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The comprehensive anaemia programme and personalized therapies (CAPPT) trial testing the effect of home visits, tailored iron therapy and women's groups to reduce anaemia in pregnant women in southern Nepal

Submission date
05/04/2021

Recruitment status
Suspended

Registration date
22/04/2021

Overall study status
Completed

Last Edited
06/05/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Anaemia is a condition where a person doesn't have the normal amount of red blood cells or if their blood is low in a protein called haemoglobin. Anaemia is common in pregnancy. Pregnant women suffering with anaemia may be pale, weak tired and breathless going about everyday tasks. Anaemic women are more likely to have complications or to die during childbirth.

In the plains of Nepal, many women suffer from anaemia in pregnancy. They have limited diets without enough iron-rich foods and may not get their fair share of nutritious foods. Although the government of Nepal gives free iron and folic acid tablets to women that go for antenatal checkups during their pregnancy, many women do not get the recommended dose of at least 180 tablets.

The Comprehensive Anaemia Programme and Personalized Therapies (CAPPT) trial aims to test the effect of a combined community intervention to reduce anaemia in pregnant women in the district of Kapilbastu in southern Nepal.

Who can participate?

Any woman or girl aged 13 to 49 years who lives permanently in one of the 54 selected population areas (clusters) in Kapilbastu district can participate in the menstrual monitoring part of the study if she is married, able to respond to questions, and could possibly get pregnant. This means that she or her husband have not had permanent contraception, she is not infertile, has not her uterus removed and has not reached menopause. Anyone taking part will be asked about whether they have missed their period every month for up to 7 months.

If a woman has missed one or more periods she can enrol in the trial if she has a positive pregnancy test, is planning to live in the cluster most of her pregnancy, and if it is less than 20 weeks since her last menstrual period. If she cannot remember her last menstrual period or has not had a period since her last child, she can be enrolled so long as her pregnancy bump is not above the level of the belly button.

What does the study involve?
For any woman who agrees, the Female Community Health Volunteer for that village will visit her every 4 weeks to ask if she has had a period or missed one or more periods. Any woman who has missed at least 1 period will be offered a free urine pregnancy test at home to confirm the pregnancy. Every pregnant women who consents (by signing or thumb-printing a consent form) will receive a trial participant card with a unique identification number. This can be shown to project staff and the health worker in the local health clinic so that they know the woman is involved in the study.
Data collectors collect pregnant women's information on tablets using electronic data collection systems. After the woman reports her pregnancy, data collectors visit her 4 times to collect information. They will record personal details such as age, education, household details, medical and obstetric history as well as many details of the pregnancy. Once before 20 weeks and again at around 30 weeks the data collectors conduct a finger prick to test the woman's haemoglobin level using a machine called a "Hemocue" to check whether the woman has anaemia or not. They also measure her weight, height, the thickness of her upper arm and ask questions about eating habits, iron supplements, antenatal care and any illness/discomfort during pregnancy. Another HERD interiewer visits the woman twice at 28-32 weeks' of pregnancy. At these visits (which are 2 to 7 days apart) they ask both the woman and her husband (or another male family member) in detail about what they ate the day before.

Home visits: For women who live in intervention areas a female HERD staff who is a qualified nurse (a "nutrition assistant") will visit her at home twice: once between 12 and 21 weeks and once between 18 and 25 weeks of pregnancy. At each visit the nutrition assistant discusses with the pregnant woman and her family members about her diet and health in pregnancy using a problem solving approach. The family come up with an agreed action plan to improve the nutrition and health of the pregnant woman. At each visit the nutrition assistant checks for anaemia by measuring the haemoglobin level with a Hemocue machine . She tells the woman her anaemia status and gives her the right dose of iron folic acid (IFA) tablets for preventing or treating anaemia in pregnancy. This means that women who have mild to moderate anaemia gets double dose of IFA compared to women who are not anaemic. Women who are severely anaemic are advised to go immediately to a hospital for treatment.

