Research Protocol

Impact of eHealth education to reduce anemia among school-going adolescent girls in rural Bangladesh: Study protocol of a randomized controlled trial

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Abstract

Adolescent girls are highly vulnerable to developing anemia due to reproductive immaturity, poor personal hygiene, and lack of nutritional intake and health education in rural Bangladesh. Digital health technology is a promising tool to overcome barriers and provide appropriate health guidelines. We aim to evaluate eHealth education's impact and changes in adolescent girls' knowledge, attitude, and practice regarding anemia. A 1:1 parallel randomized control trial was conducted among school-going adolescent girls in rural Bangladesh. A total of 138 anemic (mild and moderate) participants were enrolled. We randomized schools to reduce the health education bias through a simple coin toss technique, then allocated participants to the intervention group (n = 69) and control group (n = 69) by stratified random sampling technique. The intervention group received two online counseling sessions and 8-month eHealth education through mobile phone calls and short message service regarding anemia. The control group received the usual care. The primary endpoint changes the anemic level through changing knowledge, healthy lifestyle behavior, and an iron-rich food dietary plan. Per-protocol analysis will utilize to compare the control and intervention groups using SPSS software. Descriptive statistics (frequencies, percentages, mean, SD) will be employed, and continuous variables will be compared using the t-test/Mann–Whitney test. Two-way analysis of variance will assess outcome variables at baseline, 4 months, and 8 months. The 8-month intervention is designed from May 2022 to February 2023. Participants' age range of 10-14 years was 60.9% in the intervention group and 56.5% in the control group. Among the participants, 89.9% and 88.4% were mild anemic; 11.11 (SD ± 0.80) and 11.06 (SD ± 0.96) were mean hemoglobin in the intervention and control groups, respectively. eHealth education is expected to be an effective way to increase knowledge and healthy behavioral change, which can reduce the anemia burden among adolescent girls.

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Introduction

Globally 1.62 billion people are affected by anemia, a significant public health threat, especially in low and middle-income countries (LMICs).[1] The prevalence of anemia among nonpregnant and school-going are estimated as 30% and 25%, respectively, and 35% are thought to be distributed in the LMICs.[2,3] Anemia is a medical condition that can be developed at any stage of the life cycle, but the reproductive age of women, adolescent girls, and growing children are the vulnerable group to develop anemia.[1] Adolescent age is a critical period of developmental transmission and reproductive maturation, requiring increased nutritional intake and proper health education; otherwise, it makes adolescents more vulnerable to future development.[4] Approximately 90% of adolescents residing in LMICs have a high burden of malnutrition, under-nutation, anemia, and micronutrient deficiencies.[5] Adolescent girls (age 10-19 years)[6] are particularly concerned to be at a higher risk of anemia due to menstrual blood loss, inadequate dietary iron intake, and chronic anemia adversity impacting growth and development.[2] However, among the prevalence of anemia, about 50% is iron deficiency anemia.[7] The primary reasons for developing anemia are the lack of iron-containing food intake, contaminated water, and poor sanitation. Also, the infection with soil-transmitted helminth is one of the leading causes of anemia due to blood loss.[8] Moreover, anemia necessitates regular screening by the primary care physician in any medical facility for adolescent girls presenting with any medical condition, and if detected during clinical assessment, a comprehensive hemoglobin should be performed for further evaluation.[9]

Bangladesh is a middle-income and highly populated developing country. Among the total population, 62% live in rural areas. As per World Health Organization (WHO) 2019 data, Bangladesh has a 36.7% anemia prevalence among women of reproductive age. According to the WHO, if anemia prevalence is more than 40%, it is an alarming and concerning severe public health problem. The whole-population anemia prevalence in Bangladesh does not satisfy the criteria; however, focusing on subpopulation does. For example, among nonpregnant women's anemia, 73% live in rural Bangladesh.[10,11]

Literature reported that 51.6% of adolescent girls were suffering from anemia; among them, 46%, 5.4%, and 0.2% were mild, moderate, and severe anemia in Bangladesh, respectively.[1] Due to the high prevalence of anemia among adolescent girls in Bangladesh, they are considered to be a focused group. The main risk factors of anemia are lack of education, shortage of iron intake, poor economic status, poor personal hygiene, unhygienic toilets, and parasitic infection in Bangladesh. Proper interventions should be provided to those vulnerable populations. i.e. adolescent girls in rural areas.[1] According to WHO guidelines, public health intervention along with nutritional counseling, promotes food diversity and food combination that improves the iron status in the population. Such interventions should be implemented with proper health education for the populations.[12] Lifestyle and behavioral change depend on knowledge, and nutritional knowledge is essential for good dietary habits. Health education is an effective way to share and increase nutritional knowledge.[13] A school-based nutritional education is reported as a feasible tool for improving the hemoglobin level, knowledge, attitudes, and practices among adolescents.[14] Health education is a useful approach for creating awareness among adolescent girls to reduce preventable diseases like anemia and build a future healthy mother.

According to WHO,[15] eHealth is developed to improve public health and health care such as health education, health system management, behavioral health change support, and disease management. eHealth is a supporting tool in the healthcare area using Information and Communication Technology. Mobile technology is one of the innovative developments of Information and Communication Technology, and mHealth provides health care service through the mobile phone, which is an important part of eHealth.[16] eHealth education is a promising tool to build healthcare awareness among the mass community (WHO). The aim of this study is to evaluate the impact of eHealth education in reducing anemia among adolescent girls in rural areas of Bangladesh.

Aim and Hypothesis: We hypothesize that eHealth education will be effective in reducing anemia along with changing knowledge, attitude, and practice among school-going adolescent girls.

Methods and Materials

Design: This is a school-based two-arm (1:1) randomized control trial[17,18] study with recruited anemic adolescent girls from two schools in a rural area of Bangladesh. This study has been followed according to the guidelines of CONSORT (Consolidated Standards of Reporting Trials)[19] and SPIRIT (Standard Protocol Items Recommendation for Interventional Trials).[20] The flow chart of the study is shown in Figure 1. The intervention was started in May 2022, and the total duration was 8 months of this study.

Study sites

The study was conducted in Chandpur District, which is a part of the Chittagong division located in the south part of Bangladesh and is 106 km distance from the capital of Dhaka. The total area of the district is 1740.6 km^2, with a 2,416,018 population, and the literacy rate is 69.8%.[21] We selected two schools in the Sadar subdistrict of the Chandpur District. The schools are selected purposively due to the convenience of the laboratory investigation and easy access for the researcher.

Study population and eligibility criteria

Initially, a baseline study was conducted to screen the anemic adolescents from the Baburhat High School and College and Uttar Shahatali Zobaida Girls High School in the

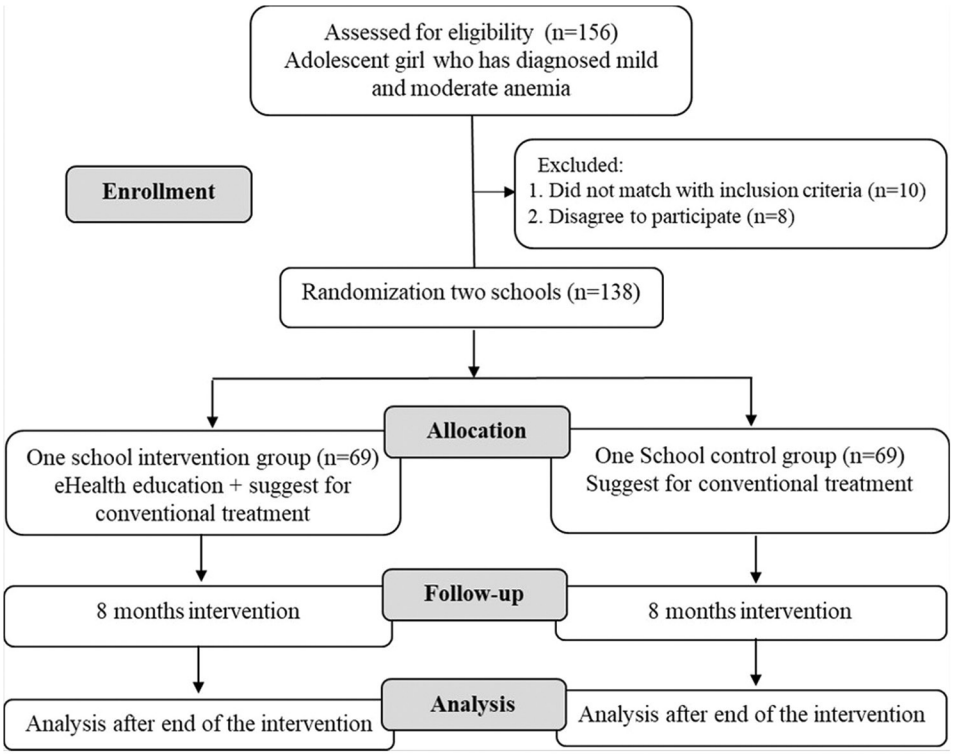

Figure 1: Study flowchart

Chandpur District, Bangladesh. After that in this study, we enrolled individual adolescent girls who were diagnosed with mild (10-11.9 g/dl) and moderate (7.0–9.9 g/dl) anemia.[22] The study inclusion criteria are as follows: aged 10-19 years studying in the schools, has a cell phone in their family, and her guardian(s) have given written consent to participate in this study. Those who had severe anemia at the baseline screening, had a mental illness, were pregnant, and disagreed to participate had been excluded from this study.

