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Influence of depressed mood and psychological stress symptoms on perceived oral contraceptive side effects and discontinuation in young minority women

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Abstract

Background—We examined the influence of depressed mood and psychological stress on oral contraceptive (OC) side effects and discontinuation.

Study Design—We administered standard psychological instruments to 354 young women (13–24 years) beginning a six-month OC continuation intervention trial and questions on OC side effects and use at six months. Logisitic regression determined the relationships between psychological conditions, perceived OC side effects and continuation rates.

Results—Baseline depressed mood (21%) and stress (19%) and six-month mood (25%) and weight changes (57%) were relatively common. Only 38% continued OCs at six months. Depressed mood (OR 2.27, CI 1.25–4.15, p=0.007) and stress (OR 2.07, CI 1.12–3.82, p=0.02) were associated with perceived OC-related moodiness; depressed mood was associated with perceived weight loss (OR 1.89, CI 1.01–3.55, p=0.05). Depressed mood (OR 0.54, CI 0.29–0.99, p=0.04), stress (OR 0.48, CI 0.25–0.91, p=0.03) and perceived weight change (OR 0.60, CI 0.38–0.94, p=0.03) all reduced the likelihood of OC continuation.

Conclusion—Young women with adverse psychological symptoms are at risk for perceived OC side effects and discontinuation.

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Keywords

depression; stress; oral contraception; side effects; discontinuation

1. Introduction

Oral contraceptives (OC) are the most commonly used hormonal birth control by sexually active young women in the United States [1–6], yet up to 60% of adolescents will discontinue their use by 12 months [7–12]. Half of the nearly one million annual U.S. unintended teen pregnancies in the United States are attributed to OC discontinuation [1–6,13].

Despite a substantial body of research refuting side effects of OCs [8,14–30], perceived side effects are the most frequently reported reason for discontinuation [8,14–21,31–36]. Rates of perceived mood and body weight changes among OC users range from 15 to 40% [16–18] and over 50%, respectively [14]. Among 1716 women ages 13 to 25 years enrolled in a prospective OC continuation intervention trial, those reporting mood and weight changes at three months were less likely to continue than those not reporting these side effects [18].

OC users with psychological conditions may have an even greater risk for perceived side effects and subsequent discontinuation. Adverse physical symptoms are common among women with clinical and subclinical mood disorders including depression, anxiety and stress [37]. Several studies have found a higher prevalence of negative mood among OC users with underlying depression [38–40]. Among 118 European current and past OC users, Segebladh et al. [39] found that 30% of women reporting adverse mood symptoms (versus 10% without mood symptoms) met criteria for anxiety and depression.

The few existing studies on psychological conditions and OC use have had conflicting results [34,35,39,40]. In the Segebladh study [39], the proportions of women meeting anxiety and depression criteria were similar among OC discontinuers and current users. Another recent study by Zink et al. [40] used Medicaid claims data to retrospectively examine OC prescription refills among 2418 mostly Caucasian teens in Ohio. The investigators found rates of unfilled OC prescriptions were higher among girls with a psychiatric diagnosis compared to those without a psychiatric diagnosis.

In addition to inconsistent findings, existing studies have also been limited by cross-sectional designs which prevent assessment of temporal associations between psychological symptoms and OC use.

We prospectively evaluated depressed mood and perceived psychological stress as risk factors for OC-related mood or weight changes and OC discontinuation among a cohort of young, minority women.

2. Materials and methods

2.1. Participants

This analysis was part of a larger randomized trial conducted between December 2006 and September 2009 which evaluated the impact of OC pill pack supply (seven-month or three-month supply) on six-month OC continuation rates among young women attending a university-affiliated community-based clinic in New York City. The methods and results of the larger study are reported elsewhere [41]. Columbia University Institutional Review Board approved this research. All participants gave informed consent.

