Impact of the UNICEF Caring for the Caregiver intervention on mental health, social support, and parenting stress: a six-country pre–post evaluation

*Stephanie Redinger, Brian Houle, Boniface Kakhobwe, Caitlin Briedenhann, Pema Tshomo, Stephanie Bispo, Albert Ndagijimana, Mila Vukovic Jovanovic, Royston Wright, Gibson Nchimunya, Peter Hangoma, Alan Stein, Tamsen J Rochat, and the CFC group**

Summary

Background Caregivers facing mental and social stressors risk negative outcomes. The UNICEF Caring for the Caregiver package is a counselling approach and behaviour change intervention that can be integrated into routine home-visiting by frontline workers, in a demand-responsive way, at a population level. We aimed to evaluate caregiver outcomes and explore intervention experiences in six low-income and middle-income countries.

Methods Using a non-randomised pragmatic design, we recruited caregivers of children using community-based sampling. Caregivers reported dose exposure and completed pre–post outcome measures of self-efficacy (General Self-Efficacy scale); social support (Multidimensional Scale of Perceived Social Support); depression (Patient Health Questionnaire-9); anxiety (General Anxiety Disorder 7-item scale); and parenting stress (Parenting Stress Index-36). Using pooled data, two-way fixed-effects regressions examined change and variations in outcomes, by dose. Perception data were collected from caregivers and frontline workers.

Findings In Bhutan, Brazil, Serbia, Sierra Leone, Rwanda, and Zambia we trained 198 frontline workers and recruited 822 pregnant and postnatal caregivers receiving home-visiting from them (April, 2021, to July, 2022). At endline (3–6 months post-baseline) we assessed 682 (83%) of 822 caregivers. We observed higher self-efficacy (β=2·63 [95% CI 1·9 to 3·3]) and social support (4·17 [2·9 to 5·4]), and lower depression (–2·23 [–2·7 to –1·7]), anxiety (–1·43 [–1·8 to –1·0]), and parenting stress (–12·35 [–15·0 to –9·7]). Higher dose was associated with greater change across outcomes. The majority of caregivers and frontline workers reported positive intervention experiences.

Interpretation Across settings, the UNICEF Caring for the Caregiver intervention was positively experienced by caregivers and frontline workers and was associated with positive changes in multiple outcomes. It has potential at population level, but evidence in controlled and longitudinal studies is needed.

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*Members are listed at the end of the Article

For the Dzongkha translation of the abstract see **Online** for appendix 1

For the Portuguese translation of the abstract see **Online** for appendix 2

For the Krio translation of the abstract see **Online** for appendix 3

For the Serbian translation of the abstract see **Online** for appendix 4

For the Kinyarwanda translation of the abstract see **Online** for appendix 5

For the Chichewa translation of the abstract see **Online** for appendix 6

SAMRC/Developmental Pathways to Health Research Unit, Faculty of Health Sciences, University of the Witwatersrand, South Africa (S Redinger PhD, Prof T J Rochat PhD); **DSI-NRF Centre of Excellence in Human Development, University of the Witwatersrand, Johannesburg, South Africa** (S Redinger, C Briedenhann MA); **School of Demography, The Australian National University, Canberra, ACT, Australia** (Prof B Houle PhD); **SAMRC/Wits Rural Public Health and Health Transitions Research Unit (Agincourt), School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa** (Prof B Houle, Prof A Stein FRCPsych); **Early Child Development, UNICEF, New York, NY, USA** (B Kakhobwe PhD); **UNICEF Bhutan Country Office, Kawajangsa-Thimphu, Bhutan** (P Tshomo MA); **UNICEF Brazil Country Office, Brasilia, Brazil** (S Bispo PhD); **College of Medicine and Health Sciences,**

Introduction

In low-income and middle-income countries (LMICs), caregivers and families often raise their children in poverty, with limited access to health and social services.[1] Caregivers who have partner, family, and community support have significant potential to promote resilience and buffer the effects of these adversities on children.[2] However, there are barriers to this important role, including low emotional and practical support and parenting stress.[3] Addressing these through community support to caregivers and families could potentially advance population health, wellbeing, and sustainable development.[4,5]

Research responding to these barriers has focused on caregiver mental health, parenting, and early childhood, including evaluating how frontline workers can enhance caregiver and child health services.[6] Frontline workers can include nurses, midwives, lay counsellors, or community health-care workers who have direct contact with caregivers, delivering care, health, or education in homes and community settings. Evidence suggests that appropriately trained and supervised frontline workers improve outcomes for children and families, but gaps remain in how this is translated to wider-scale implementation.[7]

The UNICEF Caring for the Caregiver (CFC) package is a prevention intervention responding to this gap.[8] It is not a mental health treatment. It aims to mitigate the effects of adversities and prevent the development (or escalation) of psychological distress and social isolation. It takes a system-wide approach to improving the quality of general counselling skills relevant for a range of health interventions, encouraging integration of mental health and social support content within existing government-led programmes. For additional information on the intervention see appendix 7 (p 3).

We evaluate this intervention in six LMICs, testing the hypothesis that strengthening frontline worker

School of Public Health, University of Rwanda, Kigali, Rwanda (A Ndagijimana MPH); **UNICEF Serbia Country Office, Belgrade, Serbia** (M Vukovic Jovanovic MA); **UNICEF Sierra Leone Country Office, Freetown, Sierra Leone** (R Wright MSc); **UNICEF Zambia Country Office, Lusaka, Zambia** (G Nchimunya MSc); **School of Public Health, University of Zambia, Lusaka, Zambia** (P Hangoma PhD); **Chr. Michelsen Institute, Bergen, Norway** (P Hangoma); **Blavatnik School of Government, University of Oxford, Oxford, UK** (Prof A Stein); **African Health Research Institute, KwaZulu Natal, South Africa** (Prof A Stein); **School of Psychology, Faculty of Health and Education, Manchester Metropolitan University, Manchester, UK** (Prof T J Rochat)

Correspondence to: Prof Tamsen J Rochat, School of Psychology, Faculty of Health and Education, Manchester Metropolitan University, Manchester M15 6GX, UK
t.rochat@mmu.ac.uk

For the **CFC package** see https://www.unicef.org/documents/caring-caregiver

See **Online** for appendix 7

Research in context

Evidence before this study

Mental health problems, low social support, and parenting stress are common, inter-related challenges that are linked to negative health and developmental outcomes in populations of caregivers living in low-income and middle-income countries (LMICs). The *Lancet* Commission on Mental Health (2019) and the WHO Mental Health Action Plan (2013–30) call for integrated mental health and social care services in community-based settings. How this is realised in diverse global settings remains poorly understood.

