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Effects of the Oral Contraceptive Pill: Psychological and Physiological Variables

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Abstract

Oral contraceptives are one of the most widely used contraceptives in the world. Multiple variations of the oral contraceptive pill (OCP) now exist with limited research examining the psychological impact they may have. The current study examined the psychological and physiological impact of three OCPs. Psychological and physiological variables in participants (*N*=84) were measured. Results found no significant effect on the psychological variables. An effect was observed in physiological variables; an increase in systolic blood pressure (SBP) on the fourth week of pill cycle in those using Dianette and Ovranette. Similarly, the purpose for which participants were using the OCP had an effect on SBP. This increase was also observed in diastolic blood pressure (DBP) for the group who answered 'other'. These findings in relation to the week of pill cycle and SBP are particularly interesting and pave the way for further research.

Key Words:

Oral contraceptives, BDI, BAI, PSS-14, blood pressure

Oral contraceptive pills (OCP) are hugely popular in much of the western world (O'Connell, Davis, & Kerns, 2007; Segebladh, Borgström, Odlind, Bixo, & Sundström-Poromaa, 2009). According to a report for the NHS, oral contraceptives are the second most popular method of contraception used in the UK (Office for National Statistics, 2009). Their use is also thought to be increasing within the United States (Gibson & Mark, 2011). Within Ireland, the OCP is the most common method of contraception used by women (Greene, Joy, Nugent, & O'Mahony, 1989). While limited research in the area exists, a study looking at postpartum women found that 39% used OCPs (Mason, 2003).

The use of OCPs has several benefits, such as giving women greater control over their bodies, family planning, and providing reassurance against the possibility of unwanted pregnancies. However, there have been reports of negative physical and psychological side effects of OCP use. Much of the research into oral contraceptives focuses on the physical side effects to the drug (Hannaford et al., 2007; Logan & Kay, 1989; Parkin, Sharples, Hernandez, & Jick, 2011), with less research concerned with the psychological side effects. There is evidence to suggest that the hormones contained in oral contraceptives may have an effect on the brain and could be linked to negative side effects such as depression (Civic et al., 2000; Grant & Pryse-Davies, 1968; Kulkarni, 2007; Nilsson & Almgren, 1968). The active ingredients contained in OCPs may be responsible for negative effects on hormones within the body and subsequently influence mood. Despite the reports of supposed links between OCP use and increased psychological distress, this has not been fully investigated. Moreover, whether these effects,

if evident, vary with the type and potency of oral contraception is yet to be investigated.

The combined OCP is made up of two synthetic hormones; one progesterone element and one oestrogen element. Progesterone and oestrogen are hormones which are naturally present in the body and are involved in pregnancy and the menstrual cycle. The OCP uses synthetic versions of these hormones to mimic a period in pregnancy when both hormones are elevated, thus preventing pregnancy. (Watson Oral Contraceptives Brands, 2015). Many OCPs contain ethinyl estradiol as the oestrogen element. Ethinyl estradiol is a semisynthetic alkylated estradiol, which has a high oestrogenic potency, meaning it is extremely likely to become oestrogen in the body after oral consumption (Wishart, Knox, Guo, Shrivastava, Hassanali et al., 2006). As most OCPs contain similar amounts of ethinyl estradiol, for the present study, drugs which differ in progestin were chosen. These drugs are as follows; Dianette, Ovranette and Yasmin. The chosen OCPs hormonal makeup is outlined in table 1 (Appendix A). All three OCPs have similar amounts of ethinyl estradiol. Since Yasmin is the most potent in terms of progestial potency, we can say that Yasmin is the most potent of the three brands.

Possible Adverse Effects Caused by the OCP

Many misconceptions surround the use of the OCP. A study looking at the low usage of the OCP in Turkish women found a high level of misconceptions surrounding these drugs (Küçük, 2012). Forty five percent of participants believed that OCP caused weight gain, even though this has not been found across several randomised controlled trials (Paxton, 1996). A large percentage of the participants (41%) believed OCP use lead to acne and hirsutism; studies have shown that the opposite is true with improvement of acne being a benefit of many OCPs. A smaller group of the participants, 13.4%, believed there was a link between OCPs and infertility however no such correlation has been found. Almost 8% of participants believed that the OCP caused cancer; no evidence for this has been found in previous studies. In fact, the OCP is linked with a reduced risk of some forms of cancer including ovarian (Küçük, 2012). While this study demonstrates that misconceptions do exist around this form of contraception, there may also be cultural effects linked with the sample of Turkish women.

OCP Use and Psychological Parameters

Anxiety and mood disorders are more prevalent in women than men (Toffol, Heikinheimo, Koponen, Luoto, & Partonen, 2012). The World Health Organisation (WHO) claims that anxiety, depression and psychological distress affect women disproportionately (World Health Organisation,2015). Lifetime prevalence rate of an incident of major depression is 21.3% for females compared with just 12.7% for males (Nolen-Hoeksema, 2001). According to Nolen-Hoeksema (2001), these gender differences in the prevalence of mood disorders do not appear until approximately age 13, around the time when girls begin puberty (Marshall & Tanner, 1969). However, from then on, prevalence rates of depression rapidly increase and continue to do so throughout the lifetime. Depression has been listed as a side effect of many oral contraceptives (Westhoff et al., 1998) and one of the most frequent reasons given for discontinuation of oral contraceptives is changes in mood or an increase in depressive symptoms (Herzberg, Draper, Johnson, & Nicol, 1971).

Furthermore, incidences of depression in women using OCPs have been reported at 5-6%, compared with 1-2% in women who were not using oral contraceptives and/ or were using other forms of contraception, namely barrier methods (Herzberg, Johnson, & Brown, 1970; Lewis & Hoghughi, 1970). A pilot study, carried out with 26 women, found that OCP users had higher objective and subjective depression rates than non-users (Herzberg et al., 1971). While previous research in the area does exist, as will be discussed below, there has been little research in recent years.