Women ages 13 to 35 years presenting to the clinic requesting OCs were eligible. Exclusion criteria included having 1) contraindications to OC; 2) a desired pregnancy within six months; or 3) intentions to leave the area within six months. This analysis was limited to adolescent (ages 13 to 19 years) and young adult (ages 20 to 24 years) participants.

2.2. Procedures

Each eligible, consented participant completed a structured interview. We obtained data on demographic and social characteristics, self-reported height and weight, and reproductive and contraceptive histories. The baseline interview also included the following standardized psychological instruments.

The Center for Epidemiologic Studies – Depression Scale (CES-D), a standardized 20-item screening tool, assessed depressive symptoms over the previous week [42,43]. Responses are on a Likert scale from zero (rarely) to three (most of the time). Scores range from zero to 60 with higher score indicating a higher degree of symptoms. We used the standardized cut-off of 16 points to denote elevated scores indicative of moderate depressed mood [17].

The Perceived Stress Scale (PSS-10) screened for symptoms of global psychological stress and the degree to which life situations are appraised as stressful, unpredictable, uncontrollable, and overloading over the previous week [44–46]. Responses to the 10 questions are in 5-point Likert format from zero (never) to four (very often). Scores range from zero to 40 with higher scores indicating greater perceived stress. The standardized cut-off of 21 points was used to determine elevated scores indicative of moderate stress.

Participants were randomized to the three- or seven-month pill pack supply group. Per clinic protocols, health providers gave routine clinical care including relevant history, targeted physical examination, pregnancy and other lab testing as indicated, instructions for revisits and standardized pill-taking instructions. All study staff were bilingual; materials were available in English and Spanish.

At six months, we interviewed participants by telephone to determine OC use over the study period, pregnancy since last interview, sexual activity, adverse events and perceived OC side effects.

We assessed dimensions of perceived mood and weight changes occurring with OC use with a series of questions used in our previous contraceptive studies [21]. Items included: whether participants had experienced any mood or weight changes overall during the study (occurrence); whether the change was an increase or decrease in weight, or more or less moody (type); whether it was a little, some, or a lot of change (severity); whether it was a good, bad, or neither change (quality); whether changes were attributed directly to OC use (OC-attributed). Responses to occurrence, type, and OC-attributed dimensions were on a 2-point scale; responses to severity and quality were on a 3-point Likert scale.

At the six-month interview, we defined OC continuation as having taken a pill the past seven days. The seven-day threshold was based upon sensitivity analyses from a previous trial and pilot studies [21].

2.3. Data analysis

We first used univariate statistics to describe psychological conditions, perceived mood and weight changes and OC continuation. We conducted bivariate chi-square tests, followed by multivariate logistic regression analyses to examine the following relationships: 1) baseline depressed mood and psychological stress and six-month OC continuation; 2) baseline depressed mood and stress and six-month perceived mood and weight changes; and 3) six-month perceived mood and weight changes and OC continuation. Baron and Kenny's [22] technique was used to explore any mediation effect of perceived mood and weight changes on relationships between depressed mood and stress and OC continuation. Results are presented as adjusted odds ratios with 95% confidence intervals and p-values. A two-tailed alpha of 0.05 was considered significant. All data were analyzed using SPSS 18.0 software (Chicago, IL).

3. Results

Seven hundred women enrolled in the larger trial, including 474 adolescents and young adults. With a 25% attrition rate at 6 months, this final sample comprised 354 adolescents (n=173) and young adults (n=181) (Figure 1).

Key demographic, social and reproductive history characteristics of the sample are presented in Table 1. The sample was largely Hispanic (92%), uninsured or on Medicaid, and approaching overweight (average BMI 24.50±5.00). Of the nearly half (46%) reporting prior OC use, 25% had stopped due to side effects.

3.1. Baseline psychological conditions

The mean score on the CES-D depression scale was 10.12±8.3 (standard deviation) out of 60 possible points (range 0–45). The PSS-10 stress score mean and standard deviation was 15.01±6.8 of 40 points (range 0–39). Adolescents scored similarly to young adults on the CES-D but 2.06 points lower on the PSS-10 (p=0.003).

