Counselling to include tailored use of combined oral contraception in clinical practice: an evaluation

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► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/jfprhc-2017-101736).

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Received 18 January 2017
Revised 20 June 2017
Accepted 11 July 2017
Published Online First
8 November 2017

To cite: Akintomide H, Rank KM, Brima N, *et al*. *BMJ Sex Reprod Health* 2018;**44**:36–41.

ABSTRACT

Background Combined oral contraception (COC, 'the pill') remains the most prescribed method of contraception in the UK. Although a variety of regimens for taking monophasic COC are held to be clinically safe, women are not routinely counselled about these choices and there is a lack of evidence on how to provide this information to women.

Aim To assess the usefulness and feasibility of including tailored use of monophasic COC within routine COC counselling in a sexual and reproductive health (SRH) service using a structured format.

Method Using a structured format, healthcare professionals (HCPs) counselled new and established COC users attending an SRH service about standard and tailored ways of taking the pill. Questionnaires were used to survey both the HCPs and patients immediately after the initial consultation, and then the patients again 8 weeks later.

Results Nearly all patients (98%, n=95) felt it was helpful to be informed of the different ways of using monophasic COC by the HCP, without giving too much information at one time (96%, n=108). The HCPs were confident of their COC counselling (99%, n=110) and did not think the consultations took significantly longer (88%, n=98).

Conclusion This study demonstrates that information on different pill taking regimens is useful and acceptable to patients, and can improve contraceptive pill user choice. It is also feasible for HCPs to perform COC counselling to include tailored pill use during routine consultations in a clinical setting.

Key message points

- Patients value information on the different ways of taking combined oral contraception (COC).
- COC counselling to include tailored pill use is achievable by health care professionals (HCPs) using a structured format.
- Contraceptive choice for patients can be improved by HCPs routinely counselling to include tailored pill use in clinical practice.

INTRODUCTION

Two million women are estimated to be using combined oral contraception (COC, 'the pill') in Great Britain.[1] England's sexual and reproductive health (SRH) services provided COC to over 400 000 women in the last year, a figure that has remained fairly stable over the last decade.[2 3] When the pill first became available in 1960 it was licensed for standard use which became the norm—taking the pill daily for 21 days, followed by seven pill-free days during which a 'monthly' withdrawal bleed occurs. However, alternative ways of taking the pill have slowly gained ground which have been grouped under tailored use.[4]

Tailored pill use tends to be unlicensed by the pill manufacturer but is safe, and applies only to monophasic combined oral contraceptives.[4 5] It includes:

- extended use with a shortened pill-free interval (PFI), where a woman takes a pill daily until bleeding for at least three consecutive days triggers a PFI of three or four consecutive days;
- tricycling, where one pill is taken every day for nine consecutive weeks followed by a PFI of 7 days.

We did a randomised controlled trial of tailored versus standard use to compare COC continuation rates at 1 year and user experience.[6] In those women familiar with standard use of the COC at trial

recruitment (83%, n=417), switching to tailored COC use or continuing with standard use were both associated with high COC continuation rates and high satisfaction with contraceptive regimen and bleeding pattern. Tailored COC use was associated with significantly less bleeding, suited some women very well, and provided a suitable alternative to standard use.

We also did a literature review on the evolution of extended COC use which concluded that women needed to be better informed about pill-taking regimens in line with scientific evidence.[7]

Despite national guidance, supporting scientific evidence as well as healthcare professionals' awareness, patients do not routinely receive counselling to include tailored pill use even in SRH services.[8 9] There is a lack of evidence about how to provide such counselling effectively.

We therefore wanted, as the next logical step, to assess the feasibility and usefulness of routinely providing information about different ways of taking the pill in a busy SRH service.

METHODS

A structured format and advice sheet for the study were developed and evaluated at the Margaret Pyke Centre, a London SRH service with an average of 18 000 attendances per year, of which about a fifth are for COC. These tools that had been used for the tailored versus standard contraceptive pill use trial[6] were combined, modified and validated to produce a Script for use by healthcare professionals (HCPs) and an Advice Sheet (see online supplementary appendix 1) for patients to provide information on tailored COC use. Questionnaires were also developed to obtain information from both the HCP and the patient immediately after the initial consultation (HCP and patient baseline questionnaires), and again from the patient after 8 weeks—either by telephone, email or in person at their follow-up visit (follow-up questionnaire).

