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Evaluating the effectiveness of the psychosocial, movement-based intervention TeamUp in Burundi

Submission date
17/10/2023

Recruitment status
No longer recruiting

Registration date
19/10/2023

Overall study status
Completed

Last Edited
08/10/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[X] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
While the number of children and communities affected by armed conflict, violence and displacement is on the rise, their psychosocial needs are largely neglected, remain unaddressed and under-researched. The evidence for effective Mental Health and Psychosocial Support (MHPSS) interventions, particularly for services focusing on children and adolescents in low- and middle-income countries is limited and with mixed results, particularly for community-based mental health promotion and preventive interventions.
The aim of this study is to strengthen the evidence on the TeamUp intervention. Following promising results from a study on TeamUp in Uganda, the researchers are confident about conducting a full trial to evaluate the effectiveness of the TeamUp intervention on children's psychosocial wellbeing.

Who can participate?
Children from 36 schools, in 4th grade, aged 9-15 years

What does the study involve?
The study will compare children on multiple psychosocial outcomes across four different timepoints: baseline, midline, endline and 6-month follow-up and across three groups:
1. Control group (practice as usual)
2. 12 sessions of TeamUp (3 months)
3. 24 sessions of TeamUp (6 months)

What are the possible benefits and risks of participating?
Risks to participants from the TeamUp intervention are considered to be low, based on previous experience implementing the TeamUp with children in Uganda, South Sudan, Kenya, Ethiopia and other countries. The burden to participants consists of completing questionnaires. Since the proposed project may improve the psychosocial wellbeing of children, facilitators and possibly have positive influences on the peer, class and school environment, the researchers believe that the major potential benefits outweigh the minor burden to participants in the intervention as well as the overall study.

Where is the study run from?
The PI is based in Amsterdam, the Netherlands, yet the Scientific Coordinator is based in Burundi for extended periods of time, particularly for training, pre-study coordination and baseline data collection. Data collection is conducted by Burundian Research Assistants and the daily study coordination is lead by a Burundian Research Coordinator, working closely with the Scientific Coordinator. War Child Holland has an office and operations in Burundi, thus providing human resource, logistical and financial support to the project.

When is the study starting and how long is it expected to run for?
March 2023 to December 2024

Who is funding the study?
Templeton World Charity Foundation (TWCF)

Who is the main contact?
1. Alexandra Bleile, alexandra.bleile@warchild.net
2. Prof. Mark Jordans, mark.jordans@warchild.net

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Additional identifiers

Study information

Scientific Title
Building and strengthening the evidence base of a mental health promotion intervention TeamUp: a cluster randomized control trial in Burundi

Acronym
EvalEffectivenessTeamUpBI

Study objectives
The aim is to evaluate the (cost-)effectiveness of TeamUp in Burundi.

Primary hypotheses:
1. Children in the TeamUp (12 sessions) have significantly better psychosocial outcomes compared to the control group at endline
2. Children in the TeamUp (24 sessions) have significantly better psychosocial outcomes compared to the control group at endline
3. Children in the TeamUp 'higher dosage group' (24 sessions) have significantly better psychosocial outcomes compared to the children in the TeamUp 'lower dosage group' (12 sessions) at endline

Secondary hypotheses:
4. Children who participated in TeamUp have significantly better psychosocial wellbeing at 6-month follow-up (i.e. 6 months after the end of session implementation), compared to the control group
5. Mechanisms, social connectedness, hope and emotional regulation will mediate the change in psychosocial wellbeing as a result of receiving TeamUp.
6. While it is hypothesised above that 24 TeamUp sessions are more effective than 12 TeamUp sessions, it is hypothesised that 12 TeamUp sessions will be more cost-effective compared to 24 TeamUp sessions
7. The implementation of TeamUp sessions, thus the engagement facilitators in the psychosocial movement-based activities while providing them to the children, has a spill-over effect and improves the psychosocial wellbeing of facilitators (service providers) themselves, based on facilitator-reported outcomes
8. Children's behaviour in the classroom and the teacher-student relationship improves as a result of TeamUp over time and compared to the control group classrooms, based on teacher-reported outcomes
9. Children's psychosocial wellbeing improves as a result of TeamUp over time and compared to the control group, also based on caregiver-reported outcomes

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/10/2023, Institute National de Santé Publique (INSP) (Avenue de l'Hopital, No 3, Bujumbura, B.P. 6807, Burundi; +257 (0)22 24 80 76; insp.dr@insp.bi), ref: CNE/23/2023