We searched PubMed for English language articles (inception to Jan 29, 2026) using a combination of the terms "mental health", "social support", "parenting stress", "intervention", "caregiver", "parent", "maternal", "frontline workers", "community health workers", and "LMIC". Additional searches specified countries named in this research. We found 106 articles featuring 27 randomised controlled trials (RCTs) along with qualitative and observational studies and two recent systematic reviews with meta-analyses (2017, 2024). No studies targeted mental health, social support, and parenting stress concurrently. Some RCTs (n=7) in India, Pakistan, Sri Lanka, South Africa, Viet Nam, and Zimbabwe investigated non-specialist-delivered counselling for mental health (largely maternal depression) with mixed results. A replication study of a successful RCT multicomponent intervention (RINEW trial in Bangladesh) using government-employed health-care workers failed to replicate improvements in maternal depression, and no interventions were tested in multi-country LMIC contexts.

Added value of this study

This research is the first evaluation of the UNICEF Caring for the Caregiver intervention. This intervention uses a theoretically strong conceptual framework and targets multiple outcomes affecting parenting experience and behaviour. It was evaluated in six countries and was tested within frontline worker cadres in routine government services. It is, to our knowledge, the first multi-country study to demonstrate concurrent improvements spanning mental health, social support, and parenting stress, across a range of cultures in LMICs. Despite limitations, the findings support the acceptability and potential of intervening to improve mental health and social support concurrently using a model operationalised at community level.

Implications of all the available evidence

Current evidence shows that counselling delivered by non-specialist providers can improve mental health in caregivers in LMICs. This research highlights the potential to advance this evidence by taking a broader focus on multiple outcomes, encouraging frontline worker autonomy, and moving beyond demonstrating success on single dimensions of parental experience or behaviour. More research is needed to investigate the effectiveness of this intervention with larger sample size and controlled and longitudinal designs. Importantly, implementing ministries and researchers should consider detailed evaluations of how the intervention can be integrated and adapted locally using manualised guidance published by UNICEF to maintain fidelity.

counselling skills and providing targeted behaviour-change tools, delivered in a demand-responsive way, will result in positive changes in caregiver outcomes.

The research has three aims: (1) to assess change in outcomes linked to intervention targets; (2) to explore whether change in outcomes differed by reported dose exposure level; and (3) to explore frontline workers' and caregivers' perceptions of the intervention.

Methods

Study design and participants

We conducted a non-randomised pre–post training and intervention evaluation in six LMICs. The design and outcome measures were linked to a predefined conceptual framework (appendix 7 p 2). The CFC intervention was co-created by UNICEF, the researchers, and country stakeholders through piloting in Sierra Leone, Mali, and Malawi (2018–20). A series of technical, expert, and country reviews were conducted (2021–23). It has been expanded, augmented, and manualised (2023–24) responding to reviews and study results and strengthening its system-wide approach.[8] It is published by UNICEF for use with permission.

UNICEF led consultations on research participation with ministries responsible for health, education, and social welfare in Bhutan, Brazil, Rwanda, Serbia, Sierra Leone, and Zambia. Country selection was pragmatic given the COVID-19 pandemic and the demands it placed on health-care systems in participating countries. Country selection also considered geographical, cultural, and economic diversity (including low-income [Rwanda, Sierra Leone, Zambia], lower-middle-income [Bhutan], and upper-middle-income [Brazil, Serbia] country settings).

Ethics permission was obtained from University of the Witwatersrand Human Research Ethics Committee (M201094) for a standardised research protocol and consent forms, whereafter additional country-specific reviews were undertaken (appendix 7 p 3). Country-specific safety systems were set up to ensure participants reporting concerns (eg, reporting thoughts of self-harm) received an appropriate referral.

Research communities were linked to catchment areas where trained frontline workers were undertaking routine home visiting. All sites recruited caregivers using a consistent protocol. In Bhutan, recruitment took place at early childhood development centres; otherwise, recruitment was community-based. In all settings, caregivers were consecutively approached to recruit a sample of at least 100 caregivers per country. This was

lower in Serbia due to COVID-19 lockdowns. We estimated a standardised effect size of change in parenting stress of 0·4 at endline (3–6 months post-baseline) for 100 caregivers in any given country (alpha=0·05; power=0·80).[9] While we target five outcomes, we estimated changes in parenting stress as it most consistently correlates to parental wellbeing and parenting behaviours in the literature.[10]

Included caregivers had to be: (1) at least 18 years of age, (2) either pregnant or the primary caregiver of a child aged 0–60 months, (3) a legal guardian with the right to consent, and (4) willing and able to participate. Written informed consent was obtained in the first language of the participant.

Procedures

The CFC content is described in detail elsewhere[8] and is summarised in appendix 7 (p 3). CFC provides a structured counselling process (essential skills) to build trust, make accurate assessments, and use a collaborative approach to determine the focus of counselling in a demand-responsive way. Activities target behaviour change in key areas: self-care, coping, relationships, and responsive caregiving. Additional content is provided on common caregiving challenges by developmental stage (pregnancy, 0–6, 6–12, and 12–24 months). For this evaluation, Bhutan expanded this content to 36–60 months. All materials were translated in-country, and images were adapted in Brazil, Serbia, and Bhutan.

Training used a train-the-trainer approach (appendix 7 p 4). Six master trainers (with training qualifications and >3 years' experience) trained in-country trainers remotely. In-country trainers (primary health-care supervisors, early childhood development coordinators, and nurses) delivered in-person training to frontline workers under mentorship. Frontline worker training included a standardised 3-day experiential workshop, 2–4-week practical learning period, and a standardised competency assessment using a checklist in a trainer-observed role play. In-country trainers provided frontline worker supervision as part of their routine programming.

Each country identified suitable cadres of frontline workers and services within which to integrate CFC as part of the evaluation (appendix 7 p 5). Using the system-wide approach, 548 frontline workers were trained, and of these, 198 (36%) were delivering services in the research communities where caregivers were recruited for this evaluation. Frontline worker to caregiver ratio depended on the numbers of frontline workers allocated to village catchment areas. To participate in the research, frontline workers had to have attended the first in-country training workshop, provided informed consent, and completed practical work and the competency assessment before research activities began. Frontline workers delivered the intervention, largely in a 1:1 individual counselling modality. Content included activities to use with partners and families. Caregivers could choose to use tools and activities with partners and family independent of frontline workers, or request frontline worker assistance with partner or family counselling in a frontline worker-led activity. Visits lasted 1–2 h, with 3–6 counselling sessions delivered over the 3–6 month evaluation period, dependent on need, routine home visiting schedules, and the timeframe available for research implementation and evaluation. Frontline workers were employed in government-linked services and did not receive any additional payment for delivering CFC as part of their routine work.

Data collection

Independent data collectors, who were masked to intervention content, with minimal or no contact with frontline workers, conducted assessments. They were employed by local research partners and trained using a standardised protocol (1-day workshop). Data were collected using electronic software (REDCap)[11] in an interview format, in the local language, taking approximately 30–45 min at baseline and 45–60 min at endline which included an additional 15-min post-intervention module. Data were uploaded to a secure server based at the Africa Health Research Institute (AHRI).

Sociodemographic data were collected at baseline via a study-specific questionnaire on caregiver self-reported age, their relationship to study child, education level, financial status, food security, employment, and household composition.

Outcome measures collected at baseline and endline were selected to measure change in the hypothesised conceptual framework. Depression was measured using the Patient Health Questionnaire (PHQ-9),[12] and anxiety using the Generalised Anxiety Disorder 7-item scale (GAD-7).[13] We measured self-efficacy using the General Self-Efficacy scale (GSE)[14] and social support using the Multidimensional Scale of Perceived Social Support (MSPSS).[15] Parenting stress was measured using the Parenting Stress Index (PSI-36).[16] While outcome measures are widely validated (appendix 7 pp 6–7), we acknowledge that these were not developed for local populations, and that underlying constructs and assumptions may differ from those of the study population.

A study-specific dose exposure variable was calculated using endline data. Caregivers were scored 1 for each essential skill and tool if they reported all three of the following criteria: (1) recalled the activity, (2) reported applying it in their daily life, and (3) rated it helpful (>5 on a 1–10 scale). Caregivers scored 0 if any of these three criteria were not met. Thereafter, scores were aggregated to create a composite variable for essential skill dose (0–4) and tool dose (0–4), with higher scores reflecting higher reported dose of that content. Using a matrix (appendix 7 p 8), caregivers were grouped into low dose (0–1 for both), moderate dose (combination of 2–4 for

both), or high dose (4 for both). Where feasible, fidelity was assessed by direct observation using a checklist.

To assess perceptions of the training, a study-specific pre–post training evaluation was administered to frontline workers. Questions rated knowledge and confidence, including a question on perceptions of training with descriptive information. These evaluation forms were completed without requiring frontline workers to disclose personal identifiers, before and immediately following the training. For caregivers a study-specific perception questionnaire at endline asked caregivers to rate how the intervention had influenced their stress-management, self-esteem, and relationships with partners, families, and children, including descriptive information (see appendix 7 p 8).

Statistical analysis

Statistical analyses used Stata version 19.0.[17] Descriptive statistics are reported for sample characteristics using all available data (pooled and disaggregated) at baseline. We derived a financial risks category based on latent class analysis of components of financial stress. Sensitivity analysis compared those who completed both assessments with those lost to follow-up.

All outcome measures distributions were assessed for normality and reliability was assessed using Cronbach's alpha (α). The PHQ-9 (range 0–27), GAD-7 (range 0–21), GSE (range 10–40), MSPSS (range 12–84), and PSI-36 (range 5–180) were analysed as continuous total scores (ie, no cutoffs were applied) with higher scores indicating higher levels of psychological distress and parenting stress, and increased self-belief or perceived social support. Analyses involving PSI-36 at baseline were restricted to non-pregnant women. We calculated effect sizes based on raw observed means using repeated-measures Cohen's d (mean difference over standard deviation of difference scores) and adjusted for correlation between baseline and endline.[18]

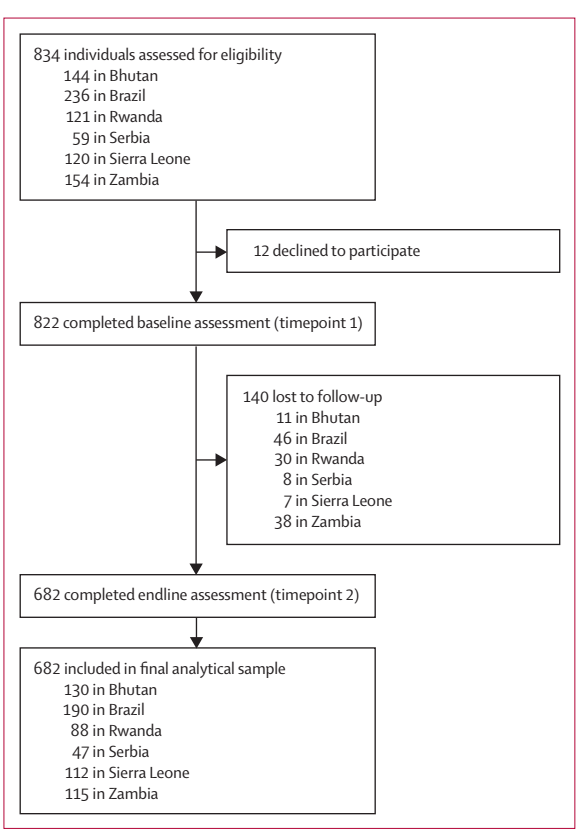

Figure 1: **Flow chart showing recruitment and retention by country**

We used two-way fixed-effects linear regression models to examine change over time. Models are restricted to caregivers with baseline and endline data. Caregiver fixed effects (unit-level) account for time-invariant caregiver characteristics—meaning the model can be interpreted as conditional on time-invariant caregiver characteristics (during the follow-up time). Time fixed effects (baseline, endline) capture time-specific influences common to all caregivers.[19] No caregiver covariates were included in this model. Multiway (village-level and caregiver-level) cluster-robust standard errors were estimated.

To assess whether there was differential change since baseline by reported dose across all outcomes, we used dose categories (low, moderate, high) based on distribution of scores to estimate the initial two-way fixed-effects linear regression models (with caregiver and time fixed effects) including an interaction between time (baseline, endline) and dose exposure (low, moderate, high). There was no main effect for dose exposure included in this model (constraining dose exposure groups to the same baseline mean). Multiway cluster-robust standard errors were estimated. A supplemental model includes an adjustment for differential follow-up time.

Using linear mixed effects models, we further explored whether variation in scores on outcomes differed by country and caregiver characteristics, with an interaction between time and country. These models were not restricted to those who only completed endline, and included nested random intercepts at the village level and caregiver level, and adjusted for caregiver age (<20, 20–29, or ≥30 years), education (less than secondary, secondary, or higher), and level of financial risk.

Free text perception data on caregivers' and frontline workers' assessments were coded using content analysis.[20] Three authors (CB, TJR, and SR) reviewed all data, by perception item, to agree a codebook. Data were then re-read and coded independently by CB, TJR, and SR, and final codes were agreed through consensus. To contextualise frontline worker and caregiver experiences, each coder identified exemplary quotations, and to address coder reflexivity (coders were not from the local populations), quotations were shared with country representatives for review and endorsement in the final selection of quotes.

	Total (n=682)	Bhutan (n=130)	Brazil (n=190)	Rwanda (n=88)	Serbia (n=47)	Sierra Leone (n=112)	Zambia (n=115)
Sample characteristics							
Caregiver age							
<20 years	63 (9%)	0	15 (8%)	5 (6%)	0	21 (19%)	22 (19%)
20–29 years	312 (46%)	39 (30%)	106 (56%)	34 (39%)	10 (21%)	62 (55%)	61 (53%)
≥30 years	283 (41%)	83 (64%)	64 (34%)	44 (50%)	36 (77%)	27 (24%)	29 (25%)
Missing	24 (4%)	8 (6%)	5 (3%)	5 (6%)	1 (2%)	2 (2%)	3 (3%)
Relationship status							
Single	94 (14%)	6 (5%)	44 (23%)	19 (22%)	5 (11%)	4 (4%)	16 (14%)
Casual relationship	33 (5%)	6 (5%)	9 (5%)	3 (3%)	3 (6%)	10 (9%)	2 (2%)
Married or cohabiting	475 (70%)	56 (43%)	134 (71%)	62 (70%)	39 (83%)	90 (80%)	94 (82%)
Missing	80 (12%)	62 (48%)	3 (2%)	4 (5%)	0	8 (7%)	3 (3%)
Education							
None or some primary	380 (56%)	108 (83%)	17 (9%)	60 (68%)	0	91 (81%)	104 (90%)
Secondary or higher	302 (44%)	22 (17%)	173 (91%)	28 (32%)	47 (100%)	21 (19%)	11 (10%)
Employment							
Unemployed	484 (71%)	35 (27%)	173 (91%)	74 (84%)	7 (15%)	81 (72%)	114 (99%)
Employed	198 (29%)	95 (73%)	17 (9%)	14 (16%)	40 (85%)	31 (28%)	1 (1%)
Financial risk*							
Low financial risk	447 (66%)	118 (91%)	132 (69%)	34 (39%)	46 (98%)	66 (59%)	51 (44%)
High financial risk	235 (34%)	12 (9%)	58 (31%)	54 (61%)	1 (2%)	46 (41%)	64 (56%)
Relationship to child†							
Mother	644 (94%)	103 (79%)	185 (97%)	86 (98%)	44 (94%)	112 (100%)	114 (99%)
Father	14 (2%)	9 (7%)	3 (2%)	1 (1%)	1 (2%)	0	0
Related caregiver	20 (3%)	17 (13%)	2 (1%)	1 (1%)	0	0	0
Unrelated caregiver	4 (1%)	1 (1%)	0	0	2 (4%)	0	1 (1%)
Child age							
In utero	77 (11%)	0	0	18 (20%)	1 (2%)	32 (29%)	26 (23%)
0–11 months	233 (34%)	0	57 (30%)	49 (56%)	11 (23%)	56 (50%)	60 (52%)
12–23 months	183 (27%)	0	106 (56%)	20 (23%)	8 (17%)	21 (19%)	28 (24%)
≥24 months	180 (26%)	130 (100%)	26 (14%)	0	23 (49%)	0	1 (<1%)
Missing	9 (1%)	0	1 (<1%)	1 (1%)	4 (9%)	3 (3%)	0
Dose exposure‡							
Low	132 (19%)	5 (4%)	84 (44%)	6 (7%)	30 (64%)	5 (4%)	2 (2%)
Moderate	346 (51%)	125 (96%)	88 (46%)	19 (22%)	16 (34%)	20 (18%)	78 (68%)
High	204 (30%)	0	18 (9%)	63 (72%)	1 (2%)	87 (78%)	35 (30%)
Outcome measures							
PHQ-9 mean (SD)							
Baseline	5·7 (4·7)	4·8 (4·4)	5·4 (4·7)	8·4 (5·2)	3·4 (3·3)	6·0 (5·2)	5·6 (3·9)
Endline	3·4 (3·8)	2·4 (3·4)	4·1 (4·6)	6·0 (4·9)	2·3 (2·4)	2·4 (2·1)	2·7 (2·5)
Standardised mean difference (95% CI)	−0·40 (−0·48 to −0·32)	−0·43 (−0·61 to −0·25)	−0·25 (−0·39 to −0·11)	−0·39 (−0·60 to −0·17)	−0·26 (−0·56 to 0·03)	−0·39 (−0·58 to −0·20)	−0·65 (−0·85 to −0·44)
GAD-7 mean (SD)							
Baseline	4·7 (4·1)	4·4 (4·3)	4·5 (3·9)	7·0 (4·5)	3·7 (4·0)	4·5 (3·7)	4·4 (3·5)
Endline	3·3 (3·7)	2·9 (3·5)	3·6 (4·0)	6·2 (5·1)	2·5 (2·6)	2·6 (2·4)	2·0 (2·0)
Standardised mean difference (95% CI)	−0·33 (−0·40 to −0·25)	−0·39 (−0·56 to −0·21)	−0·18 (−0·32 to −0·03)	−0·22 (−0·43 to −0·01)	−0·28 (−0·57 to 0·01)	−0·29 (−0·48 to −0·10)	−0·58 (−0·78 to −0·38)
PSI-36 mean (SD)§							
Baseline	89·2 (20·8)	99·1 (17·5)	82·5 (15·1)	100 (18·2)	59·2 (19·9)	89 (13·9)	93·4 (24·5)
Endline	76·7 (20·7)	79·7 (17·8)	73·3 (19·4)	88·3 (19·5)	51·9 (17·3)	75·4 (14)	83 (22·7)
Standardised mean difference (95% CI)	−0·54 (−0·62 to −0·46)	−1·14 (−1·37 to −0·92)	−0·38 (−0·52 to −0·23)	−0·76 (−1·01 to −0·50)	−0·46 (−0·78 to −0·14)	−0·40 (−0·63 to −0·17)	−0·25 (−0·45 to −0·05)

(Table 1 continues on next page)

