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Effects of Patient Monitoring While on Hormonal Contraceptives: A Benchmark Project

Ashley Simo
asimo@patriots.uttyler.edu

Effects of Patient Monitoring While on Hormonal Contraceptives: A Benchmark Project

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by

Ashley Simo

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Contents

Acknowledgments

First and foremost, I would like to thank the ever-loving God that I serve. He has heard my cries and prayers. Even when wanting to quit, he gave me the strength I needed to continue. I would like to also express my gratitude to my amazing sisters and friends who have supported and encouraged me thus far. This advancement in my nursing career has not been an easy feat, but you all have made it much easier. Thank you Dr. Greer, Dr. Rizer and Dr. Hermanns for being true angels. I have experienced some of my hardest moments during this journey to becoming a Family Nurse Practitioner. I greatly appreciate the understanding, kind words, guidance and patience displayed towards me by these amazing professors. Also Dr. McAlister who worked with me through numerous emails, phone calls and Zoom session to ensure I was more than prepared for my Capstone. Lastly, I would like to thank my wonderful parents who gave me the push I needed to even begin this advancement in my nursing career.

Executive Summary

Historically, the advancements made by the hormonal contraceptive industry have been astronomical. Scientists were able to formulate a medication that would mimic a women's natural hormones in order to suppress ovulation. By way of this invention, women have finally been given a method to independently control their bodies the way they see fit. While the benefits of hormonal contraceptives consist of autonomy, among many other non-contraceptive reasons, the side effects have prompted further examination of this drug. It has been discovered that this pro-woman drug came with its risks. Common complaints about depressive moods have begun to be noted and associated with these drugs.

Currently in practice, a patient may enter the clinic and request the initiation of hormonal therapy. Depending on the age, clinicians would normally recommend forms such as the oral pill or even Depo-Provera shot or an intrauterine device (IUD) as they would require less effort from the patient to maintain. While those methods may work well for some, it may not work for everyone. Without closely looking into each patient's psychological history and predisposing factors prior to choosing a contraceptive, the wrong form without close monitoring could lead to less than ideal outcomes. In order to avoid these potential life altering affects, implementing closer patient monitoring in the clinics is recommended.

This paper discusses the current clinical issue pertaining to the association between hormonal contraceptive (HC) use in women and depression. The PICOT question that stands to be evaluated in this paper is: In women currently taking hormonal contraceptives (P) how does individualized monitoring (I) compared to no monitoring (C) decrease the risk of hormonal contraceptive non-compliance related to depressive symptoms (O) over a 3-month period (T)? Upon drafting this topic, prior recommendations were made by the university's faculty, such as

feasibility of obtaining the necessary information, and how it could improve practice, which have been taken into consideration and altered.

Implementation and Benchmark Project

Rationale for the Project

Currently in the United States, depression is arguably one of the most controversial health issues to date. Depression, also known as major depressive disorder (MDD) or clinical depression has been identified as the fourth leading condition related to disability worldwide (Blanco et al., 2010). Seeking changes in current practice to reduce the negative outcomes of HC us has shown to be a crucial aspect in providing safe and effective care to patients.

Since its launch in the 1960's, HC remains one of the first treatments of choice for pregnancy prevention and hormone therapy. The medication presents in various forms, such as oral pills, intrauterine devices, and vaginal rings to name a few. HCs contain either a combination of progestin and estrogen, or progestin only. The wide variety HC methods help to accommodate numerous women with their lifestyle and health needs. For many, their HC use is just one facet of treatment used to balance hormones, as well as reducing the effects of gynecological disorders. The clinical issue nurse practitioners face with prescribing HC's, are its risks and benefits. HC over the years has received negative reviews, as it has been related to predisposing factors women may have that places them at an increased risk for side effects during use. Side effects including, but not limited to, weight gain, headaches and mood swings, are all possible contributing factors to depression in women. Given the extensive studies behind the benefits of HC use, it has become a top of choice for women. However, its link to potential adverse effects on a woman's psychological wellbeing is still in question. These effects then lead to lack of adherence to their regimen. Adequate monitoring of women on these contraceptive

drugs, notably in the first six months of use is vital. As the effectiveness of hormonal contraceptive monitoring is assessed, changes to current practice can be adjusted in order to provide safer and more efficient care to patients.

The aim of this paper is to cultivate a plan for change in clinical practice on the use of HC monitoring in decreasing the psychological mood effects to improve adherence. The synthesis of this nursing research is designed in such a way that it evaluates the PICOT question at hand. A conclusion to the 3-month project will provide results as to whether this change should be implemented continuously. The findings of this paper can then be integrated into the professional setting to help in improving the quality of health care.

Literature Synthesis.

While inquiring about the relationship between hormonal contraception use and depression, the use of specific keywords were used in order to condense the search results of peer reviewed articles through online databases such as, CINAHL Complete and Academic Search Complete. The databases were searched using the keywords: hormonal contraception, birth control, major depressive disorder, depression, weight gain, and risk factor. The searches of databases were further condensed to those published between the years of 2013-2020 and written by nurses and medical providers. The search was further adjusted as needed to include similar key terms to advance the search for relevant evidence. The articles selected for this literature review were heterogeneous, ranging from systematic to literature reviews. It was observed that out of the 12 articles analyzed, common results were concluded. A further review of each study follows.

During 2013-2016, 8.1% of American adults aged 20 and over experienced depression in a given 2-week period. Prevalence estimates that women (10.4%) were nearly twice as likely to

have depression than men (5.5%) (Brody et al., 2018). Unfortunately, these prevalence estimates provided do not differentiate between populations that are considered at higher risk, such as women taking hormonal contraception. It has been estimated that among the women selected to represent that majority of women, roughly 82% of women currently use or have used HC during their reproductive years (Cheslack-Postava et al., 2014). Given that percentage, lifetime prevalence estimates are about 36.8% for the development of psychological disorders for women.