Participatory Learning and Action (PLA) women's groups: In intervention areas, the nutrition assistant also invites the woman and her family members to attend monthly participatory women's groups. These groups are organised by the nutrition assistant and the Female Community Health Volunteer in all intervention areas. The groups are open to anyone in the community but are mostly attended by women. At these meetings participants discuss the problem of anaemia in pregnancy and how to reduce it through improved diet, eating iron-folic acid (IFA) tablets and going for antenatal care. Group members come up with strategies for how to improve anaemia in the community and involve community members in these activities.

What are the possible benefits and risks of participating?
Benefits: Because the study will be monitoring women's periods women may know that they are pregnant earlier than they might otherwise have known. This may help women to plan their pregnancies, seek timely and appropriate health care and eat nutritious food required for proper growth of the baby. Participating in this study helps pregnant women to know the level of haemoglobin in their body and find out whether they have anaemia or not. They also get to know if they are normal weight, underweight or overweight, which may help them to understand their nutritional health.
All women receive a participation incentive of NPR 1000 at the end of their participation in the study, after we have measured their haemoglobin at 28 to 32 weeks of pregnancy.

Women who live in the intervention areas benefit as follows:
1) They receive two counselling visits from trained individuals at their home, which may help them to get more support from family members. At these visits the health worker discusses with the woman and her family about nutrition in pregnancy and how to prevent anaemia. The health worker will test the pregnant woman's anaemia levels at home and provide the right dose of iron and folic acid tablets for her condition. If she has severe anaemia they alert herto get medical assistance from a hospital.
2) She and her family members may participate in the monthly women's group meetings about nutrition in pregnancy and how to solve the problem of anaemia in the community. These groups can be informative and enjoyable.

Risks: We do not think that any harm will come to participants from taking part, but it is possible that women might find sharing information about their periods or pregnancy uncomfortable or upsetting. They do not have to continue to take part if they don't feel like it and can talk to someone working on the study whenever needed. Finger prick blood tests to check for anaemia can be a little uncomfortable but there is minimal risk associated with them and data collectors are trained to follow all best practices of hygiene and infection control.
There is a risk that COVID-19 could be carried into participants households and communities by project staff, or that project staff could catch COVID-19 from community members participating in the study. In order to mitigate this risk a covid screening form will be filled on each and every occasion that project staff visit pregnant women. Participants will be asked if they or their family members currently have, or have had, a fever, a new persistent cough, breathing difficulties, loss of taste or smell or a positive covid test. The same questions will be asked of staff each day before going out into the community. Visits will only be made if both the household members and the project staff do not answer yes to any of the screening questions. If any covid case is detected the household will not be visited for 14 days and/or the staff member will isolate at home for 14 days as needed.
To prevent the spread of COVID-19 participants and project staff will wear masks at all times during interactions, ad will wash hands with soap and water or use sanitiser before and at the end of interactions. All equipment for measurements will be sanitised between each household. For anaemia measurements, project staff will wear gloves. If community infection rates become very high interviews, home visits and group meetings may have to be suspended for some time, depending on government guidelines.

Where is the study run from?
The study is being run by three organisations that are working together. These include a research organization based in Kathmandu called HERD International and two research organisations based in the United Kingdom called University College London (UCL) and London School of Hygiene and Tropical Medicine (LSHTM).
The location of the study is 54 population clusters (areas) in the district of Kapilbastu in Province 5, in central Nepal, near the border with Uttar Pradesh state of India. The selected areas are in the south of the district, not close to the main Mahendra Highway, in rural areas, without any big markets, where most of the people are Madheshi ethnicity. The study concentrates on Madheshi ethnic group because anaemia rates are higher in this population. None of the clusters touches one another (i.e. they are surrounded by areas where the project is not working).

When is the study starting and how long is it expected to run for?
November 2018 to October 2022.

Who is funding the study?
The study is funded by UK Medical Research Council (MRC)/ Newton Fund (MR/R020485/1). Note that, with matched funding from Indian Department of Biotechnology (DBT) a 'sister' study with

the same CAPPT abbreviation is happening in India implemented by AIIMS (All India Institute of Medical Sciences).

