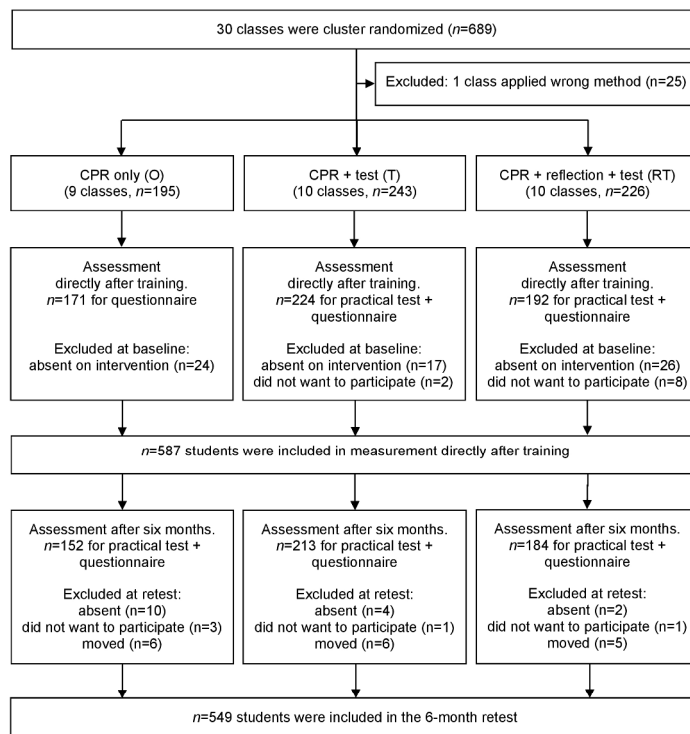


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16 451 toward cardiopulmonary resuscitation. *Resuscitation* 2008;78:340–5.  
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19 453 **Figure 1** Flow chart on randomization and inclusion.  
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Figure 1. Flowchart on randomization and inclusion.



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209x297mm (300 x 300 DPI)

## Supplementary file: the modified Cardiff test.

The modified version of the Cardiff test, adapted to the ERC guidelines of 2010,[20, 22]. The duration of the practical test was 3 minutes. The optimal conduct was 30 seconds for check responsiveness, check respiration and call for help, followed by 2.5 minutes of CPR. During the CPR, the participants were expected to perform at least 5 cycles of 30 compressions and 2 ventilations (30:2). The rules of assessment were pre-specified as follows:

Check responsiveness by talking

2. Yes, if some form of verbal communication as “are you ok” or “how are you”?

1. No, if no attempt at verbal communication was performed

Method: direct observation and real-time registration in the observation schedule by the test leader.

Check responsiveness by shaking

3. Yes, if the rescuer gently shake the victim shoulders.

2. No, if no attempt to shake the victim shoulders occurred.

1. Potentially dangerous, if the rescuer violently shakes the victim’s shoulders so the head lifted up and down against the ground, which can damage the head or the neck.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Open the airway - chin lift, head tilt.

5. Perfect, if one hand on the forehead, two fingertips on the jawbone (not soft tissue) and gently lifted the chin and bent the head back ie by ERC guidelines.

4 Acceptable/partially correct if several indicators are performed, but not all.

3. Attempted other, if the rescuer tried in other ways than ERC recommendation.

2. Only one element is performed or if the rescuer tries but fails.

1. No, if no attempt to open the airway was performed.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Checks respiration - see, listen, feel

2. Yes, if the rescuer did attempts of breath control, even if not all three actions see, listen and feel were performed and although if the total time of the control was less than 10 seconds.

1. No, if no attempt to check for breathing was performed.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Dials 112

2. Yes, dials 112 within the first minute. A call for help without dialling 112 was not enough, since students were instructed they were alone at the site.

1. No, if no attempt to get help was performed.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Compression/ventilation ratio

4. 30:2 (28-32:2), if the rescuer practical applied compressions and ventilations with the relationship 28-32:2 during the whole test. Participants unable to ventilate the manikin but who attempted a ratio of 28-32:2 were registered as such, as they apparently had learned the skill ratio.

3. Other ratio, if the rescuer applied different ratio of compressions and ventilations than 28-32:2.

2. Compressions only.

1. Ventilations only.

Method: Direct observation and real-time registration in combination with data from Laerdal PC Skill Reporter Systems transferred to the scoring sheet after the test.

Hand-position during compression

Incorrect hand-position was recorded if one compression was in the wrong place, since one wrong compression can cause rib fracture or fracture the xiphoid process of sternum.

4. Correct, if the rescuer place the heel of one hand in the centre of the victim’s chest and with the other hand above.

3. Other wrong, if the rescuer performs chest compressions too high up on the sternum or to the side of the sternum.

2. Too low, if the rescuer performs chest compressions too low on the sternum.

1. Not attempted, if no compressions were performed.

Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the test.

#### Average compression depth

The ERC guidelines recommend a compression depth of 50-60 mm,[20]. The PC Skill Reporter system version 2.4 measures up to 60 mm compression depth. To avoid that those who compress >60 mm obtain the highest score, highest score was given for an average compression depth of 50-59 mm. Those who compressed  $\geq 60$  mm received 5 points. We chose to retain the 6-point scale, as in previous studies,<sup>23</sup> even though no one could receive 3 points, which would corresponded to a >65 mm compression depth.

6. 50-59 mm.

5.  $\geq 60$  mm

4. 35-49 mm

2. 1-34 mm

1. Not attempted, if no compressions were performed.

Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the test.

#### Total compression counted

6. 140-190

5.  $\geq 191$

4. 121-139

3. 81-120

2. 1-80

1. Not attempted, if no compressions were performed.

Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the test.

#### Average ventilation volume

5. 500-600 ml

4. 1-499 ml

3.  $\geq 601$  ml

2. 0 ml, if the rescuer tried to do rescue breaths but failed.

1. Not attempted, if no rescue breaths were performed.

Method: Direct observation and real-time registration if the rescuer tried to do rescue breath. Exact volume, from Laerdal PC Skill Reporter Systems, was transferred to the scoring sheet after the test.

#### Total ventilation counted

5. 8-12

4. 1-7

3.  $\geq 13$

2. 0, if the rescuer tried to do rescue breaths but failed.

1. Not attempted, if no rescue breaths were performed.

Method: Direct observation and real-time registration if the rescuer tried to do rescue breath. Exact number, from Laerdal PC Skill Reporter Systems, was transferred to the scoring sheet after the test.

#### Total "hands-off" time

Total hands-off time was the total time when compressions were not being performed (i.e. also includes time for check responsiveness, check respiration and dial 112).

4. 0-60 s

3. 61-90 s

2. 91-135 s

1. 136-180 s

Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the test.

## Supplementary file: questionnaires used directly after training and at six months follow-up

### Questionnaire directly after training

Have you previously practiced

chest compressions? Yes  No

ventilations? Yes  No

Do you think that your skills are sufficient to perform

chest compressions? Yes  No  Do not know

ventilations? Yes  No  Do not know

Are you more confident now than before the training to act and start CPR?

Yes  No  Do not know

You are at home. How would you act if a friend or relative suffered a sudden cardiac arrest? Tick one answer:

I would not dare or want to intervene

I would give chest compressions only

I would give ventilations only

I would give both compressions and ventilations

Enter the reason that you do not dare or want to do chest compressions?

Lack of knowledge

Afraid to hurt the person

Afraid of transmitted disease

Other reasons

Do not know

Enter the reason that you do not dare or want to do ventilations?

Lack of knowledge

Afraid to hurt the person

Afraid of transmitted disease

Other reasons

Do not know

You are standing at a bus stop. How would you act if an unknown person suffered a sudden cardiac arrest? Tick one answer:

I would not dare or want to intervene

I would give chest compressions only

I would give ventilations only



I would give both compressions and ventilations

Enter the reason that you do not dare or want to do chest compressions?

Lack of knowledge

Afraid to hurt the person

I do not want to touch a stranger

Afraid of transmitted disease

Other reasons

Do not know

Enter the reason that you do not dare or want to do ventilations?

Lack of knowledge

Afraid to hurt the person

I do not want to touch a stranger

Afraid of transmitted disease

Other reasons

Do not know

#### **Questionnaire at six months follow-up**

Have you done a lifesaving intervention in real life after the CPR training? Yes  No

If yes, please describe your lifesaving intervention and the situation: \_\_\_\_\_

Do you think it is important to learn cardiopulmonary resuscitation in school? Yes  No  Do not know

Do you think that your skills are sufficient to perform chest compressions? Yes  No  Do not know

ventilations? Yes  No  Do not know

Are you more confident now than before the training to act and start CPR? Yes  No  Do not know

You are at home. How would you act if a friend or relative suffered a sudden cardiac arrest? Tick one answer:

I would not dare or want to intervene

I would give chest compressions only

I would give ventilations only

I would give both compressions and ventilations

Enter the reason that you do not dare or want to do chest compressions?

Lack of knowledge

Afraid to hurt the person

- 1  
2  
3 Afraid of transmitted disease   
4 Other reasons   
5 Do not know   
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9 Enter the reason that you do not dare or want to do ventilations?

- 10 Lack of knowledge   
11 Afraid to hurt the person   
12 Afraid of transmitted disease   
13 Other reasons   
14 Do not know   
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18 You are standing at a bus stop. How would you act if an unknown person suffered a sudden cardiac arrest? Tick  
19 one answer:

- 20 I would not dare or want to intervene   
21 I would give chest compressions only   
22 I would only give ventilations   
23 I would give both compressions and ventilations   
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27 Enter the reason that you do not dare or want to do chest compressions?

- 28 Lack of knowledge   
29 Afraid to hurt the person   
30 I do not want to touch a stranger   
31 Afraid of transmitted disease   
32 Other reasons   
33 Do not know   
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38 Enter the reason that you do not dare or want to do ventilations?

- 39 Lack of knowledge   
40 Afraid to hurt the person   
41 I do not want to touch a stranger   
42 Afraid of transmitted disease   
43 Other reasons   
44 Do not know   
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49 How many times have you used/read on the app "Save the heart" (including any lesson in school)?

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52 4-5   
53 > 5   
54 Do not know   
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56 Have you shown the app for someone else? Yes  No  Do not know   
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## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	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
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4-5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	6-7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
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	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4, 6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

1			
2		assessing outcomes) and how	
3			
4		11b If relevant, description of the similarity of interventions	5-6
5	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	6-7
6		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
7			
8	<b>Results</b>		
9	Participant flow (a	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and	7-8 and
10	diagram is strongly	were analysed for the primary outcome	Figure 1
11	recommended)	13b For each group, losses and exclusions after randomisation, together with reasons	Figure 1
12	Recruitment	14a Dates defining the periods of recruitment and follow-up	5
13		14b Why the trial ended or was stopped	N/A
14			
15	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	Table 1
16	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was	7-9 and
17		by original assigned groups	Figure 1
18			
19	Outcomes and	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its	7-9
20	estimation	precision (such as 95% confidence interval)	
21		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
22	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	N/A
23		pre-specified from exploratory	
24			
25	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
26			
27	<b>Discussion</b>		
28	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	3, 10, 11
29	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	9-10
30	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-11
31			
32	<b>Other information</b>		
33	Registration	23 Registration number and name of trial registry	N/A
34	Protocol	24 Where the full trial protocol can be accessed, if available	N/A
35	Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	12
36			

\*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](http://www.consort-statement.org).