Several studies have determined a correlation between HC use and first prescription and diagnosis of depression in women (Yonkers et al., 2017). Researchers of the Danish Sex Hormone Registry Study looked at young women ages 15-34 over the course of 13 years. They noted that out of those women, 55.5% were current or resent users of HC. From the overall study population of over a million, more than 133,000 first prescriptions for anti-depressants were prescribed. In addition, McCall et al. (2017) found that more than 23,000 women who received their first diagnosis of depression. The incidence rates of first use of antidepressants and first diagnosis of depression were 2.2 per 100 person-years and 0.3 per 100 person-years, respectively, among users of hormonal contraceptives (McCall et al., 2017). This finding bolsters the concern that the negative outcomes on psychological mood with HC use has a causative link to the onset of side effects over the course of a woman's adulthood.

Most notably, depression rates in adults have been linked to long-term use beginning in teenage years. A study of 1,236-woman ages 20-39 reported 16% of the study group who began HC during their teenage years met the criteria for depression. Whereas only 9% of women who began HC in their adult years met the criteria for depression. Suggesting that the use of HC can have long standing psychological affects later in life if initiated during early reproductive years.

Absolute risk of depression has been determined to vary among women using certain forms of hormonal contraception. Prior studies conducted by scholars suggest the link between HC and the development of depression is low in otherwise healthy women (Begsdotter et al., 2017). However, HC's such as the pill, carry higher risks than its' counterparts, as it increases a woman's risk of depression by up to 80% when compared to nonusers (Zettermark et al., 2018). Of note, reports of safety among intrauterine devices (IUD) are being concluded, when compared to other forms of birth control that relasease synthetic forms of hormones. IUD's deliver no form of hormones and are an effective and reversible form of contraception and remain good options for women who seek pregnancy prevention without the potential mood side effects (Ouyang et al., 2019).

Influences of HC use has since been related to increased psychological side effects, which continue to be one of the contributing factors of non-compliance towards their HC regimen (Schaffir et al., 2016). In women who's aim is to prevent pregnancy or alleviate unfavorable menstrual symptoms, discontinuation of these medications pose more threat. Schaffir et al. (2016) noted that the main cause of non-compliance with medication is the side effects. Studies show that it take one to three months for a woman's body to become acustom to HC use. It is at this time where many side effects such as acne, bleeding irrgularites, and also some prementrural symtpmtoms level out. However, depressive mood side effects have been shown to peak after the first six months of use. While the relative risk for complications are low, adjustments or avoidance of certain hormonal contraceptive should be adopted by clinicians for women who report signs of mood changes. When paired with this information, it would be beneficial for healthcare practitioners to incorporate the use of HC patient monitoring to seek out further evidence and expand knowledge of such issues. Taking note of this trend will allow

practitioners to continuously implement the monitoring protocol and change behaviors to promote compliance, as well as highlight the alternative hormonal contraceptive options that may be deemed effective for women with various ailments (Phiri et al., 2015).

Considering the aspects that promote depression, one article focuses on women's perceived body image while on HC. It mentioned that during the course of therapy, there were participants that removed themselves from taking the HC due to negative perceived body image from the HC. The article affirms the notion that HC increases the risk for psychological effects, as the medication was proven to cause weight gain as well as breast tenderness and abnormal peripheral edema, thus promoting depressive symptoms (Morotti et al., 2017). For some women, their perception of body image is trivial compared to the potential outcomes of not being on HC. While, for others the change can bring forth negative feelings towards it, leading to affected mood and cessation of the treatment.

In clinical practice, practitioners understand that adequate monitoring for women taking hormonal contraceptive and health risks is required. Making use of the self-report questionnaires made available such as, Clinically Useful Depression Outcome Scale (CUDOS-D) is beneficial for risk monitoring. CUDOS-D has proven to be a reliable measurement of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) definition of clinical depression. A psychiatric clinic conducted a study of 1,115 clinically depressed patients, who were given CUDOS-D questionnaire as part of their initial and subsequent treatments. Of the participants, 98% reported that the CUDOS-D questionnaire took less than 3-minutes to complete, as well as 40% who expressed their preference to integrate CUDOS-D into their visits to better monitor their treatments (Zimmerman et al., 2018). The patients depend on the counseling, care and proper disclosure provided by the practitioners throughout their treatment as well as effectiveness in

alleviating possible side effects. Utilizing the detailed history to create a personalized treatment plan along with advising patients on the various contraceptive forms, providers are able to help patients judge the level of risk for exhibiting potential side effects (Ryan et al., 2014). This will allow the patient to take control of their care alongside the counseling of a licensed practitioner, which may result in increased adherence to treatment, as well as lower psychological effects.

Project Stakeholders

Our patients who range from childbearing, to menopausal ages are the most important stakeholders for this project. Also, those impacted by this project include but not limited to the owners of the North Dallas Women's Clinic, the healthcare providers, such as the nurse practitioners, medical assistants, and pharmaceutical contracts in which the clinic is affiliated with. Depression affects not only the patient, but those around them as well, including their families and those around them in various ways. The healthcare providers in this project are collaborating to implement a new protocol to efficiently monitor the patient while on their HC regimen

It is important to understand the possible implications of HC and monitor how it can positively or negatively affect those involved. "Integrating the expertise of the stakeholders in the implementation of this project is useful in strengthening the project by forming academic partnerships in order for the constant exchange of knowledge and methods to promote patient safety and wellbeing." (Melnyk & Fineout-Overholt, 2019, p. 274). A lot is at stake when implementing a new project into practice. However, with careful planning and consideration for all those who will potentially be affected will help in the planning and follow-through of this change.

