Effectiveness-implementation hybrid type 1 trial evaluating the WHO caregiver skills training for families of children with developmental disabilities in Ethiopia and Kenya: implementation study protocol

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BACKGROUND

Africa continues to witness a growing number of children with developmental disabilities or delays (DD), estimated at over 14.4 million (1, 2). Existing interventions for children with DDs, including autism and intellectual disabilities, are largely western-oriented, require specialists, and are resource-intensive to implement. The World Health Organization (WHO) in 2016 launched the Caregiver Skills Training (CST), a caregiver-mediated intervention delivered by non-specialists, to bridge the gap in mental health services in low-resourced settings, where there are limited specialists in primary healthcare settings (3). A key CST feature is the task-sharing approach where trained and supervised non-specialists such as nurses, teachers, social workers, and experienced caregivers/parents deliver the intervention. Until recently, small-scale and pilot studies have documented early experiences with the CST implementation, particularly evaluating its acceptability and feasibility in high and low-income settings across the globe (4-13). These studies suggest CST has positive effect on caregiver wellbeing and improvements in children's developmental outcomes, especially social and communication functions. To date, the CST has been offered in a variety of formats (in-person sessions, self-directed eLearning, and virtually). Most of the previous evaluations [e.g. (5, 6, 8, 14)] used specialist facilitators to deliver CST; one study used both specialists and non-specialists (9). A small number of studies have tested the feasibility of using non-specialist facilitators (4, 10, 13). However, there is a dearth of evidence examining this task-sharing approach and effect on CST implementation in real-world contexts, especially on a larger scale and implemented across different contexts.

Aim and objectives

The aim of the study is to assess the implementation of the WHO caregiver skills training (CST) by non-specialist facilitators in the context of three clinical trial sites in Ethiopia and Kenya, facilitating an understanding of how divergent contexts influenced the implementation of the CST. This will be achieved through mixed methods approaches to understand how context influenced mechanisms that in turn influenced implementation and clinical outcomes. Ultimately, this will enable the development of an implementation blueprint to facilitate future implementation in Ethiopia and Kenya, and inform adaptation and implementation in other settings.

The study will address the following implementation questions from the perspectives of the intervention stakeholders [including caregivers of children with developmental disorders/disabilities (DD), CST delivery team, stakeholders in health, education, and community systems].

1. To what extent is the CST acceptable, appropriate, and feasible to implement in Ethiopian and Kenyan contexts?
2. To what extent was the CST delivered as intended (fidelity of delivery)?
3. To what extent was the CST received as intended (fidelity of receipt)?
4. What are stakeholders' perspectives on the sustainability of implementing the CST in the longer term?
5. What are the contextual enablers and barriers associated with the implementation of the CST at different study sites, and how does this influence the mechanisms?
6. Were there any unintended consequences of the intervention i.e. with regards to how the CST was delivered and its potential impact on recipients and the implementation context?
7. How do the divergent contexts at the different study sites, influence the delivery of the intervention on implementation and clinical outcomes?
8. What mechanisms (mediators) influence the effectiveness of the intervention?

METHODS

Study design

This is a two-arm multi-site hybrid type I effectiveness implementation parallel cluster randomised controlled superiority trial, further described in Washington-Nortey et al. (15). The SPARK trial was registered at the Pan African Clinical Trial Registry (PACTR202310908063134), on 16th October 2023.
A mixed-methods approach will be applied, incorporating qualitative and quantitative data collection approaches including intervention evaluation checklists, in-depth interviews, and focus group discussions. An integrative approach (16), will be applied in the analysis and reporting of the results. The study design was shaped by implementation science concepts and frameworks that align with the aims and objectives of the study:

- The Consolidated Framework for Implementation Research (17).
- The Context and Implementation of Complex Interventions (18).
- Implementation outcomes framework (IoF) by Proctor et al (19).
- Implementation strategies compendium reported by Powell et al (20).
- Updated framework for developing and evaluating complex interventions by the Medical Research Council (MRC) and National Institute for Health and Care Research (NIHR), UK (21).

We employed social science approaches to explore implementation-context interaction.

Study setting

The trial of the caregiver skills training was originally planned to take place in urban and rural sites in Kenya and Ethiopia. Due to ongoing security challenges in the rural Ethiopia site, the Ethiopian component of the trial is conducted exclusively in Addis Ababa, an urban setting.

