BMC Psychiatry

STUDY PROTOCOL

Open Access

A pragmatic randomized trial to examine the effect of combining healthy diet with mindfulness cognitive therapy to reduce depressive symptoms among university students in a low-resource setting: protocol for the NutriMind Project

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Abstract

Background Mental health disorders still rank as leading causes of morbidity worldwide despite increasing awareness and improvements in treatment. Notably, low- and middle-income countries like Uganda, are disproportionately affected by such disorders. The burden of depressive symptoms in these countries is particularly high among students, aggravated by poverty, malnutrition, and inadequate public health governance, yet it is clearly under-researched, making it hard to achieve several of UN Sustainability Development Goals. Current treatment options are insufficient to tackle the increased burden of depressive disease. This is more challenging for low-resource regions especially in Sub-Saharan Africa, suggesting the need for alternative treatments that can swiftly be applied if proven effective. The main aim of this randomized controlled trial (RCT) is therefore to examine if a low-cost healthy diet (based on local Ugandan foods) combined with easy-to access mindfulness cognitive therapy can reduce depressive symptoms among university students in Uganda.

Methods We will recruit female and male students at Makerere University, the largest public university in Uganda, to an open, intention-to-treat, two-armed RCT. Those who score above a predefined threshold on a self-reported assessment of depressive symptoms, measured by the Center for Epidemiological Studies – Depression score (CES-D), are eligible for study inclusion and will be randomized to either an intervention ($n=125$) or a control ($n=125$) group. The intervention group will receive educational group-based sessions on how to prepare a Mediterranean-type of healthy diet and how to adhere to the principles of mindfulness-based cognitive therapy. Outcome measures include

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self-reported depression symptoms, quality of life, and dietary intakes. In addition we will perform a cost-effectiveness analysis. The RCT intervention will last 9 months, followed by additional 15 months with regular data collections.

Discussion We here describe a novel approach to treat depressive symptoms among university students living in resource constraint settings, by combining a healthy diet with low threshold psychotherapy. If this intervention succeeds, our project can be viewed as a step towards evidence-based behavior practices for young adults with a common mental disorder (depression) that are beneficial to public mental health initiatives and management.

Trial registration The RCT is registered in ClinicalTrials.gov (ID: NCT05848973). The date of registration was August 14, 2023.

Keywords Depression, Diet, Mindfulness-based cognitive therapy (MBCT), Mental health, Randomized trial, Uganda, University students

Background

Despite increasing awareness and improvements in treatment, mental health disorders still rank as leading causes of morbidity worldwide. Low- and middle-income countries (LMICs) are disproportionately affected by these disorders due to lack of funding, shortage of health personnel and societal disapproval of those suffering from ill mental health [1]. The burden of depressive symptoms in LMICs is particularly high among students, aggravated by poverty, malnutrition, and poor public health governance. Sadly, mental health in LMICs is underresearched, making it hard to achieve UN Sustainability Development Goal (SDG) 3 (good health and wellbeing). Contrary to university-students from wealthy nations, students from LMICs are often overlooked in terms of health care, a situation fuelled with the covid-19 disruptions of teaching [2]. Notwithstanding this, also many students from high-income countries, like Norway, battle with depressive disorders [3]. With this project, we will address key aspects of research plans and strategies outlined by WHO to close the Mental Health Gap especially among LMICs and with focus on depression symptoms.

Depression is characterized by variations of emotional pain in response to life-stressors and it negatively affects the entire life span, leading to psychological-, cognitive-, social- and occupational impairments and with a pattern of relapse and remission [4–6]. From 1990 to 2017 the global number of adults with depression increased by nearly 50%, i.e. to about 26 million, being specifically rampant in sub-Saharan LMICs such as Uganda [7]. In LMICs, the burden of depression is particularly worrisome and there are many barriers to access mental health services [8]. Yet, only about 2% of the total research outputs in health in Africa were directed towards mental health disorders in 2020 [9].

