

STUDY PROTOCOL

Contraceptive Counselling and Prescribing Practices for Women With Chronic Diseases: A Mixed-methods Study Protocol in Malaysian Primary Care

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ABSTRACT

Introduction: Safe and effective contraception is crucial for women with chronic diseases, who face higher pregnancy-related risks such as congenital anomalies and preterm births. Primary care doctors, as the first point of contact, play a critical role in contraceptive counselling and prescribing. However, the factors influencing their practices, particularly in Malaysia, remain underexplored. This study aims to identify factors associated with contraceptive counselling and prescribing for women of reproductive age with chronic diseases among primary care doctors in Peninsular Malaysia. **Methods:** A concurrent mixed-methods design will be used. Phase 1 involves the development and validation of a self-administered questionnaire. Phase 2 consists of a cross-sectional survey among approximately 660 doctors, using the validated questionnaire distributed via REDCap platform, and qualitative exploration through 20 online focus group discussions (FGDs) analysed using NVivo. Independent variables include socio-demographic characteristics, contraceptive-related experience, knowledge, and attitudes; dependent variables are counselling and prescribing practices. Quantitative and qualitative data will be integrated during interpretation stage to provide a comprehensive understanding of influencing factors. **Discussion:** The study will generate evidence on provider-side determinants of contraceptive care, informing national training modules, clinical guidelines, and policy interventions. Findings will support the refinement of existing continuing medical education (CME) and LPPKN programs, helping tailor capacity-building efforts. Ultimately, this may improve access to appropriate contraceptive counselling and reduce adverse reproductive outcomes among women with chronic diseases in Malaysian primary care. **Trial Registration:** This trial has received approval from the National Medical Research Registration of Malaysia (NMRR) (NMRR ID-24-03525-REG).

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INTRODUCTION

Safe and effective contraception has significant potential to improve women's reproductive health and aligns with Sustainable Development Goal (SDG) 3 of the World Health Organisation, which targets a reduction of the maternal mortality ratio (MMR) to less than 70 per 100,000 live births by 2030 [1]. Despite these efforts, unintended pregnancies, particularly among women with chronic diseases, remain a major global health challenge and a pressing reproductive and public health concern [2].

Unintended pregnancies are defined as pregnancies that occur when a woman does not wish to conceive either at the present time or in the future [3], are linked to adverse outcomes such as preterm birth, preeclampsia, and higher rates of caesarean delivery. In low- and middle-income countries, an estimated 74 million unintended pregnancies occur annually, leading to approximately 25 million unsafe abortions and 47,000 maternal deaths [4].

In Malaysia, unintended pregnancies are common, with 42.9% of pregnancies classified as unintended, according to a national study [5]. This is particularly concerning given the rising prevalence of chronic diseases such as diabetes, hypertension, and bronchial asthma among women of reproductive age. The Malaysia National Health and Morbidity Survey 2023

reports increasing rates of hypertension and diabetes among women aged 45 and younger [1]. Women with chronic conditions are at higher risk of adverse perinatal outcomes, including congenital anomalies, preterm birth, macrosomia, preeclampsia, renal complications, and both maternal and fetal mortality [6], [7], [8]. Ensuring that women with chronic diseases are well-prepared for pregnancy is crucial to improving maternal and child health outcomes.

Delaying pregnancy until a woman's chronic condition is optimally managed has been shown to improve pregnancy outcomes. This can be achieved through effective contraceptive counselling and appropriate contraceptive prescribing by healthcare providers, as recommended by the CDC's Preconception Care Workgroup and Select Panel on Preconception Care [9]. However, contraceptive prevalence among women with chronic conditions varies considerably depending on the type of contraception and the underlying medical condition [10]. For example, while Bangladesh reports a contraceptive prevalence rate of 68.0% [11], Malaysia shows a much lower rate of only 28.8% among women with diabetes, despite the wide availability of contraceptive services, including in rural clinics [12]. This discrepancy raises concerns about the effectiveness of family planning services in Malaysia.

Although training programmes such as continuing medical education (CME) sessions and modules developed by the National Population and Family Development Board (LPPKN) are available, these initiatives have not sufficiently translated into consistent, evidence-based contraceptive counselling and prescribing practices among doctors [13]. Existing programmes are often generalised and may not adequately address the complex needs of women with chronic conditions. Moreover, many training sessions available lack practical, case-based learning and post-training evaluation, limiting their effectiveness on clinical behaviour change.

