POPULATION-LEVEL EVALUATION OF A MENTAL HEALTH CARE PACKAGE FOR CHILDREN IN UGANDA (PAMOJA TUNAWEZA): A CLUSTER RANDOMIZED CONTROLLED TRIAL

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ABBREVIATIONS

ADHD	Attention Deficit Hyperactivity Disorder
APA	American Psychiatric Association
ASSIST-FC	Alcohol, Smoking, and Substance Involvement Screening Test- Frequency and Concern
AUC	Area Under the Curve
BRQ	Brief Parenting Questionnaire
CDC	Centre for Disease Control
CI	Confidence Interval
CSI	Caregiver Support Intervention
DBDs	Disruptive Behavior Disorders
DBIS	Disruptive Behavior International Scale
DRC	Democratic Republic of Congo
DSM-5	Diagnostic and Statistical Manual of mental disorders 5
DSMC	Data Safety Management Committee
EDS	Everyday Discrimination Scale
FGD	Focus Group Discussion
GAD	Generalized Anxiety Disorder
GCP	Good Clinical Practice
GEAS	Global Early Adolescents Survey
HTQ	Havard Trauma Questionnaire
ICC	Intraclass Correlation Coefficient
IDEA-RS	Identifying Depression Early in Adolescents- Risk Score
IDPs	Internally Displaced Persons
K6	Kesseler-6
K-SADS-PL	Kiddie Schedule for Affective Disorders and Schizophrenia- Lifetime Version
LIMC	Low- and Middle-Income Countries
MAKSHS	Makerere University School of Health Sciences
MHPSS	Mental Health and Psychosocial Support
MLSS	Multidimensional Student Life Satisfaction Scale
MMAPP	Measurement of Mental health among Adolescents and young People at the Population Level
MSNA	Multi-Sector Needs Assessment
NPV	Negative Predictive Value
OBVQ-R	Olweus Bully/Victim Questionnaire- Revised
PHQ	Patient Health Questionnaire
PHQ-A	Patient Health Questionnaire Adolescents
PPV	Positive Predictive Value
PSYCHLOPS	Psychological Outcome Profiles
PTSD	Post-Traumatic Stress Disorder
R&D	Research and Development
RAs	Research Assistants
REC	Research and Ethics Committee
ROC	Receiver Operating Characteristics
SCORE-15	Systemic Clinical Outcome and Routine Evaluation-15
SSPS	Statistical Package for Social Science
UNCST	Uganda National council for Science & Technology.
UNHCR	United Nations High Commissioner for Refugees
UNICEF	United Nations Children's Fund
WCA	War Child Alliance
WEMWBS	Warwick Edinburgh Mental Wellbeing Scale
WHO	World Health Organization

DEFINITION OF KEY TERMS/OPERATIONAL DEFINITIONS

PROTOCOL SUMMARY

CONTENTS

1. INTRODUCTION

1.1. Background to the study

Mental health of children and adolescents in humanitarian settings

Crisis and conflict-affected contexts, whether induced by social unrest, war, climate change, or the outbreak and spread of infectious diseases, pose a uniquely complex and serious threat to the wellbeing of children and adolescents. Experiences of war and armed conflict—such as separation, injury or death of family members and peers/friends, displacement, poverty, disruptions of daily living and exposure to life-threatening situations—provide fertile ground to instigate high levels of stress or psychological trauma among children and their parents or caregivers. Fleeing armed conflict, violence and socio-economic/political instability, these adults and children have experienced multiple forms of violence, traumatic events, loss of family members and distress (Cohen & Minas, 2017; Hosin, 2016).

Certainly, children are the most vulnerable during the different phases of migration. Even after arrival in refugee settlements or camps, children may be exposed to unsafety, sexual violence, child labor and early marriage as well as to daily stressors of adversity and limited resources (Reed et al., 2012; Fazel et al., 2012). Many children display behavioral problems and distress symptoms e.g. aggression or low self-esteem (Reed et al., 2012; Paardekooper et al., 1999). This context gives rise to a myriad of needs, issues, and problems that disrupt the wellbeing of children and those around them. Addressing these needs, however, is not straightforward, as the wellbeing of children and adolescents is particularly dependent on, and influenced by, their social ecosystem. Mental health and psychosocial support (MHPSS) programming has tended to be targeted to individual social groupings, or ecological layers. However, improving the mental health of children and adolescents requires working at multiple social ecological levels, as well as at multiple levels of prevention and intervention. An interdisciplinary and multi-level approach is essential for addressing the social determinants and upstream factors that impact children's mental health.

Thus, there is an urgent need for an ecological, community-based approach to mental health programming with children and adolescents that is holistic, multi-layered, interdisciplinary, and coherent. The proposed study will test the population level effects of such an approach via a care

system model that comprises a package of evidence-based MHPSS interventions. This ecologically nested model will work at the individual, family/caregiver, school/teacher, and community levels. The impacts of armed conflict on psychosocial wellbeing for each of these levels is described below.

Impacts on children and adolescents

At the individual level, the impact of armed conflict on the physical, mental and psychosocial wellbeing of children and adolescents has been well established (Barber, 1999; Barenbaum et al., 2004; Panter-Brick et al., 2011). War-induced stress accumulation among children can significantly hamper children's psychosocial development and increase vulnerability for developing behavioral and mental health issues. High rates of post-traumatic stress disorder (PTSD) symptoms, behavioral and emotional symptoms and disorders, sleep problems, disturbed play, and psychosomatic symptoms are all found among conflict-affected children and adolescents (Attanayake et al., 2009; Betancourt et al., 2014; Fazel et al., 2012; Miller & Jordans, 2016; Slone & Mann, 2016; Stichick, 2001).

Mental health problems can, in turn, affect all domains of children's and adolescents' functioning, impact a person's entire life cycle, and create substantial costs to society (Kessler 2007; Ormel et al. 2017; Snell et al. 2013; Smith & Smith 2010). Indeed, most mental health problems in adults have started early in life (Lund et al., 2018). Adverse childhood experiences (ACES) have been linked to depression, anxiety, substance abuse, and increased morbidity in adulthood (De Venter et al., 2013; Campbell et al., 2016; Lund, 2018). Amongst adolescents, mental health problems have been linked, for instance, to poor school performance (Robles et al., 2019), and school drop-out (Hjorth et al., 2016), and later in life with delinquency and illegal substance abuse (Anderson et al, 2015), divorce rates, unplanned pregnancies and intimate partner violence (IPV) victimization (Jonsson et al, 2011; McLeod et al, 2016), lower labour market outcomes (Fletcher et al, 2013), and reduced income.

Impacts on parents and caregivers

Among parents and caregivers, the stress burden from armed conflict can have a significant negative effect on their individual wellbeing and can diminish their ability to protect and support the children in their care. This, in turn, adversely impacts children's wellbeing and development. It is widely recognized that a positive and nurturing family environment is essential for child development and wellbeing. Indeed, secure and consistent caregiving relationships can play a

critical role in helping children to cope effectively with exposure to armed conflict and the many other ongoing stressors in these environments (Betancourt et al., 2013; Miller & Jordans, 2016; Tol et al., 2013). Yet, in conflict-affected settings, caregivers exposed to conflict-related and other common daily stressors can have high rates of psychopathology and may have difficulty with providing responsive and effective parenting (Slone & Mann, 2016).

There is evidence that conflict-affected parents often have difficulties interacting with children, become less sensitive and responsive to children's needs, and may be less effective at maintaining rules and setting boundaries (Barenbaum et al., 2004; Khamis, 2014; Miller & Jordans, 2016). Furthermore, there is growing evidence across multiple settings that family violence increases significantly in settings of armed conflict (Catani et al., 2008; Panter-Brick et al., 2011). Taken together, these findings suggest that the family environment, parental wellbeing, and parenting behavior represent key mediators on the relationship between armed conflict and children's mental health and psychosocial wellbeing (Miller & Jordans, 2016).

Impacts on teachers and education systems

Armed conflict can have a devastating impact on teachers and education systems. In many cases, teachers are targeted for violence, abduction, and intimidation by armed groups, leading to a shortage of qualified teachers and a decline in the quality of education (UNESCO, 2019). Physical destruction of schools and educational infrastructure can also disrupt access to education, further exacerbating the impact of armed conflict on teachers and their students (World Bank, 2021). The trauma of living in a conflict zone and consequent fear of violence can also take a toll on the mental health of teachers, often leading to burnout and high rates of attrition, which ultimately limits teachers' ability to support the children under their care (Save the Children, 2019). Exposure to violence, trauma, and stress can lead to a range of mental health issues, including depression, anxiety, PTSD, and burnout (Save the Children, 2019). Fear of violence and the constant need to be vigilant can also lead to hyperarousal, sleep disturbances, and a reduced ability to concentrate, which can affect teachers' ability to perform their duties effectively (International Committee of the Red Cross, 2019).

Teachers in conflict-affected areas often feel isolated and unsupported, which can further exacerbate their mental health issues (Education International, 2021). The pressures that teachers

face impact the expression of their own social-emotional competencies which are important for supporting the development of an enabling classroom climate to improve learning and wellbeing of children. Providing teachers with access to mental health services, counselling, and support can help mitigate the impact of armed conflict on their mental health and well-being (UNESCO, 2019).

Impacts on communities and services

Violence against children is widespread in all societies, across all income levels, and in all places where children live, including within families and communities. Community-level conditions, such as the prevalence of child labor and poverty, negatively impact upon children and put children at increased risk of experiencing harm (McLeod & Shanahan, 1993; Srivastava, 2011). In times of crisis, child protection risks such as violence and exploitation increase and become exacerbated (Bartels & Hamill, 2014). Ongoing armed conflict may lead families and communities to resort to harmful coping mechanisms, such as early marriage—a strategy sometimes used to protect adolescent girls from sexual violence (Bartels & Hamill, 2014).

In addition, ongoing armed conflict results in damage to the community fabric, including the generation of distrust among members of different religious or ethnic groups, as well as damage to structures and available services in sectors such as education and health (CPWG, 2015). Collectively, these different but related and overlapping problem sets undermine the psychosocial well-being and resilience of children and adolescents in conflict- and crisis-affected contexts. Services are needed that address the multifaceted and complex challenges that conflict-affected children, adolescents, and their families/caregivers face.

While children may be subject to different types of violence in their community, communities are also an important source of protection. Community actors play important roles in looking out for children's safety—responding when children are in danger, identifying and supporting child survivors and those most at risk, and seeking accountability of perpetrators of violence. Community leaders often play a key role in maintaining the protective environment for children in the community by identifying and discussing harmful behavior and hidden taboos and reinforcing protective norms and practices. Community actors are around children 24/7 and are the first to respond in case of an emergency. Community groups organize themselves to support vulnerable children and families and liaise with government bodies and formal services to bring additional support into the community.

