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Building capacity for delivery of youth-targeted mental health interventions in Vietnam and Cambodia: Intervention Phase

Submission date
17/10/2025

Recruitment status
No longer recruiting

Registration date
17/10/2025

Overall study status
Ongoing

Last Edited
25/11/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Rates of mental health difficulties are rising among children and young people (CYP), making early intervention important to reduce personal and societal costs. Health systems in Low-and Middle-Income Countries (LMICs) often have limited resources to meet this growing need for mental health care. Vietnam and Cambodia are both LMICs with young populations, many of whom face poverty and social inequalities. Whilst many CYP in these countries experience common mental disorders, access to care is limited by stigma, limited knowledge about mental health (mental health literacy) and the concentration of services in large cities. Research shows that lay healthcare providers, such as educators and community leaders, can help to provide interventions in LMICs with appropriate training and supervision.

The Mental health capacity Building and stRengthening In Global HealTh systems (M-BRIGHT) study will test a school-based mental health literacy programme led by lay providers in Vietnam and Cambodia. M-BRIGHT builds on the Adolescent Mental Health Promotion (AMP) study, which created a programme with adolescents and other community members in Vietnam and Tanzania. Results of the AMP study showed positive impacts on youth wellbeing and strong demand to expand the work to other contexts. This study will test how feasible, acceptable and potentially effective the programme is for improving mental health literacy, good mental health and wellbeing.

Who can participate?
Adolescents from Grades 10-11 (aged 14-18 years at recruitment) who are attending participating schools in Cambodia (Siem Reap and Kampong Chhnang) and Vietnam (Khánh Hòa and Thái Bình).

What does the study involve?
Participants will volunteer and be asked to join this study at their school. The schools taking part are randomly allocated to one of two groups to either 1) receive the mental health literacy programme or 2) continue with their normal curriculum. In schools allocated to receive the programme, this will be run by trained programme providers (e.g. teachers, community leaders)

in schools to groups of at least 35 adolescents. These providers will be selected from those who took part in mental health literacy training as part of an earlier phase of the M-BRIGHT study. The programme includes 9 topics related to mental health; one topic will be covered each month through one indoor and one outdoor session of 90 minutes each, involving interactive games and activities. The study lasts 10 months (i.e., one school year). Participating adolescents will complete paper questionnaires at the beginning, end and 3 months after study on aspects of their mental health. Parent/carers will also complete paper questionnaires about their child's mental health at the beginning, end and 3 months after the study. At the end of the study, some participating adolescents, parents/carers and programme providers will take part in interviews and focus groups to understand adolescents' experiences of taking part in the programme, what did and did not work, whether they would recommend it and any suggested changes.

What are the possible benefits and risks of participating?
Taking part in this study may benefit adolescents who experience emotional or behavioural difficulties. It may help them improve their mental health literacy, learn strategies to improve their wellbeing and give them an opportunity to share their views and experiences with others. The study should inform future programmes and resources to support adolescents, families, teachers and schools, including those not taking part in the study. Ultimately, the findings should be used to strengthen and coordinate systems of mental health support for young people, including in areas where such support is currently limited.

We do not foresee this study leading to any significant ethical, legal or management issues. However, as the study explores mental health, some questionnaires may ask about common mental health symptoms (e.g., anxiety, depression). There is a chance that adolescents may find these questions upsetting. To reduce this risk, we will use questionnaires that are commonly used with this age group and have not typically led to distress. We will also balance these with questionnaires about positive mental health (e.g., wellbeing). Adolescents who become distressed will be able to take a break or stop taking part, and a trained psychologist will be available to make referrals or provide support as needed.

Another risk is that adolescents may disclose issues relating to risk to themselves or to others, even without us directly asking about this. Under some of these circumstances, the researchers will have to break confidentiality. If an adolescent discloses risk, the researchers will explain to them that they are concerned about their wellbeing and that they need to discuss these issues with a trusted school staff member or their parent/carer. We will also use a safeguarding plan that has been developed with the research teams in each country to ensure it aligns with available support and country practices. Each country team has chosen a Designated Safeguarding Lead (DSL) who is a trained clinical psychologist with experience working with children. All research team members will be trained on the safeguarding plan, and all disclosures will be discussed with the country leads, experienced psychologists who have experience working in youth mental health.

In answering questions about their children's mental health, parent/carers may become concerned or distressed about their child. A list of resources and organisations that can support parent/carers will be put together with the country teams, and this will be given to all parent /carers taking part. They will also be able to talk to a trained psychologist if needed.

The programme providers will be asked to complete questionnaires on their mental health literacy. These have been used extensively in Vietnam and are not expected to cause any distress. However, should the providers become distressed, they will be free to not answer the questions. Trained psychologists will be available to make referrals and support the providers if needed.

Where is the study run from?
The M-BRIGHT study is run by Queen Mary University of London (UK), Royal University of Phnom Penh (Cambodia) and Vietnam National University, University of Education (Vietnam) and takes place in schools in Vietnam and Cambodia.

When is the study starting and how long is it expected to run for?
September 2025 to October 2027.

