BMJ Global Health

Self-management of iron and folic acid supplementation during pre-pregnancy, pregnancy and postnatal periods: a systematic review

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To cite: King SE, Yeh PT, Rhee DK, *et al*. Self-management of iron and folic acid supplementation during pre-pregnancy, pregnancy and postnatal periods: a systematic review. *BMJ Global Health* 2021;**6**:e005531. doi:10.1136/bmjgh-2021-005531

Handling editor Stephanie M Topp

► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/bmjgh-2021-005531).

Received 28 February 2021
Revised 19 April 2021
Accepted 21 April 2021

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ABSTRACT

Introduction While the use of folic acid pre-pregnancy and iron and folic acid (IFA) during pregnancy and postnatal have been demonstrated to be effective and are recommended interventions by WHO, ensuring individuals adhere to the supplementation regimen can be a challenge. Self-care interventions that support an individual's ability to promote their own health with or without the support of health workers could help promote the uptake and adherence to supplementation. This systematic review assessed the evidence around self-management of IFA or folic acid supplementation accessed over-the-counter during pre-pregnancy, pregnancy and postnatal periods.

Methods Peer-reviewed studies were included if they compared self-management of IFA or folic acid supplementation with health worker-initiated supplement use on maternal and/or fetal and newborn health outcomes, end-users' or health workers' values and preferences, or cost and/or cost-effectiveness. We searched PubMed, CINAHL, LILACS and EMBASE for articles published through November 2020, hand-searched clinical trial registries, reviewed databases and contacted experts in the field. Abstract screening and full-text review were conducted independently by two reviewers.

Results Overall, 2344 results were identified, and 28 studies were identified for full-text review. All studies were excluded, as they were not primary research, lacked the outcomes of interest, lacked specificity in supplement type, and/or lacked a comparison group.

Conclusion No evidence was identified that distinguishes self-management of folic acid supplements pre-pregnancy and of IFA supplements during pregnancy and postnatal, highlighting a gap in our current understanding of self-care related to dietary supplementation in pregnancy. The findings of this review identify an area for further research to support the current movement towards self-care interventions as an added choice to help individuals more fully attain their reproductive health and rights.

Systematic review registration number PROSPERO CRD42020205548

Key questions

What is already known?

- Pre-pregnancy folic acid supplementation, and iron and folic acid supplementation during pregnancy and postnatal periods are effective interventions to improve both maternal and fetal and newborn outcomes.
- Ensuring people adhere to supplementation regimens can be a challenge and affects maternal and fetal and health outcomes.
- Self-care interventions that support an individual's ability to promote their own health with or without the support of health workers could help in the uptake and adherence to supplementation.

What are the new findings?

- No studies were identified that examine the difference between self-management and health worker-initiated usage of iron and/or folic acid supplements during pre-pregnancy, pregnancy or postnatal periods.

What do the new findings imply?

- There is a need to examine how women differ in their use of supplements by those who self-manage versus those who are prescribed or receive the supplements through antenatal care: to evaluate the impact of self-management on maternal and neonatal outcomes, to understand end-user and health worker values and preferences, and to assess costs to the end-user and health system.

BACKGROUND

Self-care, defined by WHO as "the ability of individuals, families and communities to promote health, prevent disease, maintain health and cope with illness and disability with or without the support of a health-care provider", allows people to access services for their health needs on their own terms.[1] This people-centred approach can help improve the self-efficacy, autonomy and engagement of individuals in their health decision-making.[1] WHO emphasises the importance of self-care interventions in supporting their Triple Billion Goals by 2023: having a billion more people protected from health emergencies,

benefiting from universal health coverage, and enjoying better health and well-being.[2] Self-care is also an integral part of the response to the COVID-19 pandemic, which has seen overstretched healthcare systems and closures of medical facilities due to country-wide lockdowns globally. Building on the recently published WHO normative guidance for key self-care interventions for sexual and reproductive health and rights,[1] WHO is expanding the evidence base to consider the use of supplements containing iron and folic acid during the pre-pregnancy, pregnancy and postnatal periods.