Compounding effects of stigmatization

At each of these socio-ecological levels, and against this backdrop of direct and indirect, as well as short-term and long-term, consequences of armed conflict, specific populations in every community will face the risk of stigmatization of various kinds. Stigma is a process of labelling, marginalization, and differential treatment (Link & Phelan, 2001) that is shaped by local, contextual norms, values, and experiences (Pescosolido & Martin, 2015). In the context of mental health and psychosocial problems, experiences of stigmatization play a significant role in service utilization, treatment trajectories, and ultimately, outcomes (Pescosolido & Martin, 2015; Link & Phelan, 2001). Social and mental health stigmas can have profound negative impacts on wellbeing, quality of life, and both mental health and child development outcomes, including increased levels of depression (Cadden et al., 2018; Yıldırım et al., 2018).

Experiences of stigmatization can result in a cascade of effects that impact use and effectiveness of mental health services, ranging from poor decision-making to decreased help-seeking behavior and decreased treatment adherence (Hartog, Hubbard, Krouwer, Thornicroft, Kohrt, & Jordans, 2020; Clement et al., 2015; Overstreet & Quinn, 2013). In addition to impacting service use and help-seeking (Clement et al., 2015; Overstreet & Quinn, 2013), stigmatization also limits quality of services (Pelleboer et al., 2017) and can lead to social withdrawal (Mitter et al., 2019), rejection (Denis-Ramirez et al., 2017) and impaired social and academic results (Puhl & Lessard, 2020). Experiencing stigmatization in childhood years may alter the activation of the stress response system later in life (Currie et al., 2019).

People with lived stigma experience have described stigmatization as worse than the disease itself (Barrett, 2005; Goodyear et al., 2021; Thornicroft et al., 2016) and stigma is an important social determinant of health and health inequity (Hatzenbuehler et al., 2013). It can be devastating for child survival and health outcomes (Nayar et al., 2014) and trigger suicidal ideation (Necho et al., 2021). Children and adolescents in contexts of armed conflict face a particular set of interacting stigmas. Youth formerly associated with armed forces and groups bear the brunt of stigmatization (Betancourt et al., 2010). In a study we conducted in the Democratic Republic of Congo, such youth described not being trusted by the broader community or given permissions to travel freely, as a result.

Other studies have demonstrated that, in settings of armed conflict, children born out of sexual violence (Denov & Lakor, 2017; Rouhani et al., 2015) or who are undocumented (Mann, 2010) face unique stigmas as well. Other characteristics, such as having a mental health condition (van

den Broek et al., 2021; Zolezzi et al., 2018), teenage pregnancy (Atuyambe et al, 2005), using contraceptives (Casey et al., 2020), being overweight (Lin et al., 2020) or belonging to the LGBTQI+ population (Ager et al., 2021) can also trigger stigmatization among children and adolescents. Stigma also impacts the community as a whole and individuals' experiences within it, as individuals may withdraw from community life or experience social and economic marginalization or fewer employment opportunities. Stigma has been described as worse than the (mental) health condition itself (Barret 2005; Goodyear et al., 2021; Thornicroft et al., 2016).

Gaps in mental health supports for children and adolescents in humanitarian settings

Although there have been innovations in evidence-based mental health and psychosocial interventions for conflict-affected children, adolescents, and their caregivers, these interventions have not received sufficient attention or funding by researchers, local governments and policy makers, or donors. As a result, mental health problems among children and adolescents in such settings, and more broadly in LMICs, often remained under-addressed. When available, psychosocial or mental health interventions for children and adolescents in these countries tend to take a piecemeal approach.

In most LMICs, mental health care support structures are poorly embedded within both the education and health sector, and the limited interaction among these parallel systems inhibits referral of children in need of mental health treatment once problems are recognized. MHPSS services have tended to be delivered in isolation, rather than as a part of a comprehensive package of services or linked to a range of social settings where children spend most of their time. Further, MHPSS services are not often designed within the framework of multilevel programmatic approach that is intended to act on more upstream factors and social determinants of health such as education, child protection, and healthcare institutions and systems. Effective mental health and psychosocial programming for children and adolescents, therefore, has not been adequately integrated into broader systems of care and is often unavailable or inaccessible to affected communities.

A siloed approach ultimately undermines the effectiveness of such programming, given that the wellbeing of children and adolescents is uniquely impacted by, and dependent on, their social ecosystem and its healthy functioning. Even when accessible and acceptable mental health care services exist, mental health and psychosocial needs can go unaddressed when cases are not detected and referred to the appropriate services. Within the educational sector, low mental health

literacy amongst educators' compromises action when a child needs referral for mental health treatment. The curricula in teaching colleges often lack modules on socio-emotional wellbeing, and educational systems differ in the availability of specific positions for professionals tasked with and skilled to assist schools in managing the psychosocial health of children and adolescents. Community or school-based programs for child and adolescent mental health often run outside of formal health systems, and often for a limited time only, making them unsustainable after project funding has ended.

Within the health sector, countries differ in how mental health services are organized, the extent to which training in mental health is available, and the type and number of professionals with child and adolescent mental health expertise. Lack of competence in child psychiatry hampers the effective diagnosis and treatment of those children that make it to health services. Community or school referral to health services for children with serious mental health problems will not lead to improvement if these services lack the necessary competencies. Mental health support interventions for children and adolescents tend to insufficiently adopt an ecological approach that simultaneously considers the mental health of significant adults around children, such as their caregivers and teachers. In conflict-affected environments, parents and teachers may suffer from psychosocial stress and mental health problems as well, which affects their ability to optimally take care of and educate children under their care. Focusing solely on children to the exclusion of their social environment, for example by ignoring community structures and resources related to child protection and social stigmas, undermines the effectiveness of mental health interventions.

1.2. Study purpose and rationale

It is not enough that we now better understand the mental health needs of children and families affected by armed conflict or that we have developed individual, evidenced-based interventions to address targeted problems and/or targeted groups. Rather, what is required to improve the mental health of conflict-affected children and adolescents is transformative, systems-level change that holistically addresses the wellbeing of children's social ecosystem. There is a vital need for a multi-level MHPSS strategy that explicitly conceptualizes and addresses phenomenological experiences and linkages across this ecosystem. To meet this need, we have developed and are proposing a care system model comprising a package of evidence-based interventions that targets multiple ecological levels and influencing factors in a coherent, interdisciplinary, and holistic manner (Jordans et al, 2016).

Interventions Targeting Multiple Levels of Care and Support

Multi-level interventions focusing on the mental health and psychosocial wellbeing of children in adversity, including complex emergencies, are commonly advocated. The Inter-Agency Standing Committee's (IASC) Guidelines for Mental Health and Psychosocial Support (MHPSS) in Emergency Settings (IASC, 2007) specifically promotes such an approach. Multi-level interventions have demonstrated feasibility and promising preliminary findings. A systematic review in 2016 found that 52% of the publications reviewed recommended that interventions should apply multi-level approaches (Jordans et al., 2016).

However, such interventions are rarely reported and evaluated (Betancourt et al., 2013; Jordans et al., 2016). There is a dearth of evidence examining the effectiveness and feasibility of multi-level or care system approaches, such as the one described in this proposal, which target multiple ecological and prevention/intervention levels, as well as work inter-sectoral. The proposed study responds to these research and programming gaps by examining the effectiveness of an ecologically grounded care system approach to MHPSS. We propose a study that will implement and test the effectiveness, feasibility, and quality of an MHPSS care system model, with a primary objective being to improve the wellbeing of children and adolescents affected by armed conflict, as well as the wellbeing of parents/caregivers, teachers, and the wider community.

1.3.Research aim, questions and hypothesis[1]

Research aim

The overall aim of the study is to evaluate the impact of a mental health care system on improving population level mental health of children in refugee settlements, with the following guiding research questions and hypotheses:

Research questions (RQ) and hypothesis

[***RQ1***] What is the population-level effectiveness of a multi-level multi-component care system on improving the wellbeing 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?

[1] A separate protocol will be developed and submitted describing a study that will be embedded within the main trial to evaluate how a care system performs in a real-world context (e.g. care pathways, quality of care, coverage etc.)

Hypothesis: 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).

[***RQ2***] What are the synergistic and indirect effects of a multi-level and multi-component care system and the associated cost-benefits?

Objectives: (i) 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; (ii) 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). (iii) Improve understanding of the population-level cost-effectiveness of the mental health care system.

2. METHODS

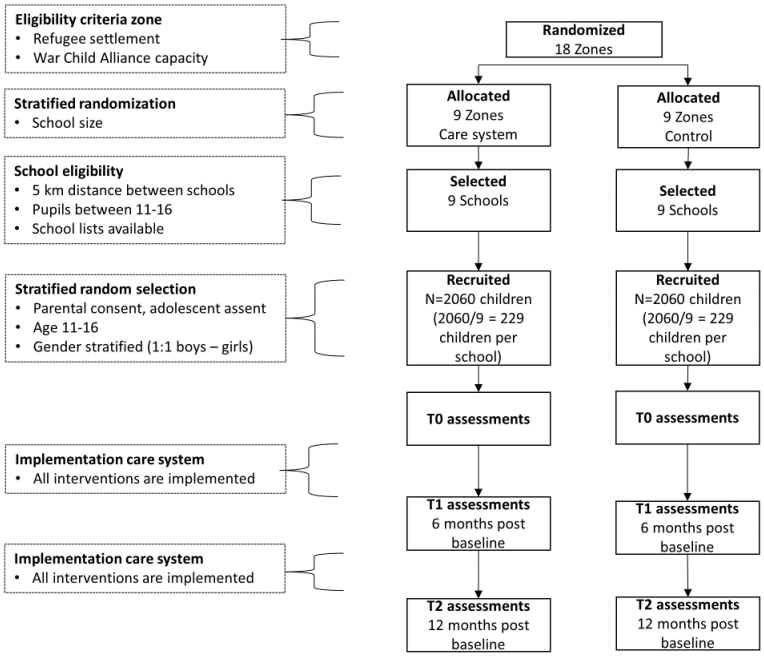
2.1.Design

The primary study design [RQ1] will be a pragmatic parallel two-arm cluster Randomized Controlled Trial (cRCT), randomizing 18 zones (i.e. clusters; a zone is an administrative unit in Uganda) in a 1:1 ratio (stratified for school size) to one of the two study arms (see Figure 1). The two arms are the multi-component mental health care system (experimental arm) *vs* waitlist control. A random population sample of children (age 11-16) 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 that are part of the experimental arm will not receive any service, and other children and their caregivers receive all available services that are part of the care system (see further details under 'Sample' below). Furthermore, children and their caregivers that are not part of the

study sample but are part of the enrolled schools in the experimental arm may also receive any or all the services being offered in the care system. This means that children that 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).

The rationale for this approach is to be able to assess the *population-level*[2] effect of a mental health care system, rather than a *participant-level effect*. Given the pragmatic implementation, intention-to-treat will be our primary analysis framework. A cRCT was selected because of the potential contamination of the implementation of a multi-component mental health care system that involves children, their caregivers and school-personnel. (*See Figure 1 for study flowchart).*

Figure 1. Flowchart



Note: All T0 and T2 assessments include children and their caregivers, T1 consists of a shortened version of the adolescent surveys only.