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Additional identifiers

Protocol serial number
MR/R020485/1

Study information

Scientific Title
Comprehensive Anaemia Programme and Personalized Therapies (CAPPT): a non-blinded cluster-randomised controlled trial testing the effect upon haemoglobin in pregnancy of participatory learning and action women's groups with home-counselling and tailored iron supplementation compared with standard care in southern Nepal.

Acronym
CAPPT

Study objectives

The haemoglobin of pregnant women at 28 to 32 weeks' gestation is ≥0.4 g/dL higher in the intervention arm (tailored dosage of oral iron-folic acid (IFA), personalized nutrition counselling at women's homes, and PLA women's groups in the community in addition to routine antenatal care (ANC)), than in the control arm (routine ANC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 03/07/2019, Nepal Health Research Council's Ethics Committee (Ramshah path, Kathmandu P.O. Box 7626, Kathmandu, Nepal; +977 - 4254220; approval@nhrc.gov.np), ref: 353 /2019
2. Approved 28/11/2018, University College London Research Ethics committee (Office of the Vice Provost Research, 2 Taviton Street, University College London, UK; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 14301/001
3. Approved 22/05/2019, London School of Hygiene and Tropical Medicine research ethics committee (Keppel Street, London, WC1E 7HT, UK; +44-(0)20 7636 8636; ethics@lshtm.ac.uk), ref: 16528

Primary study design
Interventional

Study design
Non-blinded parallel group two-arm cluster-randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention and treatment of anaemia in pregnant women

Interventions
Fifty-four clusters (mean population 2582; range 1299 to 4865) meeting cluster eligibility criteria, each surrounded by a buffer zone, have been allocated into two study arms of 27 clusters. Restricted randomization was applied to maximize similarity with respect to cluster size (number of eligible women), caste, religion and travel time to a public health facility. In the control arm pregnant women receive routine antenatal care as per government protocols. In the intervention arm pregnant women receive a combination of two home counselling visits plus they and their families are invited to join participatory learning and action women's groups in their community (PLA). Home visits and PLA are delivered by six female Nutrition Assistants (NAs) who are certified auxiliary nurse midwives or staff nurses hired by the Nepal implementing organisation HERD International.

Home visiting intervention:
Home visits are designed to work synergistically to encourage PLA group attendance, to reach women who cannot / do not leave their homes, and to engage family members in addressing anaemia. Each home visit comprises dialogical counselling, home-based anaemia screening, and tailored IFA. The NA visits each pregnant woman twice at home, first at 12 to 21 weeks and second at 18 to 25 weeks. Ideally the gap between visits is 4 to 6 weeks, unless logistical constraints imposed by the COVID 19 pandemic disrupt activities.

Home-based tailored dialogical counselling:
A dialogical approach is used to engage pregnant women and their families to think critically about the causes of anaemia in pregnancy in their household and community. The NA engages pregnant women and their families in a cycle of action and reflection: 1) listening for the key issues and emotional concerns of the household; 2) promoting participatory dialogue about these concerns; and 3) planning and taking action about the concerns that are discussed. At the first and second home visits, the NA uses stories and inductive questioning to trigger dialogue and reflection. Stories directly address issues from our formative research. NAs are trained about common issues that may arise and provide a discussion and reference manual with examples of actions that pregnant women and their families could take. Families make specific action plans to address the issues that are relevant for their family and in the second visit these are reviewed and a different story used to trigger discussion and reflection. The tailored counselling supports women and their families to take actions to change dietary practices, attend PLA groups, and access antenatal care. If The NA observes any pregnancy danger signs, as per the government's standard treatment protocol, she advises the woman to seek care straight away from the nearest appropriate health facility.