The use of iron and folic acid (IFA) supplements during pregnancy is an effective and recommended intervention to reduce maternal anaemia, puerperal sepsis, low birth weight and preterm birth.[3 4] The use of folic acid supplements is recommended as early as possible during pregnancy, and ideally prior to pregnancy, to prevent neural tube defects.[3 5] Postnatal use of iron supplements (either alone or with folic acid) may also reduce the risk of anaemia in settings with high prevalence of maternal anaemia.[6] Despite the efficacy of these supplements, IFA supplementation during pregnancy is not reaching its potential impact due to a lack of consistent use, attributed to a range of issues including supply and demand factors,[7–11] nonadherence due to side effects, cost and access. Promoting the use of over-the-counter (OTC) or home use of folic acid or IFA supplementation when planning a pregnancy (pre-pregnancy), during pregnancy and/or postnatal (after delivery) may help expand delivery of micronutrient supplementation beyond the clinical care setting and ultimately improve maternal, fetal and newborn health outcomes.

We conducted this systematic literature review with three goals: (1) to synthesise evidence on impact of self-management of folic acid or IFA supplementation on maternal and/or fetal and newborn outcomes in the pre-pregnancy, pregnancy or postnatal periods; (2) to understand the values and preferences of individuals regarding self-managed/OTC access to these supplements as an additional option to health worker-initiated access; (3) to understand the cost and/or cost-effectiveness of self-managed use of these supplements during pre-pregnancy, pregnancy and postnatal periods.

METHODS

The systematic review was conducted in accordance with the Preferred Reporting Items for Systematic review and Meta-Analysis (PRISMA) guidelines.[12] The protocol was registered on the International Prospective Register of Systematic Reviews (PROSPERO registration number CRD42020205548). Ethical approval was not required for thissystematic review, since all data came from published articles.

Research question and inclusion criteria

We sought to compare self-management of IFA or folic acid supplements to health worker-initiated provision. We defined health worker-initiated provision of supplements as occurring when supplements are directly provided by health workers at a health facility or by prescription to be accessed by the client outside of the health facility. We defined self-management as occurring when individuals purchase supplements over-the-counter (including online or in pharmacies) without a prescription for home-based use. When the consumer initiates the conversation with the health worker and the health worker offers advice, so long as the consumer is the one who actively sought out and obtained their own supplements, we considered it self-management.

This review addressed three related research questions:

1. Should individuals who are planning pregnancy self-manage the use of folic acid supplements?
2. Should pregnant individuals self-manage the use of iron and folic acid supplementation as per international guidance (currently either daily dose of 30–60 mg of elemental iron and 400 µg (0.4 mg) of folic acid or intermittent (eg, weekly) dose of 120 mg of elemental iron and 2.8 mg of folic acid)[3]?
3. Should postnatal individuals self-manage use of iron (with or without folic acid) supplementation for at least 3 months after delivery as per international guidance (currently either daily dose of 30–60 mg of elemental iron and 400 µg (0.4 mg) of folic acid or intermittent (eg, weekly) dose of 120 mg of elemental iron and 2.8 mg of folic acid)[6]?

To address these questions, articles were included in the review if they provided information relating to three aspects of self-management of IFA or folic acid supplements: (1) the effects of self-managed use of supplements on maternal and/or fetal and newborn health outcomes (effectiveness review); (2) end-users' or health workers' values and preferences around self-managed use of supplements (values and preferences review); (3) the cost and/or cost-effectiveness of self-managed use of supplements (costs review).

To be included in the effectiveness review, articles were required to have a study design that compared the self-managed use of supplements containing iron and/or folic acid with health worker-initiated provision. This included both randomised trials and observational studies (eg, quasi-experimental, cohort, case–control, cross-sectional) that compared individuals who received the intervention with those who did not. Studies also had to be published in a peer-reviewed journal and measure one or more of the following primary outcomes of interest: (1) maternal outcomes including correct use of the supplements (eg, adherence or, conversely, inappropriate use); maternal or postnatal anaemia (eg, haemoglobin concentration) and iron deficiency (eg, ferritin concentration), serum or red blood cell folate concentration, or puerperal sepsis; self-efficacy, autonomy and empowerment; and adverse events (eg, stock-outs of supplements, other access challenges, decreased follow-up with appropriate management, reduced engagement in health system for

other essential maternal health services) or (2) fetal and newborn outcomes including low birth weight, small for gestational age, preterm birth, and stillbirth.

For the values and preferences and costs reviews, articles were included if they presented quantitative or qualitative data from primary research on either values and preferences or cost and/or cost-effectiveness-related outcomes.

No restrictions were placed on language of the studies nor the location of interventions.

