

Women's experiences with tailored use of a combined oral contraceptive: a qualitative study

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STUDY QUESTION: What are women's experiences with tailored use of combined oral contraceptive pills (COCPs)?

SUMMARY ANSWER: Some women reported very positive experiences with tailored use of COCPs, others did not like the unpredictability about when they would bleed and some women reported increased anxiety about possible pregnancy.

WHAT IS KNOWN ALREADY: While many studies have investigated views toward extended use of COCPs, little research has examined women's actual experiences with these regimens.

STUDY DESIGN, SIZE, DURATION: This was a semi-structured qualitative interview study that was part of a larger randomized trial of a standard (21 daily pills followed by a 7-day pill-free interval) versus a tailored regimen (daily pills until 3-consecutive-day bleeding triggers a 3-day pill-free interval) of Microgynon 30® mcg (Ethinyl estradiol 30 mcg, Levonorgestrel 150 mcg).

PARTICIPANTS/MATERIALS, SETTINGS, METHODS: Interviews were conducted with 26 women (17 in the tailored group and 9 who switched their assigned treatment group). Data were analyzed using thematic analysis.

MAIN RESULTS AND THE ROLE OF CHANCE: Women discussed positive changes associated with tailored use of COCPs, as well as some negative consequences. The major themes identified in the interview data were: ease of tailored regimen; changes in cycle-related symptoms; adjustment to reduced/absent bleeding and unpredictability about bleeding.

LIMITATIONS, REASONS FOR CAUTION: The sample comprised mainly young, nulliparous women. The majority of women were using COCPs at the start of the study.

WIDER IMPLICATIONS OF THE FINDINGS: Clinicians discussing extended-use regimes with patients should mention that women may need time to adjust to an extended-use regime. Future research should attempt to identify predictors of response to extended use of COCPs.

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Key words: combined oral contraceptives / contraception / qualitative study / experience

Introduction

Combined oral contraceptive pills (COCPs) remain the most popular method of reversible birth control, both in the UK (Health and Social Care Information Centre, 2011) and in the USA (Mosher and Jones, 2010). Discontinuation rates, however, remain high, with up to 29% of women discontinuing COCPs in the first 6 months of use (Piepert et al., 2011). Dissatisfaction with the method, often related

to bleeding issues and side effects, is recognized as a primary reason for discontinuation (Sanders et al., 2001; Moreau et al., 2007).

Although the acceptability of continuous pill use was first studied over 30 years ago (Loudon et al., 1977), there has been renewed interest in extended-use regimes in recent years. Eliminating the pill-free interval may reduce the incidence of physical side effects (Sulak et al., 2000), but breakthrough bleeding (BTB) may be a problem for some women on extended-use regimens (Kwiecien et al., 2003).

In an attempt to reduce the frequency of BTB, a modified extended-use regime ('tailored use') was introduced (Sulak *et al.*, 2004). In this regime, women take COCPs daily until 'bothersome' BTB occurs, after which they stop taking the pill for 3–4 days and then resume taking the pill again for a minimum of 21 days. In one study, women reported less BTB with this tailored regimen compared with standard use (i.e. 21/7 regimen) (Sulak *et al.*, 2006). While the acceptability of initiating, and continuing on, extended-use regimens has been reported as high, acceptability in these studies has been narrowly defined (usually as continuation), often established from retrospective reviews of medical records of women using extended COCP regimens (Sulak *et al.*, 2002, 2004). There have also been many more studies of women's attitudes toward hypothetical use of extended-use pill regimens (Den Tonkelaar and Oddens, 1999; Glasier *et al.*, 2003, 2008; Andrist *et al.*, 2004) than of their actual use of continuous COCPs. In a Cochrane review of use of extended-cycle versus standard use of COCPs, the authors concluded that further research on women's satisfaction and menstrual-associated symptoms was needed (Edelman *et al.*, 2010). Qualitative research is important to better understand contraceptive use behaviors and the barriers or problems related to extended-use contraceptive methods (Sundstrom, 2012). Accordingly, the aim of this exploratory study was to obtain detailed, in-depth information about women's experiences of tailored use of a COCP.