Randomization and Sampling: Initially, an external statistician performed a coin toss randomization within the two schools to determine the intervention and control groups. Subsequently, to reduce the number of participants to be 69, the statistician used a computer-generated random number table to select the anemic participants in each school. Following the random selection, a list of study participants, 69 in each group, from each school was prepared and placed in separate envelopes. These envelopes were securely kept in an office locker. The principal investigator started the research process after the study participants had provided their written consent.

Study procedure

eHealth education is provided for eight months to improve participants' knowledge, attitude, and practice. The program includes online group counseling sessions of participants with their guardians, health materials (Notebook), and phone calls with short message service (SMS) through their guardian's mobile regarding anemia. At the baseline, community health workers (CHWs) took written consent from each participant and their guardians before the CHWs interviewed two pretested developed questionnaires. Through the first questionnaire, which the researcher developed and, the following data were collected: socio-economic information such as age, marital status, religion, family structure, parents' education and occupation, and monthly income; menstrual history, anemia, food habit, lifestyle, and personal hygiene of the adolescent girls. To evaluate the knowledge, attitude, and practice (KAP) regarding anemia used a validated developed questionnaire from the "Food and Agriculture Organization of the United Nations (FAO)."[23] The CHWs collected the questionnaire data at the baseline and the same data at the end of the 8th month (end of the intervention). The CHWs collected physical examination data such as height, weight, hip-waist circumference, and mid-upper arm circumference (MUAC) at the baseline, and the same data were collected at the end of the 4th and 8th month. Also, we collected blood samples to measure hemoglobin, total count of White blood cell (WBC), Red blood cell (RBC), Platelets, Mean corpuscular volume (MCV), Packed cell volume (PCV); and urine samples to measure urinary albumin, protein, sugar, and RBCs. The samples were collected by the technologist of "Lab Aid Diagnostic Center, Comilla" and carried into the diagnostic center for the test. The blood and urine samples were collected baseline, at the end of 4th and 8th months for laboratory investigation [Table 1].

CHWs training

The data collection and eHealth education were performed by the CHWs. Before starting the study, the principal investigator

Table 1: Activities of the study

	Intervention group	Control group
Baseline	● Interview the two questionnaires ● Physical examination for height, weight, hip-waist circumference, and MUAC ● Laboratory test for blood and urine	
Within the 1st week after the baseline	● Group eHealth counseling session for 1.5 hours regarding anemia through a public health physician. ● Provide health education materials (booklet) and a list of iron-containing local food.	● Usual care and suggestions for treatment.
First 4 months	● eHealth education: phone calls (5 min) and short message service (SMS) (Guardian/participants)—4 times a month by the community health worker (CHWs).	● Usual care
Midline (End of the 4th month)	● Group eHealth counseling session for 1.5 hours regarding anemia through a public health specialist. ● Provide health education materials (booklet) and a list of iron-containing local food. ● Physical examination for height, weight, hip-waist circumference, and MUAC ● Laboratory test for blood and urine	● Physical examination for height, weight, hip-waist circumference, and MUAC ● Laboratory test for blood and urine
5th and 6th months	● eHealth education: over a phone call (5 min) and SMS (Guardian/participants)—3 times a month	● Usual care
7th and 8th months	● eHealth education: phone calls (5 min) and SMS (Guardian/participants)—2 times a month	● Usual care
Endline (end of 8th month)	● Interview the two questionnaires ● Physical examination for height, weight, hip-waist circumference, and MUAC ● Laboratory test for blood and urine	

conducted one day-long training on the overall study procedure for training the CHWs. The training content was how they would collect written consent forms, survey questionnaire data, physical measurements, digital data records for data entry of the participants, and way of backup paper/copy of the study document. A public health physician also trained the CHWs who will be provided eHealth education to the study participants with their guardians.

In the intervention group

eHealth group counseling session

The intervention group is receiving online health education counseling sessions through Skype. Two times (Baseline and Midline), group education counseling sessions were conducted by a public health physician for the adolescent girls and their guardians through online video, PowerPoint presentation and discussion regarding anemia causes, consequences, prevention, and how to recover. The contents of the presentation were iron-rich food, functions and sources of iron, dietary strategies to improve iron status, food habits and plans, healthy lifestyle, and personal hygiene maintenance. After the eHealth education session, they provided health education materials (Notebook) and a list of the local iron-containing food. The modified health education materials (Notebook) were provided every month during the intervention period for each participant.

eHealth education

eHealth education is provided through mobile phone calls and SMSs by trained CHWs to enhance knowledge, improve behaviors, and raise awareness about anemia among participants. The CHWs provided education on locally available iron-rich foods and their benefits for iron absorption, as well as guidance on beverages that may hinder iron absorption when consumed with meals. They are instructed to avoid funk and oily food and wash their hands thoroughly before and after eating. Furthermore, they are advised to wash fruits carefully before consuming them, to always wear shoes when using the toilet, and to wash their hands thoroughly after using the toilet. The CHWs are also informed about the importance of taking an anti-helminth medication every six months and the use of sanitary napkins during menstruation. Each participant with their guardians engages in a 5-minute health education conversation with the CHWs over the phone, and they also receive regular informative health education messages, which are updated on a weekly basis.

In the control group

They are getting the usual care and under follow-up over the study period without health education.

Sample size calculation

The sample size was calculated through the following formula[24]

$$n_1 = \left(z_{1-\alpha/2} + z_{1-\beta}\right)^2 \frac{P_1\left(1-p_1\right)+p_2\left(1-p_2\right)}{\left(p_1-p_2\right)^2}$$

According to the previous study, we assumed that after health education, p^1 = Proportion of outcome from the intervention group (34%), p^2 = Proportion of outcome from the control group (9.3%),[25] α = Level of significance (5%), 1-β = power (90%), Z alpha value = 1.96, Z beta value = 1.3. According to the above formula, the calculated sample size was 106, and considering 30% proportion of the drop-out rate because of drop-out due to COVID-19, absence, and refusal to give blood samples. The final sample size was estimated to be 138. For each group intervention, the control sample size was 69.

The primary endpoint

Impact of eHealth education to change the anemia level among school-going adolescent girls in the peri-urban environment of Bangladesh.

Primary outcome measures

The anemia level (no anemic, mild, moderate, and severe anemia) of individuals adolescent girls will be measured through blood hemoglobin screening by the auto-hematology analyzer. According to WHO, 10-11 years adolescent girls with Hb <11.5 g/dl will be considered anemic, and 10-11.4, 7.0-9.9 g/dl, and <7.0 g/dl will be considered mild, moderate, and severe anemia, respectively. Nonpregnant adolescent girls (12-19 years) with Hb level <12 g/dl will be considered suffering any form of anemia, and 10.0-11.9 g/dl, 7.0-9.9 g/dl, and <7.0 g/dl will be considered mild, moderate, and severe anemia, respectively.[22] After eHealth education intervention, anemia level changes will be assessed (e.g., anemic to nonanemic, mild to nonanemic/moderate/severe, moderate to mild/non-anemic/severe) at baseline, midline, and endline within the intervention and control group.

The secondary endpoint

We have two different secondary endpoints;

1. Changes in KAP regarding anemia will be measured through an adapted KAP model questionnaire of the Food and Agriculture Organization (FAO) at baseline and endline.
2. Improvements in the level of body mass index, hip-waist circumference, and MUAC

Questionnaire validity

According to the forward-backward translation, the procedure was followed for the local language Bangla translation.[26] Two native speakers of the Bangla language who is fluent in English, one was a public health specialist and another one was Ph.D. graduate student, translated the English-version questionnaire into Bangla separately. Then, compiling the two, a single Bangla forward version of the questionnaire was created. Then Bangla-forwarded version was translated back into English through a professional translator with experience in medical translation, and then the same Bangla-forwarded version was translated by a medical doctor who was not involved in any previous steps. The researcher compiled and compared the back translation version. For validity, four translated versions were submitted to the expert committee for the development of a questionnaire. The developed questionnaire was pretested among 5% of school-going adolescent girls who were not involved in our study. After the pretest, we collected their feedback and accordingly fixed their feedback in the final version of the questionnaire.

Questionnaire reliability

The reliability of the researcher-developed questionnaire was determined through the test-retest method and the KAP questionnaire through Cronbach alpha.[27]

Definition

Anemia: According to WHO, girls aged 10-11 years with hemoglobin level <11.5 g/dl and nonpregnant girls aged 12-19 years with hemoglobin level <12 g/dl were considered anemia[22]

eHealth: The delivery of health services and information through the Internet and other related technologies like the mobile phone is referred to as "eHealth," an emerging topic at the nexus of health information, public health, and business.[28]

Usual Care: Study participants receive usual care, which is what participants would typically receive as part of their own regular practice. Importantly, no health education was provided during the study intervention.[29]

Statistical analysis

Data will be initially entered into Microsoft Excel 2019 software and then transferred into IBM SPSS software. To ensure comparability of randomized samples, the per-protocol analysis will be performed to compare control and intervention groups. Frequencies, percentages, mean, and standard deviation will be analyzed as descriptive statistics. The differences in continuous variables between the two groups will be analyzed by the Student's t-test/Mann-Whitney test. Two-way analysis of variance tests will be conducted to evaluate various outcome variables including hemoglobin level, knowledge, attitude, practice, and physical measurements. These comparisons will be performed at three time points: baseline, 4 months, and 8 months. We will include them in the analysis for the outcome to see if the nonadjusted and adjusted results show the same. In addition, the adjusted odds ratio will be applied to all variables that were found to be significant in the univariate analysis. All the significant levels will be considered <0.05.

Results

In this study, we enrolled 138 adolescent girls. Among them, 69 were assigned to the intervention group, and the remaining 69 were to the control group. The age group 10-14 years were 60.9% and 56.5% in the intervention and control groups, respectively. Regarding the participant's family, 30.4% and 31.9% of fathers were no formal education; 14.5% and 20.3% of mothers were no formal education in the intervention and control groups, respectively. A total of 89.9% and 88.4% of the participants had mild anemia in the intervention and control groups, respectively. Participants' mean hemoglobin and MUAC were 11.11 (SD ± 0.80), 23.80 (SD ± 2.92) in the intervention group, and 11.06 (SD ± 0.96), 22.17 (SD ± 2.94) in the control group [Table 2].

Discussion

According to our knowledge, this is the first study to see the effectiveness of eHealth education in reducing anemia among adolescent girls in Bangladesh. A study in India reported that 6 months health education program significantly increased hemoglobin levels and reduced anemia among pregnant women.[25] However, an online health education session for participants that will be given by the public health specialist and the discussion among the participants and their guardians will increase their knowledge of anemia and prevention among

Table 2: Socioeconomic and baseline data of outcome variable

Variables	*n* (%)	
	Intervention Group, *n*=69	Control Group, *n*=69
Age groups		
10-14 Years	42 (60.9)	39 (56.5)
15-19 Years	27 (39.1)	30 (43.5)
Father education		
No formal education	21 (30.4)	22 (31.9)
Primary education	18 (26.1)	28 (40.6)
Secondary	12 (17.4)	13 (18.8)
Higher secondary and above	18 (26.1)	6 (8.7)
Mother education		
No formal education	10 (14.5)	14 (20.3)
Primary education	27 (39.1)	40 (58.0)
Secondary	23 (33.3)	10 (14.5)
Higher secondary and above	9 (13.0)	5 (7.2)
Anemia types		
Mild	62 (89.9)	61 (88.4)
Moderate	7 (10.1)	8 (11.6)
Hemoglobin (Mean ±SD)	11.11±0.80	11.06±0.96
MUAC (Mean ±SD)	23.80±2.92	22.17±2.94

them. The health education through mobile phones by CHW will also motivate the participants and enhance the awareness to prevent and recover anemia among the participants. After the intervention, we expect our eHealth education will more effectively increase the KAP among the intervention group than the control group. That is, we believe that our eHealth education will have a more positive impact on reducing anemia in the target population, i.e., adolescent girls. As well primary care physicians can ensure prompt and effective management of anemia through appropriate counseling of girls, and their families.

Limitation

In our study, one of the limitations is that we applied a simple randomization technique for the control group and for the intervention group at the institutional level; there might be confounders and potential bias. We did school randomization to reduce the health education bias among the same school participants. We are conducting research on one subdistrict of rural areas, and it does not illustrate the anemia scenario in all the peri-urban/rural areas of Bangladesh.

Conclusion

If the study result shows that eHealth education is effective, we will suggest at the national level to implement this health education through counseling and phone calls with SMS as an effective tool to reduce the anemia burden among school-going adolescent girls. We also think it can improve their knowledge to be future healthy mothers.

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Ethical approval

The ethical approval was taken from the Institutional Review Board/Ethics Review (IRD/ERC) of North South University Bangladesh (Ref: 2021/OR-NSU/IRB/1102) with the Clinical Trial Registration No. NCT05185661. According to the Declaration of Helsinki, this study is being conducted.[30]

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Conflicts of interest

There are no conflicts of interest.

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