Previous research in the area

Results of previous studies have been inconsistent with regards to the effects, if any, that OCPs have on psychological variables such as depression, anxiety and stress. Some have shown that there is no link between depressive symptoms and OCP's (O'Connell et al., 2007; Toffol et al., 2012), while others such as Young et al. (2007) claim that women

taking these drugs are less depressed than a cohort of women not taking a hormonal contraceptive. In a clinical trial, participants with premenstrual dysphoric disorder, who had a score of 15 or over on the Hamilton depression questionnaire (indicating the presence of moderate depressive symptoms), were assessed on a range of psychological parameters. The trial compared: OCPs containing both oestrogen and progestin, OCPs containing progestin only and participants using no hormonal contraceptive. The results showed that those in the combined hormonal group had significantly less severity in depression scores than those who were not taking any hormonal contraceptive. Women in the combined hormonal group were also less likely to show signs of obsessive-compulsive disorder, post-traumatic stress disorder and general anxiety disorder (Young et al., 2007). These results suggest a possible positive psychological impact of hormonal contraceptives.

A randomized, placebo-controlled clinical trial investigated the effects of an OCP with 20 µg of ethinyl estradiol and 100mg of levonorgestrel. It is worth noting how much more this is than the previous listed drugs, Ovranette contains just 150µg of levonorgestrel. Although depressive symptoms decreased slightly over the course of the study, no differences between the groups were found, indicating that there is no link between oral contraceptives and depressive symptoms. However, this study recruited only females below the age of 19, who suffered from dysmenorrhea. The authors also caution that the results could be due to regression to the mean, as symptoms are likely to be their most severe at the time of sign up and so as the study progresses participants' moods may increase (O'Connell et al., 2007). These cited studies will be expanded upon by allowing participation from females without premenstrual dysphoric disorder and increasing the age range, thus increasing generalizability.

A study focusing on the effects of IUDs and OCP's on mood found no evidence of an increase in depressive symptoms. Symptoms were measured using the Mental Health Inventory (Veit & Ware, 1983). Results showed a decrease in depressive symptoms for those who entered the study with pre-existing symptoms of depression; symptoms were measured before and after beginning contraceptive treatment. Information was not sought on the participant's history of mental health and/or previous treatment for mental ill health (Westhoff et al., 1998). The current study has allowed for this possible confounding variable by gathering information on previous psychological diagnosis.

In addition to considering women's previous mental health, it is worth taking into consideration the reason's women change the type of contraceptive they use. Herzberg et al. (1971) measured women's levels of depression before they began taking any form of contraceptive and throughout their first year using either an OCP's or an IUD. Results show that; those using an IUD had higher depression ratings throughout the study, and those that remained on the OCP and did not change type were less depressed than those who stopped or changed. It is worth noting that 25% of the women who chose to stop taking or change their OCP did so due to side effects, one of which was depression (Herzberg et al., 1971). These results may indicate that many studies do not capture the true effect of the OCPs as they do not account for those who have stopped taking or switched brands due to negative psychological side effects.

A study that looked at women participating in the Australian Longitudinal Study on Women's Health (ALSWH) which took place over 20 years found a positive association between contraceptive users and depressive symptoms. However, results became statistically insignificant when possible confounding variables (such as demographic information) were taken into account. The study did not differentiate between various types of OCPs (Duke, Sibbritt, & Young, 2007).

Several studies have found positive correlations between psychological variables and OCP use. Significantly more psychiatric symptoms were found in the OCP group compared with women using 'other' forms of contraception by Nilsson and Almgren (1968). Psychiatric symptoms were defined as depressive symptoms, anxiety symptoms and neurasthenic symptoms. However, there are problems with this study as the 'other' forms of contraception are not defined and are referred to as 'more traditional contraception'. It should be noted this study was published in 1968 and therefore there

have been considerable changes in knowledge of contraceptives, prescription and availability of drugs. As well as this, the study was carried out with participants who had recently given birth, which may have impacted upon psychiatric symptoms (Nilsson & Almgren, 1968). The present study will not be using a clinical sample and thus will be more easily generalizable.

Differing from much of the previous research, Segebladh et al. (2009) ensured that their participants had no previous adverse mood affects to the OCP, by setting inclusion criteria such that only participants who had never switched brands of OCP due to adverse effects or who were not currently experiencing adverse effects due to the OCP were included. Participants were excluded if they were taking any psychotropic drugs. Mood disorders, major depressive disorder and minor depressive disorder, were found to be more common in the drug group than the control group although prevalence rates of anxiety disorders did not differ (Segebladh et al., 2009).

There are minimal studies in which differentiation of progestin compounds or investigation into one compound has been employed. Grant and Pryse-Davies (1968) found that the incidence of depression within OCP users was higher when the OCP had a strong progesterone compound, especially when the OCP contained a small amount of oestrogen. Similarly, another study also found a trend of higher depressive scores when there was a high progesterone content within the OCP (Lewis & Hoghughi, 1969). A study looking at depressive symptoms in users and non-users of depot medroxyprogesterone acetate, (DMPA) an injectable progestin contraceptive, found DMPA users were more likely to have increased depressive symptoms at the baseline than non-users (Civic et al., 2000). Results found that those using DMPA were 40% more likely to have depressive symptoms than non-users, and those who discontinued were 60% more likely to be experiencing depressive symptoms, suggesting that there is a positive association between DMPA and depressive symptoms (Civic et al., 2000). These studies provide evidence that the link between depression and OCP use may be resulting from the amount of progestin contained in OCPs. It warrants investigation into the type and amount of progestin components in OCPs. The present study will be able to examine this issue further as OCPs have been divided with respect to progestin components. Although an effect may not always be found at the time of OCP use, retrospective effects may be discovered. While no negative or positive effect was found by Oinonen and Mazmanian, women retrospectively said that they felt OCP affected their mood negatively (Oinonen & Mazmanian, 2001).

Limitations of previous research

Although there have been inconsistencies in the results of previous studies, depressive mood is listed as a side effect on many OCP brands (see for example Health Products Regulatory Authority, 2016) and mood-related side effects such as mood swings, depressive symptoms and irritability are often given as reasons for discontinuation of the OCP (Segebladh et al., 2009). This merits an investigation into the relationship between the variables. Combined oral contraceptives are the most popular form of hormonal contraceptive options (Young et al., 2007). Many of the inconsistencies in the results of previous studies may be due to the fact that the majority of these studies did not differentiate between types of OCP. Therefore, this study planned to investigate the relationship between three brands of oral contraceptives, each with different progestin components, and depressive, anxiety and stress symptoms. Physiological variables have also been examined due to existing literature reporting links between blood pressure and OCP use (Weir eta., 1974).