# BMJ Open

## Effect of test including feedback and reflection added to standard CPR training on students' practical CPR skills and willingness to act: a cluster randomized study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-014230.R1
Article Type:	Research
Date Submitted by the Author:	20-Jan-2017
Complete List of Authors:	Nord, Anette; Linköping University, Department of Medical and Health Sciences Hult, Håkan; Karolinska Institute, Department of Clinical Science, Intervention and Technology Kreitz-Sandberg, Susanne; Linköping University, Department of Behavioural Sciences and Learning Herlitz, Johan; Borås University, The Prehospital Research Centre of Western Sweden Svensson, Leif; Karolinska Institute, Department of Medicine Nilsson, Lennart; Linköping University, Department of Medical and Health Sciences
<b>Primary Subject Heading</b>:	Medical education and training
Secondary Subject Heading:	Cardiovascular medicine, Emergency medicine, Medical education and training, Public health
Keywords:	CPR training, Skill test, Reflection, Willingness, Feedback, Students

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Manuscripts

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4 1 Effect of test including feedback and reflection added to  
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6 3 willingness to act: a cluster randomized study  
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3 21 **ABSTRACT**  
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23 **Objectives:** To investigate if two additional interventions, test and reflection, after standard  
24 CPR training facilitate learning by comparing 13-year-old students' practical skills and  
25 willingness to act.

26 **Settings:** Seventh grade students in two Swedish municipalities.

27 **Design:** The classes were randomized to *CPR training only* (O), *CPR training with a*  
28 *practical Test including feedback* (T) or *CPR training with Reflection and a practical Test*  
29 *including feedback* (RT). Outcome measures of practical skills and willingness to act were  
30 assessed directly after training and at six months using a PC skill reporting system and a  
31 survey. Data on CPR skills were registered in a modified version of the Cardiff test and scores  
32 were given in 12 categories (12–48 points). Training and measurements were performed from  
33 December 2013 to October 2014, according to European Resuscitation Council guidelines  
34 2010.

35 **Participants:** Twenty-nine classes for a total of 587 seventh grade students were included in  
36 the study.

37 **Primary and secondary outcome measures:** Primary endpoint was the total score of the  
38 modified Cardiff test at six months. Total score directly after training, the individual variables  
39 of the test and self-reported willingness to make a life-saving intervention were secondary  
40 endpoints.

41 **Results:** At six months the T and O group scored 32 (3.9) and 30 (4.0) points respectively  
42 ( $p < 0.001$ ), while the RT group scored 32 (4.2) points (not significant when compared with T).  
43 There were no significant differences in willingness to act between the groups after six  
44 months.

45 **Conclusions:** A practical test including feedback directly after training improved the  
46 students' acquisition of practical CPR skills. Reflection did not increase further CPR skills. At  
47 six-month follow-up, no intervention effect was found regarding willingness to make a  
48 lifesaving effort.

49 **Keywords:** CPR training; Skill test; Reflection; Willingness; Feedback; Students  
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### Strengths and limitations of this study

The best method to teach CPR in school is unknown, therefore we evaluate key concepts in educational science in a cluster randomized trial.

Outcome measures of practical CPR skills and willingness to act were assessed directly after training and at six months follow up.

The intervention was carried out in two major municipalities with schools from all socioeconomic areas.

The study was not designed to explain the cause of any potential differences observed.

The questionnaire used to evaluate willingness to act contains only hypothetical questions, we do not fully answer how the students would act in a real situation.

## 65 INTRODUCTION

66 Sudden unexpected cardiac arrest is one of the most common causes of death in  
67 Europe,[1]. Early identification of the cardiac arrest, call to emergency medical service and  
68 prompt initiation of bystander cardiopulmonary resuscitation (CPR) are the cornerstones of  
69 resuscitation and crucial for survival in out-of-hospital cardiac arrest (OHCA),[2]. Early CPR  
70 increases the chance of survival two to three times,[3-4]. If all students receive practical CPR  
71 training in school, a large proportion of the population will have basic skills within a few  
72 decades. Such a situation could potentially increase the lay resuscitation rate,[2, 5-8].

73 Education in CPR can be delivered in different formats. There is a knowledge gap  
74 regarding what is the optimal method of CPR training to acquire CPR skills,[2]. Participants'  
75 CPR skills after training are limited and decrease within months after training,[2, 9-10].

76 Learning is a complex process, influenced by several factors,[11-12]. Key concepts in  
77 educational science are e.g. test, feedback and reflection. Studies show that tests in various  
78 formats can increase learning outcomes,[13-15]. Feedback has a powerful influence on  
79 performance,[16]. According to the Swedish school curriculum, students are expected to  
80 reflect on different situations and events and on their learning,[11]. A core content in CPR  
81 training for lay people is practical training; reflection and discussion with the other  
82 participants are limited.

83 The aim of this study was to investigate if two additional interventions, test and  
84 reflection, after standard CPR training facilitate learning by comparing 13-year-old students'  
85 practical skills and willingness to act. We hypothesized that both the test and the reflection  
86 would provide an additional learning session and contribute to improved knowledge,[12-13].

## 87 METHODS

### 88 Study population and design

89 All council schools with seventh grade students (13 years of age) in two Swedish  
90 municipalities (Linköping and Norrköping) were invited to participate in the study. Four  
91 schools did not respond and two had CPR education only in grade 9. In the framework of this  
92 study, the intervention methods have been applied in 13 schools. Before study participation,  
93 students and their guardians received a letter with study information. Participation of  
94 individual students was voluntary and all participants gave oral informed consent.

95  
96 Seventh grade students in participating schools were eligible for inclusion. Students  
97 were excluded if they did not want to participate or had a physical handicap that limited their  
98 physical performance; classes of students with development disabilities (these classes are age-  
99 integrated with fewer students per class) were also excluded.

100 The study used a cluster randomized design,[17], where each school class were  
101 allocated to one of three groups using a randomization list generated by an independent  
102 statistician. The interventions of the groups were based on core concepts in pedagogy; test,  
103 feedback and reflection. To evaluate the effect of test including feedback and reflection, the  
104 groups were as follows:

- 105 • CPR training only (O)
- 106 • CPR training with a practical skill test including feedback (T)
- 107 • CPR training with reflection and a practical skill test including feedback (RT).

108 It was important that the design of the interventions facilitated implementation, that  
109 the education was brief enough to fit into one lesson, that the lesson could be given to the

110 whole class at the same time and that training could be provided by teachers at the school  
 111 (less costly, facilitates, scheduling),[6, 9, 18-19]. Outcomes, were assessed directly after  
 112 training and at six months. Training and measurements were performed from December 2013  
 113 to October 2014.

### 114 **Standard CPR training applied in all groups**

115 All intervention groups (O, T and RT) received standardized practical CPR training  
 116 and the participants used an individual training manikin, MiniAnne (manufactured by  
 117 Laerdal, Norway), during training. The CPR education was performed in accordance with the  
 118 European Resuscitation Council guidelines 2010,[20]. Training was given to the entire class.  
 119 Classes consisted of 14–29 students. Teachers at the schools, who all were CPR instructors,  
 120 were responsible for the CPR training,[6, 9, 18]. All teachers obtained individual oral and  
 121 written information to ensure that they were up to date with the present interventions. CPR  
 122 training was carried out during a 45-60 minute lesson. The training was either mobile  
 123 application or DVD-based,[21], evenly distributed in the intervention groups (Table 1). The  
 124 teachers acted as facilitators; they introduced the lesson, gave advice on the fly, answered  
 125 questions and completed the course. After the standardized practical CPR training, the  
 126 additional interventions, test and reflection, were performed.

127  
 128 **Table 1.** Characteristics of the students.  
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	CPR only (O) (n=171)	CPR + test and feedback (T) (n=224)	O vs T p-value	CPR + reflection + test and feedback (RT) (n=192)	T vs RT p-value
Male	88 (52)	116 (52)	NS	79 (41)	0.03
Previous compression training	49 (29)	54 (24)	NS	49 (26)	NS
Previous ventilation training	34 (20)	41 (18)	NS	39 (20)	NS
DVD method	99 (58)	111 (50)	NS	97 (50)	NS
App method	72 (42)	113 (50)	NS	95 (50)	NS
Number of schools in which methods were applied	8	7		9	

130 A total of 587 participants were included in the analyses, distributed in three groups. Values are presented as *n* (%).

131 Differences in proportions between groups were analysed by Pearson's  $\chi^2$  test. NS, not significant.

132

### 133 **Additional intervention with a practical test including feedback**

134 To compare learning outcomes, the students in group T and RT performed a practical  
 135 test for three minutes directly after the CPR training. Tests can increase learning outcomes,  
 136 therefore we chose to investigate if the test contributed to the learning session,[13-15]. All  
 137 tests were conducted at the schools, one student at a time. The student was introduced to the  
 138 test by the following story: 'You see an adult, someone you know, who collapsed in front of  
 139 you. There is no one else on site. Show how you would act in a real life situation'. The test  
 140 leader answered questions about the victim's condition only if relevant actions had already  
 141 been carried out. The optimal conduct was 30 seconds to check responsiveness, check  
 142 respiration and call for help, followed by 2.5 minutes of CPR. During the CPR, participants'  
 143 were expected to perform at least five cycles of 30 compressions and two ventilations.  
 144

145 Laerdal PC skill reporting system version 2.4, linked to resuscitation manikin  
 146 ResusciAnne, was used to automatically measure quantitative data; compression/ventilation  
 147 ratio, hand-position, compression depth, total number of compressions and ventilations,  
 148 ventilation volume and hands-off time. The participants' actions regarding checking

149 responsiveness, checking respiration and calling for help were assessed by direct observation.  
150 Data were recorded directly into a scoring sheet, a modified version of the validated Cardiff  
151 test,[22]. A score was given in each category and added up to a total score of 12–48 points.  
152 All categories on the scoring sheet are described in detail in Supplementary File 1.

153 After the test, the investigator gave individual feedback for two minutes. The feedback  
154 was partly based on Hattie and Timperley’s model, which addresses the following questions:  
155 “where am I going” (the goals), “how am I going?” (feedback) and “where to next?” (advice  
156 on progress),[24].

### 157 **Additional intervention with reflection**

158 After the CPR training, the students in group RT discussed three reflective questions  
159 for 15 minutes. The teacher asked one question at a time. The students discussed and reflected  
160 on each question pairwise. The pairs then shared what they had discussed with the whole  
161 class. The teacher summarized the answers and asked the next question. In the present study,  
162 the aim of the reflection was afterthought,[25-26]. Reflections were based on the students'  
163 experience, understanding and knowledge and could be enriched with interpretations from a  
164 person with more experience,[27]. The three questions were (1) Imagine yourself in a  
165 situation where you see a person suffering from a cardiac arrest. Reflect on which factors  
166 influence if you would intervene in a real situation? Remember that your actions may be the  
167 difference between life and death. (2) You are alone when a person suffers from a cardiac  
168 arrest. According to the guidelines, you should first call 112 and then start CPR, why this  
169 order? (3) Place your hands on the correct compression position on yourself. Reflect on the  
170 compression position. Why should the heel of the hand be placed in the centre of the victims'  
171 chest? The selection of questions were based on the following: we wanted the students to  
172 think about performing a lifesaving intervention so that during the training they would  
173 consider how they would act in a real-life situation; in a pre-study, most students failed to call  
174 112; and previous studies have shown that a large proportion of participants apply an  
175 incorrect hand position during chest compression,[23, 28-29].

### 176 **Assessment**

177 Directly after training and after six months, all students in all intervention groups  
178 answered a fixed-response questionnaire, which included questions on background factors  
179 and willingness to act (Supplementary File 2). Before our study, comprehension of the  
180 questionnaire was tested and found satisfactory in a separate cohort of 175 students.

181 At the six-month follow-up, all participants in all intervention groups individually  
182 performed a practical CPR test (retention test). The retention test was carried out without  
183 prior notice and was conducted in same way as the “additional intervention with a practical  
184 test including feedback “. All measurements were carried out by one investigator (AN)  
185 experienced in the modified Cardiff test and blinded to the training method of the students.

### 186 **Study outcome measures**

187 The primary endpoint was the total score for the modified Cardiff test at six  
188 months. Total score directly after training, the scores in the individual test categories and self-  
189 reported willingness to make a lifesaving intervention were secondary endpoints.

