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Evaluation of a school mental health package in Uganda

Submission date	Recruitment status	[_] Prospectively registered
01/06/2025	Recruiting	[X] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
03/06/2025	Ongoing	[_] Results
Last Edited	Condition category	[_] Individual participant data
03/06/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
War Child has been developing a suite of interventions to improve the mental health of children affected by armed conflict. These have always been evaluated individually, never together as a package or system.
The overall aim of the study is to evaluate the impact of a mental health care system, which consists of multiple (evidence-based) interventions, on improving the population-level mental health of children in refugee settlements. So, rather than evaluating the effectiveness of single interventions on improving outcomes amongst their participants, we are not interested in seeing if a combination of interventions can improve the mental health of children, regardless of participation in all or some of the offered interventions. So, what is the population-level effectiveness of a multi-level multi-component care system on improving well-being amongst adolescents (aged 11-16), and/or reducing depression, anxiety and externalizing symptoms amongst adolescents (aged 11-16 years) with elevated levels of emotional distress?
We are also interested in understanding the synergistic and indirect effects of such a multi-component care system and the associated cost-benefits. This study aims to:
1. Improve understanding of whether and what combination of interventions result in better mental health outcomes (i.e. relative contribution to outcomes by different component parts) amongst the group of children receiving services
2. Improve understanding of the indirect effects of a mental health care system approach on other life domains, i.e. to what extent does the mental health care system result in effects beyond the intended (mental health) outcomes (i.e. school outcomes, bullying victimization or perpetration, domestic (parental) or intimate partner violence victimization or perpetration, risky sexual behavior, illegal substance use, child labor, early marriage).
3. Improve understanding of the population-level cost-effectiveness of the mental health care system.

Who can participate?
This study will primarily include all school children between 11-16 years within the selected schools in refugee settlements in Uganda, as well as their caregivers and their teachers.

What does the study involve?
The study involves two groups: the multi-component mental health care system (experimental

group) or the waitlist control group. A random population sample of children (age 11-16 years) will be drawn from schools (one school per cluster) from the selected zones and followed up 6 and 12 months later, wherein the type and extent of services received by children in the experimental arm is not a priori defined following a naturalistic service delivery framework (i.e. not all children and their caregivers will participate in the interventions, further explained below). This means that some children and their caregivers who are part of the experimental group will not receive any service, and other children and their caregivers will receive all available services that are part of the care system. Furthermore, children and their caregivers who are not part of the study sample but are part of the enrolled schools in the experimental group may also receive any or all the services being offered in the care system. This means that children who have been recruited into the study may benefit from the mental health care system either directly (i.e. receiving services) and/or indirectly (i.e. through peers and caregivers receiving services).

What are the possible benefits and risks of participating?
The expected benefits are improved mental health and well-being amongst school children in the schools where the mental health package is being implemented. The risk of participating is increased distress as a result of participating in interventions or interviews. These risks are mitigated through adverse events reporting protocols and subsequent referral and case-management systems.

Where is the study run from?
This study will be conducted with refugee populations in western Uganda, specifically the refugee settlements (Kyangwali, Kyaka and Nakivale) hosting displaced persons primarily from the DRC. Kyangwali hosts approximately 132,000 refugees, 96% of whom are from the DRC and 29% are below the age of 18 years. Kyaka hosts approximately 123000 refugees, 97% of whom are from the DRC and 29% are below the age of 18 years. Nakivale hosts approximately 180,000 refugees, 67% of whom are fromthe DRC and 27% are below the age of 18 years. In all three locations most adults are crop farmers or farm labourers. These profiles are all based on OPM /UNHCR data. Uganda was selected as the site for this study because of its large refugee population, our extensive preliminary research in this setting, and because it exemplifies a low-resource setting where a mental health care system such as the one being evaluated in this study is relevant. Uganda is one of the largest refugee-hosting nations in the world.

