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Dietary folate intake and folate status of women following a gluten free diet: a scoping review protocol

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Abstract

Objective: To scope the evidence available on the folate status and folate intake of women on a gluten free diet (GFD) and compare this against established reference ranges and recommended intake values.

Introduction: Folate is essential for cell division, DNA synthesis and amino acid metabolism. Adequate folate status is important during preconception to reduce the risk of neural tube defects. Individuals following a GFD may be at risk of inadequate folate intake due to the exclusion of fortified grain products. As women represent the majority of GFD followers, this may have health implications in cases of unplanned pregnancy.

Inclusion criteria: Eligible studies will include data on females of any age following a GFD and reporting a measurement of folate intake or folate status. There will be no restriction on language or year of publication. Peer-reviewed and grey literature sources will be included.

Methods: Following the Joanna Briggs Institute guidelines for scoping reviews, a comprehensive search for peer-reviewed literature will be conducted using specified search terms in PubMed, CINAHL Ultimate and Scopus. Other databases (ProQuest, Cochrane Library, Clinical Trials Gov and Google Scholar) will be utilised to search for grey literature. Title and abstract and then full-text screening will occur with additional backwards citation searching. Data extraction will focus on folate status and/or intake and study characteristics. Findings will be discussed in relation to gaps in the literature, adequacy of folate intake and status and implications for folic acid fortification initiatives.

Keywords: Adult; celiac; dietary quality; folic acid; micronutrient

Introduction

"Gluten" is the collective name for several plant-storage proteins found in wheat, rye, barley and sometimes oats (1). These grains are used to make staple foods like bread, pasta, noodles, flour and breakfast cereals worldwide (1). Although most people consume these staple foods and hence gluten frequently, a significant proportion of the world's population follows a gluten free diet (GFD) (1). For example, in Australia it has been found that between 2.5% and 24.2% of survey respondents were avoiding gluten (2-4). People follow a GFD for a variety of reasons such as for the treatment of Coeliac disease, management of dermatitis herpetiformis, non-coeliac gluten sensitivity and wheat allergy, lactose intolerance, irritable bowel syndrome and gastrointestinal symptoms, to aid weight loss and for general health reasons (3, 5-9). Overall, more women follow the GFD than men do and this has been confirmed worldwide (4, 10-18).

Several studies have examined the nutritional quality of the GFD and have demonstrated that it is not nutritionally adequate (19, 20). A nutrient of specific concern for those following the GFD is the micronutrient folate (19, 20). Folate plays an important role in DNA synthesis, cell division and the metabolism of amino acids (21). Furthermore, it is important for women of reproductive age (WRA, 16-44 years) as it enables the development of the foetus' neural tube in early pregnancy; in the context of folate deficiency there is an increased risk of neural tube defects (22-25). To ensure adequate folate intake and status during pregnancy, all WRA planning pregnancy, including those following a GFD, are recommended to take supplements containing 400-500 micrograms of folic acid (the synthetic form of folate) daily prior to conception (23, 26). Additionally, WRA are recommended to consume a folate-rich diet containing high-folate foods like green leafy vegetables, legumes, some fruits, eggs, tofu and foods fortified with folic acid (23, 26). In Australia, most adults consume only 3 serves of vegetables per day with folate-rich vegetables (i.e. green leafy vegetables and legumes) comprising approximately 45% or 1.35 serves daily (27). To address the low consumption of folate and folate-rich dietary sources, the Australian government mandated folic acid fortification of wheat flour for bread making in 2009 (28). This public health intervention resulted in a significant increase in population folate and folic acid intake (28). Many other governments worldwide have also encouraged or mandated public health measures to fortify wheat-based and maize-based staple foods with folic acid to good effect (29, 30). One study found that in countries with folic acid fortification, mean plasma folate levels were 50-100% higher and neural tube defect prevalence was 25-50% lower when compared to countries without folic acid fortification (30).

Around half of pregnancies are unplanned and therefore many women may miss the opportunity to select folate-rich foods and take folic acid supplements to ensure adequate folate status and intake during early pregnancy (26, 31, 32). For those following a gluten-containing diet, the fortification of wheat based staple foods with folic acid has proven to be beneficial in this case (28, 30). However, for women following a GFD, their folate intake and status may be at risk more so than the general population. As previously mentioned, folate has been identified as a nutrient of concern for those following a GFD (19, 20). This could potentially be due to many common GF (gluten free) foods and commonly used GF ingredients in staple GF foods being naturally poor in micronutrients like folate (33, 34). Furthermore, folic acid fortification strategies usually require fortification of staple foods containing wheat flour and not GF staple foods (29, 35). As such, those following a GFD, especially WRA, may not be benefiting from public health initiatives to increase the folate content of their habitual diets at the population level.