	Total (n=682)	Bhutan (n=130)	Brazil (n=190)	Rwanda (n=88)	Serbia (n=47)	Sierra Leone (n=112)	Zambia (n=115)
(Continued from previous page)							
GSE mean (SD)							
Baseline	28·5 (6·8)	26·5 (6·3)	31·3 (6·2)	23·3 (5·9)	34·0 (4·4)	30·7 (5·2)	25·8 (6·6)
Endline	31·2 (7·2)	30·7 (6·9)	33·7 (6·4)	24·0 (6·7)	34·0 (5·2)	34·6 (5·4)	28·8 (6·4)
Standardised mean difference (95% CI)	0·36 (0·28 to 0·44)	0·57 (0·38 to 0·75)	0·30 (0·15 to 0·44)	0·10 (–0·11 to 0·31)	0·00 (–0·29 to 0·29)	0·51 (0·31 to 0·71)	0·24 (0·06 to 0·43)
MSPSS mean (SD)¶							
Baseline	49·2 (21·2)	59·0 (12·4)	21·0 (4·2)	54·7 (13·6)	79·5 (5·1)	59·4 (10·3)	58·0 (14·0)
Endline	53·3 (22·0)	65·3 (8·9)	22·0 (4·5)	60·1 (14·8)	78·4 (7·4)	62·7 (11·2)	66·9 (9·2)
Standardised mean difference (95% CI)	0·39 (0·30 to 0·48)	0·63 (0·44 to 0·81)	NA	0·30 (0·08 to 0·51)	–0·13 (–0·42 to 0·15)	0·16 (–0·03 to 0·34)	0·72 (0·52 to 0·93)

Data are n (%) unless otherwise stated. PHQ-9=Patient Health Questionnaire. GAD-7=Generalised Anxiety Disorder 7-item scale. PSI-36=Parenting Stress Index short form. GSE=General Self-Efficacy scale. MSPSS=Multidimensional Scale of Perceived Social Support. NA=not applicable. *Financial risk was defined using a two-class latent class analysis, including indicators of self-rated household finances, food insecurity of child and caregiver in the past 2 weeks, experiencing debt stress, and having trouble paying bills (with standard errors clustered at the country level). The two-class solution yielded one group of respondents who had a higher probability to rate their finances as poor, and higher probability to experience debt stress and food insecurity. The second group had a higher probability to rate their finances as comfortable, and a lower probability to experience debt stress and food insecurity. Respondents were classified into high (poor finances, higher debt and food insecurity) or low (comfortable finances, less debt and food insecurity) financial risk based on their most likely predicted class. †Low dose: score of 0 or 1 on both essential skills and toolkit; moderate dose: score of 2–4 on both essential skills and toolkit (but not 4 on both); high dose: score of 4 on both essential skills and toolkit. ‡The questionnaire asked both the relationship of the caregiver to the child (mother, father, or other—specifying related or unrelated) and the caregiver's gender (male, female, or other); there was no discordance in reporting being father and male and mother and female (mother and female, n=644; father and male, n=14; other related, n=20 [16 females, 3 males, 1 missing]; other unrelated, n=4 [4 females]). §Pregnant caregivers (n=52) are excluded from the PSI-36 mean score calculation. ¶The MSPSS mean score in Brazil is based on an abbreviated 4-item version (range 4–28) and therefore Brazil was not included in the calculation of effect size.

Table 1: **Sample characteristics, dose exposure, and mean scores across outcome measures (total and by country)**

	PHQ-9	GAD-7	PSI-36	GSE	MSPSS
Time					
Baseline	..	..	..	..	..
Endline	–2·23 (–2·7 to –1·7), p<0·0001	–1·43 (–1·8 to –1·0), p<0·0001	–12·35 (–15·0 to –9·7), p<0·0001	2·63 (1·9 to 3·3), p<0·0001	4·17 (2·9 to 5·4), p<0·0001
Constant	5·66 (5·4 to 5·9), p<0·0001	4·74 (4·5 to 4·9), p<0·0001	88·93 (87·6 to 90·3), p<0·0001	28·65 (28·3 to 29·0), p<0·0001	49·33 (48·7 to 50·0), p<0·0001

Data are β (95% CI), p value. Two-way fixed-effects linear regression model including caregiver fixed effects and time fixed effects. Multiway (village-level and caregiver-level) cluster-robust standard error estimates. Endline coefficient represents the average within-caregiver baseline-to-endline change. PHQ-9=Patient Health Questionnaire. GAD-7=Generalised Anxiety Disorder 7-item scale. PSI-36=Parenting Stress Index short form. GSE=General Self-Efficacy scale. MSPSS=Multidimensional Scale of Perceived Social Support.

Table 2: **Fixed-effects model of change over time for each outcome across all countries**

	PHQ-9	GAD-7	PSI-36	GSE	MSPSS
Time					
Baseline	..	..	..	..	..
Endline	–1·07 (–1·8 to –0·4), p=0·0027	–0·76 (–1·4 to –0·1), p=0·019	–8·48 (–12·2 to –4·7), p<0·0001	1·63 (0·3 to 3·0), p=0·017	0·56 (–0·8 to 1·9), p=0·41
Time × dose exposure					
Endline × moderate dose	–0·91 (–1·8 to 0·0), p=0·058	–0·58 (–1·4 to 0·3), p=0·175	–2·62 (–8·6 to 3·3), p=0·386	1·52 (–0·2 to 3·3), p=0·090	4·22 (2·0 to 6·4), p=0·0002
Endline × high dose	–2·34 (–3·5 to –1·1), p<0·0001	–1·23 (–2·2 to –0·3), p=0·014	–9·24 (–14·2 to –4·2), p=0·0004	0·78 (–1·0 to 2·5), p=0·38	4·92 (2·5 to 7·3), p=0·0001
Constant	5·66 (5·4 to 5·9), p<0·0001	4·74 (4·5 to 4·9), p<0·0001	88·93 (87·6 to 90·2), p<0·0001	28·65 (28·3 to 29·0), p<0·0001	49·33 (48·8 to 49·9), p<0·0001

Data are β (95% CI), p value. Two-way fixed-effects linear regression model including caregiver fixed effects and time fixed effects, and an interaction between time fixed effects and CFC dose exposure. Multiway (village-level and caregiver-level) cluster-robust standard error estimates. Endline coefficient represents the average within-caregiver baseline-to-endline change. PHQ-9=Patient Health Questionnaire. GAD-7=Generalised Anxiety Disorder 7-item scale. PSI-36=Parenting Stress Index short form. GSE=General Self-Efficacy scale. MSPSS=Multidimensional Scale of Perceived Social Support.

Table 3: **Fixed-effects model of change over time by reported dose received for each outcome across all countries**

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between April 1, 2021, and July 18, 2022, a total of 834 participants were enrolled (Bhutan n=144; Brazil n=236; Rwanda n=121; Serbia n=59; Sierra Leone n=120; Zambia n=154). Of these, 822 completed baseline, and 682 (83%) completed endline. Figure 1 provides a flowchart of recruitment and retention, and the proportion of participants by country. Participants who were lost to follow-up had higher baseline mean scores for depression, anxiety, and parenting stress, and lower mean scores for self-efficacy and social support than those retained in the study (appendix 7 pp 9–10).

Sample characteristics varied by country but about half had no or primary-level education and reported high financial risk (table 1). Caregivers had children in all developmental stages, with the exception of Bhutan. Given the demand-responsive design, reported dose varied by caregiver and by country. Countries reporting higher socioeconomic risks and adversity tended to report higher dose (table 1).

Caregivers were followed up post-baseline (mean 3·5 months, SD 1·34), and received a minimum of three home visits during the intervention period, with variation due to stoppages and delays related to the COVID-19 pandemic.

All 548 trained frontline workers completed evaluations (appendix 7 pp 11–12). Bhutan's frontline workers reported consistently lower ratings of knowledge and confidence to use CFC post-training compared with the other five countries, although most ratings were above 75%. Fidelity measures (n=202 observations of counselling sessions) were conducted in two of six countries (Zambia and Sierra Leone) with n=92 frontline workers. Directly observed fidelity mean scores were 75·4%.

Psychometric outcome measures demonstrated good reliability at both timepoints (PHQ-9 and GAD-7 α>0·80; GSE, MSPSS, and PSI-36 α>0·90).

Table 2 presents the results of the fixed-effects linear regression model (including caregiver fixed effects) showing overall mean change in each outcome from baseline to endline. Using pooled data shows that, for a given caregiver, there were significantly lower scores in depression (β=–2·23 [95% CI –2·7 to –1·7]), anxiety (–1·43 [–1·8 to –1·0]), and parenting stress (–12·35 [–15·0 to –9·7]) at endline. Concurrently, self-efficacy (2·63 [1·9 to 3·3]) and social support scores (4·17 [2·9 to 5·4]) were significantly higher at endline.

Table 3 and figure 2 show the change in scores relative to baseline in a fixed-effects model by the caregiver-reported endline dose (low, moderate, or high). Relative to the low-dose group, overall, a given caregiver who reported a higher dose of CFC had greater change across all five outcomes, although not statistically significant for self-efficacy. For caregivers reporting moderate dose, although the changes were in the direction expected, they were only significant on the social support outcome. When re-estimating the model adjusting for differential follow-up timing (appendix 7 p 13), we found similar results to our main findings.

Supplemental analysis exploring variation in scores by country and caregiver characteristics, with an interaction between time and country (appendix 7 pp 14–15), showed that overall scores were generally similar across countries, although there was more variation on self-efficacy and anxiety, particularly for Rwanda, and self-efficacy, social support, and anxiety for Serbia. Age

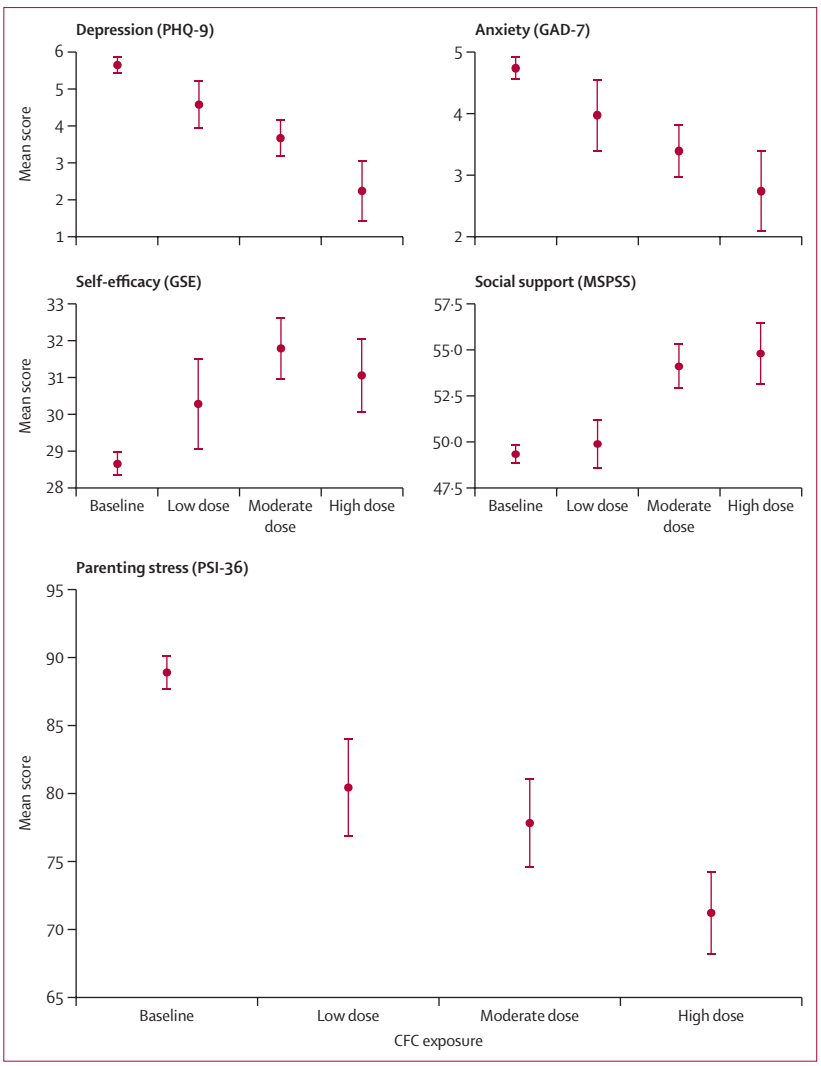

Figure 2: **Average scores by reported dose category (low, medium, high), by outcome**
Vertical bars represent 95% CIs. CFC=Caring for the Caregiver. PHQ-9=Patient Health Questionnaire. GAD-7=Generalised Anxiety Disorder 7-item scale. PSI-36=Parenting Stress Index short form. GSE=General Self-Efficacy scale. MSPSS=Multidimensional Scale of Perceived Social Support.