Who is funding the study?
The National Institute for Health and Care Research (NIHR) (UK)

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
GHR NIHR158384

Study information

Scientific Title
Mental health capacity Building and stRengthening In Global HealTh systems

Acronym
M-BRIGHT

Study objectives
Overall objective: to build capacity and strengthen systems that underlie the provision of youth-targeted mental health services in Cambodia and Vietnam.
Aim of the intervention phase: to measure the feasibility, acceptability and potential effects of the intervention in promoting good mental health.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 23/07/2025, Queen Mary Ethics of Research Committee (Joint Research Management Office (JRMO), Research Services, Dept. W, 69-89 Mile End Road, London, E1 4UJ, United Kingdom; +44 207882 6947 / 7915; research-ethics@qmul.ac.uk), ref: QME25.1128

2. approved 09/09/2025, Institutional Review Board, Vietnam National University, University of Education (VNU University of Education, 144 Xuân Thy, Cu Giy, Hanoi, 100000, Viet Nam; +84 437548092; education@vnu.edu.vn), ref: 25.13/HĐĐĐ-ĐHGD

3. approved 31/10/2025, Cambodian Ministry of Health, National Ethics Committee for Health Research (Lot #80, Samdech Penn Nouth Blvd., Tuol Kork District, Phnom Penh, 120408, Cambodia; +855 96 7224908; phinheng.khmer@gmail.com), ref: 613 NECHR

Study design
Cluster-randomized controlled feasibility trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Promotion of mental health literacy and prevention of mental health difficulties in adolescents

Interventions
The study will involve at least 700 adolescents in school grades 10-11 (age range approx. 14-18 years) recruited at schools across the 4 study sites in Vietnam (Thái Bình and Khánh Hòa) and Cambodia (Siem Reap and Kampong Chhnang), meaning there will be at least 350 participating adolescents per country. The M-BRIGHT intervention is a manualised mental health literacy intervention, which will be delivered in schools to groups of at least 35 adolescents. Participation will be over an approximate 10-month period (i.e. one school year). The intervention builds on the Adolescent Mental Health Promotion (AMP) study intervention, originally co-developed with adolescents and stakeholders in Vietnam and Tanzania. The intervention was co-adapted to the M-BRIGHT study contexts through workshops in the four study sites with adolescents, parents, teachers, community and religious leaders and government and NGO stakeholders.

The intervention will be delivered by mental health literacy trainees who took part in a prior training phase of the M-BRIGHT study. The intervention structure is as follows: one manual topic will be covered per month, via one indoor session and one outdoor session of 90 minutes each. The indoor session will be led by adult intervention providers while the outdoor session will be led by adolescents, with supervision from the adult intervention providers. In both countries, there will be two intervention providers per session (one teacher, one trained external provider), and they can rotate leading the sessions. The manual topics are as follows:
1) Introduction and overview about mental health (one indoor session);
2) Stress and anxiety (two sessions);
3) Depression and emotional regulation (two sessions);
4) Eating disorders and body image (two sessions);
5) Self-harm and suicide (two sessions);
6) Social relationships (with parents and peers) (two sessions);
7) Bullying (two sessions);
8) Internet and psychosocial issues among adolescents (one indoor session);
9) Self-care and Review (one outdoor session).

In each country, four schools will be in the ‘urban’ sites (Khánh Hòa and Siem Reap) and three in the ‘rural’ sites (Thái Bình and Kampong Chhnang), with one control school in each site. To randomise the schools, a list of all rural and urban site schools in each country will be provided to a study statistician, who will be blind to the school names. The statistician will randomise one

school in each site type to the control arm and the remaining schools in each site will be allocated to the intervention arm.

The control condition will be 'treatment as usual', with adolescents in control schools continuing with their normal school curriculum. However, they will be offered the intervention in the subsequent school year.

Outcomes of this trial will be measured using mixed methods. Data will be collected at baseline, midline (approximately four months post-randomisation, fidelity only), endline (at the end of the intervention) and three months post-intervention. The primary outcome measures relate to feasibility, acceptability, fidelity and potential effects of the intervention in promoting mental health literacy, good mental health and wellbeing, however some of the outcomes related to potential effects are secondary outcomes. Whilst fidelity is not explicit in the study aims, it is included as a primary outcome as it is integral to the overall study design.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility, acceptability and fidelity will be measured as follows:
1. The number of sessions delivered as planned (feasibility and fidelity) will be measured using the intervention monitoring template, recorded at every intervention session and checked at midline and endline;
2. The number of adolescents who took part, attrition and understanding whether any socio-demographic factors impact participation (feasibility) will be measured using the intervention monitoring template and demographic survey, with monitoring recorded at every intervention session and demographic data collected at baseline;
3. Compliance with the intervention manual and data completeness and quality (fidelity) will be measured through observations at midline and monitoring completeness of the intervention monitoring template and all participant surveys throughout the intervention;
4. Acceptability will be examined through interviews and focus groups with adolescents, their family members and other key informants (e.g., teachers, community leaders) at endline.

