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Influence of Covid-19 Pandemic on Prenatal Care Utilization and Birth outcome: Qualitative Systematic Review Protocol

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ABSTRACT

The COVID pandemic disrupted routine prenatal care, yet little is known about expectant mothers' experiences during this time. This qualitative systematic review aims to synthesize evidence on the experiences, views and impact of COVID on prenatal care utilization and birth outcomes. A systematic search is conducted in 5 databases and Google Scholar. Studies providing qualitative data on pregnant women's experiences accessing prenatal care during COVID are included. Methodological quality is assessed using CASP and thematic synthesis is used to analyse the data. Even among these patients from affluent backgrounds, those who responded to the survey stated that the pandemic had significantly disrupted many parts of their daily lives and medical care, especially regarding social activities and postpartum support. Our findings make it clear that, in addition to increased support from healthcare systems, counseling on coping mechanisms and stressor adaptation techniques should be a part of perinatal care during public health emergencies for everyone. Results have provided an in-depth understanding of pregnant women's experiences with barriers and facilitators to prenatal care during COVID, and the impact on maternal and neonatal outcomes. This review has identified recommendations to improve prenatal care access and quality during future health crises, contributing to more resilient and equitable maternity care systems.

INTRODUCTION

The COVID pandemic has caused changes in the countries, even developed or developing countries, and these changes disrupted the health system, particularly routine care across the world. Little is known about the expectant mother's perception and experience of prenatal care during COVID-19.

The COVID-19 virus was discovered for the first time in China in 2019 and rapidly spread to the rest of the world. The pandemic had a huge influence on the world, affecting nearly every business and mode of life as people were obliged to adapt new ways of living in order to curb the disease's spread (Zhu *et al.*, 2020). The pandemic has had an impact on people's lives, not only via COVID-19 infections but also through government efforts to restrict mobility and social interaction in order to reduce the virus's spread (Hale *et al.*, 2021).

According to Akowuah *et al.* (2018), the WHO defines antenatal healthcare as "care a pregnant mother receives before birth" and includes education, screening, counseling, minor ailment treatment, and immunization services. Moreover, antenatal care reduces mother morbidity and mortality by giving knowledge about risk indicators, health promotion, birthing preparation, and postpartum care (Ayalew & Nigatu, 2018). Pregnant women are a different demographic that needs specialized mental and physical health care. Pregnancy and delivery are among the leading causes of women's hospitalisation, and birth-related procedures are used in evaluating global health quality (Kozhimannil *et al.*, 2013). In accordance with official regulations, maternity care facilities have also implemented sanitary measures to control the

spread of the virus and protect health workers, expecting mothers, and their new-borns (Montagnoli *et al.*, 2021). These measures include the exclusion of partners from face-to-face antenatal and postnatal appointments, the instauration of telehealth consultations, the prohibition of visitors, sometimes giving birth without the presence of a partner, and the cancellation of parent education classes or birth afterthoughts sessions (Węgrzynowska *et al.*, 2020).

It is critical for pregnant women to have high-quality prenatal care in order for their unborn children to grow normally and for them to be healthy. Prenatal care and antenatal outcomes have both directly and indirectly been affected by the epidemic. According to recent research carried out by in the United States, a decline in antenatal care (ANC) coverage ranging from 39.3% to 51.9% owing to the pandemic might possibly result in a further 56,700 maternal fatalities (Ephi, 2019). Notably, the COVID-19 pandemic has had an indirect influence on pregnancy outcomes, with a considerable drop in institutional deliveries occurring during strict lockdown times. This reduction is linked to issues such as the lack of transportation, concern about contagion and disturbed healthcare systems. Furthermore, economic problems during the pandemic have slowed access to healthcare services (Goyal *et al.*, 2021).