Globally, about 3/4 of affected subjects acquire depression at the age of about 20–25 years, a period for several life adjustments [4, 9]. This is a critical age in career development as many young adults are pursuing higher education before entering the work force [4]. Stress due to competitive academic environments and failure to succeed may lead to depressive symptoms [10]. In line with this, many university students in LMICs are underprivileged, thus at higher risk compared with the general population of developing depressive symptoms [11], and at Makerere University (largest public university in Uganda and site for our project), depressive symptoms affect about 1 in 5 students [12]. Academic stress among students can lead to a plethora of depressive-related health problems (e.g. insomnia, anxiety, muscle pain) [10, 13]. Current treatments (various forms of psychological therapy and anti-depressants) avert less than half of the disease burden, suggesting the need for additional treatments [14, 15]. However, there is limited progress on mental health care policies, guidelines and interventions aimed at treatment in LMICs [16].

Being depressed makes one more likely to eat unhealthy foods. A systematic review of randomized controlled trials (RCTs) showed inverse associations between healthy diets and depression risk, although the findings from the RCTs were inconsistent, and there were few studies among students [17]. Another systematic review of observational studies found that diets comprised of highly processed foods (high in saturated fat and refined sugars) may have a causative effect on depression [18]. Moreover, systematic reviews on studies with omega-3 fatty acids, wholegrain foods or a Mediterranean diet, found a reduction in depressive symptoms [19, 20]. In support of this, we showed that an educational RCT comprising nutrition advice reduced the burden of depressive symptoms among Ugandan mothers over time [21, 22]. Furthermore, students' difficulties in adhering to healthy eating habits due to stressors and lack of time, increase the risk of depressive symptoms [23, 24]. Notably, RCTs with dietary interventions as treatments for depressive symptoms among students have apparently not been performed in sub-Saharan LMICs such as Uganda. This is unfortunate as dietary interventions with local foods are more accessible in LMICs than other treatment forms. Thus, there is a research gap regarding nutritional effects on depressive symptoms in LMICs, which may lead to

lost opportunities for good dietary practices to reduce the burden of depressive symptoms.

Mindfulness-based cognitive therapy (MBCT) helps patients to better understand and manage their thoughts and emotions using mindfulness practices, such as (i) stress-reducing meditation and breathing, and (ii) by exercises that promote an enhanced awareness of the present moment [25]. Using these tools, the aim is to teach patients how to break away from negative thought patterns and, partly, to increase metacognition. An RCT showed that MBCT interventions consistently reduced depressive symptoms compared to classic cognitive-behavioral therapy, maybe because of metacognitive effects [26]. Moreover, MBCT is generally safe, can be performed with little resources, and deteriorations of depressive symptoms occur no more after treatment with MBCT than with other psychotherapies [27]. Hence, MBCT should be well suited for use in LMICs. Notwithstanding the use of MBCT, its evidence-base is still inadequate, in part because most studies have been cross-sectional, limiting their strength of conclusions [28, 29]. Still, a 6-year follow-up of an RCT on mindfulness training among university students found an increase in favorable ways of coping that extended an initial reduction in mental distress [30, 31]. This indicates a psychological mechanism from such interventions in students. Notably, in LMICs, MBCT is barely applied and little known by mental health workers. Since MBCT may enhance active- and problem-focused coping and reduce avoidance coping, we believe that there may be positive interaction effects between MBCT and healthy diet practice among university students.

Apart from any intervention's clinical effectiveness, its health economic aspect also plays an important role in the decision-making process whether to implement it on a larger scale, in particular in low-resource settings [32]. It is thus pivotal to equip policymakers and stakeholders with such knowledge to promote health equity and contribute to sustainable health improvements. In line with this, we analyzed the cost-effectiveness of a maternal education intervention focusing on nutrition in a RCT performed in a Ugandan setting [33]. Such cost-effectiveness analysis is crucial to achieve the SDG 3 targets and ensure swift implementation of interventions.

