STEPPED-WEDGE CLUSTER RANDOMIZED CONTROLLED TRIAL OF THE COMMUNITY CASE DETECTION TOOL FOR CHILDREN AGED 6-18 YEARS IN NEED OF MENTAL HEALTHCARE SERVICES IN NORTHERN AND WESTERN UGANDA

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ABBREVIATIONS

CBTT	Cognitive Behavioural Trauma Therapy
CCDT	Community Case Detection Tool
CHUSS	College of Humanities and Social Sciences Uganda
CIDT	Community Informant Detection Tool
CONSORT	Consolidated Standards of Reporting Trials
DSMC	Data Safety Management Committee
FGD	Focus Group Discussion
ICC	Interclass Correlation Coefficient
ID	Identification
IG	Intervention Guide
IQR	Inter Quartile Range
JoL	Journey of Life
JRS	Jesuit Refugee Service
KII	Key Informant Interviews
LMIC	Low- and Middle-Income Country
M&E	Monitoring and Evaluation
MAKSHS	Makerere University School of Health Sciences Research and Ethics Committee.
MhGAP	Mental Health Gap Action Programme
MHPSS	Mental Health and Psycho Social Support
MSNA	Multi-Sector Needs Assessment
NGO	Non-Governmental Organisation
R&D	Research and Development
REC	Research Ethics Committee
SAEs	Serious Adverse Events
SD	Standard Deviation
SW-CRT	Stepped-wedge cluster randomized controlled trial
SWT	Stepped Wedge Trial
TPO	Transcultural Psychosocial Organisation
UNCST	Uganda National Council of Science and Technology
UNICEF	United Nations Children's Fund
VHT	Village Health Team
WCH	War Child Holland
WHO	World Health Organization

RESEARCH PROTOCOL SUMMARY

STUDY TITLE

Stepped-wedge cluster randomized controlled trial of the Community Case Detection Tool for children aged 6-18 years in need of mental healthcare services in Northern and Western Uganda.

RESEARCH QUESTIONS

1. Can proactive community case detection using the CCDT increase utilization of Transcultural Psychosocial Organisation's (TPO's) mental healthcare services among children and adolescents?
2. What is the proportion of children and adolescents who seek mental health care as a result of having been detected using the CCDT?
3. Is proactive community case detection using the CCDT acceptable, appropriate, and feasible to implement at scale?
4. How do community gatekeepers' attitudes towards individuals experiencing mental health problems relate to the implementation of the CCDT in the Bidi Bidi, Rhino and Omugo, Kyaka II, and Kyangwali settlements in Uganda?

RATIONALE FOR RESEARCH

Background of the study

As part of Uganda's Health Sector Integrated Refugee Response Plan, mental healthcare shall be integrated into general health care provision and available at every healthcare facility, by introducing the Mental Health Gap Action Programme (mhGAP). The Research and Development (R&D) department within War Child Holland (WCH) developed and tested the Community Case Detection Tool (CCDT) as part of the broader research agenda towards the creation of an integrated care and support system for children and adolescents living with violence and armed conflict. The CCDT is a low-cost scalable tool developed as a strategy to bridge the gap between available community-level Mental Health and Psycho Social Support (MHPSS) services, such as those provided through mhGAP, and children and adolescents in need of those resources. The tool employs a gatekeeper model and is developed for trusted and respected community members ('community gatekeepers') without a professional mental health background. They are trained on how to use the tool to proactively identify children in need of mental healthcare services and encourage help-seeking at available adequate MHPSS services. The aim of the CCDT is to improve help-seeking of available mental healthcare services among children and adolescents or their caregivers in need of these services.

Study objectives

The primary objective is to examine whether the CCDT is effective in increasing utilization of TPO's mental healthcare services among children and adolescents after introducing pro-active case detection using the CCDT as compared to practice-as-usual.

The secondary objectives are:

- To examine the proportion of help-seeking (i.e., mental health care utilization) following pro-active case detection using the CCDT (independent of between-group comparisons).
- To examine implementation outcomes in terms of the acceptability, appropriateness and feasibility of using the CCDT at scale for community gatekeepers.
- To examine community gatekeepers' attitudes towards mental health problems after the introduction of the CCDT, relative to rates pre-training.

METHODS

Study design

Stepped-wedge cluster randomized controlled trial

Intervention

The Community Case Detection Tool (CCDT), is a tool for trusted and respected community members. The CCDT is made up of illustrated narratives depicting common examples of childhood psychological distress, such as social withdrawal, aggression, sleep problems, unexplained physical illness and injuries, and loss of hope. It will be available in most common languages spoken in the five settlements, including Kiswahili, Kinyamwisha, Juba Arabic, Lugbara, Kakwa and Kuku. The CCDT will be integrated into routine practices and evaluated under these routine conditions, using data that are routinely collected.

Study sites

The CCDT will be introduced in 28 zones in Bidi Bidi, Rhino, Omugo, Kyaka II and Kyangwali refugee settlements in Uganda.

Duration

The CCDT will be introduced and rolled-out sequentially over the course of 9 months. The stepped-wedge cluster randomized controlled trial data will be collected during this roll out. The implementation of the programme and routine data collection continues for the entire duration of the programme (i.e., April, 2023).

Population

The catchment area of a community gatekeeper (i.e., the area they serve) is equal to a zone. Sampling therefore takes place at settlement zone level and each zone will be considered a cluster in this study. Four zones will be randomly assigned from *pre-CCDT introduction and implementation* (i.e., the control condition) to *CCDT implementation* (i.e., intervention condition), at one-month intervals (i.e., steps), until all zones are implementing the CCDT (Intervention).

The number of gatekeepers per zone will be dependent on the population size in the zone, our aim is to train 1 gatekeeper per 3000 residents. A total of up to N=200 community gatekeepers will be selected from War Child Holland's (WCH's)and TPO's existing networks and community-based structures. 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.

Children, adolescents aged 6-18 years old, and their caregivers will be proactively identified by the trained community gatekeepers based on a match with the CCDT (i.e., children and adolescents in need of mental healthcare services). The sample size, i.e., the number of children and adolescents that will be detected and that will utilize TPO's services per month within each zone will be determined as primary outcome of this evaluation. Using existing utilization data, we estimated the number of zones required to detect a 20% difference in utilization rates pre- to post-CCDT implementation with at least 90% power.

This study includes children younger than 18 years of age (minors are involved). As an organization working with children, our main priority is keeping children safe, we will therefore adhere to our strict standard Child Safeguarding policies (available upon request).

Procedures

The CCDT will be integrated into routine practices during the gatekeepers' daily routine activities and evaluated under these routine conditions. This implies that; (1) community gatekeepers will be selected

from WCH's and TPO's current networks; (2) community gatekeepers will be trained in using the CCDT during their daily routine activities to detect children and adolescent in need of care and promote help-seeking at TPO; (3) TPO will continue to assess the needs, provide adequate mental healthcare or refer to other organizations as usual to whomever accesses their services; and (4) that data collection follows existing (albeit slightly adjusted) routine monitoring systems.

All gatekeepers will follow a two-day training in how to use the CCDT in a safe and ethical way, this training covers the following topics: responsibilities and child safeguarding, detection tool and identification procedure per version, ethical issues associated with proactive case-finding, basic training on consent to gather information, stressing that referral to in-depth assessment is encouraged, but never imposed. The community gatekeepers will be linked to one clinical psychologist who will offer ongoing support and supervision. Whenever a trained gatekeeper encounters a child or adolescent that matches with the tool, they will hand out a referral information card including information about TPO and encourage help-seeking at TPO's clinical team serving their zone.

Gatekeepers will be provided with a logbook in which they will record the information about the detection. A unique study ID will be created for each new case, this code will be linked to the gatekeepers' initials and cannot be traced back to the individual. Furthermore, at service level, routine mental health utilization data will be collected at TPO for all clients seeking care. An anonymized client code will be assigned and used as the only identifier.

The trainings for the research, program and clinical team contains a separate session on how to deal with adverse events or possible persistent or worsening symptoms that may occur. Facilities are in place to monitor this and appropriate actions will be taken based on an established crisis assessment protocol (for instance, referral to more intensive psychological treatment and monitoring of participant by clinical psychologists). Furthermore, War Child has an adverse event reporting procedure in place for all research conducted.

