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Comparative Evaluation of Patient Satisfaction in Natural and Programmed IVF Cycles: A Randomized Clinical Trial.

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ABSTRACT

Background: While in vitro fertilization (IVF) outcomes are traditionally assessed using biological and clinical indicators, patient satisfaction is increasingly recognized as a key component of quality, patient-centered fertility care. Differences in treatment burden and experience between natural and hormonally programmed IVF cycles may influence patient perceptions and acceptance of care.

Objective: To compare patient satisfaction between natural IVF cycles and combined oral contraceptive pill (OCP) programmed IVF cycles in a randomized clinical trial.

Methods: This single-center, open-label randomized controlled trial enrolled 86 women undergoing IVF at a tertiary fertility center in Nigeria. Participants were randomly assigned in a 1:1 ratio to either a natural cycle IVF group (n = 43) or an OCP-programmed cycle IVF group (n = 43). Both groups underwent controlled ovarian stimulation using a standardized short GnRH agonist protocol. Patient satisfaction with ovarian stimulation was assessed at the end of the treatment cycle using a structured Likert-scale questionnaire. Data were analyzed on an intention-to-treat basis, with statistical significance set at $p < 0.05$.

Results: The mean satisfaction score was slightly higher in the OCP-programmed group compared with the natural cycle group (2.02 ± 0.83 vs. 1.79 ± 0.94); however, this difference was not statistically significant ($t = -1.216$, $p = 0.228$). Overall, participants in both groups reported favorable satisfaction levels with ovarian stimulation. Sociodemographic variables, including ethnicity and religion, were comparable between groups, although differences were observed in occupation and marital status.

Conclusion: Patient satisfaction with ovarian stimulation is comparable between natural and OCP-programmed IVF cycles. These findings support the use of either approach based on clinical indications, logistical considerations, and patient preference, without concern for reduced patient satisfaction.

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INTRODUCTION

Infertility is a global public health concern affecting approximately 10–15% of couples of reproductive age, with substantial psychosocial, emotional, and economic implications for affected individuals and families.[1] Assisted reproductive technologies (ART), particularly in vitro fertilization (IVF), have become established and effective treatment options for infertility, contributing significantly to improved reproductive outcomes worldwide.[2] While the success of IVF has traditionally been measured using clinical indicators such as fertilization rates, embryo development, implantation, and live birth rates, there is growing recognition that patient-reported outcomes, including satisfaction and

treatment experience, are equally critical indicators of quality of care.[3]

IVF treatment is inherently complex, involving repeated clinical visits, hormonal interventions, invasive procedures, financial burden, and prolonged emotional stress.[4] These factors may significantly influence patients' perceptions of care, adherence to treatment, psychological well-being, and willingness to pursue subsequent cycles when necessary.[5] Consequently, patient satisfaction has emerged as an essential component of patient-centered care in reproductive medicine and is increasingly recognized as a determinant of both short- and long-term treatment success.[6]

Controlled ovarian stimulation (COS) protocols represent a core element of IVF treatment and vary widely in their approach, intensity, and patient burden. [7] Natural cycle IVF utilizes the spontaneous menstrual cycle with minimal or no exogenous gonadotropin stimulation, aiming to retrieve a single naturally selected oocyte. This approach is associated with reduced medication exposure, lower cost, fewer clinic visits, and a diminished risk of ovarian hyperstimulation syndrome (OHSS). [8,9] However, concerns remain regarding cycle cancellation rates and perceived lower efficiency, which may influence patient expectations and satisfaction. [10]

In contrast, programmed IVF cycles employ hormonal manipulation often using oral contraceptive pills, gonadotropin-releasing hormone (GnRH) analogues, and exogenous gonadotropins to achieve controlled follicular development and scheduling flexibility.[11] While programmed cycles may optimize clinic workflow and increase oocyte yield, they are frequently associated with higher medication costs, increased physical discomfort, hormonal side effects, and greater treatment complexity.[12] These factors may negatively impact patients' treatment experience despite comparable clinical outcomes.[13]