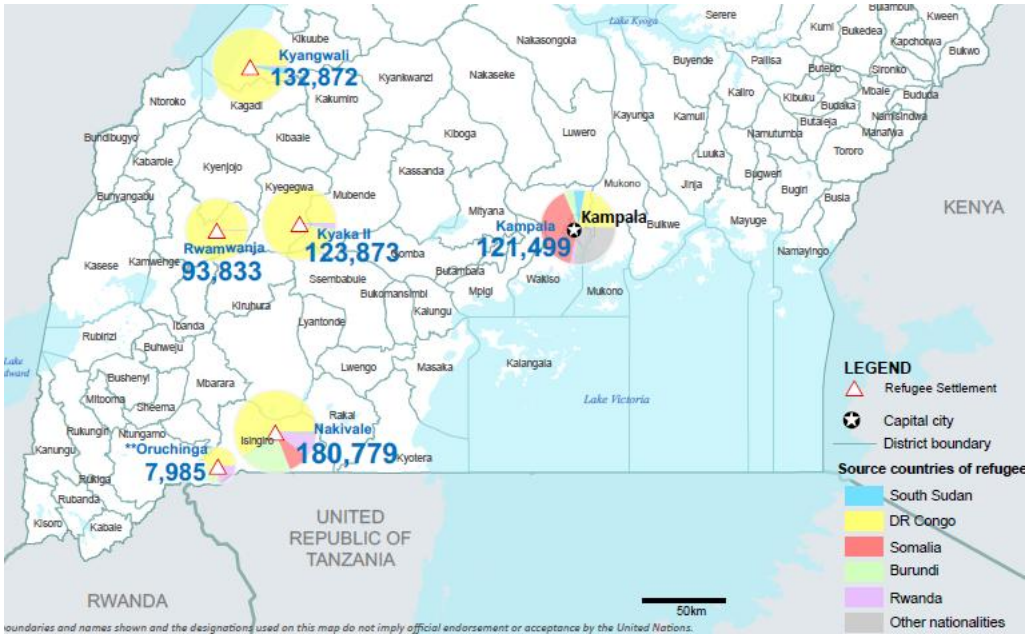
Embedded sub-studies to evaluate synergistic effects, indirect effects, and cost-effectiveness [RQ2]. First, through a surveillance design we will track which children, and their caregivers get which services at what point in time throughout the implementation period (1 school year). This allows for analyses of a sub-sample of the cRCT that receives any of the interventions to investigate whether different combinations of interventions result in different outcomes. Second,

[2] Population level in this protocol refers to 'population of school-going children'.

the cRCT study will allow for secondary analyses to investigate the degree by which participants in the experimental arm show benefits in other outcomes related to schooling and child labor, violence, substance use, risky (sexual) behavior and early marriage. Third, we will also conduct an economic evaluation, in which we will examine costs and possible offsets of delivering the care system implementation and assess the cost-effectiveness of the program. The purpose will be to gather relevant information about the potential economic value of the interventions.

2.2.Setting

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 132000 refugees, 96% of whom are from DRC and 29% are below the age of 18. Kyaka hosts approximately 123000 refugees, 97% of whom are from DRC and 29% are below the age of 18. Nakivale hosts approximately 180000 refugees, 67% of whom are from DRC and 27% are below the age of 18. In all three locations most adults are crop farmers or farm laborers. 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. Currently, Uganda hosts approximately 1.4 million refugees, primarily from South Sudan and the Democratic Republic of Congo – with more than 60% being children (UNHCR, 2019a; UNHCR, 2019b). The Ugandan's government has been quite welcoming towards refugees, providing them with a plot of land to encourage "self-reliance", as well as collaborating with humanitarian organizations to offer a variety of services. Still, the refugee influx increases pressure on already reduced resources, contributing to tensions between host and refugee communities (Adaku at al., 2016; Baron, 2002). Even when basic services (shelter, food, education) are available, children's psychosocial well-being is often overlooked, potentially leading to unidentified and unaddressed needs (Tol et al., 2015; Purgato et al., 2018).



Source: Refugees and Asylum-Seekers in Uganda as per September 2023 (UNHCR)

2.3.Intervention

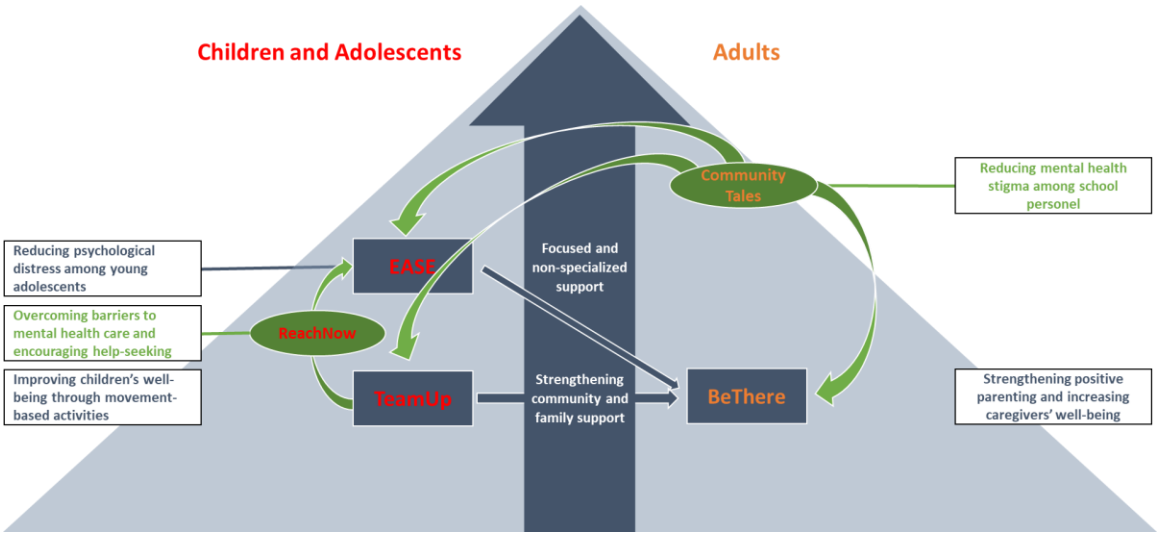
2.3.1. Mental health care system

War Child has implemented a suite of core interventions working across multiple ecological levels and that target multiple dimensions of mental health and psychosocial wellbeing among children, adolescents, parents/caregivers, teachers, and their communities. These interventions have been implemented and tested according to a systematic approach for developing and evaluating services for children and adolescents affected by armed conflict (War Child, 2022). This multi-phase process includes steps to adapt interventions to local community contexts, as well as to consult or partner with community stakeholders as appropriate. Through this process, and through work in multiple conflict-affected country contexts, War Child has gathered a strong evidence base demonstrating the feasibility, acceptability, and effectiveness of these individual interventions. This set of tested interventions are conceptually interconnected in terms of their theories of change, design, objectives, and potentials for cross-referrals. We propose to now link these interventions in practice; (a) by packaging them together as a novel, multidimensional, ecologically nested, community-based mental health care system model; and (b) by testing the synergistic impacts of this model on child and adolescent psychosocial wellbeing.

Below is a brief presentation of the interventions that make up the mental health care system that is being developed. See also Figure 2. All interventions (except Community Tales) have gone through rigorous effectiveness research as a stand-alone intervention. All interventions will go

through, or already have gone through, a systematic process of adaptation to the cultural context of this study, specifically for refugee populations primarily from the DRC in western Uganda – this process includes (i) translation of materials, (ii) cognitive interviewing to ensure understanding of the materials, (iii) pilot-testing of the adapted materials.

Figure 2. Care System



TeamUp is as 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 = .01), satisfaction with and attitude toward school (−0.57, SE = 0.2, p = .004); and secondary outcomes: traumatic stress (2.64, SE = 0.8, p < .001), health-related quality of life (−1.56, SE = 0.4, p = .001), physical health (−0.78, SE = 0.3, p = .014) and the *TeamUp* mechanisms of action scale (−3.34, SE = 0.9, p < .001), specifically the subscales social connectedness (−0.74, SE = 0.3, p = .007) and sense of agency (−0.91, SE = 0.3, p = .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 that receive 4 days 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, 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 ($d = 0.25$, $p < .05$). BeThere showed beneficial effects in the full sample at endline and follow-up on harsh parenting ($d = .17$, $p < .05$; $d = .19$, $p < .05$), parenting knowledge ($d = .63$, $p < .001$; $d = .50$, $p < .001$), and caregiver distress ($d = .33$, $p < .001$; $d = .23$, $p < .01$). 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 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.

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.

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

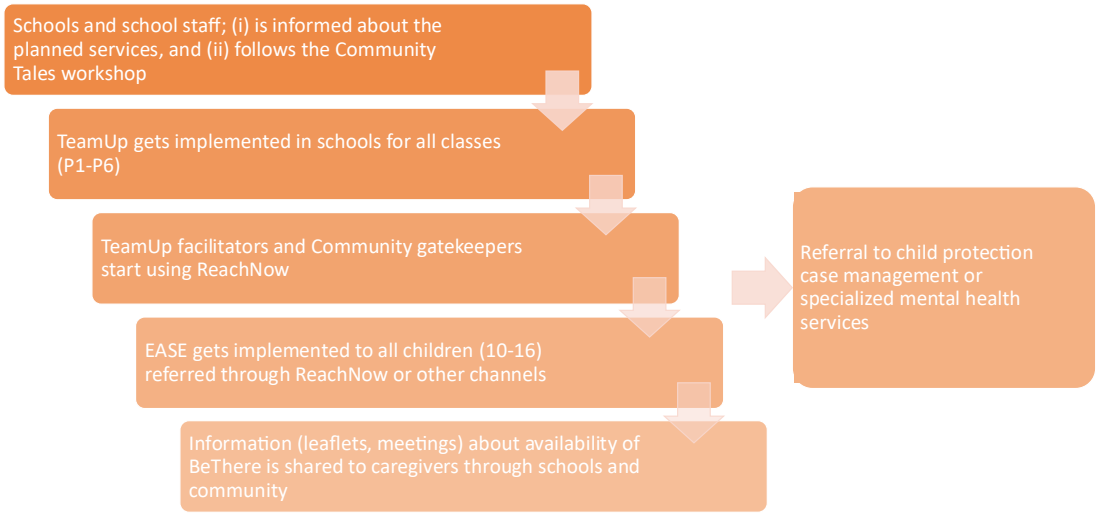
basing on assessment of needs. Fifth, EASE will be offered to all children that get referred by TeamUp facilitators and community gatekeepers using the ReachNow tool. Furthermore, children can get referred to EASE from elsewhere (e.g. teachers, BeThere facilitators, health care volunteers), following 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. See Annex 1 for an overview and example of the staffing per school to deliver the above-mentioned interventions over the course of a school year. See Table 1 below for an overview of who the different service providers are for each of the interventions, as well as details about the supervision.