POTENTIAL RISKS AND MITIGATION STRATEGIES

The research team is considerate of the fact that the study will be conducted with vulnerable children and adolescents that are exposed to adversities and experiencing psychological distress or are at higher child protection risk. However, the risks for participants in this study are considered low. Based on previous research in Nepal, Palestine and Sri Lanka, the CCDT is expected to have a benefit in encouraging and supporting more children and adolescents in need for services – to actually access these. So that eventually severe childhood psychological distress can be prevented and child protection risks can be reduced.

This trial poses minimal risks to children and adolescents. Children, adolescents and their caregivers may feel uncomfortable during some mental health sessions. Parents/caregivers will nevertheless be informed of possible psychological trauma during the different mental health management programs. Risks specific to participation include the potential for breach of confidentiality, as well as stigma and emotional risks associated with mental health in the community. To minimize these risks, gatekeepers and clinicians will be trained on how to maintain confidentiality, significant efforts are made to inform and involve local communities in new initiatives.

BENEFITS

The expected benefits include an improved and early diagnosis of mental health conditions due to the proactive approach and help-seeking encouragement using the CCDT and an enhanced prognosis due to timely and appropriate mental health treatment initiation.

PARTICIPANT'S REIMBURSEMENT

Since the study involves mental health detection and referral using the CCDT, there will not be any cost incurred by the parents or caregivers. All mental health care is provided at zone level, at a location comfortable for the child or caregiver at home, school, TPO's office or other fixed points. Gatekeepers will

be provided transportation and lunch allowance when called for the meeting. They will also be provided airtime to follow up and report on the cases. Regular monthly incentive is not planned under this project.

CONFIDENTIALITY AND DATA PRIVACY

Participant confidentiality is protected at all times and all data collection, storage and analysis procedures will be General Data Protection Regulations-compliant. Participants will be assigned a Client Code/ ID and pseudonym for qualitative data, and their names will not appear on any data collected. A master list linking IDs and names will be managed by TPO's M&E manager. This list will be stored on a password encrypted secure data server of the R&D Department of WCH. Logbooks collected from gatekeepers will be stored in a secure cabinet at TPO (as mentioned above).

INFORMED CONSENT AND ASSENT PROCEDURES

Consent and assent is obtained at different levels. For community gatekeepers verbal and written informed consent will be obtained before participating in this study. All participants (community gatekeepers and caregivers) will be given the name and number of the study contact person in Uganda in case they have further questions, or wish to withdraw from the study. All participants will have the right to withdraw from the study and without obligation to provide a reason. Upon detection by a trained community gatekeeper – all caregivers, children and adolescents will first receive a verbal summation of the project and are asked for their verbal consent/assent to collect and release their information for study purposes. Information will only be documented if both the caregiver and child/adolescent's consent. For caregivers, children and adolescent that seek help after being detected the clinical team will hand out an information letter about the project ask them to sign a release of information form that permits TPO share de-identified data with the research team regarding how many children, adolescents and caregivers sought help as a result of the CCDT, and to share the routinely collected service utilization data. Caregivers, or children/adolescents that do not consent to the sharing of data will not be included in the study, but will continue to be involved in any service delivery at any time.

CONFIDENTIALITY

Participant confidentiality is protected at all times and all data collection, storage and analysis procedures will be General Data Protection Regulations-compliant. Participants will be assigned a Client Code/ ID and pseudonym for qualitative data, and their names will not appear on any data collected. A master list linking IDs and names will be managed by TPO's M&E manager. This list will be stored on a password encrypted secure data server of the R&D Department of WCH. Logbooks collected from gatekeepers will be stored in a secure cabinet at TPO (as mentioned above). Individual mental health information obtained as result of this trial will be confidential. Team members are subject to the obligation of professional secrecy and will all be asked to sign a WCH's data confidentiality agreement and child safeguarding policy.

INTENDED USE OF RESULTS

Results will be used in the following ways: (1) published via journal articles (preferably in open access journals); publications and authorship arrangements will adhere to the WCH R&D publication policy; (2) presented in international conferences, which will be selected based on relevance of the research findings; (3) workshops will be held with key stakeholders at relevant timepoints over the course of the research study; (4) WCH reports will be written; (5) A manual detailing the design and implementation protocol for the CCDT will be written; (6) the final study results will be presented to the investigators and the national authorities. A series of documents (written detailed report, and short summary) will be released to help investigators, national authorities and participants to understand the results of the study. participants may be invited to attend a meeting during which the results will be presented and explained orally.

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STUDY TEAM

Co-Principal Investigator	Prof. Dr Mark J.D. Jordans	War Child Holland and Amsterdam Institute of Social Science Research, University of Amsterdam.
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INTRODUCTION

Rationale and background information

Some 20 percent of children and adolescents worldwide may experience a mental health condition in any given year - of whom an estimated 75 per cent experience its onset before the age of 24 [1]. Suicide is the third leading cause of death worldwide among adolescents between the age of fifteen to nineteen years, and 79 per cent of suicides occur in low- and middle-income countries [2]. As a response, mental health and psychosocial support (MHPSS) has gained increasing attention and has been listed as a key priority for both governments and national and international NGOs over recent years. This has resulted in an increase in available MHPSS services - ranging from strengthening community support structures and promoting wellbeing to more focused psychosocial support, counselling and psychiatric services.

As part of Uganda's Health Sector Integrated Refugee Response Plan, mental healthcare shall be integrated into general health care provision and available at every healthcare facility [3] by introducing the Mental Health Gap Action Programme (mhGAP)[1]. mhGAP and the attached intervention guide is developed by the World Health Organization (WHO) to aid the integration of mental healthcare, including child and adolescents' mental healthcare, into non-specialized health settings such as primary health care services [4]. Following the 'task sharing' approach, social workers are trained in providing mental healthcare as outlined in mhGAP and receive supervision and refresher trainings from specialist mental health staff. Specialist mental health staff are available for referral of severe cases. Yet despite the clear evidence on the importance of early intervention and the growing number of available evidence-based interventions such as mhGAP, fewer than ten percent of the people in need of mental healthcare services in Uganda currently access services [5].

Children and adolescents often depend on their caregivers or other important gatekeepers to identify problems, 'opening the gate to services', and support continuation of care utilization [6]. Yet research has shown that only 10 – 22 per cent of children in need of mental healthcare services in Uganda were recognized by primary health workers [7] in line with high-income country figures reporting detection rates of 0.6 - 16 per cent [8]. According to a recent needs assessment conducted by Jesuit Refugee Service (JRS) and Tutapona teachers and other frontline

[1] WHO developed the mental health gap action program (mhGAP) and the attached intervention guide (IG) to aid the integration of mental healthcare, including child and adolescents mental healthcare into non-specialized health settings such as primary health care services [4].

gatekeepers in Uganda are often not well equipped to recognize signs of psychological distress and there is a lack of available training and tools to support this work. Furthermore, a lack of knowledge of available service options, cultural stigma and negative perceptions regarding available mental healthcare services have all been found to deter help-seeking [9, 10].

Responding to this need, the Research and Development (R&D) department within War Child Holland (WCH) developed and tested the Community Case Detection Tool (CCDT) as part of the broader research agenda towards the creation of an integrated care and support system for children and adolescents living with violence and armed conflict. The CCDT is a low-cost scalable tool developed as a strategy to bridge the gap between available community-level MHPSS services, such as those provided through mhGAP, and children and adolescents in need of those resources. The tool employs a gatekeeper model and is developed for trusted and respected community members ('community gatekeepers') without a professional mental health background. They are trained on how to use the tool to proactively identify children in need of mental healthcare services and encourage help-seeking at available adequate MHPSS services, (Refer to Annex 1: CCDT, developed in Sri Lanka).

The CCDT is developed based on an evidence-based tool for the detection of adult mental health problems developed by Jordans and colleagues [11]. Research in Nepal has shown that two-thirds of the cases (64%) were accurately detected, of whom two-thirds (67%) went on to access health care [11, 12]. A concluding pragmatic Randomized Controlled Trial showed that use of the tool increased mental health service utilization by almost 50 per cent over six months [13]. The adult tool has been adapted for the detection of children and adolescents and previous studies established the accuracy of the CCDT in detecting children and adolescents in need of mental health care in two countries and two different settings. Trained community gatekeepers (i.e., teachers, community health volunteers and group activity facilitators) in Sri Lanka and Palestine used the tool in their daily routine. Nearly 70 per cent of all children included in these two studies were accurately detected using the CCDT as being in need of mental healthcare following a clinical interview with a mental health professional [14]. Based on these positive findings, the CCDT was regarded as a safe and low-cost solution to overcome under-detection of children and adolescents in need of mental healthcare.

Aim

The aim of the Community Case Detection Tool is to improve help-seeking of available mental healthcare services among children and adolescents or their caregivers in need of these services.

WCH has recently been named a recipient of a grant from a Dutch foundation that wishes to remain anonymous which will support the scaling of the CCDT to four settlements, in Northern and Western Uganda. This initiative is led by a partnership between WCH's Research and Development Department, WCH Uganda and TPO Uganda. During the roll out of the CCDT, routinely collected data will be used to evaluate the effectiveness of the CCDT in improving utilization of mental healthcare services among children and adolescents or their caregivers.

STUDY OBJECTIVES

Primary objective

To examine whether the CCDT is effective in increasing utilization of TPO's mental healthcare services among children and adolescents after introducing pro-active case detection using the CCDT in the Bidi Bidi, Rhino, Omugo, Kyaka II, and Kyangwali settlements in Uganda compared to practice-as-usual.

Secondary objectives

1. To examine the proportion of help-seeking (i.e., mental health care utilization) following pro-active case detection using the CCDT (independent of between-group comparisons).
2. To examine implementation outcomes in terms of the acceptability, appropriateness, and feasibility of using the CCDT at scale for community gatekeepers.
3. To examine community gatekeepers' attitudes towards mental health problems after the introduction of the CCDT, relative to rates pre-training.

Research questions

1. Can proactive community case detection using the CCDT increase utilization of TPO's mental healthcare services among children and adolescents in the Bidi Bidi, Rhino, Omugo, Kyaka II, and Kyangwali settlements in Uganda?
2. What is the proportion of children and adolescents who seek mental health care as a result of having been detected using the CCDT?
3. Is proactive community case detection using the CCDT acceptable, appropriate, and feasible to implement at scale in the Bidi Bidi, Rhino, Omugo, Kyaka II, and Kyangwali settlements in Uganda?
4. How do community gatekeepers' attitudes towards individuals experiencing mental health problems relate to the implementation of the CCDT in the Bidi Bidi, Rhino and Omugo, Kyaka II, and Kyangwali settlements in Uganda?

STUDY DESIGN

This study uses a pragmatic stepped-wedge cluster randomized trial (SW-CRT) design to evaluate the effectiveness of proactive case detection with a nested qualitative study to assess implementation outcomes of using the CCDT at scale. This study will be conducted in the northern (Bidi Bidi, Rhino, and Omugo settlements) and western (Kyaka II and Kyangwali) settlements in Uganda and is embedded in an ongoing programme until April, 2023.

Pragmatic stepped wedge cluster randomized design

A visual example of the SW-CRT design with key terminology as recommended by the Consolidated Standards of Reporting Trials (CONSORT) extension can be found in Figure 1. The SW-CRT is described by Hemming and colleagues [15] as a design that:

> '…includes an initial period in which no clusters are exposed to the intervention. Subsequently, at regular intervals (the "steps") one cluster (or a group of clusters) is randomised to cross from the control to the intervention under evaluation. This process continues until all clusters have crossed over to be exposed to the intervention. At the end of the study there will be a period when all clusters are exposed. Data collection continues throughout the study, so that each cluster contributes to observations under both control and intervention observation periods. It is a pragmatic study design, giving great potential for robust scientific evaluations that might otherwise not be possible.'

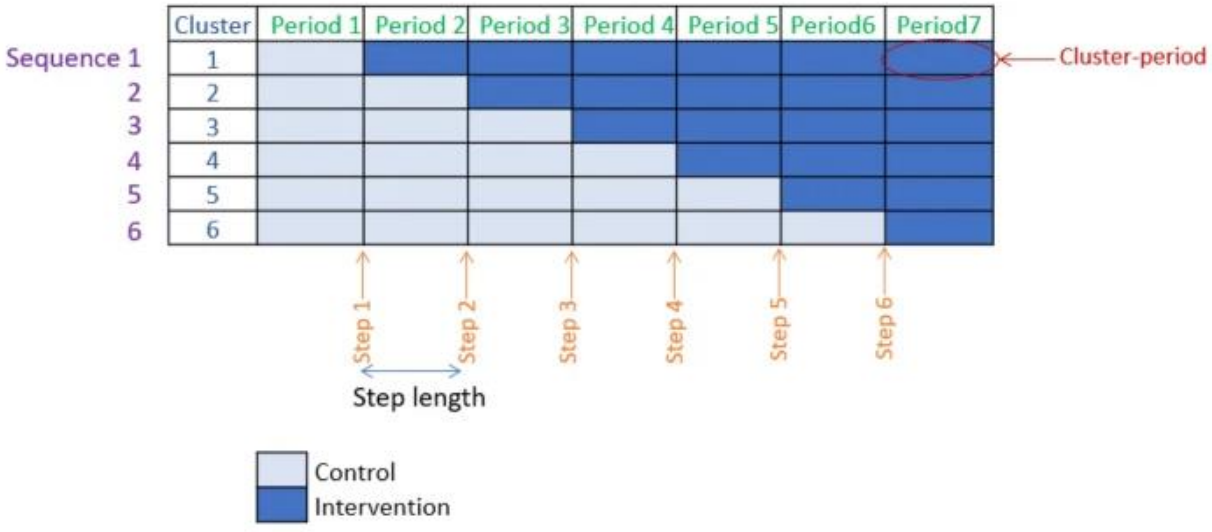


Figure 1 Example SW-CRT diagram [16]

In contrast to explanatory trials, in which the CCDT would be evaluated under 'optimal conditions', this study uses a pragmatic approach. The CCDT will be integrated into routine practices and evaluated under these routine conditions, using data that are routinely collected. This implies that; (1) users of the CCDT (i.e. 'community gatekeepers') will be selected from WCH's and TPO's current networks (i.e. community based structures, teachers, community facilitators); (2) community gatekeepers will be trained in using the CCDT during their daily routine activities to detect children and adolescent in need of care and promote help-seeking at TPO; (3) TPO will continue to assess the needs, provide adequate mental healthcare or refer to other organizations as usual to whomever accesses their services; and (4) that data collection follows existing (albeit slightly adjusted) routine monitoring systems.

The staggered approach of a SW-CRT combined with integration in routine practice is chosen because of; (1) the current lack of evaluated low-cost tools to improve community-level identification and help-seeking among children in need of mental healthcare; (2) the promising previous study findings that have shown that the CCDT is an adequate and accurate tool to fill that gap [13, 14]; and (3) logistical reasons that makes the introduction of the CCDT and training of community gatekeepers most practical if it is done per zone and in stages. Additionally, randomisation per zone minimises contamination between the two arms. The SW-CRT design is therefore particularly suitable for this study.

Qualitative study

In addition to the effectiveness, a nested qualitative study will assess the main outcomes that may influence the implementation at scale. Qualitative feedback from gatekeepers will be obtained during the adaptation process of the CCDT, during supervision meetings and post-implementation.

Since the CCDT will be integrated into routine practices of WCH and TPO, the implementation of the programme and routine data collection continues after the SW-CRT period at least for the entire duration of the programme (i.e., April, 2023).

METHODS

Study Setting

The CCDT will be introduced in the Bidi Bidi, Rhino, Omugo, Kyaka II and Kyangwali settlements in Uganda. Uganda currently hosts the fourth-largest refugee population in the world with an estimated 1,423,740 refugees and asylum-seekers in the country as of April 2020 [17]. The

majority - 880,367 - are from South Sudan, together with 414,831 from DR Congo, 48,287 from Burundi and 80,255 from other countries [17]. Children represent 61 per cent of the affected population and face a range of ongoing daily stressors such as separation from family members and peers, poverty, discrimination and protection issues that affect their psychosocial wellbeing and mental health, and can increase the vulnerability of developing mental health issues [18]. According to the joint inter-agency Multi-Sector Needs Assessment (MSNA), over 20 per cent of refugee households reported at least one member within the household experiencing psychological distress and requiring support. Furthermore, the settlements in the northern and western part of the country reported high numbers of suicides, with case records reporting up to one case per week [3].

In terms of the administrative structure, each settlement is divided into zones, and zones are divided into villages, clusters and blocks. This is an administrative unit within the settlements where the study will be implemented.