Search methods

The following electronic databases were searched through 30 November 2020: PubMed, CINAHL, LILACS and EMBASE using a pre-specified search strategy (online supplemental appendix A). Secondary reference searching was conducted on all studies included in the review, as well as on relevant reviews identified through the search. Further, selected experts in the field, including the corresponding authors of articles selected for full-text review, were contacted to identify additional articles not identified through other search methods. We also searched for ongoing randomised controlled trials through ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform, the Pan African Clinical Trials Registry and the Australian New Zealand Clinical Trials Registry. In addition, the Cochrane Library was consulted for the articles cited in its reviews that may be included in our main review. Finally, we conducted a hand-search of hits from key search terms entered into Google's search engine.

Titles and abstracts identified through the search strategy were screened to identify articles for full-text review using Covidence. Full-text articles were obtained for selected references and independently reviewed by two reviewers to determine final study inclusion. Differences were resolved through consensus with a third reviewer.

Data extraction and management

We planned for two reviewers to independently extract data from included studies using standardised data extraction forms. The standardised data extraction form included information about study identification (author, year of publication), study description (objective, location, description of supplements, description of self-management and the intervention, description of the comparison group, study design, sample size, follow-up) and study outcomes (outcome measures, effect size, confidence levels; values and preferences data; cost-related data; conclusion and limitations).

We planned to assess risk of bias for randomised trials using the Cochrane Collaboration's tool.[13] For non-randomised trials but comparative studies, we planned to assess study rigour using the Evidence Project 8-item checklist for intervention evaluations.[14]

Data analysis

We developed an analysis plan based on coding categories and outcomes. Where multiple studies reported the same outcome, we planned to conduct meta-analysis using random-effects models to combine risk ratios with the program Comprehensive Meta-Analysis (CMA). We planned subgroup stratifications by IFA dosage, forms of self-management, points of access, population vulnerabilities, country economic classification and literacy/education level.

Patient and public involvement

Patients and the public were not involved in this review, but they are involved in a global survey of values and preferences being conducted to inform the WHO normative guidance on self-care interventions.

RESULTS

In total, 2459 abstracts were retrieved from the electronic database search, and 280 additional records were identified through other search strategies (figure 1). After discarding duplicates, 2487 abstracts were initially screened by a single reviewer for eligibility. Of these, 28 abstracts were identified by both the primary and secondary reviewers for full-text review. However, five of these were conference abstracts with no extractable data and no subsequent peer-reviewed publication, so were excluded from the full-text review. All 23 of the remaining full-text articles were excluded from the main review for the following reasons: not primary research, lack of outcomes of interest, lack of specificity in which supplements were used and lack of comparison group.

Complementary reviews

A subset of eight studies were reviewed for inclusion in the values and preferences review. However, they were all excluded, primarily because the studies which presented values and preferences around self-management of dietary supplements and complementary medical products did not disaggregate findings by the type of supplement (ie, not specific to folic acid or IFA supplementation). No articles presented cost or cost-effectiveness data.

DISCUSSION

This systematic review of the literature yielded no included studies, suggesting that there is a lack of currently published evidence exploring how self-management can influence the use of iron and/or folic acid supplementation in the pre-pregnancy, pregnancy and postnatal periods. Many of the studies excluded from the review presented cross-sectional estimates of micronutrient supplement use in which iron and/or folic acid supplementation were frequently not disaggregated from other supplements[15–27] or complementary and complementary medicine products, which include herbal medicines, topical herbal preparations, vitamin