A preliminary search has revealed that there are some primary studies and a small number of reviews which examine the folate intake and folate status of people following the GFD. However, these investigations were included as part of wider investigations into the overall nutritional intake and status of those on the GFD rather than investigations particularly into folate intake and/or status alone (15, 19, 36-40). Furthermore, most of the literature does group men's and women's folate status and intake together despite clear gender-based differences in the dietary patterns of the two genders while following the GFD (18, 36). Therefore, this scoping review will be the first of its kind to examine the effect of the GFD with a specific focus on women's folate intake and status with consideration of reproductive health and public health policy.

The scoping review method was chosen to investigate the folate intake and status of women following a GFD as it is ideal for investigating research topics which have not been studied in depth, like this topic (41). Furthermore, due to the lack of studies on this research topic and the fact that the published data is heterogenous and complex, it will be important to first identify and map what body of evidence is available and scoping reviews are ideal for this purpose (41). Additionally, scoping reviews are informed by peer-reviewed and non-peer-reviewed material to ensure high search sensitivity in a context of limited evidence (41). This relates well to the chosen research topic as there is a limited availability of peer-reviewed evidence and some relevant grey literature does exist on the topic which would be remiss to be excluded. Finally, an in-depth analysis and quality appraisal of sources are generally not a characteristic of scoping reviews due to their utilisation in emerging research fields without extensive and/or reliable data available (41). As the preliminary search provided only a small body of evidence around this research topic, it was determined that an in-depth methodological analysis and bias assessment of the data would not be possible and thus the scoping review method was deemed more suitable than other types of reviews.

The aim of this scoping review is to 1) identify and map the international evidence on the folate status and intake of women following the GFD, and 2) compare the reported values against established reference ranges and recommended intake values.

Review questions

1. What is the scope and depth of evidence internationally reporting on folate status and folate intake of women following a GFD?
2. What are the reported folate status and folate intake values of women following a GFD and are these adequate in relation to established reference values and recommended intake values?

Inclusion criteria

Participants

Sources to be included in this scoping review must meet two participant-related criteria: 1) following a GFD, and 2) females aged ≥ 18 years of age. Sources excluded are those investigating only men following a GFD or studies that do not provide disaggregated data across sex, age group or life stage (i.e., children, adolescents, WRA, pregnant etc). Furthermore, any studies or materials which investigate non-human participants or topics will be excluded from this scoping review.

Concept

In addition to fulfilling the participant criteria, sources must investigate one or both of the following criteria: 1) participant dietary folate intake or 2) participant folate status. Folate status measures can include any relevant folate status tests including serum folate or red blood cell (erythrocyte) folate (42). Dietary intake is inclusive of reported quantification of folate from natural dietary sources and folic acid from fortified products and supplementation. Experimental studies without a control group following a habitual GFD will be excluded unless baseline folate status or intake measures are recorded prior to the intervention period.

Context

This scoping review will review data at the international level, from all settings and from any point in time. Therefore, no context-specific restrictions have been set regarding geographical location, cultural factors or the type of study setting.

Types of sources

This scoping review will include both observational and experimental studies of any research design. Published as well as ongoing or unpublished evidence will be considered where relevant if the data is able to be adequately sourced. Grey literature such as dissertations and theses, conference materials (including conference papers and proceedings), clinical trials and any reports or other relevant publications will also be included. Reviews will be included if the data is relevant to this scoping review. No date restriction will be applied to allow for a view overtime of the available evidence. Finally, no language restriction will be applied to the search and non-English sources will be translated were feasible.

Methods

The proposed scoping review will be conducted in accordance with the Joanna Briggs Institute (JBI) methodology for scoping reviews (41).

Search strategy

A three-step search strategy will be utilized in this review. First an initial preliminary search was conducted in CINAHL Ultimate to identify relevant articles on the topic. This initial search used several search terms established using the PCC (‘population’, ‘concept’ and ‘context’) mnemonic recommended for scoping reviews and based on the research questions (41). The titles, abstracts, index terms and some of the full texts of relevant studies were examined to generate additional search terms. This enabled the refinement of the PCC mnemonic, condensing of the search terms and the development of the full search strategy (41).