Recruitment to the study took place from 14 May 2015 until 14 March 2016, during which there were 3874 attendances for, or related to, COC. Patients aged 18–45 years wishing to start or currently taking COC, who were able to give written consent to participate, including follow-up by a short telephone interview, email questionnaire or during their next clinic visit 8 weeks later, were invited to participate in the study. These patients needed to be requesting COC as a contraceptive method for at least the next 3 months and should not have any recognised contraindications to COC use.[4] All consultations took place with two experienced HCPs, trained to use the study's Script to counsel patients on the different ways of taking COC as part of a routine COC consultation. The COC counselling was done with the aid of the study's Advice Sheet and the Family Planning Association leaflet 'Your Guide to using the combined pill'[10] as per usual clinic procedure.

The sample size was obtained by estimating that the prevalence of patients agreeing it was helpful to be offered information on the different ways of COC use would be 80%, so that a sample of 100 women would allow an estimate with good precision, with an expected 95% CI of 72% to 88%. Allowing for 10% lost to follow-up at 8 weeks, we aimed to recruit 112 women.

Descriptive statistics are presented in the tables for all patients who were eligible to participate and provided consent, and the HCPs that undertook consultations; and based on all available responses. Formal statistical testing was carried out to compare ways of taking the pill chosen after the initial consultation and that at follow-up, and to compare the ways of taking the pill chosen by patients after their initial consultation based on prior knowledge of more than one way of taking the pill (marginal homogeneity test and X^2 tests, respectively). All analyses were performed using StataSE 14. A 5% significance level was used.

Study procedure using the Script (see online Supplementary appendix 2)

- Discussion of appropriate contraceptive methods after history taking. If patient chooses COC, further information was provided on this method (counselling).
- During the consultation, the HCP discussed the different ways of using COC and provided information on tailored COC use in addition to that on standard COC use with the aid of the Script and Advice Sheet, respectively.
- Thereafter, the HCP informed the patient about the study and provided the Participant Information Sheet. If the patient was willing to participate in the study, the HCP obtained the patient's consent (written, using the Participant's Consent Form). After this, the HCP gave the patient the baseline questionnaire for completion immediately after leaving the consultation room with her supplies of COC. Should the patient require more time to decide on taking part, she could take the consent form and baseline questionnaire away with her and complete and return these to the service within 1 week of the visit (a stamped addressed envelope was provided in such circumstance) if she eventually decided to take part.
- After the consultation, the HCP completed a questionnaire to give their opinion on how the counselling on the different ways of taking the pill went with the patient.
- At 8 weeks, the patient was followed up by their method of choice (phone, email or during their clinic visit) and the follow-up questionnaire was completed.

User involvement in the design and development of this study and study materials, including questionnaires and participant information, was from Involve@MPC—the Margaret Pyke Centre's patients' forum (a public engagement group)—and experienced SRH clinicians.

Ethical approval for this evaluation was granted following review by the Proportionate Review Sub-committee of the NRES Committee Yorkshire & The Humber – Leeds West, UK. Local NHS Research

and Development approval was obtained from the North Central London Research Consortium.

RESULTS

One hundred and twelve patients were recruited to the study. Eighty-seven patients completed the follow-up questionnaire at the end of the study. Nearly all patients recruited (98%, n=110) were current or past pill users and two-thirds (68%, n=76) were already aware that there was more than one way of taking the pill. Nearly all patients also responded that they understood the different ways of taking the COC that had been explained to them, they did not feel it was too much information at the time, and they found it helpful to have received all this information in one consultation (table 1).

Straight after the initial consultation, tailored COC use (48%, n=53) was chosen by more patients than standard COC use (27%, n=30), with the tricycling way of taking the pill chosen by a third of patients (n=37). Also, almost half (44%, n=16) of those patients who had stated that before their initial consultation they were only aware of standard COC use (n=36) chose the tailored way of taking the pill. However, there was no significant difference in the ways of taking the pill chosen by patients after their initial consultation based on prior knowledge of more than one way of taking the pill (p=0.374).