Evidence suggests that patient satisfaction in ART is influenced by multiple domains, including physical burden, emotional distress, perceived control, convenience, communication with healthcare providers, and overall treatment expectations.[14,15] However, most IVF-related studies have prioritized biological and clinical endpoints, with limited attention given to systematic comparisons of patient satisfaction across different stimulation protocols.[16] Furthermore, existing studies often rely on observational designs, heterogeneous satisfaction measures, or retrospective assessments, limiting the generalizability and robustness of their findings.[17]

Randomized controlled trials directly comparing patient satisfaction between natural and programmed IVF cycles remain scarce, particularly in low- and middle-income settings where cost, accessibility, and treatment burden may play a more pronounced role in patient decision-making.[18] Understanding how different IVF protocols affect patient satisfaction is essential for informed shared decision-making, individualized treatment planning, and the optimization of patient-centered reproductive care.[19]

Therefore, this randomized clinical trial aimed to comparatively evaluate patient satisfaction between women undergoing natural IVF cycles and those undergoing programmed IVF cycles. By systematically assessing patient-reported satisfaction alongside standardized treatment protocols, this study seeks to provide evidence that may guide clinicians in balancing clinical effectiveness with patient experience, ultimately enhancing the quality and acceptability of IVF care.

MATERIALS AND METHODS

This study was conducted as a single-centre, open-label randomized controlled trial evaluating outcomes across two intervention arms. Participants who met the eligibility criteria were randomly allocated in a 1:1 proportion to either group using a simple randomization method. The study cohort consisted of women diagnosed with either primary or secondary infertility who attended the In Vitro Fertilization (IVF) clinic of the Federal Medical Centre, Abuja, a tertiary-level referral facility providing assisted reproductive services.

The study was carried out in accordance with the principles outlined in the 2013 Declaration of Helsinki governing research involving human subjects. Approval for the study protocol was granted by the Research and Ethics Committee of the Federal Medical Centre, Abuja. Written informed consent was obtained from all participants prior to recruitment, and robust safeguards were implemented to protect participant confidentiality and data privacy throughout the duration of the trial.

Women with medical contraindications to the use of combined oral contraceptive pills such as a history of thromboembolic disorders, hormone-dependent malignancies, or significant liver disease were excluded from participation. Additional exclusion criteria included women aged 21–38 years with clinical or biochemical indicators of reduced ovarian reserve or ovarian insufficiency, as well as individuals who declined enrollment or withdrew consent at any point during the study period.

INTERVENTIONS

Eligible women were allocated equally to one of two treatment arms through a concealed randomization process. Allocation was achieved using sequentially numbered, sealed, opaque envelopes containing identifiers derived from a pre-established randomization list, assigning participants to either Group A (control) or Group B (intervention).

Group A – Natural Cycle (Control)

Women assigned to Group A underwent controlled ovarian stimulation (COS) within a spontaneous menstrual cycle, without hormonal cycle preparation. A short gonadotropin-releasing hormone (GnRH) agonist regimen was employed and commenced independent of the phase of the menstrual cycle. Subcutaneous buserelin acetate (Suprefact® 1 mg/mL; Sanofi, France) was administered at a dose of 0.5 mL daily

starting on day 2 of the cycle. Follicle-stimulating hormone (FSH), either recombinant or urinary (Humog®, Bharat Pharmaceuticals, India), was initiated on cycle day 2 or 3. Starting doses were tailored according to maternal age, body mass index (BMI), antral follicle count, and baseline serum FSH concentrations. Dose adjustments included a reduction of 75 IU for women with polycystic ovarian morphology and incremental increases of 75 IU for every 5 kg/m² rise in BMI above standard dosing thresholds.

Group B – OCP-Programmed Cycle (Intervention)

Participants in Group B received menstrual cycle programming with a combined oral contraceptive pill prior to COS. Microgynon® (150 µg levonorgestrel and 30 µg ethinyl estradiol; 21 active tablets with 7 placebo) was taken orally once daily at a consistent time for at least two weeks. OCP administration began between days 10 and 30 of the cycle preceding IVF treatment, with the final active tablet taken on the day immediately before commencement of COS. Withdrawal bleeding typically occurred within the first week of the subsequent cycle. Ovarian stimulation thereafter followed the same short GnRH agonist protocol used for Group A.

