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Dietary education versus supplementation to improve folate status in women

Submission date
23/11/2025

Recruitment status
No longer recruiting

Registration date
26/11/2025

Overall study status
Completed

Last Edited
28/05/2026

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aim
Decades ago, researchers discovered that consuming enough of a B vitamin called folate can help to prevent types of birth defects known as neural tube defects (NTD). In Ayutthaya province in Thailand, the number of babies affected with NTD is more than twice the national average. Several studies in Thailand show that many young woman do not eat enough folate in their diet, and their blood folate levels are not optimal for preventing NTD. Because Thailand does not fortify staple foods, understanding whether education can improve folate status is important for public health planning. The aim of the current study was to compare two approaches to improve blood folate levels in young women: a dietary folate education program versus once-weekly folic acid supplements.

Who participated?
Participants in this study were women who were 20-34 years old and worked day shifts in three factories in Ayutthaya province, Thailand. None of them were pregnant, breastfeeding, affected by serious long-term diseases, had previously given birth, smoked, or took supplements or medicines known to affect folate levels in the body. Everyone agreed in writing to take part in the study before it began, and all personal information was removed from the data.

What did the study involve?
Participants worked in one of three factories. Each factory was assigned to one of three groups:
1. Dietary folate education group: This group took part in once-weekly sessions, each about 30 minutes long, over a period of 12 weeks. The sessions covered topics such as the health benefits of folate, foods that naturally contain a lot of folate or have added folate, understanding nutrition labels of food packaging, choosing and preparing folate-rich foods. The sessions included activities to build knowledge, increase awareness, and strengthen confidence in making folate-rich food choices. For example, a game based on the Thai nutrition flag to reduce barriers to preventing folate deficiency. The sessions were interactive, with short presentations, small-group discussions, idea sharing, food tasting, a market assignment, and meal preparation activities.
2. Folate supplementation group: This group received 12 tablets containing folic acid (2.8 mg) and iron (60 mg). They were asked to take one tablet on the same day each week for 12 weeks.
3. Comparison group: This group received no intervention.

Before the intervention, we collected basic information about the participants using a questionnaire, including their age, marital status, education level, monthly income, and the number of people living in their household. Before and after the intervention, we measured: (1.) Knowledge, perceptions, self-efficacy, and cues to action about folate and NTD using a questionnaire, (2.) dietary folate intake using a food frequency questionnaire (SFFQ), and (3.) the amount of folate in red blood cells using a standard laboratory method. The questionnaires and SFFQ were administered by the researchers. For measurement of red blood cell folate, participants were asked to give two 6ml blood samples, 12 weeks apart.

What were the possible benefits and risks of participating?
At the end of the study, participants gained information about their dietary folate intake and the amount of folate in their red blood cells. Possible risks of participating included possible side affects such as stomach upset as a result of taking the the supplement (participants in the supplementation group only) and giving two blood samples could have caused short-term discomfort and mild bruising of the forearm.

Where was the study run from?
Mahidol University (Thailand)

When did the study start and how long did it run for?
February 2019 to August 2019

Who funded the study?
Investigator initiated and funded

Who is the main contact?
1. Asst. Prof. Dr. Carol Hutchinson (Major Advisor to Ms Kannatcha Sroypechr), carol.hui@mahidol.ac.th
2. Ms Kannatcha Sroypechr (DrPH Research Student), kkannat@gmail.com

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Ms Kannatcha Sroypechr

Contact details
Bureau of Nutrition, Department of Health, Ministry of Public Health
Nonthaburi
Thailand
11000
+66 (0)890079888
kkannat@gmail.com

Type(s)
Public, Scientific

Contact name
Dr Carol Hutchinson

ORCID ID
https://orcid.org/0000-0002-9832-6011

Contact details
Department of Nutrition, Faculty of Public Health, Mahidol University
Bangkok
Thailand
10400
+66 (0)23548539
carol.hui@mahidol.ac.th

Additional identifiers

Study information

Scientific Title
Dietary education versus supplementation to improve red blood cell folate concentration in female factory workers of reproductive age women in Phra Nakhon Sri Ayuthaya, Thailand