Table 1: Characteristics of intervention facilitators and supervision

	Facilitators	Supervision
TeamUp	- Adults (non-mental health professionals) from the study context - Selected through an open recruitment process - Facilitators get remunerated per number of days worked.	- Supervision is provided by the TeamUp Master Trainer (WCA staff), TeamUp Technical coach and PO-PSS (Facilitator). - Group-based supervision takes place once per month - Online/physical Community of Practice (COP)
ReachNow	- TeamUp facilitators (all) and community gatekeepers (e.g. teachers, community health volunteers) - Community gatekeepers are selected through open recruitment process following these criteria: 1) At least 18 years of age; 2) Residing within the zones; 3) Trusted and respected members from the community; 4) Engaged in promoting child wellbeing; 5) No history of criminal record; 6) Able to write and read. - No compensation is provided (facilitated on transport refund during meetings)	- Supervision if provided by the ReachNow Master Trainer (WCA staff), Team Up trainer & PO-PSS. - Group-based supervision takes place once per 2 months

EASE	- Adults (non-mental health professionals) from the study context - Selected through an open recruitment process - Facilitators get remunerated monthly	- Supervision if provided by the EASE Master Trainer (WCA staff), EASE trainer & partners Team Leader. - Group-based supervision takes place once per month
BeThere	- Adults (non-mental health professionals) from the study context - Selected through an open recruitment process - Facilitators get remunerated monthly	- Supervision if provided by the BeThere Master Trainer (WCA staff), BeThere trainer & partners Team Leader. - Group-based supervision takes place once per month
Community Tales	- Facilitated by the War Child Alliance mental health technical advisors - No recruitment process needed, as this concerns existing staff - No separate remuneration, as this concerns War Child staff	- n/a

Figure 3. Service delivery process



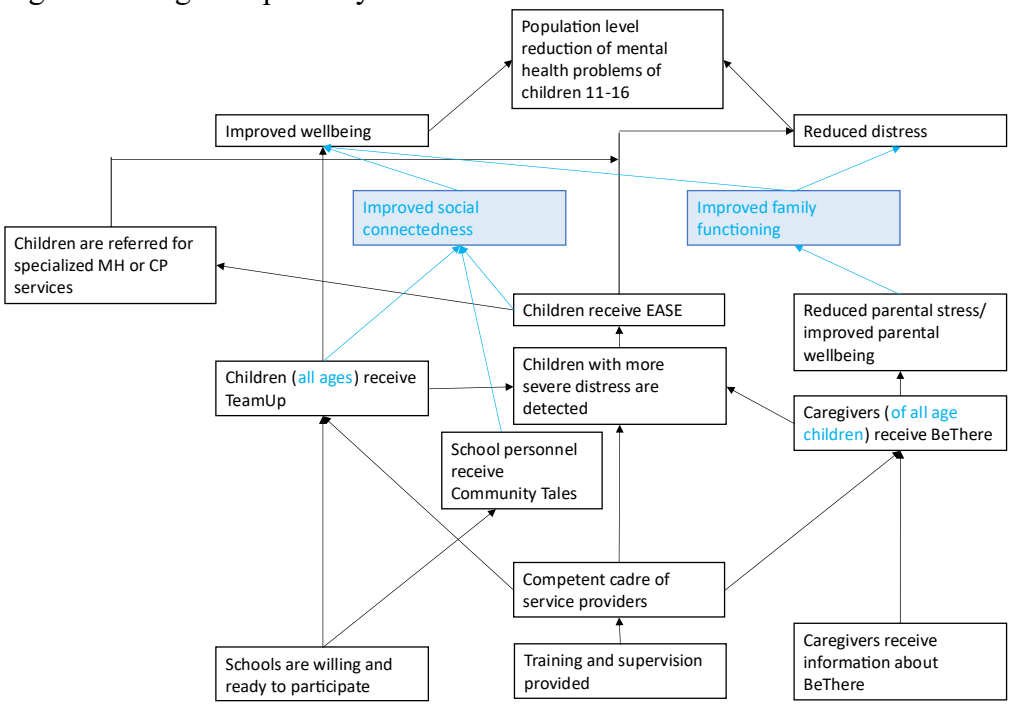
For all interventions (TeamUp, BeThere, ReachNow, Community Tales and EASE) supervision and mentoring sessions will be routinely offered. Supervisors and mentors of TeamUp, BeThere and EASE will have access to routinely collected data on the quality of implementation of each of the interventions to allow for data-driven feedback. This quality-of-care (QoC) data consists of; (i) attendance of participants for each of the intervention groups; (ii) competence of facilitators

of each of the interventions; (iii) fidelity of implementation by facilitators of each of the interventions. See below for further details on the QoC data (see further details below).

Implementation schedule: the care system will be rolled out in all schools randomly allocated to the experimental arm, starting in July 2025 and will be implemented until April 2026 (Term 2 and Term 3, and Term 1 of the next academic year).

The integrated pathways to care (Figure 4) provides an overview of the pathways by which the combination of interventions, or the care system, is contributing to the expected outcome. The pathways articulate how intermediate outcomes contribute towards the long-term outcomes, and therefore is used as the basis for selection of instruments to measure primary, secondary and mediator outcomes (see Instruments section below).

Figure 4. Integrated pathways of care



2.4.Control

The control arm consists of a waitlist-control condition. During the 1 year following baseline assessments, none of the experimental arm care system interventions will be offered to the control condition. Specifically, the control group schools will be offered:

- First, mental health sensitization workshops to teachers.

    - Two-hour workshops will be organized to all teachers interested to join. The workshop aim to increase awareness about mental health and mental health care for children and adolescents.
- Second, for children identified by researchers or teachers in need of specialized mental health care referrals will be offered and facilitated.
    - The same referral pathway and case management will be in place for all 18 schools participating in the Pamoja study. It is important to note that this referral mechanisms is in place for several mental health or child protection cases, which are identified either through research assistants during the interviews or by teachers (following the mental health sensitization workshops).
- Third, the schools will receive the full mental health care package (TeamUp, BeThere, ReachNow and EASE)

Other service providers may initiate or sustain existing services within both the experimental and control condition areas, including for example (based on prior experience, not necessarily planned or presently implemented): (1) Mental Health awareness raising activities; through psycho-education group sessions, home visits, school talk shows, radio talk shows and community dialogue sessions by Mental Health service providers and partners (e.g. TPO, IRC, HI, WCA); (2) Commemoration calendar days: such as international suicide awareness day, Mental health day, Days of the African child, world refugee day, international youth days, where people showcase different Behavioral Change Communication activities through music, dance and drama; (3) Community outreaches: care givers and children self-refer for services offered by existing partners; (4) Government health centers, e.g. HCIII, HCIVs, and district hospitals where people go for referral services.

We assume that the extent of this offer is the same in both arms, and so is accounted for by randomization. Choosing a waitlist control condition is done for ethical reasons. Given the scarcity of mental health services in refugee settlements in Uganda and given the fact that the care system consists of known evidence-based interventions, we believe it is unethical to withhold the control arm schools from these services – even if not population-level effects will be demonstrated in the study. Furthermore, we believe it is justified for the control arm schools to receive the services 1-year post-baseline, because implementation across many zones would anyways be gradually planned given the logistical and operational challenges of new starting services. Moreover, also in the experimental arm, services will be gradually offered over the three terms

between baseline and endline (noted that the *introduction* of the care system, with the various interventions, will occur in all selected schools from the same moment onwards).

2.5. Instruments

This section presents the instruments that are considered and prepared to be included in the study. The study to adapt and validate the instruments for the current study context and population has been submitted and approved in a separate protocol (MAKSHSREC [29/08/24]). The results of the adaptation and validation study may result in some changes in the presented instruments below.

2.5.1. Primary outcomes

We will employ a dual primary outcome approach in this study, namely:

- Adolescent-reported reduction in depression and anxiety symptoms assessed using the Measurement of Mental Health Among Adolescents at the Population Level (MMAPP), see Table 2.
- Adolescent-reported improvements in psychosocial wellbeing assessed using the Stirling Children's Wellbeing Scale (commonly referred to as the Stirling Scale) measuring emotional and psychological wellbeing in children and young people, see Table 2.

2.5.2. Secondary outcomes

Table 2 also present the details of the secondary outcomes amongst children (behavioral problem, personalized outcome measure, quality of life, internalized stigma, hope), and caregivers (parenting, psychosocial wellbeing, distress), exploratory child-reported indirect outcomes (education and child labor, vulnerability to violence – both victimization and perpetration, risky sexual behavior, substance abuse, early marriage), and hypothesized child-reported mediators (family functioning, school climate, social connectedness).

Table 2: Overview of instruments

Construct	**Measure**	**No of Items**	**Details of tool and properties**
Child/adolescents and Caregiver-reported measures			
Demographic, education and socio-economic household characteristics	Developed for this study.	18	This tool will be developed specifically for this study, to understand the demographic and socioeconomic situation of adolescents, their caregivers and other household members. Demographics include age, gender, household size and composition, marital status, perhaps religion/ethnicity; Socioeconomics are also important: education level and employment status

			(if relevant) of all household members, a household wealth indicator (based on dwelling characteristics and assets), length of stay in the settlement.
Primary outcome			
Child-reported measure			
Psychological distress	MMAPP	25 +3	Measuring mental health for adolescents and young people at the population level (MMAPP) is a 25-scale measure developed by (Carvajal-Velez et al., 2023), plus 3 questions on suicidality. A multistep standardized process for adaptation and validation of the MMAPP was developed, which can be replicated to adapt and/or validate measures in new settings where the tools will be used. The MMAPP initiative supports the integration of these validated tools into national or subnational survey efforts, to encourage the collection of comparable and valid data on adolescent mental health and enable assessments of trends over time and multi-country comparisons. This effort is a key step towards improved global monitoring of adolescent mental health.
Psychosocial wellbeing	Stirling wellbeing scale	15	The Stirling Children's Wellbeing Scale (commonly referred to as the Stirling Scale) measures emotional and psychological wellbeing in children and young people aged 8 to 15 (Liddle, 2010). It includes 15 self-report items answered on a 5-point scale and aims to assess wellbeing with a positive focus, rather than focusing on mental illness, in the areas of positive emotional state and positive outlook. The Stirling Scale demonstrates good internal consistency.
Secondary outcomes			
Child-reported measure			
Behavioural problems	DBIS	8	Disruptive Behavior International Scale - Nepal version (DBIS) (Burkey, 2018). The original is a 24-question scale, has been reduced to a brief 8-item version as part of another study (Lund et al, 2024) – the shorter version will be used in the present study. Response options follow a Likert scale; Never (0), Sometimes (1), Often (2), Very Often (3). Findings from the validation study in Nepal showed a good internal consistency (Cronbach's α: 0.84) and excellent test-retest reliability (intraclass correlation 0.93, r = 0.93).
Risk factors	The Identifying Depression Early in Adolescents	7	The IDEA-RS tool will be used to determine and measure burden of risk factors for future development of depression. Using the Pelotas