Implementation Plan

The location for the change project will take place at North Dallas Women's Clinic, where the practitioners see various patients from adolescents to adulthood. At this clinic, women receive family planning services as well as prescriptions for hormonal contraceptives and referrals to specialized women centers. In order to determine cause for change, data regarding the occurrence of HC cessation and non-adherence, as well as pre-existing reports of mood changes in selected study group are needed. Although specific training is not necessary, each role has a potential impact on the implementation of this project. By utilizing the knowledge of the nurse practitioner and their vast knowledge of women's health, along with the knowledge of the different forms of HC provided by the pharmaceutical department, optimizing patient care is made possible through the integration of each interpersonal role.

Permission from the facility itself is needed to conduct this project, as well as from the selected patients. Fortunately, many resources are available to aid this project, as this project has access to nearby allies in the pertaining field. Barriers exist in the efforts to implement this project. Compliance from healthcare providers to accept and adapt to the change in practice is one step. Adding on additional steps to their routine at may come as an inconvience, but with continued practice and reinforcement full adjustment is expected. To minimize these barriers, a set schedule/plan for implantation will be created and given to those involved in the project. Reminders will also be sent out to complete the necessary tasks. In order to find applicable patients and enact the project, there is a potential need to access the electronic health record (EHR). Suitble patients include those who are scheduled to begin a HC treatment withing the next two- weeks or those who have began a treatment in the past two- weeks. Prior the start of the project, flyers will be made and placed on bulletin boards for patients to view and seek

involvement if interested. This recruitment method will also bring in needed new patients to the clinic.

During the three-month course of the project, the graduate student as well as the healthcare provider will evaluate the course of the HC regimen and conduct personalized monitoring of each patient. Implementing the monitoring will include determining women who are within the first month of beginning a HC regimen. Upon approval of participation, an initial survey will be conducted on day one to determine their choice of HC, perceptions of the medication, and potential pre-existing reports of depression to create a baseline. Thereafter, a survey will be sent out electronically via the patients preferred method of communication (i.e. phone call, text, or email) every three- weeks for three-months. Special attention must be paid to identify patients whose scores are increasing. Providers will then take a closer look at the patient to identify any contributing factors. The goal of a long-term implementation of this change is to show a decrease in CUDOS-D scores during the course of treatment, if previously higher. At the end, the patient will be scheduled for a final follow-up appointment ninety days after continuous use of the HC. An assessment for any changes to their psychological wellbeing will then be compared to their baseline. By implementing this project, we expect to help provide the patient with sufficient education and possible safer alternatives based on their needs.

Timetable/Flowchart

Implementation of the patient monitoring project will begin with the start of the semester. On August 31st, 2020, a meeting with the clinic office manager, Dr. Machupali, Ms. Anush, WHNP, in order to deliver project proposal, and identify potential patients who will be reached to join this study. Once approved, a clear outline and purpose for this change will be outlined and given during a presentation to the office staff- billing manager, business manager, referral

coordinator, schedulers, and the medical assistant team lead on September 1st. During this presentation, any questions or suggestions to better tailor this change to better align with the clinics processes will be answered and considered. A week will be taken in order to reach out and receive acceptance from at least 10 patients, as well as apply any minimal changes to the project. On Monday, September 7th formal training will begin. The MD, and WHNP will receive training first, as they are the forefront of this project. Here a discussion about the clinics specific or general provider protocol for hormonal contraceptive initiation. Next, training with the medical assistants, which is split into 15-30-minute sessions, will begin and take place for two days. Their understanding of the CUDOS-D questionnaire and interview process for patients undergoing HC is crucial to the success of this project as they will be the ones delivering these to the patients during the initial and follow-up visits. Training will end September 10th so that a mock trial can take place Friday, September 11th to confirm understanding. Monday, September 14th will be the official start of the implementation which will commence on for until November 30th.

Data Collection Methods

Upon completion, evaluation of the benefits of hormonal contraceptive monitoring will be based on the patients' reports of symptoms suggesting depression using the Clinically Useful Depression Outcome Scale (CUDOS-D), as this scale can be used without extra costs for the purpose of this project. The checklist of points the providers should hit such as, asking the patient how their course of HC treatment is going. Do they notice any side effects? If so describe them, as well as asking about their adherence to the medication- have they missed a dose? Are they considering a new form or method? These questions will help assess the success of this project. In order to determine the impact of this project against the women's health clinic, an

additional short patient satisfaction survey will be sent out regarding patient's overall approval with the new implemented monitoring. From there. access to new enrollment and retention of patients will be assessed.

Cost/Benefit Discussion

With any implementation of change, there is some cost associated with the initial startup. Funding will be needing in order to cover the costs of training, which will be applied to the staff's education hours. An estimated one to two educational hours will be allocated to each staff member in order to cover the training days. On average, the six staff members that comprise the medical assistants, scheduler, and referral coordinator make an estimated $11-20 per hour, which will cost the clinic $22-40 per employee. A maximum of $300 will be needed to cover the costs of training. The remainder costs associated with this three-month project is minimal. The CUDOS-D form is readily available via the internet. Purchases are small and only require paper and printouts for flyers, costing $25 for paper and ink. The participants do not need to make frequent visits as monitoring will be done offsite. Overtime, the cost analysis of implementing this project should be beneficial for both the clinic and the patients, as positive outcomes can bring in more patients from referrals. This project allows for guaranteed better care that is patient-centered, more reliable and lastly safe, which in return grants fewer out-of-pocket expenses and visits in regard to switching HC forms overtime. The cost to benefit ratio justifies the implementation of this intervention. Not only will it benefit the patient but also provide outstanding reviews and new clients to the clinic. This in return will provide added income to the clinic.

