1 **Full title:** The effect of competency-based education in obstetric emergencies on
2 midwifery students in clinical skill lab, based on Kirkpatrick evaluation model: A
3 randomized controlled trial

4 **Short title:** the effect of competency-based education in obstetric emergencies and
5 midwifery students

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Abstract

Background:

Obstetric emergency is one of the most important causes of maternal and neonatal mortality, and competency-based education is one of the efficient approaches to cover this. Objective structured clinical examination is one of the valid methods in measuring students' competency and performance. Kirkpatrick evaluation model is a great method to assess a training impact.

Objectives: This study was designed to determine the effect of competency-based education on midwifery students based on Kirkpatrick evaluation model.

Design: Randomized controlled trial

Setting: Nursing and Midwifery School in Islamic Republic of Iran (Iran University of Medical Sciences)

Participants: eighty students in third to fifth term of associate and bachelor's degree in midwifery (intervention group=40, control group=40)

Methods:

Using stratified random sampling, research team trained learners of intervention group in 4 sessions, 5 hours/day in a month in emergency obstetric cares. Both groups had been receiving the routine schedule of the faculty. Knowledge, skills, and self-confidence were assessed three times, before, immediately and 6 weeks after training by researcher made questionnaire, Objective Structured Clinical Examination (OSCE) and self-reported questionnaire respectively. Data were analyzed with descriptive, inferential statistics.

Results:

The level of knowledge, skills, and self-confidence increased significantly in the intervention group, in immediate and 6 weeks after intervention (P<0.001). In intervention group, Mean ± S.D of all variables were 5.05±2.074, 143.30±12.146 and 11.65±2.045, which increased to 10.17±1.318, 527.70±19.995 and 18.97±1.980 and remained at the same levels 6 weeks later, 9.37±2.215, 521.80±19.784 and 19.00±2.631; in the control group, this trend was not significant (P=0.380, P=0.455 and P=0.191).

Conclusion: Competency-based education can be used in midwifery education and in-service training. We need to use new educational approaches such as competency-based to have a valuable impact on knowledge skills and self-confidence. This may affect health indexes indirectly.

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Introduction

59   One of the most important causes of maternal and neonatal mortality is the low quality
60   of care provided for mothers and babies which is probably as a result of low levels of
61   skills in health care providers especially in obstetric emergencies. The gap existed
62   between theory and clinical education, can lead to low quality of health services in
63   clinical areas (1). In 2015, almost 303000 women died during pregnancy, delivery and
64   after birth; 830 mothers lose their lives every day because of preventable complications
65   related to birth and 99 percent of them occurred in developing countries (2, 3). In 2017,
66   the maternal mortality rate (MMR) in Iran and Afghanistan were 23.3 and 299.1 per
67   100000 live births, respectively (4).

68   One of the most important instructions to constraint maternal and neonatal death is
69   promoting the quality of obstetric care (5). In order to achieve this goal, midwives and
70   gynecologists are being trained. Education using conventional approaches, do not have
71   the required durability; it illustrates the need for using modern teaching methods in the
72   education of midwifery skills (6, 7). The Competency-based educational approach is
73   one of the active and learner-centered methods which increases the ability to perform
74   skills by practicing and repeating (7, 8). Competency in emergency obstetric care is one
75   of the main professional abilities which the International Confederation of Midwives
76   (ICM) emphasizes on it. Shoulder dystocia, bimanual compression of the uterus,
77   manual removal of placenta, postpartum hemorrhage (PPH) management and neonatal
78   resuscitation are some of the common emergencies that achieving competency before
79   confronting them by midwives, can prevent maternal and neonatal mortality and
80   morbidity all over the world (9). Obstetric emergencies teaching in a clinical skill lab can
81   help students to achieve professional competency before clinical environments (10).
82   Learners 'training by using manikins in a quiet environment before entering the hospital,
83   can decline stress and enhance self-confidence and self-efficacy (11-13). This topic is
84   so important, as more than 65 percent of studies and interventions with the aim of
85   decreasing maternal and neonatal mortality, have been carried out in clinical skill lab or
86   clinical centers (14, 15). WHO and ICM have identified the minimum qualifications,
87   required for midwifery graduates. Competency-based education approach can help to
88   access skill in clinical performance and professional behavior.