### 190 **Statistical plan and analyses**

191 Sample size calculations were based on data from a pre-study,[28]. In order to detect a  
192 two-point difference in the mean of the total score of the modified Cardiff test, with an  
193 assumed standard deviation (SD) of 2.5 points, a significance level of 0.05 and a power of



194 80%, an effective total sample size of 75 students was needed [30]. The intraclass correlation  
 195 coefficient (95% CI) was 0.26 (0.24, 0.29), [17, 31]. Based on an average cluster size of 20.2,  
 196 the design effect caused by the cluster randomization was calculated to be 5.99. A total of 587  
 197 and 549 students performed the first and the second test, respectively. This corresponds to an  
 198 effective sample size of 98 and 92, respectively, which is above the 75 needed to reach a  
 199 power of 80%.

200 To evaluate the effect of test including feedback, group O was compared to group T.  
 201 To assess the effect of reflection, group T was compared to group RT. These comparisons  
 202 were pre-specified and based on separate research questions, and thus no adjustment for  
 203 multiple testing was performed. Data were presented as proportions (percent) or mean (SD).  
 204 Differences in proportions were analysed with Pearson's  $\chi^2$  test. Differences in mean total  
 205 score between the intervention groups were assessed using unpaired t-test. To account for a  
 206 potential cluster effect of the school classes, a mixed models linear test was also applied for  
 207 comparisons of the total score [17]. By calculating the (individual total score – 12)/(maximum  
 208 total score – 12)  $\times$  100, we obtained a measure of CPR quality in relation to optimal CPR.  
 209  $p < 0.05$  was considered statistically significant. Analyses were performed using IBM SPSS  
 210 version 21 and STATA version 13.1.

## 211 RESULTS

212 Twenty-nine classes involving 587 students were included in the measurements  
 213 directly after training; 549 (94%) of these students completed the retest at six months (Fig. 1).  
 214 The students' characteristics are summarized in Table 1.

### 215 CPR only (O) versus CPR with a practical test including feedback (T)

216 At six months, group T ( $n=224$ ) performed better than group O ( $n=171$ ) in terms of  
 217 total score: 32 (3.9) points (56% of maximum score) versus 30 (4.0) points (50% of maximum  
 218 score),  $p < 0.001$ . For the individual variables, group T performed significantly better in eight  
 219 of 12 variables. Results of the modified Cardiff test are summarized in Table 2.

220 **Table 2.** Assessment of CPR skills at the 6-month follow-up.

	CPR only (O) ( $n=152$ )	CPR + test and feedback (T) ( $n=213$ )	<i>p</i> -value
<i>Checks responsiveness by talking</i>			
2: Yes	23 (15)	53 (25)	0.024
1: No	129 (85)	160 (75)	
<i>Checks responsiveness by shaking</i>			
3: Yes	25 (16)	59 (28)	0.012
2: No	127 (84)	154 (72)	
3: Potentially dangerous	0	0	
<i>Open airway – chin lift, head tilt</i>			
5: Perfect	0	1 (1)	NS
4: Acceptable	2 (1)	6 (3)	
3: Attempted other	0	0	
2: Only one element	8 (5)	21 (10)	
1: No	142 (94)	185 (87)	
<i>Checks respiration – see, listen, feel</i>			
2: Yes	49 (32)	97 (46)	0.011
1: No	103 (68)	116 (54)	
<i>Call 112</i>			
2: Yes	80 (53)	171 (80)	<0.001
1: No	72 (47)	42 (20)	
<i>Compression/ventilation ratio</i>			
4: 30:2 (28-32:2)	28 (18)	67 (32)	0.011



3: Other ratio	104 (68)	129 (61)	
2: Compressions only	20 (13)	17 (8)	
1: Ventilations only	0	0	
<i>Hand position during compression</i>			
4: Correct	8 (5)	7 (3)	NS
3: Other wrong	59 (39)	107 (50)	
2: Too low	85 (56)	99 (46)	
1: Not attempted	0	0	
<i>Average compression depth</i>			
6: 50–59 mm	55 (36)	79 (37)	0.030
5: ≥ 60 mm	0	6 (3)	
4: 35–49 mm	61 (40)	97 (46)	
2: 1–34 mm	36 (24)	31 (15)	
1: Not attempted	0	0	
<i>Total compression counted</i>			
6: 140–190	52 (34)	75 (35)	NS
5: ≥191	62 (41)	100 (47)	
4: 121–139	11 (7)	19 (9)	
3: 81–120	21 (14)	14 (7)	
2: 1–80	6 (4)	5 (2)	
1: Not attempted	0	0	
<i>Average ventilation volume</i>			
5: 500–600 ml	5 (3)	7 (3)	<0.001
4: 1–499 ml	11 (7)	21 (10)	
3: ≥601 ml	27 (18)	91 (43)	
2: 0 ml	87 (57)	77 (36)	
1: Not attempted	22 (14)	17 (8)	
<i>Total ventilation counted</i>			
5: 8–12	15 (10)	34 (16)	<0.001
4: 1–7	13 (9)	44 (21)	
3: ≥13	15 (10)	41 (19)	
2: 0	87 (57)	77 (36)	
1: Not attempted	22 (14)	17 (8)	
<i>Total hands-off time</i>			
4: 0–60 s	55 (36)	62 (29)	0.024
3: 61–90 s	62 (41)	120 (56)	
2: 91–135 s	33 (22)	30 (14)	
1: 136–180 s	2 (1)	1 (1)	
<b>Total score</b>	<b>30 (4.0)</b>	<b>32 (3.9)</b>	<b>&lt;0.001*<sup>□</sup></b>

221 Results are presented as *n* (%) or mean (SD). Differences in proportions between groups were analysed by Pearson’s  $\chi^2$  test.  
 222 Differences in total score between intervention groups were analysed by mixed models linear test\* and unpaired t-test<sup>□</sup>. *P*-  
 223 values <0.05 were considered statistically significant. NS, not significant. The table lists the variable's best option at the top.  
 224 All numbers are rounded to the nearest whole number.

225 **CPR with a practical test including feedback (T) versus CPR with reflection and a**  
 226 **practical test including feedback (RT)**

227 Directly after training and at the six-month follow-up, there were no significant differences  
 228 between group RT (*n*=192) and group T (*n*=224) with regard to the total score of the modified  
 229 Cardiff test, calling 112 or hand-position during compressions (Table 3). Directly after CPR  
 230 training, both groups scored 34 points (61% of maximum score); and at the six-month follow-  
 231 up, group RT scored 31 (4.2) points (53% of maximum score) and group T scored 32 (3.9)  
 232 points (56% of maximum score). Table 3 includes the variables of the practical test that are  
 233 directly linked to the intervention of reflection as well as the total score of the test. All other  
 234 variables of the test showed no significant differences between the two groups (T versus RT)  
 235 and have not been included in the table.  
 236

237 **Table 3.** Assessment of CPR skills directly after training and at 6 months.

CPR + test and feedback	CPR + reflection +	<i>p</i> - value	CPR + test and feedback	CPR + reflection + test	<i>p</i> -value
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	(T), directly after (n=224)	test and feedback (RT), directly after (n=192)		(T), 6 months (n=213)	and feedback (RT), 6 months (n=184)	
<i>Call 112</i>						
2: Yes	161 (72)	152 (79)	NS	171 (80)	147 (80)	NS
1: No	63 (28)	40 (21)		42 (20)	37 (20)	
<i>Hand position during compression</i>						
4: Correct	21 (9)	15 (8)	NS	7 (3)	7 (4)	NS
3: Other wrong	130 (58)	115 (60)		107 (50)	95 (52)	
2: Too low	73 (33)	62 (32)		99 (46)	82 (45)	
1: Not attempted	0	0		0	0	
Total score	34 (4.4)	34 (4.3)	NS* <sup>□</sup>	32 (3.9)	32 (4.2)	NS* <sup>□</sup>
<i>How to act if at friend suffer cardiac arrest?</i>						
Compression and ventilation	178 (80)	155 (81)	NS	155 (73)	143 (78)	NS
Compressions only	35 (16)	33 (17)		41 (19)	37 (20)	
Ventilations only	2 (1)	1 (1)		1 (<1)	0	
Not dare to act	9 (4)	2 (1)		14 (7)	4 (2)	
Missing	0	1 (1)		2 (1)	0	
<i>How to act if at stranger suffer cardiac arrest?</i>						
Compression and ventilation	71 (32)	67 (35)	0.006	66 (31)	53 (29)	NS
Compressions only	116 (52)	113 (59)		111 (52)	106 (58)	
Ventilations only	3 (1)	0		0	1 (1)	
Not dare to act	34 (15)	11 (6)		34 (16)	24 (13)	
Missing	0	1 (1)		2 (1)	0	

Results are presented as *n* (%) or mean (SD). Differences in proportions between groups were analysed by Pearson's  $\chi^2$  test. Differences in total score between intervention groups were analysed by mixed models linear test\* and unpaired t-test<sup>□</sup>. *p* values <0.05 were considered statistically significant. NS, not significant. All numbers are rounded to the nearest whole number.

## 242 Willingness to act

243 In the questionnaire, students were asked how confident they felt to act in a cardiac  
 244 arrest situation after participating in the CPR training session compared to prior to training. A  
 245 lower proportion of the students in group O versus group T stated they felt more confident to  
 246 act after participating in the training session, when asked directly after training (73% versus  
 247 88%;  $p=0.002$ ) and at 6 months follow up (73% versus 82%;  $p=0.025$ ). There were also  
 248 differences in how the students considered that they had enough knowledge to do chest  
 249 compressions, 60% (O) versus 81% (T,  $p<0.001$ ), and to do rescue breathing, 57% versus  
 250 75% ( $p<0.001$ ). At six months, 84% (O) versus 91% (T, not significant) considered they had  
 251 enough knowledge to do chest compressions and 59% (O) versus 74% (T,  $p=0.007$ ) to do  
 252 rescue breathing. There were no significant differences between group T and group RT  
 253 regarding confidence about acting or self-rated knowledge either after training or at six  
 254 months.

255 Directly after training, most students responded that they would do both compressions  
 256 and ventilations if a friend suffered OHCA; 72% (O), 80% (T,  $p=NS$  when comparing O and  
 257 T) and 81% (RT, Table 3). If a stranger suffered OHCA, there was a significant difference  
 258 between group T and group RT in how the students would act, with a more positive attitude in  
 259 group RT (Table 3) but there was no significant difference between groups O and T (27% and  
 260 32% would do both compressions and ventilations).

261 At six-month follow-up, there were no significant differences between the three  
 262 intervention groups with regard to how they would act in OHCA situations; 76% (O), 73%  
 263 (T) and 78% (RT) would do both compressions and ventilations if a friend suffered a cardiac  
 264 arrest. Only 31% (O and T) versus 29% (RT) were prepared to do compressions and  
 265 ventilations if a stranger suffered a cardiac arrest.

## 266 DISCUSSION

267 The main findings of the present study are threefold. First, adding a practical test with  
268 feedback after CPR training resulted in significantly improved practical skills at the six-month  
269 follow-up. Second, reflection added to CPR training did not influence the practical skills.  
270 Third, adding a practical test with feedback or reflection to CPR training did not affect long-  
271 term willingness to make a lifesaving effort. The study was carried out in schools from all  
272 socioeconomic areas and each intervention was applied in 7–9 different schools,  
273 strengthening the generalizability of our findings.