Anaemia screening and tailored iron-folic acid therapy:
At each home visit, following the discussion of the story, the NA measures the PW's haemoglobin concentration using a hand-held Hemocue Hb 301+ analyser, measures her mid-upper arm circumference (MUAC) with a SECA tape (93/42/EEC) to assess thinness, and explains the results. Following GoN guidelines, the NA advises the PW to take IFA as follows:
• Not anaemic (Hb≥=11 g/dL) one IFA tablet (60 mg elemental iron and 400 ug folic acid) per day;
• Mildly or moderately anaemic (Hb 7 - 10.9 g/dL) two IFA tablets (120 mg elemental iron and 800 ug folic acid) per day.
• Severely anaemic (Hb < g/dL) the NA immediately refers the PW for a blood transfusion at a higher health facility.
At visit 1 (at 12 to 21 weeks) the NA provides sufficient IFA tablets for a period of 6-8 weeks until her second visit, at 18 to <25 weeks. For those with low (<230 mm) or very low (<210 mm) MUAC, the NA emphasizes the importance of consuming additional calories through more frequent and/or larger meals, taking adequate rest, as well as increasing dietary diversity and consuming micronutrient-rich food. For overweight PW with MUAC >=300mm, the NA stresses the importance of keeping active during pregnancy, increasing intake of micronutrient-rich foods, avoiding sugary or fatty foods and large portions of rice.
After repeating the haemoglobin and MUAC measurements at the second visit, the NA explains to the woman how her anaemia and thinness status have changed, and provides the appropriate IFA dose. She also assesses compliance to IFA by asking the PW about their tablet consumption and checking used blister packs. At visit 2, the NA provides a single (400 mg) albendazole tablet if the PW has not already received it as per Nepal's national protocol for women in their second trimester.
The NA records details of haemoglobin and MUAC readings, IFA and albendazole tablets provided on the Trial Participation Card (TPC) at each visit to enable participants to show health workers what treatment they have been receiving. The NA's makes two copies of discussion action sheets to record actions agreed to reduce anaemia based on the issues identified. One copy is given to PWs family and the other copy is kept by the NA for reference. The NA also records Hb, MUAC, IFA and albendazole given, and the actions agreed upon with the PW's family on an electronic data collection form just after the visit is concluded. The NA does not enter data on the tablet or phone during the visit to focus upon more fluid interaction and discussion, but takes a photograph of the TPC and the discussion action sheet before leaving the home.

Participatory learning and action women's group (PLA) intervention:
In the intervention arm, the NA, together with the local FCHV for that cluster, facilitates monthly groups at a convenient place and time for community members. As FCHVs are mandated by the health system to hold monthly mothers' groups, these groups are used where they already exist and are revitalised where they are inactive.
The groups run for a 15-month period, from the start of the first enrolment until after the last enrolled woman has completed 302 weeks gestation. NAs, who are locally recruited and trained, train the FCHVs on the PLA meeting manual each month and the FCHVs assist the NAs in group facilitation. Groups are open to anyone who is interested and participation is voluntary. As restrictive gender norms can prevent women's participation in mixed groups, the first 10 meetings are exclusive to women. Men are invited to a large community planning meeting and groups discuss how they would like to engage with men thereafter.
The PLA cycle consists of four phases 1) problem identification, 2) planning together, 3) strategy implementation and 4) strategy evaluation. During the 'problem identification' phase, over 6 monthly meetings, groups are introduced to the PLA method, discuss local definitions and beliefs about the causes and symptoms of anaemia, and local beliefs around taking IFA supplements. They then discuss barriers to good nutrition to improve anaemia, and barriers to uptake of IFA supplementation during pregnancy. During the 'planning together' phase, over 3 monthly meetings groups prioritise problems that they would like to address and plan and implement a community meeting to engage a wider group of stakeholders. Groups lead on the implementation of these strategies in Phase 3 (from meeting 10) and continue to discuss new topics related to anaemia in pregnancy. They evaluate the effect of their actions in Phase 4 by reflecting on the original problems and progress in solving them. Then they may reformulate strategies to begin another phase of implementation.
During the PLA cycle, facilitators use a pictorial meeting manual which contains varied triggers for discussion – such as a story, a quiz, or game – which are often used with picture cards. These focus on iron- rich foods and how to increase bioavailability, improve IFA compliance, reduce side effects and manage nausea and minor pregnancy ailments, and when to seek care for more serious problems.