Discussion of Results

Unfortunately, due to the COVID-19 pandemic, implementation of this project was prohibited. Given the nature of the women's health clinic, and the uncertainty of the virus course, the office manager made the decision to restrict visitors entering the clinic. Implementation was halted due to meeting and training dates being postponed until further notice. The projected results are that patients are monitored and assessed more closely during the first 3-12 months of the start of HC use.

Implementing closer patient monitoring will elicit positive outcomes for not only the patient but for the clinic as well. With the use of CUDOS-D and patient surveys, the overall patient satisfaction scores are expected to increase. Patients will be given an opportunity to express how their treatment plan is going during each follow-up. Providing patients with opportunities for their voices to be heard and a say in the management of their care will in return improve adherence to treatment plans. The goal is to provide care that bridges the gap in depression related symptoms in women as a result of HC use. Lastly, an increase in patient satisfaction is expected to increase based on appreciation and concern for the patient's well-being on HC. As patient satisfaction increases, so will the referrals to the clinic, thus presenting an increase in revenue.

Conclusions/Recommendations

Studies suggest a correlation between hormonal contraception and the risk of psychological mood effects. However, with the implementation of patient monitoring and CUDOS-D questionnaire, the extent is decreased. It is clear from a research standpoint that there is a need for adequate management prior and throughout the course of hormonal therapy for those on these forms of treatment. As certified trained practitioners, it is our duty to provide safe and effective care. Through the implementation of HC monitoring, evidence has shown an

improvement if efficiency throughout the HC course, as well as patient management. By way of frequent follow-ups and assessments of mood changes during the initial first months of HC start, patients were more inclined to adhere to their regimen. With the added trust and security this monitoring has provided, patient satisfaction has increased, thus promoting the clinic in the long run. The end result is that there will be less women who develop signs and symptoms of depression despite when they began HC use, and adherence to their regimen will improve.

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Appendix A

Synthesis Table

PICOT Question: In women currently taking hormonal contraceptives (P) how does individualized monitoring (I) compared to no monitoring (C) decrease the risk of hormonal contraceptive non-compliance related to depressive symptoms (O) over a 3 month period (T)?

Evidence Synthesis Table

Studies	Design	Sample	Intervention	Outcome
A	Randomized control trial	n=224	COC- DMS PB-DMS	COC use yielded increased rates of DMS PB had lowest risk for DMS
B	Descriptive study	n= 39	OC PD occurrence	OC use showed inc risk of PD occurrence
C	Systematic Review-Meta analysis	n= 1000000	HC- dx of DMS	HC showed positive correlation between HC use nd dx of D in adult years
D	Descriptive study	n= 21	VR- SPBI NS w/ VR- SPBI NHC- SPBI	VR showed risk of SPBI NS w/ VR showed increased rates of SPBI NHC yielded lower rates of SPBI when compared
E	Systematic review-Meta analysis	n= 216	ICD-IA NICD- IA	ICD training showed improved attitudes and compliance NICD decreased compliance with medication
F	Descriptive study	n= 90	BCT w/ HC	BCT yielded improvement with HC use
G	Literature review	n= 46	CHC- DMS	CHC use decreased positive mood
H	Cohort study	n= 490	PMS- CHC use PMS- NCHC use	Inc PMS symptoms with CHC use NCHC users yielded lower risk for PMS symptoms
I	Cross sectional study	n= 815,662	HC- PDU	PDU inc in NCHC users Decreased PDU in HC users
J	Descriptive study	n= 1115	MDD-CUDOS-D	Decreased symptoms of MDD with CUDOS-D use

Legend: A = Bengtsdotter et al.,, B = Cheslack-Postava, Keyes, Lowe, & Koenen, C = McCall, Becca, & Rosenquist, D = Morotti et al., E = Ouyang, Peng, Botfied, & McGeechan, F = Phiri, King, & Newell, G = Shafrir, Worly & Gur, H = Yonker et al., I = Zettermark, Vicente & Merlo, J =Zimmerman, Harris, Martin & McGongial. BCT- Behavior change techniques, COC- Combined oral contraceptive, CUDOS-D- Clinically Useful Depression Screen, DMS- development of mood symptoms, HC- hormonal contraceptive, (n)ICD- (non)intrauterine contraceptive device, OC- Oral contraceptive, MDD- Major depressive disorder, NHC- non-

hormonal contraceptive, NS- non-smoker, PB- placebo, PD- psychiatric disorder, PDU- psychotropic disorders, PMS- premenstrual syndrome, SPBI- self perceived body image, VR- vaginal ring.

Outcomes Table: Effect of Hormonal Contraceptive on Depressive symptom Outcomes

	A♦	B	C♦	D♦	E♦	F	G	H	I	J♦
DMS	↑	↑	↑	↑	↓*	NC	↓	↑	↑	↓
PMS	↑	NC	NC	↑	NC	NC	↓	↑	↑	↓*
Adherence	NC	NE	↓	↓*	↑	↑	↑	↓	NE	↑*
SM	NE	NE	NE	↑*	NE	NE	NE	↑	↑*	NE

* = statistically significant findings
♦ = higher level evidence

Recommendations

Hormonal contraception (HC) use is highly prevalent among women, notably in women of reproductive ages and those who are pre or menopausal. Due to ethical concerns, there is a decrease in the amount of controlled trials to help further and strengthen research regarding the association between HC and depression. However, with the studies available, recommendations for practice remain achievable. Based on the synthesis table, articles recommendations for practice can be made.