Materials and Methods

This qualitative study was part of a larger randomized trial comparing continuation and satisfaction rates of standard use and tailored use of a COCP (Microgynon 30® mcg; Ethinyl estradiol 30 mcg, Levonorgestrel 150 mcg) (Stephenson *et al.*, submitted for publication). In the larger study, 500 women were randomized either to a standard (21 daily pills followed by a 7-day pill-free interval) or to a tailored (daily pills until 3-consecutive-day bleeding triggers a 3-day pill-free interval) regimen (see Fig. 1). The inclusion criteria were 18–45 years of age and requesting COCPs as an ongoing or future contraceptive method. In the tailored group, the

majority of women ($n = 208$ of 250; 83%) had been taking a COCP at the time of recruitment. In the larger study, women kept electronic diaries of pill use, menstrual bleeding and side effects, and were seen for study visits at 3, 9 and 12 months after starting the COCP.

The strategy used to recruit the study participants was purposeful sampling (stratified). We selected women who agreed to be interviewed from the standard and tailored groups, as well as women who had switched (either from tailored or from standard to the other group). The purpose of the study was described as 'to find out more about your experiences taking part in this study and your experiences taking the pill, including any concerns or problems that you have had.'

Semi-structured interviews lasting between 20 and 40 min were carried out by the first author. Written informed consent was obtained from all the women prior to interview. The interviews were held in a private room at the Margaret Pyke Centre (Central North West London NHS Trust) and were audio-taped (with permission) and transcribed. The participants were first asked open-ended questions ('Can you tell me about your experience taking the pill during the past [X] months?'; 'Have you noticed any changes, good or bad, in the past three months that you think may be due to the birth control pills you are taking?'). This was followed by a series of more specific questions about changes related to pain, bleeding, physical or mood-related symptoms and sexual interest. The participants were also asked about any concerns or worries about pill use they had experienced since the start of the study.

A total of 60 women were invited to participate and 40 women agreed and completed interviews; of these, 17 women were in the tailored group, 14 in the standard group and 9 women switched from their assigned group (7 from the tailored to standard group and 2 from the standard to tailored use). In this article, we focus on the data obtained from the 17 women in the tailored group and the 9 women who switched groups. Of these 26 interviews, 11 were conducted at the 3-month study visit, 10 at the 9-month visit and 5 at the 12-month visit.

Data were analyzed by the first author using thematic analysis (Braun and Clarke, 2006). Another author (J.S.) read through the transcripts and agreed on the themes identified. After reading and re-reading the transcripts, an initial set of codes were generated and noted. Following this, the codes were collated into broader possible themes, thus collecting all the data relevant to each potential theme. In the next stage, the themes were refined and the transcripts were reviewed again, to consider

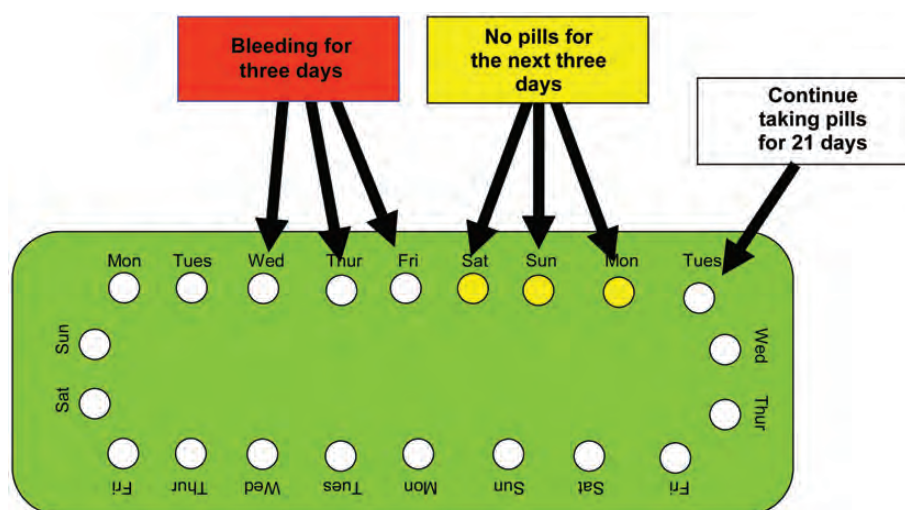


Figure 1 The tailored regimen for the use of COCPs consists of daily pills until 3-consecutive-day bleeding triggers a 3-day pill-free interval.

whether the selected themes reflected the meanings in the dataset. Finally, the themes were labeled and illustrative quotes were chosen for each. Data saturation was reached, as no new meaningful themes were identified after analysis of the first 20 transcripts.

Results

Table 1 contains the demographic characteristics for the sample.

