ISRCTN68413407 https://doi.org/10.1186/ISRCTN68413407

Karnataka Anemia Project 2: the effect of a lay health worker-led education and counselling intervention to reduce childhood anemia prevalence compared with treatment as usual

Submission date
18/09/2013

Recruitment status
No longer recruiting

Registration date
17/12/2013

Overall study status
Completed

Last Edited
08/11/2021

Condition category
Haematological Disorders

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
The state of Karnataka in Southern India has a population of 53 million residents and a childhood anemia prevalence rate of 75 %. Anganwadi workers working in the village anganwadi (village day care centre) typically interact with groups of mothers. The proposed intervention is designed to be delivered to small groups rather than individuals. Thus, creating awareness of anemia through health education. The aim of this study is to find out whether an intervention led by a local health worker reduces childhood anemia more than the national anemia control program.

Who can participate?
Children and mothers attending village anganwadi (day care center) centers in the study area in Karnataka. Children must be between 1 and 5 years old and must have documented anemia.

What does the study involve?
Each village is randomly allocated to one of two groups: the intervention group or the control group. In the control group, participants receive tablets of iron and folic acid supplements as per existing national guidelines. In the intervention group, the trained angawadi health worker gives the iron and folic acid supplements for 5 months, educates mothers (symptoms of anemia, dietary and personal hygiene advice), provides a childhood nutritional supplement for at least 20 days per month, deworms (once in 6 months, fixed day Jan/ July) and re-tests the anemic child at the end of 6 months. Children have a blood test at the beginning of the study and after 6 months. Mothers fill in a questionnaire food safety and dietary recall.

What are the possible benefits and risks of participating?
No incentives are provided to the mothers or children for participating. Risks include minimal pain during blood tests (they are carried out by expert phlebotomists).

Where does the study take place?
This study will take place in villages in defined districts located in Karnataka state in Southern India

When is the study starting and how long is it expected to run for?
October 2013 to February 2016

Who is funding the study?
Wellcome Trust/Department of Biotechnology India Alliance (India)

Who is the main contact?
Prof. Arun Shet
arunshet1@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Arun Shet

Contact details
St Johns Medical College and Hospital
Sarjapur Road
Bangalore
India
560034

Type(s)
Scientific

Contact name
Dr Maya Mascarenhas

Contact details
MYRADA
No.2, Service Road
Domlur Layout
Bangalore
India
560 071

Additional identifiers

Study information

Scientific Title

Karnataka Anemia Project 2: a cluster randomized controlled trial evaluating the effect of a lay health worker-led intervention to reduce childhood anemia prevalence compared with treatment as usual

Acronym

KAP 2

Study objectives

Current hypothesis as of 31/10/2014:
Overall hypothesis
To test the hypothesis that a frontline lay health worker (LHW) delivered education and counselling intervention, added to iron supplementation will improve individual hemoglobin levels in anemic children and resolve individuals anemic status when compared with the standard approach (iron supplementation alone).

Main objective
To test the hypothesis that a frontline lay health worker (LHW) delivered education and counselling intervention, added to iron supplementation will improve individual hemoglobin levels in anemic children and resolve individuals anemic status when compared with the standard approach (iron supplementation alone).

Secondary objectives
1. To compare mean anemia prevalence in the two arms at the conclusion of the trial (6 months after the intervention begins).
2. To compare the participants mean iron stores (ferritin in ng/dl) between experimental arms.
3. To compare the modifications of 24 hr dietary intake patterns of participants between baseline and post intervention assessments in the two experimental arms.
4. To study the effect of the intervention on adherence to IFA supplements.
5. To record the side effects of IFA supplements in participants.
6. To study the effect of the educational intervention on participant mothers knowledge and practices.

Previous hypothesis:
Objective: to study whether a community health worker-led intervention with education, counselling, supervision and closer follow-up will result in better anemia control than the existing government program to control anemia in children attending village anganwadis (day care centers) located in Karnataka, India.

Primary aim: to compare the anemia prevalence at the end of 6 months in the intervention vs the control arm after the trial intervention.