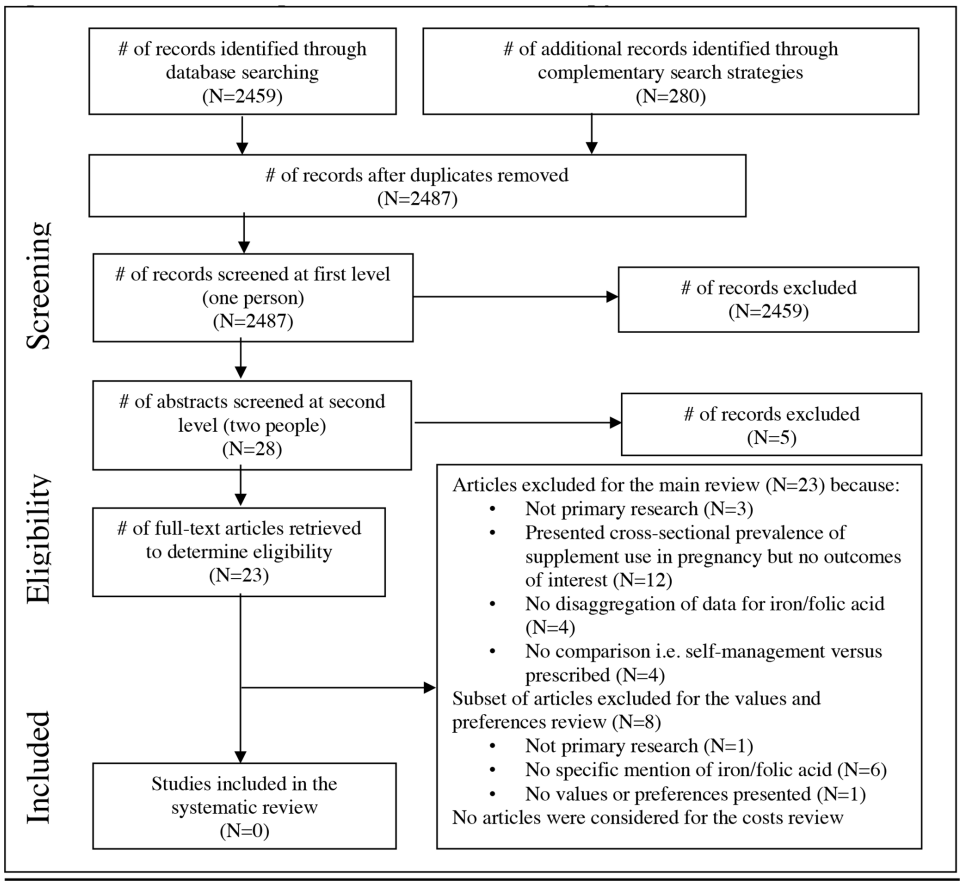

Figure 1 PRISMA flow diagram of the search and screening process.

and mineral supplements, and prebiotic and probiotic supplements.[28 29] Several studies considered in full-text review showed evidence of factors influencing the use of prenatal supplements and complementary medical products. However, they did not provide any information on self-management; nor did they report how the use of supplements or outcomes from supplement use differed between self-management and health worker-initiated provision.

We conjecture that the lack of available evidence could be influenced by several factors. First, in many studies, the data clustered micronutrient supplements including iron and/or folic acid supplementation within a broader category of complementary and complementary medicine products, obfuscating the interpretation of study findings. Studies have examined the motivation and use of complementary medical products around the time of pregnancy,[28 29] but the motivations and usage patterns of specific products within the umbrella of complementary medical products likely differs by product. For example, while there is global normative guidance for both use of ginger and chamomile tea for relief of nausea during early pregnancy and IFA during pregnancy and postnatal,[3] the reasons and likelihood of self-management for the use of herbal teas in pregnancy and the self-management of iron and/or folic acid supplements will be vastly different regarding the quality and type of evidence available. Future research disaggregating results pertaining to iron and/or folic acid supplements from other complementary medical products could provide insights into the research question at hand.

Second, folic acid supplements used prior to pregnancy, IFA supplements during pregnancy and iron supplements taken postnatal have known efficacies and present very little risk to the individual if taken in the recommended dosage.[4–6] There is little scientific and programmatic debate over the effectiveness, safety and acceptability of IFA supplement availability OTC, which may explain the dearth of research around differences in behaviours and outcomes between self-managed and health worker-initiated supplement use.

Third, the mechanisms for the acquisition of IFA during pregnancy heavily depend on the context. In most high-income countries, IFA supplements are readily and almost exclusively available as OTC products in pharmacies, stores and online. In contrast, in many low-and-middle-income countries, IFA supplements are usually provided through regular antenatal care services either for free or at a small cost, as part of countries' efforts to improve maternal and fetal and newborn health outcomes. The availability of supplements at the health centre or supplements provided with a prescription at the health centre is a mechanism to improve the access and uptake of the supplements by reducing costs, rather than to control who can obtain the supplements or how. Few health system contexts have supplement access available

both as OTC and as requiring prescription, resulting in little attention being brought to a research question comparing self-management with health worker-initiated provision. Furthermore, an influential factor in the decision to establish a system that either requires OTC/self-managed or health worker-initiated provision is who is responsible for paying for the supplements. Health worker-initiated supplementation may provide the opportunity for the health system to bear the cost, if provided for free, whereas OTC puts the burden of cost onto individual end-users. Regardless of the mode of access, prenatal supplementation is an extremely cost-effective strategy to improve maternal and birth outcomes,[30 31] but in some contexts, it may be more appropriate for the cost to be covered by the health system to improve uptake and adherence to the supplements.