Primary study design
Interventional

Study design

Three-armed cluster randomized control trial

Study type(s)
Other, Prevention, Quality of life, Efficacy

Health condition(s) or problem(s) studied
Promotion of psychosocial wellbeing/mental health

Interventions
A three-armed cRCT using a type 1 hybrid effectiveness-implementation study design will be used to evaluate/test the TeamUp intervention as well as its implementation strategy. The study will involve returnee and local children in rural areas of Burundi (grade 4, aged 9-15 years) and compare multiple psychosocial outcomes across four different time points: baseline, midline, endline and 6-month follow-up (see more details in timepoints below) and across three conditions:
1. Control group (practice as usual)
2. 12 sessions of TeamUp (3 months)
3. 24 sessions of TeamUp (6 months)

TeamUp is a psychosocial movement-based, mental health promotion intervention, with a non-verbal and embodied-learning approach, consisting of a wide variety of movement-based group games, sports, creative movement, routines, body awareness and breathing exercises.

The researchers used simple randomisation. The randomization was done based on the list of eligible schools (91 mapped, 42 met all the criteria of accessibility, sufficient children, i.e. minimum 48 children in 3rd grade (as these children would likely move on to 4th grade), suitable playground and a minimum 1.5km between schools to avoid contamination). For schools creating mini clusters, randomisation was done to select one or two.
Of the 40 schools, 36 schools were selected at random allowing six reserve schools. The 36 schools were randomly put into one of the three study arms using a computer-generated randomization sequence conducted by the Senior Statistician, based in the Netherlands (only provided with school ID codes/numbers, instead of school names).
https://www.random.org/ -> random number generator for selection of 10 schools
https://randomchoicegenerator.com -> random selection 36 out of list of 42 schools
https://www.random.org/lists/ -> list randomizer to randomize order of arms

Intervention Type
Behavioural

Primary outcome(s)
Children's wellbeing is measured using the Stirling Children’s Wellbeing Scale, comparing the endline of 12 sessions with the endline of 24 sessions and the control group (same timing as 24 sessions) (also assessed at midline for the 24 session arm and control arm)

Key secondary outcome(s)
1. Children's traumatic stress is measured using Children's Revised Impact of Event Scale (CRIES-8) at baseline, endline and follow up
2. Children's satisfaction with school is measured using the Multidimensional Students Life Satisfaction Scale (MSLSS) subscale School at baseline, endline and follow up
3. Children's satisfaction with Friends/Friendships is measured using the MSLSS subscale Friends at baseline, endline and follow up

4. Children's health-related quality of life is measured using the KIDSCREEN-10 measuring at baseline, endline and follow up
5. Children's physical Health is measured using the KIDSCREEN-52 subscale physical activity and health at baseline, endline and follow up
6. Children's hope is measured using the Children's Hope Scale at baseline, endline and follow up
7. Children's emotional regulation is measured using the Emotional Regulation Questionnaire (ERQ) at baseline, endline and follow up
8. Children's depression symptoms are measured using the Short Moods and Feelings Questionnaire-13 at baseline, endline and follow up
9. Children's behaviours/skills and TeamUp-specific mechanisms of action are measured using the TeamUp-specific mechanisms of action scale (self-developed and used during a prior quasi-experimental study in Uganda, currently under review) at baseline, endline and follow up
10. Children's relationship with their teachers are measured using the Student-Teacher Relationship Scale – Short Form (STRS-SF, 15 items) at baseline, endline and follow up
11. Children's academic and social skills of students, thus classroom behaviour and participation measured using the Classroom Performance Survey 15-item scale at baseline, endline and follow up
12. Children's health-related quality of life (psychosocial wellbeing) is also measured using the KIDSCREEN-10 parent/caregiver-report at baseline, endline and follow up
13. TeamUp Facilitators' wellbeing and functioning is measured using the Warwick-Edinburgh Mental Wellbeing Scales (WEMWBS, 14 items) at baseline and endline
14. TeamUp Facilitators' burden, satisfaction and perceived support is measured using the Facilitator Survey (self-developed) at baseline and endline

Completion date
10/12/2024

Eligibility

Key inclusion criteria
1. Is present in the area for the study duration
2. Is registered in grade 4
3. Caregiver consent is obtained
4. Assents to participating in the research
5. Has the capacity to participate in the study

