Co-designing and piloting a mental health intervention among young adults in post-secondary education in post-conflict areas in Colombia: A study protocol

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Abstract

Purpose

Colombia has endured more than five decades of internal armed conflict, which led to substantial costs for human capital and mental health. There is currently little evidence about the impact of incorporating a mental health intervention within an existing public cash transfer programme to address poverty, and this project aims to develop and pilot a mental health support intervention embedded within the human capital programme to achieve better outcomes among beneficiaries, especially those displaced by conflict and the most socioeconomically vulnerable.

Methods

The study will consist of three phases: semi-structured one-to-one interviews, co-design and adaptations of the proposed intervention with participants and pilot of the digital intervention based on cognitive behavioural therapy and transdiagnostic techniques. to determine its feasibility, acceptability, efficacy, and usefulness in 'real settings'. Results will inform if the intervention improves clinical, educational and employment prospects among those who use it.

Results

Knowledge will be generated on whether the mental health intervention could potentially improve young people's mental health and human capital in conflict-affected areas? We will evaluate of the impact of potential mental health improvements on human capital outcomes, including educational and employment outcomes.

Conclusion

Findings will help to make conclusions about the feasibility and acceptability of the intervention, and it will assess its effectiveness to improve the mental health and human capital outcomes of beneficiaries. This will enable the identification of strategies to address mental health problems among socioeconomically vulnerable young people that can be adapted to different contexts in in low and middle-income countries.

Introduction

Internal conflicts lead to substantial human and economic losses for civilian populations [1]. Physical assets are often destroyed or seized, and armed groups disrupt markets, seeking territorial strong-holds. Internal conflicts leave a legacy of structural poverty [2] and undermine young people's development of human capital – defined as skills, knowledge, and experience necessary to succeed economically and improve their future. Human capital costs of armed conflict persist long after peace agreements have been reached [3]. In turn, armed conflicts also have severe mental health consequences: young people exposed to conflict experience losses of relatives and friends, witness violent events, or can be the direct
victims of violence, increasing the risk of MHP, such as post-traumatic stress disorder (PTSD), depression, and anxiety [4]. MHPs can affect young people’s ability to build human capital and increase the risk of structural poverty, undermining peacebuilding efforts and restoring the vicious cycle.

This project aims to demonstrate that supporting mental health, using interventions that jointly improve mental well-being and strengthen human capital, can improve young people’s chances to enhance their learning outcomes and potentially interrupt the vicious cycle of poor attainment, poverty, and mental health problems. Mental health is essential to human capital formation, influencing educational attainments and labour productivity [5, 6]. Human capital and mental health can be part of a vicious cycle that must be broken to improve young people’s lives in post-conflict societies. The combination of poverty and mental health problems (MHP) makes conflict-affected areas in Colombia a clear example of a vicious cycle (Fig. 1). This project examines whether this vicious cycle can be broken through a mental health intervention embedded within a national cash transfer programme that supports young people in accessing post-secondary education.

Colombia endured more than five decades of internal armed conflict, leaving high rates of MHP among Colombian youth between the ages of 13 and 28 [8]. Epidemiological studies in conflict-affected areas have shown high prevalence rates of anxiety (52%), depression (43%), and PTSD (11%-47%) [9–11], which often intersect with socioeconomic deprivation. Mental health interventions can help young people overcome the psychological effects of war and conflict, build resilience, and increase their ability to engage and succeed in their educational and training programmes [12], thus reducing the future risk of poverty. Our project aligns with recently enacted legislation in Colombia that aims to expand mental healthcare provision for the population affected by the internal conflict. This legislation led to the creation of the “Program of Psychosocial Care and Integral Health for Victims” (PAPSIVI) [13], together with a newly adopted National Mental Health Policy [14]. Yet, evidence suggests that mental health services remain inadequate and underfunded, especially for young people. Less than 10% of the 9.3 million people recognized as conflict victims in Colombia have received some form of psychosocial support [16], and a treatment gap remains [17].