274 The group with a practical test including feedback (T) added after CPR training  
275 showed superior practical skills at six months compared with the group with CPR training  
276 only (O). However, the clinical relevance of the two-point difference in the total score for the  
277 modified Cardiff test is unclear. We discuss possible reasons for the outcome linked to  
278 learning theories. The result may be due to a further three minutes of hands-on training under  
279 the supervision of the investigator, or due to the individual feedback the students received  
280 after the test,[14]. Previous studies indicate that testing can increase learning outcomes  
281 compared with an equal amount of time spent on training,[13, 15]. The test was not only a  
282 tool to assess skills but also an opportunity to give the students feedback,[32]. The feedback  
283 aimed to reduce discrepancies between present understanding and the goal,[24]. Qi et al,[32]  
284 indicate that a pre-test and feedback can inspire learners to develop strategies to minimize  
285 their dependence on feedback from the instructors, which improve skill acquisition and skill  
286 retention. At feedback, the question “where to next?” was assumed to be the most important  
287 question, while praise for a task seems to be less effective,[24, 33]. A limitation is that the  
288 feedback to the students was given when the training was completed. In a pre-study, some  
289 students indicated that feedback helped to strengthen their self-esteem,[28]. According to  
290 Bandura,[34] and social cognitive theory, an individual's self-efficacy may affect a person's  
291 performance. Self-efficacy is about a person's confidence in their own ability (not actual  
292 ability) in a given situation. Self-efficacy can be affected by verbal persuasion,[35]. Further  
293 studies are needed to elucidate whether the results were caused by the additional training  
294 during supervision or by the feedback given to the students. Use of a feedback device is  
295 another form of feedback that may improve skill acquisition,[2]. A feedback device was not  
296 tested in this study.

297 According to the Swedish school curriculum, knowledge “can be expressed in a  
298 variety of forms, as facts, understanding, skills, familiarity and accumulated experience”,[11].  
299 Reflection and practical training are two teaching methods that can contribute to  
300 understanding, skills and familiarity. There are many definitions of reflection, which implies  
301 that there are many different models,[26-27]. In this study, the aim of the reflection was  
302 afterthought,[25-26]. Adding reflection to CPR training did not influence the students’  
303 practical skills. In particular, reflection did not improve calling 112 and hand positioning  
304 during compressions, despite both being included in the reflective questions. Directly after  
305 training, a higher proportion of students in the reflection group were willing to intervene if a  
306 stranger suffered a cardiac arrest, but this difference could not be observed at six months. This  
307 result might, at least in part, be explained by the content and the framing of the reflective  
308 questions. The first question, concerning how the students would act in an OHCA situation, is  
309 based on ethical considerations, which may provoke emotions and empathy in students,[36].  
310 These emotions might have affected the participants close to the training but not in the long  
311 term. Question two (calling 112) and question three (hand positioning during compressions)  
312 were a cognitive complement to the practical training. Thus, the students might have  
313 discussed and answered these questions as knowledge questions, rather than questions to

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3 314 reflect upon. Perhaps the outcome would have been different if these reflective questions had  
4 315 been asked when the action was practiced, so-called reflection on action,[27]. Mann et al,[26]  
5 316 stated that there is no evidence to support or refute the assumption that reflection will enhance  
6 317 competence. Ixer,[37] stated that we do not know enough about reflection or how it can  
7 318 enhance learning. Further research is needed to clarify whether and how reflection can be  
8 319 used as a successful teaching tool in CPR training.

10 320 Practical training increases willingness to intervene in a real situation,[2, 38]. At the  
11 321 six-month follow-up, the three intervention groups did not differ with regard to willingness to  
12 322 make a lifesaving effort. Regardless of the intervention method, we found, in accordance with  
13 323 previous studies, a huge difference in willingness to intervene in an OHCA situation  
14 324 involving a friend compared with a situation involving a stranger,[38-41].

### 17 325 **Study limitations**

18 326 First, we cannot exclude that students who performed a test directly after training were  
19 327 more familiar with the test manikin at the retention test at six months. However, during the  
20 328 test the participants do not take part of the technical feedback received from the full-body  
21 329 Resusci-Anne and should thus not have any advantage. The same design has also been used in  
22 330 other studies,[14, 23].

24 331 Second, it is a risk that the instructors' experience and/or enthusiasm affect learning.  
25 332 Therefore, the methods were standardized to ensure equivalent education; the teacher only  
26 333 had a role as a facilitator and the practical exercises were based on instructions from the app  
27 334 and the DVD.

29 335 Third, the intervention was carried out in two major municipalities. We do not know  
30 336 how applicable the results are for other locations, but a strength of the present study is that  
31 337 schools from all socioeconomic areas were included.

33 338 Forth, the questionnaire used to evaluate willingness to act contains only hypothetical  
34 339 questions. They do not fully answer how the students would act in a real situation.

### 37 340 **CONCLUSIONS**

38 341 This study contributes to knowledge on the efficiency of two additional CPR training  
39 342 interventions. A practical test with feedback in connection with CPR training is an efficient  
40 343 strategy to increase learning outcome, both practical skills and self-rated knowledge, when  
41 344 teaching seventh grade students. Further studies are needed to find alternative methods for  
42 345 testing and feedback, and to elucidate how feedback works most effectively in the CPR  
43 346 learning process. Reflective questions, in the format applied in this study, did not increase the  
44 347 participants' practical CPR skills. Importantly, regardless of the intervention applied, most  
45 348 students indicated they would intervene in an OHCA situation.

### 48 349 **Competing interests**

49 350 None declared.

### 51 351 **Acknowledgments**

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53 353 study.

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3 354 **Contributors**

4 355 AN contributed to the study design, developed the modified Cardiff test and the  
5 356 questionnaire, conducted all measurements, analysed results and wrote the initial draft of the  
6 357 manuscript. LS and JH contributed to the study design, developed the modified Cardiff test  
7 358 and revised the manuscript. HH and SKS contributed to the study design and revised the  
8 359 manuscript. LN contributed to the study design, developed the modified Cardiff test and the  
9 360 questionnaire, analysed results and revision of the manuscript.

11  
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16 365 data analysis, decision to publish, or preparation of manuscript.

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18  
19 366 **Ethics approval**

20 367 The study was approved by the Regional Ethical Review Board of Linköping, Sweden  
21 368 (2013/358-31).

22  
23 369 **Data sharing statement**

24 370 No additional unpublished data is available.  
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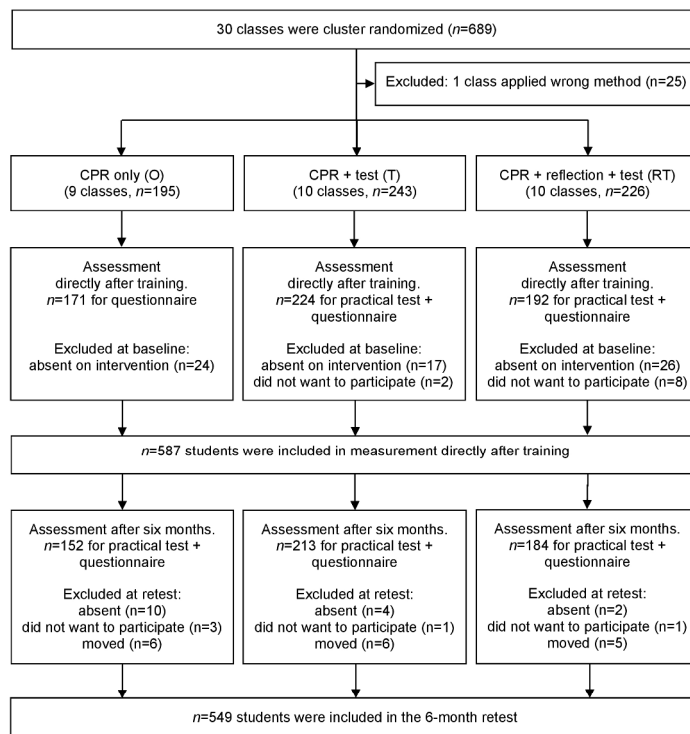


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**Figure 1** Flow chart on randomization and inclusion.

Figure 1. Flowchart on randomization and inclusion.



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209x297mm (300 x 300 DPI)

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## Supplementary file: the modified Cardiff test.

The modified version of the Cardiff test, adapted to the ERC guidelines of 2010,[20, 22]. The duration of the practical test was 3 minutes. The optimal conduct was 30 seconds for check responsiveness, check respiration and call for help, followed by 2.5 minutes of CPR. During the CPR, the participants were expected to perform at least 5 cycles of 30 compressions and 2 ventilations (30:2). The rules of assessment were pre-specified as follows:

Check responsiveness by talking

2. Yes, if some form of verbal communication as “are you ok” or “how are you”?

1. No, if no attempt at verbal communication was performed

Method: direct observation and real-time registration in the observation schedule by the test leader.

Check responsiveness by shaking

3. Yes, if the rescuer gently shake the victim shoulders.

2. No, if no attempt to shake the victim shoulders occurred.

1. Potentially dangerous, if the rescuer violently shakes the victim’s shoulders so the head lifted up and down against the ground, which can damage the head or the neck.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Open the airway - chin lift, head tilt.

5. Perfect, if one hand on the forehead, two fingertips on the jawbone (not soft tissue) and gently lifted the chin and bent the head back ie by ERC guidelines.

4 Acceptable/partially correct if several indicators are performed, but not all.

3. Attempted other, if the rescuer tried in other ways than ERC recommendation.

2. Only one element is performed or if the rescuer tries but fails.

1. No, if no attempt to open the airway was performed.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Checks respiration - see, listen, feel

2. Yes, if the rescuer did attempts of breath control, even if not all three actions see, listen and feel were performed and although if the total time of the control was less than 10 seconds.

1. No, if no attempt to check for breathing was performed.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Dials 112

2. Yes, dials 112 within the first minute. A call for help without dialling 112 was not enough, since students were instructed they were alone at the site.

1. No, if no attempt to get help was performed.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Compression/ventilation ratio

4. 30:2 (28-32:2), if the rescuer practical applied compressions and ventilations with the relationship 28-32:2 during the whole test. Participants unable to ventilate the manikin but who attempted a ratio of 28-32:2 were registered as such, as they apparently had learned the skill ratio.

3. Other ratio, if the rescuer applied different ratio of compressions and ventilations than 28-32:2.

2. Compressions only.

1. Ventilations only.

Method: Direct observation and real-time registration in combination with data from Laerdal PC Skill Reporter Systems transferred to the scoring sheet after the test.

Hand-position during compression

Incorrect hand-position was recorded if one compression was in the wrong place, since one wrong compression can cause rib fracture or fracture the xiphoid process of sternum.

4. Correct, if the rescuer place the heel of one hand in the centre of the victim’s chest and with the other hand above.

3. Other wrong, if the rescuer performs chest compressions too high up on the sternum or to the side of the sternum.

2. Too low, if the rescuer performs chest compressions too low on the sternum.

1. Not attempted, if no compressions were performed.

1  
2  
3 Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the  
4 test.

5  
6 Average compression depth

7 The ERC guidelines recommend a compression depth of 50-60 mm,[20]. The PC Skill Reporter  
8 system version 2.4 measures up to 60 mm compression depth. To avoid that those who compress  
9 >60 mm obtain the highest score, highest score was given for an average compression depth of 50-59  
10 mm. Those who compressed  $\geq 60$  mm received 5 points. We chose to retain the 6-point scale, as in  
11 previous studies,[23 even though no one could receive 3 points, which would corresponded to a >65  
12 mm compression depth.

13 6. 50-59 mm.

14 5.  $\geq 60$  mm

15 4. 35-49 mm

16 2. 1-34 mm

17 1. Not attempted, if no compressions were performed.

18 Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the  
19 test.

20  
21 Total compression counted

22 6. 140-190

23 5.  $\geq 191$

24 4. 121-139

25 3. 81-120

26 2. 1-80

27 1. Not attempted, if no compressions were performed.

28 Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the  
29 test.

30  
31 Average ventilation volume

32 5. 500-600 ml

33 4. 1-499 ml

34 3.  $\geq 601$  ml

35 2. 0 ml, if the rescuer tried to do rescue breaths but failed.

36 1. Not attempted, if no rescue breaths were performed.

37 Method: Direct observation and real-time registration if the rescuer tried to do rescue breath. Exact  
38 volume, from Laerdal PC Skill Reporter Systems, was transferred to the scoring sheet after the test.

39  
40 Total ventilation counted

41 5. 8-12

42 4. 1-7

43 3.  $\geq 13$

44 2. 0, if the rescuer tried to do rescue breaths but failed.