When is the study starting and how long is it expected to run for?
October 2023 to September 2027

Who is funding the study?
Irene M. Staehelin Foundation

Who is the main contact?
Prof. Mark Jordans is the Principal Investigator. He is Professor of Child and Adolescent Global Mental Health at the University of Amsterdam, and Child and Adolescent Mental Health in Humanitarian Settings, at the Center for Global Mental Health, King’s College London. He is a child psychologist and works as Director of Research & Development for the NGO War Child Alliance in the Netherlands. His research interests are the development, implementation and evaluation of psychosocial and mental health care systems in low- and middle-income countries, especially for children in adversities and in fragile states.
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Population-level evaluation of a mental health care package for children in Uganda (Pamoja Tunaweza): a cluster randomized controlled trial

Study objectives
Children in the experimental arm (i.e. mental health care system) regardless of whether and what services they received will have a greater improvement in wellbeing and/or reduction in depression, anxiety and internalizing symptoms amongst those with elevated levels at baseline, over a period of 12 months compared with children in the control arm (i.e. waitlist control).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/11/2024, The AIDS Support Organization (TASO) Uganda REC (Mulago Hospital Complex, Kampala, PO Box 10443, Uganda; 256414532580; mail@tasouganda.org), ref: TASO-2024-440

Study design

Parallel two-arm cluster randomized controlled trial (cRCT)

Primary study design
Interventional

Study type(s)
Prevention, Quality of life, Treatment

Health condition(s) or problem(s) studied
Mental health (i.e. improved wellbeing and reduction in depression and anxiety symptoms)

Interventions
18 zones (i.e. clusters; a zone is an administrative unit in Uganda) are randomized in a 1:1 ratio (stratified for school size) to one of the two study arms. The two arms are the multi-component mental health care system (experimental arm) vs the waitlist control. A random population sample of children (age 11-16 years) will be drawn from schools (one school per cluster) from the selected zones and follow-up 6 and 12 months later, wherein the type and extent of services received by children in the experimental arm is not a priori defined following a naturalistic service delivery framework (i.e. not all children and their caregivers will participate in the interventions, further explained below). This means that some children and their caregivers who are part of the experimental arm will not receive any service, and other children and their caregivers will receive all available services that are part of the care system. Furthermore, children and their caregivers who are not part of the study sample but are part of the enrolled schools in the experimental arm may also receive any or all of the services being offered in the care system. This means that children who have been recruited into the study may benefit from the mental health care system either directly (i.e. receiving services) and/or indirectly (i.e. through peers and caregivers receiving services).

TeamUp is a movement-based mental health promotion intervention developed for children affected by armed conflict, violence, displacement and ongoing adversity (https://www.warchild.net/intervention-teamup/). The intervention consists of movement- based activities aiming to improve children's psychosocial wellbeing by strengthening social connectedness, reducing stress and tension, as well as facilitating self- regulation and a positive outlook and, through creating positive experiences, developing their playing resources and offering a safe space where children are protected, heard and respected. In a quasi-experimental study amongst refugee children (primarily from South Sudan) in north-western Uganda (Bleile et al., 2024), children joining TeamUp, showed significantly more improvements on primary outcomes: emotional and psychosocial wellbeing (M.diff = −1.49, SE = 0.6, p = 0.01), satisfaction with and attitude toward school (−0.57, SE = 0.2, p = 0.004); and secondary outcomes: traumatic stress (2.64, SE = 0.8, p < 0.001), health-related quality of life (−1.56, SE = 0.4, p = 0.001), physical health (−0.78, SE = 0.3, p = 0.014) and the TeamUp mechanisms of action scale (−3.34, SE = 0.9, p < 0.001), specifically the subscales social connectedness (−0.74, SE = 0.3, p = 0.007) and sense of agency (−0.91, SE = 0.3, p = 0.005), compared to the control group. TeamUp is offered to groups of children (approximately n = 20-30), consisting of 24 weekly sessions of 1.5 hours. Facilitators are non-specialists who receive 4 days of training and ongoing mentoring. TeamUp groups are co-facilitated by two or more trained facilitators.