A study looking at blood pressure effects in women taking the OCP and a control group, using either a diaphragm or an IUD (intrauterine devices) found a rise in systolic blood pressure. Systolic blood pressure rose in every woman in the OCP group. Diastolic blood pressure had fewer clear results, rising in some and falling in others. No significant difference was found in the control group. In order to assess whether progesterone had an impact, different progestogen concentrations were evaluated. No significant difference was found (Weir et al., 1974). The amount of oestrogen component in the OCP now warrants investigation in relation to blood pressure increments, especially in systolic blood pressure. As

Dianette has the highest dose of oestrogen it is hypothesized that the greatest increase in blood pressure will be noted in this participant group.

The link between depression and anxiety has been widely researched. Although they are distinct concepts and present themselves very differently there has been a great deal of clinical overlap between the two (Chang, 1998; Goldberg, 2014; Lovibond & Lovibond, 1995; Spada, Nikčević, Moneta, & Wells, 2008). As well as the link between depressive symptoms and anxiety symptoms, these variables have also been linked to stress (Spada et al., 2008). Stress can be the cause of episodes of anxiety or depression. It is thought that stressful life events can be linked to psychological responses similar to those caused by anxiety or depression (Lovibond & Lovibond, 1995). Stress, or more specifically, stressful life events have been previously linked to depression (Hammen, 2005). Thus, if a person is perceiving things as stressful, they are more likely to have depressive symptoms. The Perceived Stress Scale (PSS-14) has been used to monitor stress in conjunction with depressive scales such as the BDI, and it has been found to show correlations between perceived stress, anxiety measured using State and Trait Anxiety Inventory (STAI), Hospital Anxiety and Depression Scale (HADS) and depression (Bergdahl & Bergdahl, 2002; Hewitt, Flett, & Mosher, 1992; Spada et al., 2008). Furthermore, The General Health Questionnaire is a good predictor of psychological distress and is found to have an association with depressive symptoms (Aalto, Elovainio, Kivimäki, Uutela, & Pirkola, 2012). No previous studies have examined the relationship between either perceived stress levels or general health questionnaire and OCP use. Previous studies which have examined OCP use have not differentiated between various times of OCP.

The present study is distinct in that three commonly prescribed OCPs have been highlighted and separated into groups. This enables us to investigate whether or not each OCP differs in respect to the variables of stress, anxiety and depressive symptoms. If so, it can be postulated that this may be due to the type and dose of progestin used in the OCP. The present study addresses a number of gaps in the literature, as it looks at more than one type of OCP and investigates the link between OCP use and anxiety, depression and stress scores. In addition, the study was carried out using a non-clinical population, which has not previously been the case. In addition to the psychological variables mentioned, systolic and diastolic blood pressure will be examined. As previously mentioned, increased blood pressure is a known side effect of OCP use, and prior research has examined the effects of progestin levels on blood pressure (Weir et al., 1974). With this in mind, the present study will look at the effect of oestrogen strength on blood pressure. As well as this, hypertension has links to perceived stress (Katsarou, Triposkiadis, & Panagiotakos, 2013). The present study plans to examine the effects of psychological variables as well as the possible effects of the various OCPs on blood pressure ratings.

The hypotheses which will be tested in this current study are as follows:

1. H_1 OCP use has an effect on Beck Depression Inventory (BDI) scores when comparing OCP users with a control group of non-users.

H_0 OCP use has no effect on BDI scores when comparing OCP users with a control group of non-users.

2. H_1 The greatest effect on BDI scores will be seen in those using Yasmin. When comparing drug groups with a control group of non-users.

H_0 The greatest effect on BDI scores will not be seen in those using Yasmin. When comparing drug groups with a control group of non-users.

3. H_1 OCP use has an effect on Beck Anxiety Inventory (BAI) scores when comparing OCP users with a control group of non-users.

H_0 OCP use has no effect on BAI scores when comparing OCP users with a control group of non-users.

4. H_1 The greatest effect on BAI scores will be seen in those using Yasmin. When comparing drug groups with a control group of non-users.

H_0 The greatest effect on BAI scores will not be seen in those using Yasmin. When comparing drug groups with a control group of non-users.

5. H_1 OCP use has an effect on perceived stress scores when comparing OCP users with a control group of non-users.

H_0 OCP use has no effect on perceived stress scores when comparing OCP users with a control group of non-users.

6. H_1 The greatest effect on perceived stress scores will be seen in those using Yasmin. When comparing drug groups with a control group of non-users.

H_0 The greatest effect on perceived stress scores will not be seen in those using Yasmin. When comparing drug groups with a control group of non-users.

7. H_1 OCP use has an effect on GHQ scores when comparing OCP users with a control group of non-users.

H_0 OCP use has no effect on GHQ scores when comparing OCP users with a control group of non-users.

8. H_1 The greatest effect on GHQ scores will be seen in those using Yasmin. When comparing drug groups with a control group of non-users.

H_0 The greatest effect on GHQ scores will not be seen in those using Yasmin. When comparing drug groups with a control group of non-users.

9. H_1 OCP use will increase diastolic blood pressure when compared with a control group of non-users.

H_0 OCP use will not increase diastolic blood pressure when compared with a control group of non-users.

10. H_1 The highest diastolic blood pressure reading will be seen in Dianette users. When comparing drug groups with a control group of non-users.

H_0 The highest diastolic blood pressure reading will not be seen in Dianette users when comparing drug groups with a control group of non-users.

11. H_1 OCP use will increase systolic blood pressure when compared with a control group of non-users.

H_0 OCP use will not increase systolic blood pressure when compared with a control group of non-users.

12. H_1 The highest systolic blood pressure reading will be seen in Dianette users when comparing drug groups with a control group of non-users.

H_0 The highest systolic blood pressure reading will not be seen in Dianette users when comparing drug groups with a control group of non-users.

Methods

Sample and Participant Selection

The sample consisted of female participants aged 18-44 (M = 23.02 years, SD= 6.57). Participants were invited to participate either via an email sent to the entire student and staff population of the University of Limerick, or through Sona, a research participation site used by the Psychology Department to grant course credit to students. These methods of recruitment were chosen in line with ethical requirements (ethics approval number 2014_06_1). Inclusion criteria were fluency in English, women who were not taking any form of hormonal contraceptive (control group), or who were currently taking Dianette, Ovranette or Yasmin.

