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Evaluation of the community case detection tool in Northern and Western Uganda

Submission date
28/12/2021

Recruitment status
No longer recruiting

Registration date
30/12/2021

Overall study status
Completed

Last Edited
19/07/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
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 the help-seeking of available mental healthcare services among children and adolescents or their caregivers in need of these services.
The main aim of this study 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 aims are:
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 before training

Who can participate?
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 a 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 the primary outcome of this evaluation.

What does the study involve?
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 adolescents 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 whoever accesses their services; and (4) that data collection follows existing (albeit slightly adjusted) routine monitoring systems.
All gatekeepers will follow a 2-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 the 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 training 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 participants by clinical psychologists). Furthermore, War Child has an adverse event reporting procedure in place for all research conducted.

What are the possible benefits and risks of participating?
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 of services to actually access these so that eventually severe childhood psychological distress can be prevented and child protection risks can be reduced.
This study 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. 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.

Where is the study run from?
The CCDT will be introduced in 28 zones in Bidi Bidi, Rhino, Omugo, Kyaka II and Kyangwali refugee settlements in Uganda.

When is the study starting and how long is it expected to run for?
November 2020 to November 2022

Who is funding the study?
A funder that wishes to remain anonymous. Available upon request.

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MAKSHSREC-2021-167

Study information

Scientific 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

Study objectives
Mental healthcare utilization among children and adolescents will increase after introducing pro-active case detection using the community case detection tool (CCDT) in the Bidi Bidi, Rhino, Omugo, Kyaka II, and Kyangwali settlements in Uganda.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/10/2021 by the Makerere University School of Health Sciences REC (PO Box 7072, Kampala, Uganda; +256 (0)774313924; healthsciences.irb@gmail.com, istella@chs.mak.ac.ug), ref: MAKSHSREC-2021-167

Study design
Stepped-wedge cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Mental health conditions

Interventions
The Community Case Detection Tool (CCDT) is a tool for trusted and respected community members to proactively identify children in need of mental healthcare and to encourage help-seeking. 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. The tool is available in the most common languages spoken in the five settlements in Uganda, 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. This study is led by a partnership between War Child Hollands (WCH) Research and Development Department, WCH Uganda and Transcultural Psychosocial Organisation (TPO) Uganda.

Method of randomization
The CCDT will be introduced and rolled out sequentially in five refugee settlements over the course of 9 months. The catchment area of a community gatekeeper using the CCDT (i.e., the area they serve) is equal to a zone. A zone is an administrative unit in a refugee settlement. Each settlement is divided into zones, and zones are divided into villages, clusters and blocks. Data is therefore collected per zone, instead of on the individual child, adolescent or caregiver level. Each zone in which War Child Holland and TPO Uganda are active will be considered a cluster in this study and randomization takes place at the zone 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. Four zones will transition from pre-CCDT introduction and implementation (i.e., the control condition) to CCDT implementation (i.e., intervention condition) at 1-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. By the end of the SW-CRT period the CCDT will be introduced and implemented in all 28 zones.

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome is the 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'. Service utilization data will be collected monthly from each zone (i.e. cluster) the day before the next step. Furthermore, every cluster provides before and after utilization data, one month before the first step and one month after the final step of the SWT.
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:
2.1. 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. Gatekeeper logbooks will be collected bi-weekly by one of WCH's facilitators attached to the zone and handed over to the project officers who will be trained in entering the data in a digital master sheet.
2.2. 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.

Key secondary outcome(s))

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 of the CCDT according to trained community gatekeepers. 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, the researchers have worked with a local artist to create context-sensitive illustrations. A focus group discussion (FGD) was organized in the five 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.

2. Feasibility of using the CCDT at scale, defined as the extent to which the CCDT can be successfully used at scale to detect children and adolescents in need of mental healthcare and promote help-seeking. Qualitative data from gatekeepers will be gathered at two moments:
2.1. During monthly 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.
2.2. Post-implementation FGDs (n = 2) and KIIs (n = 6). Questions will focus on the barriers and facilitators that gatekeepers faced in using the CCDT. 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 (i.e. after 6 months of using the CCDT) 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. The Social Distance Scale (SDS) will be used for this. Explicit stigmatizing attitudes questionnaire widely used in mental health in global stigma comparisons; the Nepali version will be adapted for this and has 12 self-report questions on a scale of 1 to 6. 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, the researchers will be conducting cognitive interviews on all measures being used, in order to assess the understandability of the translated tools. The translated tools will be further adapted on the basis of these cognitive interviews.

Completion date
08/11/2022

Eligibility

Key inclusion criteria
Two groups of participants are identified. The CCDT employs a gatekeeper model and is developed for trusted and respected community members ('community gatekeepers'). Community gatekeepers use the CCDT to proactively detect children in need of mental healthcare to encourage help-seeking.

Community gatekeepers:
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:
1. At least 18 years of age
2. Trusted and respected members from the community
3. Engaged in promoting child wellbeing
4. Access to children, adolescents and caregivers
5. Demonstrate a high level of empathy and interest in children's wellbeing
6. Willing to provide informed consent and participate in supervision meetings to provide feedback on the feasibility of the approach
7. Willing to sign and follow WCH's Child Safeguarding Policy, Code of Conduct and Code of Ethical conduct in using the CCDT

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.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

Total final enrolment
3323

Key exclusion criteria
Not providing consent/assent

Date of first enrolment
01/02/2022

Date of final enrolment
08/11/2022

Locations

Countries of recruitment
Uganda

Study participating centre
Transcultural Psychosocial Organisation (TPO) Uganda
HO at Wamala Close Road, Kampala
Settlement offices in Kyaka II, Kyangwali, Yumbe, Rhino
Kampala (HO)
Uganda
Plot 3271

Sponsor information

Organisation
War Child

ROR
https://ror.org/01tq9ra93

Funder(s)

Funder type
Other

Funder Name
Wishes to remain anonymous

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from War Child Holland. Data will be stored on a secure server. The contact person for this study is Myrthe van den Broek (myrthe.vandenbroek@warchild.nl). All data will be anonymized.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/07/2024	19/07/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 4.0	21/09/2021	30/12/2021	No	No
Statistical Analysis Plan	version 1	14/09/2022	17/10/2022	No	No