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The impact of short message service reminders or peer home visits on adherence to antiretroviral therapy and viral load suppression among HIV-Infected adolescents in Cameroon: a randomized controlled trial

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Abstract

Background Adherence to antiretroviral therapy (ART) and viral load suppression (VLS) constitute one of the key challenges to control human immunodeficiency virus (HIV), especially during adolescence. This trial aimed at assessing the impact of short message services (SMS) or peer home visits (PHV) on adherence to ART and VL suppression among adolescents living with HIV (ALWHIV) in Cameroon.

Methods A randomized controlled trial (RCT) was conducted from July 2018 to February 2019 at the Mother and Child Center of the Chantal Biya Foundation in Yaounde. Eligible ALWHIV (15–19 years), with a fully disclosed HIV status, with availability of phone and guardian's consent, were randomly assigned to receive either daily SMS or bi-weekly PHV for a six-months period. The control-group received standard of care according to the national guidelines. Study investigators and participants were not blinded to the interventions group allocation, and no adverse events or side effects were observed. Adjusted logistic regression was used to assess the impact of interventions on outcomes. The study was approved by The Pan-African Clinical Trials Registry with **PACTR201904582515723** at (www.pactr.org**).**

Results Adherence to ART increased in the PHV (aRR: 4.3; 95% CI: 2.2–8.3; $p < 0.001$) and SMS (aRR: 3.1, 95% CI: 2.1–5.3; $p < 0.001$) groups compared to the control-group. Likewise, VL suppression was higher in PHV (aRR: 2.1; 95% CI: 1.9–7.5 $p < 0.001$) and SMS (aRR: 3.2; 95% CI: 1.8–5.4; $p < 0.001$) groups compared to the control-group. Based on CI, both interventions showed similar benefits on improving adherence and VLS.

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Conclusions Among ALHIV, SMS or PHV contribute substantially to improving adherence and VL suppression among ALWHIV. Implementing such strategies would support efforts in eliminating pediatric AIDS in low- and middle-income countries.

Keywords HIV, Adolescents, Short message services, Peers home visits, Adherence to ART, Viral load suppression

Introduction

Adolescents aged 15–19 continue to encounter suboptimal ART outcomes due to non-adherence, which significantly contributes to the alarming rate of non-suppressed viral load, morbidity and mortality in low- and middle-income countries (LMICs) including Cameroon [1–3]. Of note, the Cameroon Population-based HIV Impact Assessment (CAMPHIA) conducted during the in 2018 revealed a national HIV prevalence of 1.2% among adolescents and youths, with 2.0% among females and 0.4% among males, indicating a five folds higher burden and girls [3]. Over the past two decades, the observed gender disparity remains consistent, with adolescent girls aged 15–19 being six times more likely to be infected than their male counterparts [3]. These challenges are coupled with limited access to quality healthcare for adolescents living with HIV (ALHIV), without any specific programmatic interventions deployed toward this vulnerable population in several LMICs including Cameroon. Of note, studies have investigated interventions to enhance adherence and viral load suppression (VLS) among adults in Cameroon [4, 5], but none have focused on ALHIV. Adherence refers to the whole process from choosing, starting, managing to maintaining a given therapeutic medication regimen to control HIV viral replication and improve function of the immune system. In this frame, the World Health Organization (WHO,2012) recommended the provision of adolescent-friendly services to improve access to HIV interventions, but without peculiarities applicable to LMICs like Cameroon [6]. Emerging evidence suggests that collaborative efforts with healthcare providers and peer support can enhance care for ALWHIV and young adults aged 20–24 [7]. Additionally, preliminary evidence supports the use of mobile health (m-Health) approaches, particularly Short Message Service (SMS)-based interventions, in improving ART adherence among ALHIV who are increasingly familiar with mobile phones and text messages [8, 9]. This SMS-approach appeared appealing when further confirmed in a systematic review and network meta-analysis of RCTs with superiority of SMS-based approaches over standard-of-care (SoC) both at global level (odds ratio [OR] 1·48, 95% credible interval [CrI] 1·00 – 2·16) and in LMICs (1·49, 1·04 – 2·09) [10]. In the same line, another intervention such as Peer Home Visit (PHV) appeared as a support system to improve ALWHIV well-being by enhancing their overall outcomes. Of note, PHV is a strategy that provides services to ALHIV at their door steps in order to maintain their health and reduce morbidity and mortality associated with HIV/AIDS. However, national studies to confirm the clinical significance of these interventions have not yet been conducted to inform decision-making.

This Randomized Controlled Trial (RCT) sought to assess the impact of daily SMS reminders and bi-weekly PHV on adherence to ART and VLS among ALHIV in a typical sub-Saharan African (SSA) context like Cameroon.

Materials and methods

Registration

Authors of this RCT certify the accuracy and completeness of the data and analyses and compliance to the trial's protocol, approved by The Pan-African Clinical Trials Registry with PACTR201904582515723 at www.pactr.org.

Trial design

This RCT was conducted from July 2018 through February 2019 among ALHIV at the Mother and Child Center of the Chantal Biya Foundation (national reference pediatric center) in Yaoundé, Cameroon. This was a three-arm trial to evaluate the impact of daily SMS reminders (first intervention group) or bi-weekly PHV (second intervention group) on adherence to ART and VLS among ALHIV. Each of these two interventions were compared with the SoC-group (known as reference or control group) that was managed according to national guidelines on HIV/AIDS [11]. The participants in the first first-interventional group were receiving daily SMS from trained investigators while those from the second-interventional group were receiving bi-weekly PHV from adolescents with suppressed VL. After enrollment, each participant was followed-up for a six-months period.

Participants

After administrating the study information sheet and obtaining informed assent and parental consent, participants were enrolled at the study site during their clinical appointment. Data were collected from participants through self-reporting; study questionnaire was administered by trained investigators under strict confidentiality and privacy measures; basic clinical, therapeutic and laboratory data were collected from the participant's medical files.

Eligible participants were ALHIV aged 15–19 years and with a fully disclosed HIV status. In addition, participants enrolled met all of the following criteria: (a) literate; (b) provided assent to participate in the study alongside parental/guardian consent; (c) on ART for at least 6 months and (d) VL performed and result documented; and (e) have a cell phone at their disposal. Exclusion criteria were: (a) loss of phone and (b) withdrawal of guardian's consent. Participants were randomly assigned, in a 1:1 ratio, to either receive daily SMS reminders, biweekly PHV, or the SoC at trial baseline (Fig. 1).

Interventions

Daily short message service

Messages were sent daily during the intervention period of 6 months via local telephone company networks 30 min before the set time for ART administration. The two study investigators, recruited and trained for the purpose of the study, were sending messages to participating ALHIV, under the daily coordination of the study principal investigator. The content of the message was: "*Hello, please, don't forget to take your drug*", without an option for the study participant to respond to the message received.

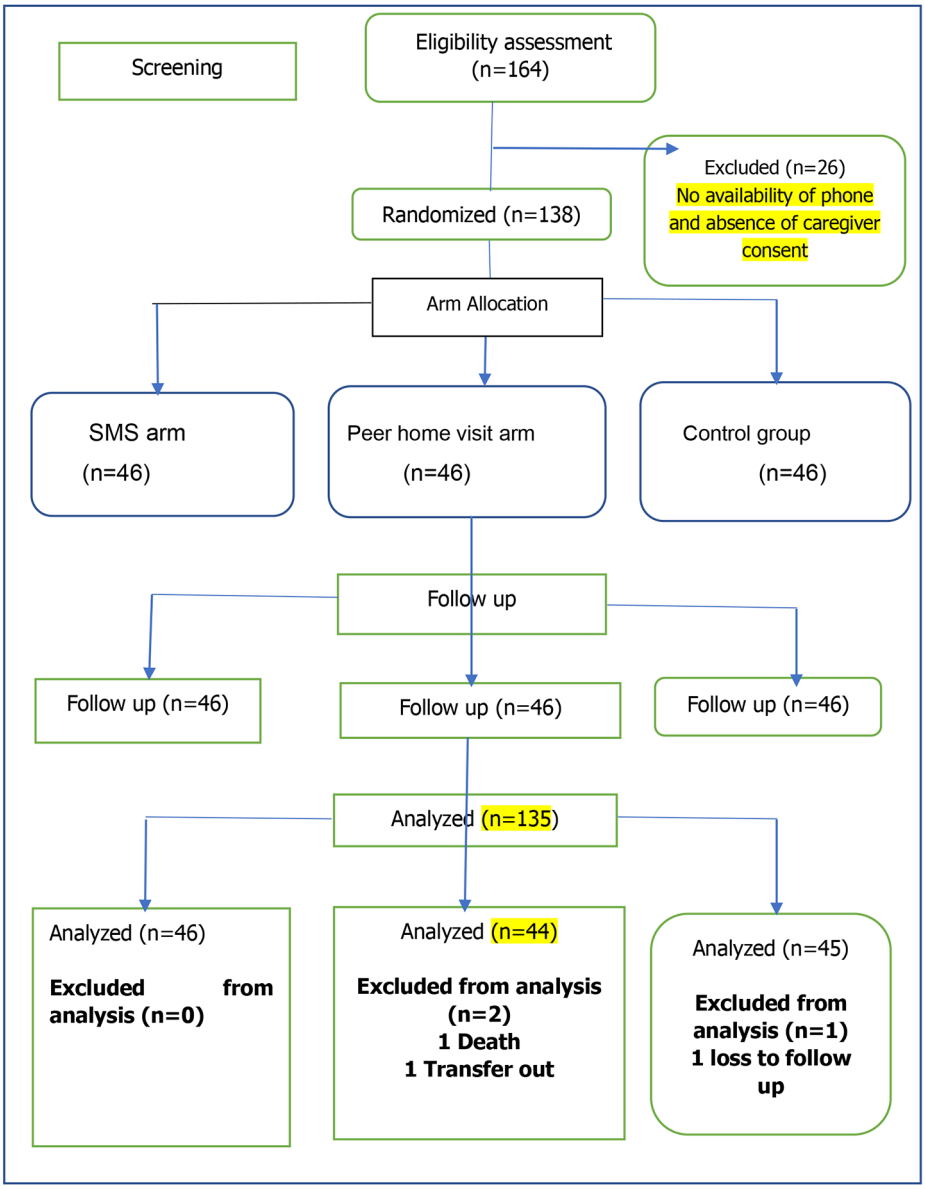

Fig. 1 Randomization and analysis of participants in the trial groups

Peer home visits

PHVs were done by a group of 12 study investigators who were adolescent peers with suppressed VL (< 1,000 copies/ml) known as champions or role models recruited from the Cameroonian network of positive youths (the leading platform of ALHIV in Cameroon). These trained investigators had to visit participants bi-weekly throughout the six months study period. During their visit, they discussed on: (a) the effects of ART in the body; (b) the experience living with HIV; (c) HIV and sexuality; (d) HIV and drug abuse; (e) adherence to ART and its real-life challenges; (f) mental health and therapeutic education; (g) counseling and tips to improve adherence to ART.

Plasma viral load monitoring

Plasma VL (PVL) was measured at the reference laboratory of the health facility, and data on VL were collected from the facility database and recorded into the study case reporting form. All participants had a documented VL performed both at inclusion and another PVL performed 6 months after intervention.

Outcomes

The main estimated outcomes included: (i) rate of good adherence and (ii) rate of VLS.

Adherence measurement this parameter was based on three different approaches, of which (1) self-reported by the patient, (2) pharmacy pill count, and (3) composite of both self-report and pharmacy pill count. For self-reported adherence, the Centre for Adherence Support Evaluation (CASE) adherence index tool, consisting of three questions summing-up to a total score of 19 points, was used. Participants with a CASE Index score ≥ 10 were classified as good adherence and those with a CASE Index score < 10 considered as poor adherence [12]. Pharmacy pill count was calculated by subtracting the number of pills returned by a client from the expected number of pills to be available. Good adherence based on pill count was defined as a score ≥ 95% of drug intake, that is corresponding to 29 out of 30 days of intake for a single pill prescribed daily. Finally, the composite adherence assessment was based on the combination of both methods (CASE index score and pill count), and good adherence by the composite method was defined as both a CASE Index score ≥ 10 and a pharmacy pill count of ≥ 95% as aforementioned.

- **VL outcome**: this parameter was measured according to the number of copies of HIV per milliliter of blood; with a VL less than 1,000 copies/µl considered as suppressed and a VL outcome ≥ 1,000 copies/µl considered as unsuppressed viremia.

Sample size determination for the randomized controlled trial

The sample size was estimated using the formula n = c X [p1(1 – p1) + p2(1 – p2) (p1 – p2)2]; where n was defined as the minimum size per group, c equals to 7.9 for 80% statistical power, p1 and p2 are the estimated proportions at baseline (20.7% for the control group and each of the intervention groups) [8]. The variables are based on the assumption, considering 20.7% of ALHIV achieving 100% adherence in the control group and 50% participants maintaining 100% adherence in intervention groups after administering the study intervention. With a statistical power of 80% and alpha = 0.05, the minimum number of participants per study group was 38, rounded-up to 46 to mitigate for possible attrition of 18% due to loss to follow up at the trial endpoint.

Randomization of participants into the intervention and control groups

Participants were randomly allocated to either the intervention or control group. This was done using a block randomization with excel software. Random number was inserted in sealed envelopes ranked in a randomly assigned order. Envelopes were opened according to the participant's position by trained research assistants. The intervention targeting each participant was known only by the investigators for the sole purpose of the study (Fig. 1).

Data collection

Data were collected by trained research assistants within the health facilities, after obtaining a written informed consent from each parent/guardian, alongside a written informed assent obtained from each ALHIV. Key variables included participant's demographic and clinical details, ART regimen(s) of each participant, baseline VL, exposure to interventions, adherence to ART and endpoint VL monitoring after 6-months of intervention.

Statistical analysis

An analysis-by-protocol approach was used to evaluate the outcome. All missing values were verified. The impact of interventions was compared between study interventional groups versus the SoC by estimating the RR to measure association for categorical variables. The significance of the difference was estimated using the Z test, confidence intervals and p-value. Multiple logistic regression model was used to control and potentially mitigate the effects of measured confounders. The level of confidence of our estimates was 95% and the level of significance of p-value was set at ≤ 0.05.

Table 1 Adherence to ART and viral load suppression before and after interventions

Groups	Adherence at baseline			Adherence 24 weeks after interventions			
	Good *n* (%)	Poor *n* (%)	*N*	Good *n* (%)	Poor *n* (%)	*N*	*p*-value
*PHV	9(20)	37(80)	46	37(84)	7(16)	44	**< 0.001**
†SMS	13(28)	33(72)	46	39(85)	7(15)	46	**< 0.001**
Control	10(22)	36(78)	46	12(27)	33(73)	45	Ref
	VLS at baseline			**VLS 24 weeks after interventions**			**p-value**
	Yes n (%)	**No n (%)**	**N**	**Yes n (%)**	**No n (%)**	**N**	
*PHV	5(11)	41(89)	46	31(70)	13(29)	44	**< 0.001**
†SMS	12(26)	34(74)	46	37(80)	9(20)	46	**< 0.001**
Control	14(30)	32(70)	46	13(29)	32(71)	45	Ref

**PHV: Peers Home Visit;†SMS: Short Message Service Reminders; VLS: viral load suppression; Ref: reference*

Table 2 Impact of interventions on adherence and viral load suppression

Group	Adherence *n* (%)	cRR95%CI	*p*-value	aRR95%CI	*p*-value
*PHV	37(84)	4,60(2.38–9.30)	**< 0.001**	4.33(2.29-8,03)	**< 0.0001**
†SMS	39(85)	4,32(2.38–9.75)	**< 0.001**	3.19(2.07-5,34)	**< 0.0001**
Control	12(27)	1			
	VLS n (%)				
*PHV	31(70)	2.41(1.47–3.94)	**< 0.001**	2.17(1.98-7,52)	**< 0.0001**
SMS	37(80)	3.63(1.96–6.72)	**< 0.001**	3.22(1.89-5,44)	**< 0.0001**
Control	13(29)	1			

Peers Home Visit;†Short Message Service Reminders;cRR.**Crude Relative risk;**aRRr.**Adjusted Relative risk;**CI.**Confidence Interval. VLS: viral load suppression.*

Results

Sociodemographic characteristics of the adolescents

A total of 138 ALWHIV were enrolled as trial participants and randomly allocated into the SMS group, PHV and to the control group, for a total of 46 participants randomized into each of the three trial arms.

Descriptive statistics for baseline and post intervention adherence and viral load suppression

Overall, the required minimum sample size was met in each of the study arm, thus ensuring representativeness of the study outcomes. Table 1 revealed a significant increase in adherence rate after both interventions, namely PHV and SMS ($p < 0.001$). Likewise, VLS rate significantly increased after both interventions ($p < 0.001$). It is important to notice that during the interventional period, one adolescent in the PHV died and one was transferred-out to another township; also one adolescent in the control group was lost to follow up.

Impact of the SMS and peers home visit on adherence and viral load suppression

Both participants in the PHV and SMS reminder arms of the trial had a good level of adherence when compared to those in the control group. Also, both participants in the SMS reminder and PHV arms of the trial had a significantly higher VLS when compared with those in the control group as detailed in Table 2. Specifically, PHV increased by 4-folds the likelihood of good adherence while SMS had 3-folds. Similarly, PHV increased by 2-folds the likelihood of achieving VLS while SMS had 3 folds. Considering the CI, both interventions had similar benefits on improving adherence and VLS among ALHIV (Table 2).

Discussion

Adherence and VLS are two related determinants of treatment success that deserve to be support with locally feasible strategies to achieve HIV elimination in LMICs. Such initiatives are of particular importance for the management of vulnerable populations such as ALHIV in LMICs. The present RCT is therefore a footprint for identifying operational framework guiding favorable outcomes among ALHIV in LMICs like Cameroon, with the goal to enhance pediatric AIDS elimination within these vulnerable populations.

From this trial, either SMS reminders or PHV interventions promote adherence to ART or VLS. Of note, the significant difference in both adherence and VLS places these strategies as very efficient for LMICs (aRR: 4.3 for PHV and aRR: 3.1 for SMS). Hence, poor adherence to ART is herein confirmed as a major barrier to the achievement of optimal treatment outcomes among ALHIV in settings like Cameroon. These adherence challenges are due to forgetfulness, lack of appropriate information, their unique emotional state and lifestyles in this stage of transition toward adulthood [13, 14]. Forgetfulness as the major risk factor to poor adherence could be addressed efficiently using the trial interventions or even ideally by a digital adherence tool. Even

though there is limited evidence on the contribution of the growing availability of mobile phones in Cameroon and other LMICs with respect to promoting ART adherence, our findings stand in favor of such approaches, especially with the advent of social networks. Of note, a recipient of a simple SMS reminder was about 3 times more likely to adhere to ART compared to SoC. Previous studies have even reported higher rates of adherence to ART after having incentives added to the SMS reminder, but sustainability of such strategy is uncertain in LMICs [15–17]. Specifically, a RCT of personalized text message reminders to promote medication adherence among HIV-positive adolescents and young adults showed a considerable higher performance over the 6-months intervention (≥ 90% adherence rate) [17]. Another study conducted in Uganda in 2015 on SMS-based intervention reported an improved adherence if provided with needed reminders and social support [15]. in a nutshell, tailoring SMS reminders to mitigate barriers of forgetfulness in ART-adherence would therefore improve drug compliance, VLS and quality of life among these vulnerable populations [16]. The significance of SMS on enhancing adherence to ART was further confirmed with superiority of SMS-based approaches over SoC both at global level (odds ratio [OR] 1·48, 95% credible interval [CrI] 1·00 – 2·16) and in LMICs (1·49, 1·04 – 2·09) [14]. Despite some few conflicting observations [18, 19], the growing evidence in favor of SMS suggests lower statistical power of those studies concerned and hence underscore the need to adopt the implementation of SMS reminders to support ART programs targeting adolescents, wherever feasible.

Our findings also revealed that, beyond improved ART adherence, SMS alerts also had a substantial impact of VLS after six months compared to the control group, and a similar outcome was observed with the strategy led by PHV (aRR: 3.2 and 2.1, respectively). In several trials where patients received daily or weekly mobile phone text messages, risk of viral failure was very minimal within one year period of intervention [20]. With respect to easy application in LMICs, such strategies to improve and support adherence should be individualized and promoted to the child/adolescent and/or caregivers based on the barriers identified, developmental stage and unique circumstances. “Peer support” increasingly forms part of adolescent responsive service packages as a proof of concept that can support adolescents to access, engage and sustain treatment in settings like Cameroon.

Regarding PHV intervention, adolescents in this group were about 4 and 2 times more likely to have good adherence and VLS respectively. As a new approach in the ecosystem of ALHIV within the African context in general and Cameroon in particular, exploring best practices from similar outcomes found in Kenya would be relevant (65–86% VLS after 4 only months) [18].

A RCT on PHV in Zimbabwe also showed improved virological response among adolescents and young people failing ART [21], in line with evidence from a peer mentorship program on youth engagement with HIV services, acceptability of the program, and its contribution to increase linkage to care and VL response. Of note, youths found their peers friendly and inspiring, allowing them to have free exchanges [10]. In southern Uganda, peer mentorship has been fundamental for school-going orphaned adolescents in terms of health promotion by incorporating peer mentoring programs with matched age and culturally appropriate HIV information [22]. This is in line with a study from Zimbabwe supporting peer support as a predictor of self-confidence, opportunities to develop and strengthen future plans, good adherence and consequently optimal VL responses for both adolescence and AIDS-orphaned children [23]. The uniqueness of PHV resides on the fact that mentoring is between a person who has lived through a specific experience (peer mentor) and a person who is new to that experience (peer mentee). This alone justifies the likelihood to have a good adherence and VLS through such mentorship framework. Thus, even though sending SMS were less expensive than PHV, setting-up adolescent/youth specialized centers where peers meet together and share their realities between each other, would be relevant in closing the gap of inaccessibility to cell phones within LMICs.

Strengths

The major strength of this trial is its evidence-based application of the findings to optimize adherence and ART response among adolescents retained in care, by using an affordable strategy with generalizability of the findings to the target populations of ALHIV in LMICS sharing similar sociocultural and programmatic features with Cameroon. This further underscores the implementation of studies combining the evaluation of retention to care and mental health among adolescents for greater impacts toward HIV elimination in pediatric populations.

Study limitations

Evidence from the present RCT might not reflect the population of ALHIV aged below 15 years, those whose HIV status have not been disclosed, or living in a rural context (not covered in our study design). Future studies should consider targeting these other popultions of ALHIV and younger children, to ensure a broader impact. In addition, the fact that a confirmatory receipt of the SMS by the ALHIV (and not a third party) was not verifiable could affect (though minimally) the outcome. Finally, long-term assessment of these interventions

could lead to time dependent adaptive interventions as ALHIV grow toward adulthood.

Conclusions

In a nutshell, the use of daily SMS or bi-weekly PHV improves adherence to ART and VLS among ALHIV. Based on multivariate analysis, the choice of the intervention (PHV or SMS) should consider feasibility within LMICs, with the ultimate goal to achieve and maintain high adherence and viral load undetectability so as to contribute in eliminating pediatric HIV in LMICs by 2030.

Abbreviations

ALWHIV	Adolescents Living With HIV
ART	Antiretroviral Therapy
AIDS	Acquired Immunodeficiency Syndrome
VLS	Viral Load Suppression
RCT	Randomized Controlled Trial
PHV	Peer Home Visits
SMS	Short Message Service
SSA	Sub-Saharan Africa
LMICs	Low- and Middle-Income Countries
CASE	Centre for Adherence Support Evaluation
SoC	Standard of Care
aRR	Adjusted Relative Risk
cRR	Crude Relative Risk
CI	Confidence Interval
NNT	Number Needed to Treat
N	Number of Participants
HIV	Human Immunodeficiency Virus

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

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Author contributions

AK, JF, JA and FA designed and implemented the study; AK collected the data; AK, FA, EK, JA, CDN and FA analyzed and interpreted the data; AK initiated the manuscript; JA, FA, JF, FA, AFA, JNBH, GRPD and JA revised the initial version of the manuscript; all authors revised and approved the final version of the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Written informed consent was obtained from each guardian/caregiver as well as informed assent from each participant prior to engaging in this study. The trial protocol received ethical clearance from both the Regional Delegation of Public Health of the Centre region - CE02243N°/CRERSHC/2017 and the Institutional Review Board of the Faculty of Health Sciences of the University of Buea – 2018/024/UB/SG/IRB/FHS. Data were managed using specific identifiers and stored in a password-protected computer for purposes of confidentiality and privacy.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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