Procedure

Participants attended a twenty-minute session with the experimenter. Data collection occurred over nine weeks, in a health lab in the psychology department of the University of Limerick. In order to ensure that the routine was exactly the same for each participant and that all equipment was in order, a pilot study of four participants was carried out before collecting data. Instructions were given to participants verbally, and it was ensured that each participant received the exact same instructions (Appendix B). Participants were given an information sheet (Appendix C), with all the necessary details of the study, and were then asked to sign a consent form (Appendix D), if they

agreed to participate in the study. The consent forms were securely stored in a separate location to all data sheets, ensuring the anonymity of participants. After the consent form was signed, participants filled out the questionnaire containing the demographic information, BDI, BAI, PSS-14 and GHQ. Once the participant had completed the questionnaire, their weight, height, and blood pressure were taken. Participants were required to wear flat shoes and due to this we asked all participants to keep their shoes on for the height and weight measurements. Blood pressure readings were taken twice. An average of the two measures was used to allow for the white coat effect, an increase in blood pressure due to a clinical setting (Pickering, Gerin, & Schwartz, 2002), as well as controlling for the movement involved in taking the other measures. Participants were given a debriefing sheet (Appendix E) once blood pressure was taken and thanked for their participation.

Participants who applied through SONA (an online program which allows students to sign up to participate in research studies in return for course credits) were given one course credit in return for their participation. While recruitment of control participants was unproblematic, recruitment of participants in each OCP group proved difficult, despite re-advertisement of the study without the control group requirement. There was also a difference in the availability of participants on each OCP, it was much easier to recruit those taking Yasmin compared to those taking Dianette. This may be due to the fact that Dianette is predominately prescribed for acne treatment and not contraception ("Dianette 2mg/35microgram coated tablets", 2014). The recruitment email was sent out a second time during data collection in order to increase participant numbers, outlining the need for participants who were taking one of the three OCPs listed. The information on SONA was also changed to accommodate the need for more participants taking Dianette. One participant's age was coded as missing as it was not provided on the questionnaire. All participants either worked or studied in the University of Limerick.

Materials

Materials used in the study included: a blood pressure monitor, which was used to gain blood pressure readings for each participant; a measuring tape for height measurements and weighing scales for weight measurements. Systolic blood pressure (SBP) and diastolic blood pressure (DBP), were measured using a GE Dinamap Pro 300 series blood pressure monitor (GE Medical Systems, Freiburg, Germany). Blood pressure ratings were taken by placing the cuff over the brachial artery on the non-dominant arm (Gallagher, Meaney, & Muldoon, 2014). Height and weight measurements were taken in order to calculate BMI for each participant. BMI is a potential confound of blood pressure and has been measured in similar studies (Duke et al., 2007). A demographic questionnaire (Appendix F) was also given to each participant, the questionnaire consisted of questions relating to age, what type of OCP, purpose of taking the OCP and what week of their cycle the participant was on. A questionnaire containing various psychological measures was also attached. All measures were provided in pencil-and-paper format.

Beck Depression Inventory. The Beck Depression Inventory (BDI-II; Beck, et al., 1961) is a 21 item self-report questionnaire used to assess depression symptoms in clinical and non-clinical populations. Each question is rated on a scale ranging from 0 to 3 based on severity of each item. The maximum total score is 63. A score of 0–13 is considered minimal range, mild range is categorised as 14–19 and moderate scores fall between 20–28. Scores above 29 indicate depression in the severe range.

The BDI-II was chosen for this study as it had been widely used in previous studies relating to OCP use (Herzberg et al., 1971; Kulkarni, 2007;Toffol, Heikinheimo, Koponen, Luoto, & Partonen, 2011;Toffol et al., 2012). The BDI-II has evidenced high reliability as well as good concurrent, content and structural validity (Wang & Gorenstein, 2013).

Beck Anxiety Inventory. The Beck Anxiety Inventory (BAI; Steer & Beck, 1977), is a 21 item self-report questionnaire used to assess symptoms of anxiety. Similarly, to the BDI-II the maximum total score is 63. Categorisation of scores is as follows: minimal anxiety 0-7, mild anxiety 8-15, moderate anxiety 16-25 and severe anxiety 26-63. The BAI was used to measure symptoms of anxiety in order to maintain similarity with the depression measures.

The BAI has demonstrated good test-retest reliability, good internal consistency and good convergent validity (Beck et al., 1988; Osman et al., 1997).

Perceived Stress Scale. The 14-item Perceived Stress Scale (PSS-14; Cohen 1983) is self-report questionnaire assessed on a 5-point Liker scale ranging from 'never' to 'very often'. It is scored by summing all items, Items 4, 5, and 7 are reverse coded. Scores of above 20 are considered high stress. The PSS-14 has been used in other studies which investigate the relationship between stress and anxiety and/or depression (Bergdahl & Bergdahl, 2002; Chang, 1998). As well as this, there has been significant research reporting its validity and reliability and relatedness to the BDI (Andreou et al., 2011; Hewitt et al., 1992; Mimura & Griffiths, 2004).

General Health Questionnaire. The 12 item General Health Questionnaire (GHQ; Goldberg & Williams, 2000) has been used previously alongside the BDI in the area of hormonal contraceptives and mental health (Toffol et al., 2011). The 12-item GHQ assesses the severity of a mental problem over the past few weeks using a 4-point Likert scale ranging from 0-3, with a maximum score of 36. Higher scores indicating worse conditions. The GHQ has good validity and reliability and is considered a good measure of general mental health (Goldberg et al., 1997) thus it was included in the questionnaire.

Design

The study was a between-subject differential design, all participants answered the same questionnaires and the identical measures were taken. Dependent variables were the scores derived from the various questionnaires, BDI, BAI, PSS-14, GHQ and blood pressure readings. The independent variable was the OCP that the participant was currently taking (none, Dianette, Ovranette or Yasmin). The three brands of OCPs were chosen from preliminary research on common OCPs; researcher's peers and colleagues were asked which OCP, if any, they were using and the most common were selected from this list. It was also ensured that the OCPs were of varying progestins while containing similar amounts of ethinyl estradiol.