Bidi Bidi, Rhino, Omugo are located in the Northern part of Uganda. Bidi Bidi settlement was established in September 2016, and has rapidly become Uganda's largest, and the world's second largest refugee settlement. Bidi Bidi is composed of five zones, with an estimated total population of children and adolescents aged 5-17 years old of 125,923. Originally established in 1980, Rhino Camp is estimated to be the fourth largest refugee camp in Uganda. Rhino camp is composed of six zones. Omugo is an extension of Rhino Camp and is composed of one Zone, which is sub-divided into six small sub-zones. It has an estimated total population of children and adolescents of 58,898. Kyaka II and Kyangwali are located in Western part of Uganda. Kyaka II was established in 2005, and has a total estimated child and adolescent population of 49,776 and is composed of nine zones. Kyangwali was established in 1960, is composed of ten zones, and has a total estimated child adolescent population of 48,264 [19].

Selection of study sites

The total number of zones in the study catchment area will be 28 zones. These zones will be selected from Bidi Bidi (3 zones: zone 3, zone 4, zone 5), Rhino (5 zones: Ofua Zone, Odobu Zone, Siripi Zone, Tika Zone, Eden Zone), Omugo (1 zone: Omugo Zone), Kyaka II (9 zones: Sweswe, Byabakora, Mukondo, Itambabiniga, Bwiriza, Kakoni, Buliti, Kaborogota, Bukere) and Kyangwali (10 zones: Maratatu, Mombasa, Maratatu, Kavule, Nyampindu, Kyebitaka, Maratatu, Mukarange, Maratatu, Kentomi) refugee settlements (Annex 2: overview of all the zones names).

The study sites were chosen based on the following criteria:

1. Availability of MHPSS services for children, adolescents and caregivers:
    - TPO will be present in each study site. Therefore, each study site has social workers and a supervising clinical psychologist with sufficient capacity to respond to an increase in children and adolescents seeking help for mental health problems;
2. Sufficient and safe referral options for children and adolescents in need of acute (mental) health or child protection assistance not offered by TPO:
    - TPO will be present in each study site and will follow standard operating procedures with regards to referral to adequate services in case TPO is not able to respond. This will be handled by the supervising clinical psychologists, and includes for example referral to psychiatrists at district or regional referral hospitals. Referral pathways for each settlement are available upon request.
3. Strong community relationships and access to community gatekeepers;
    - TPO and WCH Uganda will be present in all study sites, and the work will be implemented through existing networks of trusted and respected community members.
4. Routine data collection systems in place:
    - Sites need to be able to yield reliable outcome data on utilization of TPO's mental healthcare services among children and adolescents or their caregivers.

Clusters

The CCDT will be introduced and rolled-out sequentially in 28 geographically distinct zones over the course of 9 months, which are nested within five settlements. The CCDT, and proactive case detection, is implemented at zone-level. The catchment area of a community gatekeeper (i.e., the area they serve) is equal to a zone. Each zone will therefore be considered a cluster in this study. The number of gatekeepers per zone will be dependent on the population size in the zone, our aim is to train 1 gatekeeper per 3000 residents.

Four zones will transition from *pre-CCDT introduction and implementation* (i.e., the control condition) to *CCDT implementation* (i.e., intervention condition), at one-month intervals (i.e., steps), until all zones are implementing the CCDT (Intervention). The order in which the CCDT is introduced in each zone will be determined at random prior to the start of the implementation (before October, 2021). By the end of the SW-CRT period (i.e., 9 months after the start) the CCDT will be introduced and implemented in all 28 zones.

The implementation of the programme and routine detection and utilization data collection continues for the entire duration of the programme (i.e., April, 2023).

Participant Recruitment and Eligibility Criteria

Community gatekeepers

A total of up to N=200 community gatekeepers will be selected from WCH's and TPO's existing networks and community-based structures. They include: Village Health Teams (VHTs), teachers, group activity facilitators, child protection committee members, local community leaders and refugee committee leaders. They will be selected, based on the below criteria, by WCH's and TPO's Project Coordinators, responsible for ongoing programming with children and adolescents in each cluster.

Specific inclusion criteria are:

- At least 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.

Community gatekeepers will be invited for a two-day training and monthly supervision and debrief meetings (for the duration of CCDT implementation in each of the zones) as part of this project. During the first two months, the supervision sessions will be bi-weekly, after that it will continue on a monthly basis. Consent will be sought for their participation in the project as community gatekeepers and for their participation in the nested qualitative study to capture their feedback on the implementation outcomes (see Annex 4.3). Following usual practices within WCH and TPO's current work, active gatekeepers will be provided transportation and lunch when called for the meeting. They will also be provided airtime to follow up and report on the cases. Regular monthly incentive is not planned under this project. Community gatekeepers from the same zone will be linked to TPO's clinical team serving their zone.

Children, Adolescents, and their Caregivers

Children, adolescents aged 6-18 years old, and their caregivers will be proactively identified by the trained community gatekeepers based on a match with the CCDT (i.e., children and adolescents in need of mental healthcare services). Whenever a trained gatekeeper encounters a child or adolescent that matches with the tool, they will hand out a referral card for TPO and encourage help-seeking at TPO's clinical team serving their zone. Consent procedures are described in the following sections and in Annex 3.

Research, Program and Clinical team

The research team consists of the following roles and individuals:

- Principal investigator: Prof. Dr Mark J.D. Jordans, War Child Holland and Amsterdam Institute of Social Science Research, University of Amsterdam.
- Co-Principal investigator: Dr Rosco Kasujja, Department of Mental Health & Community Psychology, Makerere University College of Humanities & Social Sciences (CHUSS), Uganda
- Co-investigator: Sandra Agondeze, War Child Holland Uganda.
- Co-investigator: Myrthe van den Broek, War Child Holland and Amsterdam Institute of Social Science Research, University of Amsterdam
- Co-Investigator: Prof. Dr. Brandon Kohrt, Department of Psychiatry and Behavioural Sciences, George Washington University, USA.
- Co-Investigator: Dr M. Claire Greene, Columbia University Mailman School of Public Health, Program on Forced Migration, Heilbrunn Department of Population and Family Health, USA
- Collaborator: Racheal Kisakye, Clinical Psychologist, TPO Uganda, P.O. Box 21646 Kampala, Uganda

This team will be responsible for the oversight of the present research, including the monitoring of the conduct and progress of the research in adherence with the present research protocol. The research coordinator will be working full-time for the project duration and will oversee all aspects of data collection and lead the contextualization and local adaptation of processes and tools.

The program team consists of:

- WCH Uganda's Programme Manager
- TPO's Head of Programmes

- WCH and TPO's M&E Managers
- WCH's Project Coordinators (2) in the West Nile and South West

This team is responsible for the in-country oversight and management of programme activities and will support the contextualization and adaptation of research tools and processes, support data analysis and training of gatekeepers. Furthermore, this team is responsible for routine monitoring and evaluation of the project.

The clinical team consists of:

- TPO's clinical psychologists
- TPO's social workers
- TPO's volunteer psychosocial assistants

The clinical psychologist leads the clinical team and is overall responsible for assessing the needs and ensuring adequate mental healthcare for the detected children and adolescents – either at TPO or through a referral to external services. The clinical psychologists supervise a team of social workers. Group based focused mental healthcare is provided by social workers, under close supervision from a clinical psychologist. Children and adolescent in need of specialized, individual treatment, will be treated by the clinical psychologist and or referred to external services. Clinical psychologist and social workers are assisted with translations and community mobilization whenever needed by the volunteer psychosocial assistants. The clinical team will be linked to a group of community gatekeepers that are active and live in the same zone.

Outcome measures

Primary outcome measure

The primary outcome is utilization of TPO's mental healthcare services among children and adolescents detected by the CCDT. Utilization in this study will be defined as initial encounters with TPO's mental healthcare among children and adolescents 6-18 years old or their caregivers, or re-entry into services for children and adolescents that have not been using TPO's services for 6 months. This is measured in two ways:

(1) Service utilization data: the number of children and or adolescents aged 6-18 years old that seek mental healthcare services from TPO, compared to utilization rates of practice-as-usual (i.e., during the pre-CCDT period). TPO's routinely collected monthly mental health service utilization data will be used for this. Following routine practices, upon intake, TPO's clinical team completes a 'case registration form' (see Annex 4.1).

(2) The proportion of children and adolescents detected by the CCDT as in need of mental healthcare that seeks help at TPO. Two data sources will be used and compared for this:

a. Detection data: number of detected cases per gatekeeper. Gatekeepers will be trained in keeping a log of the number of detected children while using the CCDT (see Annex 4.2). Gatekeeper logbooks will be collected bi-weekly by one of WCH's facilitators attached to the zone and handed over the project officers who will be trained in entering the data in a digital master sheet.
b. Service utilization data: Number of cases contacting TPO as a result of a community gatekeeper trained in the CCDT handing out a referral card. The same 'monthly mental health service utilization data' (see outcome 1 above) will be used for this. TPO's clinical team will be trained to ask all new clients (children, adolescents or caregivers) an intake question regarding the reason for seeking help (including the community gatekeeper handing out the referral card as one of the options). This data is entered by the clinical psychologist in the 'case registration form' used upon entry.