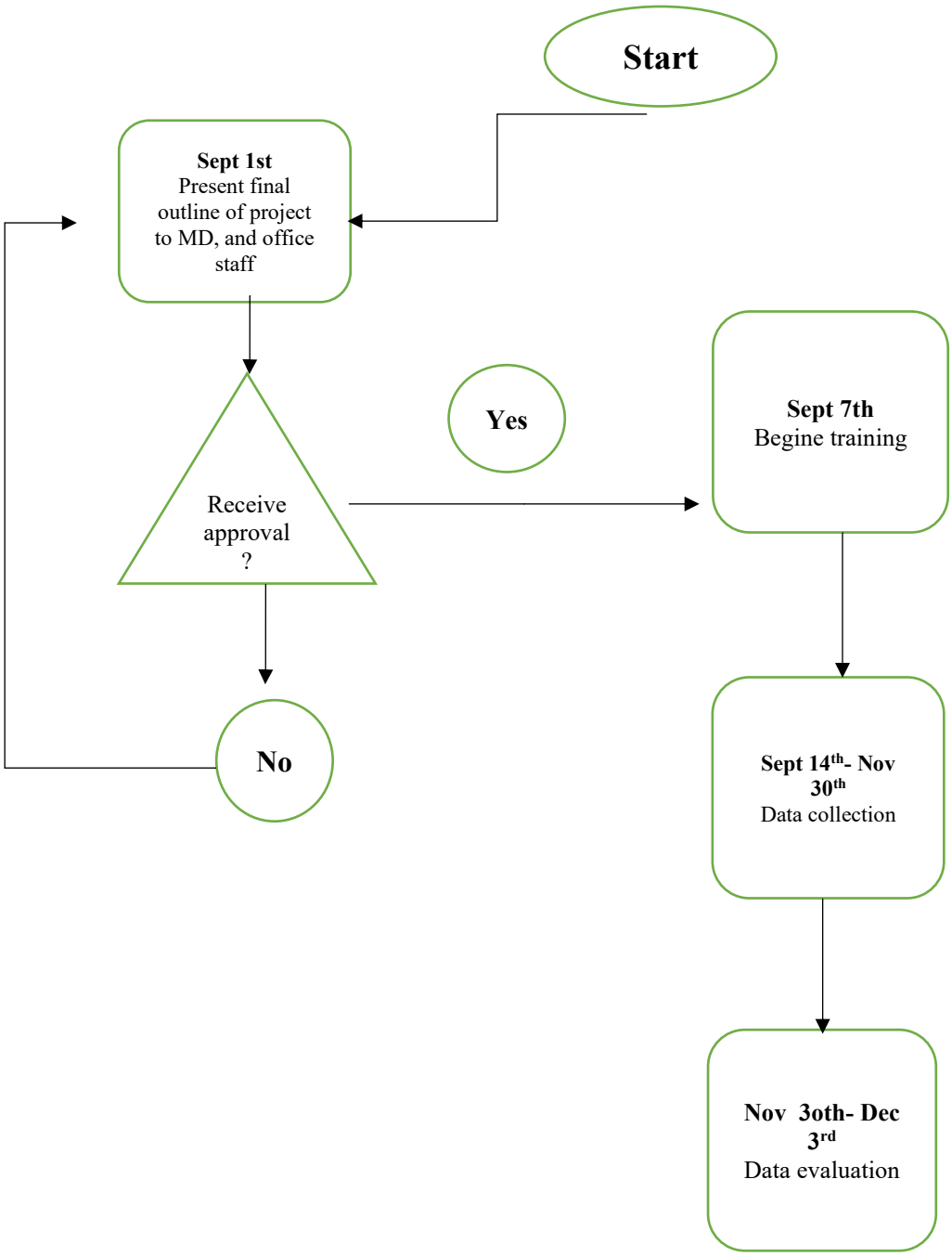
Predisposing factors such as current smoker,s drug user as well as previous or current psychiatric disorders apart from depression must be assessed. According to Morotti et., . and Zettermark, Vicente, & Merlo, smoking is associated with increased instances deprrssive mood symotoms as lowered adherence to medication. Use of personalized patient monitoring or counseling with the prescribing provider and patient should be conducted to evaluate the pros and cons of a patient initiaing a HC regimen. By doing so, we help provide the patient with sufficient education and possible safer alternatives based on their needs.

While the majority of studies displayed a total increase of depressive symptoms as it correlates with HC use, a couple studies showed an ulterior effect. Ouyang, Peng, Botfied, and McGeechan's studies showed evidence of a lower risk of depressive symptoms in patients who received prior counseling before HC was initiated as well as continued monitoring throughout a specific duration of time during the HC use. For women with predisposing factors that increase their risk of exhibiting depressive symptoms, I recommend these women to be asses more frequently, instead of every 3 weeks, a weekly CUDOS-D survey will be sent via email or texted link weekly after the first 3 weeks. Also, I recommend that participants provide a seven-day journal. The journal should include current mood, and overall mood for the days prior to the survey, if any changes to behavior, energy level, and motivation have been noted. By providing this log, the provider is able to determine the best form of treatment based on the findings.

Lastly, due to the numerous forms of HC whether it is an oral pill or transdermal patch, it can be difficult to determine the best route for the patient. Having a hormonal contraception information binder that includes side effects, what they are best used to treat, maintainability, compatibility with certain comorbidities etc. should be available to use in practice.

Appendix B

Flowchart



Appendix C

Instrument

Name_____ Date_____ **DEPRESSION SCALE**

INSTRUCTIONS
This questionnaire includes questions about symptoms of depression. For each item please indicate how well it describes you during the PAST WEEK, INCLUDING TODAY. Circle the number in the columns next to the item that best describes you.

RATING GUIDELINES
0=not at all true (0 days)
1=rarely true (1-2 days)
2=sometimes true (3-4 days)
3=often true (5-6 days)
4=almost always true (every day)

During the PAST WEEK, INCLUDING TODAY....