Statistical Analysis

The data gathered was analysed using the software SPSS Statistics 22 (IBM, 2013). Descriptive analysis and frequencies were first run to allow for a first look at the data. From this, an exploratory correlation test was carried out. This allowed us to examine variables which were related to each other. Using the variables which were significantly associated with one another, a Kruskal-Wallis was carried out to investigate the differences, if any, between the four groups. Kruskal-Wallis tests were also carried out on groups examining the effect of OCP use on the hypothesised variables. Kruskal-Wallis were used as the data did not meet the assumptions for One-Way ANOVAs.

Results

Descriptive Statistics

A descriptive analysis was first run on all data in relation to their OCP group. Means and standard deviations can be found below in Table 2. There were a number of missing values in the dataset. Values for blood pressure for 6 participants were missing in addition to one participant's age and one participant's GHQ score. Any participant with missing data was excluded from that particular analysis, but not overall, as all analyses were conducted separately.

There were 28 participants in the control group; these participants were not using any hormonal contraceptives for example OCPs, implants or intra-uterine devices (IUDs). There were 56 overall in the drug groups: 13 taking Dianette, 22 taking Ovranette and 21 taking Yasmin. The majority of participants in the drug group (35%), were using their OCPs for contraceptive purposes, 16% were using OCPs for both the treatment of acne and contraceptive purposes, 4% were using the OCP for acne treatment and the remaining 13% were using OCPs for other reasons. Participant numbers were divided reasonably equal across the weeks of the pill packet. The majority of participants were on week 2 of their packet (n= 18) while only 11 were on week 4. BMI

and age of participants were similar across all groups.

Mean BDI scores were higher for all OCPs when compared with the control group. The highest mean score was seen in Dianette. Similarly, mean BAI scores for all OCPs were higher than the control group score, although the Ovranette group had the highest mean score. Once again PSS-14 scores were slightly higher across the OCP groups than the control group; with the highest score seen in the Ovranette group. Likewise, GHQ scores were higher in the control, however the highest mean score was shown to be the Dianette group.

Table 1: *Means and Standard Deviations of Dependent Variables*

		Control		**Dianette**		**Ovranette**		**Yasmin**	
	N	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*
BMI	84	23.56	4.64	24.56	4.03	24.22	4.67	22.91	2.65
SBP	78	113.59	10.75	129.61	14.30	127.55	16.48	120.64	7.88
DBP	78	67.72	7.78	73.67	8.03	71.18	7.12	69.22	5.07
Age	83	24.23	8.75	20.41	1.65	22.28	4.97	23.74	6.55
BDI	84	8.00	5.88	12.11	13.10	10.91	9.00	11.28	10.73
BAI	84	7.89	7.34	10.44	8.80	12.68	8.76	11.72	11.03
PSS-14	84	24.96	6.37	27.22	8.53	28.86	7.75	25.22	8.46
GHQ	83	11.26	4.49	13.44	8.56	13.36	5.08	12.72	7.62

Note. BMI= Body Mass Index; SBP=Systolic Blood Pressure;DBP=Diastolic Blood Pressure; BDI=Beck Depression Inventory= Beck Anxiety Inventory; PSS-14=Perceived Stress Scale-14; GHQ= General Health Questionnaire

Inferential Statistics: Correlations

An exploratory correlation matrix was carried out on the variables, in order to establish which variables were associated with each other. A non-parametric test, Spearman's *r*, was used to examine the associations between the different variables as the data did not meet the assumptions for a parametric test: the groups were unequal in numbers, not all data were normally distributed and there was a lack of homoscedasticity across all groups. Correlation coefficients and significance levels for all analyses can be found in Table 2.

Physiological correlations. There were weak but positive correlations between age and BMI and also age and DBP. DBP was also positively associated with which week of the pill cycle participants were on, although the correlation was weak. Unsurprisingly, there was also a positive correlation with week and SBP, this association was of moderate strength. Furthermore, SBP was moderately correlated with BMI, type of OCP and the purpose for which participants were using their OCP for. These associations were all of moderate strength. There was also a moderate positive correlation between DBP and the purpose for which participants were using the OCP. Once again this is unsurprising as there was an association between purpose and SBP. There is a strong positive correlation between SBP and DBP, however this is to be expected. It is also worth noting that there was a strong positive correlation between type of OCP and the purpose for which participants were using their OCP.

Psychological correlations. There was a positive but weak association between SBP and BAI. BAI was also associated with age, although the correlation was a weak negative one. Additionally, age was correlated with both BDI and GHQ however these were both negative correlations of moderate and weak strength respectively. The week of pill packet was positively correlated with BAI, BDI and PSS-14 scores, however all correlations were weak.

As expected, there was a positive correlation between Diagnosis and BDI. Diagnosis was also positively correlated with GHQ. As would be suggested by the literature all psychological outcome variables (BDI, BAI, PSS-14 and GHQ) had strong, positive correlations with one other.

Inferential Statistics: Non-Parametric Tests

One-Way ANOVAs were initially planned to further investigate those variables which had significant associations with each other as well as the hypothesized outcomes. However, as previously discussed the assumptions of this test were not met thus non-parametric Kruskal-Wallis tests were carried out. Descriptive statistics are presented in Appendix A.

Further analysis of correlates. Week of pill cycle was found to have an effect on SBP (H (4) = 18.66, p = .01), as those who were on week four of their OCP packet had higher SBP than the control group (*Mdn*= 115 for control, *Mdn*=126 for week one, *Mdn*=120.50 for week two, *Mdn*= 122.75 for week three and *Mdn*= 134.50 for week four). There was no difference between those in the control group and those on week one to three of their pill packet. There was also no difference between those on weeks one to three.

It was revealed that the purpose for which participants were using their OCP had an effect on SBP (H (4)= 19.64, p=.001), as those who were using the OCP for a reason stated as 'other' and those using the OCP for both contraception and acne treatment had higher SBP than the control group (*Mdn*= 115 for control, *Mdn*= 121 for contraceptive, *Mdn*= 122 for acne, *Mdn*= 129 for both contraception and acne and *Mdn*= 129.5 for reasons stated as other). There was no difference between those in the control group and those using the OCP for contraception and acne.