	Helped you to cope with stressful situations	Helped you feel better about yourself	Helped your relationship with your partner or others	Helped your relationship with your child or children
Bhutan				
Endorsed	97/130 (75%)	96/130 (74%)	Partner: 83/130 (64%); others: 88/130 (68%)	104/130 (80%)
Illustrative quotes	"It showed me how to control emotions and be able to deal with stress"; "I felt I could share my problems and I feel lighter"	"I think it's changed my life to be more positive"; "It changed my way of thinking"; "It made me feel strong"	"It changed my life, and how to deal with my partner"; "It helped the way we communicate with our neighbours and improved our relationship with them"	"It made me change my mind set about my kids"
Brazil				
Endorsed	142/190 (75%)	157/190 (83%)	Partner: 133/190 (70%), others: 143/190 (75%)	171/190 (90%)
Illustrative quotes	"I considered myself very stressed, now I know how to deal better with day-to-day situations"; "I can better control emotions and solve problems"; "I see the importance of having proactive people around me and moving away from people with bad energy"	"I discovered myself as a mother and a woman, I had difficulties in everyday life but found new ways to deal with things"; "I feel more supported and empowered. I feel more interested in talking, because I see myself having a big change"	"My relationship with my husband has improved a lot"; "Our routine became calmer, and communication with my partner improved"; "It improved dialogue and brought more quality of life"; "In the family we talk more at home, we play more with each other"	"My 2-year-old son is very agitated, and I learned to deal with him better"; "I learned how to show my child affection"; "I can deal better with situations, especially with children's emotions"
Rwanda				
Endorsed	72/88 (82%)	78/88 (89%)	Partner: 65/88 (74%); others: 74/88 (84%)	81/88 (92%)
Illustrative quotes	"It helped me know to stay calm in different life challenges"; "It helped me be patient in stressful situations so I can see a way to cope with my problems"; "It improved my relationship with others, I am no longer alone in my stress"	"I no longer feel lonely like I used to be, I feel valued like never before"; "It boosted my self-esteem and hope for the future"; "It helped me to feel free in my heart, and to share my needs with people"	"I learnt to solve problems together with my partner"; "I learnt about sharing caregiving with my husband and coping with life challenges together"; "Having conversations can help us"; "It helped to be open, and share life difficulties"	"I learnt how to cope with emotional problems as when I avoided it, it could affect the baby"; "It changed my life because now I know how to care well for my child"
Serbia*				
Endorsed	38/47 (81%)	37/47 (79%)	Partner: 21/45 (47%); others: 24/45 (51%)	37/47 (79%)
Illustrative quotes	No quotes available	No quotes available	No quotes available	No quotes available
Sierra Leone				
Endorsed	66/112 (59%)	76/112 (68%)	Partner: 77/112 (69%); others: 77/112 (69%).	88/112 (79%)
Illustrative quotes	"I learnt ways of coping with stressful situations"; "It has helped me so much in understanding ways to calm myself when I feel stressed"	"It shows me how to be self-confident as a woman"; "It has helped me to speak about my emotions to others"	"Now we try to resolve conflict amongst ourselves"; "I learnt to identify the source of stress, and possible solutions to conflicts with my partner"; "Family can share a lot of ideas with each other especially being able to resolve conflicts amongst ourselves"	"It has helped me to understand my baby and my partner's relationship and their communications"; "It has changed my understanding about how to take care of my baby and family"
Zambia				
Endorsed	101/115 (88%)	105/115 (91%)	Partner: 96/115 (83%); others: 101/115 (88%)	108/114 (95%)
Illustrative quotes	"I have learnt coping strategies, dealing with emotions, and importance of being happy…how we can deal with a lot of thinking…and finding something that we can be able to do every day"; "It helped to guide me on how to solve a lot of problems practically which was not the case before"	"I learnt how to love myself"; "It brought mental clarity in many areas of my life"; "I am able to control my emotions better now"	"My relationship with my husband has improved due to better communication and better stress management"; "We have become united as a family and communicate better than before"; "Previously were not eating together, now we eat together and talk to each other more often"	"Based on the lessons I received it's not good for the child if they see that I stay angry for most of the time. Both the parent and the child need to understand their emotions so that they can know how to handle their anger"

*In Serbia, structured questions were included in the assessment, but qualitative data were not collected due to time and resource constraints.

Table 4: **Caregiver descriptions of how the Caring for the Caregiver package improved stress management, self-esteem, and relationships with partners, families, and children**

was not consistently associated with outcomes. Higher education levels had a protective association across all outcomes; financial risk was associated with higher depression, anxiety, and parenting stress and lower self-efficacy and social support.

Caregiver perceptions (table 4) aligned to changes observed in the quantitative analysis. Most indicated that CFC had helped them to cope with stressful situations, problem solving, and partner and parent–child relationships. Caregivers in Sierra Leone reported slightly lower endorsement of usefulness for stress management relative to other countries, although at least 70% of caregivers endorsed its helpfulness. Serbia reported low endorsement regarding helpfulness for partner and family relationships, but endorsed helpfulness for the parent–child relationship.

Discussion

This research, using pooled data from multiple countries, is one of the first to evaluate a frontline-worker-delivered intervention for caregivers of children and to find change across five targeted outcomes, with caregivers reporting higher dose also reporting greater change. Although there are variations by country, as might be expected given the range of sociocultural and economic contexts, quantitative findings are supported by perception data across contexts. Changes observed are in line with the hypothesised pathways, providing preliminary support for the CFC intervention and its potential at a population level.

Mental health difficulties and social and parenting stress are common in high-adversity settings.[21] The standardised mean differences for depression (–0·40) and anxiety (–0·33) in this research are comparable to controlled studies targeting mental health using continuous outcome measures and similar to a meta-analysis of controlled studies in LMICs reporting 0·46 (95% CI 0·33–0·59) for depression and 0·24 (0·09–0·39) for anxiety.[22] This is an important finding given mental health benefits shown in controlled studies are seldom replicated when tested for feasibility through larger scale routine services using pragmatic designs.[23]

Parenting stress is associated with difficulties in the caregiver–child relationship, particularly in the context of socioeconomic hardship.[24] Parenting stress is also strongly and inversely associated with parental wellbeing.[10] The lower scores over time in parenting stress across all caregivers, including a 20-point decrease on the PSI-36 for the high-dose group and effect size of –0·54, is comparable to interventions such as the Incredible Years programme, with meta-analyses often finding moderate effect sizes (0·40–0·60) for parent-reported stress.[25]

Social support is evidenced to mitigate against the effects of adversity on parenting.[26] This research found that caregivers with higher social support also reported higher intervention dose, although this did vary by country. We also found that social support is strongly inversely associated with financial risk. It is likely that in high-adversity contexts even small improvements in social support would be meaningful at a population level. We also provide perception data that confirm that caregivers observed benefits of the CFC intervention in their partner and family relationships, highlighting the importance of this relational social support for caregivers.