Using standard instrument score cut-offs, 21% (n=73) and 19% (n=67) of the sample met criteria for elevated depressed mood and stress, respectively. Proportions with elevated depressed mood (p=0.39) and stress (p=0.09) were similar between adolescents and young adults.

3.2. Reported mood changes

Rates of reported side effects are presented in Tables 2. Twenty-five percent of the sample reported mood changes overall (yes/no) at six months, with adolescents and young adults reporting similar rates (p=0.90). The rates of mood changes among subjects with high depressed mood and perceived stress were 37% (n=27/73) and 31% (n=21/67) versus 21% (n=60/281) and 23% (n=66/287) among those without depressed mood and perceived stress, respectively.

Of those reporting mood changes (n=87), the majority reported more moodiness (84%, n=73), a "little" mood change (49%, n=43) and considered it a "bad" (47%, n=41) change (Table 2). Nearly half of those reporting mood changes attributed the change to OC (46%, n=40). Type of change (both more and less moody) was correlated with severity ("a little" change) [Pearson's correlation (r) = −0.86)]. Participants with more moodiness (64%) and "a lot" of change (62%) considered it a "bad" change, whereas those with less moodiness considered it "good" (55%, r = −0.93).

3.3. Reported weight changes

Over half of the sample (57%, n=200) reported weight changes (yes/no) at six months (Table 2). Adolescents and young adults had similar weight change rates (p=0.42). The rates of weight change among subjects with high depressed mood and perceived stress scores were 70% (n=51/73) and 63% (n=42/67) versus 52% (n=149/281) and 54% (n=158/287) among those without depressed mood and perceived stress, respectively.

The majority reported weight gain (87%, n=135), "a little" weight change (68%, n=104), considered the change "bad" (51%, n=79) and attributed the weight change to the pill (66%, n=102) (Table 2). Similar numbers of those who both gained (50%) and lost (54%) weight experienced only "a little" change ($r = -0.74$). Those who lost weight considered it a "good" change (52%); those who gained (48%, $r = -0.80$) and those reporting "a lot" of change considered it "bad" (62%, $r=0.68$).

3.4. Associations between psychological conditions and perceived side effects

Unadjusted associations among psychological conditions and perceived OC side effects are also presented in Table 2. Participants with baseline depressed mood symptoms had higher rates of perceived mood ($p=0.01$) and weight changes ($p=0.02$) (rates presented above) at six months than those without depressed mood. Depressed mood was associated with specific dimensions of both mood and weight changes: "a lot" of mood change ($p<0.001$), "more" moodiness ($p=0.02$), weight loss ($p=0.05$) and "a little" weight change ($p=0.04$). Mood and weight changes (overall or by dimension) did not vary by baseline stress.

In the final logistic regression models adjusting for significant covariates including education, randomization group, and BMI, all associations between depressed mood and perceived side effects remained significant; participants with depressed mood were over twice as likely to report perceived mood and weight changes at six months compared to those without depressed mood (OR 2.30, CI 1.30–4.07, $p=0.004$ and OR 2.14, CI 1.20–3.80, $p=0.01$, respectively) (Table 3). Additionally, participants with stress were also over twice as likely to report "a lot" of mood change compared to those without stress (OR 2.07, CI 1.12–3.28, $p=0.02$).

3.5. OC continuation and its association with psychological conditions and perceived side effects

At six months, only 38% of participants (n=136) were still using OCs. Continuation rates were similar among adolescents and young adults ($p=0.45$). In the unadjusted analysis, rates of OC continuation were lower among young women with baseline perceived stress symptoms than those without symptoms (27% versus 41%, $p=0.03$). Similar trends were noted among those with depressed mood symptoms versus those without symptoms (29% versus 41%, $p=0.06$). In multivariate models examining psychological conditions and OC continuation (Table 4), young women with baseline depressed mood (OR 0.54, CI 0.29–0.99, $p=0.04$) and stress (OR 0.48, CI 0.25–0.91, $p=0.03$) were approximately half as likely to continue OCs at six months as those without psychological conditions.