The ‘Youth in Action’ programme (Jóvenes en Acción in Spanish- JeA) is a major initiative of the Colombian government to decrease economic disparities by strengthening the formation of human capital among vulnerable young people living in poverty. Introduced in 2012, JeA supports young beneficiaries undertaking vocational training or university education with tuition fees and a living allowance given upon successful attendance and performance verification. JeA also offers a “skills for life” (Habilidades Para la Vida, in Spanish) training component to strengthen general skills that might increase long-term employability. The program currently hosts 445,000 beneficiaries, 14% living in conflict-affected municipalities. Although the program has been shown to impact educational outcomes and employment opportunities significantly, high levels of MHP among beneficiaries have been identified as an essential barrier to success [17].
Our study builds upon evidence that training and education interventions with mental health programmes substantially increase the likelihood of breaking the "vicious cycle" of poverty and poor mental health in young adulthood [18]. There is some evidence that mental health interventions can help young people affected by conflict, but significant gaps in knowledge [19, 20]. Some mental health interventions have shown partial success. Still, high levels of mental comorbidity, low uptake and adherence, high dropout rates, lack of flexibility and trained therapists, and difficulties accessing treatment remain critical challenges. Although comorbidity is common, interventions often address only one type of MHP [21–23], which has led to the introduction of transdiagnostic approaches [24, 25]. Transdiagnostic interventions simultaneously address a variety of mental health problems with a single intervention, such as the Common Elements Treatment Approach (CETA) [26], Interpersonal Counselling (IPC) [27], and the Unified Protocol (UP) [28]. The main difference is that CETA, can be delivered by trained lay people or community health workers, and has proof of efficacy. On the contrary, for instance, UP is intensive and requires specialized therapists. These three transdiagnostic interventions should be reserved for more severe cases, whilst milder cases might only require early detection and minimal help through a digital platform with a remote delivery [29, 30].

There are few studies on digital mental health interventions in Colombia. A recent study of an internet intervention for college students, assisted by a trained person, showed positive results but high dropout rates (around 80%) [31]. Members of our team have developed and tested several simple mental health digital tools with good adherence and outcomes in other Latin American countries [32–35]. With the advent of the Covid-19 epidemic, remote delivery is an additional underexplored challenge that this project aims to address. This study is particularly unique in that we work directly with Government within a public programme. So far, no studies have assessed the impact of incorporating a mental health intervention within an existing public cash transfer programme to address poverty.

This project aims to develop and pilot a mental health support intervention embedded within the JeA human capital programme to achieve better outcomes among beneficiaries, especially those displaced by conflict and the most socioeconomically vulnerable. We aim to develop and test the feasibility and acceptability of a mental health intervention that addresses comorbid mental health problems among beneficiaries of the JeA programme. We also aim to make a first evaluation of the impact of potential mental health improvements on human capital outcomes, including educational and employment outcomes.

We will also assess the several outcomes of the mental health intervention to improve the chances of JeA beneficiaries of completing the program and building human capital. Specifically, we will assess preliminary clinical outcomes of the relationship between the mental health intervention, compared to a control group, with dimensions related to human capital formation using a combination of administrative data and survey data collected as part of the intervention, that includes data on academic performance and attendance, as well as data on employment following the completion of the programme.
The project has three main research questions leading to methodological, empirical, and policy-related contributions:

1. Is a digital mental health intervention feasible and acceptable for inclusion in the JeA programme in conflict-affected areas in Colombia?
2. Can this mental health intervention potentially improve young people's mental health and human capital in conflict-affected areas?
3. Can this mental health intervention potentially improving young people's chances of succeeding in their training and educational outcomes?

**Study design and overview**

This study has three phases:

**Phase 1**

Phase 1 aims to determine the mental health needs and perceptions of the participants and facilitators of JeA and the barriers and facilitators that may contribute to the sustainability of the mental health intervention within the program. This will be done through literature and database review, a survey to study the prevalence of common mental health disorders in our population, and interviews.

*Interviews.* We will conduct semi-structured one-to-one interviews with 8 JeA staff to explore their experiences supporting young people with mental health issues and their views on potential barriers and facilitators to embedding the intervention in the JeA programme. We will also carry 10 one-to-one interviews with young people who are beneficiaries of the JeA programme to explore their views around mental health and their experiences of seeking or providing (to friends, for example) support for emotional distress and mental well-being. The qualitative interviews will be recorded via Teams in video and audio, according to the participants’ preferences. Trained research team members will carry them out before administering the questionnaires and starting the intervention.

**Phase 2**

Phase 2 consists of the co-design and adaptations of the proposed intervention with JeA participants. The research team will invite JeA beneficiaries and staff to three group discussions led by a facilitator and based on co-design principles and practices. These sessions will enable participants to share their perspectives on mental health issues for young people in Colombia and then discuss and refine the essential features of the intervention and its delivery strategies. If no changes are possible on the digital intervention, we will listen to young people's views about how this platform could be better delivered, and use this information to adapt our intervention framework. The refined intervention will then be presented
to JeA beneficiaries during a final co-design meeting to identify any more necessary adaptations. In this phase, we will also pilot the survey from which we will obtain the data.

