Iodine Concentration Effects on Linear Growth of Children after Nutrition Behavior intervention, Central Highland of Ethiopia: A Cluster Randomized Community Trial

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Abstract: *Background*: To improve the iodine status and growth of children was not documented in Ethiopia. This study aimed to determine the effects of nutrition behavior communication change (BCC) on improving iodine status and growth of children 6 to 59 months.

Methods: A community cluster randomized trial with a single treatment arm was conducted from February 2018 to April 2020. *"Kebeles"* [lower administrative units] were randomly assigned to either the intervention or the control cluster. Mothers and their paired children were randomly selected from *kebeles.* Anthropometry data and urine samples were collected at baseline and end-line surveys. Percentile rank and Independent t-test were used to determine the difference between arms. Finally, Generalized Estimating Equation (GEE) is used to isolate independent predictors.

Results: At baseline, 97.83 % (n = 812) mothers/ caregivers and paired children were enrolled for the trial study, but at the end-line, 88.05% (n =715) of children completed the intervention. Iodine deficiency prevalence was higher (11.82%, n = 96) at baseline and reduced to 6.15 % (n =44) at the end-line. The growth defect among children was 41 %(n = 332) at the baseline and declined to 28.67 %(n=205) at the end-line, while among interventions reduced by more than two times (39% to 12.81%). At the baseline, the median UIC among the intervention group was 106.0µg/L and increased to 207.190µg/L. The prevalence of iodine deficiency among intervention was 14.29% (n = 58) at the baseline and lowered to 3.45% (n=14) at the end-line, but a slight increment observed among control from 9.36% to 9.71% at end-line. The end-line median UIC was very high (210.56µg/L ± 150 compared to the baseline median UIC (107µg/L ± 8.66). Most (43.6%) of the intervention group found in the 4th and 5th percentile ranks factions of UIC by Height (Ht) mean differences. Being an intervention group increased Ht by 10.85cm (β =10.85, Std. E = 0.33). Likewise, for 1µg/l UIC change a 1cm (β = 1.0, p = <0.05) Ht change predicted at the end-line.

Conclusions: Findings from this trial enhance nutrition behavior communication to improve the iodine status and growth of young children in the community. Longitudinal studies are needed to determine the level of iodine deficiency disorders in the community.

Keywords: Children, Linear-growth, Iodine-concentration, Nutrition-behavior, Cluster-random.

1. INTRODUCTION

Iodine deficiency is one of the micronutrient deficiencies that have a detrimental effect on the growth and development of human beings [1]. The first 1000 days of a child's life is a "window of opportunity" for potential interventions [2, 3]. Over the past two decades, progress has been made to eliminate iodine deficiency as the primary cause of preventable brain damage in the fetus, newborns, and infants with iodized salt [4]. Iodised salt is a safe, effective, and sustainable way of addressing iodine deficiency and is highly cost-effective [5, 6].

Iodine deficiency occurs in preschool children when iodine intake falls below the recommended level of 90µg/l [7]. Infants are at the highest risk of Iodine deficiency (ID) due to their high requirement of iodine per body weight [8]. Iodised salt intake with complimentary food in younger than three years of children is mostly inadequate. As a consequence, the positive probability of the risk of iodine deficiency disorders [IDD] increases in children [9].

Permanent preventable condition of brain damage reduces children's cognitive function during infancy [10]. Currently, more than 19 million newborns are at high risk of brain damage related to iodine deficiency (ID), and likely to continue for the next years [2]. According to a report by UNICEF, 3.9 million young children in southeast Africa are at risk of brain damage from ID than in any other region [2]. It is difficult to determine the iodine status in plasma thyroxine. But, UIC is an appropriate measurement surrogate marker of the amount of iodine found in thyroxine [11]. Measuring UIC is also recommended in young children to indicate the intensity of IDD in a specific community [4]. Correcting ID timely at the age of 6 to 59 months has a significant effect on reducing IDD burden and its

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negative consequences on linear growth in the developing world [12]. In Africa, especially in Sub-Saharan, the slow progress in combating IDD has not significantly reduced brain damage among young children and individual life outcomes [7].