For associations between perceived side effects and OC continuation, unadjusted analysis showed perceived weight change (overall and by dimension) was associated with lower discontinuation rates compared to no perceived weight change (p-values ≤ 0.03). When adjusting for the significant covariates (Table 4), young women with weight changes (yes/no) were 40% less likely to continue OCs than those without weight changes (OR 0.60, CI 0.38–0.94, $p=0.03$), with similar point estimates for the dimensions of weight gain (OR 0.60, CI 0.36–0.99, $p=0.04$) and "a lot" of weight change (OR 0.47, CI 0.23–0.97, $p=0.04$). Mood changes (overall or by dimension) were not associated with OC continuation in bivariate or multivariate models.

Finally, we used Baron and Kenny's [22] model for mediation effect to determine whether perceived mood or weight changes mediated the relationships between depressed mood and stress and OC continuation. In these models with continuation regressed on depressed mood and stress, mood or weight changes did not meet mediation criteria since there were no significant changes in any point estimates after controlling for perceived side effects.

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4. Discussion

Depressed mood, psychological stress and perceived weight changes were independent predictors of OC discontinuation among young minority women in our study. Other researchers have reported on associations between perceived weight side effects, in particular weight gain, and OC misuse [14–17]. Our findings offer further support that perceptions of weight side effects remain a persistent barrier to contraceptive continuation.

Ours is the first study of which we are aware to prospectively examine the adverse psychological conditions and OC use. It is unclear from these data why women with depressed mood or psychological stress are more likely to discontinue OCs. Existing theories on psychiatric mechanisms related to pill misuse more generally suggest that women with adverse psychological conditions may lack insight into their psychological distress and its impact on daily functioning, including pill-taking [47]. They may have diminished perceptions of benefits and threats of a contraceptive treatment and susceptibility to pregnancy [48] or limited capacities for risk assessment, planning and social learning [47–50]. All of these cognitive processes could interfere with a woman’s contraceptive behavior and ability to make health decisions but require further investigation in regards to OC use and depression and stress.

Our findings also suggest that psychological conditions may contribute to or exacerbate perceptions of negative OC-related symptoms. While researchers have refuted the claim that negative OC-associated mood changes are clinically significant [16, 32, 51], none have examined the impact of existing depressive and stress conditions on perceptions of OC-attributed mood changes.

Mood improvements with OC use have been documented [16,17, 52–54]. Yet, these studies have largely focused on premenstrual symptoms and on healthy populations. We are not aware of any studies examining mood benefits of OC in women with underlying psychological conditions. Unfortunately, these data do not illuminate whether potential mood benefits of hormonal contraception are mediated or limited by the pathology of mood disorders.

We also found that depressed mood was associated with perceived weight loss. Although weight loss is often a physical manifestation of depression [37], it has not been evaluated in the context of OC use. Our finding may reflect a general lack of insight into the pathology and symptomatology of depression, in addition to misperceptions of OC.

It may be that OC-related neuroendocrine changes are amplified in women with mood disorders, which could lead to heightened negative or dampened positive physiologic symptoms. This has yet to be studied. Alternatively, it may be that cognitive processes related to “perceptions” of physical symptoms, rather than pathophysiological processes, are altered in OC users with adverse psychological conditions. Rubino-Watkins et al. [55] examined the influence of OC on the cognitive-emotional processes of psychological stress in 76 women and found OC users with stress had higher self-reported negative cognitive patterns and emotions over time than non-users. Greater negative affect was attributed to more daily stressors among OC users versus nonusers.