The impact of the above outcome measures will be determined in three ways: (1) Trends in monthly utilization data from TPO's service points; (2) comparison of clusters where the CCDT has been implemented (experimental condition) with clusters where the CCDT has not yet been implemented (control condition); and; (3) proportion of CCDT cases detected that sought help at one of TPO's service points. This data will be captured through routine reporting using the referral card, and intake questions.

Secondary outcome measure

Secondary outcomes include the (1) acceptability and appropriateness of the CCDT according to trained community gatekeepers, (2) the feasibility of using the CCDT at scale, and (3) changes in attitudes towards individuals experiencing mental health problems among community gatekeepers:

1) Acceptability and appropriateness are defined as the satisfaction of community gatekeepers with various aspects of the CCDT tool and perceived fit and relevance of the CCDT tool, adapted to the local context in which it will be employed in the refuge settings. This will be assessed prior to implementation and will be assessed as part of WCH's ongoing program activities. Where, four community adaptation workshops were conducted with 20 community gatekeepers about the different emotional and behavioral problems related to mental health amongst children, these were subsequently used for the creation of the vignettes (one for emotional problems and one for behavioral problems). Furthermore, based on the problems that have been identified in the

communities, we have worked with a local artist to create context-sensitive illustrations. A focus group discussion (FGD) was organized in the 5 settlements in selected zones with 25 community gatekeepers to assess; (a) the level of understanding of the illustrations and vignettes, (b) if they recall a child in their vicinity who experienced similar symptoms, (c) whether they were comfortable by the way the cases were presented in the vignettes and illustrations and (d) the extent to which the CCDT can be successfully used by gatekeepers during their daily routine tasks. The FGD was conducted in their local languages using the translated vignettes including Swahili, Kinyabwisha, Lugbara, Kakwa, Kuku, and Juba Arabic. Based on the FGD further adaptations to the tool were made. Please refer to Annex 4.3 for the topic guides used for this.

2) Feasibility is defined as the extent to which the CCDT can be successfully used at scale to detect children and adolescent in need of mental healthcare and promote help-seeking. Qualitative data from gatekeepers will be gathered at two moments:

i. During supervision sessions: feedback will be gathered about their satisfaction, the actual fit and utility of the CCDT for everyday use and their motivation with regards to using the CCDT during their daily routine tasks. Questions will focus on the barriers and facilitators that gatekeepers face in using the CCDT. Please refer to Annex 4.3 for the topic guides for supervision.
ii. Post-implementation FGDs (n=2) and KIIs (n=6). Questions will focus on the barriers and facilitators that gatekeepers faced in using the CCDT. Please refer to Annex 4.3 for the topic guides for the FGDs and KIIs.

This qualitative data will also be used to interpret the detection trends and supervision attendance per gatekeeper over time, using the gatekeeper logbooks.

3) Attitudes among community gatekeepers towards mental health problems are measured through preferred social distance towards individuals experiencing mental health problems. This will be assessed at pre-training, intermediate and at the end of the project. Social distance is defined as the degree to which people are willing to accept the individuals experiencing mental health conditions in regular social life [20]. Social Distance Scale (SDS) will be used for this. Explicit stigmatizing attitudes questionnaire [21] widely used in mental health [22] in global stigma comparisons [23]; the Nepali version will be adapted for this and has 12 self-report questions on a scale of 1 to 6. Please refer to Annex 4.4. The tool will be translated to the six different languages (Swahili, Kinyabwisha, Lugbara, Kakwa, Kuku, and Juba Arabic), following a process for use in cross-cultural research. Also, we will be conducting cognitive interviews on all measures being

used, in order to assess understandability of the translated tools. The translated tools will be further adapted on the basis of these cognitive interviews.

Instruments

Table 1 Outcomes, Indicators, Data Source, and Tools

Outcome Measure	Indicator	Data source	Tools/Instruments
Utilization of mental healthcare services	Initial encounters with TPO's mental healthcare per month among children and adolescents 6-18 years old, or re-entry into TPO's mental healthcare services for children and adolescents that have not been using TPO's services for 6 months.	TPO's routine mental health utilization data.	TPO's standardized case registration form (Annex 4.1)
Proportion of CCDT positives that sought help at TPO as a result of the CCDT.	Number of CCDT positives that utilized TPO's mental healthcare as a result of the CCDT.	Detection data: Gatekeeper log on number of detected children.	Gatekeeper Log (Annex 4.2).
		Service utilization data: TPO's routine mental health utilization data.	Single intake question included in the case registration form about the referral method.
Acceptability and appropriateness of the CCDT	Satisfaction with various aspects of the CCDT and perceived fit and relevance of CCDT.	Feedback from potential gatekeepers prior to using the tool.	Topic guide FGD (Annex 4.3)
Feasibility of using the CCDT at scale	Barriers and facilitators in using the CCDT in routine activities.	Gatekeepers' attendance and feedback during supervision meeting	Topic guide supervision (Annex 4.3)

		Gatekeepers feedback during post-implementation FGD and KII's.	Topic guide FGD/KII (Annex 4.3)
Attitudes towards mental health problems	Social distance defined as the degree to which people are willing to accept the individuals experiencing mental health conditions in regular social life.	Pre-, intermediate and post-training	Social Distance Scale (Annex 4.4)

Sample Size

Sampling takes place at zone level. The number of children and adolescents that will be detected and that will utilize TPO's services/service points per month within each zone will be determined as primary outcome of this evaluation. Using existing utilization data, we estimated the number of zones required to detect a 20% difference in utilization rates pre- to post-CCDT implementation with at least 90% power. Among the zones for which we had existing utilization data available (n=26 zones), we estimated a mean of 17.1 initial encounters with mental healthcare per month per zone (SD=20.1, Median=11.8, IQR=4-24). We conservatively estimated utilization to equal zero in the two zones for which we had missing information. We also conducted a sensitivity analysis by imputing utilization rates for the two zones with missing data by selecting a random number from a Poisson distribution that reflected available utilization data. The intraclass correlation of utilization among zones within a settlement was estimated to be low (ICC=0.115).

Following methods developed by Woertman and colleagues [24], we estimated the minimum sample size required for parallel-groups randomized controlled trial and multiplied that value by the design effect for a stepped-wedge trial over a range of steps to estimate the number of zones required for this study [25]. Twenty-eight zones with seven steps would provide greater than 90% power to estimate a 20% difference in utilization between pre-CCDT and post-CCDT implementation. CCDT will be introduced in four zones per step (i.e., one-month each in length) and monthly utilization data will be collected from each zone the day before the next step.

Randomization

Due to the community-based nature of the approach (i.e., implemented at the level of the zone) and integration of the CCDT into routine practice, randomization takes place at the zone level.

Data is therefore collected per zone, instead of on the individual child, adolescent or caregiver level. Each zone will be randomized to a sequence and start timing for when the CCDT will be introduced there using a random number generator in Stata, Version 17. Randomization will be done by the lead statistician based in the USA.

Intervention: Community Case Detection Tool

The Community Case Detection Tool (CCDT), is a tool for trusted and respected community members, without a professional mental health background, that supports proactive identification of children and adolescents in need of mental healthcare services to encourage help-seeking at available adequate mental health services. The CCDT capitalises on people's almost universal skill to easily recognise overall patterns of behaviour in others. The CCDT is made up of illustrated narratives depicting common examples of childhood psychological distress, such as social withdrawal, school refusal, aggression, sleep problems, unexplained physical illness and injuries, and loss of hope. See Annex 1 for an example of the CCDT, developed in Sri Lanka. Each narrative is based on specific cultural idioms of distress to allow for simple identification. We are currently adapting the tool to the Ugandan context through input from local key stakeholders and service providers. It will be available in most common languages spoken in the five settlements, including Kiswahili, Kinyamwisha, Juba Arabic, Lugbara, Kakwa and Kuku.

The narratives avoid using any stigmatising or psychiatric terminology and are phrased in simple, familiar language. The illustrations make the tool even more accessible to people with different literacy levels. These narratives are paired with a simple decision diagram - which allows community gatekeepers to determine the level of match and advise on follow-up actions.

When a child matches the patterns of behaviour presented through the tool, the community gatekeeper will encourage help-seeking and hand out a referral card with information about TPO. If they decide to seek help, TPO's clinical team will conduct a formal assessment and provide care or they refer the child and caregiver to other available services, depending on their needs. Children and adolescents in need of urgent support will be directly referred to a mental health professional.

Control Condition

In the control condition (i.e., zones pre-introduction of the CCDT), practice-as-usual with regards to identification and referral takes place until the CCDT in introduced. Practice-as-usual consists of awareness raising activities organized by TPO. This happens through psycho-education group

sessions, home visits, radio talk shows and community dialogue sessions. These methods are used as community entry strategy, to provide information about mental health services, to assess broad mental health needs in the community and provide therapy or medication follow up. As a result, caregivers will refer themselves, or the volunteer psychosocial assistants or social workers identify children and adolescents in need of care.

Any changes in identification methods during the implementation of this study will be reported to the research team.

Procedures

Training and supervision of clinical team

All members of the clinical team will be trained on the protocol, using the case register forms, informed consent/assent, ethical principles, child safeguarding, reporting and managing adverse events, and data management. The training will be conducted by the research team, and will be a two-day training. Since this study is embedded in routine practices, the clinical team will already be trained by TPO in their clinical procedures and treatment but a one day of refresher training will be organized by TPO for the clinical team.

Training and supervision of program team

The project officers involved in data collection and management will be trained in the protocol, study procedures and informed consent/assent, ethical principles, data collection and management, child safeguarding and reporting and managing adverse events. The training will be conducted by the research team, and will be a two-day training. The co-investigator/research coordinator will oversee ethical conduct, data collection and data management and will arrange monthly meetings with the clinical and program team involved in data collection and management.

Training and supervision community gatekeepers

The research team will arrange a two-day training of trainers in using the CCDT for TPO's clinical psychologists and WCH's psychosocial support project officers before the start of the study. Gatekeepers attached to the same zone will be trained in the week prior to the transition step. This will be a two-day training in using the CCDT and help-seeking promotion and will be conducted by one of TPO's clinical psychologist and one of WCH's psychosocial support project officers working in the same zone/settlement. The training will be conducted in English and their local language and involves multiple interactive discussions, case studies and role-plays and will address the following topics:

- Responsibilities and child safeguarding
- Basic information about the topic of child and adolescent mental health
- Detection tool and identification procedure per version
- Ethical issues associated with proactive case-finding
- Basic training on consent to gather information
- Stressing that referral to in-depth assessment is encouraged, but never imposed

All gatekeepers will conduct several simulation sessions of the use of the tool, in order to develop their skills and to allow the research and program team to detect any problems with implementation.

The community gatekeepers will be linked to one clinical psychologist who will offer ongoing support and supervision. During the first two months, the supervision sessions will be bi-weekly, after that a monthly supervision meeting will be organized at the end of every month. These sessions will be led by a clinical psychologist and supported by one psychosocial support project officer. The purpose of these sessions is to support the gatekeepers' wellbeing, to oversee the quality of their work and to discuss challenges and possible ways to overcome them.

Local Permissions and authorization

Local permissions to approach communities and support to conduct this study will be sought from community and district officials in the study areas, prior to commencing the trial.

Informed Consent and Assent procedure

Consent and assent will be sought from caregivers, children and adolescents that seek help, and from community gatekeepers:

<u>Caregivers, children and adolescents</u>

Informed consent/assent will be obtained at two levels:

- By gatekeepers, at community level upon detection: This study will be integrated in routine practices and community gatekeepers will engage caregivers, children and adolescents as they would usually do in routine practice. They visit the family and provide information about TPO's services and encourage help-seeking. At this stage, there is no engagement in any study activity yet, however some information will be collected for study purposes. Gatekeepers will therefore provide a verbal summary of the project to caregivers, adolescents and children upon detection and help-seeking encouragement (see Annex 3.2). After providing this information, gatekeepers will ask verbal consent/assent to document and release their

information to the study team for study purposes. Information will only be documented if both the caregiver and child/adolescent give their verbal consent. Caregivers, or children/adolescents that do not consent to the sharing of data will not be included in the study, but will continue to be involved in any service delivery they need– if they desire to make use of these services. If a child/adolescent is detected but there is no caregiver available, they will be provided similar information regarding help-seeking but their data will not be used. For caregivers, adolescents and children that consented, gatekeepers will record the date of verbal consent and document the child's and family name, contact details, age, version of the CCDT used and if it concerns a new or an old detection in their logbook.

- By clinical team, at service level, upon entry to care: consent will be sought from caregivers/parents of children below 17 years and adolescents, and assent form for children between 6 to 17 years, that seek help at TPO. The clinical team will provide information about the study and ask for consent to document and release their de-identified information with WCH for study purposes (see Annex 3.3 and 3.4). Caregivers, or children/adolescents that do not consent to the sharing of data will not be included in the study, but will continue to be involved in any service delivery at any time. Since it concerns routinely collected data, their family name, age and phone number is needed in order to delete their information and exclude it from analysis.

Community gatekeepers: verbal and written informed consent will be obtained before participating in this study. They will first be given written information about the program and their role in their local language. This information will be handed out by the project officer engaged in selecting the gatekeepers (see Annex 3.1). For community gatekeepers that consented, the project officer will record the gatekeepers' name, age and level of education, occupation and role in the community.

All completed consent documents will temporarily be retained at TPO's field offices for monthly collection by the research team. All participants (community gatekeepers and caregivers) will be given the name and number of the study contact person in Uganda in case they have further questions, or wish to withdraw from the study. All participants will have the right to withdraw from the study and without obligation to provide a reason.

DATA COLLECTION AND PROCESSING

Description of data collected

Both quantitative and qualitative data will be collected.

Quantitative data

Quantitative data will be collected at two levels:

1) Detection data – Gatekeepers will be provided with a logbook in which they will record the information about the detection (see Annex 4.2). A unique study ID will be created for each new case, this code will be linked to the gatekeepers' initials and cannot be traced back to the individual. The following information will be collected by gatekeepers:

- Study ID
- Child's demographic information: age, gender, status (refugee/host), village, zone and settlement of residence
- Contact details family
- Version of the CCDT used (i.e., the CCDT vignette that matched their observations)
- Date of detection and engagement
- Date of verbal consent/assent obtained

This data will be collected in the zones where the CCDT is introduced, from the moment that the gatekeepers start using the CCDT, until the end of the project duration (i.e., April, 2023).

2) Service utilization (TPO) - routine data will be collected at TPO for all clients seeking care. An anonymized client code will be assigned and used as the only identifier. The following variables will be collected in the Case Registration Form (see Annex 4.1):

- Client ID
- Demographic information: age, gender, status (refugee/host), village, zone and settlement of residence
- Referral type: through CCDT or routine
    - This will be obtained through the referral card handed out by the gatekeeper using the CCDT (i.e., 'someone in the community approached me, handed out a referral card and encouraged me to seek help here')
- Date of intake
- Type of visit: new, re-entry or recurring/maintenance visit.
- Mental health diagnosis
- Service or type of treatment provided by TPO, or referral made

- If treatment was initiated and completed.

This data will be collected from the beginning of the study in all zones, until the end of the project duration (i.e., April, 2023). A study specific data extraction sheet will be developed which will be used to collect all the information according to the primary and secondary outcomes.

Qualitative data

Qualitative feedback from community gatekeepers who will be using the using the tool to understand the acceptability, appropriateness and feasibility of using the CCDT will be collected during the pre-implementation FGD's, supervision meetings and post-implementation FGD's and key informant interviews (KIIs) with community gatekeepers. These will be selected by identifying; (i) active community gatekeepers (i.e. those that detected most of the children), and; (ii) non-active community gatekeepers (based on number of cases they detected) to hear from both their experiences. We will sample these two groups based on a 1:1 ratio.These feedback meetings will be led by the clinical psychologist and supported by the project officer where a topic guide with semi structured questions regarding the barriers, facilitators and experience in using the CCDT will be used. These sessions will be conducted in their different local languages. Detailed written notes of the feedback during the supervision meetings will be collected by WCH's project officer in a structured format and digitalized after each session. The post-implementation FGDs (n=2) and KIIs (n=6) will be audio recorded, transcribed and translated for analysis.