	Risk Score (IDEA-RS)		cohort in Brazil, Kieling and colleagues identified a constellation of 11 risk factors easily collectable directly from adolescents and found that their combination achieved a 0.78 discriminative ability to predict depression onset between 15 and 18 years of age. (Rocha, 2021). IDEA-RS includes only sociodemographic risk factors and does not rely on sub-syndrome symptoms. (Rocha et al., 2021; Brathwaite et al., 2021) Among the risk factors in the composite score are being minority, female sex, parental and peer relationships, neglect, maltreatment, school performance and other factors. This prediction model was tested in a Nepali cohort, with being low caste/ethnic minority substituted for non-White, and it was found to perform equally well at predicting depression (c=0.73). (Brathwaite, 2021). The predictive model for depression has also been tested in high-income country samples including the UK (c=0.59) and New Zealand (c=0.63), (Rocha TB, 2021) as well as replication in Brazil (c=0.70) and a prospective sample in Nigeria (c=0.62). (Brathwaite, 2021). By using the IDEA-RS, we can stratify students based on their risk scores and conduct secondary analyses on the benefit of interventions in the study.
Personalised outcome measure	PSYCHLOPS	3	PSYCHLOPS (Psychological Outcome Profiles; (Ashworth, 2007), is a friendly tool designed as a mental health outcome measure. It was designed to capture what the client thinks the main psychological problem is and score this problem. As such, the pre-therapy score is compared with subsequent scores (during therapy and post-therapy). The difference is the 'change score'. The 2 qualitative measures are meant to ask participants to think about their biggest worries and stressors, and the 4 questions are spread across a 5-point Likert scale. Two validation studies have found that it is a more sensitive measure of change than existing outcome measures, and both internal and test-retest reliability were found to be satisfactory (Ashworth, 2007).
Quality of life, health, and functioning	KIDSCREEN	10	The KIDSCREEN-10 is developed for children and adolescents aged 10-18 years (Ravens-Sieberer, 2008). It contains a 10-item on a Likert scale, based on health-related Quality of Life measures (physical and mental health, and socioeconomic status were examined). A validation study conducted showed a good

			internal consistency (Cronbach-α = 0.82). both internal and test-retest reliability were found to be satisfactory (ICC=0.7).
Internalized stigma	Everyday Discrimination scale	8 (+ 3)	The 8-item Everyday Discrimination Scale (EDS) has been used across populations, contexts and stigmas with good psychometric properties. This measure has also been applied in DRC, (Glass, 2018; Verelst, 2014) and Uganda (Amone-P'olak, 2022) with adolescents showing Cronbach's α value of 0.79-0.87.
Hypothesized Mediators (child reported)			
Family functioning	Systemic Clinical Outcome and Routine Evaluation-15 (SCORE-15)	15	Used for both adolescents and caregivers. This 15-item scale measures crucial aspects of family life that are relevant to the need for therapy and for therapeutic change and covers subscales of: strengths and adaptability, overwhelmed by difficulties, disrupted communication (Stratton, 2010). It consists of 15 items that are rated on a 5-point Likert scale rating how much this applies to the family. It has demonstrated good internal consistency (0.90), good test-retest reliability, and good criterion validity, discriminating between clinical and non-clinical cases. (Hamilton, 2015). It was adapted and translated to Arabic for the target population and used in our previous studies, with good evidence of internal consistency (α=0.80).
Hope	Hope scale	6	The 6-item scale developed by (Snyder, 1997), measures a child's hopeful thinking and goal-directed beliefs, with higher sum scores indicative of more hope and goal-directed behavior. Response options are on a six-point scale ranging from None of the time (1) to All of the time (6). A validation study on Psychometric properties of the children's Hope Scale among South Sudanese refugee children. Results showed significant correlations in the expected directions for each of the factors of the Child and Youth Resilience and good internal consistency (Cronbach's alpha=0.79. (Metzler, 2023).
Social connectedness	Social connectedness scale	8	This scale assesses the degree to which youth feel connected to others in their social environment. used for adolescents aged 10 t0 18 years. It has 8 items, Responses to the scale range from 1 (strongly disagree) to 6 (strongly agree). Items are summed; a higher score indicates more connectedness to others, (Lee, 1995).
Exploratory Indirect effects (child reported)			

Friendship	Friendship	3	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)
Bullying	Olweus Bully/Victim Questionnaire-Revised Scale (OBVQ-R).	14	A 20-item OBVQ-R has been used with adolescents in various contexts. While this instrument has not been applied in Uganda with adolescents, other bullying instruments used in Uganda have included OBVQ-R-inspired questions, with a reliability coefficient (α) of 0.81 (Ashaba, 2018). The WHO core-expanded Global School-based Health Survey, also used in Uganda, includes similar items. The questionnaire included ten items related to Bully Victimization and ten items related to Bully Perpetration.
Sexual and gender-based violence experience	Sexual behaviour and gender-based violence (4 items + [conditional on having sex] 10 extra items)	3	The Global Early Adolescent Survey (GEAS) aims to understand the factors in early adolescence that predispose young people to subsequent sexual health risks and promote healthy sexuality, to provide the information needed to promote sexual and reproductive well-being. Relevant subsections of the GEAS, developed by the WHO and Johns Hopkins University and used amongst others in DRC, Kenya and Burundi, are included (4+10 items in a stepped manner) (Mmari, 2021; WHO, 2018)
Alcohol and substance use	ASSIT-FC	3	To assess alcohol and substance use, the 5- item scale of the Alcohol, Smoking and Substance Involvement Screening Test – Frequency & Concern Items (ASSIST-FC). ASSIST-FC is a manual used globally and adapted by WHO for use in primary care (Humeniuk, 2008).
Parental violence	GEAS and INSPIRE (UNICEF guidelines on measuring adolescent harms)	11	Based on GEAS and INSPIRE to measure child-reported experiences of parent neglect and violence in the home (10 items).
Care giver-reported measures			
Socio-demographics and household roster	Developed for this study	20	To understand the demographic and socioeconomic situation of caregivers and household members

Child labor module		19	
Housing and assets		9	
Service utilization		22	History of mental health services accessed
Parenting	Brief parenting questionnaire (BRQ)	24	The Brief Parenting Questionnaire (BRQ) was developed for use in the evaluation of the Caregiver Support Intervention (CSI), a nine-session preventive group intervention for conflict-affected caregivers of children aged 3-12 years. The internal consistency of the full measure was good (α=0.72), (Miller et al., 2024).
Caregiver wellbeing	Warwick Edinburgh mental wellbeing scale (WEMWBS)	14	WEMWBS is a measure of mental well-being focusing entirely on positive aspects of mental health among parents of children. It is a 14-item Likert scale. it offers promise as a tool for monitoring mental well-being at a population level. Criterion validity was explored in terms of correlations between WEMWBS and other scales and by testing whether the scale discriminated between population groups in line with pre-specified hypotheses. Test-retest reliability was assessed at one week using intra-class correlation coefficients. WEMWBS showed good content validity. Confirmatory factor analysis supported the single factor hypothesis. A Cronbach's alpha score of 0.89 (student sample) and 0.91 (population sample). (Stewart-Brown, 2009).
Psychological distress	Kessler-6 (K6)	6	The 10-item (K10) version and reduced six-item (K6) version both were originally developed to assess the severity of psychological distress experienced among the general population, (Kessler, et al; 2002; 2003; 2005; 2010). Due to brevity and reliability, the K6 has been often used as a screening tool to assess any psychological distress and serious mental illness in the community and primary care settings. It has been used in the WHO World Mental Health Surveys and validated in many different countries. Each item is rated on a 5-point Likert scale, and higher scores indicate more distress (Kessler et al.; 2002; 2003). War Child has translated the tool to simple spoken Arabic for use in Lebanon, and this version of the tool has shown good internal consistency (α=0.80). (Kessler et al.; 2010)

Traumatic experience	Harvard Trauma Questionnaire (HTQ)	16	The HTQ is one of the most used instruments to measure trauma with war-affected populations (Hollifield et al., 2002). Adequate cultural adaptation and psychometric evaluation is needed to capture the unique trauma experiences of men and women in conflict zones. The 17 item sub-scales were used in the South Sudanese study IDPs to assess the psychometric properties of war-related trauma amongst IDPs men and women in South Sudan. Good validity and internal consistency reliability were reported, (Sharma M, 2022).
Family functioning	Systemic Clinical Outcome and Routine Evaluation-15 (SCORE-15)	15	Used for both adolescents and caregivers. This 15-item scale measures crucial aspects of family life that are relevant to the need for therapy and for therapeutic change and covers subscales of: strengths and adaptability, overwhelmed by difficulties, disrupted communication (Stratton, 2010). It consists of 15 items that are rated on a 5-point Likert scale rating how much this applies to the family. It has demonstrated good internal consistency (0.90), good test-retest reliability, and good criterion validity, discriminating between clinical and non-clinical cases. (Hamilton, 2015). It was adapted and translated to Arabic for the target population and used in our previous studies, with good evidence of internal consistency (α=0.80).

In addition to 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.

2.6. Implementation outcomes

The study will employ three measures for the assessment of protocol adherence and quality control: (i) competency of facilitators, (ii) fidelity to the intervention protocol, (iii) attendance by adolescents and caregivers. First, the competency of facilitators of EASE and TeamUp will be assessed using the Working with Children Assessment of Competencies Tool (WeACT) (13-items and 8-items, respectively) (Jordans et al., 2021) and facilitators of BeThere will be assessed using the 15-item Enhancing Assessment of Common Therapeutic factors (ENACT) instruments (Kohrt et al., 2015). The WeACT and ENACT instruments aim to assess common factors in psychological treatments, including task-sharing initiatives with non-specialists across diverse cultural settings. The WeACT is used to assess competencies for working with children and

adolescents, whereas the ENACT assesses competencies for working with adults (in this study, the caregivers of enrolled adolescents). Competencies of facilitators will be assessed using in-session observation of every facilitator by coaches/supervisors once per 2 months. . The WeACT and ENACT have already been translated and adapted for use in Uganda. Second, the fidelity to intervention protocol will be assessed using self-developed instruments designed to assess the implementation of TeamUp, EASE and BeThere. Intervention fidelity is assessed by facilitators themselves for all sessions and through observations of every facilitator by team-leader/ project officer once per week . Third, attendance of TeamUp, EASE and BeThere intervention sessions by children and caregivers will be monitored using attendance logs (EASE and BeThere) and digital attendance app or attendance logs (TeamUp). Collected data on these implementation indicators (competence, fidelity and attendance) will routinely be made available to all supervisors/mentors for TeamUp, EASE and BeThere. This will allow for data-driven supervision and mentoring, wherein all supervisors/mentors will be trained to access the data and techniques and strategies to apply if the data on any of these indicators shows that implementation is inadequate (i.e. competence rating that indicate potentially harmful behavior [e.g. level 1 on ENACT items]; fidelity and attendance scores that indicate low levels [e.g. below 70%]). See Table 3 for an overview.