The full search strategy (refer to Appendix I) will be used to locate peer-reviewed sources and reviews in PubMed, CINAHL Ultimate and Scopus. Additionally, the search will be conducted in ProQuest, Cochrane Library, Clinical Trials Gov and Google Scholar to further locate sources including

grey literature. Minor changes to the full search strategy will be necessary to adapt accordingly to the requirements of each database. Any relevant incomplete, partially published or full-text not available sources will be sourced where possible by utilizing interlibrary requests or by contacting the corresponding author. Finally, the backwards citation searching of included sources will be conducted to check for missed citations.

Study/Source of evidence selection

After the full search has been completed, all identified citations will be collated and uploaded into Endnote version 21 (Clarivate Analytics, PA, USA). Duplicates will be removed first through Endnote's 'find duplicates' function and then manually by title and author. After deduplication, all remaining sources will be imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI) (JBI, Adelaide, Australia) (43).

Titles and abstracts will then be screened by two independent reviewers for assessment against the inclusion criteria. The remaining sources will have their full text retrieved and imported into JBI SUMARI. At full text screening, each source will be assessed in detail against the inclusion criteria by two or more independent reviewers. Sources which meet the inclusion criteria after full text screening will be used in the final scoping review. The details for exclusion of any sources will be recorded and reported in the scoping review. Any disagreements regarding inclusion or exclusion of sources between the reviewers will be resolved through a discussion between the researchers. A backwards citation search of the included sources will be undertaken with suitable sources sought for full text review.

The results of the full search, deduplication, title and abstract screening, full text screening and backwards citation searching and related screening will be reported in full in the final scoping review and presented in a PRISMA flow diagram (44).

Data extraction

The research team identified the study characteristics and data to be obtained from the sources to answer the research questions. A data extraction form was then created and piloted using the full texts of three studies which were identified as highly relevant for this scoping review (18, 39, 45). Modifications were made to the original data extraction form during piloting to ensure that the data required to answer the research questions would be adequately captured. The data extraction form will obtain the following data:

- Source characteristics: including title, authors, year of publication, key words, name of journal (if applicable), publishing language, correspondence information, years of data collection (if applicable), country in which the study was conducted, study type or grey literature type, aim and/or purpose, funding, conflicts of interest and research methodology.
- Sample characteristics: including sample size, sample recruitment details, sample demographics (including age of participants, participant population, presence of Coeliac disease and diagnostic methodology (if relevant), length of time on a GFD and details related to GFD adherence) and participant inclusion and exclusion criteria.

- Research findings and analysis: including details around which data was included in the analysis, findings related to folate intake and/or folate status data, data related to folate intake recommendations (if applicable), data related to folate status reference ranges (if applicable).
- Potential confounders and study strengths and limitations.

For any sources that do not adequately provide the information required to be obtained for this scoping review (for example, number of participants in the sample or folate status reference ranges), the authors will be contacted to obtain the missing information.

The data extraction form is shown in Appendix II and will be modified and reviewed throughout the data extraction process where required. Any modifications made to the extraction form during data extraction will be detailed in the scoping review.

Data analysis and presentation

The data extracted from the sources will be analysed to identify key patterns and differences. Dominant trends, outliers and gaps in the evidence will also be identified. If required, folate intake recommendations or folate status reference ranges may be sought from the relevant bodies to enable a comparison between the data contained within the sources and the recommendations. The analysis will enable an overview of the body of evidence, the data around folate intake or status contained within the body of evidence and how this relates to folate status or intake recommendations.

The findings of this scoping review will be presented both graphically and in tabular form. In addition to this, the results will be presented in a thesis format and this will include a narrative description of the findings and how the findings of this scoping review relate to the objectives and research questions. There will be three specific areas of discussion including characteristics and mapping of the body of evidence, data located within the body of evidence and finally a discussion of how the data found relates to folate intake and status recommendations.

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Author contributions

DP, KG and RT contributed to the conceptualization of this scoping review. DP created and finalised the search strategy with inputs from KG and RT. DP will conduct the full search, obtain the sources and conduct deduplication. DP and KG will contribute to the title and abstract screening and all authors will contribute to full text screening. DP will extract the data from the sources and perform the analysis with supervision from KG and RT. DP will write the thesis in which the narrative description and graphic and tabular presentation of the data will be contained within. KG and RT will provide critical guidance and feedback during the thesis writing stage.

Conflicts of interest

There is no conflict of interest in this project.

Appendices

Appendix I: Search strategy

PubMed was searched in June 2025 as per the details in appendix I.

Appendix II: Data extraction form

The data extraction form used in the scoping review is located in the appendix II.

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