Description of quantitative data flow and entry system

The different forms of data will follow a different data flow and entry system as described below:

Detection data (gatekeeper logbook)

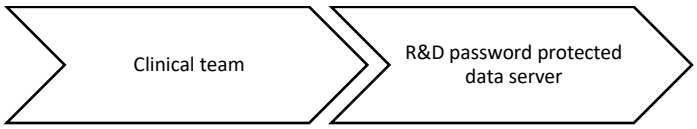
Figure 2 Data flow: Detection

Gatekeeper logbooks will be collected every two weeks by zone facilitator/psychosocial volunteers linked to that zone, and handed over to the clinical psychologists at TPO. The paper versions will be stored in a secure lockable cabinet at TPO's field office. A two-week timeframe is selected to allow for quality monitoring and follow up.

TPO's M&E Manager will enter the number of cases detected in a master excel sheet, stored on a password encrypted secure data server of the R&D Department of WCH.

Service utilization (case registration forms)

Figure 3 Data flow: Service utilization



Following routine practices, all clinical data will be collected and consolidated by the clinical team at TPO. Case registrations forms will be completed by the clinical team using an electronic data entry form on a tablet. Data entered will be saved and stored on a password encrypted secure data server of the R&D Department of WCH, which will be password protected and synced. Access to the study data sets will only be accessible by the WCH core research team members.

Pretesting of data collection tools

Data collection tools will be pretested to ensure consistency prior to the study start:

- The Case Registration form: will first be used at TPO service points together with other case registration forms, prior to the study start to ensure adaptation to the local context during routine serve provisions,
- The gatekeeper log book: will be pretested during the training. Information that is not clear will be updated prior to the study start. This will be translated to Swahili, Kinyabwisha, Lugbara, Kakwa, Kuku, and Juba Arabic.
- Interview tools (FGD and Supervision Topic Guides, and Social Distance Scale): will be pretested prior to using the tools. A number of selected gatekeepers will be invited for a meeting after reading information sheet and signing consent form, during this meeting, selected questions in the topic guides and social distance scale will be asked. Questions which are not clear, will be changed. The tools will also be translated to Swahili, Kinyabwisha, Lugbara, Kakwa, Kuku, and Juba Arabic.

Data management

The WCH Data Management Policy serves as guidance on all data management and data sharing issues (policy available upon request).

Quantitative data

To further improve the quality of data collected, the research coordinator/co-investigator 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 field teams through the M&E managers 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 the M&E Managers, and the remaining data issues will be adjudicated.

The paper data files will be collected from the field offices on a monthly basis and stored in a locked cabinet in the WCH office.

Qualitative data

The project officer will upload the note forms on a password encrypted secure data server of the R&D Department of WCH after each supervision meeting.

Audio files will be stored on a password encrypted secure data server of the R&D Department of WCH after each supervision meeting. The server will be password protected and accessed from password protected and encrypted laptops. The project officer will only get the rights to upload documents, not to access any data. The paper data files will be collected from the field offices on a monthly basis and stored in a locked cabinet in the WCH office.

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 WCH CCDT research team, the M&E managers and project officers. The latter parties and any other external 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 WCH 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 on a monthly basis and be stored securely in the lockable cabinet at one of TPO's field offices in the settlement.

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. Mental health records will be stored at TPO as per standard practices.

Data ownership and sharing

WCH has, in all cases, ownership of the research data, and for the purpose of this study a data sharing agreement will be signed between WCH and TPO.

Statistical Analysis plan

We will present the following results, based on both qualitative and quantitative data:

Primary outcome: Utilization of mental healthcare services (quantitative). This will be determined in three ways: (1) Trends in monthly utilization data from TPO's service points; (2) comparison of clusters where the CCDT has been implemented (experimental condition) with clusters where the CCDT has not yet been implemented (control condition); and; (3) proportion of CCDT cases detected that sought help at one of TPO's service points. This data will be captured through routine reporting using the referral card, and intake questions.

Secondary outcomes:

1) Proportion of CCDT positives that sought help at TPO as a result of the CCDT (quantitative)
2) Acceptability and appropriateness of the CCDT (qualitative)
3) Feasibility of using the CCDT at scale (qualitative)
4) Attitudes towards mental health problems (qualitative)

Mixed-effects Poisson regression using a log link with clustering of zones within settlements and repeated measures within zones will be used to estimate the ratio of monthly mental health services utilization from the pre-CCDT to post-CCDT implementation periods. Utilization will be standardized using an offset of the log of the child population size estimate in each zone. CCDT implementation, time, and the interaction between CCDT and time since cross-over will be included as fixed effects. The effect of CCDT will be reported as an incidence rate ratio (IRR, 95% CI). Settlement and zone will be included as a random intercept. Heterogeneity across zones and settlements in time trends and treatment effects will be explored as random effects using the interaction between settlement/zone with time and CCDT implementation. If the assumptions of

Poisson regression are not fulfilled, we will estimate a mixed-effects negative binomial model. All analyses will be conducted using Stata, Version 17.

In addition, descriptive within-group analyses will be conducted to assess the proportion of children and adolescents detected by a gatekeeper using the CCDT that utilized TPO's mental healthcare during the entire project period. Among that group we will also assess the number of children and adolescents that initiated treatment and completed treatment.

PROTECTING RESEARCH PARTICIPANTS

Monitoring and ensuring ethical practice

Four committees (Ethics; Data safety management; Research; Implementation) will be responsible for monitoring and ensuring ethical practice in this study.

Table 2 Committee roles and membership

Committee	*Role*	*Members*
Ethics	Oversee the ethical conduct of the research and implementation; Take appropriate action to safeguard research participants.	MAKSHS-REC UNCST
Data Safety Management Committee (DSMC)	Monitor adverse events reports. Take appropriate action to safeguard research participants; Has the mandate to stop the study in case of unreasonable risks to research participants and/or staff.	External to the research team (to be identified)
Research management team	Oversee the research agenda in Uganda; Monitor the conduct and progress of the research and ensure that protocol is adhered to. Take appropriate action to safeguard the quality of the trial.	Principal investigators Investigators Clinical Supervisor TPO Uganda
Implementation	Ensure coordination between research and program implementation.	Principal investigators Investigators Collaborators Programme manager WCH Uganda Head of Programs TPO Uganda

	Clinical Supervisor TPO Uganda
	Programme coordinators WCH – West Nile & South West
	M&E managers

Note. MAKSHS REC = Makerere University School of Health Sciences Research and Ethics Committee. UNCST = Uganda National council for Science & Technology.

Ethical considerations

- **Involvement of minors:** This study includes adults and children younger than 18 years of age (minors are involved). As an organization working with children, our main priority is keeping children safe, we will therefore adhere to our strict standard Child Safeguarding policies (available upon request).
- **Ethical approval:** Similar study with children in the occupied Palestinian territories and Sri Lanka have also been fully approved by a local ethics review committee (i.e., BirZeit University and Eastern University) and endorsed by the Ministry of Education.
- **Informed consent and assent:** Consent and assent is obtained at different levels. Upon detection by a trained community gatekeeper – all caregivers, children and adolescents will first receive a verbal summation of the project and are asked for their verbal consent/assent to collect and release their information for study purposes. Information will only be documented if both the caregiver and child/adolescent's consent. For caregivers, children and adolescent that seek help after being detected the clinical team will hand out an information letter about the project ask them to sign a release of information form that permits TPO share data with the research team regarding how many children, adolescents and caregivers sought help as a result of the CCDT, and to share the routinely collected service utilization data. Caregivers, or children/adolescents that do not consent to the sharing of data will not be included in the study, but will continue to be involved in any service delivery – if they desire to make use of these services. For community gatekeepers verbal and written informed consent will be obtained before participating in this study. All participants (community gatekeepers and caregivers) will be given the name and number of the study contact person in Uganda in case they have further questions, or wish to withdraw from the study. All participants will have the right to withdraw from the study and without obligation to provide a reason.
- **Stigma:** We seek to ensure that involvement in the research does not stigmatize participants in any way, through the following mechanisms: (a) it is a community-based approach, implemented by carefully selected and trusted key-people in the community, rather than

professionals. First of all, the tool and case stories are written with and by local community members – avoiding negative or stigmatizing language. Second, the location of the appointment will be decided by the family and children themselves, and will either be at a community centre/facility or at their house. Third, the community gatekeepers will be thoroughly trained in approaching families, confidentiality and minimizing stigmatization or negative labelling. Fifth, help-seeking as a result of this project will only be encouraged, never imposed. The research team has an extensive background in appropriate adaptation of instruments, consent forms, recruitment material, and other study related resources to minimize stigma and optimize mental health / child protection benefits to all participants.