Moreover, there is an increase in women's illiteracy in the developing world, especially in Ethiopia, where 63% of women are illiterate [13]. However, women are likely not to use iodized salt in the country [10]. Consequently, the need for nutrition behavior change communication to promote iodized salt use in the community is imperative [14]. Particularly in Ethiopia, a community-based interventional study aims to reduce iodine deficiency and associated growth deficit among children. In this study, we set out to evaluate the effeteness of nutrition behavior modification on the adequacy of iodine levels and the growth of young children.

2. MATERIALS AND METHOD

Trial Design

A community-based cluster randomized trial (CRCT) was applied to implement nutrition BCC.

Participants

All children aged 6 to 59 months with their paired mothers/caregivers were selected with a systematic sampling method from randomly assigned kebeles from both intervention and control clusters.

Study Setting

The study area included districts and towns found around Chilallo Mountain. A multistage sampling method was used to select sixteen *kebeles* from Highland Districts and towns.

Intervention

The intervention was conducted for fifteen months (from February 2018 to April 2020). The nutrition behavior intervention was provided for the intervention cluster. About 406 Mothers/ caregivers who had children aged six to fifty-nine months from the intervention cluster were included in nutrition behavior intervention about dietary intake enriched with iodine for their children. But, 406 children and their paired mothers/ caregivers from the control cluster had not addressed the nutrition behavior intervention.

Purposely two health extension workers (HEW) permanently assigned in each *Kebele* had been trained to carry out intervention approaches. These trained HEW had assisted child feeding activities and provision of a program demonstration and visiting. The adoption of food for children certainly contained iodized salt and exploitation of iodized salt.

The exploitation of iodized salt and use of iodized salt in the household provided by local EXW every three weeks for mothers/ caregivers included in the intervention cluster. Various activities contained in the intervention were spotted to improve child iodide status and adopted rigorous infant and young child feeding practices and dietary diversity. Specific communications strategies were applied for the messages and audience, and communications materials were used, such as pictures, leaflets, and posters.

Sample Size

The sample size determines using Gpower 3.0 software with assumptions of a power of 95%, a precision of 5%, and an effect size of 0.25 giving 834. However, 812 (97.83%) mothers/ caregivers and paired children were enrolled in the trial study

Randomization

Community-based cluster randomization was used for the sequence generation of two *kebeles* randomly selected from each selected district and the towns. A total of 16 *kebeles* from 202 kebeles were selected for randomization.

Distribution

Kebeles were randomly allocated either to the intervention or control group (cluster) with an equal allocation ratio using Emergency Nutritional Assessment (ENA, 2011) computer software. Intervention clusters included participants within eight *kebeles*, whereas control clusters included another eight *kebeles*. About 406 children aged 6-59 months and parried mothers/caregivers were selected from the intervention cluster assigned to the intervention cluster. The other 406 mothers and paired children were assigned to the control cluster.

Masking /Concealment

Community-based trials require cluster masking to maintain behavioral information at the intervention cluster [15]. The sixteen selected clusters from the large number of *kebeles* provided sufficient protection of nutrition behavior information from contamination with the control.

Execution of Randomization

Principal and co-investigators generated allocation sequence, and participants enrolled by study recorders before data collection time—Health Extension Workers (HEWs) who were found in each *kebele* responsible for delivering the intervention.

Measurements

Following the baseline survey of knowledge and attitude about the prevention of IDD and dietary intake of iodine salt by children, the baseline data were collected from 812 participants before the nutrition behavior intervention was implemented. The end-line survey was conducted after nutrition behavior intervention communication ended. Urine samples were collected from 715 children collected for the second time at the end-line. At each specimen collection, the urine container tubes were clearly labeled and packed in cold boxes. The collected urine samples were transported to the Ethiopian Public Health Institute laboratory. Orientation was given to laboratory professionals to prevent contamination and keep the specimen tubes closed firmly to protect against evaporation in the laboratory. Median UIC was scrutinized using ammonium persulfate methods in the Ethiopian Public Health Institute laboratory based on the World Health Organization (WHO) requirement [16].