1. I felt sad or depressed	0	1	2	3	4
2. I was not as interested in my usual activities	0	1	2	3	4
3. My appetite was poor and I didn't feel like eating	0	1	2	3	4
4. My appetite was much greater than usual	0	1	2	3	4
5. I had difficulty sleeping	0	1	2	3	4
6. I was sleeping too much	0	1	2	3	4
7. I felt very fidgety, making it difficult to sit still	0	1	2	3	4
8. I felt physically slowed down, like my body was stuck in mud	0	1	2	3	4
9. My energy level was low	0	1	2	3	4
10. I felt guilty	0	1	2	3	4
11. I thought I was a failure	0	1	2	3	4
12. I had problems concentrating	0	1	2	3	4
13. I had more difficulties making decisions than usual	0	1	2	3	4
14. I wished I was dead	0	1	2	3	4
15. I thought about killing myself	0	1	2	3	4
16. I thought that the future looked hopeless	0	1	2	3	4

17. Overall, how much have symptoms of depression interfered with or caused difficulties in your life during the past week?
    0) not at all
    1) a little bit
    2) a moderate amount
    3) quite a bit
    4) extremely

18. How would you rate your overall quality of life during the past week?
    0) very good, my life could hardly be better
    1) pretty good, most things are going well
    2) the good and bad parts are about equal
    3) pretty bad, most things are going poorly
    4) very bad, my life could hardly be worse

Appendix C

Evidence Table

PICOT Question:

In women currently taking hormonal contraceptives (P) how does individualized monitoring (I) compared to no monitoring (C) decrease the risk of hormonal contraceptive non-compliance related to depressive symptoms (O) over a 3 month period (T)?

PICOT Question Type (Circle): Intervention Etiology Diagnosis or Diagnostic Test Prognosis/Prediction Meaning

Place your APA Reference here (Use correct APA reference format including the hanging indentation):

Bengtsdotter, H., Lundin, C., Danielsson, K. G., Bixo, M., Baumgart, J., Marions, L., … Poromaa, I. S. (2018). Ongoing or previous mental disorders predispose to adverse mood reporting during combined oral contraceptive use. *The European Journal of Contraception & Reproductive Health Care*, *23*(1), 45–51.

Brody, D. J., Pratt, L. A., & Hughes, J. P. (2018). Prevalence of Depression Among Adults Aged 20 and Over: United States, 2013–2016. *NCHS Data Brief*,(303), 1-8. Retrieved from https://www.cdc.gov/.

Cheslack-Postava, K., Keyes, K. M., Lowe, S. R., & Koenen, K. C. (2014). Oral contraceptive use and psychiatric disorders in a nationally representative sample of women. *Archives of Womens Mental Health*, *18*(1), 103–111.

McCall, W., Becca, R., & Rosenquist, P. (2016). Study suggests hormonal contraception can lead to depression. *The Brown University Psychopharmacology Update*, *28*(1), 4-5. doi:10.1002/pu.30199

Melnyk, B. M., & Fineout-Overholt, E. (2019). *Evidence-based practice in nursing & healthcare a guide to best practice* (4th ed.). Philadelphia: Wolters Kluwer.

Morotti, E., Casadio, P., Guasina, F., Battaglia, B., Mattioli, M., & Battaglia, C. (2017). Weight gain, body image and sexual function in young patients treated with contraceptive vaginal ring. A prospective pilot study. *Gynecological Endocrinology*, *33*(8), 660–664.

Ouyang, M., Peng, K., Botfield, J. R., & Mcgeechan, K. (2019). Intrauterine contraceptive device training and outcomes for healthcare providers in developed countries: A systematic review. *Plos One*, *14*(7).

Phiri, M., King, R., & Newell, J. N. (2015). Behaviour change techniques and contraceptive use in low and middle income countries: a review. *Reproductive Health*, *12*(1). doi: 10.1186/s12978-015-0091-y

Schaffir, J., Worly, B. L., & Gur, T. L. (2016). Combined hormonal contraception and its effects on mood: a critical review. *The European Journal of Contraception & Reproductive Health Care*, *21*(5), 347–355.

Yonkers, K. A., Cameron, B., Gueorguieva, R., Altemus, M., & Kornstein, S. G. (2017). The Influence of Cyclic Hormonal Contraception on Expression of Premenstrual Syndrome. *Journal of Womens Health*, *26*(4), 321–328. doi: 10.1089/jwh.2016.5941

Zettermark, S., Vicente, R. P., & Merlo, J. (2018). Hormonal contraception increases the risk of psychotropic drug use in adolescent girls but not in adults: A pharmacoepidemiological study on 800 000 Swedish women. *Plos One*, *13*(3).

Zimmerman, M., Harris, L., Martin, L., & McGonigal, P. (2018). Reliability and validity of a self-report scale for daily assessments of the severity of depressive symptoms. *Psychiatry*