Women discussed positive changes associated with tailored use of the pill, as well as some negative consequences. Four major themes were identified in the analysis: ease of the tailored regimen; changes in cycle-related symptoms; adjustment to reduced/absent bleeding and unpredictability about occurrence of bleeding.

Ease of the tailored regimen and associated benefits

Most of the 26 women interviewed ($n = 19$, including 3 in the 'switched' group) commented on the ease of the tailored regimen:

I always found it difficult when I had a break... just to keep off when I had the seven days and then when to take the next packet. And now the longest break you had to do is three days, it's easier to follow. [Tailored]

Yes, it's like I don't need to start counting the days again and write it out in my diary; it's a lot easier. [Tailored]

For four women, the lack of a break in pill taking meant that they were forgetting fewer pills:

Because this is consistent and day after day after day, I've found it easier. I've forgotten less. [Tailored]

Most of the women ($n = 15$) experienced less or no bleeding on the tailored regimen and reported associated benefits of this:

I've noticed taking this, there are fewer periods. I think on average once every three months or so and a lot lighter and a lot more convenient. Like even going on holiday, I used to worry and be paranoid about 'I really hope I don't have a period' so that's a lot easier. [Tailored]

Four participants mentioned not having the expense of buying sanitary products as an advantage of having fewer periods and another commented:

If I don't bleed, I feel like the daily challenge of coping with checking your trousers for any marks disappears. [Tailored]

Changes in cycle-related symptoms

Eighteen women reported changes in menstrual cycle-related symptoms after starting on the tailored regimen. For seven participants, the reduced number of withdrawal bleeds resulted in less severe physical symptoms, such as pain:

The pain has minimized as well. I used to get really bad cramps and build-up... and quite bad headaches as well. Now just a little bit of a cramp and that will be an indicator, but nothing like as severe as it was. [Tailored]

Two women noticed less mood fluctuation after starting on the tailored regimen:

Not bleeding every month... I found that to be an enormous improvement to just general quality of life. Because I used to get – even on the pill – quite dramatic shifts in mood and appetite. [Tailored]

Eight women (five in the switched group and three in the tailored group) reported positive changes in physical or mood-related symptoms, and eight women reported increased physical changes, such as bloating and breast tenderness. In most cases, these were symptoms that they had previously experienced during the pill-free week of COCP use, i.e. just prior to bleeding. However, during tailored

Table 1 Baseline characteristics of participants.

Groups variable		Switchers ($n = 9$)	Tailored Ps ($n = 17$)
Socio-demographic factors			
Age	Median (IQR), years	29.7 (27.8, 29.3)	29.5 (25.8, 32.6)
Marital status	Single	4	6
	Married/cohabiting	5	11
Ethnic origin	White	6	11
	Mixed	1	4
	South Asian	1	1
	Black	0	1
	Other	1	0
Occupation	Professional/managerial/tech.	6	13
	Student	3	3
	Other	0	1
Reproductive health factors			
Parity (all live birth)	No children	9	16
	Yes children	0	1
Abortion in past year	No	8	13
	Yes	1	4
Oral contraceptive	Previous COCP use	9	17

use for three women, these symptoms occurred without any associated bleed. All of these women eventually switched from the tailored to the standard group.

So I get a few twinges and breast tenderness and sometimes some bloating and it goes up and down a little bit... And then 'cos I ran the two packs together, I just felt like that for the whole of the next pack. [Switched]

I basically felt like just before I feel when I have a period normally – those first few days I feel a bit 'off' – I was feeling like that constantly for a couple of weeks before I decided to switch back. So, yes a bit bloated, tired, a few headaches. [Switched]

One woman reported no physical symptoms in the first 2 months of use, but abdominal cramps in the third month that lasted a week, with no accompanying bleed; she explained that she had decided to switch back to standard use because she did not know how long the cramps would last.

I just thought 'Is this going to continue until I have a bleed and I don't know when I'm going to have a bleed'. [Switched]

Seven women reported changes in sexual interest over the course of the study and these were as likely to be positive changes as negative ones. One woman who had switched from the tailored to the standard group linked a noticeable reduction in thoughts about sex with tailored use, which she attributed to being unsure about whether and when she would have a bleed:

Because I was worried about when I was going to have a bleed and how long that would last, it meant that I was probably a lot less inclined to think about sex and also to want it because... I don't normally have sex when I'm bleeding so I was just unsure and worried and definitely more on edge. That definitely had a negative effect on positive sexual feelings I would have had.