The procedure used for urine iodine determination during baseline and end-line surveys

1. In first, for each specimen mixing urine procedure was made to suspend sediment.
2. Pipette 250µg/l of each urine sample into a 13 x 100 mm test tube. The pipette was used for each iodine standard in a test tube, and then H2O was added as needed to make a final volume of 250µg/l. Duplicated iodine standards and a set of internal urine standards were included in each assay.
3. One ml 1.0 M ammonium persulfate was added to each tube.
4. All tubes were heated for 60 minutes at 100^{o}C.
5. Each tube was cooled to room temperature.
6. Following the above sequence, 2.5ml arsenious acid solution was added and mixed by inversion or vortex and then allowed the test tube to stand for 15 minutes.
7. Subsequently, 300µl of ceric ammonium sulfate solution was added to each tube (quickly mixed) at 15-30 second intervals between the pipes successive. With practice, a stopwatch was used for this; a 15-second period was convenient.
8. Each test tube containing the treated specimen had been allowed to sit at room temperature.
9. Exactly after 30 minutes of addition of ceric ammonium sulfate to the first tube, read its absorbance at 420 nm. And read successive tubes at the same interval as when adding the ceric ammonium sulfate.

NoteBook: ml, mil-litter; µl, micro litter; nm, nano-meter; oC, degree ciliate.

Median UIC Laboratory Result Remarks

The WOH reference for the cut-off value of iodine adequacy is median UIC=100µg/L and the higher substantially adequate [16]. However, median UIC blow 100µg/L was classified as inadequate. This was further classified into insufficient (50 to 99µg/L) and severe (<50µg/L) iodine deficiency [16].

The height (ht) and weight (Wt) of children were measured according to standard procedures recommended by the World Health Organization [17, 18]. A spring balance (Salter Scale) was used to measure wt of children aged < 2 years. A digital scale for children aged two years and above measured without shoes and with light clothes. Besides, Ht was measured barefoot using a stadiometer for children in the age group 24 months and above. The recumbent position was used to measure the length of children aged less than 24 months. Additionally, the Wt reading and Ht reading were made to the nearest 0.1 kg and 0.1 cm, respectively. The average of two independent observers' readings was applied for the final analyses [17, 18].

Data Processing and Analysis

ENA software was used to generate height for age Z-score (HAZ), which was HFA < −2 z-score was indicated as a growth defect. The classification of growth defects in the children was defined as very high > 40%, high 30 to 39%, and medium 20 to 29 and low < 20% [17, 18].

The urinary iodine excretion was ordered into quintiles, and its association with height was compared between the intervention and control groups at baseline and end-line. A T-test was used to compare group outcomes, finally. The generalized Estimating Equation model was fitted to determine the independent effect of iodine concentration on the linear growth of children. GEE was applied to predict further the differences in beta coefficients [19], and 95% confidence intervals were reported. Statistical significance was declared at P < 0.05.

3. RESULTS

Community-Based Randomization

Study participants were selected with proportionate numbers from all randomized *kebeles*. About 406 study participants were selected from each cluster. At the baseline survey of Feb. 2018, a total of 812 (98.9%) participants were recorded. However, in the end-line survey of Apr. 2020, 87.1% (n= 715) of children were participated. All study participants selected from the intervention cluster (n = 406) received nutrition behavior intervention, but 406 mothers/ caregivers from the control cluster had not.

Finally, about 406 participants from the intervention group and 309 participants from the control group participated in the final survey, whereas 97 (23.89%) children render non-eligible to complete their follow-up because of their ages greater than 59 months.

At baseline, 70.21%, and at the end-line, 99.0% of mothers/ caregivers were aged equal to or greater than 20 years. The illiteracy popularity among mothers/caregivers was 41.81%. Regarding children's socio-demographic statuses, 48.39% were females and age <24 months were 65.15% (n = 529) at baseline. However, this age group was reduced to 33.6% at the end line survey.

The end-line median UIC was very high (210.56µg/L ± 150 compared to the baseline median

Table 1: Iodine Deficiency and Growth Defect at the Baseline and End-Line among Children with Socio-Demographic and Nutritional Statuses

Variables	Baseline survey n=812		End line Survey n=715	
	Intervention n=406 [%]	Control n=406 [%]	Intervention n=406 [%]	Control n=309 [%]
Age				
≥ 24 Months	106(26.11)	177(43.60)	332(65.61)	246(79.62)
< 24 Months	300(73.89)	229()56.40	174(34.39)	63(26.58)
Sex				
Male	205(50.50)	193(47.54)	268 (52.96)	148(47.90)
Female	201(49.50)	213(52.46)	238(47.04)	161(52.10)
HAZ				
≥ -2SD	236(58.13)	244(60.01)	354 (87.19)	156(50.49)
< -2SD	170(41.87)	162(39.90)	52(12.81)	153(49.51)
WHZ				
≥ -2SD	359(88.42)	373(91.87)	370(91.13)	210(67.96)
< -2SD	47(11.58)	33(8.13)	36(8.97)	99(36.04)
WAZ				
≥ -2SD	348(85.71)	366(90.15)	473(93.48)	141(45.63)
< -2SD	58(14.29)	50(12.31)	33(6.52)	168(68.57)
Median UIC				
≥100µg/L	348(85.71)	368(90.64)	392(96.55)	279(90.29)
<100µg/L	58(14.29)	38(9.36)	14(3.45)	30(9.71)

HFA, height for age; WFH, weight for height; WFA, weight for age, SD, Standard Deviation.

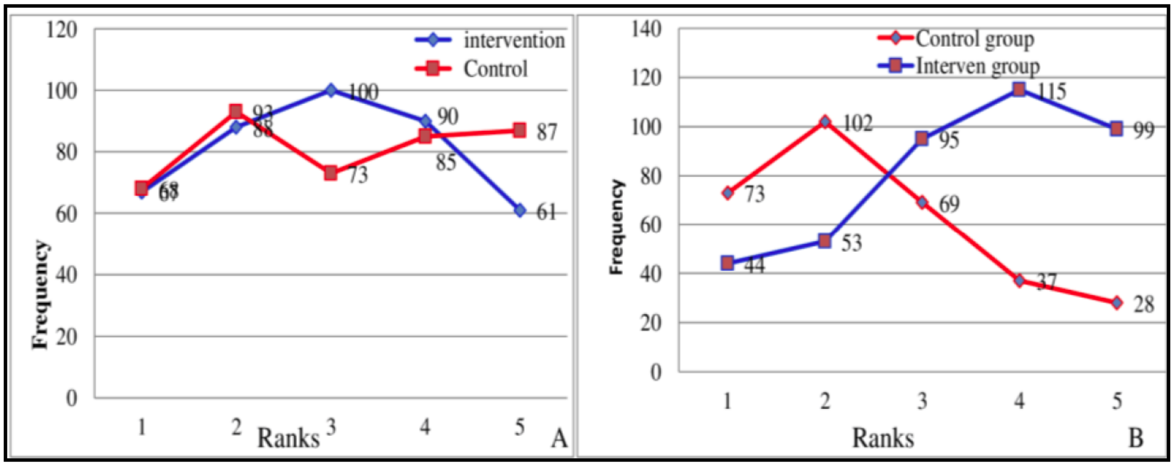

Figure 1: Diagram '**A**' shows the factions of UIC by the height ranks between the intervention and control group at baseline, 2018. Diagram' **B**' shows the rank of UIC by the height between the intervention and control group at the end-line, 2020.

UIC (107µg/L ±8.66). At the baseline, the median UIC among the intervention group was 106.0µg/ and at the end-line increased by more than two times (367.22µg/L). The prevalence of iodine deficiency (median UIC < 100µg/L) among children who participated in this study at baseline was 11.82%, (n= 96), which was a slightly higher proportion found among the intervention group. At the end-line, iodine deficiency was lowered to 6.15%, n=44), but more proportion (75%) of iodine deficiency was found among the control group. The effect of the nutrition behavior change communication critically lowered the prevalence of iodine deficiency among the intervention group by more than 80%. Commonly, more than 93% of children who participated in the study had achieved their iodide nutrient requirement. Furthermore, 6.15% of children had mild iodine deficiency (50 to 99µg/L). However, severe iodine deficiency iodine intake was below the estimated average requirement (EAR < 65µg/L/day) and accounted for 0.8 % [13].

Of women who had formal education, 78.32% of children did not have an iodine deficiency. Although using iodized salt at the early cooking time had high iodine deficiency (63.64 %, n = 28) than 13.64% (n=6) of women who used it at the end of cooking food. At baseline, growth defect among entire children was 41 %(n = 332) and declined to 28.67 %(n=205), while among intervention reduced by more than two times (39% to 12.81%) (Table **1**).

Quintile of UIC Correlation to Height

The rank analysis of UIC by height among groups, at the baseline, markedly difference observed that more of the control group found at the 4th plus 5th rank (42.36%, n = 172) than the intervention group (37.20%, n = 151). But, the plausibility of the significance faction of UIC by height with the intervention group was higher (52.71%, n=214) at ranks 4th plus 5th compared to the 17.80% of the control group (Figure **1A** and **B**).

From this analysis, end-line – baseline means UIC differences by mean Ht differences between the intervention and control groups indicated that a high proportion (43.6%) of the intervention group was found at the 4th and 5th ranks compared to 22.33% of the control group (Figure **2**).

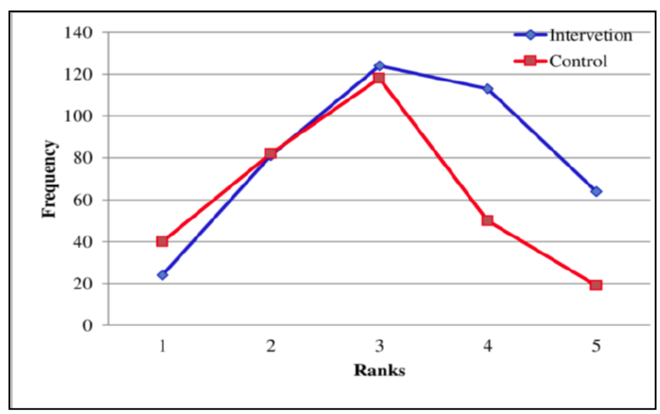

Figure 2: Shows the factions of end-line – baseline mean differences of UIC by a mean difference of Ht between intervention and control groups, 2020.

End-Line - Baseline Mean Differences of UIC and Height

The growth defect of children was very high (40.90%, n =332 at baseline and among the intervention was very higher (41.87%, n = 170) than the control (39.90, n = 162). But, at the end-line, growth deficit within study subjects considered a high level of prevalence (28.53%, n=204) reduced by more than 38%, significantly among the intervention group reduced to 29.8%.

In the independent t-test, the baseline and end-line mean difference (MD) was analyzed for different variables between the intervention and control groups. The baseline and end-line mean difference of mean UIC between the intervention and control were significant at 114.84μg/L (SE=10.55, P>0.05). The amiability mothers/caregivers to read and write (MD = 34.53μg/L, p = 0.015), strongly improved conclusive communication about iodine (MD = 43.253μg/L, p = 0.001) and age children <24 months had significant association with UIC MD (-0.34μg/L, p = 0.027) compared to the counters (Table **2**).

In GEE model showed that being in the intervention group increased height by 10.85cm (β =10.85, Std. P <0.0001) as compared to the control children. Being male increased height by 1.46cm (β =1.46, P= 0.005) as compared to females. Being a child of a mother who

Table 2: The Mean UIC Difference of End-Line - Baseline between Different Variables in Central Highland of Ethiopia

Variables	n=715(%)	Mean	M D	SED	Pv
Groups at end-line					
Intervention	406(56.78)	207.1900			
Control	309(43.22)	92.3500	114.84	10.55	0.001
Mother caregiver age					
≥ 20years	708(99.02))	157.9804			
< 20 years	7(0.98)	115.0057	42.975	57.317	0.454
Ability to read and write					
Yes	576(80.56)	164.2731			
No	139(19.44)	129.7397	34.533	14.207	0.015
Household Income					
≥ 5000 Birr	98	183.5405			
< 5000 Birr	617	153.4330	30.108	16.377	0.066
Conclusive communication on iodine					
▲improved	378	177.9462			
▼improved	337	134.6927	43.254	11.193	0.001
Age children in months					
Age ≥ 24	475(66.43)	157.4500			
Age < 24	240(33.57)	157.7800	-0.34	11.54	0.027
Sex of children					
Male	369(51.60)	159.08			
Female	346(48.40)	155.94	3.14	11.29	0.713
HFA Z score End-line					
≥ - 2 SD	511(71.47)	160.40			
< - 2 SD	204(28.53)	150.43	9.97	12.49	0.530
WFH Z -Score at end-line					
≥ -2SD	648(90.63)	156.59			
< -2SD	57(7.97)	166.96	-10.37	19.36	0.125
WFA Z score at end-line					
≥ -2SD	640(89.51)	162.84			
< -2SD	75(10.49)	112.52	50.31	18.32	0.024

Birr, Ethiopian currency; MD, mean difference, ▲improved, Strong improved; ▼improved, low improved; μg/L, Microgram per liter of urine; SD, Standard Deviation; SED, Standard Error differences.

Table 3: Significant Parameters from the End-Line Height of the Children GEE Analysis

Parameter	Exp(B)	95% CI (B)			
		Lower	Upper	Std. E	Sig.
(Intercept)	1.680	1.660	1.703	2.3561	0.000
Intervention group	10.85	5.723	20.59	0.3266	0.000
Male children	1.464	1.125	1.905	0.1344	0.005
Formal education of mother	2.682	1.898	3.790	0.1764	0.000
Vitamin A source of food	0.178	0.059	0.544	0.5689	0.002
Deworming children	1.093	1.043	1.146	0.0241	0.000
Growth Monitoring follow-up	2.471	1.986	3.073	0.1113	0.000
Conclusive Communication on iodine	0.568	0.262	1.232	0.3950	0.152
Current access to communication	3.666	3.199	4.200	0.0694	0.000
Use iodized salt in food every day	0.175	0.102	0.300	0.2761	0.000
adequately iodized for child's food	0.988	0.153	6.369	0.9508	0.990
Iodized salt using in cooking	0.898	0.221	3.655	0.7162	0.881
No purchasing iodized salt in market	0.167	0.009	3.182	1.5046	0.234
No consume goitrogenic food	0.204	0.150	0.276	0.1554	0.000
Consume micronutrient-rich foods	1.651	0.739	3.688	0.4100	0.221
Age of children	0.986	0.958	1.015	0.0149	0.350
UIC at baseline	1.006	0.983	1.031	0.0121	0.599
UIC at end-line	1.006	1.002	1.010	0.0021	0.005
Height at baseline	1.036	1.004	1.068	0.0156	0.025
Weight at baseline	1.111	1.071	1.151	0.0183	0.000
Household income	1.000	1.000	1.000	0.0002	0.481
Family Size	0.957	0.892	1.028	0.0364	0.232
Duration of breastfed	0.990	0.982	0.997	0.0039	0.007
Complementary food introduction time	1.008	0.989	1.027	0.0098	0.415

CI, Confidence interval; Exp (B), Beta Estimate; Std. E, Standard Error.

attended formal education increased height by 2.6cm (β = 2.68, P<0.0001) compared to the counter group. Likewise, having current access to behavior communication and growth monitoring follow-up moderately increased the Ht of children by 3.666cm (β =3.666, P<0.0001). The association between for one microgram per liter increase in end-line UIC, height increased by 1.006 cm (β = 1.006, p = 0.005) (Table **3**).

4. DISCUSSION

A study proposed to promote dietary iodine intake of children in the community leading to a successful; reduction of iodine deficiency and increased the daily intake of iodine nutrients by the children. In this intervention study, the adequacy of iodine nutrients improved to 94%. The prevalence of iodine deficiency decreased to the mild category of the WHO grade (UIC within 50–99 μg/l would and no median UIC below 50μg/L)[20]. These could be undoubtedly achieved through behavioral change intervention. Behavior intervention fundamental approach encourages people to acquire knowledge and attitude about using iodized salt.

The mean UIC among the intervention group was higher than the control group. Mothers/caregivers who previously followed a formal education, current access to Behavior can age communication, and follow-up of child growth monitoring were moderately associated with increased children's height. Additionally, the associations of UIC at end-line and height at baseline were succeeding the odds of increasing end-line Ht. These judgments could be from the results of seriously modifying the knowledge attitude afforded to exploit exploitation of iodized salt to prevent iodine nutritional problems [4, 10].