Other researchers have found that higher levels of somatization (recurrent, frequently changing physical symptoms not explained by known medical conditions) and hypochondriasis (excessive worry about illness; belief that one has an undiagnosed physical disease) are associated with higher rates of reported side effects with both active and placebo medication [56, 57]. Depressed and stressed patients often experience non-specific somatic sensations interpreted as medication side effects [58–60]. Yet, some have hypothesized that perceived contraceptive side effects result simply from the psychological response of “practicing birth control” [51]. Whether these psychological tenets are true for OC-using women with depression and stress symptoms and OC-attributed side effects requires additional research.

Although we used a prospective design, cross-sectional measurement of individual variables limited our ability to assess dynamic relationships. Self-report measures on psychological conditions, side effects and body weight may have been biased. The sample size was appropriate for an exploratory analysis but offered limited power to assess independent associations between key variables. Finally, we may have limited generalizability given our urban, Hispanic, convenience sample.

5. Conclusion

Our data suggest that young, OC-using women with depressed mood and stress are at increased risk for perceived side effects and OC discontinuation than women without psychological symptoms. Careful consideration of psychological symptoms can inform contraceptive education, counseling and management strategies and determine the most optimal contraceptive methods, which may include long-acting reversible contraception. Additional research is required to determine the influence of screening, referring or treating adverse psychological conditions on OC behavior in reproductive health contexts.

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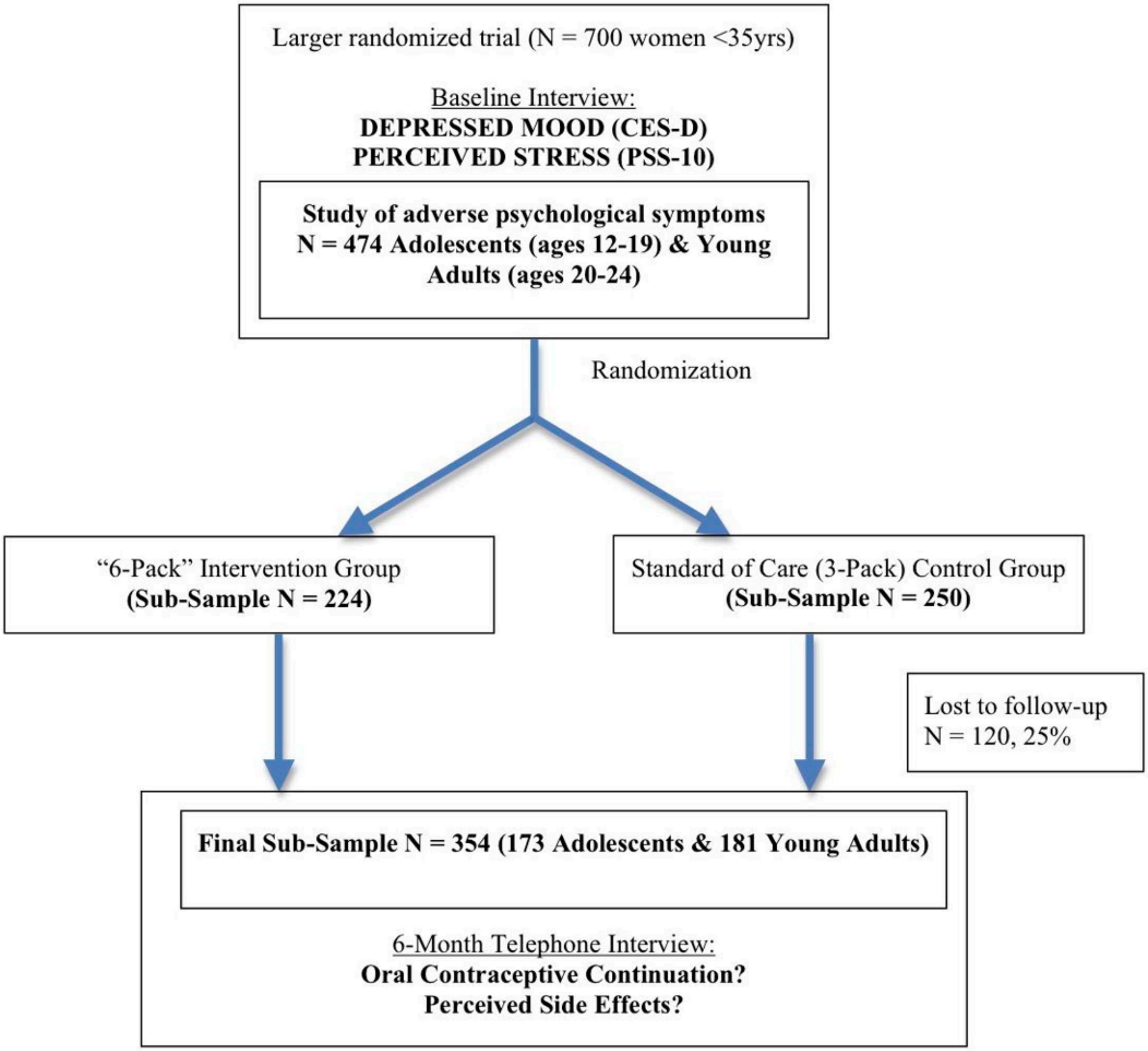