Table 3: Overview of assessment of Quality-of-Care indicators

	Competence		Fidelity		Attendance	
	What?	How?	What?	How?	What?	How?
BeThere	ENACT (+ selected GroupACT)	• 8 items + x g-ACT • In session observation of every facilitator by coaches at once per 2 months	BeThere Fidelity tool	• 8 items • Self report every session • In session observation of every facilitator by team-leader/ PO at once per week	Paper and pencil	• Every session, completed by facilitator
EASE	WeACT (+ selected GroupACT)	• 13 items + x g-ACT • In session observation of every facilitator by coaches at once per 2 months	EASE Fidelity tool	• 10 items • Self report every session • In session observation of every facilitator by team-leader/ PO at once per week	Paper and pencil	• Every session, completed by facilitator
TeamUp	WeACT (+ selected GroupACT)	• 8 items + x g-ACT • In session observation of every facilitator by coaches at once per 2 months	TeamUp Fidelity tool	• 24 items • Self report every session • In session observation of every facilitator by team-leader/ PO at once per week	Attendance app or Paper and pencil	• Every session, completed by facilitator

2.7. Monitoring

In addition, we will (i) track the number of cases detected and referred by gatekeepers using the ReachNow tool, (ii) track the number of referrals made to case management of specialized mental

health services, (iii) track the number of schools personnel that participated in the Community Tales workshops. Furthermore, before and after assessments will be done for each of the TeamUp, BeThere and EASE intervention groups on 25% of the participants (randomly selected), using the some of the same instruments that are also used in the cRCT (Instruments section above). See Table 4 below for an overview. In addition we will interview n=2 intervention participants per cohort/term to elicit Stories of Change and n=5 intervention participants for Community Feedback and Response Mechanism interviews (which is standard monitoring and evaluation practice within War Child).

Table 4: Overview of outcome monitoring

Intervention	When	Instrument	Construct	Extra
BeThere	Before and after each intervention group (25%)	BPQ Kessler-10	Parenting	Stories of Change with n=2 per intervention per cohort CFRM with random n=5 per intervention per months
EASE		MMAPP	Psychological distress	
TeamUp		Stirling Wellbeing Scale	Psychosocial wellbeing	

2.7.1. Instrument preparation

Instruments will be administered in Kinyabwisha, Congolese Kiswahili, Runyankole, Runyoro/Rutooro, which are the most spoken languages in the study sample. Prior to the current study we went through a rigorous process of translation, adaptation and validation of the above-mentioned instruments for the above-mentioned languages and for use within the context and sample of the current study, specifically for the current study. This work has already been IRB approved (MAKSHSREC [29/08/24]), hence details are not included in this protocol. In brief, the process included; (i) translation by bilingual translator; (ii) review and back-translation by a bilingual mental health professional; (iii) cognitive interviewing (n=108 children; n=24 caregiver – across different instruments and languages); (iv) Focus Group Discussions (n=180 children; n=40 caregivers – across different instruments and languages); (v) harmonization and final adaptations by investigator team; (vi) final back-translation by different bi-lingual expert as step #2; (vii) psychometric testing (n=400 children; n=200 caregivers– across different instruments and languages).

2.7.2. Costs analyses instruments

Cost-analyses tool [RQ2] In order to perform an exploratory economic evaluation of the care system, the following instruments will be used: (i) a cost template form where we request information about resource inputs that go into the delivery, training and supervision the intervention(s) and their unit costs; (ii) resource use questionnaires for adolescents and caregivers, to assess in-patient and outpatient service use and costs, whereby caregivers will report for themselves and the index adolescent participant, and adolescent participants will report for themselves; this will be completed at all follow-up assessments (T1-T2). Costs of the different intervention components will be combined with information from the implementing team about the intensity of the interventions that were delivered during the study. Information sources that we will draw from include project administration data such as manuals, attendance and budget sheets.

The cost template form includes 71 items categorized into 12 domains covering information about staff or volunteer hours required for the delivery of the intervention, training and supervision, as well as other resource inputs such as costs linked to venue hire, traveling, material and equipment. The adolescent/caregiver resource use questionnaires to assess service use will be adapted from the Client Service Receipt inventory developed by Beecham and Knapp (2001); https://www.pssru.ac.uk/csri/international-versions/). The caregiver version of the questionnaire consists of two parts (a, b): part a includes 7 questions about caregivers past use of physical and mental health services and wider support and advice (e.g., with debt, career), as well as changes in ways they save and spend money (including for their children's education). Part b) asks 8 questions about their children's use of physical and mental health services and support and advice, as well as about school attendance, and changes in ways they save or spend money. In the version for adolescents, adolescents are asked the same 8 questions.

2.8. Cluster randomization and participant selection

2.8.1. Randomization of clusters

For research question 1 [RQ1], we will follow a two-stage sampling process. The first stage involves stratified randomization of the 18 clusters. Clusters (i.e. zones) are selected based on the following eligibility criteria: (i) Presence of DRC refugees (target is majority >70% in overall sample); (ii) Operational capacity for War Child Alliance or partner; (iii) No War Child Alliance evidence-based mental health interventions (i.e. TU, BeThere, EASE) or comparable interventions by other organizations implemented in the 6 months prior to baseline; (iv) OPM

Approval or District authorities approvals. The cRCT will randomize 18 clusters to experimental or control arm, using a covariate-constrained or stratified randomization to achieve baseline balance. Within each of the 18 clusters, 1 school is selected following criteria (*Note*: most Zones only have one school that matches these criteria): (i) Willingness and permission to participate; (ii) sufficient pupils between 11-16 (n > 300); (iii) Pupil lists or registers are available; (iv) Schools are > 5 km from a school in an adjoining clusters/zone that has been enrolled in the study (in that case, we will use simple random selection to determine which school gets excluded); (v) Government-run schools. In case of multiple eligible schools per Zone (cluster), one school that meets the eligibility criteria will be randomly selected. Stratification will be done based on the number of learners in the 11-16 age group per school, wherein all clusters will be ranked from high to low and each pair from top to bottom of the list will be randomly allocated. Randomization will be performed by an independent statistician using a random number generator in Stata statistical software. Randomization will be performed before conducting baselines because this is necessary for logistics (planning of venues, transport).

2.8.2. Random selection of participants

Next, we will employ a stratified block random selection approach to recruit children into the study. We will divide the total sample of children (see below) equally over all eligible schools across the clusters (i.e. Total sample/ Total eligible schools across zones = Sample per school), to make sure there is an equal distribution across schools. That number of children (n=252 per school) will be randomly selected from the school's pupil lists, stratified for gender (1:1), only including eligible children in that random selection process. Eligibility criteria for individual participant are: (i) Residents of the program area; (ii) Age 11-16 at the time of baseline; (iii) Speaking primary language (Kinyabwisha, Congolese Kiswahili, Runyankole, Runyoro/Rutooro). Random selection will be performed by an independent statistician using a random number generator in Stata statistical software. Siblings will not be excluded.

2.8.3. Sample size calculation

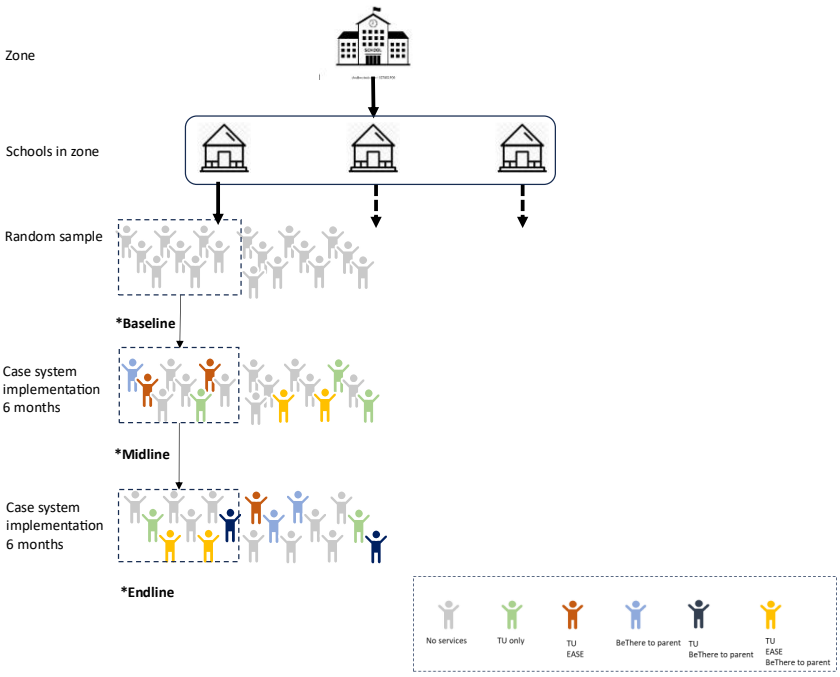
This cRCT was designed to have at least 80% power to detect a moderate effect size of Cohen's d = 0.30 for the primary outcome (MMAPP) at the primary time point (endline). Assumptions were the following: intra-cluster correlation coefficient (ICC) due to clustering by zone/school of 0.04 (based on population level data from two systematic reviews on ICCs [Shackleton et al, 2016; Parker et al, 2023]), 2-tailed 5% significance level, resulting in an estimation of 18 clusters (9 per arm) and n=176 children per cluster. Adjusted for a loss to follow-up rate of 30% makes the total sample size n=4536 (across study arms) – translating to n=252 per school. The LTFU

rate is a somewhat conservative estimate, as we will attempt to follow-up all participants enrolled at baseline, even if they leave school. We will not adjust for household level clustering (as siblings are included) in the analyses, and therefore this has not been included in the sample size calculations.

2.8.4. Sample description

Important for this study, as described above, the randomly selected sample of children may or may not receive services following baseline assessments, similarly peers of the recruited children (children in the same school) may or may not receive services. This means that the impact of the mental health care system on recruited children may be direct (receiving TeamUp and/or EASE), and/or it may be indirect through their caregivers (receiving BeThere), and/or it may be indirect through their peers (receiving TeamUp or EASE, or their caregivers receiving BeThere). Furthermore, this service provision might happen in the first [approximate] 6 months or the second [approximate] 6 months. This is summarized in Figure 5.