89   To evaluate the effectiveness of this kind of programs, Kirkpatrick evaluation model
90   which assesses the course effect in learners in four levels (Reaction, Learning,
91   Behavior, and impact) can be used. In various studies, different levels of Kirkpatrick

92 evaluation model have been used (16). Since the evaluation of knowledge, skills, and
93 self-confidence in the medical field, especially in midwifery, have a direct relationship
94 with mother and baby lives, therefore it is very important to pay attention to it. This study
95 was conducted to determine the effect of competency-based training in obstetric
96 emergencies on midwifery students in the clinical skill lab based on the Kirkpatrick
97 evaluation model.

Materials and Methods

Trial design

100 This study is a randomized controlled trial with a control group which investigated the
101 effect of competency-based education in obstetric emergencies in midwifery
102 undergraduate students. Using stratified random sampling, learners were divided into
103 two groups by researcher. To control information bias, the evaluation of control group
104 were completed before intervention started. Both groups received regular midwifery
105 emergency obstetric care topics by the faculty members in accordance with the
106 approved syllabus of this country ministry of ministry of health and medical education.

Participants and setting

108 All midwifery students in semester 3 to 5, associate and bachelor 'degrees in nursing
109 and midwifery faculty, informed by posters or directly by the researcher. These students
110 who do not have especial experience in practical skills except internship were eligible to
111 participate. Not participating even in one session was the criterion for exclusion.

Sample size:

113 To determine the sample size for each objectives, the sample size separately was
114 calculated using the following formula; in which the confidence level (1-α), 95 percent,
115 the test power (1-β), 80 percent, standard deviation (σ) 12.1 and accuracy, 0.5 were
116 considered (17); so the sample size in each group was 40 people.

117 $$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 \delta^2}{d^2} = \frac{(1 \cdot 96 + 0 \cdot 84)^2 (1 \cdot 12)^2}{(0 \cdot 5)^2} \simeq 40$$

118 $$z_{1-\frac{\alpha}{2}} = z_{0 \cdot 975} = 1 \cdot 96$$

119 $$z_{1-\beta} = z_{0 \cdot 8} = 0 \cdot 84$$

120 $$d = 0 \cdot 5$$

Intervention

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122 This study was done in accordance to the ethics guideline of Iran University of Medical
123 Sciences (IR.IUMS.REC1397.026) and registered in Iranian Registry of Clinical Trials
124 (IRCT20180609040017N1). All students signed the informed consent. 86 students
125 registered and they were assigned into two groups, intervention (n=43) and control
126 (n=43). First, the objectives and methods of research were explained to learners. All
127 learners completed demographic, knowledge and self-confidence questionnaires. Then,
128 they participated in an OSCE in clinical skill lab based on checklists. The course
129 content was prepared using textbooks and "Emergency Obstetric Care Course
130 Package" of California University. The topics included diagnosis and management of
131 dystocia, postpartum hemorrhage, newborn resuscitation and shock which were taught
132 in the classroom and skill lab center. The validity and reliability of all questionnaire and
133 checklists was verified by 11 midwifery experts and faculty members; the CVI index
134 was generally 0.95 (0.91 - 0.97) and the correlation coefficient using "test-retest"
135 method in the knowledge dimension 0.91, in skill 0.79 and in self-confidence 0.89. Also,
136 the assessors were trained by the researcher and the Kappa coefficient of assessors
137 was calculated at each station which was more than 0.7 in various stations.

138 The research team conducted the training in 4 sessions which every session duration
139 was 5 hours, once a week, and the assessment was carried out before, immediately
140 and 6 weeks after the end of the intervention. The selected educational approach was
141 competency-based. Firstly, the training began with theoretical topics with different
142 teaching methods such as lectures, watching videos and PowerPoint presentations. The
143 course content in every session was as follows:
144 Session 1, the reasons for using partograph, filling and interpreting partograph;
145 episiotomy procedure, and its repair, practicing the skill of episiotomy and its repair;
146 Session 2, causes, diagnosis and management of dystopia and its variants, practicing
147 the skill of shoulder dystocia, Session 3, causes, diagnosis and management of
148 newborn resuscitation and shock management in adults; practicing the skill of neonatal
149 resuscitation and shock management, Session 4, causes, symptoms, diagnosis and
150 management of postpartum hemorrhage; practicing the skill of manual removal of
151 placenta and uterine bimanual massage.
152 In every session, after the theory session, skills were simulated on a model in the
153 clinical skill lab by the researcher. The following checklists were used: episiotomy and
154 its repair, shoulder dystocia, newborn resuscitation, uterine bimanual compression,
155 manual removal of placenta and shock management. Then the learners started group
156 discussion and practicing the skills with supervision. The researcher provided
157 appropriate feedback during practice, and it was continued until competency gained by
158 every learner.
159 Knowledge assessment was done by a questionnaire consists of 12 multiple choice
160 questions. Every correct answer had one score and the overall score was 12. Self-
161 confidence questionnaire was measured by Likert range of three options from score 1

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162 for "no self-confidence" to 3 for "fully self-confident". Skills assessed by OSCE in 7
163 stations. The stations included: Using partograph, episiotomy and its repair, shoulder
164 dystocia, neonatal resuscitation, uterine bimanual compression, manual removal of
165 placenta, and shock management. The assessments were conducted by trained
166 assessors using checklists. Each step was scored by Likert 'range of 5 options, from
167 score 1 "completely unsatisfactory" to 5 "completely satisfactory". The total score in
168 each checklist varied based on the number of steps. Cut-off point in knowledge
169 dimension was 80 percent and in skill dimension was 90 percent (18).

170 ## Analysis:

171 Data were analyzed by SPSS version 16. Descriptive statistics such as tables of
172 frequency, numerical indexes and inferential statistics such as Chi-square, Independent
173 t-test, and repeated measures analysis of variance were used to describe the results.
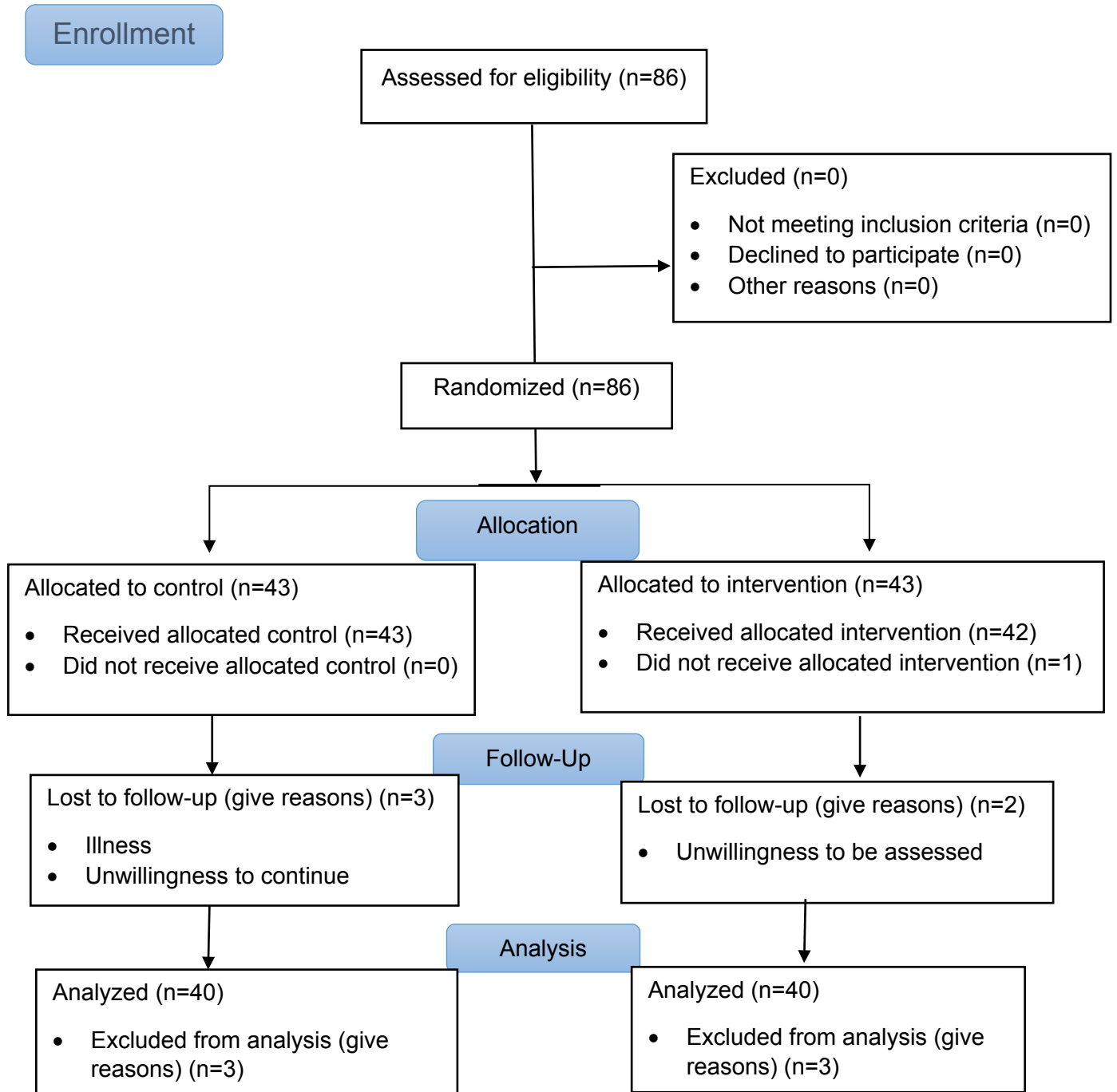174 The level of significance was considered $P < 0.05$.