Furthermore, it was seen that the purpose for which participants were using their OCP had an effect on DBP (H (4) = 11.05, p=.03), as those who were using the OCP for a reason stated as 'other' had higher DBP than the control group (*Mdn*= 66 for control, *Mdn*= 68.25 for contraceptive, *Mdn*= 68.5 for acne, *Mdn*= 70.75 for both contraception and acne and *Mdn*= 74.75 for reasons stated as other). There was no difference between those in the control group and those using the OCP for contraception, acne or both.

Hypothesized outcomes.

Psychological Variables. No significant effect of OCP on BDI was found (H (3)= 2.25, p=.52), with similar scores seen across all groups (*Mdn*= 6.5 for control, *Mdn*= 9 for Dianette, *Mdn*= 8 for Ovranette, *Mdn*= 10 for Yasmin). Thus, the study fails to reject the null hypotheses 1 and 2.

OCP also did not have a significant effect on BAI (H (3)= 6.98, p=.07), again with similar scores seen across all groups (*Mdn*= 6 for control, *Mdn*= 13 for Dianette, *Mdn*= 10 for Ovranette, *Mdn*= 8 for Yasmin). The null hypotheses 3 and 4 are similarly retained.

Similarly, OCP did not have a significant effect on PSS-14 (H (3)= 4.25, p=.24), again with similar scores seen across all groups (*Mdn*= 25.5 for control, *Mdn*= 28 for Dianette, *Mdn*= 29.5 for Ovranette, *Mdn*= 24 for Yasmin). Once again, the null hypotheses 5 and 6 fail to be rejected.

Lastly, it was found that OCP had no significant effect on GHQ scores (H (3)= 2.11, p=.55), again with similar scores seen across all groups (*Mdn*= 11 for control, *Mdn*= 11.5 for Dianette, *Mdn*= 13 for Ovranette, *Mdn*= 11 for Yasmin). Scores for all participants were below the threshold considered as evidence for distress. In line with the previous hypotheses, null hypotheses 7 and 8 fail to be rejected.

Physiological variables. It was found that the type of OCP had an effect on SBP (H (3)= 16.16, p=.01), as those not taking an OCP had lower SBP than those using Dianette and Ovranette (*Mdn*= 115 for control,

Mdn= 127.25 for Dianette, *Mdn*= 124.25 for Ovranette and *Mdn*= 122 for Yasmin). There was a significant difference between the control group and Dianette users as well as Ovranette users. Thus, the null hypotheses 11 and 12 are rejected.

Table 2: *Correlations Coefficients among Variables*

1 BMI	1	2	3	4	5	6	7	8	9	10	11	12
2 SBP		.324**	.218	.234*	.001	.086	.105	-.025	-.119	-.122	-.004	-.071
3 DBP			.617**	-.014	.278*	.425**	.499**	-.033	.123	.227*	.159	.042
4 Age				.276*	.152	.291**	.359**	.150	.014	.063	.038	.010
5 OCP					.107	.024	.017	.060	.335**	.292**	.257*	.297**
6 Week						.796**	.675**	-.161	.090	.201	.085	.049
7 Purpose							.701**	-.169	.141	.242*	.238*	.202
8 Diagnoses								-.109	.085	.199	.119	.060
9 BDI									.303**	.199	.186	.278*
10 BAI										.662**	.608**	.774**
PSS-14											.573**	.603**
GHQ												.733**

* significant correlation at $p < .05$, ** significant correlation at $p < .01$

No significant effect of OCP on DBP was found ($H(3)= 6.67$, $p= .08$), with similar scores seen across all groups (*Mdn*= 66 for control, *Mdn*= 71.5 for Dianette, *Mdn*= 69.5 for Ovranette, *Mdn*= 69 for Yasmin). Thus, it was not possible to reject null hypotheses 9 and 10.

Discussion

The aim of this present study was to investigate the effects of OCP use on psychological (BDI, BAI, GHQ and PSS-14) and physiological variables, such as blood pressure. The null hypotheses (1-8) failed to be rejected as there was no effect of OCP use on the psychological variables measured. There was also no significant effect of OCP use on diastolic blood pressure and so, null hypotheses 9 and 10 are retained. However, the 11th null hypothesis was rejected as there was a significant effect on SBP due to OCP use. The highest SBP mean was seen in Dianette and thus null hypothesis 12 was also rejected.

There was no significant effect of OCP use on depressive symptoms. The majority of participants did not display clinically relevant levels of depressive symptoms as 61% scored below 10 on the BDI. Additionally, 82% of participants' scores fell below 16, scores ranging from 14 to 19 indicate mild depression (Beck et al, 1961), this is broadly in line with expectations as 21% of participants indicated that they had received a previous diagnosis of a psychological disorder. Results from Toffol et al. (2011) also showed no significant effect on BDI scores due to OCP use. The present study examined OCP use to a greater degree than Toffol et al. as three OCP brands were investigated, however results were similar, thus the present study adds to the validity of Toffol et al..'s results (Toffol et al., 2011).

As well as this, a randomised placebo-controlled trial found no significant difference in depressive scores (measured with the CES-D) at the end of the trial between those in the OCP group and those in a placebo group (O'Connell et al., 2007). While depressive symptoms were measured differently, the results are in line with those seen presently. Depressive symptoms measured through BDI in Duke et al. (2007) also found no effect due to OCP. However, the non- OCP group was not defined, so it is unclear whether participants of this group were using other hormonal contraceptives or not (Duke et al., 2007).

The present study contradicts research (Kulkarni, 2007; Nilsson & Almgren, 1968; Segebladh et al., 2009), which has suggested that OCPs have an impact on depressive symptoms. One such study found that OCP users had higher depressive symptoms than non-users; participants were interviewed twice during a two-week period. It is worth noting that this method of measurement differs greatly from the BDI self-report used within the present study and previous others (Kulkarni, 2007). Psychiatric symptoms were also reported as higher in an OCP group when compared with a control group in a study looking at women in the post-partum period (Nilsson & Almgren, 1968). However, this study once again does not describe the type or potency of the OCP and looks at a sample far removed from the sample used in the current research. Segebladh et al. (2009) reported that depression and anxiety were common in women who reported adverse mood effects from the OCP, however the authors could not say whether these conditions were due to the OCP or were pre-existing. The study used differing measures for assessing anxiety and depression than the present study and did not mention which type of OCP the participants were using. There are a number of possible reasons why this present study achieved dissimilar results; different measurements, differing samples and the differentiation of the OCP into brand type helps to explain the differing results.