Figure 5. Study samples



2.9.Procedures

2.9.1. Data collection – quantitative outcomes

The administration of the instruments will be conducted by 60 research assistants employed by the War Child Alliance. All research assistants will be specifically trained to conduct quantitative assessments. Research assistants receive a 5-day training course that includes research ethics, practice administration of surveys through interviews, communication skills, research procedures etc. Data collection for children will take place in a closed venue (e.g. classroom) or private room either on school premises or in their homes (only for school dropouts at follow-up), following War Childs child safeguarding procedures. Following the training, research staff will have 2 weeks of practice assessments and interview role plays until the start of the trial. Research assistants will also be trained in the Adverse Events Reporting Mechanism, which guides the process of reporting and supporting/referral in case of any adverse events (see further details below). First, the interview-administered instruments will take approximately 60-90 minutes to complete. The instruments will be administered individually to each participant, though participants may be asked to self-administer several key sensitive items to avoid social desirability. Such items will be identified from the adaptation work currently underway and for which we have ethics approval from MAKSHSREC [29/08/24] The administration of the instruments for the primary caregiver will take place either on school premises, or in the participants' homes, and should last approximately 30 minutes. Data collection with adolescents and caregivers will be done in person. Data will be collected electronically using Android tablets linked to the ODK platform (https://getodk.org/). All data collection will be conducted in Kinyabwisha, Congolese Kiswahili, Runyankole, Runyoro/Rutooro, which are the most spoken languages in the study sample. Each study participant will receive a small receive a gift for compensation (e.g. pens for adolescents and sugar for caregivers) for each assessment. Furthermore, refreshments (i.e. something to drink, and a snack) will be provided during all assessment sessions, for adolescents and caregivers.

2.9.2. Timepoints for assessments

Quantitative outcome data will be collected at three timepoints. At baseline (T0), at midline 6 months post baseline (T1), and at endline 12 months post baseline (T2; primary time point for between-group comparisons). T1 assessments consist of adolescent surveys only (i.e. no caregivers), and will only include MMAPP, DBIS, Stirling and Hope. Implementation of services in the experimental arm will be introduced after baseline assessments are completed and will run

throughout the academic year (three terms). Service delivery will be ongoing for the entire study period to ensure a pragmatic implementation approach and ensure the evaluation of population-level outcomes (which requires for some of the experimental arm participants to not receive services between measurement points). At T1 and T2 we will attempt to follow-up all participants enrolled at baseline, also those that have left school in the meantime. Data collection will follow this schedule:

Baseline evaluation study (T0)	Start June 2025	Period
Implementation services	Start July – November 2025	Terms 2 and 3
Midline evaluation study (T1)	Start December 2025	
Continued implementation	January/February – April (2026)	Term 3
Endline evaluation study (T2)	May (2026)	

2.9.3. Data management

The War Child Alliance Research and Development Data Management Policy serves as guidance on all data management and data sharing issues (policy available upon request). Names and phone numbers obtained on the consent forms will be kept in locked cabinets in locked offices or encrypted and password protected in the case they are stored digitally. Quantitative data. All data obtained via ODK will be anonymized using participant ID numbers during data collection and when exported for analysis and storage. To further improve the quality of data collected, the study scientific coordinator will conduct routine data checks and follow up to check for any inconsistencies and missing data in the database. Any errors identified in the data collected will be sent to the research assistant teams for correction. Statistical monitoring will also be implemented to look at variables for which distributions differ from the rest of the observed data, to highlight systematic (non-random) faults in filling the case registration forms and logbooks, compliance, SAEs, and to guide targeted monitoring. Comparison of distributions is made by statistical tests or models.

At the end of the data collection exercise, a final data review will be conducted by the co-investigators and lead statistician, and the remaining data issues will be adjudicated. The paper data files will be collected from the field offices monthly and stored in a locked cabinet in the War Child Uganda office. Qualitative data. The study scientific coordinator will upload any qualitative data, including audio files, on a password encrypted secure data server of the Research and Development Department of War Child Alliance. The server will be password protected and

accessed from password protected and encrypted laptops. Data security. Data entered electronically will be backed-up securely and password protected and encrypted. Any queries identified will be resolved promptly by the trial management team. Data entered on the server will only be available to the War Child Alliance research team. Any external partner or parties who require access to the data will only have access once a data sharing agreement has been signed, in which the party agrees to abide by the War child Alliance Data Management Policy. Paper copies of informed consent forms (i.e., signed release of information forms) and data files will be collected from the field offices monthly and be stored securely in the locked cabinet in the War Child Uganda office. Length of data retention, archiving conditions and management. Both qualitative and quantitative data will be stored for a period of at least 7 years after completion of the study. Any modification or deletion of data will be granted via the standard authentication and access-control features. Data ownership and sharing. War Child Alliance has, in all cases, ownership of the research data.

2.9.4. Contamination and drifting

To assess the extent of contamination across trial arms, participants in both arms will be asked several structured questions at each of the measurement points (excluding baseline) about the extent to which they shared information and materials about the intervention received with others in the community (experimental arm), and whether they have heard of information or materials about the intervention from others. This information will be used descriptively to assess the level of contamination and drifting.

2.9.5. Masking

Research assistants and lead investigators (i.e. all named investigators on this protocol, including the lead statistician) will remain masked to allocation status of participants enrolled into the study – except the Scientific Coordinator, as it will be impossible to remain masked while coordinating all field operations. A Standard Operating Procedure (SOP) will be put in place with details on who can know what, on what scripts can be used when communicating about the study and what strategies are in place to prevent and assess unmasking. The main strategies to maintain masking will be (1) working with separate research assistants for qualitative and quantitative assessments; (2) having separate convening places for research assistants and intervention facilitators, as part of a larger strategy to avoid contact between both groups; (3) research assistants will also prompt participants (adolescents and caregivers) not to share any information on the type of services that

they receive. The level of (un)masking will be assessed at the end of each of the three time-points assessments.

2.10. Analyses

2.10.1. Effectiveness analyses [RQ1]

Primary comparison: (i) Baseline-to-endline comparison on MMAPP total score and (ii) baseline-to-endline comparison on Stirling total score.

Secondary comparisons: (iii) Baseline-to-endline comparison on all secondary, indirect and mediating outcomes; (iv) Baseline-to-midline on all outcomes; (v) Midline-to-endline on all outcomes. The analysis will follow an intention-to-treat approach, analyzing all participants based on their random assignment to the trial arms. Preliminary analysis will compare baseline characteristics to assess successful randomization across trial arms. Multilevel mixed-effect linear or logistic regression models (depending on outcome) will be employed for all primary, secondary, mediation, and indirect outcomes, treating the intervention group as a fixed effect. These models will account for the hierarchical structure of the data, with children nested within schools. Demographic variables and baseline outcome measures will be included as covariates. Additionally, (vi) we will evaluate mediation effects of social connectedness, hope and family functioning; (vii) Separate models will estimate differences between trial arms at the 6-month midline and 12-month endline, with distinct sub-group analyses for boys and girls; (viii) sensitivity analyses will be conducted wherein siblings are excluded; and (ix) analyses of the relative contribution of interventions or combination of interventions to change in the primary outcomes. A detailed Statistical Analyses Plan (SAP) will be developed and will be made publicly available before the end of the last data collection has been completed.

2.10.2. Cost analyses

First, we will calculate the costs of delivering each of the separate interventions under real-world conditions. For this we will estimate unit costs for staff time and apply unit costs to time inputs of staff to calculate workforce costs. Similarly, we will determine market prices for other cost items such as material, travel and equipment as needed. Sensitivity analysis will be conducted to reflect uncertainty of some of the parameters.

2.11. Ethics

2.11.1. Consent and assent procedures

Permission to conduct the cRCT will be sought first from the education authorities (Uganda). Then, permission from the schools' headteacher will be sought following in-person meetings to describe the study and answer any questions they may have. The research assistants will then

coordinate with teachers or school authorities to identify a time suitable to approach potential participants identified following random selection (stage 2 in the sampling process) and introduce the study in group or individually. Written assent from the enrolled children and written consent from their caregiver will then be sought. This will entail asking the children to bring a study information sheet and consent forms home and discuss with caregivers. The fieldworkers will then follow-up each caregiver telephonically, or visit in person, or bring groups of caregivers together, within one week to ensure that they have received the information sheets and consent forms, have understood the study fully and to give them an opportunity to ask questions. In cases of low literacy, the fieldworkers will read the information letter out loud. If the caregivers agree to participate and for their child to participate, caregivers will be asked to provide verbal consent on the phone. The children will be asked to return signed consent forms from their caregiver and their signed assent form back to the research assistant directly, or to their teacher (the research assistants) will then liaise with the teachers to collect the signed consent and assent forms. We will give children and caregivers one week to decide whether to participate in the study, thus children will not need to decide at the time of the information session, in the presence of their teacher or other school representative. Nonetheless, to avoid children feeling pressurized into participating, fieldworkers will make it very clear to potential participants and their caregivers that their decision to participate or not will not affect their grades or treatment at school. Potential participants will not be informed of the content of the study arms. Indeed, it is important that participants know as little as possible about the interventions provided in the study arms, to avoid contamination. It is also important to withhold the information about the study arms to avoid any undue repercussions on willingness to participate, attrition or outcomes should participants prefer the intervention provided in other arms.

2.11.2. Adverse events reporting

Adverse events reported by research participants, or observed or suspected by members of the research, program or clinical team, will be reported according to War Child Alliance Research and Development Adverse Events Reporting Procedure (Annex 6). Serious adverse events include: (i) Physical, sexual, emotional abuse, neglect or exploitation of a research participant, program team member or research team member. (ii) Any child safeguarding concern or case, including any form of abuse and excessive punishment. (iii) Participant disclosure of any of the 6 Grave violations of Children During Armed Conflict (Recruitment and use of children in armed groups, Killing and maiming of children, Sexual violence against children, Attacks against schools and hospitals, Denial of humanitarian access). (iv) Disclosure of current or recent intimate

partner violence between adults. (v) Recent suicidal ideation, combined with recent plan or attempt of a research participant or member of the research of the CCDT team. (vi) Death of a research participant. (vii) Injuries or accidents that occur on the route to research activities. Adverse events will be reported to the Data Safety Management Committee (DSMC) (see below) using the Incident Reporting Form (Annex 7). Immediate response, referral, and child safeguarding/child protection reporting process for each kind of adverse event will be determined based on the specific local context, prior to commencement of the study in collaboration with War Child Alliance and partner organization's clinical supervisory team. However, the principal investigators will be responsible for ensuring appropriate response to all adverse events. Any adverse events relating to child safeguarding and child protection (e.g., domestic violence, child sexual, physical or emotional abuse, or neglect) will be reported by the implementation team to local child safeguarding focal points for appropriate investigation if this has not already occurred. These are the War Child Alliance child safeguarding focal points in study implementation sites.

2.11.3. Potential risks and mitigation strategies

This trial poses minimal risks to adolescents and caregivers. They may feel uncomfortable during assessments, and some questions may make them feel distressed. They will be informed of the possible psychological effect some questions may pose before the start of the questionnaire. Risks specific to participation include the potential for breach of confidentiality, as well as emotional risks associated with mental health in the community. To minimize these risks, Research Assistants and study team will be trained on how to manage likely incidents (refer to *section 2.8.2*). In addition, we shall work closely with school and settlement leaders to ensure safety and confidentiality while administering the tools. Ensure a safe environment such as classroom free from obstructions. Observations and assessments will be made from time to time to ensure there are no influencing factors that may affect the outcomes from the interviews and surveys, as well as risks to participants.

2.11.4. Benefits

This study provides the following potential direct opportunities for children and adolescents in need of mental health care: An improved and early detection of mental health concerns, an enhanced prognosis due to timely and appropriate mental health treatment initiation, and together these factors will positively impact positive mental health outcomes. It is also hoped that lessons learned from this trial will help to improve mental health care efforts at national level programs and policies. The risk benefit ratio for this trial for individual child and adolescent is seen to be favorable with low risk and reasonable additional benefits due to participation.

2.11.5. Time compensation

Caregivers will be reimbursed 10,000/= (Ten thousand Uganda shillings) as transport refund in addition to soap and sugar. Adolescents will be given books and pens. Refreshments will be provided during assessments.

2.11.6. Gender Consideration

Selection of participants will be through random sampling, where every adolescent will be given equal chances to participate in the study. Data will be analyzed by gender, through sub-group analyses. The same applies to the research team, both genders will be recruited. During assessments, boys and girls will be interviewed differently, as they have different needs and challenges, the same applies to caregivers.

2.11.7. Longer term duty of care

Where appropriate, War Child's and partner active programming in these communities will ensure adequate coordination with other agencies, and (state and non-state) referral options including case management and child protection, to ensure the safety and wellbeing of participants, and to ensure the continuation of service delivery programs for research participants, after the completion of the research. Referrals will be made either internally within existing services, or to external services when necessary; costs of these services will be covered as per standard referral processes in Uganda.

2.12. Trial governance

2.12.1. Research team

Professor Jordans (Principal Investigator) 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.

Dr Byamah Mutamba (Co-Principal Investigator) has dual expertise in public health and mental health. He is the co- founder of YouBelong and the Technical Director at YouBelong Uganda. DR Mutamba obtained his degree in Psychiatry from Makerere University School of Medicine in Uganda. He completed his master's degree in public health in Developing Countries from the London School of Hygiene and Tropical Medicine in the UK, and a PhD from the University of Amsterdam in the Netherlands. He also works as a Consultant Psychiatrist at Butabika National

Referral Mental Hospital where he is involved with clinical management of both in and outpatients with various psychiatric disorders, and is the head of the Alcohol and Drug Unit at the hospital

Sandra Agondeze (Scientific Coordinator) has a master's degree in public health, and her research has focused on occupational health, mental health and psychosocial support, social research, as well as global health research (including HIV and emerging infectious diseases).

Myrthe van den Broek (Co-Investigator) is an anthropologist and applied researcher at War Child Holland. She is a PhD candidate at the Amsterdam Institute for Social Science Research. She is interested in improving access to evidence-based interventions for children and adolescents experiencing mental health problems. Specifically, her research focuses on the development, implementation and evaluation of strategies to overcome demand-side barriers to mental healthcare for children and adolescents in conflict-affected and low resource settings. In her work she collaborates with other international and national non-governmental organizations, national mental healthcare providers and specialists and academic institutions.

Anthony Guevara (Co-Investigator) has a degree in anthropology. He is currently a Mental Health & Psychosocial Support Researcher at War Child Alliance and a PhD Candidate at University of Amsterdam.

Dr. Gabriela Koppenol-Gonzalez (Co-Investigator) is a psychologist with a PhD in applied statistics & research methods. She works as a senior researcher in methodology and statistics at the R&D department of War Child Alliance. Her research is focused on the application of different analysis techniques, especially latent class analysis, in the field of mental health care, effectiveness studies, cognitive psychology, and education. Her expertise lies in the translation of research methods from a controlled clinical setting to a real-world and challenging context, such as conflict-affected areas.

Dr Sebastian Kurten (Co-Investigator – Lead Statistician) is a researcher with a background in statistics (MSc) and social work (MA), studying adolescent wellbeing in challenged contexts. He teaches statistics and scientific programming at the University of Cambridge's School of Clinical Medicine.

Professor Wendy Janssens (Co-Investigator) is Professor in Development Economics at the Vrije Universiteit Amsterdam. She is an Academic Board member of the Amsterdam Institute for Global Health and Development (AIGHD), Director of HERA institute (Health Economics Research institute Amsterdam), and research fellow at the Tinbergen Institute. Her work focuses on understanding the impacts of development programs and drivers of behavior in the areas of global health (including mental health, sexual and reproductive health, equitable health financing), child development, microfinance, household dynamics and gender. She has extensive experience in designing and coordinating multi-disciplinary research programs to provide rigorous and locally grounded policy advice to national and international organizations as well as governments (such as Oxfam Novib, Pathfinder International, the Ministry of Foreign Affairs, the World Bank).

Professor Brandon Kohrt (Co-Investigator) is an anthropologist and psychiatrist, holds the Charles and Sonia Akman Professorship in Global Psychiatry at George Washington University, where he is Professor of Psychiatry and Global Health and Director of the Center for Global Mental Health Equity. Dr. Kohrt has worked with children and families affected by war and political violence, disasters, and other forms of adversity. Dr. Kohrt serves as the Scientific Co-Chair of the Health Research in Humanitarian Crises initiative at the Fogarty International Center of the National Institutes of Health. He is also the scientific advisor for the World Health Organization's EQUIP program which is establishing global competency standards for non-specialists delivering psychological interventions.

2.12.2. Trial registration

The study will be registered on the ISRCTN repository (https://www.isrctn.com/). Once the protocol gets approved it will be linked to the ISRCTN registry so that it will be open access, to be followed by that Statistical Analyses Plan (SAP).

2.12.3. Trial steering committee

A Trial Steering Committee (TSC) will be put in place, with the responsibility to oversee the conduct and progress of the trial and ensure compatibility with the trial protocol (including decisions to deviate from protocol). More specifically, the role of the TSC will be to: (i) monitor the progress of the trial towards stated objectives; (ii) supervise adherence to trial protocol; (iii) consider the recommendations of the Data Monitoring Committee (see next slide); (iv) oversee the timely reporting of trial results; and (v) advise on publicity and the presentation of all aspects

of the trial. The TSC will consist of the Principal Investigator, the scientific coordinator, and lead statistician.

2.12.4. Data Safety Management Committee

A Data Safety Management Committee will be established prior to the start of the pilot trial and will continue until final data has been collected (12 months post baseline). It will provide oversight on adverse events and safety protocols for the trial, to determine if interim analyses should be undertaken, and to make decisions as to the continuation of the trial in case of severe adverse events. The DSMC will consist of at least three members, one of whom is an independent statistician. The DSMC will meet every three months for the duration of the trial. Specifically, the DSMC will: (i) Review safety information from the study (Adverse events (AEs) and serious adverse events (SAEs)) and monitor whether adequate response has been taken by the research team, as well as monitor whether (S)AEs might be related to participation in the trial. (ii) Consider if blind or unblinded interim analyses should be undertaken, plus any additional safety issues for the ALIVE trial and relevant information from other sources. (iii) Report (following each DSMB meeting) to the TSC and provide recommendations for continuation, termination or other modification of the trial based on the DSMB's review. (iv) Consider any requests for release of trial data prior to the completion of the primary analysis, and to recommend to the TSC on the advisability of this. All (S)AEs that might take place during the study will be reported following the above-mentioned Adverse Events Reporting Procedure. The PIs are responsible for sharing the (S)AE reports to the DSMC, as well as other ethics committees. Each report of an (S)AE will be sent to the DSMC, who will ascertain whether the (S)AE is because of participating in the trial, and whether the adequate response has been taken. Responses within one week, over email, will be required in case of a severe adverse event (the definition of which will be determined before the start of the study).

2.13. Dissemination

The study will lead to the following outputs. (i) Academic journal articles: Results will be published via journal articles (preferably in open access journals); publications and authorship arrangements will adhere to the War Child Alliance Research and Development Department publication policy. Any publication or communication (oral or written) is decided by mutual agreement between the investigators, and will respect the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Journals". (ii) Conferences: Results will

be presented at international conferences, which will be selected based on relevance of the research findings. (iii) Workshops with key stakeholders, including schools where the study will take place: Workshops with school personnel, caregivers, community members and children will be held at each of the schools included in the study - once results have been finalized. The final study results will be presented to the national-level (health) policy makers. A series of documents (e.g. briefs with summary results, infographics, small videos) will be released to allow for wide-scale dissemination of the results of the study.

2.14. Limitations / Anticipated Problems

Before the start of the research/project, engagements were made with school leadership, settlement leadership and other education stakeholders to discuss the proposed research and solicit their commitment and collaboration. Their advice and guidance, as well as soliciting their input and support upfront, will help us to implement the project. Leadership will be part of the random sampling procedures to avoid potential bias.

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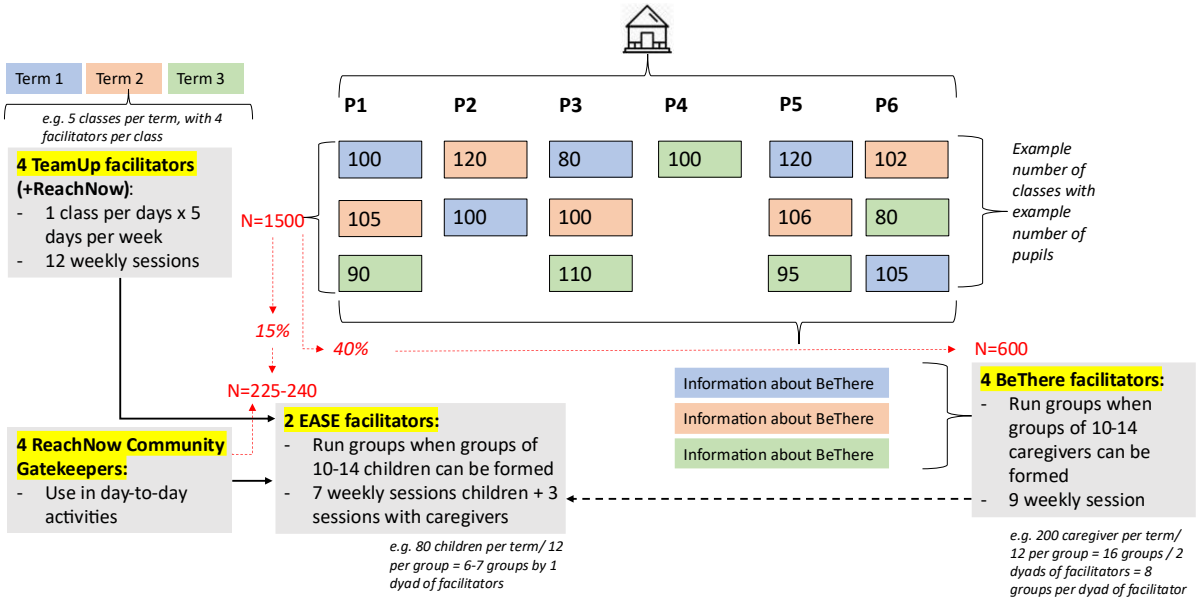
ANNEXES

Annex 1. Staffing overview per schools



Annex 2: Budget

Annex 3: Work plan

Annex 4: Consents

Annex 5: Instruments

Annex 6: Adverse event documentation form

Annex 7: Incident Reporting Form