175 # Results

176 ## Characteristics of participants

177 From 86 participants, (43 students in control and 43 in intervention group), 6 participants
178 excluded from the study; in the control group, 3 students due to illness and unwillingness
179 to continue the study, and in the intervention group, one student due to overlapping the
180 course with her training in hospital and 2 students due to unwillingness to be evaluated
181 had not continued the course and its evaluation. In conclusion, data analysis was carried
182 out on 80 students, 40 participants in each group (table 1: consort diagram).

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184   Table 1: Consort diagram

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Enrollment

Assessed for eligibility (n=86)

Excluded (n=0)
- Not meeting inclusion criteria (n=0)
- Declined to participate (n=0)
- Other reasons (n=0)

Randomized (n=86)

Allocation

Allocated to control (n=43)
- Received allocated control (n=43)
- Did not receive allocated control (n=0)

Allocated to intervention (n=43)
- Received allocated intervention (n=42)
- Did not receive allocated intervention (n=1)

Follow-Up

Lost to follow-up (give reasons) (n=3)
- Illness
- Unwillingness to continue

Lost to follow-up (give reasons) (n=2)
- Unwillingness to be assessed

Analysis

Analyzed (n=40)
- Excluded from analysis (give reasons) (n=3)

Analyzed (n=40)
- Excluded from analysis (give reasons) (n=3)

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187 Both groups did not have a significant difference in age, residential place, last term
188 average, number of deliveries with coach supervision and independent attendance,
189 experience in dystocia, newborn resuscitation, postpartum hemorrhage and shock
190 management. The majority of students (33.75%) were living in the governmental hostel.
191 Mean and standard deviation of the learner's age was 21.94 ± 0.475, the last term
192 average was 16.55 ± 0.109. Learners' demographic features and previous experience in
193 obstetric emergency skills are reported in Table 2.