Secondary aims:
1. To compare individual hemoglobin and ferritin levels (an index of iron stores) between the two groups.
2. To assess adherence to iron and folic acid (IFA) supplements measured with an adherence questionnaire using self-reporting (30-day visual analog scale) and pill counting.
3. To compare dietary iron intake at baseline and at the end of the intervention.
4. To compare mothers' knowledge about anemia at baseline and at the end of the intervention period.

5. To study the process of the intervention particularly with regard to fidelity and by performing qualitative studies after completion of the trial to understand the experiences of anganwadi workers and mothers participating in the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee, St Johns Medical College and Hospital (Bangalore, India), 20/07 /2013, ref: 115/2012

Primary study design
Interventional

Study design
Cluster randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anemia

Interventions
Current interventions as of 31/10/2014:
Cluster definition:
A cluster in this study is defined as a village in the geographic area of this trial that is randomly allocated to one of the study arms, its ADC or one of its ADCs, the LHW in charge of the selected ADC, all children aged 12 59 months registered in the ADC and the mothers/care givers of these children.

In particular, the following activities will take place in the intervention group:
1. Distribution of supplementary IFA (20 mg, 1 tablet taken biweekly) to the mother/care giver of all non anemic children (supplied at 8 tablets/month, for a duration of 6 months of the trial; total 48 tablets).
2. Distribution of therapeutic IFA (20 mg/day) 20 tablets/month to the mother/care giver of all anemic children for a total duration of 5 months meant for consumption by the anemic child (total 100 tablets).
3. Monthly education and counselling of mothers of anemic children by the LHW trained for delivery of this intervention covering the following topics regarding:
3.1. Symptoms and signs of anemia
3.2. Treatment with IFA and its side effects
3.3. Education regarding IFA compliance and its monitoring
3.4. Information about local iron rich foods and dietary diversification
3.5. Information about personal hygiene and deworming
The education and counselling with occur either at the ADC or at the mothers home at the discretion of the LHW.
4. Ensuring that all children attend the village ADC for retesting at the end of 6 months.

Control arm (treatment as usual or CA):
There will be no active training of LHW in this arm nor is there a specified format defined for

counselling and education as detailed in the intervention arm, or provision of supplementary material to guide counselling as provided in the intervention arm. Mothers of anemic children in the control arm will not receive any education and counselling sessions by this LHW.
In particular, the following activities will take place in the control group:
1. Distribution of supplementary IFA (20 mg, 1 tablet to be by the child biweekly) to the mother /care giver of all non-anemic children (supplied at 8 tablets/month, for a duration of 6 months of the trial; total 48 tablets).
2. Distribution of IFA for therapeutic use 20 tablets/month to the mother/care giver of anemic children for a total duration of 5 months meant for consumption by the anemic child (total 100 tablets).
3. Ensuring that all children attend the village ADC for retesting at the end of 6 months.

At the end of 6 months, all trial participants in both study arms will undergo repeat phlebotomy for assessment of anemia, anthropometry and 24-hour dietary recall and mothers will answer a questionnaire regarding knowledge and practice with respect to anemia.

Previous interventions:
Each village, its village day care center (anganwadi) with its community health workers (LHWs), and the children that LHWs care for is defined as a cluster. Each cluster is randomly allocated to the intervention arm or the control arm (treatment as usual as per the national anemia control program guidelines).

The 'intervention arm' consists of the following components:
1. Give IFA (20 mg) 20 tablets/month for 5 months
2. Educate and counsel during one-on-one sessions one per month for a total of five sessions:
2.1. Symptoms and signs of anemia (using flip book)
2.2. Side effects of IFA and compliance
2.3. Sources of local iron-rich foods (using flip book)
2.4. Diet advice and provision of a diet chart
2.5. Personal hygiene and the importance of deworming
3. Provide a childhood nutritional supplement for at least 20 days per month
4. Deworm once in 6 months (biannual January/July)
5. Retest the anemic child at the end of 6 months

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Iron and folic acid (IFA) supplements

Primary outcome(s)
Current primary outcome measures as of 31/10/2014:
The primary outcome will be the difference between experimental groups in the prevalence of anemia among children found to be anemic at baseline, as detected at the end of 6 months and the net improvement in individual hemoglobin values in gm/dl (difference of baseline and 6-month values).