While patient-side barriers such as cultural beliefs, fear of side effects, or partner opposition have been previously explored, this study focuses on provider-side factors because healthcare providers are a modifiable point of intervention within the health system [14]. Improving providers' knowledge, attitudes, perceived confidence, and addressing structural barriers are key strategies to strengthen contraceptive counselling practices and ultimately improve reproductive outcomes for women with chronic illnesses.

To date, few studies have investigated provider-related factors influencing contraceptive use among

women with chronic diseases, and there is limited research on this topic within the Malaysian context. However, studies from the USA and Nigeria identified barriers such as limited provider knowledge of modern contraceptive methods, perceptions toward counselling, time constraints, competing demands related to chronic condition management, and the influence of providers' positive beliefs and perceptions on counselling and prescribing practices [15], [16].

In view of these gaps, this article presents a study protocol to evaluate contraceptive prescribing practices among primary care doctors in Peninsular Malaysia. The study will examine factors such as sociodemographic characteristics, clinical experience, and knowledge of contraception. It will also explore the facilitators and barriers to optimal practices in contraceptive counselling and prescribing for reproductive-age women with chronic diseases, which is an essential step towards reducing unintended pregnancies among this high-risk population.

METHODS

Study Location

The study will involve primary care doctors, including family medicine specialists and medical officers, working in public health clinics in Peninsular Malaysia. Malaysia is geographically divided into Peninsular Malaysia and East Malaysia. Peninsular Malaysia comprises four main regions: the Northern Region (Perak, Penang, Kedah, and Perlis), the Central Region (Selangor and the Federal Territories of Kuala Lumpur and Putrajaya), the Southern Region (Melaka, Negeri Sembilan, and Johor), and the Eastern Region (Kelantan, Terengganu, and Pahang). East Malaysia consists of Sabah and Sarawak.

Participants for the Phase 1 study will include primary care doctors (medical officers and family medicine specialists) from public health clinics in the Federal Territories of Kuala Lumpur and Putrajaya, located in the Central Region. Phase 2 will expand to involve primary care doctors from selected health districts in the Northern, Southern, and Eastern Regions of Peninsular Malaysia.

Study Design

This study comprises two phases. Phase 1 focuses on the development and validation of a questionnaire to be used in the cross-sectional study in Phase 2. Phase 2 adopts a concurrent mixed-methods design, consisting of a cross-sectional study utilizing the validated questionnaire from Phase 1 and a generic qualitative study conducted through semi-structured online focus group discussions.

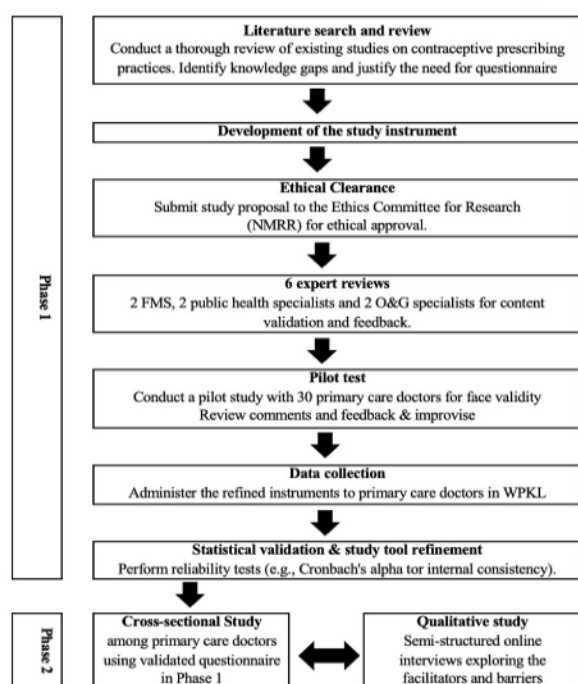


Figure 1: Flowchart of the Mixed-Methods Research Process

Study Duration

Phase 1 spanned 12 months, from January 2024 to January 2025. It began with an extensive literature review (January to April 2024), followed by questionnaire development (May to August 2024) and the creation of an online version (August to September 2024). Ethical clearance was obtained between September and November 2024. Content and face validation will take place after ethical clearance, followed by construct validity and reliability assessments, ensuring a comprehensive validation process.