Ovarian Stimulation and Monitoring

Both groups underwent COS using an identical short GnRH agonist approach. Buserelin acetate (0.5 mL subcutaneously once daily) was started on cycle day 2, followed by individualized FSH stimulation with Humog®. Injections were administered subcutaneously in the peri-umbilical region. Ovarian response was evaluated through serial transvaginal ultrasonography and serum hormonal assays, conducted every 48 hours from the seventh day of stimulation. Dose modifications were guided by follicular growth until dominant follicles reached diameters of 18–21 mm and endometrial thickness ranged between 8 and 15 mm.

Ovulation Trigger and Oocyte Retrieval

Final oocyte maturation was induced using intramuscular human chorionic gonadotropin (Hucog® 5,000 IU; Bharat Pharmaceuticals, India), administered 35–36 hours before oocyte retrieval. Oocyte collection was performed under transvaginal ultrasound guidance with conscious sedation using intravenous pethidine (100 mg) and midazolam (5 mg). Aspirated follicular fluid was immediately transferred to a pre-warmed incubator at 37 °C for oocyte identification and enumeration by the embryology team.

Fertilization, Embryo Culture, and Transfer

Fertilization was achieved either by conventional IVF or intracytoplasmic sperm injection (ICSI), depending on semen quality. Embryos were cultured in a closed, single-step medium within a CO_2 incubator (6% CO_2, ambient oxygen). Fertilization assessment was performed 16–18 hours after insemination. Cleavage-stage embryos were evaluated on day 2 according to cell number, blastomere symmetry, and degree of fragmentation (Grades 1–4), while blastocyst development was assessed on day 5. Embryo transfer was carried out under transabdominal ultrasound guidance using a Wallace® catheter, with up to three high-quality embryos deposited 0.5–1 cm below the uterine fundus. Luteal phase support consisted of vaginal progesterone (Cyclogest® 400 mg twice daily), intramuscular progesterone (Gestone® 100 mg every 48 hours), oral estradiol valerate (Progynova® 4 mg three times daily), low-dose aspirin (Vasoprim® 75 mg daily), and oral prednisolone (Perilon® 5 mg twice daily).

Pregnancy Assessment and Follow-Up

Biochemical pregnancy was assessed 14 days following embryo transfer by measuring serum β-human chorionic gonadotropin levels. Clinical pregnancy was confirmed through transvaginal ultrasonography demonstrating an intrauterine gestational sac with fetal cardiac activity. Participants were followed for six weeks after confirmation, after which care was transitioned to routine antenatal services. Women with negative pregnancy outcomes received post-treatment counselling regarding further management options, including repeat IVF attempts, alternative stimulation strategies, or the use of donor gametes.

PRIMARY OUTCOME MEASURES

The primary outcome measure was the difference in patient satisfaction scores between natural and OCP-programmed IVF cycles, assessed using a structured Likert-scale questionnaire at the end of the treatment cycle.

SAMPLE SIZE DETERMINATION

The required sample size was calculated using an established formula for comparing outcomes between two independent groups. The estimation incorporated the anticipated difference in mean values between the study arms, the assumed variance within the population, a two-tailed alpha level of 0.05, and a statistical power of 80% to reliably detect the target effect size. An additional allowance of 20% was made for possible attrition and incomplete responses. Based on these parameters, a total of 86 participants were needed, with 43 individuals assigned to each group.

RECRUITMENT

Eligible women attending the IVF clinic were enrolled consecutively based on their presentation and willingness to participate. The principal investigator or a trained research assistant approached all women diagnosed with infertility and scheduled for ovarian stimulation. Eligibility and exclusion criteria were verified through review of medical records and patient interviews. Women with contraindications to oral contraceptives, evidence of diminished ovarian reserve or ovarian failure, or those who declined participation were excluded.

The study's purpose, procedures, potential benefits, and possible risks were communicated in clear, accessible language. Participants were assured of the confidentiality of their information and the safety of study procedures. Written

informed consent was obtained from all women who demonstrated understanding of the study and voluntarily agreed to participate.