Figure 1.
Flow of participants through study

Table 1

Description of the final sample

Demographic, social and reproductive characteristics (N=354)	Results M ± SD or N (%)
Age (M ± SD)	19.6 ± 2.6
Adolescents (aged 13–19 years)	173 (49)
Young Adults (aged 20–24 years)	181 (51)
Race/Ethnicity	
Hispanic	324 (92)
Non-Hispanic	30 (8)
White	6 (1)
African-American	23 (7)
Other	1 (<1)
Pill supply	
7 months	171 (48)
3 months	183 (52)
Insured (yes)	152 (43)
Medicaid (yes)	133 (38)
Education: highest grade completed	11.7 ± 1.9
Tobacco use past 30 days (yes)	46 (13)
Height (in)	63.6 ± 2.5
Weight (lb)	138.8 ± 31.8
Mean BMI (SD)	24.5 ± 5.0
Median BMI (range)	23.5 (15.1 – 47.8)
Body mass index (BMI) by category Normal/underweight (BMI <25) Overweight (BMI 25–29.9) Obese (BMI >30)	215 (61) 89 (25) 41 (16)
Age at first sex	15.9 ± 2.3
Ever pregnant (yes)	137 (39)
Previous OC user (yes)	163 (46)
Prior time on pill (months)	3.0 ± 8.1
Stopped pill due to side effects (yes)	41 (25)
Main partner (yes)	338 (96)

Results reported as frequencies (N) with percentages (%) or means (M) ± standard deviations (SD).

Table 2

Unadjusted rates of dimensions of perceived mood and weight changes reported with oral contraceptive use at six-months among young women with baseline depressed mood and perceived stress