Current depression treatments are often expensive, stigmatizing, and time-consuming. Most university students in LMICs study part-time and after daytime working. Reaching out to them using a smart phone app provides immediate access and increased trial adherence. Systematic reviews on digital mental health interventions show that these are effective for improving depression, anxiety, and psychological well-being among students [34]. However, the majority of interventions have focused on web-based technologies, and it remains a need for further research on interventions delivered via mobile phones as these can reach more students. The wide reach and low cost of applying such technology makes it attractive for delivering health interventions in LMICs. We will thus apply digital technology (app on smartphones) to facilitate MBCT to the intervention group.

Aim and hypothesis

The main aim of our RCT is to examine if a combination of a healthy diet (Diet) and MBCT can reduce depressive symptoms among university students in a low-resource setting (Uganda).

To address this, we have developed the following hypothesis: The combined intervention with Diet and MBCT will reduce depressive symptoms compared with a control group. Assuming that this hypothesis will be supported by the RCT results, we will assess whether the combined intervention of Diet and MBCT is cost-effective.

Methods

Design

We will perform an open intention-to-treat RCT organized into two work packages (WP) as illustrated in Fig. 1.

WP1: participant recruitment

We will involve students, university-staff, and university health care clinics in preparing the RCT. Specifically, we have performed a pilot-study where we tested the various study-tools with 10 students (who will not participate in the RCT) to ensure that relevant perspectives are appropriately included in the project. Training of the research team will include gender integration and awareness to avoid possible biases, preferences, interests and values of the research team throughout the whole trial period.

We will recruit female and male students at Makerere University in Kampala. Those who score 16–25 points on the Center for Epidemiological Studies – Depression score (CES-D) scale, a self-reported assessment of depressive symptoms, are eligible, while those who score ≥ 25 points (a threshold for major depression [35]) will not be included, but referred for treatment. We will recruit students from all colleges and from different classes, using social media and notice boards. In our study-setting, characterized by high mobility of students within the university-campus, performing a cluster analysis is not feasible. Trained master students in clinical psychology will recruit the participants. Inclusion criteria are (i) completed ≥ 1 year of study and having ≥ 2 years before graduation; (ii) not using any medication regularly that might interfere with their dietary intakes or adherence to MBCT; (iii) not being diagnosed with any chronic disorder/non-communicable disease; (iv) not pregnant;

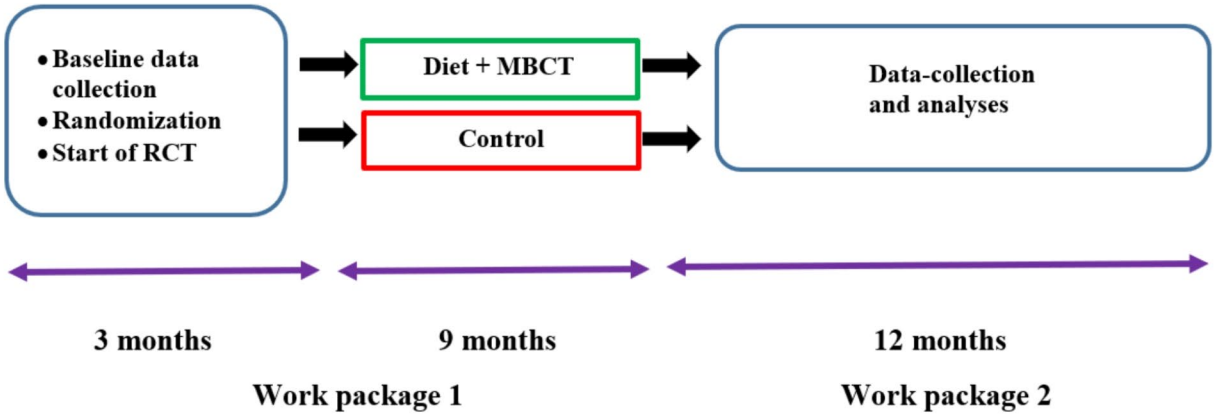

Fig. 1 Illustration of the design of the NutriMind RCT. University students with depressive symptoms will be randomized (1:1) into either a combined intervention (healthy diet [Diet] and mindfulness-based cognitive therapy [MBCT]) or a control group

(v) not having food allergy or food-intolerance; (vi) not experienced any recent major personal loss (e.g. divorce); and (vii) consenting to participate.

WP 1: the healthy diet and the MBCT interventions

Educating the study participants (university students) about the healthy diet (Diet) and MBCT interventions will occur concomitantly. The Diet will be based on available and affordable Ugandan local foods (rich in vegetables, fruit, wholegrain/fibre, and fish; moderate in lean red meat and low-fat dairy products). We will target energy and nutrient contents to meet the recommended dietary intake requirements for adults [36]. The participants will receive 8 weekly, one-hour group sessions by trained nutritionists. Food models and metric measuring utensils will be used to assist with the estimation of portion sizes. Participants will be provided with written information specifically designed for the intervention to assist with achieving dietary adherence, i.e. recipes and meal plans. To evaluate possible adherence differences in dietary intake and physical activity, we will measure anthropometry (e.g. weight) and use two validated questionnaires regarding uptake of dietary and physical advice [37, 38].

The MBCT training will be group-based (n=6–12) and contain 8 weekly sessions (1 h) of mind-body intervention integrating mindfulness meditation with concepts of cognitive behavioural therapy led by trained staff (clinical psychologists). MBCT encourages the participants to disengage from habitual, ("automatic") dysfunctional cognitive routines, in particular depression-related ruminative thought patterns as a way to reduce symptoms and future risk of relapse and recurrence [39]. Through guided meditation practices and activities, they will be taught to develop present-focused, non-judgmental awareness of their thoughts and feelings instead of focusing on the content of them [40]. Negative cognitive processes make individuals prone to depression and are a primary driver of persistent depressive symptoms [41]. In addition, the intervention group will get access to *StressProffen*, an app-based stress management program [42]. *StressProffen* combines mindfulness and cognitive-behavioral stress management strategies and was designed and developed according to user-centered design methods with close collaborations between researchers, users, health care providers, and eHealth experts [43]. The program contains 10 modules with mindfulness, cognitive-behavioral and stress management educational material and exercises. *StressProffen* is available for android and ios, contains English text and sound and the content can be downloaded and used without internet connection. The *StressProffen* app will facilitate adherence to MBCT skills and information and strengthen stress management skills.

To remind the participants about the interventions, SMS/e-mail will be sent weekly. No particular intervention will be offered to the control group.

WP 1: randomization and sample size calculation

A person independent of the RCT excecution will conduct the radnmization and study group allocation. The randomization sequence will be created using the shiny app random allocation generator (https://icostatistics.shinyapps.io/randlist/) developed at Oslo University Hospital, Norway, and the participants will be stratified by college with a 1:1 allocation using random block sizes of 4, 6 and 8. The sample size is based on CES-D, which assesses depressive symptoms experienced in the previous week, with 20 items and a sum score 0–60 points. A total score ≥16 points indicates depression [44]. Francis et al. [45] reported a mean difference in CES-D score of 6 points between young adults on a healthy diet vs.

controls (mean scores 15 and 21, respectively and standard deviation = 12). Based on their data and with significance level 0.05 and power 0.80, 119 students per group (intervention and control) are needed to detect a similar difference. Assuming 5% dropout/non-response, we will include 250 students (125 per group). Reportedly about 7,200 of the total of 36,000 students at Makerere University suffer from depression [12] and hence, the calculated sample size will be possible to recruit during three months.

WP 2: data collection and data analyses

At all time points (3, 6, 12 and 24 months after start of the RCT) data will be collected (and stored electronically according to guidelines of the University of Oslo) from the students when they visit our project office on site at Makerere University. All methods are accessible from the project partners or commercially available. We will describe each study group (intervention and control) using means (standard deviations), medians (interquartile range) or frequencies (%). Mixed model for repeated measurements will be used for the statistical analyses of the main outcome, adjusted for the stratification factor (i.e. the various colleges). We will adhere to the CONSORT guidelines for analyses and reporting. In this paper we have used the SPIRIT reporting guidelines.

The primary outcome is change in CES-D score from before to after the intervention. Notably, diagnosing depression in LMICs can be challenging. Hence, formal diagnostic procedures will be replaced with the CES-D score for measuring depressive symptoms. As secondary outcomes, we will measure health-related quality of life using the validated and widely used 36-Item Short Form Health Survey [46], a validated questionnaire regarding adherence to a Mediterranean diet [37], and a validated questionnaire regarding adoption of physical advice [38]. We will also conduct a model-based cost-effectiveness analysis from a provider perspective to quantify the health and economic outcomes associated with the combined intervention compared to the control over a 24-month time horizon. Cost measures will be obtained from project accounts and interviews with key personnel, and sensitivity analyses will be conducted to evaluate model uncertainty [47], as we recently demonstrated in a RCT in Uganda [33]. The included health benefits in the model will be measured using the CES-D score.

Dissemination of study findings

We plan to develop a broad, overarching strategy for dissemination and communication of our project experiences and research findings, as outlined below:

- *Target receivers*: Recipients and users of our research findings are primarily the health policymakers (in particular those devoted to mental health issues), higher education students (and their teachers), and scientists within the field of mental health and nutrition, not limited to Uganda and other LMICs, but also to relevant stakeholders and scholars in Norway. We will use our extensive network to also convey our findings to international policy- and decision makers (e.g. within WHO) and relevant non-governmental organizations. Importantly, we will conduct feedback sessions of our study findings to participants (university students) and identify their dissemination plans to provide a powerful voice to their peers.
- *Plan for dissemination and communication*: We will prioritize to approach mental health care workers and food and nutrition policymakers with peer-reviewed papers, lectures, seminars, and workshops. A web-site has been developed (https//www.med.uio.no/imb/english/research/projects/nutrimind/index.html).

Project participants, organization and collaborations

Our study team (as listed in the Acknowledgement-section) is characterized by (i) interdisciplinary knowledge and skills, (ii) gender balance, and (iii) equitable sharing of responsibilities between the project partners. Importantly, this project is conceived and designed in close collaboration with our Ugandan partners to tailor-make the intervention components to the study-participants' needs and sociodemographic/cultural/ language acceptability/ preference.

User involvement

For the NutriMind Project we define three main groups of users, namely (i) the university students, their teachers, health policy makers and scientists in the field of mental health and nutrition who were involved in the trial practical preparation phase (i.e. the pilot study). We will have continuous dialogue with them during data collection), (ii) those involved in analyses and implementation of the RCT results, and (iii) those who will be responsible for any long-term (sustainable) use of the knowledge gained from our project. We shall inform, consult, involve, cooperate, and co-create with these users as appropriate in the processes of our research engagement. For example, during the idea phase, we informed relevant users on what we wanted to do, formulated the project study design, study outcomes and study population.

Discussion

The NutriMind Project will establish evidence-based data for including locally available foods to manage depressive symptoms combined with MBCT. This will facilitate

the implementation of healthy diets, and thus promote Uganda's contribution in delivering solutions that comply with its commitments to the SDGs, in particular no. 3 (good health/wellbeing), but also 4 (quality education). Moreover, today's world economic pressures are often detrimental to mental health, therefore adaptive behavior changes are needed to reverse this negative trend, not only among LMICs, but globally. Although sustainability linked to dietary issues is receiving considerable public attention, its application in mental health research is lacking. Our project can thus be viewed as a step towards evidence-based behavior practices for young adults that are beneficial to public mental health initiatives. The lessons learnt can possibly be projected onto other age groups, and the project design and targets are in line with the needed action on mental health issues, such as equity in LMICs as voiced by e.g. the WHO [16], and the EAT-Lancet Commission's call for a substantial global shift toward healthy dietary patterns [48]. Importantly, inclusion of MBCT in our project and with the collaboration of academic and non-governmental organizations, fits well to a One Health-aspect (research where multiple sectors communicate and work together) to achieve better public health outcomes. Of note, many of the triggers of depression among our study population (e.g. time-stress, economic challenges, stigmata related to mental health) also affect university students residing in more wealthier regions, hence our study results should also be valuable and transferable to students living in high-income countries.

Below we summarize some putative risks with the NutriMind Project and ways to mitigate these.

- Lack of adherence to the RCT activities: The dietary intervention is designed to make it affordable for a student's budget. However, if necessary, we will support the study participants with means to access the necessary foods and to purchase smartphones if needed. To motivate the control group, we will give advice about Diet and MBCT after the end of the RCT, including access to the *StressProffen* app. The participants in both study groups will receive a financial support also for travel to data collection appointments.
- Disentangling which of the intervention components (Diet and MBCT) that works: By combining the two interventions we cannot precisely unravel the contribution of each of them separately to the study findings. However, each of them has in previous studies shown reducing effects on depressive symptoms, but the combination has not been tested.
- Bureaucracies in releasing research funds: Our experience with administering transfer of funds from Norway to both individuals and to collaborating Ugandan institutions for more than a decade, has devised strategies to avoid this.

If our intervention results in lowering of the burden of depression symptoms among the participating university students, we would like to swiftly roll out our intervention activities on a wider scale. Additional file 1 outlines schematically how we plan to implement this (Additional file 1).

Abbreviations

CES-D	Centre for Epidemiological Studies–Depression score
Diet	Healthy diet
LMICs	Low- and middle-income countries
MBCT	Mindfulness-based cognitive therapy
RCT	Randomized controlled trial
SDG	Sustainability Development Goal
UN	United Nations
WHO	World Health Organization
WP	Work package

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12888-024-06056-9.

Supplementary Material 1

Supplementary Material 2

Acknowledgements

We are grateful for the dedicated work by our research assistants: Paul Akampurira, Osire Maurice Tukei, Nuwakunda Alias, Joshua Namanya, Nantege Doreen, Aphia Atuhumurize and Linda Miriam.

Author contributions

KRK drafted the first version of the manuscript. POI designed and provided funding for the study. ANK and GM provided inputs on the methodology to be used. MBV provided inputs on the data analysis, randomization procedures and statistical evaluations to be used. KRW provided inputs on the handling of the data from the health economic analysis to be used. EB is responsible for the use of the StressProffen app. PAF initiated, designed and provided funding for the study in addition to recruit project partners. All authors contributed to the final protocol and approved submitting the manuscript for publication.

Funding

The study is supported by the University of Bergen, Henning och Johan Throne Holsts Stiftelse and Throne Holst Foundation, Norway. Henning och Johan Throne Holsts Stftelse was the major funder through an annual call with projects selected after a review process by an independent, international committee. More details can be found at: https://throneholst.org.

Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

We have obtained all necessary approvals, i.e. from the TASO-Internal Review Board in Uganda (TASOREC/034/2021-UG-REC-009) and from the Regional Committee for Medical and Health Research Ethics in Norway (#441814). We comply to the Declaration of Helsinki. Written informed consent will be obtained from all study participants.

Consent for publication

Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 13 May 2024 / Accepted: 2 September 2024
Published online: 11 September 2024

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