RANDOMIZATION AND ALLOCATION CONCEALMENT MECHANISM

Allocation Sequence Generation

Randomization was conducted using WINPEPI software, which produced a balanced sequence numbering 1 to 86. Each number corresponded to either Group A (control) or Group B (intervention). Participants in Group A underwent ovarian stimulation without prior use of combined oral contraceptives (OCPs), while those in Group B received OCPs for menstrual cycle programming before stimulation.

Allocation Concealment

To ensure concealment, the numbered assignments were placed inside small, sealed opaque envelopes, which were stapled and stored securely. This procedure prevented prior knowledge of group allocation by study personnel.

Implementation

Eligible participants selected an envelope at random, and the number inside was referenced against the randomization chart to determine assignment to Group A or B. Randomization was performed by the principal investigator or a trained research assistant who was not involved in oocyte retrieval or embryology procedures, maintaining separation between treatment allocation and outcome assessment.

Data Collection

A structured proforma was used to record socio-demographic characteristics, reproductive and gynecological history, BMI, and other pertinent clinical information. Data were collected by trained research assistants and reviewed for completeness and accuracy.

Data Management

Information from the proformas was entered into IBM SPSS Version 23, with double-entry verification performed to minimize transcription errors. All electronic datasets were securely stored on a password-protected computer accessible only to the research team.

Data Monitoring

Trial oversight adhered to the study center's standard operating procedures, ensuring compliance with the protocol, accurate data recording, and participant safety. The principal investigator regularly monitored adherence to study procedures throughout the trial period.

DATA ANALYSIS

All analyses were conducted following the intention-to-treat (ITT) approach. Participant characteristics were described using descriptive statistics, with continuous variables presented as means ± standard deviations and categorical variables reported as counts or percentages. Group comparisons were performed using the student's t-test for continuous variables and Pearson's chi-square test for categorical variables. Findings were summarized in tables and figures where appropriate. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 86 participants were randomly assigned in equal numbers to the OCP group ($n = 43$) and the natural cycle group ($n = 43$). The mean age was 32.10 ± 3.96 years for the natural cycle group and 33.05 ± 3.65 years for the OCP group, representing a statistically significant difference ($p = 0.001$). Significant differences were also noted in participants' occupation and marital status ($p < 0.05$), whereas no significant differences were observed for ethnicity ($p = 0.418$) or religion ($p = 0.211$). The majority of participants were married and identified as Christians.