45 1. Not attempted, if no rescue breaths were performed.

46 Method: Direct observation and real-time registration if the rescuer tried to do rescue breath. Exact  
47 number, from Laerdal PC Skill Reporter Systems, was transferred to the scoring sheet after the test.

48  
49 Total "hands-off" time

50 Total hands-off time was the total time when compressions were not being performed (i.e. also  
51 includes time for check responsiveness, check respiration and dial 112).

52 4. 0-60 s

53 3. 61-90 s

54 2. 91-135 s

55 1. 136-180 s

56 Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the  
57 test.

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3 **Supplementary file: questionnaires used directly after training and at six**  
4 **months follow-up**  
5  
6

7 **Questionnaire directly after training**  
8

9 Have you previously practiced

10 chest compressions? Yes  No

11 ventilations? Yes  No

12 Do you think that your skills are sufficient to perform

13 chest compressions? Yes  No  Do not know

14 ventilations? Yes  No  Do not know

15 Are you more confident now than before the  
16 training to act and start CPR?

17 Yes  No  Do not know

18 You are at home. How would you act if a friend or relative suffered a sudden cardiac arrest? Tick one answer:

19 I would not dare or want to intervene

20 I would give chest compressions only

21 I would give ventilations only

22 I would give both compressions and ventilations

23 Enter the reason that you do not dare or want to do chest compressions?

24 Lack of knowledge

25 Afraid to hurt the person

26 Afraid of transmitted disease

27 Other reasons

28 Do not know

29 Enter the reason that you do not dare or want to do ventilations?

30 Lack of knowledge

31 Afraid to hurt the person

32 Afraid of transmitted disease

33 Other reasons

34 Do not know

35 You are standing at a bus stop. How would you act if an unknown person suffered a sudden cardiac arrest? Tick one answer:

36 I would not dare or want to intervene

37 I would give chest compressions only

38 I would give ventilations only

39 I would give both compressions and ventilations



1  
2  
3 Enter the reason that you do not dare or want to do chest compressions?

- 4 Lack of knowledge
- 5  
6 Afraid to hurt the person
- 7  
8 I do not want to touch a stranger
- 9  
10 Afraid of transmitted disease
- 11  
12 Other reasons
- 13  
14 Do not know

15 Enter the reason that you do not dare or want to do ventilations?

- 16 Lack of knowledge
- 17  
18 Afraid to hurt the person
- 19  
20 I do not want to touch a stranger
- 21  
22 Afraid of transmitted disease
- 23  
24 Other reasons
- 25  
26 Do not know

27 **Questionnaire at six months follow-up**

28  
29 Have you done a lifesaving intervention in real life after the CPR training? Yes  No

30  
31 If yes, please describe your lifesaving intervention and the situation: \_\_\_\_\_

32  
33 Do you think it is important to learn  
34 cardiopulmonary resuscitation in school? Yes  No  Do not know

35  
36 Do you think that your skills are sufficient to perform  
37 chest compressions? Yes  No  Do not know

38  
39 ventilations? Yes  No  Do not know

40  
41 Are you more confident now than before the  
42 training to act and start CPR? Yes  No  Do not know

43  
44 You are at home. How would you act if a friend or relative suffered a sudden cardiac arrest? Tick one answer:

- 45  
46 I would not dare or want to intervene
- 47  
48 I would give chest compressions only
- 49  
50 I would give ventilations only
- 51  
52 I would give both compressions and ventilations

53  
54 Enter the reason that you do not dare or want to do chest compressions?

- 55 Lack of knowledge
- 56  
57 Afraid to hurt the person
- 58  
59 Afraid of transmitted disease
- 60  
Other reasons
- Do not know

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2  
3 Enter the reason that you do not dare or want to do ventilations?

4 Lack of knowledge

5  
6 Afraid to hurt the person

7  
8 Afraid of transmitted disease

9 Other reasons

10 Do not know

11  
12  
13 You are standing at a bus stop. How would you act if an unknown person suffered a sudden cardiac arrest? Tick  
14 one answer:

15 I would not dare or want to intervene

16 I would give chest compressions only

17 I would only give ventilations

18 I would give both compressions and ventilations

19  
20  
21  
22 Enter the reason that you do not dare or want to do chest compressions?

23 Lack of knowledge

24 Afraid to hurt the person

25 I do not want to touch a stranger

26 Afraid of transmitted disease

27 Other reasons

28 Do not know

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31  
32 Enter the reason that you do not dare or want to do ventilations?

33 Lack of knowledge

34 Afraid to hurt the person

35 I do not want to touch a stranger

36 Afraid of transmitted disease

37 Other reasons

38 Do not know



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

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	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
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4-5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	6-7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
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	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4, 6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

1			
2		assessing outcomes) and how	
3			
4		11b If relevant, description of the similarity of interventions	5-6
5	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	6-7
6		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
7			
8	<b>Results</b>		
9	Participant flow (a	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and	7-8 and
10	diagram is strongly	were analysed for the primary outcome	Figure 1
11	recommended)	13b For each group, losses and exclusions after randomisation, together with reasons	Figure 1
12	Recruitment	14a Dates defining the periods of recruitment and follow-up	5
13		14b Why the trial ended or was stopped	N/A
14			
15	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	Table 1
16	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was	7-9 and
17		by original assigned groups	Figure 1
18			
19	Outcomes and	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its	7-9
20	estimation	precision (such as 95% confidence interval)	
21		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
22	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	N/A
23		pre-specified from exploratory	
24			
25	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
26			
27	<b>Discussion</b>		
28	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	3, 10, 11
29	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	9-10
30	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-11
31			
32	<b>Other information</b>		
33	Registration	23 Registration number and name of trial registry	N/A
34	Protocol	24 Where the full trial protocol can be accessed, if available	N/A
35	Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	12
36			

\*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](http://www.consort-statement.org).

# BMJ Open

## Effect of two additional interventions, test and reflection, added to standard cardiopulmonary resuscitation training on seventh grade students' practical skills and willingness to act: a cluster randomized trial

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1 **Effect of two additional interventions, test and reflection, added to standard**  
2 **cardiopulmonary resuscitation training on seventh grade students'**  
3 **practical skills and willingness to act: a cluster randomized trial**

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3 20 **ABSTRACT**  
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5 21

6 22 **Objectives:** To investigate if two additional interventions, test and reflection, after standard  
7 23 CPR training facilitate learning by comparing 13-year-old students' practical skills and  
8 24 willingness to act.

9 25 **Settings:** Seventh grade students in two Swedish municipalities.

10 26 **Design:** The classes were randomized to *CPR training only* (O), *CPR training with a*  
11 27 *practical Test including feedback* (T) or *CPR training with Reflection and a practical Test*  
12 28 *including feedback* (RT). Outcome measures of practical skills and willingness to act were  
13 29 assessed directly after training and at six months using a PC skill reporting system and a  
14 30 survey. Data on CPR skills were registered in a modified version of the Cardiff test and scores  
15 31 were given in 12 categories (12–48 points). Training and measurements were performed from  
16 32 December 2013 to October 2014, according to European Resuscitation Council guidelines  
17 33 2010.

18 34 **Participants:** Twenty-nine classes for a total of 587 seventh grade students were included in  
19 35 the study.

20 36 **Primary and secondary outcome measures:** Primary endpoint was the total score of the  
21 37 modified Cardiff test at six months. Total score directly after training, the individual variables  
22 38 of the test and self-reported willingness to make a life-saving intervention were secondary  
23 39 endpoints.

24 40 **Results:** At six months the T and O group scored 32 (3.9) and 30 (4.0) points respectively  
25 41 ( $p < 0.001$ ), while the RT group scored 32 (4.2) points (not significant when compared with T).  
26 42 There were no significant differences in willingness to act between the groups after six  
27 43 months.

28 44 **Conclusions:** A practical test including feedback directly after training improved the  
29 45 students' acquisition of practical CPR skills. Reflection did not increase further CPR skills. At  
30 46 six-month follow-up, no intervention effect was found regarding willingness to make a  
31 47 lifesaving effort.

32 48 **Keywords:** CPR training; Skill test; Reflection; Willingness; Feedback; Students  
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60**Strengths and limitations of this study**

The best method to teach CPR in school is unknown, therefore we evaluate key concepts in educational science in a cluster randomized trial.

Outcome measures of practical CPR skills and willingness to act were assessed directly after training and at six months follow up.

The intervention was carried out in two major municipalities with schools from all socioeconomic areas.

The study was not designed to explain the cause of any potential differences observed.

The questionnaire used to evaluate willingness to act contains only hypothetical questions, we do not fully answer how the students would act in a real situation.

## 64 INTRODUCTION

65 Sudden unexpected cardiac arrest is one of the most common causes of death in  
66 Europe,[1]. Early identification of the cardiac arrest, call to emergency medical service and  
67 prompt initiation of bystander cardiopulmonary resuscitation (CPR) are the cornerstones of  
68 resuscitation and crucial for survival in out-of-hospital cardiac arrest (OHCA),[2]. Early CPR  
69 increases the chance of survival two to three times,[3-4]. If all students receive practical CPR  
70 training in school, a large proportion of the population will have basic skills within a few  
71 decades. Such a situation could potentially increase the lay resuscitation rate,[2, 5-8].

72 Education in CPR can be delivered in different formats. There is a knowledge gap  
73 regarding what is the optimal method of CPR training to acquire CPR skills,[2]. Participants'  
74 CPR skills after training are limited and decrease within months after training,[2, 9-10].

75 Learning is a complex process, influenced by several factors,[11-12]. Key concepts in  
76 educational science are e.g. test, feedback and reflection. Studies show that tests in various  
77 formats can increase learning outcomes,[13-15]. Feedback has a powerful influence on  
78 performance,[16]. According to the Swedish school curriculum, students are expected to  
79 reflect on different situations and events and on their learning,[11]. A core content in CPR  
80 training for lay people is practical training; reflection and discussion with the other  
81 participants are limited.

82 The aim of this study was to investigate if two additional interventions, test and  
83 reflection, after standard CPR training facilitate learning by comparing 13-year-old students'  
84 practical skills and willingness to act. We hypothesized that both the test and the reflection  
85 would provide an additional learning session and contribute to improved knowledge,[12-13].

## 86 METHODS

### 87 Study population and design

88 All council schools with seventh grade students (13 years of age) in two Swedish  
89 municipalities (Linköping and Norrköping) were invited to participate in the study. Four  
90 schools did not respond and two had CPR education only in grade 9. In the framework of this  
91 study, the intervention methods have been applied in 13 schools. Before study participation,  
92 students and their guardians received a letter with study information. Participation of  
93 individual students was voluntary and all participants gave oral informed consent.

94  
95 Seventh grade students in participating schools were eligible for inclusion. Students  
96 were excluded if they did not want to participate or had a physical handicap that limited their  
97 physical performance; classes of students with development disabilities (these classes are age-  
98 integrated with fewer students per class) were also excluded.

99 The study used a cluster randomized design,[17], where each school class were  
100 allocated to one of three groups using a randomization list generated by an independent  
101 statistician. The interventions of the groups were based on core concepts in pedagogy; test,  
102 feedback and reflection. To evaluate the effect of test including feedback and reflection, the  
103 groups were as follows:

- 104 • CPR training only (O)
- 105 • CPR training with a practical skill test including feedback (T)
- 106 • CPR training with reflection and a practical skill test including feedback (RT).

107 It was important that the design of the interventions facilitated implementation, that  
108 the education was brief enough to fit into one lesson, that the lesson could be given to the

109 whole class at the same time and that training could be provided by teachers at the school  
 110 (less costly, facilitates scheduling),[6, 9, 18-19]. Outcomes, were assessed directly after  
 111 training and at six months. Training and measurements were performed from December 2013  
 112 to October 2014.