At follow-up 87 responses were received and most respondents (94%, n=82) were still using COC. The majority (97%, n=84) also felt it was helpful to have been informed about the different ways of taking COC (table 2). Twenty-one of the 82 patients still using COC at follow-up were patients who had stated they were 'undecided' after their initial consultation.

There were therefore 61 responses available to compare the way of taking the pill chosen by patients after their initial consultation and then at follow-up. Of these 61 patients, 29% (n=17) had changed the way they took the COC since their initial consultation, a difference which was statistically significant (p=0.046). One patient changed

Table 1 Patient baseline questionnaire responses (post initial consultation), n=112

Question	Answer	%, (n)
1. I am clear about the three different ways the pill can be taken that has just been explained to me	Strongly agree	25.5 (28)
	Agree	74.5 (82)
	Neither agree nor disagree	0
	Disagree	0
	Strongly disagree	0
2. I previously knew there was more than one way to take the pill	No	32.1 (36)
	Yes	67.9 (76)
3. I am already using or have used the pill in the past	No	1.8 (2)
	Yes	98.2 (110)
4. It was helpful to be told the three different ways to take the pill	Strongly agree	71.1 (69)
	Agree	26.8 (26)
	Neither agree or disagree	2.1 (2)
	Disagree	0
	Strongly disagree	0
5. It's better to be told just one way of taking the pill	Strongly agree	1.0 (1)
	Agree	2.1 (2)
	Neither agree or disagree	9.2 (9)
	Disagree	46.9 (46)
	Strongly disagree	40.8 (40)
6. Hearing about more than one way of taking the pill was too much at one consultation	Strongly agree	2.7 (3)
	Agree	0
	Neither agree or disagree	0.9 (1)
	Disagree	52.7 (59)
	Strongly disagree	43.7 (49)
7. After receiving the information, my chosen way of taking the pill is:	Standard	27.1 (30)
	Extended	14.4 (16)
	Tricycling	33.3 (37)
	Still undecided	25.2 (28)

Table 2 Patient follow-up questionnaire responses, n=87

Question	Answer	%, (n)
1. I found it helpful to be given a choice of ways to take the combined pill	Strongly agree	69 (60)
	Agree	27.6 (24)
	Neither agree or disagree	2.3 (2)
	Disagree	1.1 (1)
	Strongly disagree	0
2. Being given the option of three ways of taking the pill has increased my chances of continuing with it	Strongly agree	17.2 (15)
	Agree	26.4 (23)
	Neither agree or disagree	36.8 (32)
	Disagree	14.9 (13)
	Strongly disagree	4.7 (4)
3. I have changed the way I decided to take the combined pill since the first questionnaire	No	56.3 (49)
	Not sure	2.3 (2)
	Yes	41.4 (36)
4. My current way of taking the combined pill is:	Standard	46.0 (40)
	Extended	18.4 (16)
	Tricycling	27.6 (24)
	No longer taken pills	5.7 (5)
	Bicycling*	2.3 (2)

*As reported by patients

from standard to tailored (extended) COC use, six patients (extended n=1, tricycling n=5) changed from tailored to standard COC use, and 10 patients changed their way of tailored use—two changed from extended to tricycling, one patient from extended to bicycling, six patients from tricycling to extended, and one patient from tricycling to bicycling.

The HCPs were confident of their pill taking explanations (99%, n=110) and believed the patient to have understood and retained the information (98%, n=109) for almost every consultation. Nearly half of the patients (48%, n=53) had demonstrated to the HCP some prior knowledge of the different ways of taking the pill. No HCP reported that the consultation had taken significantly longer than it would have done if they had not followed the Script (table 3).