Moreover, a reduction in prenatal visits and hospital births may lead to greater issues during pregnancy, increasing the need for intensive care and increasing maternal death rates. As a result, the pandemic might hinder worldwide attempts to achieve maternal health-related sustainable development targets (Goyal *et al.*,

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2021; Khalil *et al.*, 2020). Furthermore (Chmielewska *et al.*, 2021) claimed that, gaps in care exposed expecting mothers to great risk during the COVID-19 pandemic, possibly leading to undesirable delivery outcomes and increased mortality. This qualitative systematic review protocol aims to synthesis qualitative evidence on the experience and perception of the expectant mothers on accessing prenatal care service during the COVID-19 pandemic and how care changes may have impacted on their birth outcome. In order to learn more about how affluent obstetric patients adjusted to the COVID-19 pandemic's effects on perinatal care and postpartum support, we polled a group of these patients. Our objective was to comprehend how COVID-19 affected their perinatal care experiences, general wellbeing, and coping mechanisms. By reviewing the qualitative studies from various countries to obtain in depth understanding of the expectant mother's care experiences in this health crisis. It also assesses to synthesize qualitative evidence on pregnant women experience with prenatal care disturbed during pandemic and how these disruptions have influence on maternal and child health outcome. This systematic qualitative review protocol could contribute to shape recommendations for improving prenatal care access during health-care system disruptions.

This Qualitative systematic review protocol aims to synthesise the qualitative systematic review and will provide answer for the following research question:

Research Questions

1. What are the experiences, views and perceptions of the expectant mothers in accessing perinatal care during the COVID-19 pandemic?
2. What are challenges and barriers faced by the mothers in accessing the perinatal care during the pandemic, including disruption of the routine care and changes in the health care system?
3. How have these changes in perinatal care services system during COVID-19 influences on maternal and neonatal outcome, and overall well-beings?
4. What potential strategies and recommendations can be identifies from the qualitative evidence can enhance the perinatal care access and quality in the context of the global health crisis?

LITERATURE REVIEW

The global economy, society at large, and healthcare systems have all suffered as a result of the COVID-19 pandemic. One of the most fragile health systems in the world is still the one in Liberia. The current Covid-19 epidemic and the Ebola outbreaks that occurred in 2014–2016 are the main causes of Liberia's health system's instability (Kezelee *et al.*, 2023). The pandemic-related lockdowns, fear of seeking medical attention, and disruptions in healthcare services have probably had an impact on women's and their children's health. The COVID-19 pandemic is posing challenges for maternal and child health services(Lalor *et al.*, 2023). A study

carried out in low- and middle-income nations predicted that 28,000 maternal deaths could occur from a 10% drop in the coverage of critical healthcare services for expectant mothers and new-borns(Wall & Dempsey, 2023).

In low- and middle-income countries, the pandemic has caused disruptions to healthcare services, which has resulted in a decrease in critical interventions related to maternal and child health. Worsening maternal health outcomes have been linked to changes in healthcare-seeking behaviour and a decrease in maternity services(Senkyire *et al.*, 2023). Maternal mortality, ectopic pregnancies, maternal depression, ruptured pregnancies, and stillbirths have all increased, according to a systematic review and meta-analysis. The literature claims that pregnant women infected with COVID-19 have a more severe form of the illness, increasing their risk of death by up to 35.0 percent and leading to almost a quarter of them developing pneumonia (El Debek, 2023). Additionally, there is evidence indicating a worsening of fetal outcomes, with higher rates of stillbirth and preterm birth(Gelete *et al.*, 2023). The COVID-19 pandemic presents a serious obstacle to the provision of necessary maternity, new-born, and child health services in many nations. Because of limitations, anxiety, fear of contracting the virus, and transportation concerns, women may have trouble getting access to maternity healthcare(Septianingrum *et al.*, 2023). The use of crucial maternity healthcare services has significantly decreased, according to a systematic review and meta-analysis.

Maternal health services have been disrupted and the risk of maternal illness and death has increased as a result of the resources being diverted toward the pandemic response. This makes managing COVID-19 while providing necessary services across the maternity care continuum even more difficult(Tungwarara & Godfrey Musuka, 2023). Recent data indicates that maternity care given to mothers during pregnancy, childbirth, and the postpartum period may have been influenced by government initiatives such as stay-at-home directives, women's healthcare-seeking behaviour, community perception, perceived low quality of care during the pandemic, and fear of contracting COVID-19. On March 13, 2020, Ethiopia announced the country's first COVID-19 case that was confirmed(Chua *et al.*, 2023).