194 **Table 2: Demographic and previous experience in obstetric emergencies workshops in participants**

variables	Intervention	Control	Statistics
Age Average ± SD	21.60 ± 2.38	22.27 ± 3.00	t=1.11; p=0.269
Last term Average ± SD	16.64 ± 0.97	16.47 ± 0.98	t=0.73; p=0.442
Residential Place			
Governmental dorm	16	11	df=2
Non-governmental dorm	11	14	χ^2=2.735
Living with parents	13	15	p=0.434
Experience in normal delivery			
Yes	29	32	df=1
No	11	8	χ^2=0.620
			p=0.430
Experience in Neonatal Resuscitation			
Yes	1	2	p=1.00
No	39	38	
Experience in PPH Management			
Yes	4	5	p=1.00
No	36	35	

195 ## Main outcomes

196 Knowledge, skills and self-confidence of intervention group increased significantly in
197 immediately and 6 weeks after intervention compared to the control group (Table 3). In
198 comparison between groups, based on repeated measures of variance test, Before the
199 intervention, There were no significant differences in the level of knowledge, skill, and
200 self-confidence among students between groups (respectively P = 0.673, P = 0.153, and

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201 P =0.156). The scores of knowledge, skill and self-confidence in all dimensions between
202 groups had a significant difference (P<0.001).

203 **Table 3: The effects of intervention on participants**

Variables	Evaluation Time	Groups (Mean ± SD)		Confidence Interval		p-value[1]
		Intervention	Control	Lower bound	Upper bound	
Knowledge	Before	5.05 ± 2.07	4.87 ± 1.58	4.29	5.63	0.673
	Immediately after	10.17 ± 1.31	5.20 ± 1.55	4.74	10.62	<0.001
	6 weeks after	9.37 ±2.21	5.32 ±1.50	4.72	9.97	<0.001
p-value[2]	<0.001					
Skill	Before	118.47 ± 10.14	116.22 ± 8.32	113.30	121.39	0.282
	Immediately after	416.92 ± 19.76	116.47 ± 7.07	111.80	421.59	<0.001
	6 weeks after	415.07 ± 17.28	117.90 ± 9.12	113.54	419.42	<0.001
p-value	<0.001					
Self-confidence	Before	10.52 ± 1.88	11.17 ± 1.78	9.94	11.75	0.117
	Immediately after	16.70 ± 1.75	10.75 ± 1.42	10.24	17.20	<0.001
	6 weeks after	16.75 ± 2.30	10.35 ± 2.10	9.65	17.44	<0.001
p-value	<0.001					

204 [1] Independent t test

205 [2] Repeated Measures Analysis

206 In comparison between groups, the score of knowledge, skill and self-confidence in all
207 dimensions, increased significantly in immediately and 6 weeks after intervention
208 (P<0.001). To compare the scores within groups, knowledge, skills, and self-confidence
209 increased significantly from before to immediately, and 6 weeks after intervention, in
210 intervention group (P<0.001); by Bonferroni Post-hoc tests in all dimensions, there was a
211 significant difference between before and immediately and 6 weeks after intervention
212 (P<0.001). There was no significant difference between scores of immediate and 6 weeks
213 after intervention in all mentioned areas, which means that knowledge, skill, and self-
214 confidence were consistent 6 weeks after intervention (respectively P = 0.167, P = 0.464,
215 P = 1.00). Chart 1-3 illustrates the changes and comparisons of knowledge, skill, and self-
216 confidence in intervention and control.

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217 S1-3. Chart 1-3

Discussion

219 One of the effective factors in high maternal mortality is the gap of skill performance
220 between theoretical knowledge and clinical activities in "real world". Based on research
221 team experience, In Iran, despite the appropriate theory teaching which is based on the
222 latest scientific references, midwifery students in a clinical environment do not have the
223 opportunity to achieve experience in obstetric emergency management. University
224 professors train their students in clinical skill lab limitedly and the major part of clinical
225 education is performed in bedside in hospitals. However, they were not allowed to
226 participate in high-risk pregnancy care and management; this can result in
227 dissatisfaction in competency and self –confidence.
228 Competency-based education is one way to diminish this gap. Also, it is needed to
229 choose an acceptable and efficient method to teach and evaluate skills, first in clinical
230 skill lab, then in the hospital such as simulation and Objective Structured Clinical
231 Examination (OSCE). The ultimate goal of many studies is to upgrade the level of health
232 index in the country in line with Sustainable Development Goals. By using an
233 appropriate design of evaluation like Kirkpatrick Evaluation Model, it is possible to
234 understand the impact of the study on higher levels.
235 This study was conducted with the aim to determine the effect of Competency-based
236 education of obstetric emergencies on knowledge, skills, and self-confidence of
237 midwifery students with OSCE and using Kirkpatrick evaluation model in its second
238 (knowledge, skills) and third levels (self-confidence). Based on our findings, this study is
239 the first research in the context of educational evaluation with OSCE in obstetric
240 emergencies with a competency-based educational approach in the clinical skill center
241 by using kirckpatric model of evaluation in Iran. All previous studies in these trainings
242 had been done as in-service courses, but our research conducted on students. As half
243 of the students participated in this study were international trainees and they were
244 supposed to return to their country (Afghanistan), it was needed to use a special
245 method which can enhance health indexes such as MMR.
246 In addition, one of the most precious evaluation method in clinical skills is OSCE
247 that we used in this study. OSCE can generate a beautiful relationship between
248 teaching and assessment. This high valid method can investigate a broad spectrum of
249 clinical skills and individual abilities. Despite the fact that the best place for applying
250 newly taught skills is "real world" and "real patient", one of the best methods of teaching,
251 practicing and evaluation in some rare urgent activities such as obstetric emergencies,
252 needed to be fulfilled before graduation, is OSCE in clinical skill center (19, 20). The
253 study by Collado-Yurrita at Madrid University approved that utilizing this approach has
254 progressively developed in recent years (21). OSCE investigates the created changes
255 in each individual, but it is clear that it is not enough. The main goal for training is not

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256 individual changes, promotion in organization performance is the ultimate goal; one of
257 the foremost methods is Kirkpatrick which assesses the effect of our intervention on
258 different levels of stakeholders such as the impact on the organization, government or
259 country.
260 Data analysis revealed that knowledge, skill, and self-confidence increased significantly
261 in immediate and 6 weeks assessments after the intervention. The study by Ameh et al.
262 (2018) in which, knowledge and skill retention after emergency obstetric care training
263 with "skills and drills" approach, was investigated, their result was the same as ours;
264 knowledge and skill levels increased significantly immediately and three months after
265 training (P<0.01). The improvement in skill scores was much higher than knowledge
266 and previous job experience more than 13 years caused lower retention and more drop
267 in scores, especially in skill assessment (22). This reduction seems to be due to more
268 skill retention with passing time and increasing experience. This is one of the reasons to
269 start this course during university days, not after graduation or in-service.
270 This approach leads to competency achievement for all students after the intervention
271 and retention six weeks later in the intervention group and no competency in the control
272 group. In our study cut-off point in knowledge was 80% and in skill 90%. Mirkuzie et al.
273 (2014) studied the reaction and knowledge of health care providers in Ethiopia. 70% of
274 the learners achieved competency in the first assessment after the intervention, and
275 scores remained up until 6 months after training (23). It seems that the course planning
276 after completion of the theory session at university or before starting the internship can
277 have the best impact in results.
278
279 The coincidence between teaching and learning education of clinical skills in skill lab by
280 practicing them with a simulation-based approach can improve retention of knowledge
281 and skill as well as self-confidence of students in performing clinical skills. walker et al.
282 study (2015) was conducted with a simulation approach and group practices, an
283 increase and retention of knowledge in a self-report evaluation were observed (24).
284 Their results were in the same line with our study. The results of Walker et al. (2013),
285 showed growth in scores of knowledge and confidence, immediately after intervention;
286 but significant fall within 6 weeks after training (6). Also, the study by Tang et al. (2015)
287 aimed to improve obstetric emergencies 'knowledge and skills in Malawi also led to an
288 increase in knowledge and skill after intervention (P<0.001), but 6 months after training,
289 both variables decreased significantly (25). It showed that despite the fact that,
290 traditional approaches have this capacity to enhance knowledge and skill levels
291 immediately, but they were not effective knowledge and skill retention. In addition,
292 based on Miller Pyramid, "Know" about a special topic is not enough, and without
293 "Show" and "perform" and practicing skills, we encounter more decay and lower
294 retention. Tang and Walker study results showed that we need to use new educational