Previous primary outcome measures:
Hemoglobin value collected at baseline and after 6 months of participation in the trial, expressed in g/dl. Haemoglobin measured by the automated cell counter (cyanmethhemoglobin).

Key secondary outcome(s)
Current secondary outcome measures as of 31/10/2014:
These include:
1. Difference in anemia prevalence at the level of each cluster in the two arms at the conclusion of the trial (6 months after the intervention begins)
2. Difference in anemic participants mean ferritin value (an index of iron stores) between experimental arms at the conclusion of the trial (6 months after the intervention begins)
3. Difference in the 24 hr dietary iron intake of all participants between baseline and post intervention assessments in the two experimental arms
4. Change in mothers knowledge and practices between baseline and 6 months follow up for all children in the two arms of the study
5. The proportion of child-delivered IFA doses (adherence to iron treatment)
6. Incidence of side effects of IFA supplements in children

Previous secondary outcome measures:
1. Individual serum ferritin levels (ng/ml) measured at baseline and after 6 months
2. Adherence to iron and folic acid measured with an adherence questionnaire using self-reporting (30-day visual analog scale) and objective pill count methods assessed every month in both arms
3. Dietary iron intake (mg/24hrs) assessed at baseline and after 6 months
4. Mothers' knowledge about anemia at baseline and after 6 months
5. Fidelity measures to capture delivery of the intervention by assessing audits, log books and trial registry information, measured at baseline and monthly for 6 months
6. Qualitative studies will be performed at the end of the trial

Completion date
01/02/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 31/10/2014:
Cluster inclusion criteria:
A cluster randomized to either study arm will be included in the study if it fulfils the following criteria:
1. Functioning ADC in the village
2. LHW in charge of the ADC willing to participate in the activities detailed in the study
3. LHW attends ADC for at least 75% of the duration of the study

Participant inclusion criteria:
1. Age 12-59 months
2. Registration in the village ADC register
3. Residence in a village located in the study site (living in the Chamarajnagar taluk for at least 6 months after enrolment in the trial)
4. Accompanied by mother/care giver who is willing to participate in the study and accept follow-up visits

5. Mother of anemic participants in the intervention arm should be willing to receive LHW-led education, counselling, and monitoring of adherence to iron.

Previous inclusion criteria:
1. Documented anemia (hemoglobin 8.0-11.0 gm/dl)
2. Age 1-5 years
3. Residence in a village located in the study site and willingness to participate in the study and follow-up visits

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Months

Upper age limit
59 Months

Sex
All

Total final enrolment
1144

Key exclusion criteria
Current exclusion criteria as of 31/10/2014:
Cluster exclusion criteria:
1. No functioning ADC in the village
2. No LHW in charge of the ADC present in the village to work in ADC or lead intervention
3. LHW unwilling to participate and deliver the intervention

Participant exclusion criteria:
1. Severe anemia (Hb ≤ 7.9 gm/dl) These children in both the intervention and the control arm will be referred to the primary health centre/first referral unit for assessment and medical management as per guidelines in the National Iron + initiative. After referral, children in the intervention arm although excluded from the trial will be eligible to receive the intervention elements from the LHW described in the trial.
2. Ill health (active infection or fever >101° F) These children will be managed as per usual guidelines either by referral to the primary health centre/first referral unit or recommendation to the LHW to inform the mother/care giver to take the child to such a facility in case the mother does not report for the trial/is unavailable.

Previous exclusion criteria:
1. Children with severe anemia (hemoglobin ≤ 7.9 gm/dl)
2. Children who are unwell (active infection or fever >101 ° F) will be referred to the local primary health centre

Date of first enrolment
28/10/2014

Date of final enrolment
17/06/2015

Locations

Countries of recruitment
India

Study participating centre
St John's Medical College and Hospital
Bangalore
India
560034

Sponsor information

Organisation
Wellcome Trust/DBT India Alliance (India)

ROR
https://ror.org/04reqzt68

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust/Department of Biotechnology (DBT) India Alliance (India) (Ref: IA/S/12/2/500647)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Arun Shet (arunshet1@gmail.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/09/2017		Yes	No
Results article	results	22/07/2019	23/07/2019	Yes	No
Results article	Secondary analysis	05/11/2021	08/11/2021	Yes	No
Protocol article	protocol	30/12/2015		Yes	No