MOOD AND WEIGHT CHANGE DIMENSIONS									
	Type X^2 (P) r n (%)		**Severity X^2 (P) r n (%)**			**Quality X^2 (P) r n (%)**			**Attribution X^2 (P) r n (%)**
Reported mood changes (overall, N=87, 25%)	More n=73	Less n=14	Little n=43	Some n=23	Lot n=21	Good n=18	Bad N=41	Neither n=28	Due to pill n=40
Depressed mood[a] (≥16-pts CES-D) n=27/73 (37%) p=0.01	7.70 (0.02) −0.15		19.41 (<0.001) 0.21			3.23 (0.20) 0.08			0.53 (0.47) 0.04
	n=23 (32%)	n=4 (29%)	n=9 (21%)	n=6 (26%)	n=12 (57%)	n=6 (33%)	n=11 (27%)	n=10 (36%)	n=10 (25%)
Perceived stress[a] (≥21-pts PSS-10) n=21/67 (31%) p=0.15	5.18 (0.08) −0.10		2.66 (0.50) 0.09			0.32 (0.85) 0.02			0.03 (0.85) 0.01
	n=20 (27%)	n=1 (7%)	n=9 (21%)	n=6 (26%)	n=6 (29%)	n=3 (17%)	n=9 (22%)	n=9 (32%)	n=8 (20%)
Reported weight changes (overall, N=200, 57%)	Gain n=135	Loss n=65	Little n=104	Some n=44	Lot n=52	Good n=67	Bad N=79	Neither n=52	Due to pill (vs. other) n=102
Depressed Mood[a] (≥16-pts CES-D) n=51/73 (70%) p=0.02	8.32 (0.02) −0.10		9.40 (0.02) 0.11			4.07 (0.13) 0.07			2.08 (0.15) 0.08
	n=31 (23%)	n=20 (31%)	n=25 (24%)	n=15 (34%)	n=11 (21%)	n=19 (28%)	n=18 (28%)	n=13 (25%)	N=26 (25%)
Perceived Stress[a] (≥21-pts PSS-10) n=42/67 (63%) p=0.26	1.31 (0.52) −0.05		5.40 (0.14) −0.01			0.65 (0.72) 0.01			0.04 (0.84) 0.01
	n=28 (21%)	n=14 (22%)	n=25 (24%)	n=11 (25%)	n=6 (12%)	n=15 (22%)	n=14 (18%)	n=12 (23%)	n=20 (20%)

Center for Epidemiologic Studies – Depression Scale (CES-D); Perceived Stress Scale - 10 (PSS-10).

Depressed mood and perceived stress: Results are presented as numbers (n) and rates (%) of reported mood and weight changes overall (yes/no) among those with elevated depressed mood and perceived stress scores.

[a]Pearson's chi-square (X^2) compares rates of overall reported mood and weight changes among those with and without depressed mood and perceived stress.

Columns 1–4: For dimensions of perceived side effects, results are presented as numbers (n) and rates (%) of dimensions of reported mood and weight changes. Statistical analysis for associations between depressed mood and stress and side effect dimensions are Pearson's chi-square test (X^2) with p-value (p) and Pearson's correlation coefficient (r). P-values considered statistically significant at alpha <0.05, <0.01, or <0.001 for all tests.

Table 3

Logistic regression results for associations between baseline depressed mood and perceived stress and reported mood and weight changes (overall and by dimension) at six months among oral contraceptive users

Effect of psychological conditions on perceived mood and weight changes	By dimension OR (CI) p-value					
	Type		Severity	Quality		Attribution
Reported mood changes overall (yes/no)	**More** vs Less/none	**Less** vs More/none	**Lot** vs Some/ little/none	**Bad** vs Good/ neither	**Good** vs Bad/ neither	**Pill** vs Other
Depressed mood[a] (≥16-pts CES-D) 2.30 (1.30–4.07) 0.004	2.27 (1.25–4.15) 0.007	1.60 (0.48–5.34) 0.45	6.31 (2.51–15.83) <0.001	1.65 (0.77–3.53) 0.19	2.31 (0.82–6.53) 0.11	1.26 (0.56–2.82) 0.58
Stress[a] (≥21-pts PSS-10) 1.67 (0.91–2.99) 0.10	2.07 (1.12–3.82) 0.02	0.31 (0.04–2.42) 0.26	1.79 (0.66–4.86) 0.25	1.33 (0.59–2.98) 0.49	0.94 (0.26–3.40) 0.92	1.15 (0.49–2.66) 0.75
Reported weight changes overall (yes/no)	**Gain** vs Loss/none	**Loss** vs Gain/none	**Lot** vs Some/ little/none	**Good** vs Bad/ neither	**Bad** vs Good/ neither	**Pill** vs Other
Depressed mood[a] (≥16-pts CES-D) 2.14 (1.20–3.80) 0.01	1.33 (0.78–2.29) 0.30	1.89 (1.01–3.55) 0.05	1.09 (0.52–2.30) 0.83	1.45 (0.77–2.80) 0.25	1.26 (0.68–2.34) 0.46	1.47 (0.83–2.60) 0.18
Stress[a] (≥21-pts PSS-10) 1.47 (0.83–2.59) 0.18	1.31 (0.75–2.28) 0.34	1.19 (0.61–2.34) 0.61	0.51 (0.20–1.27) 0.15	1.30 (0.67–2.54) .45	0.91 (0.47–1.77) 0.79	1.14 (0.63–2.05) 0.67