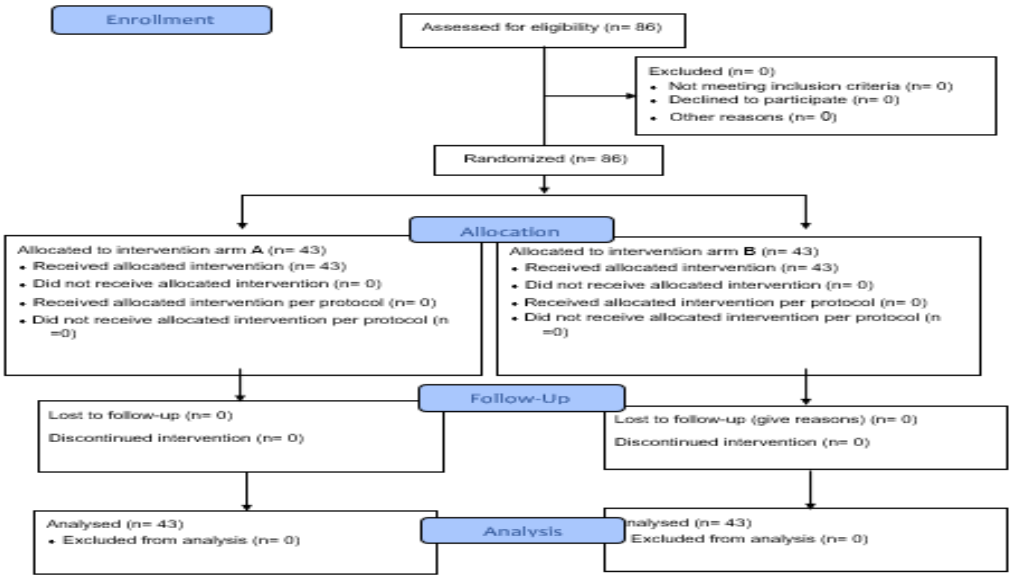

Figure 1: Study Flow Diagram

Table 1: Socio-demographic characteristics of study population

Parameters	**OCP Group (n=43)**	**Natural cycle Group (n=43)**	***Chi square value***
	Mean ±*SD*/n (%)	Mean ±*SD*/n (%)	
Mean age (year)	±SD 33.05±3.65	33.05±3.96	
Age grouping (years)			
1- 25	1(50%)	1(50%)	
26 -30	**10(41.7%)**	**14(58.3%)**	
31 -35	**20(64.5%)**	**11(35.5%)**	**0.247**
36 -40	**12(41.4%)**	**17(58.6%)**	
Ethnicity			
Hausa	**5(31.3%)**	**11(68.8%)**	
Yoruba	**9(52.9%)**	**8(47.1%)**	**0.418**
Igbo	**16(53.3%)**	**14(46.7%)**	
Others	**13(56.5%)**	**10(43.5%)**	
Occupation			
Employed	**31(64.6%)**	**17(35.4%)**	**0.006**
Unemployed	**9(35.3%)**	**23(64.7%)**	
Student	**3(50.0%)**	**3(50.0%)**	
Marital Status			
Married	**38(63.3%)**	**22(36.7%)**	
Single	**2(10.5%)**	**17(89.5%)**	**0.001**
Divorced	**3(42.9%)**	**4(57.1%)**	
Widow	**0(0%)**	**0(0%)**	
Religion			
Christianity	**35(55.6%)**	**28(44.4%)**	
Islam	**7(33.3%)**	**14(66.7%)**	**0.211**
Others	**1(50%)**	**1(50%)**	

The OCP and natural cycle groups were similar in mean age (33.05 ± 3.65 vs. 33.05 ± 3.96 years), ethnicity, and religion ($p > 0.05$). Significant differences were observed in occupation and marital status, with more employed and married participants in the OCP group ($p = 0.006$ and $p = 0.001$, respectively). Age group distribution did not differ significantly between groups ($p = 0.247$).

Table 2: Patient's level of satisfaction

Parameters	***Study group***	***N***	***T***	***Mean***	***SD***	***P-value***
Patient's level of satisfaction						
	OCPs Group	43	1.216	2.02	0.831	*0.228*
	Natural cycle	43		1.79	0.940	

There was no statistically significant difference in level of satisfaction for simulation among OCPs participants (*M*=2.02, *SD*=0.831) and participants with natural cycle (*M*=1.79, *SD* =0.940); *t* (84) = -1.216, *p*=0.228. Both groups were satisfied with stimulation.

DISCUSSION

This study evaluated patient satisfaction in women undergoing natural versus OCP-programmed IVF cycles, focusing specifically on satisfaction with ovarian stimulation. Patient satisfaction is an essential component of IVF

treatment, as it not only reflects the tolerability of medical protocols but also influences adherence to treatment, psychological well-being, and overall success rates[1, 2]. High satisfaction has been associated with reduced stress, improved cooperation, and greater continuation of fertility treatment, which are critical for achieving optimal outcomes[3].

In this study, no statistically significant difference was observed in patient satisfaction between the two groups. The OCP-programmed group reported a mean satisfaction score of 2.02 (SD = 0.831), while the natural cycle group had a mean of 1.79 (SD = 0.940); $t(84) = -1.216$, $p = 0.228$. These findings suggest that both protocols are generally acceptable to patients and provide a similar quality of experience during ovarian stimulation. Importantly, both groups reported satisfaction levels above the midpoint of the scale, indicating positive perceptions of their care.

The comparable satisfaction observed may be explained by several factors. First, proper patient counseling and individualized monitoring during stimulation likely minimized anxiety and enhanced confidence in the treatment process[4, 5]. Second, although programmed cycles involve the use of OCPs to synchronize and schedule stimulation, which could potentially increase perceived complexity or burden, the predictable timing and structured follow-up may have offset these drawbacks. Patients may have appreciated the scheduling convenience and reduced uncertainty inherent in programmed cycles, leading to satisfaction levels comparable to those in natural cycles[5].