Phase 2 data collection will start in February 2025 and ends in December 2025.

Phase 1: Development and Validation of a Questionnaire on Doctors' Knowledge and Attitudes towards Contraceptive Prescribing Practices.

Phase 1 of the study aims to develop and validate a questionnaire that assesses the knowledge, attitudes, and practices (including counselling and prescribing contraception) of primary care doctors regarding contraceptive prescribing habits. The process began by identifying relevant domains and developing questionnaire items through a comprehensive review of both local and international literature outlining key areas related to primary care doctors' knowledge, attitudes, and practices concerning contraceptive prescription [16], [17], [18], [19]. Existing questionnaires were adapted from previous studies. Based on the findings, the research team compiled an initial draft consisting of 22 items on knowledge, 19 items on attitude, and 5 items on practice.

The questionnaire will undergo content and face

validation to evaluate the relevance, clarity, and comprehensibility and redundancy of the items, providing preliminary data for construct validity. Subsequently, psychometric evaluations will be conducted to assess the questionnaire's construct validity and reliability, ensuring it serves as a robust and reliable tool for the study.

A total of six panel experts, including two obstetricians, two family medicine specialists and two public health experts will be recruited to assess the content validity of the questionnaire. These experts will review and rate each item in terms of relevance, clarity, and potential redundancy [20]. Each item will be graded on a scale from 1 (Not relevant) to 4 (Highly relevant). The study will employ the content validity index (I-CVI) method to determine content validity. An item will be considered relevant if it has a score greater than 0.79; items scoring between 0.70 and 0.79 will require revisions, while items with an I-CVI below 0.70 will be discarded [20]. The data obtained will be analysed, and modifications to the content will be made based on the majority opinion. For face validity, 30 primary care doctors will be selected to conduct an informal review of the questionnaire. These participants will evaluate the clarity, comprehensibility, appropriateness, and meaningfulness of the items for the target audience. Each item will be rated on a scale from 1 ("Not clear and understandable") to 4 ("Very clear and understandable"). Responses rated as 1–2 will be scored as 0, while those rated as 3–4 will receive a score of 1. Participants will also be encouraged to provide feedback and suggestions for improvements. The responses will be analysed using the item face validity index (I-FVI) [20]. For construct validity, a total of 250 primary care doctors will be recruited. This sample size considers the 41 items in the questionnaire, applying a participant-to-item ratio of 5:1 with an additional 20% to account for dropouts. Construct validity will involve several steps to evaluate both the validity and reliability of the questionnaire. Factor analysis will be performed on the collected data to identify relationships and patterns among variables and provide insights into the questionnaire's dimensionality. The internal consistency of the questionnaire will be assessed using Cronbach's alpha coefficient, with a threshold of ≥ 0.7 . Items with low corrected item-total correlation will be removed.

Finally, the reproducibility of the questionnaire will be evaluated through a test-retest procedure. Thirty participants from the initial group will complete the questionnaire a second time after a two-week interval. The consistency of responses between the first and second administrations will be compared to assess the stability of the questionnaire over time. This step ensures that the questionnaire produces consistent and reproducible outcomes.

Phase 2 – Concurrent Mixed-Methods Study

This Phase 2 study will adopt a concurrent mixed-

methods design, where the quantitative and qualitative components will be conducted simultaneously. By integrating both approaches, the study aims to achieve a more comprehensive understanding of contraceptive counselling and prescribing practices among primary care doctors in Peninsular Malaysia. The quantitative component will consist of a cross-sectional study, while the qualitative component will follow a generic qualitative study design.

Cross-Sectional Survey

The cross-sectional study will utilise the validated online questionnaire developed in Phase 1 and will be conducted among primary care doctors practicing in both urban and rural health clinics across Peninsular Malaysia. The sampling population consists of primary care doctors in public health clinics who meet the selection criteria.

Sample Size

The sample size was calculated based on the prevalence and factors associated with contraceptive prescribing reported in previous studies [16], [21], [22]. To account for multistage sampling, a design effect (Deff) of 1.5 was applied, considering an average cluster size of 8 (average number of family medicine specialists per district) and an intraclass correlation coefficient of 0.05 [23]. Adjusting for this design effect increased the sample size to 510. Accounting for a 20% non-response rate further increased the total sample size to 660 for this phase. For each region, the number of participants will be calculated proportionately.