### 113 **Standard CPR training applied in all groups**

114 All intervention groups (O, T and RT) received standardized practical CPR training  
 115 and the participants used an individual training manikin, MiniAnne (manufactured by  
 116 Laerdal, Norway), during training. The CPR education was performed in accordance with the  
 117 European Resuscitation Council guidelines 2010,[20]. Training was given to the entire class.  
 118 Classes consisted of 14–29 students. Teachers at the schools, who all were CPR instructors,  
 119 were responsible for the CPR training,[6, 9, 18]. All teachers obtained individual oral and  
 120 written information to ensure that they were up to date with the present interventions. CPR  
 121 training was carried out during a 45-60 minute lesson. The training was either mobile  
 122 application or DVD-based,[21], evenly distributed in the intervention groups (Table 1). The  
 123 teachers acted as facilitators; they introduced the lesson, gave advice on the fly, answered  
 124 questions and completed the course. After the standardized practical CPR training, the  
 125 additional interventions, test and reflection, were performed.

127 **Table 1.** Characteristics of the students.

	CPR only (O) (n=171)	CPR + test and feedback (T) (n=224)	O vs T p-value	CPR + reflection + test and feedback (RT) (n=192)	T vs RT p-value
Male	88 (52)	116 (52)	NS	79 (41)	0.03
Previous compression training	49 (29)	54 (24)	NS	49 (26)	NS
Previous ventilation training	34 (20)	41 (18)	NS	39 (20)	NS
DVD method	99 (58)	111 (50)	NS	97 (50)	NS
App method	72 (42)	113 (50)	NS	95 (50)	NS
Number of schools in which methods were applied	8	7		9	

129 A total of 587 participants were included in the analyses, distributed in three groups. Values are presented as *n* (%).

130 Differences in proportions between groups were analysed by Pearson's  $\chi^2$  test. NS, not significant.

131

### 132 **Additional intervention with a practical test including feedback**

133 To compare learning outcomes, the students in group T and RT performed a practical  
 134 test for three minutes directly after the CPR training. Tests can increase learning outcomes,  
 135 therefore we chose to investigate if the test contributed to the learning session,[13-15]. All  
 136 tests were conducted at the schools, one student at a time. The student was introduced to the  
 137 test by the following story: 'You see an adult, someone you know, who collapsed in front of  
 138 you. There is no one else on site. Show how you would act in a real life situation'. The test  
 139 leader answered questions about the victim's condition only if relevant actions had already  
 140 been carried out. The optimal conduct was 30 seconds to check responsiveness, check  
 141 respiration and call for help, followed by 2.5 minutes of CPR. During the CPR, participants'  
 142 were expected to perform at least five cycles of 30 compressions and two ventilations.

143

144 Laerdal PC skill reporting system version 2.4, linked to resuscitation manikin  
 145 ResusciAnne, was used to automatically measure quantitative data; compression/ventilation  
 146 ratio, hand-position, compression depth, total number of compressions and ventilations,  
 147 ventilation volume and hands-off time. The participants' actions regarding checking

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3 148 responsiveness, checking respiration and calling for help were assessed by direct observation.  
4 149 Data were recorded directly into a scoring sheet, a modified version of the validated Cardiff  
5 150 test,[22]. A score was given in each category and added up to a total score of 12–48 points.  
6 151 All categories on the scoring sheet are described in detail in Supplementary File 1.  
7

8 152 After the test, the investigator gave individual feedback for two minutes. The feedback  
9 153 was partly based on Hattie and Timperley’s model, which addresses the following questions:  
10 154 “where am I going” (the goals), “how am I going?” (feedback) and “where to next?” (advice  
11 155 on progress),[24].  
12

### 13 156 **Additional intervention with reflection**

14 157 After the CPR training, the students in group RT discussed three reflective questions  
15 158 for 15 minutes. The teacher asked one question at a time. The students discussed and reflected  
16 159 on each question pairwise. The pairs then shared what they had discussed with the whole  
17 160 class. The teacher summarized the answers and asked the next question. In the present study,  
18 161 the aim of the reflection was afterthought,[25-26]. Reflections were based on the students'  
19 162 experience, understanding and knowledge and could be enriched with interpretations from a  
20 163 person with more experience,[27]. The three questions were (1) Imagine yourself in a  
21 164 situation where you see a person suffering from a cardiac arrest. Reflect on which factors  
22 165 influence if you would intervene in a real situation? Remember that your actions may be the  
23 166 difference between life and death. (2) You are alone when a person suffers from a cardiac  
24 167 arrest. According to the guidelines, you should first call 112 and then start CPR, why this  
25 168 order? (3) Place your hands on the correct compression position on yourself. Reflect on the  
26 169 compression position. Why should the heel of the hand be placed in the centre of the victims'  
27 170 chest? The selection of questions were based on the following: we wanted the students to  
28 171 think about performing a lifesaving intervention so that during the training they would  
29 172 consider how they would act in a real-life situation; in a pre-study, most students failed to call  
30 173 112; and previous studies have shown that a large proportion of participants apply an  
31 174 incorrect hand position during chest compression,[23, 28-29].  
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### 36 175 **Assessment**

37 176 Directly after training and after six months, all students in all intervention groups  
38 177 answered a fixed-response questionnaire, which included questions on background factors  
39 178 and willingness to act (Supplementary File 2). Before our study, comprehension of the  
40 179 questionnaire was tested and found satisfactory in a separate cohort of 175 students.  
41

42 180 At the six-month follow-up, all participants in all intervention groups individually  
43 181 performed a practical CPR test (retention test). The retention test was carried out without  
44 182 prior notice and was conducted in same way as the “additional intervention with a practical  
45 183 test including feedback “. All measurements were carried out by one investigator (AN)  
46 184 experienced in the modified Cardiff test and blinded to the training method of the students.  
47  
48

### 49 185 **Study outcome measures**

50 186 The primary endpoint was the total score for the modified Cardiff test at six months.  
51 187 Total score directly after training, the scores in the individual test categories and self-reported  
52 188 willingness to make a lifesaving intervention were secondary endpoints.  
53

### 54 189 **Statistical plan and analyses**

55 190 Sample size calculations were based on data from a pre-study,[28]. In order to detect a  
56 191 two-point difference in the mean of the total score of the modified Cardiff test, with an  
57 192 assumed standard deviation (SD) of 2.5 points, a significance level of 0.05 and a power of  
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193 80%, an effective total sample size of 75 students was needed [30]. At the first measurement  
 194 point we included all available classes (more than calculated) since it is difficult to estimate  
 195 the size of missing at six month follow up. Cluster randomization implies that the number of  
 196 participants is not equal in each training method group due to the different size of the classes.  
 197 Therefore, a higher number needs to be included, to ensure a sufficient number of participants  
 198 for each method. The intraclass correlation coefficient (95% CI) was 0.26 (0.24, 0.29), [17,  
 199 31]. Based on an average cluster size of 20.2, the design effect caused by the cluster  
 200 randomization was calculated to be 5.99. A total of 587 and 549 students performed the first  
 201 and the second test, respectively. This corresponds to an effective sample size of 98 and 92,  
 202 respectively, which is above the 75 needed to reach a power of 80%.

203 To evaluate the effect of test including feedback, group O was compared to group T.  
 204 To assess the effect of reflection, group T was compared to group RT. These comparisons  
 205 were pre-specified and based on separate research questions, and thus no adjustment for  
 206 multiple testing was performed as this gives no further information about the cause of  
 207 differences. Data were presented as proportions (percent) or mean (SD). Differences in  
 208 proportions were analysed with Pearson's  $\chi^2$  test. Differences in mean total score between  
 209 the intervention groups were assessed using unpaired t-test. To account for a potential cluster  
 210 effect of the school classes, a mixed models linear test was also applied for comparisons of  
 211 the total score [17]. By calculating the (individual total score - 12)/(maximum total score -  
 212 12)  $\times$  100, we obtained a measure of CPR quality in relation to optimal CPR.  $p < 0.05$  was  
 213 considered statistically significant. Analyses were performed using IBM SPSS version 21 and  
 214 STATA version 13.1.

## 215 RESULTS

216 Twenty-nine classes involving 587 students were included in the measurements  
 217 directly after training; 549 (94%) of these students completed the retest at six months (Fig. 1).  
 218 The students' characteristics are summarized in Table 1.

### 219 CPR only (O) versus CPR with a practical test including feedback (T)

220 At six months, group T ( $n=224$ ) performed better than group O ( $n=171$ ) in terms of  
 221 total score: 32 (3.9) points (56% of maximum score) versus 30 (4.0) points (50% of maximum  
 222 score),  $p < 0.001$ . For the individual variables, group T performed significantly better in eight  
 223 of 12 variables. Results of the modified Cardiff test are summarized in Table 2.

224 **Table 2.** Assessment of CPR skills at the 6-month follow-up.

	CPR only (O) ( $n=152$ )	CPR + test and feedback (T) ( $n=213$ )	<i>p</i> -value
<i>Checks responsiveness by talking</i>			
2: Yes	23 (15)	53 (25)	0.024
1: No	129 (85)	160 (75)	
<i>Checks responsiveness by shaking</i>			
3: Yes	25 (16)	59 (28)	0.012
2: No	127 (84)	154 (72)	
3: Potentially dangerous	0	0	
<i>Open airway – chin lift, head tilt</i>			
5: Perfect	0	1 (1)	NS
4: Acceptable	2 (1)	6 (3)	
3: Attempted other	0	0	
2: Only one element	8 (5)	21 (10)	
1: No	142 (94)	185 (87)	
<i>Checks respiration – see, listen, feel</i>			
2: Yes	49 (32)	97 (46)	0.011



1: No	103 (68)	116 (54)	
<i>Call 112</i>			
2: Yes	80 (53)	171 (80)	<0.001
1: No	72 (47)	42 (20)	
<i>Compression/ventilation ratio</i>			
4: 30:2 (28-32:2)	28 (18)	67 (32)	0.011
3: Other ratio	104 (68)	129 (61)	
2: Compressions only	20 (13)	17 (8)	
1: Ventilations only	0	0	
<i>Hand position during compression</i>			
4: Correct	8 (5)	7 (3)	NS
3: Other wrong	59 (39)	107 (50)	
2: Too low	85 (56)	99 (46)	
1: Not attempted	0	0	
<i>Average compression depth</i>			
6: 50–59 mm	55 (36)	79 (37)	0.030
5: ≥ 60 mm	0	6 (3)	
4: 35–49 mm	61 (40)	97 (46)	
2: 1–34 mm	36 (24)	31 (15)	
1: Not attempted	0	0	
<i>Total compression counted</i>			
6: 140–190	52 (34)	75 (35)	NS
5: ≥191	62 (41)	100 (47)	
4: 121–139	11 (7)	19 (9)	
3: 81–120	21 (14)	14 (7)	
2: 1–80	6 (4)	5 (2)	
1: Not attempted	0	0	
<i>Average ventilation volume</i>			
5: 500–600 ml	5 (3)	7 (3)	<0.001
4: 1–499 ml	11 (7)	21 (10)	
3: ≥601 ml	27 (18)	91 (43)	
2: 0 ml	87 (57)	77 (36)	
1: Not attempted	22 (14)	17 (8)	
<i>Total ventilation counted</i>			
5: 8–12	15 (10)	34 (16)	<0.001
4: 1–7	13 (9)	44 (21)	
3: ≥13	15 (10)	41 (19)	
2: 0	87 (57)	77 (36)	
1: Not attempted	22 (14)	17 (8)	
<i>Total hands-off time</i>			
4: 0–60 s	55 (36)	62 (29)	0.024
3: 61–90 s	62 (41)	120 (56)	
2: 91–135 s	33 (22)	30 (14)	
1: 136–180 s	2 (1)	1 (1)	
<i>Total score</i>	30 (4.0)	32 (3.9)	<0.001* <sup>□</sup>

225 Results are presented as *n* (%) or mean (SD). Differences in proportions between groups were analysed by Pearson's  $\chi^2$  test.  
 226 Differences in total score between intervention groups were analysed by mixed models linear test\* and unpaired t-test<sup>□</sup>. *P*-  
 227 values <0.05 were considered statistically significant. NS, not significant. The table lists the variable's best option at the top.  
 228 All numbers are rounded to the nearest whole number.