Adjustment to reduced/absent bleeding

Five participants described the first few months of tailored use as a process of adjustment to having reduced or no bleeding, as this woman described:

For the first sort of three months, the thing I found most noticeable and interesting was the adjustment to not bleeding monthly which initially I found – not unpleasant, but something to get used to – and I felt like I'd lost a bit of a routine, like there was something missing, just like a kind of consistency that has gone and it felt a bit strange to be out of that routine. [Tailored]

The above participant went on to say that these feelings were 'outdone' by the benefits of not bleeding every month. Another woman described feeling initially 'unsettled' by the lack of a monthly bleed, but again noted the advantages of not having a regular bleed:

Because initially I thought would I feel less of a woman for not bleeding every month and I found that a little bit unsettling but I have to say that the reduction of inconvenience of not having a monthly bleed is a real benefit. [Tailored]

Seven participants related that when they first started with the tailored regimen, they were uncertain what to expect in terms of bleeding:

So to begin with I was slightly anxious about whether I would end up having sort of a big... like whether would just build up... like whether

I'd have just a terrible period but then when I spoke to the doctor... she explained to me that it doesn't really work that way so I felt ok.

One participant described the initiation of tailored use as a 'challenge' and one that had provoked consideration of her feelings about menstruation:

It gives me the control of deciding whether, as a woman, I would like to have bleeding. At the same time, it made me question whether I want to actually stop it [bleeding]. [Tailored]

Three women described how not having a monthly period had led to worry that they might be pregnant.

The only worry I have is at least before when I was having a period, I knew I wasn't pregnant, whereas now I keep thinking... I don't know, you keep hearing all these horror stories about girls who were pregnant for three months and didn't know... So I think, 'God, I could be pregnant and I wouldn't know until it's too late.' [Tailored]

Yes, I think that psychologically... it's not so reassuring to kind of have this happen and think 'I'm not pregnant'... it's just that you don't have this monthly tick [Tailored]

Consistent with the idea that changing from a standard to a tailored regimen entailed a period of 'adjustment,' five women indicated that they thought that worry about the possibility of pregnancy might dissipate with greater experience of tailored use.

And I would love to have less periods in a year. I think the longer I did it for, with the pregnancy worry, would probably put my mind at ease. I think I'd get used to it.

Only two women discussed the standard pill regimen as being more 'natural' and 'normal' than the tailored regimen, even while recognizing that the withdrawal bleed that occurred with pill use was not a 'normal' period.

And also that psychological feeling of although it's not a period in the traditional way, it just makes you feel like 'I've cleansed myself,' it's that psychological thing of I'm not poisoning my body, I'm getting rid of nature's tension.' [Tailored]

I don't really know what it is. It's sort of that's being released and with this pill, you get the sensation that it's building up, which I know it's not, but in the back of your head you feel like that. And I think that's because I was on the pill for so long before and I got used to that habitual, every month. You would know when it was coming, you would usually know how long it would last for. [Tailored]

Unpredictability about bleeding

Seven participants (all but one in the group that switched from the tailored to the standard regimen) disliked the fact that they did not know when or whether they would have a bleeding episode during tailored use:

I really didn't like the fact that I didn't really know when my period was going to come. [Switched]

The unpredictability of it is the biggest difference, I think. And that isn't that much fun when you're trying to plan a lot of things. [Tailored]

For five of the women who switched from the tailored to the standard group, this unpredictability about bleeding was cited as their reason for

switching, even when they experienced benefits from tailored use. One woman stated that while not having a period had been 'absolutely amazing,' she had found the uncertainty about whether she would have a bleed difficult:

I think from a psychological point of view like I always used to like know exactly where I was at... so I knew when I stopped taking it within a matter of days I'd start to get moody and then I'd start bleeding and then I knew when it had finished and that was fine. [Switched] b

Another woman found that the uncertainty made her feel stressed:

I was really worried about the uncertainty of when I would have a bleed, and it started to stress me out a bit, and so I just really got to the stage where I thought I would be much more comfortable on the standard week. [Switched]

Other findings: concerns about extended pill use

When asked about whether they had any concerns or worries about pill use since the start of the study, only one woman (who had switched from tailored to standard use) expressed concerns.

I suppose – not based on any reason – I was worried about a sense of overdosing or having a build-up of hormones with no break [Switched]

Interestingly, however, three women said that their partners or families (but not themselves) had concerns about their taking the pill on an extended-use basis. One of these women, who switched from the tailored group to the standard regimen, cited her mother and boyfriend's negative reactions to her extended use of the pill as the sole reason for her switching back to standard use.

Discussion

While the majority of women in the tailored group reported very positive experiences with the regimen, others did not like the unpredictability about when they would bleed and some women reported increased anxiety about possible pregnancy. These women were more likely to have switched from the tailored regimen back to standard use of COCPs. This is consistent with previous studies that have identified fear of pregnancy (Viegratz et al., 2004; Sundstrom, 2012) as the main reason why some women prefer having a withdrawal bleed. In a study of women who had hormone withdrawal symptoms during the pill-free week, 9% of the sample did not take up the option of continuous use; the most common reasons for declining extended use was a preference for monthly menses or fears or concerns about taking the pill on a continuous basis (Sulak et al., 2002). In the current study, some of the women who had concerns about pregnancy continued with tailored use, but others switched to the standard regimen. Future research should try to identify the predictors of these two groups.

One of the themes identified from the interviews was that starting on a tailored COCP regimen involved a period of adjustment. Some of the participants interviewed seemed surprised that they found the lack of withdrawal bleed something that they had to become accustomed to, and as a 'routine' that had been lost (even when they appreciated the advantages of a reduced bleeding pattern). When discussing

extended-use regimes with patients, clinicians should mention that women may need time to adjust to an extended-use regime.

Another theme evident in the data was unpredictability about the occurrence of bleeding, which evoked a negative response in some women, but not in others. In an early study of women's attitudes towards changes in bleeding patterns caused by COCPs or hormone replacement therapy (Den Tonkelaar and Oddens, 1999), unexpected bleeding was disliked by over 90% of women (and regarded as more negative than changes in flow or amenorrhea). There may, however, be individual personality differences in how women respond to such unpredictability. One such trait is the intolerance of uncertainty (IU), defined as 'a predisposition to react negatively to uncertain event or situation, independent of its probability of occurrence and its associated consequences.' (Ladouceur et al., 2000). Recent studies have suggested that differences in the intolerance of uncertainty predict negative mood states such as anxiety and worry, but also that a supportive interaction with a health provider can lower anxiety, even in individuals high in IU (Rosen et al., 2010). As brief screening tools to identify individuals high in IU have been developed (Carleton et al., 2007), it might be possible to identify women who are likely to react negatively to the unpredictability of bleeding that can occur with extended COCP use.

This study had several limitations. First, the sample comprised mainly nulliparous women with a median age of 29.7 years who were using COCPs as a method of contraception; adolescent women may have different experiences of tailored use of COCPs. Women are also prescribed extended use of COCPs for gynecological conditions such as endometriosis, dysmenorrhea and menorrhagia (Archer, 2006); the use of a tailored regimen for these reasons will likely influence women's experiences. Second, more than four out of five participants were using COCPs at the start of the study; because of this, women were likely comparing their experience with tailored use with their previous experiences of standard use of COCPs. Moreover, women may previously have been using a COCP containing a type or dose of progestin different from Microgynon and this may have impacted on their perception of the tailored regimen. Future studies should be done with women who are starting on a tailored regimen of COCPs for the first time. Negative attitudes and concerns among clinicians of extended-use regimens have been evident (Hitchcock and Prior, 2004) and these may also affect women's perceptions and experiences of extended-use regimens. Notwithstanding these limitations, the findings suggest that while many women following a tailored regimen of COCP use experience benefits from the reduced bleeding and find the regime easy to follow, some women find the unpredictability of bleeding difficult. Clinicians might suggest that women who are considering extended COCPs use should try the method for a few months and switch back to a standard regimen if they find the unpredictability of bleeding difficult or if they have physical symptoms. Future research is needed to explore better methods of counseling women who are considering extended use of COCPs.

Previous studies have assessed women's attitudes toward, and knowledge about, extended use of COCPs (Den Tonkelaar and Oddens, 1999; Glasier et al., 2003, 2008; Andrist et al., 2004), but little research has examined their actual experiences of continuous use. Moreover, the few studies that have assessed women's experiences have been limited in scope and have most often used adherence

to COCPs as a 'proxy' measure of satisfaction (Edelman *et al.*, 2010). The findings of this exploratory study provide more detailed information about women's actual experiences of tailored COCP use.

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Authors' roles

C.A.G. conceived and designed the study, acquired and analyzed the data and drafted and revised the article; S.P. participated in conceiving the study, acquiring the data and revising the article; J.S. participated in conceiving the study and revising the article; J.S. participated in conceiving the study and revising the article; all the authors approved the final version of the article.

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Conflict of interest

None declared.

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