Table 3 Healthcare professional questionnaire responses (post initial consultation), n=111

Question	Answer	%, (n)
1. I was able to clearly describe the three different ways the combined pill can be taken to the patient	Strongly agree	69.4 (77)
	Agree	29.7 (33)
	Neither agree or disagree	0
	Disagree	0
	Strongly disagree	0.9 (1)
2. The patient demonstrated previous knowledge of more than one way to take the combined pill	No	52.3 (58)
	Yes	47.7 (53)
3. Describing more than one way of taking the combined pill took too long for one consultation	Strongly agree	0
	Agree	0
	Neither agree or disagree	11.7 (13)
	Disagree	73.0 (81)
	Strongly disagree	15.3 (17)
4. It was helpful to be able to offer the patient three different ways of taking the combined pill	Strongly agree	18.0 (20)
	Agree	65.8 (73)
	Neither agree or disagree	15.3 (17)
	Disagree	0.9 (1)
	Strongly disagree	0
5. It is better to teach the patient just one way of taking the combined pill	Strongly agree	0.9 (1)
	Agree	0
	Neither agree or disagree	4.5 (5)
	Disagree	83.8 (93)
	Strongly disagree	10.8 (12)
6. The patient understood and retained the counselling information	Strongly agree	32.4 (36)
	Agree	65.8 (73)
	Neither agree or disagree	1.8 (2)
	Disagree	0
	Strongly disagree	0

DISCUSSION

The findings of our study show that counselling information including tailored COC use appeared to have been both conveyed by the HCPs and received by the patients very clearly. This outcome was better than we had expected. Patients welcomed all the information and did not find it confusing, nor did the HCPs think it too time-consuming to discuss in one consultation. COC counselling to include tailored use of the pill was determined feasible for HCPs as well as useful to patients with the aid of a Script and an Advice Sheet.

We have tested a format of consultation that was experienced positively by both patients and HCPs; it gives patients additional useful information about the COC in a way that works within a busy SRH service. As these findings are positive, there should be little difficulty in adopting this aspect of clinical practice within the service in conjunction with other members of the SRH team. With the Script providing guidance to HCPs and the Advice Sheet an additional visual aid for patients during COC counselling, it seems that consultations take no longer than usual, perhaps because a structured format is followed. Patients will also receive improved contraceptive choice and advice and, furthermore, can make their own decision on which way to take their pill.

Only two-thirds (n=53) of those patients who stated in their questionnaire they were previously aware of more than one way of taking the pill (n=76) appeared to have shared this information with their HCP. This finding may not be surprising. For many years, some established COC users have skipped their PFIs to avoid withdrawal bleeds with or without discussion with an HCP. A picture has emerged from research and clinical experience that some patients may feel they are doing something reprehensible by straying from the standard way of taking the pill, even though an alternative regimen may suit them better. Some patients may consider it unwise to skip a PFI since it is unlicensed or they have not been advised by an HCP to do so. Or they may deem it unhealthy not to have a 'period' monthly.[11 12] Such patients may not confess to tailored pill use.

Our study findings may be considered contrary to those of a randomised trial[13] that used a version of a WHO decision-making tool for structured contraceptive counselling as an intervention in comparison to their usual physician individualised counselling on effective contraceptive options. Recipients of structured contraceptive counselling were not more likely to choose a very effective contraceptive method or initiate their method compared with recipients of usual care. However, this study was in a different clinical setting and following termination of pregnancy. Also, their outcomes were choice and initiation of methods of contraception and not the feasibility or usefulness of informing patients of different ways of using their chosen contraceptive method.

A possible limitation of our study is the fact that only two participants were new COC users. It would be useful to gain information from more women starting the COC for the first time. A second limitation could be that we did not ask current COC users which way they were taking the pill at their initial visit. Also, the number of patients who had changed the way they were taking their COC some weeks later at follow-up may be reflective of the HCPs not warning patients they may need more time to adjust to tailored COC use if they chose this way of pill taking.[14] We did not attempt to collect demographic information, such as age, parity or educational attainment. This was in line with recommendations of our public engagement group and the need for the questionnaire to be as short and anonymous as possible.