Research.:doi:10.1002/ajcp.12273

Citation: (i.e., author(s), date of publication, & title)	**Conceptual Framework**	**Design/ Method**	**Sample/ Setting**	**Major Variables Studied and Their Definitions**	**Measurement of Major Variables**	**Data Analysis**	**Study Findings**	**Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses])**
Author, Year, Title	**Theoretical basis for study** **Qualitative Tradition**		**Number, Characteristics, Attrition rate & why?**	**Independent variables (e.g., IV1 = IV2 =)** **Dependent variables (e.g., DV =)**	**What scales were used to measure the outcome variables (e.g., name of scale, author, reliability info [e.g., Cronbach alphas])**	**What stats were used to answer the clinical question (i.e., all stats do not need to be put into the table)**	**Statistical findings or qualitative findings (i.e., for every statistical test you have in the data analysis column, you should have a finding)**	• **Strengths and limitations of the study** • **Risk or harm if study intervention or findings implemented** • **Feasibility of use in your practice** • **Remember: level of evidence (See Melnyk & Finout-Overholt, pp. 32-33) + quality of evidence = strength of evidence & confidence to act** • **Use the USPSTF grading schema http://www.ahrq.gov/clinic/3rduspstf/ratings.htm**
Bengtsdotter et al., 2018, Ongoing or Previous Mental Disorders Predispose to Adverse Mood Reportng During Combined Oral Contraceptive Use	None stated	Randomized control trial	Total- 224 screened women 2 excluded. 20 withdrew 202 included, meeting study requirments. 20-29 years of age	IV- COC DV- development of adverse mood reportings	MINI DRSP Scales	CI RR P M	57.8% -COC and 44.4%- placebo placebo, M difference 1.3 (95% CI 0.3–2.3) DRSP scores- placebo/COC M difference 0.3 (95% CI --0.5–1.1)	**Strengths-** • Double-blinded RCT • Included exclusion criteria • Tabled results **Limitations-** • Limited number of women • Subjects located through advertisement • Study inclusion date not clear **Risk-** There is risk for harm in implemetinging studies on psychological eefects of COC. Feasability- This study is feasible to cnduct in practice. **Level of Evidence**- Level II **USPSTF Grade**: B- Moderate
Cheslack-Postava, Keyes, Lowe, & Koenen,	None stated	Descriptive Study	NHANES database 1999-2004 Women 20-39 years	**IVs**: OC use **DVs:** Development of	Stata/IC 10.1	OR RR CI R P	PD occurance- 2.6% in past-year/ never OC users 8.7% in former users FY- (OR=0.34; p<0.05)	**Strengths** • Search criteria stated • Tabled results • Highlight of key findings • Included the exclusion criteria **Limitations** • Review was limited to English language

2015, Oral Contraceptive Use and Psychiatric Disorders in a Nationally Representative Sample of Women				psychiatric disoders.			PY- (p<0.05) OR of 0.37 PY prevalence- PD, GAD, MDD- #.6% 3.4%, 9.4%	• Only one major database used • Information n consistency of OC use/timing There is risk associated with implementing this study. **Feasibility**- this study is not easily feasible and resources are not readily available **Level of Evidence-** I **USPSTF Grade**- B
McCall, W., Becca, R., & Rosenquist, P. (2016). Study suggests hormonal contraception can lead to depression. *The Brown University Psychopharmacology Update, 28*(1), 4-5. doi:10.1002/pu.30199	None stated	Descriptive study	Total- 1 million women 15-34 yo From 2000-2013	**IV**- HC **DV**- dx of depression	None stated	RR, P, IR	133,0001st prescriptions 23,000 1st diagnosis HC users-2.2 (0.3) per 100 person years Nonusers- 1.7 (0.28) per 100 person years	**Strengths** • Search criteria stated • Tabled results • Included the exclusion criteria • Large sample size. **Limitations** • Review was limited to English language • Study inclusion start date not clear • Possibility the subjects may have misunderstoonor incorrectly answered questions There is risk associated with implementing this study such as pt harm **Feasability**- this study is feasible and resurces are available **Leve of Evidence**- IV **USPSTF Grade**- B
Morotti et al., 2017, Weight Gain, Body Image and Sexual Function in Young Patients Treated with Contraceptive Vaginal Ring. A Prospective Pilot Study	None Stated	Descriptive study	Jan-Dec 2013 Total-21 eumenorrheic women 18-35 years old 19 completed study No hormonal therapy in last 6 months Non-smoker/RD users	**IVs**: VR **DVs:** Self-percieved body image	Cronbach alpha-reliable SFRS BDI MFSQ	CI P M PC	BW- (60.0±8.3; p1⁄40.050) BMI (22.1±3.1; p1⁄40.028) BDI- (7.7 ± 5.0 versus 5.8 ± 3.1)	**Strengths** • Search criteria stated • Inclusion/exclusion criteria included • Data retrieval source **Limitations** • Study was limited to English • Data source conducted on small homegeneos group • Larger study needed. • Potential for under/over-reporting in questionnaries • Limited study population **Riso of harm-** Implementing this study is feasible in practice with little harm risk. **Feasability**- Feasable to recreate **USPTSF Grade**- B

Ouyang, Peng, Botfied, & McGeechan, 2019, Intrauterine contraceptive device training and outcomes for healthcare providers in developed countries: A systematic review	None Stated	Systematic Review w/ meta-analysis	**Primary search**: PRISMA guidelines used Jan-Mar 2017 216 studies **Population**-F 14-44 years of age; ICD-9 code	**IVs**: ICD training **DVs:** Improved attitudes/use	Cronback alpha-reliable	HR CI P M R	FP- (70.4% vs. 9.9%) [16] NP-(12% vs. 66%) OR = 2.4, 95%CI: 1.10 to 5.33)	**Level of evidence**- VI **Strengths** • Inclusion of Meta-analysis • Search criteria included • Summary of inclusion and exclusion criteria included • Low risk of bias due to high quality **Limitations** • Included only observational studies • Some confounders not controlled • Differences in study population, desing and analyzing methods **Risk of harm**: There are risks in implementing this study such as: Harm to pt **Feasability**: Feasable **Level of Evidence**: Level IV **USPSTF Grade**: B
Phiri, King, & Newell, 2015, Behaviour change techniques and contraceptive use in low and middle income countries: a review	None stated	Descrpitive review	SR, RCT 90 studies selected 6 used	IV- BCT DV- Contraception use	Cochrane review	OR P	EDU: I- 37 %;40 %; 42 % across arms EDU: I-47 %,control 33 % INFO-baseline use 21.5 %, after intervention- 93.6 % Peers Info- I- 78 %, control- 59 % INFO FP:I- 20 %, control- 14 % INFO meeting: I- 23 %, control- 20 % HC containing less	**Strengths** • Search criteria stated • Data extraction completed by 2 reviewers • Tabled results • Highlight of key findings • Included the exclusion criteria **Limitations** • Review was limited to English language • Study inclusion start date not clear • Restricted to RCT only • Small study sample **Risk of Harm-**There is risk associated with implementing this study. **Feasibility**- this study is feasible and resources are available **Level of Evidence-** I **USPSTF Grade**- B **Strengths** • Search criteria included