As a result, people were told not to travel around much, were not allowed to get together, and anyone who thought they might have the virus had to notify the local health authorities. In addition, upon arrival, foreign visitors had to self-isolate for 14 days and show a negative COVID-19 test result(Lee & Singh, 2023). There is a dearth of national data regarding the effect of COVID-19 on the use of critical maternity healthcare services in Ethiopia. Furthermore, not enough information has been provided about the obstacles pertaining to the government and healthcare facilities, as well as the ways in which individual and community perceptions affect the use of maternal healthcare services during the pandemic(Cruz-Ramos *et al.*, 2023). Thus, by estimating the overall decline and

difficulties in the use of crucial maternal healthcare services in Ethiopia, this systematic review and meta-analysis sought to close this gap.

METHODOLOGY

The systematic review is done in accordance with the Centre of Research and Dissemination Guidelines (CRD, 2021). The CRD focuses on gathering, synthesizing, and evaluating research evidence from a wide range of studies to generate evidence that can be used to enhance healthcare practice and policymaking. The enhancing transparency in reporting qualitative research synthesis (ENTREQ) (See Appendix A) checklist is used in this systematic review, as it was developed to encourage explicit and comprehensive reporting of qualitative studies synthesis (Tong *et al.*, 2012). The report is also done following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) 2015. PRISMA-P guideline (See Appendix B) is an internationally recognized protocol that helps in improving accuracy, completeness, and transparency in systematic reviews and meta-analyses (Moher *et al.*, 2015). Thus, ENTREQ and PRISMA-P 2015 is used to cover all the necessary process of making systematic review of qualitative evidence.

Eligibility Criteria

Inclusion and Exclusion Criteria

The inclusion criteria set boundaries for the review, indicating which studies are possibly relevant to the study and which are not (Stern *et al.*, 2014).

Inclusion Studies were considered if they met the following criteria:

- Qualitative studies, such as but not limited to interviews, focus groups, and observations, as well as mixed-method studies having a significant qualitative component.
- Studies focusing on pregnant women's experiences and views of obtaining prenatal care services during the COVID-19 epidemic.
- Studies that investigate the obstacles and restrictions that pregnant women had in getting prenatal care during the pandemic, including as interruptions in routine care and changes in the healthcare system.
- Studies that examine the influence of care changes on birth outcomes include mother and neonatal health and over all well beings.
- Studies that have been published in English or have an English translation accessible.
- Studies conducted and published during the COVID-19 pandemic, perhaps beginning in 2020.

Exclusion Criteria

- Studies that are solely quantitative based and do not include any qualitative components.
- Studies that tend to focus on pregnant women's experiences and views of obtaining prenatal care during the COVID-19 epidemic.

• Research that focuses only on the experiences of healthcare professionals or other stakeholders without taking into account the views of pregnant mothers.

• Studies that do not investigate the challenges and barriers that pregnant women had in getting prenatal care during the pandemic, as well as the possible influence of service alterations on birth outcomes.

• Studies published in languages other than English without English translation available.

• Studies that were done and published before to the COVID-19 pandemic or after the epidemic were declared over by relevant health authorities.

Information Sources

The search is done on five key electronic databases. The first one will be the Cumulative Index to Nursing and Allied Health Literature (CINAHL) database. When performing a review of qualitative evidence, the CINAHL database is generally thought as reliable source to search (Wright *et al.*, 2015). The second electronic database is Excerpta Medica Database (EMBASE) which is contains published information. The third source is Medical Literature Analysis and Retrieval System Online (MEDLINE) which is a bibliographic database on issues related to biomedical and life sciences. The fourth source is the (PsycINFO), an electronic database with studies on psychology. The final data base is the (SCOPUS) and finally Search engines like Goggle and Google Scholar is utilised to search for additional studies. The information obtained through the six sources is used to answer the formulated research question.