Study objectives
To compare the effect of a dietary folate education program based on the Health Belief Model and once-weekly folic acid supplementation on the red blood cell folate concentration of reproductive-aged women.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/01/2019, Ethical Review Committee for Human Research, Faculty of Public Health, Mahidol University (Human Research Ethics Unit, Research and Innovation Division, Public Health Wisit Building (Building 1), 4th Floor, 420/1 Ratchawithi Road, Ratchathewi District, Bangkok, 10400, Thailand; +66 (0)23548543 ext. 1412, 1127; thitirat.boo@mahidol.edu), ref: MUPH 2019-011

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Pre-test post-test quasi-experimental study

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Improving folate status in women of reproductive age

Interventions
This was a pre-test post-test quasi-experimental study with comparison group, involving three factories, and conducted from February to August 2019. Factory 'A' received the dietary folate education program because the managers were willing to allow the researchers to conduct activities there. Factories 'B' and 'C' were then designated as the folic acid supplementation and comparison groups, respectively.

Dietary folate education group:
This group participated in 12 sessions, each lasting around 30 minutes, once weekly, over 12 weeks in between pretest and post-test measurements. We developed the program using information gathered from observations of the factories' canteens, local markets and convenience stores, and each intervention session was tailored around the constructs of the Health Belief Model (HBM). The topics were as follows:
1. Health benefits of folate, including neural tube defect (NTD) prevention
2. Naturally folate-rich food
3. Foods fortified with folic acid and nutrition label information
4. Dietary reference intake for folate and serving sizes of folate-rich food
5. Folate-rich foods in the factory canteen and community
6. Choosing ready-to-eat meals or folic acid fortified products
7. Varying folate-rich meals from ready-to-eat foods and folic acid fortified products to meet the recommended intake
8. Making folate-rich meals
Topics 4, 5, 7, and 8 were repeated at weeks 9, 10, 11, and 12. Activities were designed to enhance knowledge, perceptions of susceptibility, severity and benefits, and self-efficacy in relation to dietary folate, folate status and NTD. For example, a game centered around the Thai nutrition flag was intended to reduce barriers of folate deficiency prevention. The sessions were interactive, involving short presentations, small group activities, idea-sharing, food tasting, a market assignment and meal making.

Folic acid supplementation group:
This group was provided with 12 tablets that contained folic acid (2.8 mg) and iron (60 mg) (Ferrofolic, Government Pharmaceutical Organization, Bangkok, Thailand). This dose and regime was used because in 2019 the Thai Ministry of Public Health launched policy and practice to offer a once-weekly supplement containing folic acid (2.8 mg) and iron (60 mg) to Thai women aged 20-34 years. Furthermore, a once-weekly iron and folic acid supplement has been endorsed by the World Health Organization as an efficacious and safe public health intervention.Therefore, participants were asked to consume one tablet once weekly on the same day for 12 weeks, in between pretest and post-test measurements. Participants completed a diary to document whether they followed instructions and to note any adverse effects. Once a month, participants received a reminder to take the supplements. They also returned the supplement packaging and diary at post-test.

Comparison group:
These participants did not receive any intervention in between the pretest and post-test measurements.

Intervention Type
Mixed

Primary outcome(s)
1. Red blood cell folate concentration measured using ARCHITECH 12000 Chemiluminescent folate immunoassay (Abbott, Northern Illinois, USA) at pre-test / baseline (week 0) and post-test (week 12)

Key secondary outcome(s)

Completion date
20/08/2019

Eligibility

Key inclusion criteria
1. Female
2. Aged 20-34 years
2. Worked day shifts
3. Able to give written informed consent to participate

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
20 Years

Upper age limit
34 Years

Sex
Female

Total final enrolment
76

Key exclusion criteria
1. Pregnancy
2. Lactation
3. Metabolic, hereditary or chronic infectious diseases
4. Having previously given birth
5. Smoking

6. Supplement use
7. Use of medicines known to interfere with folate metabolism

Date of first enrolment
11/02/2019

Date of final enrolment
04/03/2019

Locations

Countries of recruitment
Thailand

Sponsor information

Organisation
Mahidol University

ROR
https://ror.org/01znkr924

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/05/2026	28/05/2026	Yes	No