### 229 CPR with a practical test including feedback (T) versus CPR with reflection and a 230 practical test including feedback (RT)

231 Directly after training and at the six-month follow-up, there were no significant differences  
 232 between group RT (*n*=192) and group T (*n*=224) with regard to the total score of the modified  
 233 Cardiff test, calling 112 or hand-position during compressions (Table 3). Directly after CPR  
 234 training, both groups scored 34 points (61% of maximum score); and at the six-month follow-  
 235 up, group RT scored 31 (4.2) points (53% of maximum score) and group T scored 32 (3.9)  
 236 points (56% of maximum score). Table 3 includes the variables of the practical test that are  
 237 directly linked to the intervention of reflection as well as the total score of the test. All other  
 238 variables of the test showed no significant differences between the two groups (T versus RT)  
 239 and have not been included in the table.

240

241 **Table 3.** Assessment of CPR skills directly after training and at 6 months.

	CPR + test and feedback (T), directly after (n=224)	CPR + reflection + test and feedback (RT), directly after (n=192)	p-value	CPR + test and feedback (T), 6 months (n=213)	CPR + reflection + test and feedback (RT), 6 months (n=184)	p-value
<i>Call 112</i>						
2: Yes	161 (72)	152 (79)	NS	171 (80)	147 (80)	NS
1: No	63 (28)	40 (21)		42 (20)	37 (20)	
<i>Hand position during compression</i>						
4: Correct	21 (9)	15 (8)	NS	7 (3)	7 (4)	NS
3: Other wrong	130 (58)	115 (60)		107 (50)	95 (52)	
2: Too low	73 (33)	62 (32)		99 (46)	82 (45)	
1: Not attempted	0	0		0	0	
<i>Total score</i>	34 (4.4)	34 (4.3)	NS* <sup>□</sup>	32 (3.9)	32 (4.2)	NS* <sup>□</sup>
<i>How to act if a friend suffer cardiac arrest?</i>						
Compression and ventilation	178 (80)	155 (81)	NS	155 (73)	143 (78)	NS
Compressions only	35 (16)	33 (17)		41 (19)	37 (20)	
Ventilations only	2 (1)	1 (1)		1 (<1)	0	
Not dare to act	9 (4)	2 (1)		14 (7)	4 (2)	
Missing	0	1 (1)		2 (1)	0	
<i>How to act if a stranger suffer cardiac arrest?</i>						
Compression and ventilation	71 (32)	67 (35)	0.006	66 (31)	53 (29)	NS
Compressions only	116 (52)	113 (59)		111 (52)	106 (58)	
Ventilations only	3 (1)	0		0	1 (1)	
Not dare to act	34 (15)	11 (6)		34 (16)	24 (13)	
Missing	0	1 (1)		2 (1)	0	

242 Results are presented as n (%) or mean (SD). Differences in proportions between groups were analysed by Pearson's  $\chi^2$  test.  
 243 Differences in total score between intervention groups were analysed by mixed models linear test\* and unpaired t-test<sup>□</sup>. p  
 244 values <0.05 were considered statistically significant. NS, not significant. All numbers are rounded to the nearest whole  
 245 number.

### 246 Willingness to act

247 In the questionnaire, students were asked how confident they felt to act in a cardiac  
 248 arrest situation after participating in the CPR training session compared to prior to training. A  
 249 lower proportion of the students in group O versus group T stated they felt more confident to  
 250 act after participating in the training session, when asked directly after training (73% versus  
 251 88%;  $p=0.002$ ) and at 6 months follow up (73% versus 82%;  $p=0.025$ ). There were also  
 252 differences in how the students considered that they had enough knowledge to do chest  
 253 compressions, 60% (O) versus 81% (T,  $p<0.001$ ), and to do rescue breathing, 57% versus  
 254 75% ( $p<0.001$ ). At six months, 84% (O) versus 91% (T, not significant) considered they had  
 255 enough knowledge to do chest compressions and 59% (O) versus 74% (T,  $p=0.007$ ) to do  
 256 rescue breathing. There were no significant differences between group T and group RT  
 257 regarding confidence about acting or self-rated knowledge either after training or at six  
 258 months.

259 Directly after training, most students responded that they would do both compressions  
 260 and ventilations if a friend suffered OHCA; 72% (O), 80% (T,  $p=NS$  when comparing O and  
 261 T) and 81% (RT, Table 3). If a stranger suffered OHCA, there was a significant difference  
 262 between group T and group RT in how the students would act, with a more positive attitude in  
 263 group RT (Table 3) but there was no significant difference between groups O and T (27% and  
 264 32% would do both compressions and ventilations).

265 At six-month follow-up, there were no significant differences between the three  
 266 intervention groups with regard to how they would act in OHCA situations; 76% (O), 73%

267 (T) and 78% (RT) would do both compressions and ventilations if a friend suffered a cardiac  
268 arrest. Only 31% (O and T) versus 29% (RT) were prepared to do compressions and  
269 ventilations if a stranger suffered a cardiac arrest.

## 270 DISCUSSION

271 The main findings of the present study are threefold. First, adding a practical test with  
272 feedback after CPR training resulted in significantly improved practical skills at the six-month  
273 follow-up. Second, reflection added to CPR training did not influence the practical skills.  
274 Third, adding a practical test with feedback or reflection to CPR training did not affect long-  
275 term willingness to make a lifesaving effort. The study was carried out in schools from all  
276 socioeconomic areas and each intervention was applied in 7–9 different schools,  
277 strengthening the generalizability of our findings.

278 The group with a practical test including feedback (T) added after CPR training  
279 showed superior practical skills at six months compared with the group with CPR training  
280 only (O). However, the clinical relevance of the two-point difference in the total score for the  
281 modified Cardiff test is unclear. We discuss possible reasons for the outcome linked to  
282 learning theories. The result may be due to a further three minutes of hands-on training under  
283 the supervision of the investigator, or due to the individual feedback the students received  
284 after the test,[14]. Previous studies indicate that testing can increase learning outcomes  
285 compared with an equal amount of time spent on training,[13, 15]. The test was not only a  
286 tool to assess skills but also an opportunity to give the students feedback,[32]. The feedback  
287 aimed to reduce discrepancies between present understanding and the goal,[24]. Qi et al,[32]  
288 indicate that a pre-test and feedback can inspire learners to develop strategies to minimize  
289 their dependence on feedback from the instructors, which improve skill acquisition and skill  
290 retention. At feedback, the question “where to next?” was assumed to be the most important  
291 question, while praise for a task seems to be less effective,[24, 33]. A limitation is that the  
292 feedback to the students was given when the training was completed. In a pre-study, some  
293 students indicated that feedback helped to strengthen their self-esteem,[28]. According to  
294 Bandura,[34] and social cognitive theory, an individual's self-efficacy may affect a person's  
295 performance. Self-efficacy is about a person's confidence in their own ability (not actual  
296 ability) in a given situation. Self-efficacy can be affected by verbal persuasion,[35]. Further  
297 studies are needed to elucidate whether the results were caused by the additional training  
298 during supervision or by the feedback given to the students. Use of a feedback device is  
299 another form of feedback that may improve skill acquisition,[2]. A feedback device was not  
300 tested in this study.

301 According to the Swedish school curriculum, knowledge “can be expressed in a  
302 variety of forms, as facts, understanding, skills, familiarity and accumulated experience”,[11].  
303 Reflection and practical training are two teaching methods that can contribute to  
304 understanding, skills and familiarity. There are many definitions of reflection, which implies  
305 that there are many different models,[26-27]. In this study, the aim of the reflection was  
306 afterthought,[25-26]. Adding reflection to CPR training did not influence the students’  
307 practical skills. In particular, reflection did not improve calling 112 and hand positioning  
308 during compressions, despite both being included in the reflective questions. Directly after  
309 training, a higher proportion of students in the reflection group were willing to intervene if a  
310 stranger suffered a cardiac arrest, but this difference could not be observed at six months. This  
311 result might, at least in part, be explained by the content and the framing of the reflective  
312 questions. The first question, concerning how the students would act in an OHCA situation, is  
313 based on ethical considerations, which may provoke emotions and empathy in students,[36].

314 These emotions might have affected the participants close to the training but not in the long  
315 term. Question two (calling 112) and question three (hand positioning during compressions)  
316 were a cognitive complement to the practical training. Thus, the students might have  
317 discussed and answered these questions as knowledge questions, rather than questions to  
318 reflect upon. Perhaps the outcome would have been different if these reflective questions had  
319 been asked when the action was practiced, so-called reflection on action,[27]. Mann et al,[26]  
320 stated that there is no evidence to support or refute the assumption that reflection will enhance  
321 competence. Ixer,[37] stated that we do not know enough about reflection or how it can  
322 enhance learning. Further research is needed to clarify whether and how reflection can be  
323 used as a successful teaching tool in CPR training.

324 Practical training increases willingness to intervene in a real situation,[2, 38]. At the  
325 six-month follow-up, the three intervention groups did not differ with regard to willingness to  
326 make a lifesaving effort. Regardless of the intervention method, we found, in accordance with  
327 previous studies, a huge difference in willingness to intervene in an OHCA situation  
328 involving a friend compared with a situation involving a stranger,[38-41].

### 329 **Study limitations**

330 First, we cannot exclude that students who performed a test directly after training were  
331 more familiar with the test manikin at the retention test at six months. However, during the  
332 test the participants do not take part of the technical feedback received from the full-body  
333 Resusci Anne and should thus not have any advantage. The same design has also been used in  
334 other studies,[14, 23].

335 Second, it is a risk that the instructors' experience and/or enthusiasm affect learning.  
336 Therefore, the methods were standardized to ensure equivalent education; the teacher only  
337 had a role as a facilitator and the practical exercises were based on instructions from the app  
338 and the DVD.

339 Third, the intervention was carried out in two major municipalities. We do not know  
340 how applicable the results are for other locations, but a strength of the present study is that  
341 schools from all socioeconomic areas were included.

342 Forth, the questionnaire used to evaluate willingness to act contains only hypothetical  
343 questions. They do not fully answer how the students would act in a real situation.

### 344 **CONCLUSIONS**

345 This study contributes to knowledge on the efficiency of two additional CPR training  
346 interventions. A practical test with feedback in connection with CPR training is an efficient  
347 strategy to increase learning outcome, both practical skills and self-rated knowledge, when  
348 teaching seventh grade students. Further studies are needed to find alternative methods for  
349 testing and feedback, and to elucidate how feedback works most effectively in the CPR  
350 learning process. Reflective questions, in the format applied in this study, did not increase the  
351 participants' practical CPR skills. Importantly, regardless of the intervention applied, most  
352 students indicated they would intervene in an OHCA situation.

### 353 **Competing interests**

354 None declared.

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5 357 study.

7 358 **Contributors**

9 359 AN contributed to the study design, developed the modified Cardiff test and the  
10 360 questionnaire, conducted all measurements, analysed results and wrote the initial draft of the  
11 361 manuscript. LS and JH contributed to the study design, developed the modified Cardiff test  
12 362 and revised the manuscript. HH and SKS contributed to the study design and revised the  
13 363 manuscript. LN contributed to the study design, developed the modified Cardiff test and the  
14 364 questionnaire, analysed results and revision of the manuscript.

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20 369 data analysis, decision to publish, or preparation of manuscript.

22 370 **Ethics approval**

23 371 The study was approved by the Regional Ethical Review Board of Linköping, Sweden  
24 372 (2013/358-31).