There was no significant effect of OCPs on anxiety. Anxiety scores across all groups are within the range described as 'moderate anxiety'. The vast majority of the participants, 86%, had a BAI score of 22 or below. Scores below 16 are considered mild anxiety Scores ranging from 16-25 are described as moderate anxiety scores. Any score above 36 is described as a cause for concern (Beck & Steer, 1993). Fourteen percent of participants scored above 22 in the BAI. Only two participants in the study scored above 36. Those who scored above 22 may be explained by the 21% which have previously been diagnosed with a psychological disorder.

This result is contrary to Segebladh et al. (2009), who reported that depression and anxiety were common in women who reported adverse mood effects from the OCP, however the authors could not say whether these conditions were due to the OCP or were pre-existing. The study used differing measures for assessing anxiety and depression than the present study and did not mention which type of OCP the participants were using. Pre-existing psychological diagnoses were also not established. These major differences may be responsible for the differences between the current results and the results seen in Segebladh et al.'s (2009) study.

There was no significant effect on perceived stress levels due to the OCP. The PSS-14 norm for the general community is a mean of 25.4 (*SD*= 7.8) (Stauder & Thege, 2006). Dianette and Ovranette groups were slightly above the norm. Over half of the participants, 56%, had PSS-14 scores higher than the norm for the general community (Stauder & Thege, 2006). The higher stress scores may be due to the population of the sample, as the study was conducted during term time and many of the participants were students, thus higher PSS-14 scores could be due to academic stresses although it is unusual that high anxiety scores are not also seen if this is the case. The PSS-14 has not been used in relation to OCP use in the past so the results gained from this study are unique.

GHQ scores for each group were within a healthy range, below 15, (Goldberg & Williams, 2000), once again there was no significant effect due to OCP use. The majority of participants, 77%, scored below this threshold indicating no evidence of distress. However, 8% of participants had GHQ scores above 20 indicating 'severe problems and psychological distress'. These figures are roughly in line with the fact that 21% of participants had a psychological diagnosis. The difference in the numbers (8% and

21%) may be due to psychological diagnosis versus a diagnosis that would contribute to a score of 'severe psychological distress'. Previous research also found that OCP use had no impact on GHQ scores (Toffol et al., 2011). There were no significant differences between control and OCP groups in relation to psychological variables, as the majority of scores for the measures were within the normal ranges.

A number of physiological effects were found; SBP was found to be associated with: week of the pill cycle, purpose and blood pressure. There was a significant difference between the control groups SBP and the break week, week four. The fact that it is week four in which there is a significant effect on blood pressure raises the question of whether the OCP controls for an increase in blood pressure or whether this increase in week four is due to a build-up of hormones resulting from daily intake of OCPs over the previous three weeks. Recent research has found prolonged hormonal contraceptive use is linked to an increase in the risk of glioma, malignant brain tumours, and this risk increases with duration of use (Andersen et al., 2014). Similarly, during times of the inactive pill phase, grey matter volume was found to be larger than times of active pill use in the fusiform face area (FFA), parahippocampal gyrus (PPA) and cerebellum (Pletzer, Kronbichler, & Kerschbaum, 2015). Although, there has been no evidence to suggest SBP is related to grey matter volume, these results of increased physiological risk due to prolonged hormonal contraceptive use collaborate the findings of the present study relating to week 4 of the pill, suggesting hormone build up causes a number of negative health impacts.

There was a significant increase in SBP and DBP ratings for those who answered 'other', in relation to the purpose of their OCP use and an increase in SBP for those who were using the OCP for both contraceptive and acne treatment purposes, compared to the control group. Likewise, prior research has found a link between purpose of OCP use and outcome variables. However, this effect was seen in psychological variables, namely depressive symptoms (Duke et al., 2007). From the findings of the present study and Duke et al.'s study, it appears that the purpose for which women choose to use OCPs has an impact on their health. The opposite should also be considered; health may impact on the purpose of OCP use. This finding suggests that reasons other than pharmaceutical ones may be behind the differences in variables, other possible reasons have not been investigated as of yet.

Additionally, OCP and SBP were found to be associated with one another; in particular those taking Dianette and Ovranette had higher SBP than the control group. It is unsurprising that SBP is related to OCP use, as high blood pressure is listed as a side effect on nearly all OCPs (see for example Health Products Regulatory Authority, 2016), and has been found to increase with contraceptive use (Khaw & Peart, 1982). Cyproterone-containing OCPs such as Dianette have been associated with higher risk of developing high blood pressure and side effects of this condition, like blood clots, when compared with levonorgestrel-containing OCPs such as Ovranette (Vasilakis-Scaramozza & Jick, 2001. As hypothesised, Dianette has the highest SBP rating, it also contains the largest dose of oestrogen, if only slightly. However, there was a significant effect on SBP in Ovranette; Ovranette and Yasmin contain the same dose of oestrogen. Weir et al. (1974) suggest oestrogen may be responsible for increased blood pressure, however if this was the case the present study would have seen similar levels of SBP in Ovranette and Yasmin. As mentioned previously, it is difficult to examine the effects of oestrogen in OCPs as in Ireland the most commonly prescribed OCPs contain the same oestrogen component and have similar doses. This suggests the reason for increased SBP could be due to reasons not yet investigated. Variables such as length of time on the OCP could be investigated in the future to establish their relationship with SBP.

There were positive correlations found between reported diagnosis of a psychological disorder, BDI and GHQ scores, although not with BAI or PSS-14. The results add to the validity of the BDI and GHQ questionnaires. The strong positive correlation found between the BDI and BAI confirmed results for previous studies which link depression and anxiety symptoms to each other (Lovibond & Lovibond, 1995). As suggested by research in relation to depressive symptoms and stress, BDI was also correlated strongly with PSS-14 and GHQ (Hammen, 2005). Similarly, the strong association

between BAI, GHQ and PSS-14, is broadly in line with the finding that anxiety and perceived stress are correlated (Bergdahl & Bergdahl, 2002; Spada et al., 2008).