ReachNow is a community case detection tool for children and adolescents suffering from mental health problems. The tool is based on a community version of the 'prototype-matching' approach, originally developed to simplify diagnosis. Furthermore, the tool consists of culturally adapted illustrated vignettes depicting a child experiencing signs indicative of childhood

psychological distress. Each vignette was culturally adapted following an iterative process including four adaptation workshops (held with various stakeholders, including national mental health professionals), blind-back translation and four focus group discussions with potential end-users to ensure the acceptability and appropriateness of the vignettes. Previous Community Case Detection Tool (CCDT) studies in the occupied Palestinian territories and Sri Lanka demonstrated that nearly 70% of children were accurately detected as needing mental healthcare when compared with structured clinical interviews (van den Broek et al., 2021, 2022). In a recent Stepped Wedge Trial conducted across five of Uganda's 14 formal refugees settlements—Bidi Bidi, Kyaka II, Kyangwali, Omugo, and Rhino— (partly overlapping with the settlements and refugee populations targeted in the current study) ReachNow implementation, compared to control, was associated with an increase in mental health-care service use in the first month after implementation (20·91-fold change [95% CI 12·87–33·99]) (van den Broek et al, 2024). Despite a slight decline in service use over time in both the CCDT and pre-CCDT zones, CCDT zones maintained a time-average 16·89-fold increase (95% CI 8·15–34·99) in mental health service use. Community gatekeepers, in the current study TeamUp facilitators and other key community members, will receive a 2-day training in the use of the ReachNow tool, which they subsequently integrate into their day-to-day activities.

Early Adolescent Skills for Emotions (EASE) was developed by WHO in response to the need for mental health programs for young adolescents, which is a brief, transdiagnostic intervention and aims to reduce internalizing problems such as anxiety and depression (Dawson et al, 2018) This program comprises 7 group sessions for adolescents that focus on arousal reduction, behavioral activation, and problem management as these strategies have been shown to be key for reducing internalizing problems in adolescents. The intervention also comprises 3 group sessions for caregivers that teach coping skills, positive parenting, and inform them of the strategies taught to the adolescents. A randomized controlled trial of EASE in Jordan indicated that at 3 months, EASE resulted in greater reduction on the PSC-internalizing scale than EUC (estimated mean difference 0.69, 95% CI 0.19 to 1.19; $p = 0.007$; effect size, 0.38) but there were no differences on other outcomes. In a subsequent trial of EASE in Pakistan, improvements were shown on all outcomes. EASE has been adapted to the Ugandan context. EASE facilitators are non-mental health specialists and receive an 8-day training and subsequent mentoring to deliver EASE to children 11-16 years of age. EASE sessions last approximately 1-1.5 hours. EASE groups are co-facilitated by two trained facilitators.

BeThere is a nine-session group intervention for conflict-affected parents of children aged 3–16 years, that aims to strengthen parenting both indirectly, by lowering stress and improving psychosocial wellbeing among parents, and directly, by increasing knowledge and skills related to positive parenting. A randomized controlled trial of BeThere in Lebanon (Miller et al., 2023) showed a significant effect on overall parenting skills among participants receiving the full intervention ($d = 0.25$, $p < 0.05$). BeThere showed beneficial effects in the full sample at endline and follow-up on harsh parenting ($d = 0.17$, $p < 0.05$; $d = 0.19$, $p < 0.05$), parenting knowledge ($d = 0.63$, $p < 0.001$; $d = 0.50$, $p < 0.001$), and caregiver distress ($d = 0.33$, $p < 0.001$; $d = 0.23$, $p < 0.01$). There were no effects on parental warmth and responsiveness, psychosocial wellbeing, stress, or stress management. BeThere consists of a nine-session weekly group intervention, co-facilitated by trained and supervised non-mental health specialists. Groups are offered separately to women and men, with 8–12 participants per group. BeThere is adapted to the study context and population (i.e. refugees primarily from DRC in Kyangwali, Kyaka and Nakivale), for the purpose of this study. Training of BeThere facilitators takes 8 days. BeThere groups are co-facilitated by two trained facilitators.