26 373 **Data sharing statement**

27 374 No additional unpublished data is available.  
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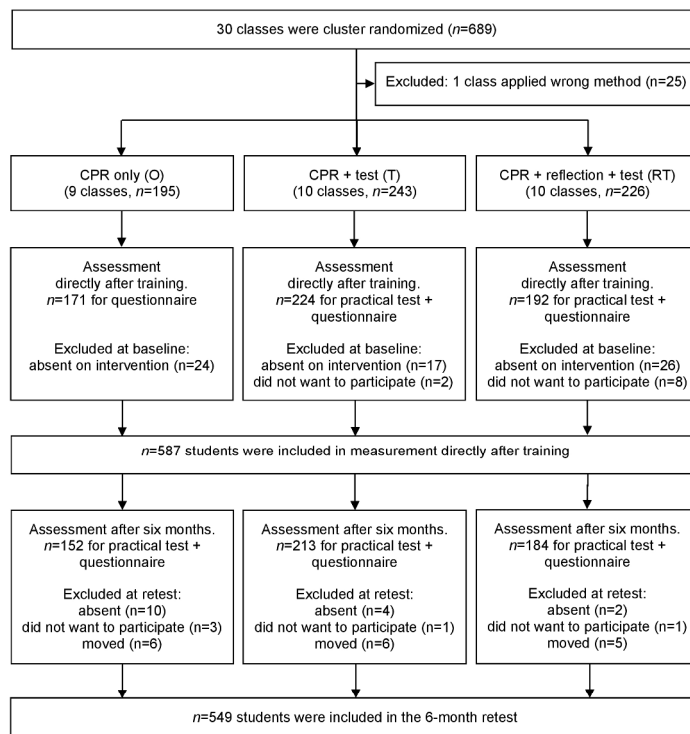


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**Figure 1** Flow chart on randomization and inclusion.

Figure 1. Flowchart on randomization and inclusion.



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209x297mm (300 x 300 DPI)

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## Supplementary file: the modified Cardiff test.

The modified version of the Cardiff test, adapted to the ERC guidelines of 2010,[20, 22]. The duration of the practical test was 3 minutes. The optimal conduct was 30 seconds for check responsiveness, check respiration and call for help, followed by 2.5 minutes of CPR. During the CPR, the participants were expected to perform at least 5 cycles of 30 compressions and 2 ventilations (30:2). The rules of assessment were pre-specified as follows:

Check responsiveness by talking

2. Yes, if some form of verbal communication as “are you ok” or “how are you”?

1. No, if no attempt at verbal communication was performed

Method: direct observation and real-time registration in the observation schedule by the test leader.

Check responsiveness by shaking

3. Yes, if the rescuer gently shake the victim shoulders.

2. No, if no attempt to shake the victim shoulders occurred.

1. Potentially dangerous, if the rescuer violently shakes the victim’s shoulders so the head lifted up and down against the ground, which can damage the head or the neck.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Open the airway - chin lift, head tilt.

5. Perfect, if one hand on the forehead, two fingertips on the jawbone (not soft tissue) and gently lifted the chin and bent the head back ie by ERC guidelines.

4 Acceptable/partially correct if several indicators are performed, but not all.

3. Attempted other, if the rescuer tried in other ways than ERC recommendation.

2. Only one element is performed or if the rescuer tries but fails.

1. No, if no attempt to open the airway was performed.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Checks respiration - see, listen, feel

2. Yes, if the rescuer did attempts of breath control, even if not all three actions see, listen and feel were performed and although if the total time of the control was less than 10 seconds.

1. No, if no attempt to check for breathing was performed.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Dials 112

2. Yes, dials 112 within the first minute. A call for help without dialling 112 was not enough, since students were instructed they were alone at the site.

1. No, if no attempt to get help was performed.

Method: direct observation and real-time registration in the observation schedule by the test leader.

Compression/ventilation ratio

4. 30:2 (28-32:2), if the rescuer practical applied compressions and ventilations with the relationship 28-32:2 during the whole test. Participants unable to ventilate the manikin but who attempted a ratio of 28-32:2 were registered as such, as they apparently had learned the skill ratio.

3. Other ratio, if the rescuer applied different ratio of compressions and ventilations than 28-32:2.

2. Compressions only.

1. Ventilations only.

Method: Direct observation and real-time registration in combination with data from Laerdal PC Skill Reporter Systems transferred to the scoring sheet after the test.

Hand-position during compression

Incorrect hand-position was recorded if one compression was in the wrong place, since one wrong compression can cause rib fracture or fracture the xiphoid process of sternum.

4. Correct, if the rescuer place the heel of one hand in the centre of the victim’s chest and with the other hand above.

3. Other wrong, if the rescuer performs chest compressions too high up on the sternum or to the side of the sternum.

2. Too low, if the rescuer performs chest compressions too low on the sternum.

1. Not attempted, if no compressions were performed.

1  
2  
3 Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the  
4 test.

5  
6 Average compression depth

7 The ERC guidelines recommend a compression depth of 50-60 mm,[20]. The PC Skill Reporter  
8 system version 2.4 measures up to 60 mm compression depth. To avoid that those who compress >60  
9 mm obtain the highest score, highest score was given for an average compression depth of 50-59  
10 mm. Those who compressed  $\geq 60$  mm received 5 points. We chose to retain the 6-point scale, as in  
11 previous studies,[23]. even though no one could receive 3 points, which would corresponded to a >65  
12 mm compression depth.

13 6. 50-59 mm.

14 5.  $\geq 60$  mm

15 4. 35-49 mm

16 2. 1-34 mm

17 1. Not attempted, if no compressions were performed.

18 Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the  
19 test.

20  
21 Total compression counted

22 6. 140-190

23 5.  $\geq 191$

24 4. 121-139

25 3. 81-120

26 2. 1-80

27 1. Not attempted, if no compressions were performed.

28 Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the  
29 test.

30  
31 Average ventilation volume

32 5. 500-600 ml

33 4. 1-499 ml

34 3.  $\geq 601$  ml

35 2. 0 ml, if the rescuer tried to do rescue breaths but failed.

36 1. Not attempted, if no rescue breaths were performed.

37 Method: Direct observation and real-time registration if the rescuer tried to do rescue breath. Exact  
38 volume, from Laerdal PC Skill Reporter Systems, was transferred to the scoring sheet after the test.

39  
40 Total ventilation counted

41 5.8-12

42 4. 1-7

43 3.  $\geq 13$

44 2. 0, if the rescuer tried to do rescue breaths but failed.

45 1. Not attempted, if no rescue breaths were performed.

46 Method: Direct observation and real-time registration if the rescuer tried to do rescue breath. Exact  
47 number, from Laerdal PC Skill Reporter Systems, was transferred to the scoring sheet after the test.

48  
49 Total "hands-off" time

50 Total hands-off time was the total time when compressions were not being performed (i.e. also  
51 includes time for check responsiveness, check respiration and dial 112).

52 4. 0-60 s

53 3. 61-90 s

54 2. 91-135 s

55 1. 136-180 s

56 Method: Data from Laerdal PC Skill Reporter Systems was transferred to a scoring sheet after the  
57 test.

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3 **Supplementary file: questionnaires used directly after training and at six**  
4 **months follow-up**  
5  
6

7 **Questionnaire directly after training**  
8

9 Have you previously practiced

10 chest compressions? Yes  No

11 ventilations? Yes  No

12 Do you think that your skills are sufficient to perform

13 chest compressions? Yes  No  Do not know

14 ventilations? Yes  No  Do not know

15 Are you more confident now than before the

16 training to act and start CPR? Yes  No  Do not know

17 You are at home. How would you act if a friend or relative suffered a sudden cardiac arrest? Tick one answer:

18 I would not dare or want to intervene

19 I would give chest compressions only

20 I would give ventilations only

21 I would give both compressions and ventilations

22 Enter the reason that you do not dare or want to do chest compressions?

23 Lack of knowledge

24 Afraid to hurt the person

25 Afraid of transmitted disease

26 Other reasons

27 Do not know

28 Enter the reason that you do not dare or want to do ventilations?

29 Lack of knowledge

30 Afraid to hurt the person

31 Afraid of transmitted disease

32 Other reasons

33 Do not know

34 You are standing at a bus stop. How would you act if an unknown person suffered a sudden cardiac arrest? Tick one answer:

35 I would not dare or want to intervene

36 I would give chest compressions only

37 I would give ventilations only

38 I would give both compressions and ventilations



1  
2  
3 Enter the reason that you do not dare or want to do chest compressions?

- 4 Lack of knowledge
- 5  
6 Afraid to hurt the person
- 7  
8 I do not want to touch a stranger
- 9  
10 Afraid of transmitted disease
- 11  
12 Other reasons
- 13  
14 Do not know

15 Enter the reason that you do not dare or want to do ventilations?

- 16 Lack of knowledge
- 17  
18 Afraid to hurt the person
- 19  
20 I do not want to touch a stranger
- 21  
22 Afraid of transmitted disease
- 23  
24 Other reasons
- 25  
26 Do not know

27 **Questionnaire at six months follow-up**

28  
29 Have you done a lifesaving intervention in real life after the CPR training? Yes  No

30  
31 If yes, please describe your lifesaving intervention and the situation: \_\_\_\_\_

32  
33 Do you think it is important to learn  
34 cardiopulmonary resuscitation in school? Yes  No  Do not know

35  
36 Do you think that your skills are sufficient to perform  
37 chest compressions? Yes  No  Do not know

38  
39 ventilations? Yes  No  Do not know

40  
41 Are you more confident now than before the  
42 training to act and start CPR? Yes  No  Do not know

43  
44 You are at home. How would you act if a friend or relative suffered a sudden cardiac arrest? Tick one answer:

- 45  
46 I would not dare or want to intervene
- 47  
48 I would give chest compressions only
- 49  
50 I would give ventilations only
- 51  
52 I would give both compressions and ventilations

53  
54 Enter the reason that you do not dare or want to do chest compressions?

- 55 Lack of knowledge
- 56  
57 Afraid to hurt the person
- 58  
59 Afraid of transmitted disease
- 60  
Other reasons
- Do not know

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3 Enter the reason that you do not dare or want to do ventilations?

4 Lack of knowledge

5  
6 Afraid to hurt the person

7  
8 Afraid of transmitted disease

9  
10 Other reasons

11  
12 Do not know

13  
14 You are standing at a bus stop. How would you act if an unknown person suffered a sudden cardiac arrest? Tick  
15 one answer:

16 I would not dare or want to intervene

17 I would give chest compressions only

18 I would only give ventilations

19  
20 I would give both compressions and ventilations

21  
22  
23 Enter the reason that you do not dare or want to do chest compressions?

24 Lack of knowledge

25  
26 Afraid to hurt the person

27 I do not want to touch a stranger

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29 Afraid of transmitted disease

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31 Other reasons

32  
33 Do not know

34  
35 Enter the reason that you do not dare or want to do ventilations?

36 Lack of knowledge

37  
38 Afraid to hurt the person

39 I do not want to touch a stranger

40  
41 Afraid of transmitted disease

42  
43 Other reasons

44  
45 Do not know



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

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	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
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4-5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	6-7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
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	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4, 6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

1			
2		assessing outcomes) and how	
3			
4		11b If relevant, description of the similarity of interventions	5-6
5	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	6-7
6		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
7			
8	<b>Results</b>		
9	Participant flow (a	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and	7-8 and
10	diagram is strongly	were analysed for the primary outcome	Figure 1
11	recommended)	13b For each group, losses and exclusions after randomisation, together with reasons	Figure 1
12	Recruitment	14a Dates defining the periods of recruitment and follow-up	5
13		14b Why the trial ended or was stopped	N/A
14			
15	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	Table 1
16	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was	7-9 and
17		by original assigned groups	Figure 1
18			
19	Outcomes and	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its	7-9
20	estimation	precision (such as 95% confidence interval)	
21		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
22	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	N/A
23		pre-specified from exploratory	
24			
25	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
26			
27	<b>Discussion</b>		
28	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	3, 10, 11
29	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	9-10
30	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-11
31			
32	<b>Other information</b>		
33	Registration	23 Registration number and name of trial registry	N/A
34	Protocol	24 Where the full trial protocol can be accessed, if available	N/A
35	Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	12
36			

\*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](http://www.consort-statement.org).