We used a structured format for COC counselling with specialists in SRH; hence some of our study outcomes—for example, similar duration of consultation—may not be generalisable to other clinical settings like general practice or pharmacy. HCPs in the study had not been asked to time the consultations. So their responses on whether the consultation took too long as a result of discussing different ways of taking the pill was opinion-based. However, both the Script and Advice Sheet were brief, had been developed in conjunction with HCPs, and had been validated for use in patient consultations. There is also evidence that structured contraceptive counselling can be provided effectively by non-SRH specialists in a clinical research setting[15] so it is likely that this intervention can be successfully used by non-SRH specialists and in other clinical settings.

The option of tailored COC use is believed to be one of the most important changes since the pill became available over five decades ago.[16] Tailored pill use does not reduce COC efficacy nor cause significantly more side effects than standard pill use. In fact, studies have reported similar safety, increased efficacy, the alleviation of menstrual symptoms, and acceptable bleeding patterns with tailored COC use.[5 6 17–22] We therefore recommend that HCPs consider routinely including information about tailored COC use for patients in different clinical settings. Further research could explore the benefits and disadvantages with new COC users and explore demographic or contextual factors that might affect information on tailored COC use being given by HCPs or understood or accepted by patients.

COC is a user dependent contraceptive method. Hence correct use and user satisfaction will affect the efficacy and continuation of the method, respectively. There appears to be no evidence that counselling in a clinical setting reduces unintended pregnancy rates.[23] Nevertheless for a contraceptive method that is widely used, the potential to better efficacy, improve choice and COC users finding the information useful, this structured counselling is unlikely to be harmful. Structured counselling is also patient-centred, standardised, and uses visual aids to provide adequate information during the consultation, which is efficient for both HCPs and patients.[24]

CONCLUSION

A structured format by which patients are informed by their HCP about the different ways of COC use during routine consultations has not been previously reported in the literature as far as we are aware. Our study does not provide a quality of evidence comparable to that of a randomised trial, but its findings are interesting and potentially useful for consultations regarding COC. Patients value information on tailored COC use in addition to standard use of COC. This information can be provided in a structured manner using aids—a Script for the HCP and an Advice Sheet for the patient—during routine counselling before prescribing COC.

Acknowledgements We are grateful to all the patients and staff of the Margaret Pyke Centre for their involvement in this study. Sam Khan, Lisa Charles and their great admin team deserve mention as well as Kate O'Donnell for providing data on attendances and study support.

Funding This study was funded by a small grant received from the Margaret Pyke Centre Research Awards Scheme.

Competing interests None declared.

Ethics approval NRES Committee Yorkshire & The Humber - Leeds West.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

1 Office for National Statistics. *Opinions Survey Report No. 41: contraception and sexual health, 2008/09*, 2009.
2 NHS Digital. *Sexual and reproductive health services, England - 2015-16*. Leeds: NHS Digital (formerly The Health and Social Care Information Centre), 19 OCt 2016.
3 NHS Digital. *NHS contraceptive services - England, 2005-2006*. Leeds: NHS Digital (formerly The Health and Social Care Information Centre), 24 OCt 2006.
4 Clinical Effectiveness Unit. *Clinical guidance: combined hormonal contraception*. London: Faculty of Sexual and Reproductive Healthcare, 2011.
5 Edelman A, Micks E, Gallo MF, *et al*. Continuous or extended cycle vs. cyclic use of combined hormonal contraceptives for contraception. *Cochrane Database Syst Rev* 2014;(7):CD004695.
6 Stephenson J, Shawe J, Panicker S, *et al*. Randomized trial of the effect of tailored versus standard use of the combined oral contraceptive pill on continuation rates at 1 year. *Contraception* 2013;88:523–31.
7 Panicker S, Mann S, Shawe J, *et al*. Evolution of extended use of the combined oral contraceptive pill. *J Fam Plann Reprod Health Care* 2014;40:133–41.
8 Sauer U, Mann S, Brima N, *et al*. Offering extended use of the combined contraceptive pill: a survey of specialist family planning services. *Int J Womens Health* 2013;5:613–7.
9 Nappi RE, Kaunitz AM, Bitzer J. Extended regimen combined oral contraception: a review of evolving concepts and