Community Tales is an intervention that aims to reduce stigmatizing beliefs and behaviors by school personnel, including teachers and school management. Community Tales is a board game

that gets played by 6-8 participants (i.e. school personnel), which invites 'players' to reflect on processes and the impact of stigmatization. A Community Tales session lasts 2.5 hours, which is followed up by a few brief follow-up sessions. Facilitators are trained in 1 day to facilitate sessions. Community Tales has been adapted to the study context and population (i.e. refugees primarily from DRC in Kyangwali, Kyaka and Nakivale), for the purpose of this study.

The case management and referral system will be activated (based on existing services by War Child and other humanitarian organizations working in the refugee settlements) for children for whom the above-mentioned interventions are not enough, and for whom other and/or more specialized care is required.

The implementation model for the care system follows a pragmatic approach. This means that implementation is offered and implemented as it would be in a real-world context, rather than highly controlled (as would be the case in regular efficacy trials). Pragmatic implementation means that we accept close to real-world conditions and that we do not work with pre-set targets for participants (see also under sample below). In the case of the above-mentioned interventions, this means: First, within all enrolled schools all school personnel will be invited to participate in Community Tales workshops. Second, using schools as the entry point, TeamUp will be offered to P1-P6 school classes including children aged 11-16 over the period of 12 months. Importantly, planning of TeamUp will have two restrictions; (1) implementation will follow a randomized rotation system of classes to avoid bias of sequence, and (2) 10-20% randomly selected classes will be excluded from receiving TeamUp (because in real-world implementation contexts not all children can be reached by mental health interventions, yet we still want to evaluate the population-level effects, our design deliberately excludes classes from participation). TeamUp will be implemented as an extra-curricular activity, and participation for children is voluntary. Third, the caregiver support intervention, BeThere, is open to any caregiver with children between 3-16 years of age in the catchment area of the enrolled schools. Caregivers are recruited via information sessions that are held at school and the community-at-large about the availability and aims of BeThere. Fourth, ReachNow is implemented by TeamUp facilitators, as well as other selected community gatekeepers (i.e. trusted and respected members in the community). Selection of community gatekeepers (other than TeamUp facilitators) will be determined for each catchment area for each enrolled school, aiming for a rate of 1 trained gatekeeper per 3000 zone population. The number of gatekeepers per zone is dependent on the population size in the zone, our aim is to train 1 gatekeeper per 3000 residents. They include: Village Health Teams (VHTs), teachers, group activity facilitators, child protection committee members, local community leaders and refugee committee leaders. Specific inclusion criteria are: 18 years of age; trusted and respected members from the community; engaged in promoting child wellbeing; access to children, adolescents and caregivers; demonstrate high level of empathy and interest in children's wellbeing; willing to provide informed consent and participate in supervision meetings to provide feedback on feasibility of the approach; willing to sign and follow WCH's Child Safeguarding Policy, Code of Conduct and Code of Ethical conduct in using the CCDT. Upon detection of children in need of mental health care (of children in and out of schools), using the ReachNow tool, these children will be referred to Project Officers Psychosocial support (PO PSS)/case worker who will then refer to EASE facilitators (for children 11-16 years) and to external referral basing on assessment of needs. Fifth, EASE will be offered to all children that get referred by TeamUp facilitators and community gatekeepers using the ReachNow tool. Furthermore, children can get referred to EASE from elsewhere (e.g. teachers, BeThere facilitators, health care volunteers), following a brief information session on the availability and aims of EASE. Sixth, EASE facilitators will be trained in referring children to subsequent specialized mental health care – when EASE is

providing insufficient support, or when acute mental health problems arise (e.g. suicidality). Furthermore, EASE and TeamUp facilitators will refer children to child protection service in case of indications of severe maltreatment of abuse.

Intervention Type
Mixed

Primary outcome(s)
Measured at baseline, midline at 6 months, and endline at 12 months:
1. Adolescent-reported reduction in depression and anxiety symptoms assessed using the Measurement of Mental Health Among Adolescents at the Population Level (MMAPP)
2. Adolescent-reported improvements in psychosocial wellbeing assessed using the Stirling Children's Wellbeing Scale (commonly referred to as the Stirling Scale)

Key secondary outcome(s))
All measured at baseline and endline at 12 months:

Child-reported measures:
1. Behavioural problems measured using the Disruptive Behavior International Scale - Nepal version (DBIS)
2. Risk factors for future development of depression measured using the Identifying Depression Early in Adolescents Risk Score (IDEA-RS)
3. Personalised outcome measure PSYCHLOPS 3 (Psychological Outcome Profiles)
4. Quality of life, health, and functioning measured using KIDSCREEN-10
5. Internalized stigma measured using the Everyday Discrimination Scale (EDS)

Hypothesized mediators (child reported):
1. Family functioning measured using the Systemic Clinical Outcome and Routine Evaluation-15 (SCORE-15)
2. Hope measured using the Hope scale
3. Social connectedness measured using the Social Connectedness Scale

Exploratory indirect effects (child reported):
1. Two modules based on the Global Early Adolescent Survey (GEAS) to (i) measure trust in adults (not being family or relatives) in the neighborhood (4 items) and (ii) measure friendship (number and engagement) 2 (items)
2. Bullying measured using the Olweus Bully/Victim Questionnaire-Revised Scale (OBVQ-R)
3. Sexual and gender-based violence experience measured using the Global Early Adolescent Survey (GEAS)
4. Alcohol and substance use measured using the 5- item scale of the Alcohol, Smoking and Substance Involvement Screening Test – Frequency & Concern Items (ASSIST-FC)
5. Parental violence measured using GEAS and INSPIRE (UNICEF guidelines on measuring adolescent harms)

Caregiver-reported measures:
1. Socio-demographics and household roster developed for this study to understand the demographic and socioeconomic situation of caregivers and household members
2. Parenting measured using the Brief Parenting Questionnaire (BRQ)
3. Caregiver wellbeing measured using the Warwick-Edinburgh mental wellbeing scale (WEMWBS)
4. Psychological distress measured using Kessler-6 (K6)

5. Traumatic experience measured using the Harvard Trauma Questionnaire (HTQ)
6. Family functioning measured using the Systemic Clinical Outcome and Routine Evaluation-15 (SCORE-15)

In addition to the above mentioned outcome instruments we will also collect the following data: (1) education performance results for all the learners enrolled on the study (this has been approved by school authorities), which will be collected at the time of baseline and endline data collection; (2) a 12-question school form is completed, one per enrolled school, at the time of baseline and endline interviews – mapping basic characteristics of the school.

Completion date
01/09/2027

Eligibility

Key inclusion criteria
1. Residents of the program area
2. Age 11-16 years at the time of baseline
3. Speaking primary language (Kinyabwisha, Congolese Kiswahili, Runyankole, Runyoro/Rutooro)

Participant type(s)
Carer, Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
02/06/2025

Date of final enrolment
31/05/2026

Locations

Countries of recruitment

Uganda

Study participating centre
War Child Alliance - Uganda
Off Tank Hill Road
Kampala
Uganda
N/A

Sponsor information

Organisation
War Child Alliance

Funder(s)

Funder type
Charity

Funder Name
Irene M Staehelin Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the study will; first, be stored in a non-publicly available repository (War Child Alliance), and datasets are available upon request; second, after 3-5 years the data sets will be made available in a publicly available repository (OSF) following the data management policy of the Research and Development Department of War Child Alliance. Data Manager: Gabriela Koppenol-Gonzalez (Gabriela.Koppenol@warchild.net).

IPD sharing plan summary
Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 8.0	12/05/2025	03/06/2025	No	No