The majority of participants, 64%, had a BMI which fell in the range considered healthy, 11% were classed as obese, and 6% underweight. The remaining 19% were classed as overweight. A representative sample among 18–64-year-olds, obtained from the National Adult Nutritional Survey (NANS), found 39% percent of the population had BMI considered within the normal range (Irish Universities Nutrition Alliance, 2011). A larger percent of the sample was considered obese or overweight than the present study, 21% of the women were obese and 31% were considered overweight. The present study showed healthy BMI among participants, although it should be noted the current sample were younger and only consisted of females unlike the NANS sample (Irish Universities Nutrition Alliance, 2011).

Physiological variables were restricted to BMI and blood pressure within the present study, however other physiological variables could be examined in relation to OCP use as seen in a recent study. Naturally cycling women were compared with users of either OCPs which contain androgenic (results in the development of male characteristics) ("Medical Definition of Androgenic", 2015), or anti-androgenic progestins, they found that OCP use altered the structure of the brain. It was revealed that relative grey matter volumes were larger in OCP users than non-users. The results show that the differences are attributable to anti-androgenic progestins. The study suggested that the duration of OCP use relates to the structural changes in the brain (Pletzer et al., 2015). The present study did not define OCPs based on androgenicity, although two of the OCPs used do have anti-androgenic properties, Dianette and Yasmin ("Dianette 2mg/35microgram coated tablets", 2014, "Yasmin 0.03 mg/3mg film-coated tablets" 2014), while Ovranette is an androgenic progestin ("Ovranette 150micrograms/30micrograms Coated Tablets", 2014. The present study could be expanded in the future by examining androgenic effects on psychological variables such as BDI, BAI, PSS-14 and GHQ, physiological effects could also be monitored through variables such as blood pressure.

Limitations of present study and suggestions for further research.

One of the major limitations of this study is the small sample size. The small number of participants and the difficulty in recruitment of participants on each specific OCP meant group sizes were small. The sample size may have been improved from a wider recruitment criterion and thus making divisions of participant's based on OCP type at a later stage; the reason behind not doing this was the need for participants not to be using any other form of hormonal treatment, in order to keep accurately defined groups. As the sample was taken from the University of Limerick community the mean age was relatively low (M = 23); although the age range was from 18- 44, 81% were 26 or under. The low mean age means it is difficult to generalize the results of the present study to a full range of women of child-bearing age. As well as this, the majority of the sample were students. This also decreased the ability to generalize the results. These limitations in relation to the sample could be improved in future research by increasing the time allocated to the testing phase as well as recruiting from different places and thus, ideally increasing the sample size.

The week of the control group's menstrual cycle was not taken, preventing us from extensively examining the impact of week of pill packet and week of cycle. In future research, the interaction between week and contraceptive could be explored further provided that week is seen to have an effect on the variables. Menstrual cycle is known to contribute to depressive symptoms in some way (Kiesner, 2009) so future research could compare depressive symptoms during the natural cycle and the cycle of the pill within participants.

It may be considered a limitation that measures were not taken over a period of time. This would have enabled us to look at the change in physiological and psychological variables across the cycle. Future research could focus on these changes and this may allow us to understand why the fourth week of the pill cycle seems to be the point at which there is a significant effect on SBP. By measuring responses

to the questionnaire at various points during the cycle, researchers could grasp more extensive knowledge into the psychological as well as physiological changes which occur during a natural cycle and the cycle of the OCP.

Information regarding the length of OCP use or whether it was the participants first OCP was not taken. This may have impacted upon the results as it does not account for a possible 'survivor bias' (Elton, Gruber, & Blake, 1996). Those experiencing negative effects are likely to discontinue OCP use (or switch to a different OCP) early on. Pletzer et al. (2015) discussed the confounding variable of duration of OCP use; this is a measure which was not examined in the present study. The current study does not differentiate between those using the OCP for a short period of time and those who have been using it for several years. A question pertaining to length of use could be added in further research in order to investigate the effect of duration of use on psychological and physiological variables. While it was ensured that the control group was not taking any hormonal contraceptives, the question of how long they had not been taking them was not addressed. This means that some control participants may have been taking OCPs in the recent past and this could have impacted results. In future research, participants who had recently been using OCP could be excluded from the control group so as to ensure there is no lingering effect of the OCP on their responses.

As OCPs with varying progestin potencies were examined in the present study, future research could focus on the effects of different oestrogen in OCPs, although OCPs with an oestrogen component other than ethinyl estradiol are difficult to find. Those with larger differences in the dosage of ethinyl estradiol could also be examined.

Strengths of the Present Study

There are a variety of strengths which differentiate the present study from those carried out previously. The use of three OCPs within this study allowed differences in outcomes between different brands of OCP to be seen. This sets the study apart from many others and has proved extremely useful in the case of blood pressure, where increased blood pressure was seen in users of some OCPs, but not others. The differentiation is vital as it allows us to examine why one OCP may have different effects compared with another. The OCPs were chosen as they were all widely prescribed brands, and each contained a different progestin component.

This present study has extensively examined the relationship between OCP use and various psychological variables, while others had concentrated solely on depression. As anxiety, stress and depression symptoms have been shown to be associated with one another (Lovibond & Lovibond, 1995; Spada et al., 2008), it was deemed worthwhile to also investigate their relationship with OCPs.

Practical Implications

The present research confirms previous findings that the OCP does not have an effect on psychological well-being. This result adds to an evidence base which demonstrates the lack of effect of OCPs on psychological variables. While there is an increase in blood pressure, this is widely accepted and can be easily monitored by general practitioners. Further evidence that OCP use does not impact on psychological well-being is a reassurance to many women. The fact that a highly popular contraceptive method has been shown to be safe in regard to psychological health is positive. The findings relating to increased blood pressure confirm previous findings and highlight the possible dangers of the OCP for those with hypertension. The present piece of research adds to the literature and expands upon previous results as it demonstrates that a wider variety of psychological variables are not impacted by OCP use.

Conclusion

In summary, while the sample size of the study is small the findings are of great interest. The confirmation of a lack of impact on psychological variables due to OCP use is very positive. As Yasmin contained the most potent of the progestins in the drugs it was expected that differences would be seen between Yasmin and the control group, however this was not the case. While the impact on blood pressure

is expected, what is of particular interest is the impact on blood pressure dependent on the week of the pill. This present research paves the way for further research in the area, in particular looking at the impact that the "break week" appears to have on blood pressure. The present study confirms the findings of previous studies and also allows for a more extensive examination of various OCPs.

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