Potential effects of the intervention will be measured at baseline, endline and three months post-intervention through the survey for adolescents as follows:
5. Mental health literacy will be measured by the Mental Health Literacy Scale (MHLS) (O'Connor & Casey, 2015);
6. Mental health will be measured by Children Patient Health Questionnaire for symptoms of depression (PHQ-8) (Kroenke & Spitzer, 2002) and the Generalised Anxiety Disorder Questionnaire (GAD-7) (Spitzer et al., 2006);
7. Wellbeing will be measured by WHO Five Wellbeing Index Questionnaire (WHO-5) (World Health Organization, 1998);
8. Health-related quality of life (HRQOL) will be measured by the EQ-5D (Rabin & De Charro, 2001).

Key secondary outcome(s))
Children's emotional and behavioural relationships and social networks. These will be measured at baseline, endline and three months post-intervention through the survey for adolescents and parents/guardians as follows:
1. Adolescent survey:
1.1. Social networks, key relationships and loneliness will be measured by the #BeeWell survey

(Heather & Manzi, 2024);
1.2. Self-esteem will be measured by Rosenberg's Self-esteem Scale (RSES) (Rosenberg, 1965).
2. Parent/carer survey:
2.1. Child behaviour and emotions will be measured by the Strengths and Difficulties Questionnaire (SDQ) (Goodman, 1997).

An additional secondary outcome measure is the impact of the mental health literacy training from a previous phase (phase 2) of the M-BRIGHT study. This will be measured by comparing the mental health literacy of intervention providers prior to the training, at the end of the training (in phase 2) and midway through the intervention (phase 3), using the Mental Health Literacy Scale (O'Connor & Casey, 2015) in the intervention provider survey. We will also interview a small number of trainees who do not go on to deliver the intervention approximately three months after the training to understand the impact that the training may have had on them despite not delivering the intervention.

Completion date
31/10/2027

Eligibility

Key inclusion criteria
Participants for the intervention must meet the following criteria to take part:
1. A school student of any gender in one of the participating schools;
2. 10th-11th grade (age range 14-18 years)
3. Able and willing to take part for the duration of the study (i.e. one school year)
4. Able and willing to provide written assent to participate;
5. Able to obtain written informed consent from a parent/guardian;
6. Not planning to transfer to a different school in the next 12 months.

For each participant, we will also recruit one of their parents/legal guardians, also of any gender and willing and able to provide written consent for themselves and their child.

Intervention providers must meet the following criteria to take part:
An adult of any gender identified as interested and capable during the stakeholder analysis – i.e., these providers will be selected from the trainees who completed mental health literacy training in phase 2 of the M-BRIGHT study.

Participant type(s)
Healthy volunteer, Learner/student

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
14 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Have a severe mental health condition and/or physical health or medical condition - i.e., students whose health status inhibits their capacity to attend school regularly, participate in study activities or provide written informed consent;
2. They are a participant in a concurrent or similar intervention or research project, as enrolment in another programme or trial may confound outcomes;
3. They have a high likelihood of dropout, such as students expected to leave the school within the study period (e.g., due to planned relocation).

Date of first enrolment
15/09/2025

Date of final enrolment
15/12/2025

Locations

Countries of recruitment
Cambodia

Viet Nam

Study participating centre
Vietnam National University, University of Education
VNU University of Education, 144 Xuân Thy, Cu Giy, Hanoi
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Study participating centre
Royal University of Phnom Penh
Russian Federation Boulevard, Toul Kork, Phnom Penh
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Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
After the publication of the main findings, the researchers will operate an open data policy, following the FAIR principles e.g. Findable, Accessible, Interoperable and Reusable. The anonymised datasets generated during and/or analysed during the current study will be available from the co-Principal Investigator on reasonable request: Fiona Samuels (f.samuels@qmul.ac.uk).

All quantitative study data will be collected on paper forms completed by the participants and entered by the site teams directly into an online data collection platform (the Joint Research Management Office (JRMO) REDCap server, hosted at Queen Mary University of London (QMUL)). As this study will include data collected in outside the UK, authorised study staff in Vietnam and Cambodia will be able to access data required directly for analysis. Paper forms will be stored in locked filing cabinets in lockable rooms in the country in which the data were collected. Only authorised study staff will have access to the stored data in both countries. The method for sharing the data externally (if required) will be decided in due course.

A full digital dataset will be kept on QMUL servers after the study. Electronic anonymous unlinked data will be stored on the Queen Mary Research online repository or on a public repository (e.g., Figshare.com) once the 24-month study exclusive use (to allow for publication) period has expired. Paper forms will be stored in the country in which they were created, for at least five years, in allocated locked filing cabinets in lockable offices at the respective universities, after which they will be securely destroyed. The study will use electronic data for analysis, sharing and archiving.
Audio recordings of qualitative data will be stored on the JRMO REDCap file repository, or on a secure SharePoint folder in the UK, until the transcriptions have been checked at which time the recordings will be securely destroyed.

Assent from the adolescents and informed consent from the parents/guardians will be obtained from all participants involved in the study. All participants are assigned a participant ID at the point of enrolment and all subsequent data collected will be linked to this ID, without any link to identification data, following Good Clinical Practice.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes