



Research Paper

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Evaluation of the clinical pharmacist's role in educating women about the benefits and risks of combined oral contraceptive pills in Jordan

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Abstract

Objective To assess the pre-intervention knowledge of women regarding the risks and benefits associated with the use of combined oral contraceptive (COC) pills. Then, to investigate the effect of an educational intervention on the knowledge of women about the risks and benefits of COC pills.

Methods The study adopted two methodologies: a structured interview technique with women selected according to inclusion criteria, and a pre- and postintervention to measure the effect that clinical pharmacist's intervention may have had on them. Women who attended family-planning clinics in the north of Jordan were interviewed using a structured questionnaire. The questionnaire included questions about demographics and questions to assess women's knowledge about COC pills. Then, women attended a 45-min educational session about COC pills. One month later, the questionnaire was redistributed to the participants to assess any difference in their knowl-

Key findings Two hundred and ten women were enrolled in the study. One hundred and seventy-seven women completed the study. At baseline, a quarter of the participants relied on other people's experiences as their main source of information with regards to COC pills. Moreover, 28.1% of women considered COC pills harmful. In addition, the results showed that the frequency of correct answers postintervention increased significantly compared to pre-intervention (P < 0.005) including general information about COC pills and the relation between the use of COC pills and cancer.

Conclusion Educational intervention introduced by clinical pharmacists improved the knowledge of women in Jordan regarding COC pills.

Keywords clinical pharmacist's role; combined oral contraceptive pills; educational intervention; Jordan

Introduction

Combined oral contraceptive (COC) pills are one of the most commonly used contraception methods.^[1] For example, in the United States a report presenting estimates of contraceptive use among women aged 15-49 in 2015-2017 found that the most common methods used were female sterilization (18.6%) followed by the pill (12.6%).^[1] COC pills are a very effective contraception method; their efficacy in preventing pregnancy with typical use is about 92% per year. [2] The appropriateness of the use of COC pills depends on several factors such as a woman's health status, age, medical history, smoking status and other related factors.^[3] The World Health Organization classified medical eligibility for contraceptive use into four categories ranging from no restrictions for their use to an unacceptable health risk if used. [4]

In Jordan, the Jordan Population and Family Health Survey 2012 (JPFHS 2012), which was conducted by the Jordan Department of Statistics, interviewed 11 352 evermarried women aged from 15 to 49 years. The results of this survey revealed that although 99.5% of the interviewed women knew about contraceptive pills, only 7.7% of

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the women were currently using contraception pills. Interestingly, 17.9% of the participating women were using traditional contraception methods including periodic abstinence and withdrawal.^[5]

A validated questionnaire-based study investigated 1571 Jordanian women who used oral contraceptives at least once in their lifetime. The results showed that although the majority of women received consultation from physicians (82.5%) about the oral contraceptive pills, only half of the participants knew how to use them properly. In addition, the pharmacists had a minimal role in counselling women about oral contraceptive pills. [6] Therefore, there is an urgent need to adopt educational programmes to improve Jordanian women's knowledge about oral contraceptives. Pharmacists in Jordan provide patient education and drug information services free of charge. In addition, pharmacists are the most accessible primary healthcare providers in Jordan; therefore, they can have a vital role in educating women about oral contraceptives.

A number of studies investigated the role of pharmacists in educating patients in various disease states. [7-10] In Australia, a prospective study was conducted to evaluate the role of pharmacists in asthma management. Pharmacists' responsibilities included patient education. The results showed that pharmacists' interventions resulted in improvement in asthma control. [9] Moreover, a randomized controlled trial was conducted to investigate the role of pharmacists in diabetes mellitus management. Pharmacists' role included patients counselling. The results showed that patients who received pharmacists' interventions were more engaged in healthy lifestyle compared to patients who received usual care from their primary healthcare providers. [10]

Proper education about contraception affects the choice of the contraceptive method and improves women's knowledge of contraception.[11,12] In France, a multicentre prospective, randomized study showed that women who received structured information about COC pills had an average score of understanding the information significantly higher than women who received unstructured information.[13] Another study that was conducted in primary care clinics found that educating women about one specific method of contraception increased the likelihood of them using that method of contraception.^[14] In Jordan, a recent study was published on the impact of an information booklet provided by pharmacists to women using oral contraceptives. This study randomized oral contraceptive users into an intervention group (n = 80) where women received the information booklet from a pharmacist and a control group that received conventional counselling (n = 80). Participants were assessed at three points of time: at baseline, immediately after intervention and after 3 months. This study found an increase in the knowledge score of the intervention group at baseline compared to the same group immediately after the intervention from 1.76/5 to 5/5 (P value <0.00). [15] However, the intervention group score decreased after the follow-up period to 4.93/5 but was still significantly higher than baseline. The knowledge score of the control was 1.29/ 5 at baseline and did not change significantly over time. [15]

The objectives of the current study were to assess women's knowledge of the risks and benefits associated with the use of COC pills in the north of Jordan including

both rural and urban areas. In addition, to assess the effect of an educational intervention that involved both a 45-min educational session and distribution of an educational brochure and introduced by clinical pharmacists on the knowledge of women regarding the risks and benefits associated with COC pills.