Intervention Type
Mixed

Primary outcome(s)
Blood haemoglobin level is measured using a portable battery-operated electronic Haemoglobin Photometer (HemoCue Hb 301+, Angelhom, Sweden) between 28 and 32 weeks' gestation. Note that if logistical constraints imposed by the COVID-19 pandemic disrupt follow-up haemoglobin may be measured any time from 28 weeks to delivery

Key secondary outcome(s)
1. Prevalence of anaemia in enrolled pregnant women, defined as % with blood haemoglobin <11g/dL measured using a portable battery-operated electronic Haemoglobin Photometer (HemoCue Hb 301+, Angelhom, Sweden) between 28 and 32 weeks' gestation
2. Pregnant women's Mid-Upper Arm Circumference (MUAC) in cm, measured SECA head circumference tapes (93/42/EEC) between 28 and 32 weeks' gestation
3. Count of antenatal care visits (ANC) at a health facility, measured between 28 and 32 weeks' gestation
4. Mean Probability of micronutrient Adequacy (MPA) of 11 micronutrients in enrolled pregnant

women's diets including vitamin A, riboflavin (B2), niacin (B3), pyridoxine (B6), cobalamin (B12), thiamin (B1), folate (B9), vitamin C iron, zinc and calcium, measured between 28 and 32 weeks' gestation from duplicate quantitative 24-hour dietary recalls taken 2 to 7 days apart

Completion date
31/10/2022

Eligibility

Key inclusion criteria
Cluster inclusion criteria:
1. Cluster does not adjoin the main East-West which crosses the country Prithivi highway
2. Located in the southern part of Kapilbastu district (closer to the Indian border) where there is low population heterogeneity and low forest coverage
3. Rural area with no major market
4. Populated by predominantly Madhesi (plains ethnicity) population since the burden of anaemia is higher in this group
5. Projected population was ≥1100 and <3200 (although actual populations were found to be higher when the pre-trial census was conducted)
6. Surrounded by a buffer zone of non-study clusters

Menstrual monitoring:
1. Married woman
2. Aged between 13 to 49 years
3. Able to respond to questions
4. Resident of study cluster (whether husband's or parental home)
5. Husband and women have not had permanent family planning (tubal ligation or vasectomy)
6. Intact uterus (not had hysterectomy)
7. Non-menopausal
8. Has not been told by a doctor that they are infertile
9. Consenting to being asked about menstrual status (to detect pregnancy) once every 4 weeks for up to 7 months

For trial enrolment and follow up
1. Same inclusion criteria as for menstrual monitoring (above)
2. Tested positive for pregnancy
3. Less than 20 weeks' gestation estimated from recall of last menstrual period or uterus not clearly visible above the level of the umbilicus if LMP is not recalled/not available
4. Plans to live in the cluster most of pregnancy or is able to return for counselling and/or data collection
5. Consents to participate in interventions (in intervention arm) and data collection

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Key exclusion criteria
1. Woman is unable to become pregnant (is infertile, has had a hysterectomy, post-menopausal, tubal ligation or husband has had a vasectomy) or does not have a positive pregnancy test
2. Aged <=12 years or >=50 years
3. Not-consenting
4. Unable to respond to questions
5. ≥20 weeks' gestation as estimated from LMP (or uterus clearly visible above the level of the umbilicus if LMP is not recalled/not available)
6. Not planning to reside in the study cluster for most of her pregnancy

Date of first enrolment
13/06/2021

Date of final enrolment
12/01/2022

Locations

Countries of recruitment
Nepal

Netherlands

Study participating centre
Community cluster
Kapilbastu district
Lumbini Province (no. 5)
Nepal
-

Sponsor information

Organisation
Health Research and Social Development forum (HERD)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Newton Fund

Alternative Name(s)
The Newton Fund, NF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.
Sharing of fully anonymised sharing participant-level data will begin 1 year after the publication of the main trial paper. As personal information (but no identifiers) will be included we will require users to apply to download the data from the UCL data repository, after review and approval of the application.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article		01/03/2022	06/05/2025	Yes	No
Protocol file		13/06/2021	14/06/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes