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Project HASHTAG: testing a school-based intervention to improve adolescent mental health in Nepal and South Africa

Submission date
27/07/2021

Recruitment status
No longer recruiting

Registration date
16/08/2021

Overall study status
Completed

Last Edited
12/01/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Current plain English summary as of 11/02/2022:

Background and study aims
HASHTAG is a multi-level intervention for young people in Grade 8 or equivalent that aims to promote positive mental health and prevent mental health conditions (specifically, depression and anxiety) and reduce risk behaviours. As this is a feasibility trial, we will evaluate the feasibility of the intervention and trial procedures.

The HASHTAG intervention comprises two modules: 1) Thriving Environment in Schools (TES), a whole-school intervention, and 2) Thriving Together (TT), a group-based intervention delivered directly to young adolescents. TES is a school climate improvement strategy that seeks to modify adolescents' social and emotional environment through a whole-school approach to create a school culture of connectedness and supportive relationships. It is implemented through three activities: 1) School Action Groups, 2) Teacher-focused training, and 3) Mental health awareness-raising activities. TT will be implemented by trained and supervised facilitators on a weekly basis over a six-week period.

Who can participate?
School going adolescents in South Africa (Grade 8) and Nepal (Grade 8-9).

What does the study involve?
Students will be recruited from a select group of schools in South Africa and Nepal, working with local research and implementation partners at both sites. Schools will be randomized to intervention or control conditions before (Nepal) or after (South Africa) baseline data collection. Follow-up data collection will involve a midline timepoint during intervention rollout (in Nepal) and an endline timepoint (in both countries) after the rollout of the intervention.

What are the possible benefits and risks of participating?
There are minimal risks to participating in this behavioral intervention; benefits may include improved mental health and contribution to ongoing research about school-based mental health interventions for adolescents in low and middle income country settings.

Where is the study run from?
Stellenbosch University (South Africa)

When is the study starting and how long is it expected to run for?
July 2019 to July 2022

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof Mark Tomlinson, markt@sun.ac.za

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Previous plain English summary:

Background and study aims
HASHTAG is a multi-level intervention for young people in Grade 8 or equivalent that aims to promote positive mental health and prevent mental health conditions (specifically, depression and anxiety) and reduce risk behaviours. As this is a feasibility trial, we will evaluate the feasibility of the intervention and trial procedures.

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Who can participate?
School going adolescents in South Africa (Grade 8) and Nepal (Grade 7-9).

What does the study involve?
Students will be recruited from a select group of schools in South Africa and Nepal, working with local research and implementation partners at both sites. Schools will be randomized to intervention or control conditions after baseline data collection. Follow-up data collection will occur after the rollout of the intervention in both sites.

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Who is funding the study?
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Who is the main contact?
Prof Mark Tomlinson, markt@sun.ac.za

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Feasibility trial of a school-based intervention to promote positive mental health, prevent mental health disorders, and reduce risk behaviours in young adolescents in Nepal and South Africa

Acronym
Project HASHTAG

Study objectives
Students who receive the HASHTAG intervention will show greater improvements in positive mental health, greater decrease in depressive and anxiety incidence and symptomatology, increase in psychosocial functioning and social support, better experiences in school, and greater decrease in risk behaviours between baseline and post-intervention follow-up, when compared to a control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 17/02/2020, Health Research Ethics Committee, Stellenbosch University (Education Building, Tygerberg Campus, Faculty of Medicine and Health Sciences, Francie van Zijl Drive, Tygerberg 7505, South Africa; +27 (0)21 938 9819; afortuin@sun.ac.za), ref: N19/07/088
2. Approved 18/07/2019, School of Nursing and Midwifery School Research Ethics Committee (Queen's University Belfast, Medical Biology Centre, 97 Lisburn Road, Belfast BT9 7BL, UK; no telephone number provided; o.perra@qub.ac.uk), ref: MTomlinson.SREC_July19_V1
3. Approved 23/07/2020, Government of Nepal, Nepal Health Research Council (NHRC) (Ramshah Path, PO Box 7626, Kathmandu, Nepal; +977 14254220; nhrc@nhrc.gov.np), ref: 342 /2020P

Primary study design
Interventional

Study design
Cluster randomized feasibility trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Positive mental health, depression, anxiety in adolescents in Nepal and South Africa

Interventions
Current interventions as of 11/02/2022:

In each country (South Africa and Nepal), a random-number generator will be used to randomize two schools to intervention condition, and two to control condition, after evaluating equivalency

across a number of domains. Intervention arm recipients will receive a school climate and mental health intervention, HASHTAG, comprised of two parts: Thriving Environment in Schools (TES) and Thriving Together (TT). In South Africa, trained community-based facilitators will implement the intervention; in Nepal, trained staff nurses will fulfill this role.

TES will include 1) School Action Groups, 2) teacher-focused workshops, and 3) mental health awareness raising activities. School Action Groups will involve students from across multiple grade levels, as well as teachers and administrators; they will meet regularly and act as a steering committee at the school level to facilitate implementation of HASHTAG, as well as overseeing the implementation of the mental health awareness activities. Two teacher workshops totaling 12 hours and will aim to improve psychosocial wellbeing and classroom management skills. Mental health awareness raising activities will include text messaging to parents/caregivers, students, and teachers, a school-wide campaign, and parent meeting components. TT will be delivered to students in Grade 8 in South Africa and Grade 7-9 in Nepal. It will include six 90-minute weekly sessions focused on emotional regulation, stress management, problem-solving, interpersonal skills and relationships, and assertiveness training. Control arm schools will receive a shortened version of the student sessions after follow-up interviews are complete (i.e. “enhanced treatment as usual” [eTAU]).

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Previous interventions:

In each country (South Africa and Nepal), a random-number generator will be used to randomize two schools to intervention condition, and two to control condition, after evaluating equivalency across a number of domains. Intervention arm recipients will receive a school climate and mental health intervention, HASHTAG, comprised of two parts: Thriving Environment in Schools (TES) and Thriving Together (TT). In South Africa, trained community-based facilitators will implement the intervention; in Nepal, trained school counsellors will fulfill this role.

TES will include 1) School Action Groups, 2) teacher-focused workshops, and 3) mental health awareness raising activities. School Action Groups will involve students from across multiple grade levels, as well as teachers and administrators; they will meet regularly and act as a steering committee at the school level to facilitate implementation of HASHTAG, as well as overseeing the implementation of the mental health awareness activities. Three teacher workshops totaling 7 hours and will aim to improve psychosocial wellbeing and classroom management skills. Mental health awareness raising activities will include text messaging to parents/caregivers, students, and teachers, a school-wide campaign, and parent meeting components. TT will be delivered to students in Grade 8 in South Africa and Grade 7-9 in Nepal. It will include six 90-minute weekly sessions focused on emotional regulation, stress management, problem-solving, interpersonal skills and relationships, and assertiveness training. Control arm schools will receive a shortened version of the student sessions after follow-up interviews are complete (i.e. “enhanced treatment as usual” [eTAU]).

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline and immediately post-intervention (~5 months):
1. Positive mental health, measured using the Stirling Children’s Wellbeing Scale (15 items); a culturally-suitable adaptation of Resilience Scale (8 items); and the Multidimensional Student Life Satisfaction Scale (family subscale, 7 items, South Africa only).

2. Depression will be assessed using the 9-item Patient Health Questionnaire – Adolescent version (PHQ-A). Incidence of depression will be measured at or above a threshold of 10. In addition, we will measure change in depressive symptomatology.
3. Anxiety symptomatology will be assessed using the 7-item Generalized Anxiety Disorder-7 (GAD-7; 7 items). Incidence of anxiety will be measured at or above a threshold of 10. In addition, we will measure change in anxiety symptomatology.

Key secondary outcome(s)
Measured at baseline and immediately post-intervention (~5 months):
1. Psychosocial functioning is measured using the Strengths and Difficulties Prosocial Scale (5 items), and the World Health Organization Disability Assessment
2. Schedule (WHODAS) 2.0 (life activities items, 9 items).
3. Substance use will be measured using the Alcohol Use Disorders Identification Test (10 items) and one self-report question on tobacco and illicit drug use.
4. Aggression will be measured using the Aggression Scale (11 items).
5. Self-harm and suicidality will be measured using 9 self-report questions on self-harm intentions and behaviours.
6. Social support will be measured by the Social Connectedness Scale (8 items) and the Oslo Social Support Scale (3 items).
7. School environment will be measured using the Beyond Blue School Climate Questionnaire (28 items).
8. Bullying experiences will be measured using the Gatehouse Bullying Scale (4 items with 2 follow-ups each; potential total of 12 items).

Completion date
31/07/2022

Eligibility

Key inclusion criteria
School going adolescents in South Africa (Grade 8) and Nepal (Grade 7-9)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
468

Key exclusion criteria
Unable to assent and/or participate

Date of first enrolment
01/03/2021

Date of final enrolment
21/05/2022

Locations

Countries of recruitment
Nepal

South Africa

Study participating centre
Institute for Life Course Health Research
4009 Education Building
Faculty of Medicine and Health Sciences
Stellenbosch
Tygerberg
South Africa
7505

Study participating centre
TPO Nepal
Anek Marga
Baluwatar
Kathmandu
Nepal
44600

Sponsor information

Organisation
Stellenbosch University

ROR
https://ror.org/05bk57929

Funder(s)

Funder type

Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Development of HASHTAG	11/12/2023	12/01/2024	No	No
Participant information sheet			30/07/2021	No	Yes