METHODOLOGY

The five electronic databases are used in the current review contain a wide range of information on healthcare challenges. Therefore, the need to select and identify specific articles related to the topic of discussion. The main search terms for this study include 'Covid-19' 'Pandemic' 'prenatal care' 'perinatal care' 'antenatal care' 'Expectant mothers' 'pregnant women' 'maternal health' 'neonatal health' 'experiences' 'perceptions' 'access to health care' 'barrier' 'challenge' 'health care system' 'disruptions'. Search terms are matched with the appropriate Boolean operators ('OR' 'AND') to connect the search as well as medical subject headings (MESH) terms. Titles, abstracts, and themes are searched for terms. To find additional articles, the reference lists of the included studies and studies that quote the listed research are searched.

Selection Process

Titles, abstracts, and complete texts are reviewed for eligibility by the PI (KH) and 40 % are randomly checked by the screeners in this study. Full-text articles are retrieved once it meets the inclusion criteria. If the title and abstract are insufficient to determine inclusion, the complete text was requested. Then, if complete texts were not available, the relevant authors of the research was contacted. Screeners discussed eligibility until an

agreement is achieved if it is unclear at the title, abstract, or full-text stage. If no agreement is achieved, a third independent screener was served as an adjudicator. Exclusion reasons were documented at each level, and the inclusion and exclusion process were documented with a flow diagram, as recommended by the PRISMA guidelines (Moher *et al.*, 2009). The endnote software version x20 was used to encode.

Data Extraction and Management

The data extraction process was performed by the PI and three reviewers. The first reviewer re-examined the articles and gather the relevant information about the topic from the PI, while the second reviewer validated the gathered information by the first reviewer. The data extraction was based on a predetermined form incorporating important components of the studies. The main concepts addressed in the forms included in bibliographic details, a summary of the study design, study participants (pregnant mothers faced the challenges on accessing the perinatal care during COVID-19 pandemic regardless of age, ethnicity, occupation status, economic status, and educational level), and aim of the study, evidence appraisal, results, and conclusion. Any concerns that occur throughout the process were handled by a consensus discussion between the reviewers. The reviewers used systematic approach to ensure that the comprehensiveness of information (Campbell, 2010). In cases where further information is required, the reviewers contacted the authors to collect missing data or insights into the articles before proceeding to the next step of the project. Data extraction, analysis, and duplicate removal will be used by Microsoft excel.

Critical Appraisal

The included papers will be evaluated using the Critical Appraisal Skills Programme Qualitative Research Checklist (CASP). The CASP tool is a commonly used checklist/criteria-based tool for quality appraisal in health and social care-related qualitative evidence syntheses (Long *et al.*, 2020). The checklist contains ten items that address the following: the study aims, methodology, design of the studies, recruitment, data collection method, participant-researcher relationship, ethical considerations, data analysis, findings, and the study value (Coates *et al.*, 2019). In addition, the Critical Appraisal Skills Programme (CASP) is a checklist for qualitative studies that provides as a quality assessment tool and recommended by Cochrane to use. Thus, this tool was chosen because it provides for rapid review through the use of a 10-item checklist which can easily be used by the researcher. Moreover, the checklist can be applied to several types of qualitative designs to assess the studies' credibility, transferability, dependability, and conformability (Aziz *et al.*, 2016).

RESULTS

The data was extracted for all studies included in the review, and qualitative summaries were generated. The

generated data is analysed by using thematic analysis. A theme is described as a consistent combination of various pieces of data that create the findings (Sandelowski, 2000). Thematic analysis includes searching for and finding common themes throughout given data (DeSantis & Ugarriza, 2000). According to Braun and Clarke, (2006), thematic analysis is a comprehensive and useful research approach that provides a full, detailed, and nuanced explanation of data. The importance of a theme is determined not by quantifiable measures, but rather by whether it captures everything vital in relation to the research aim (Braun & Clarke, 2006). The six analytical phases defined by Braun and Clarke (2006) are the following: (a) becoming acquainted with the data, (b) developing initial codes, (c) searching for themes among codes, (d) reviewing themes, (e) defining and naming themes and (f) completing the final report. The included studies will be read several times and classified by using preliminary codes to identify sub-themes among the articles. The sub-themes were formed from descriptive information within the data and can be considered as an expression of the text's manifest sub-themes (Graneheim & Lundman, 2004). Following the familiarisation process, it will produce the initial codes for sub-themes of interest across all articles in a systematic way. Despite the fact that the main goal will guide the research, the initial sub-themes were data-driven without trying to integrate the sub-themes into a previous thematic framework. Then carefully discussing subthemes that emerged from the data to arrange the overall theme. All the themes that were examined were part of a recursive process in which they were moved back and forth between the studies and the identified themes (Braun & Clarke, 2006). The themes will then be reviewed several times to ensure that they accurately and completely represent the coded semantic extraction of the data. Each sub-theme within the topics is described as closely to the source studies as possible, with direct quotations included if available (see figure 3).

DISCUSSION

Pregnant women reported feeling more fear, uncertainty, and anxiety during the COVID-19 pandemic, according to research (Cox *et al.*, 2023). One of the main causes of these symptoms has been found to be the absence of information given during prenatal care as a result of cancelled or remote appointments. It has become challenging to deliver consistent and accurate information due to the ever-changing health restrictions and protocols (Tikouk *et al.*, 2023). Women have felt less prepared and informed as a result, which is consistent with earlier research that links a lack of information to unfavourable childbirth experiences and elevated anxiety and fear in mothers. Promoting healthy practices during pregnancy on the basis of reliable information is crucial (Septianingrum *et al.*, 2023).

Because of the protective measures that were put in place, the women in this study felt secure during their hospital stays, even in spite of any potential misinformation

during pregnancy. This result is in line with earlier studies showing that in less congested hospitals, these measures offered patients privacy and peace of mind. Healthcare providers concentrated on giving women a normal birth experience even though prenatal care may have been compromised during the pandemic (Alabi *et al.*, 2023). The mothers' perception of their experience as safe and positive was probably greatly aided by the close support these professionals offered. Despite the workload, physical and mental exhaustion, and fear of contagion experienced by healthcare workers during the pandemic, emotional and practical support is a crucial component in boosting confidence during labour and can be maintained (De Genna *et al.*, 2023).

The fact that women voluntarily choose to isolate themselves out of a fear of spreading infection is another finding that is consistent with earlier research. Despite the fact that lack of social support and worries about infection have been linked to postpartum depression, the mothers in this study said they appreciated the closeness and peace that the COVID-19 health restrictions provided (Jahromi *et al.*, 2023). This pandemic-era postpartum way of life is reminiscent of customs from other cultures. For instance, in order to avoid infections, strengthen their bond with their infants, and accept their new role as mothers, new mothers customarily spend up to sixty days at home alone. Perhaps there are unacknowledged advantages to postpartum isolation in Western societies. As a result, cultural expectations surrounding early motherhood ought to be modified to accommodate each individual's physical and psychological needs (Thapaliya *et al.*, 2023). In addition to the findings discussed in this review, it is crucial to emphasize the promotion of emotional well-being and self-care among healthcare professionals. This becomes especially important during times of crisis, such as the COVID-19 pandemic, which has placed immense pressure on the healthcare sector (Toh & Shorey, 2023). Healthcare professionals who are calm, composed, and well-informed can enhance communication with patients and foster trust, ultimately leading to the provision of better overall healthcare services (Tungwarara & Godfrey Musuka, 2023).

Future Implications

This review study has future implications for the researches to identify the relevant qualitative studies that explore the experience, view and perceptions of the expectant mothers in accessing perinatal care during the COVID-19 pandemic.

It will help to investigate the challenges and barriers faced by the mothers in accessing the perinatal care during the pandemic, including disruption of the routine care and changes in the health care system. Furthermore, it will also evaluate the influences of these changes on maternal and neonatal outcome, and overall well-beings. Identification of the potential strategies and recommendations to enhance the perinatal care access and quality in the context of the global health crisis will be beneficial for the coming years.

CONCLUSION

This qualitative systematic review protocol aims to synthesise and deeply understand the experiences, views, and perceptions of expectant mothers when accessing perinatal care during the COVID-19 pandemic. Further, the review will explore the potential impact of care access changes on maternal and birth outcomes and identify the strategies and recommendations that guide policymakers to enhance care access and quality in the context of the global health crisis. By including the diverse and enormous range of evidence from multiple countries, this will contribute to a better understanding of the mothers' experiences and views during an unprecedented period. In addition to the findings of this study, it will highlight potential areas for improvement in service provision and policy changes to support expectant mothers, their newborns, and their families during the future health crisis. Eventually, this study will add to the evidence foundation for the establishment of more resilient, patient-centred, and equitable prenatal care systems.

This Qualitative systematic review protocol registered with the International Prospective Register of Systematic

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Contribution

KH is the PI leading protocol development and the systematic review. In addition, the co-authors FA, JM, NO typically actively help search papers, extract data, evaluate bias risk, analyse data, write sections, and edit or revise the review throughout the process. Co-authors are accountable for ensuring the final review's overall rigour, openness, and trustworthiness will be contributed by all the authors.

Registration

Reviews in compliance with the standards (PROSPERO), registration number (CRD42023428034). The registration of systematic review protocol details is now considered as vital to promote and maintain transparency in the systematic review process, contributing in the reduction of biases and the removal of consequently study duplication (Stewart *et al.*, 2012).

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APPENDIX

Table 1: The enhancing transparency in reporting qualitative research synthesis (ENTREQ) (Tong et al. 2015).

No	Item	Guide and description
1	Aim	State the research question the synthesis addresses.
2	Synthesis methodology	Identify the synthesis methodology or theoretical framework which underpins the synthesis, and describe the rationale for choice of methodology (e.g. meta-ethnography, thematic synthesis, critical interpretive synthesis, grounded theory synthesis, realist synthesis, meta-aggregation, meta-study, framework synthesis).
3	Approach to searching	Indicate whether the search was pre-planned (comprehensive search strategies to seek all available studies) or iterative (to seek all available concepts until they theoretical saturation is achieved).
4	Inclusion criteria	Specify the inclusion/exclusion criteria (e.g. in terms of population, language, year limits, type of publication, study type).
5	Data sources	Describe the information sources used (e.g. electronic databases (MEDLINE, EMBASE, CINAHL, psycINFO, Econlit), grey literature databases (digital thesis, policy reports), relevant organisational websites, experts, information specialists, generic web searches (Google Scholar) hand searching, reference lists) and when the searches conducted; provide the rationale for using the data sources.
6	Electronic Search strategy	Describe the literature search (e.g. provide electronic search strategies with population terms, clinical or health topic terms, experiential or social phenomena related terms, filters for qualitative research, and search limits).
7	Study screening methods	Describe the process of study screening and sifting (e.g. title, abstract and full text review, number of independent reviewers who screened studies).

8	Study characteristics	Present the characteristics of the included studies (e.g. year of publication, country, population, number of participants, data collection, methodology, analysis, research questions).
9	Study selection results	Identify the number of studies screened and provide reasons for study exclusion (e.g. for comprehensive searching, provide numbers of studies screened and reasons for exclusion indicated in a figure/flowchart; for iterative searching describe reasons for study exclusion and inclusion based on modifications to the research question and/or contribution to theory development).
10	Rationale for appraisal	Describe the rationale and approach used to appraise the included studies or selected findings (e.g. assessment of conduct (validity and robustness), assessment of reporting (transparency), assessment of content and utility of the findings).
11	Appraisal items	State the tools, frameworks and criteria used to appraise the studies or selected findings (e.g. Existing tools: CASP, QARI, COREQ, Mays and Pope [25]; reviewer developed tools; describe the domains assessed: research team, study design, data analysis and interpretations, reporting).
12	Appraisal process	Indicate whether the appraisal was conducted independently by more than one reviewer and if consensus was required.
13	Appraisal results	Present results of the quality assessment and indicate which articles, if any, were weighted/excluded based on the assessment and give the rationale.
14	Data extraction	Indicate which sections of the primary studies were analysed and how were the data extracted from the primary studies? (e.g. all text under the headings “results / conclusions” were extracted electronically and entered into a computer software).
15	Software	State the computer software used, if any.
16	Number of reviewers	Identify who was involved in coding and analysis.
17	Coding	Describe the process for coding of data (e.g. line by line coding to search for concepts).
18	Study comparison	Describe how were comparisons made within and across studies (e.g. subsequent studies were coded into pre-existing concepts, and new concepts were created when deemed necessary).
19	Derivation of themes	Explain whether the process of deriving the themes or constructs was inductive or deductive.
20	Quotations	Provide quotations from the primary studies to illustrate themes/constructs and identify whether the quotations were participant quotations or the author’s interpretation.
21	Synthesis output	Present rich, compelling and useful results that go beyond a summary of the primary studies (e.g. new interpretation, models of evidence, conceptual models, analytical framework, development of a new theory or construct).

Table 2: PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol Shamseer et al (2015).

Section and topic	Item No	Checklist item
Administrative Information		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review

Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources	5a	Indicate sources of financial or other support for the review
Sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
Introduction		
Rationale	6	Describe the rationale for the review in the context of what is already known
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
Methodology		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I ² , Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

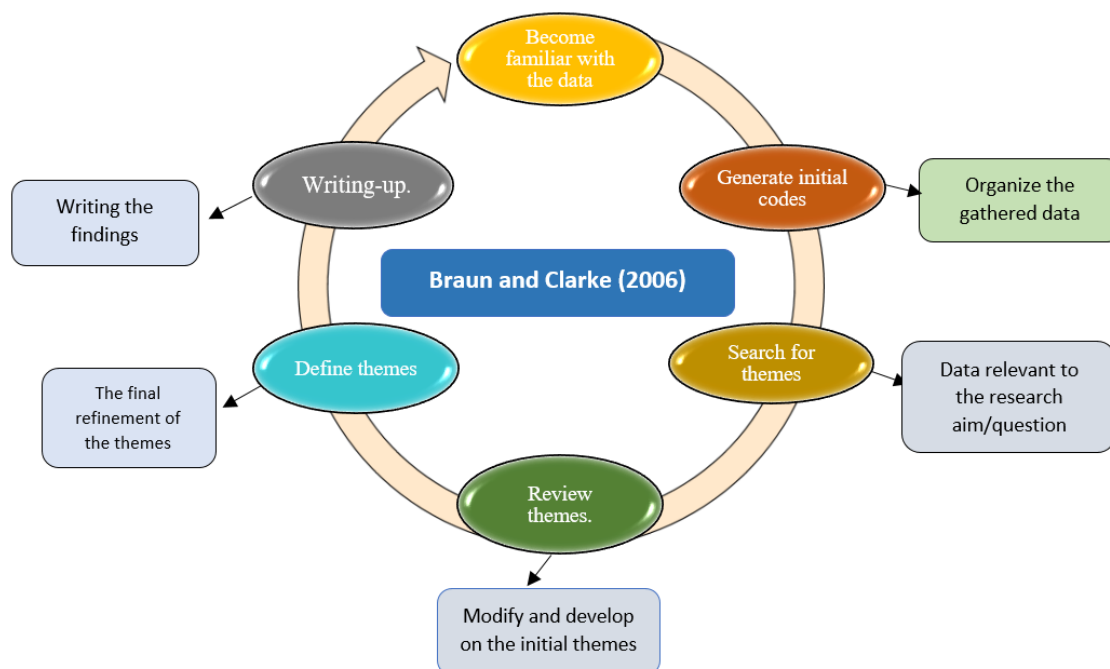


Figure 1: Braun and Clarke thematic analysis approach (Braun & Clarke, 2006).