Intervention development: co-design and adaptation: We will hold a virtual workshop with stakeholders (six JeA central staff and four from the FSFB) to draw a joint Theory of Change plan and a clear plan of action to launch the pilot study (Phase 3). The main stakeholders involved in the co-design are JeA beneficiaries and staff. We will aim to conduct this co-design work in small groups of between 4 and 8 people for staff-only and beneficiaries-only discussions and 10–15 people for joint workshops, representing all the territories involved. Team members with experience in facilitating and co-designing will plan each group session. These team members will also facilitate the workshops. Potential participants will be identified and recruited with the help of JeA staff members.

**Phase 3**

During Phase 3, we will pilot the intervention to determine its feasibility, acceptability, efficacy, and usefulness in 'real settings'. Results will inform if the intervention improves clinical, educational and employment prospects among those who use it. A sample of beneficiaries studying in our areas of interest will be invited to participate in a survey containing measures of mental health human capital. All those beneficiaries scoring above cut-off points will be automatically invited to access the intervention, and anyone suspected at risk will be offered support and referral to health services.

Intervention: The study will pilot a stepped-care mental health program that aims to be structured, brief and includes evidence-based components. This program is designed to facilitate the participants' social and labour insertion. The intervention will target depression, anxiety, PTSD, and comorbidities. Participants from the intervention sites will be classified in four levels of severity (asymptomatic, mild, moderate, and severe) according to their scores in these three dimensions and will be offered differential attention strategies (see Fig. 2).

Asymptomatic participants will receive an email with online resources and tools to help them manage their mental health, and they will not be included as part of the study. Participants with mild symptoms will receive access to SilverCloud®, a virtual mental health platform with eight modules with different tools for comorbid depressive and anxiety symptoms. This platform has been used in the university student population in Colombia, and has proven to be effective [36]. The access to the web-based platform will be self-guided. They will also receive an invitation to participate in a mental health workshop in their territories. For participants with moderate symptoms, the platform will also be available, but in addition, asynchronous feedback will be provided by trained guides [37]. Those with severe symptoms will also access SilverCloud® with asynchronous feedback and receive a person-centred intervention delivered by trained psychologists face-to-face or virtually, depending on the participant’s choice.
A group of local psychologists will be trained on different evidence-based tools for depression and anxiety. The training will be done through virtual sessions, and they will receive a manual (developed by the research team) with a step-by-step guide on the intervention. A pre-pilot of the intervention will be done with 10–15 participants with severe scores to supervise adherence to the manual from the psychologists and adjust the protocol, if needed. The intervention is based on CBT and transdiagnostic techniques. It consists of up to five face-to-face or online sessions in which participants will be offered one introduction session with psychoeducation of depression and anxiety from a CBT approach, and at least two psychological tools depending on their symptoms. These tools include problem-solving, behavioural activation, strengthening of social support, and reduction of safety behaviours. Psychologists will access the participant’s screening scores and progress in SilverCloud ® and choose the tools depending on what they observe in the first session. Additionally, psychologists will regularly meet with a clinical psychiatrist to discuss participants’ progress.

Participants from the control groups will not receive the intervention until the measures are completed. Afterwards, they will receive access to SilverCloud ® (self-guided) and an email with mental health promotion tools. Those who are at risk and need specialized mental health attention (e.g. those with suicidal risk) will be referred to the psychologist of their institutions.

Sample size: As a pilot study with no pre-specified effect size hypothesis, it is not relevant to estimate a sample size for hypothesis testing. However, to carry out preliminary analysis of impact, we defined the sample size as follows: assuming an intraclass correlation coefficient of 0.04, an effect size of .125 (index f) equivalent to Cohen’s d = .25, with a significance level of 5% and a statistical power of 80%, the minimum sample required would be 501 participants (167 per site, of three locations). Our goal is to recruit a minimum of 170 participants from each site, given an expected moderately high attrition rate.

Study design, Sample and Recruitment

Recruitment

Participants in Phases 1 and 2 will be invited via email or in person by JeA programme leaders and facilitators. During Phase 3, participants will be invited via email and text messages. Participation is entirely voluntary and will not affect participation in the JeA programme. It will be possible for participants to contact researchers directly for further information should they wish not to inform JeA staff of their participation.