Caregivers with higher self-efficacy tend to use adaptive coping techniques and positive parenting behaviours in difficult situations.[27] Although higher scores in self-efficacy were relatively small (standardised mean difference 0·36) compared with targeted interventions 0·46 (95% CI 0·27–0·65),[28] this suggests potential as we observe these small positive shifts in feelings of self-efficacy in settings where control over one's own circumstances is likely difficult given systemic adversity (eg, limited access to education or income).[29]

Taken together these concurrent changes in mental health, social support, and self-efficacy have important potential to buffer the effects of future adversity for caregivers. Although these results and frontline worker and caregiver experiences are largely positive, it is important to acknowledge that no intervention will work for all families, in all settings, as illustrated by some participants who rated the applicability or usefulness of CFC lower than others. This intervention, tested through routine services in diverse settings, is potentially feasible to be delivered at a larger scale (see appendix 7 p 16). Our results support the hypothesis that appropriately trained frontline workers, with autonomy to tailor interventions, can deliver benefits, with potentially minimal burden, similar to findings on the value of multicomponent interventions in the literature.[22,23,30] Realistically, the ability to mitigate adversity will always be relative to the levels and types of adversity (such as lower education or higher financial risk) being experienced in local populations. Variation in change across countries highlights how specific cultural and contextual factors might influence outcomes. In Bhutan, for example, both frontline workers and caregivers rated the training and intervention lower than other countries, suggesting room for adaptation that may increase relevance. Likewise, reporting lower ratings of endline parenting stress in Bhutan could reflect that parenting stress increases as children grow and therefore aspects of the adapted intervention might have been particularly relevant for this age group. To support and encourage similar sensitive adaptation before implementation UNICEF has published specific guidance.[31]

Particular strengths of this research include that it targeted multiple outcomes, tested these in multiple country settings, and included both quantitative and end user perception data to support findings. It is also a strength that caregivers themselves report what they remember receiving and whether it was helpful and could be applied to daily life, because this reduces the potential bias involved when implementors report on delivery of interventions which form part of their own work

responsibilities.[30] We recognise the limitation that fidelity observations could not be implemented in all countries and that anonymised frontline worker data could not be directly linked to caregivers. Additionally, in interpreting this research, it is important to acknowledge the potential cultural biases involved in using outcome measures not developed in the populations under study. While our results align with post-intervention effects reported in the literature, the absence of a control group (home visiting as usual) and the relatively short follow-up period suggests caregiver-level changes should be interpreted cautiously. Future research also needs to pay attention to gaps in the evidence on the benefits and/or burden on frontline worker themselves in delivering interventions like CFC. Given data limitations, we are also unable to account for caregivers being nested within frontline workers in our models, which might overestimate the precision of our estimates and warrants caution in interpreting the results—given we used village as the best available proxy. Likewise, it is plausible that excluded participants with worse outcomes at baseline might have experienced similar benefits had they participated. Alternatively, they might not have benefited and therefore attenuated results, or they might have faced barriers to participation. Given high retention rates overall, this is unlikely to have had a substantial impact on the results. While there are strengths in using community-based sampling across diverse settings, it is possible participants recruited might not be fully representative of the broader communities. More evidence is needed from larger, controlled, and longitudinal studies.

See Online for appendix 8

While acknowledging these limitations, this research is an important contribution to the field as it provides support for the CFC conceptual approach and highlights the potential contribution that this intervention can make to mental, social, and relational coping across diverse country and cultural contexts. That this is achieved through brief experiential training, a short practice period, and low literacy user-friendly counselling processes and tools, reiterates the enormous potential frontline workers have as key change agents in communities when they are trained, and enabled to provide support and care in LMICs.

The Caring for the Caregiver (CFC) group
Erinna C Dia (Early Child Development, UNICEF, New York, NY, USA), Njabulo Dayi (African Health Research Institute, KwaZulu-Natal, South Africa), Luzia Laffite (Instituto da Infância-IFAN, Fortaleza, Brazil), Pierre Nzeyimana (UNICEF Rwanda Country Office, Kigali, Rwanda), Ivana Vojvodic (UNICEF Serbia Country Office, Belgrade, Serbia), Jelena Brankovic (Harmony Center for Enhancing Early Development and Family Relations, Novi Sad, Serbia), Ivana Mihic (Faculty of Philosophy, Department of Psychology, University of Novi Sad, Serbia), Hailemariam Legesse, Katherine Kay Faigao-Samonte (UNICEF Sierra Leone Country Office, Freetown, Sierra Leone), Chris Mweemba (School of Public Health, University of Zambia, Lusaka, Zambia), Cecilia Banda, Given Daka, Zewelanji Natashya Serpell (UNICEF Zambia Country Office, Lusaka, Zambia).

Contributors
Conceptualisation: SR and TJR. Accessed and verified the data: BH, SR, and TJR. Data analysis: BH, SR, TJR, and CB. Funding acquisition: SR, TJR, BK, and AS. Investigation (data collection): AN and PH. Project administration: PT, SB, MVJ, RW, GN, and PH. Original draft: SR, TJR, BH, AS, CB, and BH. Review of manuscript: all authors. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Equitable partnership declaration
The authors of this paper have submitted an Equitable Partnership Declaration (appendix 8). This statement allows researchers to describe how their work engages with researchers, communities, and environments in the countries of study. This statement is part of The Lancet Group's broader goal to decolonise global health.

Declaration of interests
We declare no competing interests.

Data sharing
Data documentation (including data field descriptions, study protocol, and analysis datasets) are available on the AHRI Data Repository (https://doi.org/10.23664/ahri.cfc.lancet.global.health.dataset). Data access will include de-identified pooled participant data, and subject to approval from relevant ministries, country identifiers can be provided. Data access will be granted to users who have submitted a request for data, users must consent to the data-sharing agreement, sign a confidentiality agreement, and provide written plans and justification for what is proposed with the data. Data requests will be reviewed by dataset custodians (including primary investigators and UNICEF) and where appropriate participating country ministerial representatives. Given the sensitive, and potentially stigmatising nature of data available, additional conditions may include that at least one team member have relevant qualifications and/or expertise to utilise and interpret mental health and social data sensitively, that appropriate ethical clearances be secured prior to data analysis commencing, and that in some instances a presentation to the participating country's ministerial representatives may be requested, prior to finalisation of data analysis plans and data access.

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