Shaffir, Worly, & Gur, 2016, Combined Hormonal Contraception and its Effects on Mood: a Critical Review	None stated	Literature Review	Total-46 studies Within last 30yrs	**IV**-CHC **DV**- effects on mood/ discontinued use.	No outcome measuring tools	OR CI P M	androgenic progestins have fewer adverse effects on mood. Continuous/non-oral dosing of CHC has fewest mood effects; Women w/underlying MD-predisposed to mood effects	• Heterogenous studies • Summary of inclusion and exclusion criteria included **Limitations** • Study inclusion dates range begin in late 1980s • Incosistencies in methodology • Differences in study population, desing and analyzing methods **Risk of harm**: There are no risks in implementing this study **Feasability**: Feasable **Level of Evidence**: Level IV **USPSTF Grading Schema**: B- Moderate
Yonker et al., 2017, The Influence of Cyclic Hormonal Contraception on Expression of Premenstrual Syndrome	None stated	Cohort study	Total- 2 cohorts screened- 103 CHC, 387 non-CHC Randomized- 41 CHC, 21 non-CHC Mixed races	**IV**- Perimentrural symptoms **DV**- CHC use	DRSP	OR CI I^2 P M CI	Screened Cohort: F(30, 27000) = 0.35, p > 0.99, Randomized Cohort: F(30, 14000) = 0.20, p > 0.99 CHC use and symptom type -[F(10, 27000) = 3.12, p < 0.001] and the Randomized Cohort [F(10, 14000) = 3.40, p < 0.001]. depressed, hopeless, or guilty (p = 0.03); anger or irritability (p = 0.002); diminished interest (p = 0.001); difficulty concentrating (p = 0.03), feeling overwhelmed (p = 0.05), and physical symptoms (p = 0.04)	**Strengths** • Search criteria stated • Tabled results • Included the exclusion criteria **Limitations** • Review was limited to English language • Study inclusion start date not clear **Risk of Harm-**There is no risk associated with implementing this study such as pt harm **Feasability**- this study is feasible and resurces are available **Leve of Evidence**- IV **USPSTF Grade**- B
Zettermark, Vicente, & Merlo, 2018, Hormonal contraception Increases the Risk of	None Stated	Cross sectional study	Women 12-30yrs 5 year span included- 815,662 variables for inclusion- HC	**IV**-HC use **DV**- Psychotropic drug use	None noted	OR CI P	Adolescent- 1st time psychotropic drugs of 1.34 (95% CI: 1.30–1.37) association w/ psychtropic drug use-non-oral progesterone-only OR 4.47 (95% CI: 2.08–8.78) COC users had an OR of 1.52 (95% CI: 1.41–1.64)	**Strengths** • Search criteria stated • Large sample size • Tabled results • Included the exclusion criteria **Limitations** • Lack of accurate measurement • Small sample size There is risk associated with implementing this

Psychotropic Drug Use in Adolescent Girls but not in Adults: A Pharmacoepi Demiological Study			use, psychotropc drug use, socioeconomic				Adult- DMPA inj- OR of 1.56 (95% CI: 1.34–1.82). IUD- OR of 2.90 (95% CI: 2.22–3.79)	study such as pt harm **Feasability**- this study is feasible and resurces are available **Leve of Evidence**- IV **USPSTF Grade**- B
Zimmerman, M., Harris, L., Martin, L., & McGonigal, P. (2018). Reliability and validity of a self-report scale for daily assessments of the severity of depressive symptoms. *P sychiatry Research*.:doi:10.1002/ajcp.12273	None stated	Descriptive study	1,115 patients Varibales for inclusion, MDD	**IV**- MDD **DV**- CUDOS-D score	CUDOS-D	CI, z, M, P	Study size- 1,115. M= 102.7 sec to complete CUDOS-D. 40% vs. 14% prefer use in tmt plan. Z= 2.31, p. 05	**Strengths** • Search criteria stated • Inclusion criteria specidfied • Tabled results • Stated exclusion critiria • Test-retest reliability performed **Limitations** • Test-retest not performed on all study patients. • Trained diagnoster not used for on all patients. **Feasability**- This study is feasible and able to be replicated. **Level of Evidence-** Level IV **USPSTF**- B

Legend:
COC- combined oral conrceptive
MINI- Mini Interatioal Neuropsychiatric Interview
DRSP- Daily Record of Severity of Problems
CHC- Cyclic Hormonal Contraception
RD-Recreational Drug
VR- Vaginal Ring
SFRS- Stunkard Figure Rating Scale
BDI- Beck's Depression Inventory Questionnare
MFSQ- McCoy Female Sexuality Questionnare
PC- Pearson's Correlation
PD- Panic disorder
HC- Hormonal contraception
BCT- Behaviral Change Techniques

M- Median
NPA- No physican advice
OC- Oral Contraceptive
OR- Odds Ratio
P- Precentage
PAA- Physcian advice against
PE- Pulmonary embolism
POP- Progestin only
RR – Risk Ratio
R- Range