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295 approaches such as competency-based to have a valuable impact and retention of
296 knowledge and skills and self-confidence.
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298   Our results revealed that using this way of teaching and evaluation can enhance
299 learner's self- confidence. Increasing self-confidence leads to self-efficacy and as a
300 result, midwives ability in performing skills can grow. Walker et al. study in Mexico
301 resulted in simulation training enhanced self-efficacy followed by better management in
302 emergencies (26, 27). Self-efficacy and self-confidence, especially in emergency case
303 management, are key factors to show competency(8). Studies found that professionals
304 who have more self-confidence and self-efficacy can manage emergency situations
305 better (17, 26).
306   The results of Glasgow et al. study revealed that a competency-based approach
307 can improve the transparency, efficiency, impact, and quality of education, as well as
308 increasing the accountability of learners and educators (28). KC et al. (2017) also aimed
309 to assess the retention of newborn resuscitation skills after training with Time-series
310 design. In that study, the knowledge and skill scores increased significantly in the
311 immediate evaluation and remained stable until six months after intervention (29). In
312 addition, Urbute et al. (2017) investigated the changes in learners knowledge and self-
313 esteem in obstetric emergencies, with self-assessment and Likert scale (30). Although
314 the results were the same as ours, self-assessment with Likert scale is not an
315 appropriate method to evaluate knowledge and it was one of the items which we pay
316 attention to.
317 Results of Repeated Measures ANOVA illustrated that knowledge, skills and self-
318 confidence, immediately and 6 weeks after training increased significantly. The
319 Competency-based could enhance the learning outcomes through practice and
320 repetition, especially in medical sciences (21). The results of Ameh et al. (2012) study
321 with Kirkpatrick evaluation method revealed knowledge, and skills increased at the
322 second level and self-confidence at the third level among learners (17). Also, the study
323 by Grace et al in Cameron (2015) was similar to our study. The results showed that
324 knowledge, skills, and self-confidence of learners immediately increased significantly
325 after the intervention. The persistence of knowledge and skills a six-month after the
326 intervention has led to a high level of self-confidence in managing midwifery emergency
327 situations. The theoretical framework of this research was based on Bloom's theory of
328 education, which divides the educational objectives into cognitive and psychomotor
329 areas; this suggests that using educational approaches which are more likely to sustain
330 the competencies after the intervention, can probably improve the level of self-
331 confidence in managing specific skills. In fact, there is a two-way relationship between
332 these three components, competence, self-confidence, and stress, and all of them are
333 being affected by each other (31). Research by Frank et al. (2009) with 68 interns of
334 obstetrics and gynecology ward, in terms of knowledge and skills, increase immediately

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335 after intervention, was in the same line with our study. The results of that study showed
336 that training in a topic like obstetric emergencies using lectures, simulation approach,
337 and instructions of how to use mannequins and pre-prepared scenarios as case study
338 questions, could be effective in increasing knowledge and skills (32). Research by
339 Walker et al. (2014) in Mexico, was in accordance with the present study. The results
340 showed that evidence-based knowledge in the management of obstetric emergencies
341 could be increased with an inter-professional and simulation-based approach,
342 immediately and 3 months after training, followed by self-efficacy. Some evidence
343 suggested that self-efficacy improved as a result of increased self-confidence to
344 diagnose and manage obstetric emergencies (33).

345 Considering that in-service training has significant costs for the hospital and the
346 government (34), the implementation of this program during university enrollment, after
347 the completion of training and before the start of the internship, could result in a
348 significant reduction in costs. By inserting this course in the midwifery curriculum, and
349 it's implementation as a part of the midwifery program in the country, as well as
350 conducting in-service training by short-term retraining programs, our peers 'information
351 can be updated. This intervention was designed to improve the knowledge, skills, and
352 self-confidence of midwifery students in the field of obstetric emergencies. It is
353 recommended that these workshops would be held in codified and approved form in the
354 country.

Limitations

356 This study was the results of MSc midwifery thesis and due to lack of time, we could not
357 assess the impact of our study in hospitals. It is recommended that the next study would
358 be conducted in this area.

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Acknowledgments:

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