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
9 Years

Upper age limit
15 Years

Sex
All

Total final enrolment
2162

Key exclusion criteria
1. Resides in a child-headed household, i.e. head of household is under 18 years old. As child is required to have an 18+ year old to provide consent and socio-demographics
2. Hearing, vision, and speech impediments that significantly impair the ability to participate in the TeamUp intervention or assessments
3. Children unable to understand the explanations of TeamUp sessions or other classroom lessons (as determined on a case-by-case basis by the research team)
4. Behaviour that poses risks to the safety of other children or the TeamUp sessions

Date of first enrolment
17/10/2023

Date of final enrolment
17/11/2023

Locations

Countries of recruitment
Burundi

Study participating centre
Ecofo Namba
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Mukungu 3
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Mukimba
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Rubindi 2
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Mvugo
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Biniganyi
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Mugerama 3
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Mugerama 4
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Kazirabageni
Nyanza Lac
Burundi
n/a

Study participating centre

Ecofo Buheka 2
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Karobane
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Ruvumera
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Mukubano
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Mugumure
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Mareka
Nyanza Lac
Burundi
n/a

Study participating centre

Ecofo Kabo
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Mutwazi 2
Mabanda
Burundi
n/a

Study participating centre
Ecofo Nyabusunzu
Mabanda
Burundi
n/a

Study participating centre
Ecofo Mudaturwa
Mabanda
Burundi
n/a

Study participating centre
Ecofo Mabanda 3
Mabanda
Burundi
n/a

Study participating centre
Ecofo Kibimba
Mabanda
Burundi
n/a

Study participating centre

Ecofo Mara
Mabanda
Burundi
n/a

Study participating centre
Ecofo Mutwazi 3
Mabanda
Burundi
n/a

Study participating centre
Ecofo Bogorwa
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Nynaza Lac 5
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Kigembezi
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Muyange 3
Nyanza Lac
Burundi
n/a

Study participating centre

Ecofo Kigara 2
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Muyange 1
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Ruvyagira
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Mwimbiro
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Rangi
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Nyabigina 1
Nyanza Lac
Burundi
n/a

Study participating centre

Ecofo Gasaba
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Kabonga
Nyanza Lac
Burundi
n/a

Study participating centre
Ecofo Mukerezi
Nyanza Lac
Burundi
n/a

Sponsor information

Organisation
War Child

ROR
https://ror.org/01tq9ra93

Funder(s)

Funder type
Charity

Funder Name
Templeton World Charity Foundation

Alternative Name(s)
Templeton World Charity Foundation, Inc., Templeton Foundation, The John Templeton Foundation (Templeton Foundation), templetonworld, TWCF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Bahamas

Results and Publications

Individual participant data (IPD) sharing plan
This proposed research follows the data management guidelines of War Child's Research & Development (R&D) department (available upon request). All electronic data files will be stored on a password-protected cloud server (SharePoint), accessible only on password-protected and encrypted laptops. Access to this data will only be available to the core research team. Research Assistants and transcribers will sign a confidentiality clause. The detailed War Child Data Management Policy will serve as guidance on all data management and data sharing issues.

All survey data will be collected via the Kobo Toolbox. Research Assistants will upload data to the Kobo server at the end of each data collection day. Only the core research team will have access permissions to edit the questionnaires and download the data from the Kobo server. Data will be downloaded from the Kobo server every day and stored as a backup on a secure data server of the R&D Department of War Child. This server is password-protected and accessed from password-protected and encrypted laptops.

At the end of data collection, the complete data file will be downloaded at the War Child head office from the Kobo server and the master file will be saved securely on a separate server and uploaded into relevant software for data analysis. All data cleaning and analysis processes will be tracked through saved syntax from data analysis software.

Any hard copies of data, including informed consent forms, will be stored in a dry, lockable cabinet. Data sets will be accessible by the War Child core research team members. The Research & Development department at War Child has, in all cases, ownership of the research data, except where there is an alternative contractual relationship between War Child and an individual research committee member organisation. All recording devices will be stored directly after data collection in a locked cabinet.

Participant confidentiality is protected at all times and War Child data collection, storage and analysis are all General Data Protection Regulations-compliant. In the case of a participant requiring specialist mental health care or protection services due to imminent risk of harm, research and programme staff are trained to take the appropriate steps to maximise participant confidentiality, whilst protecting participant safety and ensuring that adequate care is received. This is explained to participants during consent sessions.

The researchers will ensure secure data storage and de-identification of participant data prior to analysis and write-up.

Datasets generated during and analysed during the study will be available upon request from alexandra.bleile@warchild.net or mark.jordans@warchild.net. The researchers may be able to also make data available publicly, this will need to be discussed and confirmed at a later stage.

IPD sharing plan summary

Available on request, Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		20/01/2025	01/04/2025	No	No