Inclusion criteria

For all parts of the study, participants must be adults aged 18–28 and registered with the public social programme (JeA) living in seven Colombian municipalities affected by the armed conflict. These 7 municipalities are part of the 170 municipalities categorized as “The Development Programs with a Territorial Approach” (PDET in Spanish) by the Havana peace agreement to prioritise social and economic
development programmes and are the areas most hardly hit by the armed conflict. JeA users are characterized by their low socioeconomic status, according to the National Social Services’ criteria. Many of them are victims of the armed conflict as defined by the victims’ law in Colombia. Participants who meet the inclusion criteria and present anxiety, depression, or post-traumatic stress disorder symptoms will be invited to participate in Phase 3 – piloting the mental health intervention.

**Study design**

Our study is based on a cross-over design, whereby participants in three treatment municipalities (Florencia, Santa Marta, and Valledupar) will be offered the intervention, while participants in four control municipalities (Apartadó, Buenaventura, Ciénega, and San Andrés de Tumaco) will serve as control. Due to ethical reasons, we are required to offer the intervention to beneficiaries in the control municipalities following the period of intervention in the treatment group. Control municipalities will thus receive the intervention once the two post-treatment measures are taken.

**Control municipalities**

Control municipalities were selected based on the fact that they share common characteristics with the intervention municipalities in terms of levels of poverty, armed conflict, health, living conditions, public service availability, number of internally displaced people per 100,000, demography, and ethnicity. Additionally, they all have received the “skills for life” training. Control municipalities are also covered by JeA and are PDET territories (conflict-affected areas). To arrive at the control municipalities a proximity score was calculated using the variables with correlations no greater than .3 following their standardization (0–1) of their normalized distances.

**Exclusion criteria**

At each phase, if suicidal risk is identified, participants will be referred to the mental health services of their educational institutions or other mental health services in their municipality of residence. They will also be offered access to SilverCloud®. In case of immediate risk to self or others, the consent form will clearly state that we may need to inform the emergency contact participants provide.

**Informed consent**

*and withdrawal.* Informed consent will be on the opening page of the online survey. Participants volunteering to participate in interviews and group discussions will also receive the consent form stating that the conversations will be audio recorded. The consent form will clearly explain what participation entails, that it is possible to withdraw from the study, and that participants can request that their own data be removed from the study until the time the analysis is conducted. A final withdrawal date will also be provided in the information sheet, after which participants may no longer withdraw their data from the study.

**Data collection**
Quantitative data will be collected through an online survey hosted in Redcap. Data collection will be conducted online. The qualitative and co-design elements of the study will be carried out with beneficiaries and staff of the JeA programme via video-conferencing software (Teams).

**Screening Questionnaire**

To better understand young people’s mental health needs and priorities, the resources available, and any contextual factors relevant to the successful implementation of a mental health intervention, we will conduct a brief and focused survey of approximately 150 participants (50 per territory). This survey will use the same screening questionnaires we envisage for the intervention to further test their acceptability with this population. JeA will send the questionnaire via email and text messages, and invite participants through phone calls. Beneficiaries will be asked what they think about the survey and how it can be improved. We will make changes according to their feedback. This survey will be administered before the intervention and in two follow-ups (immediately after the intervention and three months after).

**Questionnaire Instruments**

We will invite all students across the selected PDET municipalities to complete the mental health and human capital survey. The following tools will be used to determine the severity of mental health symptoms and human capital outcomes. 1) *Patient Health Questionnaire - PHQ-9*, which is widely used to assess depression symptoms (Kroenke et al., 2010), has been validated for use in Colombia (Cassiani-Miranda et al., 2019; Pérez-Aníbal et al., 2018) and with low income, limited education populations in rural areas with good results (Arrieta et al., 2017; Wulsin et al., 2002). 2) Anxiety will be assessed with GAD-7 [38]. 3) A Post-traumatic stress disorder brief screen will also be included PC-PTSD-5 [39]. 4) Two questions from the Insomnia Severity Index [40, 41]. 5) AF5 Self-Concept Questionnaire 6) Rosenberg Self-esteem scale (RSE) [42].

In terms of short-term/immediate assessment of the potential of the intervention to improve human capital, we will look at: school attendance (using administrative data on academic enrolment reports), educational permanence (using administrative data on academic permanence reports, every six months), and academic performance (using administrative data on academic excellence report, every six months). Based on data directly collected as part of the pilot intervention, we will also assess the short-term efficacy of the number of hours spent on average during the past academic period studying weekly, the number of hours that beneficiaries dedicate in this academic period to study weekly and the self-reported grade point average in current and past academic periods. In terms of the longer-term efficacy of the intervention, we will look at: certification (whether completed educational program, based on JeA administrative records) and formal labour market inclusion (whether working in a formal job, based on PILA Administrative Registry). Furthermore, we will also assess the efficacy of the mental health intervention on self-esteem (RSES) and self-concept (AF5).
Data analysis

Assessing Feasibility and Acceptability

Feasibility, acceptability, and potential efficacy will be assessed using a "hybrid effectiveness-implementation" approach [43]. We will use standard measures across all study sites to facilitate within and cross-site comparisons in efficacy. We will conduct interviews with a subsample of 5–6 participants in each municipality at month three to explore acceptability qualitatively and learn if different municipalities need different implementation strategies and possible reasons why the intervention failed or succeeded.

Quantitative analysis of impact

To assess the impact of the intervention on our mental health and human capital outcomes, we will use a difference-in-differences approach that compares changes in outcomes before and after the intervention across participants in treatment and control areas. In the absence of treatment randomisation that assures that treatment and control groups are exchangeable, this quasi-experimental design helps us to control for time-invariant differences between treatment and control areas, by focusing on changes, rather than levels, in outcomes. To address bias from time-varying confounders, we will incorporate controls for time-varying factors in all analyses.

Qualitative analysis

One-to-one semi-structured interviews will be transcribed and analysed thematically to identify any emotional ‘touchpoints’ [44] in the experiences of seeking or providing support for mental and emotional distress. The findings from the interviews will inform the questions that will be discussed during the group sessions. These will be audio and video-recorded via video conferencing software but not transcribed fully. Two members of the qualitative sub-team will review the recording for analytical purposes and transcribe any segments relevant to the analysis. Analysis of the co-design workshops will aim to identify the essential intervention adaptations suggested by participants.

Ethics and Data Management

This study was approved by the Ethics Committees of Fundación Santa Fe de Bogota (CCEI-13269-2021) and King’s College London (HR/DP-21/22-22947). We have established a data management protocol, and procedures for team communications, data storage, security, and backup. All scales used are available in the public domain.

One-to-one interviews will be transcribed by a research team member or by professional transcribers providing a suitable formal confidentiality agreement as per our data management plan. Full
confidentiality cannot be guaranteed for focus groups and co-design group work. Still, we will ensure that participants know this and commit to avoiding sharing the information discussed in the groups outside of the sessions. Qualitative and quantitative data will be deidentified when writing the results.

Participating JeA staff and beneficiaries will be recruited with the help of JeA staff. It is possible that, where power differentials are involved, some participants may feel obliged to participate in the study (perceived coercion) if invited by senior managers and/or course tutors. To mitigate this possibility, we will ensure that all the study information clearly indicates that participation is voluntary and that declining to participate has no financial, professional, academic, or other implications. No identified data will be shared with JeA.

**Discussion**

There is some evidence that mental health interventions can help the millions of vulnerable populations affected by conflict, but challenges in their implementation remain (Idrobo 2018, Tamayo-Agudelo 2019). JeA is a major national programme of the Colombian government to decrease economic disparities by promoting post-secondary education among vulnerable young people from low-income backgrounds. Yet, participants in the programme face major mental health problems and lack adequate access to treatment and support. Our project aims to test the impact of a stepped-care mental health intervention that offers digital and professional mental health support to students with symptoms of depression, anxiety or PTSD who live in conflict-affected areas in Colombia. The study will examine the feasibility and acceptability of the intervention, and it will assess its effectiveness to improve the mental health and human capital outcomes of beneficiaries. Findings from this study will help identify strategies to address mental health problems among socioeconomically vulnerable young people that can be adapted to different contexts in low and middle-income countries.

**Declarations**

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*Competing Interests:* The authors have no relevant financial or non-financial interests to disclose. The authors have no competing interests to declare that are relevant to the content of this article.

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**Figures**

![Diagram of the vicious cycle of poverty, armed conflict, and mental health](image)

**Figure 1**

The vicious cycle of poverty, armed conflict and mental health in low-and-middle-income countries. From The Mental Health and Poverty Project (2008), Breaking the vicious cycle of mental ill-health and poverty [7]
Figure 2

Flow chart of strategies offer within the stepped-care mental health program intervention sites to four levels of severity (asymptomatic, mild, moderate, and severe)