Methods

Study design

A multicentre, interventional educational study was conducted. All women in their reproductive age who attended obstetrics and gynaecology clinics as well as family-planning clinics in public health centres (n=7 sites) in North Jordan between February 2018 to March 2018 were invited to participate in this study.

The inclusion criteria were women in their reproductive age who attended family-planning clinics and obstetrics and gynaecology clinics for any purpose. An informed consent was obtained from all women who agreed to participate in the study. The study procedure and goals were explained to participants both verbally and through the consent form. Women who agreed to participate in the study and signed the consent were asked to fill the questionnaire and to attend the education session afterwards. The study protocol was approved by the Jordan University of Science and Technology (JUST) Institutional Review Board committee (IRB) (Research Number 3/111//2017) and by the Ministry of Health in Jordan (Research Number MOHREC180017).

Study tools

A validated closed- and open-ended questionnaire was utilized based on the one used by Jaber *et al.* (in press). The original questionnaire was developed by two clinical pharmacists, one statistician and one sociologist in order to ensure face validity. The modified questionnaire was validated by specialists (a pharmacology PhD holder, three clinical pharmacists and a clinical pharmacy master student). To improve clarity and limit response bias, the questionnaire was piloted before the study in a small sample of 27 women, and minor modifications were made. Modifications included adding an option 'others' to the question regarding baseline physical examination and laboratory workup.

The questionnaire was written in Arabic, which is the native language in Jordan, and consisted of four parts. Part A was designed to collect demographic information including age, education, occupation, medical affiliation and marital status. Part B assessed women's knowledge about the effect of the use of COC pills on conception, infertility and menstruation. In addition, part B included questions about the correlation between COC pills and expected risks such as cervical and breast cancers and expected benefits such as the prevention of ovarian cancer and anaemia. Part C assessed the pattern of women's use of COC pills in case of missed doses, and the sources of information utilized by women with regard to COC pills. Part D was designed especially for those who had used COC pills at least once in their life. Questions included the duration of

the use of COC pills, the time of starting COC pills in relation to the participant's pregnancy schedule (before first pregnancy, after first pregnancy, after second pregnancy or at any time), any baseline physical examination and laboratory workup (e.g. examination of the uterus, pelvic, and/or breasts and monitoring of the lipid profile), the trade name of the used COC pills and whether or not the participant had received a consultation or a prescription before using the COC pills. After completing the questionnaire, participants received an educational brochure and attended a 45min educational session. The educational brochure was prepared by two expert clinical pharmacists after an extensive literature review. The researchers prepared a checklist of the information to be provided during the educational session to ensure that all women in different centres received the same information. The educational session was provided by a pharmacist (a clinical pharmacy master's degree student) who was trained to conduct educational sessions. The pharmacist training included conducting mock educational sessions under the supervision of an experienced clinical pharmacist. The educational session was face-toface lecture style and focused on discussing the issues related to the use of COC pills such as the risks, benefits and other related concerns. During the educational session, the pharmacist answered women's questions related to COC pills. The same pharmacist provided the educational session for all women in all participating centres. One month later, all participants were contacted. Those who were reached and agreed to complete the study were interviewed by phone or in person. The same questionnaire was distributed to participants to assess any change in their knowledge.

A score was assigned for each completed questionnaire. The total score was calculated pre- and postintervention for each participant. For each question, a score of one was given to correct answers and zero for incorrect answers. The total score for a fully answered questionnaire was 20 points. Data collection took place from February 2018 to March 2018.

Statistical methods

The sample size was calculated based on the Vogt and Schaefer study. [16] To detect a medium effect size with a two-sided 5% significance level and a power of 80%, a sample size of 79 women per group was calculated for the follow-up measurement. For an anticipated dropout rate of 25-30%, initial recruitment of 99-103 women per group was needed. The Statistical Package for Social Science (SPSS (version 22), Chicago, IL, USA software) was used to analyse the data. Frequency distribution was used to describe patient demographics (age, education and material status). The dependent t-test was used to compare the means of the scores to assess the effect of the intervention on participants' knowledge. McNemar's test was used to compare the per cent of correct answers pre- and postintervention. In addition, an ANOVA and linear regression tests were used to analyse the effect of different demographic characteristics on pre-intervention scores. A P value of <0.05 was considered statistically significant.