Selection Criteria

Inclusion and Exclusion Criteria

The inclusion and exclusion criteria for Phase 2 are similar to those of Phase 1. Participants must meet the following inclusion criteria: licensed Malaysian primary care doctors who provide care to reproductive-age women and have been practicing in primary care for at least one year. Exclusion criteria include doctors currently on long leave or working in administrative departments.

Sampling frame

All primary care doctors working in either urban or rural public health clinics during the study period who meet the inclusion and exclusion criteria will be included.

Sampling unit

Each individual primary care doctor working in urban or rural public health clinics during the study period who meets the inclusion and exclusion criteria.

Sampling Method

The cross sectional study will involve multistage sampling whereby the states and district health offices selected for each region through simple random sampling. The primary care doctors will be chosen through systematic

random sampling from the lists of doctors provided by the district health offices.

Study variables

The independent variables of this study include various factors such as sociodemographic characteristics (age, gender, ethnicity, religion, living arrangements, professional designation, highest medical qualification, marital status, and number of children), personal clinical history (doctors' personal experience using modern contraceptive methods, including type and duration), and clinical work experience (years of practice, recent training, frequency of training sessions, and types of training attended). Participants will be asked about specific types of training, such as workshops on family planning, Continuing Medical Education (CME) courses, online courses/webinars, community outreach programs, and educational seminars or conferences. Additionally, they can specify any other relevant training they have attended. Knowledge on contraceptive prescriptions, particularly for women with chronic diseases, and attitudes towards contraceptive use—such as perspectives on unplanned pregnancies, cultural and religious beliefs, and confidence in prescribing—are also key factors. Additionally, the availability of contraceptive methods at clinics and reasons for unavailability are considered.

The dependent variables focus on contraceptive counselling and prescribing practices, including the proportion of reproductive-age patients seen, frequency of contraceptive prescriptions, engagement in discussions with patients and their spouses, sharing knowledge with colleagues, and the influence of colleagues' practices. These variables collectively aim to provide a comprehensive understanding of factors influencing contraceptive practices among primary care doctors.

Study instrument

The study instrument used in this research is a validated questionnaire from Phase 1. The questionnaire is divided into seven sections, each focusing on critical variables relevant to the study objectives.

Section A captures the participants' sociodemographic characteristics, including 10 items such as age, gender, ethnicity, religion, living situation, professional designation, highest educational qualification, marital status, and number of children. This section provides a comprehensive demographic profile of the participants. Section B focuses on the participants' personal history of contraceptive use. It consists of a single item evaluating their personal experience with modern contraceptive methods, which offers insights into their familiarity with contraceptive practices.

Section C assesses clinical work experience, comprising three items. These items measure the participants'

years of clinical practice, recent contraception-related training, and the types of training attended. This section explores the role of professional experience and training in shaping contraceptive prescribing practices.

Section D evaluates the participants' practices in prescribing contraception. This section includes nine items that assess the frequency of contraceptive prescriptions, the proportion of reproductive-age patients seen, and the nature of discussions about contraception with patients and their spouses. It also examines the influence of colleagues' knowledge and feedback on participants' practices. Responses are recorded using Likert scales and dropdown options to capture the variability in practice.

Section E investigates the availability of contraception at the workplace. This section consists of four items assessing the types of contraception available and identifying reasons for unavailability, providing valuable information on systemic barriers.

Section F evaluates the participants' knowledge of modern contraception, particularly for women with chronic diseases. It consists of 22 questions with "Yes," "No," and "Not Sure" response options. A composite knowledge score will be calculated by summing the number of correct answers, expressed as a percentage. Section G examines attitudes toward contraception prescription through 22 items measured on a Likert scale ranging from "Strongly Disagree" to "Strongly Agree." This section explores the cultural, social, and personal beliefs that may influence participants' prescribing behaviours. Reverse-coded items (if any) will be appropriately handled before summation. An overall attitude score will be calculated by averaging the item scores, with higher scores indicating a more positive attitude. Scores will be divided into tertiles (low, moderate, high) for descriptive purposes, and continuous for regression analysis.

Data Collection

The validated questionnaire in Phase 1 will be inserted into an online platform/tool called REDCap (Research

Electronic Data Capture). REDCap is a secure web platform for building and managing online databases and surveys. There will be a briefing session about the research study to research assistants and enumerators. The QR code and online link to the questionnaires will be distributed to the participants via emails and WhatsApp numbers. Any incomplete or missing data from participants were regarded as incomplete submissions and will be excluded for the data analysis.