Center for Epidemiologic Studies – Depression Scale (CES-D); Perceived Stress Scale - 10 (PSS-10). Results are odds ratios with 95% confidence intervals and p-values based upon multiple logistic regression examining depressed mood and stress as independent variables and mood and weight changes as dependent variables.

[a]Regression results for overall reported mood and weight changes (yes/no) noted under depressed mood and stress. Significant covariates included in all final regression models are education, BMI, randomization. P-value considered significant at alpha <0.05.

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Table 4

Likelihood of oral contraceptive continuation among young women with depressed mood, perceived stress and oral contraceptive-related side effects

Independent predictors of oral contraceptive continuation	OR	95% CI	p-value
Depressed mood (CES-D Score ≥ 16pts)	0.54	0.29–0.99	0.05
Perceived mtress (PSS-10 Score ≥ 21pts)	0.48	0.25–0.91	0.03
Mood changes (yes/no)	0.93	0.55–1.57	0.80
Type of mood change (more, less, none) None vs more (n = 267 vs 73) None vs less (n = 267 vs 14)	1.10 0.30	0.64–1.91 0.06–1.40	0.73 0.13
Severity of mood change (none, little, some, lot) None vs little (n = 267 vs 43) None vs some (n = 267 vs 23) None vs lot (n = 267 vs 21)	1.62 0.50 0.68	0.82–3.21 0.14–1.14 0.25–1.88	0.17 0.09 0.46
Quality of mood change (none, good, bad) None vs good (n = 267 vs 18) None vs bad (n = 267 vs 41)	0.48 1.05	0.16–1.45 0.52–2.13	0.19 0.89
Attribution of mood change (pill vs. other/no change) (n = 40 vs 314)	1.14	0.56–2.33	0.71
Weight changes (yes/no)	0.60	0.38–0.94	0.03
Type of weight change (none, gain, loss) None vs gain (n = 154 vs 135) None vs loss (n = 154 vs 65)	0.60 0.60	0.36–0.99 0.31–1.14	0.04 0.12
Severity of weight change (none, little, some, lot) None vs little (n = 154 vs 104) None vs some (n = 154 vs 44) None vs lot (n = 154 vs 52)	0.63 0.67 0.47	0.37–1.09 0.32–1.42 0.23–0.97	0.10 0.30 0.04
Quality of weight change (none, good, bad) None vs good (n = 154 vs 67) None vs bad (n = 154 vs 79)	1.00 0.74	0.55–1.83 0.42–1.32	1.00 0.31
Attribution of weight change (pill vs. other/no change) (n = 102 vs 252)	0.97	0.59–1.60	0.90
[a]Education (number of grades completed)	1.18	1.04–1.33	0.01
[a]BMI: Normal weight vs overweight Normal weight vs obese	1.28 1.39	0.75–2.16 0.67–2.89	0.36 0.37

Center for Epidemiologic Studies – Depression Scale (CES-D); Perceived Stress Scale - 10 (PSS-10). BMI = body mass index by: normal/underweight (BMI < 25), overweight (BMI 25–29.9) and obese (BMI > 30). Results shown are from multiple logistic regression models with each psychological and side effect variable entered separately into models; point estimates were stable in combined models with all variables entered together. Results are presented as adjusted odds ratios (OR) with 95% confidence intervals (CI) based upon logistic regression. P-values for alpha <0.05 or <0.01 considered significant. Randomization treatment group was included in all models and was highly significant at alpha <0.001.

[a]Point estimates of covariates education and BMI shown are those from the depressed mood model but were stable among all models.