Results

Demographic data

Two hundred and thirty-three women were invited to participate; of these, 210 women agreed and signed the informed consent (response rate of 90.1%). Of the 210 participants, only 177 participants completed the study and were interviewed 1 month after receiving the educational intervention. Thirty-three participants dropped out of the study; two participants did not fill the questionnaire although they signed the consent form. In addition, 16 participants refused to receive the intervention, and 15 participants could not be contacted due to incorrect contact details provided at enrolment.

The mean age of respondents was 35.1 ± 9.3 years (mean \pm SD), and the majority of women were married (90.5%). Further, <50% of the respondents had a diploma degree or higher. Participants' baseline demographic details are shown in Table 1.

Use pattern of combined oral contraceptive pills

The results showed that 41.4% of participating women used COC pills. The resources of information related to COC use varied; about 25% of women stated that they relied on other people's experience, 23% relied on physicians, and only 5.2% relied on pharmacists as their source of information. About 24% of participants perceived COC pills as safe medications, while 28% considered them harmful. Less than 50% of women who reported using COC pills used these pills after their first delivery. In addition, about 41% of the women who used COC pills stated that they used them for 1–6 months.

Regarding prescription details, about 36% of women who were taking COC pills stated that the physician

Table 1 Participant's demographics and characteristics at baseline (N = 210)

Participants' characteristics	N (%)	
Age		
Mean ± SD	35.1 ± 9.3	
Median (Range)	34.0 (17.0– 56.0)	
Missing	28 (13.3)	
Educational level		
Illiterate	3 (1.4)	
Primary	29 (13.8)	
Secondary	74 (35.2)	
Diploma degree	41 (19.5)	
Bachelor's degree	54 (25.7)	
Graduated studies	6 (2.9)	
Missing	3 (1.4)	
Marital status		
Single	9 (4.3)	
Married	190 (90.5)	
Widowed/Divorced	8 (3.8)	
Missing	3 (1.4)	
Nationality		
Jordanian	197 (93.8)	
Non-Jordanian	13 (6.2)	

prescribed the pills while the same percentage (\sim 36%) was advised to use COC pills by midwives. Less than half of the women who used COC pills received medical advice about the pills, and \sim 33% received laboratory or physical assessment prior to using these pills (Table 2).

With regard to the scores of each completed questionnaire pre- and postintervention, the results showed that the mean of pre-intervention scores for participants was 5.17 ± 3.80 , and the mean postintervention score was 9.85 ± 4.88 , *t*-value = 13.30, P < 0.001.

Table 3 shows the frequencies of correct answers pre-intervention and postintervention for each question assessing general information about COC pills and the relation between using COC pills and cancer as well as their association with other diseases. For example, the frequency of

Table 2 The prescription details of combined oral contraceptive pills (N = 87)

Questions	N (%)
Time of starting COC pills use	
After first delivery	36 (41.4)
After second delivery	10 (11.5)
After third delivery	15 (17.2)
After fourth delivery	4 (4.6)
After fifth delivery or more	12 (13.8)
Missing	10 (11.5)
Duration of use	
1–6 months	36 (41.4)
7–12 months	9 (10.3)
13–18 months	4 (4.6)
19–24 months	10 (11.5)
More than 24 months	15 (17.2)
Missing	13 (14.9)
COC pills were prescribed by	· · · · ·
Physician	31 (35.6)
Pharmacist	6 (6.9)
Relatives	8 (9.2)
Midwives	31 (35.6)
Missing	11 (12.6)
Did you receive any medical advice about COC pills?	` ′
Yes	40 (46.0)
No	37 (42.5)
Missing	10 (11.5)
Did you have any laboratory or physical examination locol pills?	before using
Uterus examination	12 (13.8)
Pelvic examination	0 (0)
Cholesterol and lipids test	4 (4.6)
Breast examination	6 (6.9)
Others	8 (9.2)
Nothing	46 (52.9)
Missing	11 (12.6)
The brand name of the pills you used	
Yasmin	11 (12.6)
Marvelon	15 (17.2)
Diane	2 (2.3)
Microgynon	4 (4.6)
Others	3 (3.5)
Not sure	42 (48.3)
Missing	10 (11.5)

COC, combined oral contraceptive.

correct answers postintervention increased significantly compared to pre-intervention in regards to questions assessing general information about combined oral contraceptive pills and the relation between using COC pills and cancer as well as its association with vascular occlusion, stroke, heart attack and others (P < 0.005).