Data analysis

The data obtained from online questionnaires (REDCap) will be coded, analysed, and interpreted using descriptive statistical methods with the Statistical Package for the Social Sciences (SPSS) version 29.0. Descriptive statistics will be used to summarise sociodemographic characteristics, personal and clinical experience, practice patterns, service availability, knowledge, and contraceptive counselling and prescribing practices. Parametric tests will be employed to determine associations between variables, with statistical significance set at a P value of <0.05. Subsequently, multivariate analysis will be conducted to explore the relationships between dependent and independent variables. We will use multivariable linear and logistic regression models to examine associations between knowledge, attitude, and training (independent variables) and practice outcomes (i.e., counselling frequency and prescribing behaviour). Knowledge and attitude scores will be analysed as continuous independent variables, while training (yes/no) will be included as a categorical predictor. All models will adjust for potential confounders, including age, gender, and years of clinical experience. Results will be reported as adjusted odds ratios (OR) or beta coefficients with corresponding 95% confidence intervals (CI).

Generic Qualitative Study

The generic qualitative study will be conducted to explore the facilitators and barriers in contraceptive counselling and prescribing practices among primary care doctors in public health clinics in Peninsular Malaysia. The interview guide is available in Table I.

Table I: Interview Guide: Facilitators and Barriers in Contraceptive Prescribing

Section	Details
Title	Facilitators and Barriers in Contraceptive Prescribing Practice Among Primary Care Providers in Malaysia
Definition of Good Practice	Good practice: Often or very often discuss contraception. Poor practice: Rarely or never discuss contraception.
Criteria for Selection of FGD Participants	Do you routinely discuss contraception with your patients?
Introduction	- Introduce yourself (name and workplace). - For poor practice group: "We understand you rarely/never prescribe contraception." - For good practice group: "We understand you often/very often prescribe contraception." - Explain the purpose of the project: exploring facilitators and barriers in contraceptive counseling and prescribing. - Emphasize open and honest responses. - Confidentiality: Assure participants that all information will be kept safe and confidential. - Identity: Inform that names or identifying information will not be used.

CONTINUE

Table 1: Interview Guide: Facilitators and Barriers in Contraceptive Prescribing (CONT.)

Section	Details
Interview Guide	1. Please share your working experience in the primary care clinic. 2. Please tell me about your experience discussing contraception with your patients. 3. What are the facilitators (enabling factors) that help you discuss contraception with your patients? 4. What are the barriers (challenges) you face when discussing contraception with your patients? 5. Please tell me about your experience prescribing contraception to your patients. 6. What are the facilitators that help you prescribe contraception effectively? 7. What are the barriers you face when prescribing contraception? 8. Please share your ideas or opinions on how to improve contraception counseling and prescribing practices in the primary care setting.
Follow-Up Questions (Optional)	- Can you give an example of when this facilitator helped you in your practice? - Can you describe a situation where this barrier was particularly challenging for you? - Have you encountered any successful strategies or interventions that could improve counseling or prescribing?
Closure	Thank participants for their time. Ask if they are willing to be contacted again for further questions or clarification.
END	Thank you for your participation.

Selection criteria

Inclusion criteria

The inclusion criteria is similar to the ones in the cross sectional study, i.e. include Malaysian licensed primary care doctors in public health clinics in Peninsular Malaysia who provide care to reproductive-age women and have been practicing for at least one year. In addition, it includes participants who were involved in the cross-sectional study.

Exclusion criteria

Exclusion criteria include doctors who are currently on long leave or working at administrative department.

Sampling method

Purposive sampling method will be applied based on the selection criteria. Participants who were involved in the quantitative study will be invited to participate in the focus group discussion. A choice of suitable dates and times will be scheduled according to the convenience of the participants. Maximum variation will also be applied to ensure the participants include:

1. Both family medicine specialist and medical officers;
2. Both types of practices, never/rarely and often/very often practices counselling and prescribing contraception;
3. Each selected state will have at least four focus group discussions (FGDs) which consist of:
 - a. medical officers who rarely practice counseling and prescribing contraception;
 - b. medical officers who often practice counseling and prescribing contraception;
 - c. family medicine specialists who rarely practice counseling and prescribing contraception;
 - d. family medicine specialists who often practice counseling and prescribing contraception;

Data collection

Data collection and analysis will be conducted concurrently and iteratively. Data will be collected through semi-structured online focus group discussions

(FGDs) until data saturation is reached. Participants will be invited to join the focus group discussions after completing the questionnaire. It is estimated that approximately 20 FGDs will be required to reach data saturation, with each FGD consisting of five to six participants. The interviews will be conducted online and audio-recorded. All interviews will be moderated by a researcher with experience in conducting qualitative research, and each session will last approximately 1 to 1.5 hours. After each interview session, the researcher will reflect on and document the interview process. The interviews will then be transcribed. English will be used for coding and analysis. Saturation point will be guided by inductive thematic saturation, whereby data collection will continue until additional data no longer yield new themes [24].

Data analysis

Thematic analysis will be conducted concurrently with data collection. The transcripts will be reviewed repeatedly to identify initial codes and develop themes using an inductive process, following the phases described by Braun and Clarke [25]. Transcripts will be reviewed repeatedly to generate initial codes and identify themes through an inductive process. Coding and theme development will be managed using NVivo software (version 14.23.0; QSR International Pty Ltd, Australia). The entire dataset will be coded, and themes will be refined and finalized in discussion with the research team. Data analysis will be concluded when data saturation has been reached, as outlined in the section on data collection.

Trustworthiness of the Study

Several strategies will be employed to enhance trustworthiness. An audit trail will be maintained throughout the study. Member checking will be conducted by sharing the interpretation of findings with participants to ensure and confirm accuracy and validity. Reflexivity will be an ongoing process, with the researcher continuously reflecting on biases and assumptions that may influence the analysis. Peer review

among the research team will be carried out to ensure the credibility of the findings, involving critical assessment of emerging themes. As this is a concurrent mixed-methods study, the qualitative data will be triangulated with the quantitative data. Findings from the quantitative component will be integrated and corroborated with those from the qualitative component.

Ethical Considerations

This trial has received approval from the National Medical Research Registration of Malaysia (NMRR) (NMRR ID-24-03525-REG). Informed consent will be obtained from all participants, ensuring their confidentiality and the right to withdraw from the study at any time without penalty. Data will be anonymised and securely stored to protect participant privacy.

Consent for publication and dissemination

Consent will be obtained from participants for both participation and publication. Research findings will be presented at conferences and published in international journals, with all participant information kept confidential and not disclosed in any publications.

DISCUSSION

Reducing maternal mortality remains a global challenge. The Sustainable Development Goals (SDGs) aim to lower the global maternal deaths to less than 70 per 100,000 live births [26]. Contraception is a key component of preconception care, as it helps to optimise women's health prior to pregnancy. This approach is widely recognised as essential for improving both maternal and child health [27].

CoPPa is a two-phase study. Phase 1 focuses on developing and validating a questionnaire, while Phase 2 assesses primary care doctors' knowledge and attitudes toward contraceptive prescribing using the validated tool. It also explores facilitators and barriers through semi-structured interviews. Primary care doctors play a crucial role in providing contraceptive counseling, especially for high-risk women with chronic medical conditions. Their guidance significantly influences women's contraceptive choices [8].

Despite existing training programmes in sexual and reproductive health, gaps remain in translating knowledge into routine clinical practice. Many primary care doctors continue to report uncertainty when prescribing contraceptives for women with chronic illnesses or complex medical histories [28]. This study is therefore timely and necessary, as it aims to identify not only knowledge gaps but also practical, attitudinal, and systemic barriers that affect the quality and consistency of contraceptive counselling in primary care.

The findings from this study will be directly relevant to providers by offering insights into areas where additional

support or resources are needed. It can inform targeted professional development initiatives, such as focused training modules or refresher courses, especially in managing contraception for high-risk populations.

Moreover, the evidence generated can guide policymakers in refining national guidelines and shaping continuing medical education programmes. By addressing modifiable barriers and reinforcing enablers, the study may contribute to the development of more responsive, evidence-informed family planning policies that are aligned with frontline provider realities.

Given Malaysia's low modern contraceptive prevalence rate, this study also aims to identify barriers faced by primary care doctors in providing contraception counselling [29]. These insights will support the design of targeted interventions to strengthen family planning services across the country.

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