acceptance by women and clinicians. *Eur J Contracept Reprod Health Care* 2016;21:106–15.
10 The Family Planning Association. *Your guide to the combined pill*, 2014.
11 Edelman A, Lew R, Cwiak C, *et al*. Acceptability of contraceptive-induced amenorrhea in a racially diverse group of US women. *Contraception* 2007;75:450–3.
12 Wiegratz I, Hommel HH, Zimmermann T, *et al*. Attitude of German women and gynecologists towards long-cycle treatment with oral contraceptives. *Contraception* 2004;69:37–42.
13 Langston AM, Rosario L, Westhoff CL. Structured contraceptive counseling--a randomized controlled trial. *Patient Educ Couns* 2010;81:362–7.
14 Graham CA, Panicker S, Shawe J, *et al*. Women's experiences with tailored use of a combined oral contraceptive: a qualitative study. *Hum Reprod* 2013;28:1620–5.
15 Madden T, Mullersman JL, Omvig KJ, *et al*. Structured contraceptive counseling provided by the Contraceptive CHOICE Project. *Contraception* 2013;88:243–9.
16 Szarewski A, Mansour D, Shulman LP. 50 years of "The Pill": celebrating a golden anniversary. *J Fam Plann Reprod Health Care* 2010;36:231–8.
17 Howard B, Trussell J, Grubb E, *et al*. Comparison of pregnancy rates in users of extended and cyclic combined oral contraceptive (COC) regimens in the United States: a brief report. *Contraception* 2014;89:25–7.
18 Anttila L, Bachmann G, Hernádi L, *et al*. Contraceptive efficacy of a combined oral contraceptive containing ethinyloestradiol 20 μg/drospirenone 3 mg administered in a 24/4 regimen: a pooled analysis of four open-label studies. *Eur J Obstet Gynecol Reprod Biol* 2011;155:180–2.
19 Anderson FD, Gibbons W, Portman D. Long-term safety of an extended-cycle oral contraceptive (Seasonale): a 2-year multicenter open-label extension trial. *Am J Obstet Gynecol* 2006;195:92–6.
20 Nakajima ST, Archer DF, Ellman H. Efficacy and safety of a new 24-day oral contraceptive regimen of norethindrone acetate 1 mg/ethinyl estradiol 20 micro g (Loestrin 24 Fe). *Contraception* 2007;75:16–22.
21 Jacobson JC, Likis FE, Murphy PA. Extended and continuous combined contraceptive regimens for menstrual suppression. *J Midwifery Womens Health* 2012;57:585–92.
22 Jensen JT, Garie SG, Trummer D, *et al*. Bleeding profile of a flexible extended regimen of ethinylestradiol/drospirenone in US women: an open-label, three-arm, active-controlled, multicenter study. *Contraception* 2012;86:110–8.
23 Moos MK, Bartholomew NE, Lohr KN. Counseling in the clinical setting to prevent unintended pregnancy: an evidence-based research agenda. *Contraception* 2003;67:115–32.
24 Rodriguez J, Abutouk M, Roque K, *et al*. Personalized contraceptive counseling: helping women make the right choice. *Open Access J Contraception* 2016;7:89–96.

Anne Szarewski Journal Memorial Award

The *Journal of Family Planning and Reproductive Health Care* established an award to commemorate the life of Anne Szarewski, our Editor-in-Chief until 2013. Anne was an inspiring editor, a great sexual and reproductive healthcare doctor and a pioneering researcher in the prevention of cervical cancer.

The award will be made annually for a period of 5 years from June 2015. In addition to publication of the winning article in the journal (subject to satisfactory peer review), the winner will be offered the opportunity to present their work at one of the FSRH conferences during the year following the award, and will receive a complimentary registration for that conference.

Entries for the award should take the form of a single-author article, suitable for publication in the journal, on new initiatives or improvements in clinical practice. In response to previous submissions, the eligibility criteria were extended and made more inclusive. The author must be a healthcare practitioner working in the area of sexual and reproductive healthcare or genitourinary medicine. Priority in judging will be given to excellent work by junior or recently qualified practitioners, or those for whom sexual health is not their main specialty.

Full details of the award can be found on the FSRH (https://www.fsrh.org/about-us/fsrh-scholarships-and-awards) website.