Satisfaction with stimulation is influenced not only by logistical aspects but also by the physical and emotional experience of IVF. Ovarian stimulation can be associated with discomfort from injections, bloating, fatigue, and anxiety about treatment outcomes [6, 7]. In this study, the similar satisfaction levels across groups suggest that both protocols were equally well tolerated in terms of physical side effects and psychological burden. This is consistent with previous research indicating that effective patient education, clear communication, and supportive clinical care can mitigate stress and discomfort, thereby maintaining high satisfaction regardless of stimulation protocol[8].

Patient satisfaction is also shaped by expectations and previous experiences. For instance, women with prior fertility treatments may have different benchmarks for tolerability compared to treatment-naïve patients[3]. While this study did not stratify participants by prior IVF experience, the overall positive satisfaction scores imply that both protocols are broadly acceptable across a typical clinical population.

Clinically, these findings have important implications. OCP-based programmed cycles offer logistical advantages for both patients and clinics, such as flexibility in scheduling, coordination of procedures, and optimization of laboratory resources. The absence of a negative impact on patient satisfaction supports the use of these cycles when indicated, allowing clinicians to balance clinical efficiency with patient-centered care[5]. Furthermore, maintaining high satisfaction may reduce treatment discontinuation, a common challenge in IVF, and contribute to better overall outcomes[2, 4].

STRENGTHS AND LIMITATIONS

This randomized clinical trial employed a robust design with intention-to-treat analysis, minimizing bias and enhancing the validity of the findings. By focusing on patient satisfaction, the study contributes valuable patient-centered evidence to IVF research, an area often dominated by clinical outcome measures. Standardized clinical protocols across both groups further strengthened internal consistency, while conducting the study in a low-resource setting increased its practical relevance.

However, the single-center design may limit generalizability. The sample size, although adequate for primary analysis, may not have detected subtle differences in satisfaction. The use of quantitative assessment tools and the open-label design may have influenced subjective responses. Additionally, satisfaction was assessed after only one treatment cycle, restricting conclusions about long-term patient experiences.

CONCLUSION

Patient satisfaction with ovarian stimulation is high and comparable between natural and OCP-programmed IVF cycles. These findings support the clinical flexibility to choose either protocol based on patient preference, scheduling convenience, or clinical indications, without compromising patient experience.

RECOMMENDATIONS

Based on the comparable levels of patient satisfaction observed between natural and programmed IVF cycles, clinicians should consider offering both approaches as acceptable options, tailoring cycle selection to individual patient preferences, clinical indications, and resource availability. Counseling should emphasize that satisfaction with ovarian stimulation is similar across both protocols, allowing patients to participate more actively in shared decision-making. Future studies involving multiple centers, larger sample sizes, and mixed-methods designs are recommended to further explore patient experiences, including psychological and emotional dimensions, across repeated IVF cycles.

AUTHOR CONTRIBUTIONS

Idea/Concept: Augustine Osayande, Atemie Gordon, Okafor C. Nwachukwu, John Ekweani; Design: Augustine Osayande, Atemie Gordon, John Ekweani, Okafor C. Nwachukwu, Collins E. Iyelobu, Michael J. Ofem; Control/Supervision: Augustine Osayande, John Ekweani, Collins E. Iyelobu, Michael J. Ofem, Amiete E. Fetepigi; Data Collection and/or Processing: Augustine Osayande, John Ekweani, Collins E. Iyelobu, Michael J. Ofem, Amiete E. Fetepigi, Okafor C. Nwachukwu; Analysis and/or Interpretation: Amiete E. Fetepigi, Okafor C. Nwachukwu;

Literature Review: Atemie Gordon, Amiete E. Fetepigi, Okafor C. Nwachukwu; Writing the Article: Augustine Osayande, Atemie Gordon, Okafor C. Nwachukwu; Critical Review: Augustine Osayande, Atemie Gordon, John Ekweani, Collins E. Iyelobu, Michael J. Ofem, Amiete E. Fetepigi, Okafor C. Nwachukwu

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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