The questionnaire also assessed women's knowledge about the relationship between COC pills and other symptoms and side effects and the relationship between smoking and breastfeeding and using COC pills. The differences in participants' knowledge regarding the aforementioned issues pre- and postintervention are presented in Table 4.

The current or previous users of combined oral contraceptive pills in the studied sample were also asked about the interaction between COC pills and other drugs. The results showed that 63.2% of the pre-intervention participants stated that there is no interaction between COC pills and other medications. However, this per cent declined postintervention to reach 33.3%. Postintervention data showed an increase in the per cent of participants who stated that COC pills could interact with other medications (35.6%) compared to 11.5% of the women pre-intervention. The frequency of correct answers in regards to COC pills drug interactions postintervention increased significantly compared to pre-intervention (P < 0.001).

The results of an ANOVA and linear regression tests showed a significant relationship between some demographical characteristics and pre-intervention scores. For example, pre-intervention scores were higher in women with diploma and university degrees compared to women who were illiterate, with school degrees and with graduate studies (P < 0.001). Moreover, pre-intervention scores of Jordanian women were higher than non-Jordanian women (P < 0.014). In addition, pre-intervention scores of women who were more than 25 years old were higher than women who were <25 years old (P < 0.019). Whereas, marital status did not show a significant relation with pre-intervention scores (P = 0.2).

Discussion

This study measured the baseline knowledge about COC pills among women in Jordan and investigated the effect of proper education provided by a clinical pharmacist on their knowledge. The educational intervention included a face-to-face educational session, and written material distributed to participants. At baseline, knowledge about COC pills among participants was inadequate; this was improved significantly by education provided by a clinical pharmacist.

The result of this study was in accordance with some aspects of previously published studies. [6,12] One cross-sectional study investigated the knowledge, patterns and attitudes women in Jordan have towards oral contraceptives. The previous study found that only half of the women knew how to use oral contraceptives, and only 15% knew that oral contraceptives can interact with concomitant medications and their efficacy can be compromised. [6] In the current study, at baseline the majority of the women did not have sufficient knowledge about COC pills (96.2%) and 20.7% of the participants stated that COC pills can interact

Table 3 Participants' knowledge of combined oral contraceptive pills related issues pre- and postintervention (N = 177)

Question	Frequency of correct answer pre-intervention $N (\%)$	Frequency of correct answer postintervention <i>N</i> (%)	P value*
Are there any other uses for COC pills?	N = 20565 (31.7)	N = 176122 (69.3)	< 0.001
How do COC pills affect fertility?	N = 20577 (37.5)	N = 177119 (67.2)	< 0.001
Combined oral contraceptive pills effect on	N = 20363 (31.0)	N = 177118 (66.7)	< 0.001
fertility based on administration time concerning number of pregnancies after birth number.			
How do COC pills affect menstrual cycle?	N = 20481 (39.7)	N = 177107 (60.5)	< 0.001
Cervical cancer	N = 20532 (15.6)	N = 17767 (31.9)	< 0.001
Ovarian and uterine cancer	N = 20519 (9.3)	N = 17760 (33.9)	< 0.001
Breast cancer	N = 20628 (13.6)	N = 17776 (42.9)	< 0.001
Infections	N = 20557 (27.8)	N = 17787 (49.2)	< 0.001
Vascular occlusion	N = 20329 (14.3)	N = 17770 (39.5)	< 0.001
Heart attack	N = 20634 (16.5)	N = 17767 (37.9)	< 0.001
Stroke	N = 20528 (13.7)	N = 17760 (33.9)	< 0.001
Hypertension	N = 20643 (20.9)	N = 17775 (42.4)	< 0.001
Anaemia	N = 2068 (3.9)	N = 17742 (23.7)	< 0.001

COC, combined oral contraceptive.

Table 4 Participants' knowledge of combined oral contraceptive pills side effects and other related issues pre- and postintervention (N = 177)

Variable	Frequency of correct answer pre-intervention $N\left(\%\right)$	Frequency of correct answer postintervention $N\left(\%\right)$	P value
Effect on menstrual pain	33 (15.7)	64 (30.5)	<0.001*
Effect on headache	111 (52.9)	130 (61.9)	<0.001*
Effect on mood disturbances	132 (62.9)	132 (62.9)	0.12^{*}
Effect on weight	104 (49.5)	115 (54.8)	0.525^{*}
Relationship with smoking	33 (15.7)	84 (40.0)	<0.001*
Relationship with breastfeeding	64 (30.5)	80 (38.1)	<0.001*

COC, combined oral contraceptive.

with and other medications. In addition, Bardaweel *et al.*^[6] found that 77.9% of the women took oral contraceptives based on a physician's prescription; however, in the current study, only 35.6% of women were prescribed COC pills by physicians. Of note, pharmacists do not have prescribing authorities in Jordan. However, drug regulations are not strictly enforced and the public can buy a wide range of medications without a prescription except for controlled substances. With regards to women's perception of the safety of COC pills, Bardweel *et al.* found that 59.2% of the women perceived oral contraceptives as safe; however, in the current study only 23.8% of the participants perceived COC pills as safe.^[6] This inconsistency in results could be due to the educational background of the participants as well as their beliefs.

As expected women with diploma and university degrees had higher pre-intervention knowledge score compared to women with school degrees. This finding was inconsistent with a study that was conducted in Singapore, in which educational level of participants was not associated with good knowledge of contraception methods including oral contraceptive pills among participants. [17] Unexpectedly, in the current study, women with postgraduate degrees had lower pre-intervention scores compared to women with diploma and university degrees. In addition, Jordanian women had higher pre-intervention scores compared to non-Jordanian. Most of the non-Jordanian participants were Syrian refugees. The inadequate knowledge of COC pills can be one of the many implications of the Syrian crisis.

The current study showed a significant improvement in women's knowledge after participating in the session and receiving the educational material, which is consistent with previous findings.^[13,15] In Germany, a double-blind, parallel-group randomized study was conducted to compare the effect of two types of educational brochures on women's knowledge of COC benefits and risks using a knowledge questionnaire. A significant improvement was seen in number of correct answers after receiving the educational brochures compared to number of correct answers before receiving the brochures.^[16]

^{*}McNemara's test was used to detect P value.

^{*}McNemara's test was used to detect P value.

There are a number of differences between the current study and the Akour *et al.* study. [15] Akour *et al.* conducted their study mainly in Amman, the capital of Jordan located in the centre of the country. However, the current study was conducted in the north of Jordan and covered rural areas in addition to urban. In addition, Akour *et al.* investigated oral contraceptives users; however, the current study studied both users and non-users. In the current study, the intervention involved both a 45-min educational session and distribution of an educational brochure. However, Akour *et al.* studied the impact of a written information booklet only.

This is an interventional observational multicentre study. It was the first study to evaluate the role of a clinical pharmacist in educating women in the north of Jordan about COC pills and enhancing their knowledge using both verbal and written methods. The current study has several imitations. First, although this study was a multicentre study, it focused on one region (north of Jordan); thus, the results might not be generalized to other areas. Other limitations were the environments of some of the centres and the time limitation that restricted the time of interaction between the researcher and participants, thus limiting the information exchange process. In addition, at the follow-up participants were interviewed by phone which might have affected their responses as compared to face-to-face interviews which were not feasible. Additionally, recruitment process took place at family-planning clinics and obstetrics and gynaecology clinics; thus, participants were women engaged in women's health services; accordingly, the results may not be generalized to women who are not engaged in women's health services. A future study investigating women in different settings and various geographical areas in Jordan will provide more generalizable data.

Conclusion

This study showed the importance of the role of a clinical pharmacist in educating women about COC pills and in healthcare settings in Jordan especially in public health centres. At baseline, knowledge about COC pills among participants was inadequate. Counselling and education provided by clinical pharmacists resulted in improved women's knowledge. However, continuous communication and encounters between women and healthcare providers including pharmacists are needed to ensure sufficient knowledge about the risks, benefits and other related issues regarding COC pills.

The present authors recommend implementing clinical pharmacy services in family-planning clinics and obstetrics and gynaecology clinics. Continuous counselling is recommended to ensure adequate knowledge. In addition, it is recommended to have a phone line that provides services and answers women's different inquiries such as the appropriate actions to take in the case of missing pills.

Declarations

Conflict of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

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Authors' contributions

Linda Tahaineh gave the idea, contributed to design of the research, interpreted the data, followed up with the clinical pharmacist and wrote the manuscript. Mayssam M. Alkyam provided clinical pharmacist's services and performed data collection and analysis. Nour A. Al-Sawalha contributed to design of the research and writing the manuscript. Deema Jaber contributed to design of the research and data analysis. Abla M. Albsoul-Younes contributed to design of the research and writing the manuscript..

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