The lack of an integrated approach in the community has limited the efforts addressing brain damage, poor I.Q., high school attrition rate, and poor physical growth of children due to iodine deficiency related to the utilization of iodized salt [21, 22]. These findings are not surprising because the nutrition behavior intervention is an intended strategic method to improve dietary adequacy, diversity, and quality intake of complementary foods in children. Although, modifying or replacing the traditional behaviors with newly learned improves the health and environment of the community [14]. The effect of behavior change intervention study on linear growth of children was not evaluated among young children. However, in highly developed and transition nations, such as Norwegian toddlers, the median UIC was lesser (129µg/L) [23] compared to the current study finding (209.9µg/L), and especially difference is higher among the intervention group (367.22µg/L). But, the present study finding had a lesser median UIC than Korean preschool children's median UIC, which was 438.8µg/L [24]. This improvement may be due to the frequency of behavior change intervention sessions, the probability of home follow-up visits by HEW, and updating the information delivered in the neighborhood *kebeles*.

Height for age z-score >-2 was correlated with higher median UIC. Changes in dietary intake behavior change can contribute to a child's nutritional status and development [25]. These UIC and growth differences are the minimum effect of nutrition behavior change that the study deliberately measured. Evidence shows that nutrition behavior change intervention is effective in nutrition and health issues for the benefit of the community or individuals abroad [14, 26].

The impact of nutrition behavior change intervention on iodine concentration and linear growth of children was interpreted sequentially using three critical surveys. The first survey appraisal included the knowledge and attitude about preventing iodine deficiency disorders (IDD) among women and quantifying iodine salt. The second survey accomplished the baseline median UIC laboratory examination. These were followed by the implementation of the intervention and, finally, the conduct of the end-line survey.

During the intervention period, all p study subjects in the intervention group were involved in the baseline and end-line survey, but 76.1% of the control group participated in the study.

In the current study, the prevalence of iodine deficiency decreased to 6.15% after the intervention project was terminated. The median UIC among children increased to 210.56µg/L, and the mean among intervention was 207.19µg/L which differs from the control group by 114µg/L. Thus, the intervention group was 7.88% at the baseline and decreased to 1.54%, showing a more than 80% reduction.

The burden of growth deficit among children was very high (40.90%) at baseline, which significantly declined to 28.71% in the intervention group at the end-line. End-line UIC, formal education of mother, current access to communication about iodine exploration, growth monitoring follow-up, and baseline weight and height variables were associated with the height of children.

At the end of this intervention, mothers'/caregivers' knowledge and attitude toward iodine salt utilization were improved. The improvement of mothers' knowledge level will critically prevent iodine nutrient deficiency and the risk of brain impairment and physical growth in future newborns. This implies that not only children but also the entire household members will benefit from using iodized salt.

5. CONCLUSIONS

We examined whether a change in the knowledge and attitude of women would lead to the utilization\ of iodized salt in households. Longitudinal studies are essential to determine the incidence of IDD in children with regular monitoring and evaluation systems on iodized salt use in developing countries where elimination of IDD is not yet successful.

The existing health care services should continuously be scaled up to prevent young children from growth failures via nutrition behavior change intervention. Furthermore, there should be regular nutrition behavior change communication concerning child nutrition in the health care system to reduce the disparities of knowledge and attitude among mothers/caregivers.

Strength and Limitation of the Study

This interventional study included a high proportion of children aged less than 24 months appreciable as an advantage. Of course, minor imbalances in the age of children at baseline are established by randomizing Kebeles rather than the individual and affect the control group. Following this, some children from the control group lost to follow-up due to their age before the intervention ended. Confront from this limitation did not cause a change in the analysis. However, the effect of the rate of attrition was enormously small.

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CONFLICT OF INTEREST

Declared no Conflicting Interests.

FUNDING DETAILS

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ETHICAL APPROVAL /PATIENT CONSENT

Our research was approved by Jimma University intuitional Review ethics Board (IRB) with the reference number IHRPGD/3007/18 on January 01, 2018 (*Statement copy available*).

Informed consent was obtained from each child's mother/caregiver. Each mother/caregiver was informed about the need for her voluntary and free participation in the study.

TRIAL PROTOCOL

Trial registration**:** ClinicalTrials.gov Identifier: NCT04846062.

url: https://clinicaltrials.gov/ct2/show/NCT04846062

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