Our review has several strengths. We searched multiple databases, considered both non-randomised/comparative observational and randomised studies for inclusion, and did not exclude studies by language of publication or geographical location. In addition, we took extra measures in our search strategy, including contacting study authors and reviewing grey literature, to increase comprehensiveness and ensure that any and all existing evidence was likely to be found. Furthermore, this review explores a novel question expanding on the work being conducted by WHO to develop further normative guidance around self-care interventions with known effectiveness and safety.

However, our search failed to yield any studies meeting our inclusion criteria. Due to the variation by context in IFA supplement acquisition (OTC vs prescription), few settings offer the opportunity to study our research question, as we defined self-care interventions, with quantitative comparisons. However, a review of a different conceptualisation of self-care, for example, the extent to which health workers are needed to support daily adherence to supplement usage during pregnancy, could yield richer results.[11 32] It should be noted that self care should never replace care provided by the health system and should instead be a bridge for users to engage with the health system.

Further research should seek to explore settings in which IFA supplements are available to pregnant women both as OTC or home-based products and provided through healthcare providers to identify values and preferences around modes of access of supplements. Research conducted to address this knowledge gap would have inherent limitations. Studies would most likely need to be observational studies, as experimental designs would not be appropriate or ethical. Studies would need to be conducted in a setting where IFA supplements are available OTC, which limits the research context to settings with a strong pharmaceutical industry and robust regulatory systems. Potential experimental intervention studies could be conducted to test the use of education or behaviour change mechanisms outside of provider service to promote self-management of IFA supplement use pre-pregnancy, during pregnancy and postnatal. Furthermore, as many pregnancies are not planned, research and programming efforts to integrate pre-pregnancy supplementation with family planning efforts could promote initiation of pre-pregnancy supplementation following the discontinuation of contraceptive use. However, prior to designing or conducting intervention trials to test the impact of self-management of IFA supplements, there is a need for a general understanding of dietary supplementation self-management behaviours, values and preferences, and cost. Given the existing challenges of poor adherence to supplementation, particularly during pregnancy,[33] research should explore how different modes of supplement access and uptake, including self-management, may influence adherence, acceptability and cost.

CONCLUSION

Folic acid supplements pre-pregnancy, IFA supplements during pregnancy and iron supplements postnatal are known to improve maternal and birth outcomes and present few safety concerns when taken in recommended doses. In this review, we aimed to identify literature that distinguished between self-management and provider-initiated management of these supplements to identify the effect on maternal and fetal and newborn health outcomes, as well as end-users' and providers' values and preferences, cost and cost-effectiveness. We were unable to identify any studies on this topic, highlighting a gap in current understanding of self-care interventions relating to IFA supplementation during pregnancy and identifying an area for further research to support the current movement towards self-care interventions as a mechanism to help individuals more fully attain their right to health.

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Acknowledgements We thank Caitlin Kennedy for her guidance in developing and conducting this review, and Maurice Bucagu, Laura Ferguson and Nandi Siegfried for their thoughtful comments on the protocol. Shannon King gratefully acknowledges the Harry D. Kruse Publication Award in Human Nutrition, awarded by the Kruse family

Contributors MN, OT and LMR conceptualised the study. PTY designed the protocol, with feedback from SEK, MN, OT and LMR. PTY ran the database search and oversaw the search, screening, full-text review, and data extraction process conducted by SEK and DR. SEK drafted the manuscript. PTY, DR, OT, LMR and MN reviewed the draft, provided critical review, and read and approved the final manuscript. The corresponding author, as guarantor, accepts full responsibility for the finished article has access to any data and controlled the decision to publish. The corresponding author attests that all listed authors meet the authorship criteria and that no others meeting the criteria have been omitted.

Funding We gratefully acknowledge financial support of The Children's Investment Fund Foundation (CIFF). All authors had full access to all of the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

Disclaimer The funder played no part in the decision to submit the article for publication, nor in the collection, analysis and interpretation of data.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on request. List of screened articles and reasons for exclusion is available on request.

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