Description of the CST

The main trial testing the effectiveness of the CST is currently ongoing and detailed description of the trial is available in the published protocol (15). **Table 1** presents a high-level overview of the CST intervention**.**

Table 1: The CST intervention and setting description

Trial details	**Additional description**
Study sites	**Kenya** Urban (16 clusters): Informal settlements in Ruaraka and Dagoretti North sub-counties, Nairobi. Clusters were delineated from the Ministry of Health community health strategy, community health units (n=56 units) in Kawangware, Kabiro, Gatina, and Mathare North wards, each with an average of 5000 residents. Rural (16 clusters): Kilifi County, covering Kilifi North, Kilifi South, and Ganze sub-counties. Clusters delineated from 186 enumeration zones under the Kilifi Health Demographic Surveillance System (KHDSS) overseen by the KEMRI/Wellcome Trust, which covers 250,000 residents.
	Ethiopia* Urban (32 clusters): Addis Ababa site covers sub-cities Kolfe Keraniyo (population size 604,226 in 15 *woredas* [districts]), Kirkos (population size 311,765 in 11 *woredas*), Addis Ketena (population size 359,735 in 10 woredas), Lideta (population size 365,744 in 10 *woredas*), and Nifas-Silk (population size 401,344 in 13 *woredas*). Clusters are catchment areas surrounding health centres, each attached to 3-5 *kebeles*.
Intervention structure and sample size	A cluster randomized controlled trial (cRCT) with 64 geographic clusters and a total of 544 families with children with developmental disabilities.
Sample and cluster description	▪ Number of clusters: 16 clusters (8 intervention and 8 waitlist enhanced care as usual) per site* ▪ Sample per cluster: 7 – 10 families ▪ Cluster description: a geographical area or unit with an estimated 1,000 children between 2 to 9 years.
Intervention duration	12-week intervention: 9 CST group sessions and 3 individualised (home) visits at a central location (e.g. health centres or community-based venues). Individualised (home) visits are scheduled at the start, midway, and end of the last CST group session.
Follow-ups	▪ T1: Endpoint assessment (18 +/- 2 weeks post-randomisation). ▪ T2: Follow-up assessment (44 +/- 2 weeks post-randomisation).
(Co)primary outcomes	1. Changes in child behavioural problems measured by Child Behaviour Checklist (CBCL) at T1. 2. Changes in caregiver quality of life measured by the Paediatric Quality of Life (PEDsQL) at T1.
Secondary outcomes	To examine if there are any sustained effects at follow-up for the PEDsQL and CBCL measures and 10 additional outcomes using the following measures: 1. CBCL at T2. 2. PEDsQL at T2. 3. Adapted affiliate stigma scale at T1. 4. Adapted family interview schedule stigma scale at T1. 5. Patient Health Questionnaire-9 (depressive symptoms screening) at T1. 6. Household Food Insecurity Access Scale at T1.

Trial details	Additional description
	7. UNICEF's Multiple Indicator Cluster Survey (MICS)-discipline section MICS6 at T1. 8. WHO caregiver knowledge skills checklist at T1. 9. Euroqol© EQ5D-5L (caregiver quality of life) at T1. 10. Euroqol© EQ5D-Y (child with DD quality of life) at T1 in Kenya only as no validated version approved by the licence holder is available for use in Ethiopia. 11. Oslo Social Support scale at T1. 12. Communication-Profile-Adapted focus on the child's mode and function of communication at T1.
Training of the CST team: [master trainers, supervisors and non-specialist facilitators (NSFs)]	A cascade training was provided by a WHO CST international trainer to CST master trainers and supervisors, who later trained NSFs in the Ethiopian site. In the Kenyan site, this expert-led training was delivered directly to supervisors and NSFs. The training covered WHO CST content, role plays and demonstrations, live practice with child-caregiver dyads to practice CST strategies, and competency assessment post-training. A series of joint booster training sessions were organised for supervisors and master trainers in Ethiopia, and NSFs and supervisors in Kenya. **CST team background:** Non-specialist facilitators in Ethiopia and Kenya include professionals with diploma or degree level educational training (including health, nursing, nutrition, social work or early childhood development and education) and prior working experience in disabilities or mental health. CST supervisors in Kenya have graduate level education in nursing and early childhood development, while Ethiopian supervisors are specialists in psychiatry.

**NOTE: Ethiopia trial runs only in urban sites in Addis Ababa, which instead consists of 32 clusters (16 intervention and 16 waitlist enhanced care as usual)*

Participants and sampling procedures

Data will be obtained from child-caregiver dyads enrolled in the trial, non-specialist facilitators who deliver the training, CST supervisors and master trainers, and diverse stakeholders (i.e. service providers, community, education, and health system actors).

Qualitative sampling and data collection approach

We will conduct focus group discussion (FGDs) with non-specialist facilitators (1 FGD per country; total 5-8 facilitators) and supervisors (1 FGD per country) to explore perspectives on how well the CST worked and contextual barriers and facilitators that influence the effectiveness of implementation strategies in delivering the CST, especially focusing on longer term sustainability.

Forty in-depth interviews (IDIs) will be conducted with caregivers in the intervention arm (n=10 per site in Kenya; n=20 in the larger Ethiopia site). Purposive sampling will be used, and discussions held with CST supervisors and NSFs to identify respondents with diverse attributes, that is:

- Child-related factors: i) child's level of impairment and varying developmental disabilities e.g. autism, attention deficit hyperactivity disorders, global developmental delay or intellectual disabilities, with other comorbidities); ii) child gender; and iii) child age (young and old).

- Caregiver-related factors: gender (at least 1 male caregiver), level of engagement in the CST (e.g. good, moderate, or poor attendance), socio-economic status, educational level, and cluster representation.

Qualitative interviews will take place after the T1 or T2 assessment. In our main trial protocol paper (15), we indicated the interviews would take place after T2. We have revised this timeline and will conduct most interviews after T1 to minimize recall bias in the respondents' CST experiences. In addition, some interviews are done after T2, to allow us to explore sustainability issues, and long-term benefits and challenges. FGDs with facilitators and supervisors will be done after T1 or T2, with recall bias not playing a role because the trained CST facilitators will continue delivering CST sessions to families in the waitlist control arm. In addition, we may conduct interviews, discussions and workshops with stakeholders during and after the trial to better understand the longer-term impact of the CST intervention.

Data collection plan and study measures

Table 2 outlines the data collection plan in relation to the research questions being addressed, describes the implementation outcomes, operational definitions, data sources and timepoints, and stakeholder group of interest. In the section that follows, we describe the data collection plan and activities for each research question.

Table 2: Data collection plan for the CST trial implementation protocol

Implementation outcomes	Operational definition	Data point	Sample indicators or measures	Data source	Stakeholder or level of evaluation
Acceptability	Extent to which the CST intervention is perceived to be agreeable and acceptable	Post-trial	Perceived benefit or value of the intervention Perceived acceptability of the intervention components and delivery	FGDs	NSFs CST master trainers & supervisors
				IDIs	Caregivers of children in the CST
Appropriateness	Extent to which CST intervention is perceived to be fit and relevant	Post-trial	Perceived relevance or fit of the intervention	FGDs	NSFs CST master trainers & supervisors
				IDIs	Caregivers of children in the CST
Feasibility	Extent to which the CST intervention can be successfully used or carried out	Post-trial	Perceived ease/difficulty of implementing and engaging with the CST	FGD	NSFs CST master trainers & supervisors
				IDIs	Caregivers of children in the CST
Fidelity of delivery	Extent to which the CST intervention is delivered as intended	Pre-trial	Adult-child interaction rating	Intervention checklists (supervised sessions) Process tracker	NSFs CST master trainers & supervisors
		During the trial	ENACT scale scores Activity completion checklists rating Supervision notes		
		Post-trial	Intervention features implemented as per protocol and quality of delivery	FGDs	NSFs CST master trainers & supervisors

Implementation outcomes	Operational definition	Data point	Sample indicators or measures	Data source	Stakeholder or level of evaluation
Fidelity of receipt	Extent to which the CST intervention is received as intended	During the trial	Number of CST sessions attended Number of home visits attended Number of home practice done	Attendance logs Process tracker	Caregivers of children in the CST
		Post-trial	Qualitative exploration of engagement with intervention as intended	IDIs	Caregivers of children in the CST
Adoption	Willingness to adopt and use the knowledge and skills learnt in the CST intervention	Post-trial	Willingness to continue using CST information or skills gained Willingness to recommend the CST to others	IDIs	Caregivers of children in the CST
		Post-trial	Willingness to integrate CST in existing health, social, and education sectors	FGDs	NSFs CST master trainers & supervisors
				Meetings and workshops	Health, education and community stakeholders*
Sustainability	Facilitators and barriers to the sustained implementation of the CST intervention.	Post-trial	Perceived role of actors and opinion leaders on the continuity of CST in their context	IDIs	Caregivers of children in the CST
				FGDs	CST team
				Meeting and workshops	Stakeholders
Unintended consequences	Positive or negative consequences that are not anticipated at the time of the CST intervention implementation	During the trial	Social support Social relations Stigma experiences (Serious) adverse events records	Trial database	Survey (T0, T1, T2)
			Perceived effect of CST engagement on social relations, support, stigma, or any other unintended harms	IDIs	Caregivers of children in the CST
				FGDs	NSFs CST master trainers & supervisors
Contextual factors	Facilitators and barriers to the implementation of the CST intervention.	During and post-trial	Factors that may influence the implementation of the intervention Activity reports (risk registers and reports)	IDIs	Caregivers of children in the CST
				FGDs	NSFs CST master trainers & supervisors
				IDIs Theory of change workshops	Community stakeholders

Implementation outcomes	Operational definition	Data point	Sample indicators or measures	Data source	Stakeholder or level of evaluation
Mechanisms	A mediator is a proposed mechanism that is influenced by an exposure that in turn influences the outcome	Through out the trial	Social support Harsh child discipline Caregiver wellbeing Caregiver depression assessed at T1 Explore perspectives on how the intervention brought about any benefits	Trial outcomes	Interventional effects (social support, stigma, socio-economic, DD severity)
				IDIs FGDS	Caregivers of children in the CST CST team

**NOTES: CST – caregiver skills training; DD – developmental disability; FGDs – focus group discussion; ENACT – Enhancing Assessment of Common Therapeutic factors scale; IDI – in-depth interviews; NSF – non-specialist facilitator*

1. *To what extent is the CST acceptable, appropriate, and feasible to implement in the Kenyan and Ethiopian contexts?*

In-depth interviews and focus group discussions will be conducted with different stakeholder groups. The interviews will explore perceptions and experiences of the intervention in terms of acceptability, appropriateness, and feasibility. Interview guides will be developed drawing from the implementation determinant and outcomes frameworks, and pre-tested to account for implementation outcomes, as well as potential contextual barriers and enablers.

Stakeholders refer to families and caregivers of children with DDs receiving the intervention, the team delivering CST including non-specialist facilitators, supervisors, and master trainers. We may also have discussions with actors or opinion leaders in the study sites who may influence the future implementation of the intervention, for instance, government officials, local leaders, civil society organisations among others.

2. *To what extent was the CST intervention delivered as intended (fidelity of delivery)?*

CST trained supervisors and master trainers will observe, supervise, and provide ratings to inform the extent to which the CST intervention was delivered as intended. The ENACT scale (22), will be completed for three out of nine CST group sessions (33%) to assess the level of competency of non-specialist facilitators delivering the CST. Similarly, the activity completion checklists will be completed in the same supervised sessions, to assess the extent to which CST is being implemented as specified in the intervention guides. Information captured in our process trackers and supervision notes will assist in elaborating contextual details in the delivery of the intervention.

Before the trial, supervisors provided rating using the WHO adult-child interaction scale to assess facilitator competence in applying CST strategies when interacting with the child during the individualised home visits.

3. *To what extent was the CST intervention received as intended (fidelity of receipt)?*

We will assess the extent to which the intervention was received as intended by recording the number of sessions participants attended as well as their engagement and completion of home practise tasks assigned after every group session. This information will be collected using an attendance log and process data tracking logs. Qualitative interviews will explore the extent caregivers engaged with the intervention as intended. This will help advance our knowledge of the CST in terms of how easy or difficult it is for individuals to engage with the content, as well as to understand and apply the taught CST strategies in managing their children with developmental disabilities.

4. *What are stakeholders' perspectives on the sustainability of implementing the CST in the longer term?*

Interviews, meetings, and workshops with a range of stakeholders will aim at exploring facilitators and barriers to sustained use of the CST in the longer-term. Activities linked to this research question will further be investigated through the theory of change workshops with stakeholders (see theory of change section below).

5. *What are the contextual enablers and barriers associated with the implementation of the CST at different study sites?*

Interviews and group discussions will explore potential facilitators and barriers to sustained use of the intervention after the trial is completed from the perspectives of providers (CST team) and the caregivers of children with developmental disabilities. With the providers, the focus will be on understanding the potential facilitators and barriers to the implementation of the intervention to the local services after the trial is completed. In contrast, with caregivers of children with developmental disabilities the focus will be on exploring the potential and experienced facilitators and barriers to sustained use of knowledge and skills gained in long-term management of their children.

6. *Were there any unintended consequences of the intervention i.e. with regards to how the CST was delivered and its potential impact on recipients and the implementation context?*

Interviews and focus group discussions will explore the potential unintended consequences arising from participation in the CST intervention. For instance, explore if and how the involvement in the CST may have impacted on social relations, support and care, as well as stigma experiences. We will explore both potential positive and negative impact due to participation in the CST intervention. See section 8 on quantitative data.

7. *How do the divergent contexts at the different study sites, influence mechanisms, on implementation and clinical outcomes? (See section 8 below)*

8. *What mechanisms (mediators) influence the effectiveness of the intervention*

Questions 7 and 8 will be addressed using both qualitative and quantitative approaches:

<u>Quantitative data for Research Questions 7 and 8</u>

The quantitative approach will adapt the interventional effects approach to mediation to evaluate how exposure to the intervention influence the mediators, that in turn influence children's behaviour (Child Behavioural Checklist (CBCL) (23), and the caregiver-focused Paediatric Quality of Life Inventory (PedsQL) (24). Interventional effects are the latest in a series of recent developments to assessment of mediation that overcome the limitations of methods such as structural equation modelling (SEM). Specifically, unless each mediator acts along distinct pathways or all relationships are linear, it is not possible to identify the specific contributions of the various mediators using traditional approaches such as SEM.

Initially, we will develop a directed acyclic graph (DAG) to identify all potential mediators and mediators-outcome confounders. Potential mediators-outcome confounders include severity of the child's disability, and caregiver education. Potential mediators, further described in Table 2, include:

- Symptoms of depression captured using the Patient Health Questionnaire version 9 (PHQ-9) scales validated for use in Ethiopia and Kenya (25, 26);
- Caregivers' knowledge and skills acquired during the training as used in other CST studies (8, 14);
- Health-related quality of life measures for caregivers in Ethiopia and Kenya assessed using the EQ-5D-5L (27);
- Health-related quality of life measures for children with DDs in Kenya only assessed using the EQ-5D-5Y (28);
- Household Food Insecurity Access Scale (HFIAS) used in Ethiopia and Kenya (29, 30);

- Oslo Social Support Scale (OSS-3) used in Ethiopian studies (31);
- UNICEF's Multiple Indicator Cluster Survey (MICS) module on child discipline (32);
- Stigma assessed using the family interview schedule and adapted affiliate stigma measures (33, 34).

Mediators associated with the intervention include proportion of CST activity attended (group sessions and home visits), and proportion of home practice tasks completed.

Qualitative data for research questions 7 and 8

The in-depth interviews and FGD data described above include detailed questions about the mechanisms through which the CST may or may not work. Caregivers and facilitators are asked to consider how strategies learnt in the CST were applied and whether they noted any changes in themselves or their child following the training. Analysis will also consider how contextual differences between the three study sites may have affected CST delivery and impact of the training on child and caregiver outcomes.

In addition, we will use a Theory of Change (ToC) approach (35), to map out care pathways for children with developmental disability, from identification in the community to ensuring children are referred to relevant services such as DD assessment, and then to the CST programme and other services to meet their additional needs, such as health services for additional health needs (e.g. epilepsy), nutrition programmes, and education services. This approach involves different key stakeholders. At the end of this process, we will develop a ToC map that shows the pathway to care and underlying mechanisms, including mechanisms through which the CST programme is hypothesised to work, that may lead to desired long-term outcome of improved quality of life of children with DD and their caregivers. We will also specify the programme assumptions and indicators of success. ToC related activities will primarily concentrate on the Ethiopian context. This may be expanded to Kenya if resources permit.

Data management and analysis

This section describes the analytic approach for the qualitative and quantitative data sources. As a multi-disciplinary team, we will work collaboratively in the formulation of tools, data collection, analysis, interpretation, and reporting of the results. During analysis, an integrative approach will be used to triangulate results across different sources and respondents, to identify areas of convergence and further exploration (16). This process will happen at the interpretation stage of the analysed datasets.

Quantitative analysis

Descriptive statistics will be reported. Parametric and non-parametric tests will be employed to compare the survey responses (see Table 2 for time points) between the two arms of the trial, while controlling for a variety of demographic and socioeconomic variables. Random intercept linear, logistic, and Poisson regression models (depending on the distribution of the outcome) will be used to explore the relationship between implementation outcomes and clinical outcomes. Mediation analysis using interventional effects will be used to examine pathways through which the intervention unfolds. All analyses will be conducted in either Stata version 18 or R statistical programme version 4.4.1.

Mediation Analysis: We will conduct two mediation analyses for our different co-primary outcomes using the Interventional In(direct) Effects approach (36), that allows us to simultaneously account for post-randomisation mediators such as fidelity as well as multiple mediators associated with psychological mechanisms (e.g. caregiver symptoms of depression) as well as mechanisms associated with the social determinants of health (e.g. social support and food insecurity). The mediation analysis will allow us to determine the extent to which the intervention-induced change in child behavioural problems (our main mediator for the co-primary outcome for the caregiver), brings about change in caregiver quality of life. By simultaneously including multiple mediators, their interactions and non-linearities, the interventional

(in)direct effects can reduce biases that are often present in analyses that use traditional approaches (37). Importantly, this approach ensures the direct and indirect effects are summed to reach the total effect.

The above approach provides a framework for decomposing the total effect of the intervention into the following indirect effects: (i) the indirect effect of intervention on change in child behaviour; (ii) the indirect effects through post-baseline mediator factors including number of CST sessions attended, fidelity of CST group sessions, knowledge and skills of caregiver, proportion of home practice activities completed, and competence of the CST facilitator; (iii) the indirect effects of the intervention through other mediators including social support, improved child behaviour, quality of life of caregiver insecurity, caregiver perceived stigma, caregiver symptoms of depression, and physical punishment.

In line with Damschroder and Hagedorn's guidance (38, 39), we plan to link determinants of implementation to the implementation strategies, implementation outcomes, and clinical outcomes as part of the quantitative analyses described above. Further, we propose to link the pragmatic implementation outcome data with the trial outcome data, the logistic, and Poisson regression models. We will prespecify our exact mediation analysis plan and publish the plan on OSF before unlocking the database.

Qualitative analysis

Audio files from interviews with CST trial participants and group discussions with the CST facilitators and supervisors/master trainers will be transcribed verbatim. Inductive and deductive approaches will be used to develop the codebook and analysis performed using a Framework approach (40), in NVivo-Lumivero© software. Constructs from the implementation determinant frameworks will be applied to guide the coding, analysis during charting, mapping and interpretation of data to identify barriers and facilitators to the implementation and sustainment of the intervention, across different contexts. This approach has been used previously, that is, CFIR has been applied post-implementation to investigate facilitators and barriers to implementation among stakeholders who had already adopted and implemented an innovation, thus identifying determinants of implementation post hoc (41).

Ethical consideration

Ethics approval were obtained from all the collaborating institution: in Ethiopia through the Addis Ababa University (CDT/5564/22; AAYMF 03–008); in Kenya through the institutional review boards at the Aga Khan University (2021/IERC-99), KEMRI/Wellcome Trust Research Programme (KEMRI/SERU/CGMR-C/272/4872), and a research permit from the National Commission for Science, Technology and Innovation (NACOSTI/P/24/33550). In the UK, ethics approval was granted by the King's College London, Health Faculties (purple) Research Ethics Subcommittee (RESCM-23/24–33742). Written informed consent will be obtained from participants prior to engaging in study activities.

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Conflicts of interest

There are no conflicts of interest to declare.

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