- **Managing adverse effects:** The research team is considerate of the fact that the study will be conducted with vulnerable children and adolescents that are exposed to adversities and experiencing psychological distress or are at higher child protection risk. However, the risks for participants in this study are considered low. The tool is expected to have a benefit in encouraging and supporting more children and adolescents in need for services – to actually access these. So that eventually severe childhood psychological distress can be prevented and child protection risks can be reduced. The trainings for the research, program and clinical team contains a separate session on how to deal with adverse events or possible persistent or worsening symptoms that may occur. Facilities are in place to monitor this and appropriate actions will be taken based on an established crisis assessment protocol (for instance, referral to more intensive psychological treatment and monitoring of participant by clinical psychologists). Furthermore, War Child has an adverse event reporting procedure in place for all research conducted.
- **Reason for conducting the research in a Low and Middle Income Setting with a vulnerable population:** It is essential to conduct this research in a vulnerable population and with this age group, because rigorous evidence needs to be collected on the effectiveness of this tool and approach which has been especially developed for this vulnerable population. Additionally, it will provide valuable information about how to adapt the intervention and other important considerations for scale up.
- **Longer term duty of care**: Where appropriate, War Child's and TPO's 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 TPO's existing services, or to external services when necessary; costs of these services will be covered as per standard referral processes in Uganda.

Potential risks and mitigation strategies

This trial poses minimal risks to children and adolescents. They may feel uncomfortable during some mental health sessions. Parents/caregivers will nevertheless be informed of possible psychological trauma during the different mental health management programs. Risks specific to participation include the potential for breach of confidentiality, as well as stigma and emotional risks associated with mental health in the community. To minimize these risks, gatekeepers and clinicians will be trained on how to maintain confidentiality, significant efforts are made to inform and involve local communities in new initiatives.

Benefits

The use of the CCDT detection tool provides the following potential direct opportunities for children and adolescents in need of mental health care:

- An improved and early diagnosis of mental health conditions due to the proactive approach and help-seeking encouragement using the CCDT;
- An enhanced prognosis due to timely and appropriate mental health treatment initiation.

Together these factors will positively impact the local MHPSS by improving case detection rates as well as mental health outcomes. It is also hoped that lessons learned from this trial will help to improve MHPSS efforts at national level, when the CCDT is adopted and integrated into MHPSS 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.

Participant's reimbursement

Since the study involves mental health detection and referral using the CCDT, there will not be any cost incurred by the parents or caregivers. Gatekeepers will be provided transportation and lunch allowance when called for the meeting. They will also be provided airtime to follow up and report on the cases. Regular monthly incentive is not planned under this project.

Confidentiality and data privacy

Participant confidentiality is protected at all times and all data collection, storage and analysis procedures will be General Data Protection Regulations-compliant. Participants will be assigned

a Client Code/ ID and pseudonym for qualitative data, and their names will not appear on any data collected. A master list linking IDs and names will be managed by TPO's M&E manager. This list will be stored on a password encrypted secure data server of the R&D Department of WCH. Logbooks collected from gatekeepers will be stored in a secure cabinet at TPO (as mentioned above).

Procedure for keeping the necessary trial data confidential

Individual mental health information obtained as result of this trial will be confidential. Team members are subject to the obligation of professional secrecy and will all be asked to sign a WCH's data confidentiality agreement and child safeguarding policy. Individual data will be made available upon request to the investigators, clinicians in charge of patients' care, and representatives of the ethical and regulatory health authorities in case of external audit or inspection. Disclosure to other third parties is strictly prohibited. Parent(s)/caregivers' consent for this is obtained as part of the consent process. The data recorded during this study will be subjected to computer processing.

Adverse Events and Child Safeguarding

Adverse events reported by research participants, or observed or suspected by members of the research, program or clinical team, will be reported according to WCH Uganda Adverse Events Reporting Procedure (Annex 5). Serious adverse events include:

- Physical, sexual, emotional abuse, neglect or exploitation of a research participant, programme team member or research team member.
- Any child safeguarding concern or case, including any form of abuse and excessive verbal or physical punishment.
- 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).
- Disclosure of current or recent intimate partner violence between adults.
- Suicidal ideation, plan or attempt of a research participant or member of the research of the CCDT team.
- Death of a research participant.
- Injuries or accidents that occur on the route to research activities.

Adverse events will be reported to the Data Safety Management Committee (DSMC) using the *Incident Reporting Form* (Annex 5). 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 WCH and TPO's clinical supervisory team. However, the principal investigators will be responsible for ensuring appropriate response to all adverse events.

The DSMC will regularly review all reports and follow-up of adverse events on a monthly basis and make decisions on further actions to be taken. Adverse events will be reported by the PI to the relevant ethical committees providing oversight, as per their reporting procedures. 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 WCH and TPO's child safeguarding focal points in CCDT implementation sites.

We do not expect serious adverse events to arise from the implementation of the CCDT. Nonetheless, (refresher) trainings for all WCH and TPO's staff involved in this study, including community gatekeepers, will be organized in responding to distress, and protocols to follow in the unlikely event of significantly increased distress. Before being deployed, community gatekeepers will be made aware of the potential stressful nature of the job, and will be supported through debriefing sessions and information on self-care strategies during the monthly supervision meetings.

All partners involved in this study have committed to adhering to War Child Holland's Child Safeguarding Policy (available upon request) which are based on international child safeguarding standards, developed by Keeping Children Safe. Staff will be required to adhere to the Child Safeguarding policy of their organization, which must in turn adhere to these standards and will follow associated reporting procedures and emergency response plans. Any adverse events will be reported as outlined above.

Monitoring (quality control of the study)

Monitoring of the trial implementation and research will be done at three levels:

- Settlement level: monitoring at service level will be done by clinical psychologists. They will ensure that all registers all well filled and completed, all children referred are captured. The right code is assigned.

- Coordination level: monitoring at the coordination level will be done by WCH's program manager and M&E managers. They will ensure that all master sheets are complete.
- Regulatory level: during routine review of patient registers by clinical psychologists, completed participants consents will also be reviewed to ensure completeness and to ensure that every child/adolescent has a consent or assent signed before any data collection procedure. During monthly visits to the field, the research coordinator will also review 10% of the completed participants consents and registers. Any regulatory monitoring by the ethics committee will be communicated and planned on time by the concerned parties.

OUTPUTS AND DISSEMINATION

Outputs

Outputs will include:

- *Academic journal articles*: Results will be published via journal articles (preferably in open access journals); publications and authorship arrangements will adhere to the WCH R&D publication policy. This research project is part of the completion of a PhD degree by Myrthe van den Broek, supervised by the study's Principal Investigator, Professor Mark Jordans (University of Amsterdam). The current project will lead to multiple publications, which will involve all of the study team members. At least two of these publications will be part of the PhD dissertation of Myrthe van den Broek. Together with three other publications by the PhD candidate from prior studies on the same topic, this will constitute the final dissertation. Any publication or communication (oral or written) is decided by mutual agreement between the investigators, and will respect the recommendations: "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Journals".
- *Conferences*: Results will be presented in international conferences, which will be selected based on relevance of the research findings.
- *Workshops*: Workshops will be held with key stakeholders at relevant timepoints over the course of the research study.
- *WCH reports*: One report and memo will be written for the study.
- *CCDT Training and supervision model*: A manual detailing the design and implementation protocol for the CCDT will be written.

Procedure for writing up the final report

The investigators will establish the final report of the study as well as summary report within a year after the end date of the study.

Procedure for informing the study participants of the overall research findings

The final study results will be presented to the investigators and the national authorities. A series of documents (written detailed report, and short summary) will be released to help investigators, national authorities and participants to understand the results of the study. participants may be invited to attend a meeting during which the results will be presented and explained orally.

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ANNEXES

Annex 1: Community Case Detection Tool - Uganda

Annex 2: Study sites overview

Annex 3: Informed consent/Assent forms

Annex 3.1: Invitation and Informed consent form for Community Gatekeeper

Annex 3.2: Verbal Information sheet and consent to record to release CCDT information for Caregiver and Child

Annex 3.3: Information sheet and Informed Consent form for parents or caregivers and adolescents aged 18 years to release mental health service utilization data

Annex 3.4: Information sheet and Child Assent form for children and adolescents 6 to 17 years to release mental health service utilization data

Annex 4: Research Instruments

Annex 4.1: Case Registration Form - CCDT Uganda

Annex 4.2: Gatekeeper logbook

Annex 4.3: FGD and Supervision Topic Guides

Annex 4.4: Social Distance Scale

Annex 4.5: Data extraction sheet

Annex 5: CCDT Adverse Events Reporting Mechanism and Incident reporting form