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The impact of digital mental health technology on mental health, education, and economic outlook of young adults

Submission date
14/01/2025

Recruitment status
No longer recruiting

Registration date
20/01/2025

Overall study status
Ongoing

Last Edited
11/06/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Mental health challenges can exacerbate poverty by limiting educational attainment, reducing social mobility, and hindering economic advancement. Globally, increasing higher education participation among low-income students is a key policy priority to combat poverty. While efforts typically target financial or access barriers, the critical role of mental health is often overlooked. Digital mental health technologies have emerged as scalable and potentially cost-effective solutions to bridge the mental health care gap, particularly for vulnerable young adults. While evidence suggests these interventions can improve mental health in the short term, existing studies are often small-scale, underpowered, and predominantly from high-income countries. This study examines the effects of digital mental health technology on the mental health, educational, and economic outcomes of low-income students in Colombia. The trial is embedded within the Renta Joven program, a nationwide government initiative offering a conditional cash transfer as an initiative to support low-income young people to access, persist in, and graduate from higher education. The primary research questions are: 1. To what extent does access to digital mental health technology improve the mental health of low-income students, as measured by a composite index of depression and anxiety symptoms?; and, 2. How does a digital mental health intervention affect educational performance and retention in higher education? The secondary research questions are: 1. Can a digital mental health intervention influence decision-making linked to human capital investments, such as self-control and patience?; and, 2. How does digital mental health support shape students' labor market outlook?

Who can participate?
Participants who are enrolled in college or vocational training and aged 18 or older will be drawn from the Renta Joven program

What does the study involve?
Participants will follow a structured procedure beginning with a screening survey to confirm their eligibility, consent, and access to necessary resources for the study. Eligible participants will then complete a baseline survey that assesses various variables, including mental health symptoms using three validated tools. These assessments will categorize participants into mild,

moderate, or severe symptom levels. Participants identified as being at acute risk of suicide will be excluded from the intervention, referred to a safety protocol, and directed to appropriate mental health services.

Eligible participants will be randomly assigned to either the control (usual care) or treatment group (digital platform) using stratified randomization based on symptom severity. Participants in the treatment group with mild symptoms will access the digital platform, while those with moderate or severe symptoms will be further randomized to either platform-only or platform-plus-peer support. Follow-up assessments will occur at 3, 6, and 9 months post-intervention, measuring effectiveness and implementation outcomes. Engagement data will be automatically collected via the platform, and administrative data will be used to assess educational and employment outcomes for participants who consent.

Treatment groups will have access to the Wellbeing Digital platform, a 10-week, digital, transdiagnostic mental health intervention grounded in cognitive behavioural therapy. The transdiagnostic approach addresses multiple mental health problems simultaneously. The Youth Well-being platform, co-designed with young beneficiaries and staff of the Renta Joven program, comprises six modules and an emotional regulation toolbox for flexible use. All modules and tools rely on and are inspired by components of protocols tested in comparable populations.

Peer support is aimed to clarify any questions regarding the platform’s tools and to motivate participants to remain engaged with the platform. Peers are trained to provide relatable guidance and emotional encouragement to enhance user engagement, help participants navigate the resources available in the platform, and ensure the sustainability of the intervention. Peers will have contact with participants through personalized messages on the platform. Peer support will slightly vary by severity, with moderate cases receiving asynchronous, participant-initiated support, and severe cases being offered asynchronous, proactive engagement.

What are the possible benefits and risks of participating?
Participation in the study is designed to contribute to participants' emotional well-being and foster positive changes in their daily lives, such as improvements in work or educational progress. As a gesture of appreciation for their time and involvement in completing each survey, participants will have the opportunity to enter a raffle for gift vouchers and they may receive a small incentive for each survey.

The study involves no significant risks. However, if participants feel uncomfortable answering any questions or engaging with any part of the provided services, they may choose to pause or withdraw from the study at any time.

All participation is confidential. However, in cases where a severe emotional health situation is identified that poses a significant risk to the participant’s life, physical or mental integrity, or that of another individual, the mental health team will provide appropriate guidance and referrals. If necessary, this could include contacting a trusted individual provided by the participant or notifying the wellness center of the participant's institution.

Where is the study run from?
The study is run by the University Hospital Fundación Santa Fe de Bogotá (FSFB), in collaboration with the Colombian Government’s Department of Social Prosperity (Prosperidad Social), the University of Basel, and the Centre for Primary Care and Public Health at the University of Lausanne (Switzerland).

When is the study starting and how long is it expected to run for? Who is funding the study?
September 2022 to January 2026

Who is funding the study?
1. The Swiss National Science Foundation (SNSF)
2. The Swiss Agency for Development and Cooperation (SDC)

Who is the main contact?
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Study website
https://wp.unil.ch/youthwellbeing/

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Swiss National Scientific Foundation (SNSF) 400440_213267

Study information

Scientific Title
The impact of a digital mental health platform (Youth Well-Being) vs. usual care on mental health, education and economic outcomes: A randomized controlled trial among Low-income Young Adults in the Renta Joven programme in Higher Education in Colombia

Acronym
Youth Well-being

Study objectives
1. Compared to participants in the control group (usual care), participants who will access the digital mental health intervention will show less symptoms of depression and anxiety.
2. Compared to participants in the control group (usual care), participants who will access the digital mental health intervention will have a higher average cumulative Grade Point Average (GPA).
3. Compared to participants in the control group (usual care), participants who will access the digital mental health intervention will have higher retention rates in their study program they were enrolled in at baseline.
4. Compared to participants in the control group (usual care), participants who will access the digital mental health intervention will show more future orientation (combination of self-control

and patience).
5. Compared to participants in the control group (usual care), participants who will access the digital mental health intervention will have a better labour market outlook.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 29/07/2024, Corporate Ethics Committee of the Santa Fe de Bogota Foundation [Original name in Spanish: Comité Corporativo de Ética de Investigación de la Fundacion Santa Fe de Bogota] (Carrera 7 B No. 123-90, Bogota, 110111, Colombia; +(571) 603 0303; info@fsfb.org.co), ref: CCEI-16632-2024; CCEI-16198-2024

2. Approved 28/01/2025, Corporate Ethics Committee of the Santa Fe de Bogota Foundation [Original name in Spanish: Comité Corporativo de Ética de Investigación de la Fundacion Santa Fe de Bogota] (Carrera 7 B No. 123-90, Bogota , 110111, Colombia; +(571) 603 0303; info@fsfb.org.co), ref: CCEI-17269-2025

Study design
Single-centre unblinded three-arm effectiveness-implementation randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Internet/virtual, University/medical school/dental school

Study type(s)
Prevention, Treatment, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Mild, moderate or severe symptoms of depression, anxiety or post-traumatic stress disorder (PTSD)

Interventions
Recruitment of participants is through the the Youth Income (Renta Joven) scheme, a government nationwide program that provides regular conditional cash transfers to university and technical education students from low-income backgrounds. The trial takes place in close collaboration with the Administrative Department for Social Prosperity, the national government agency responsible for the Renta Joven programme.
Comparison groups are as follows:
1) Treatment group 1 will have access to the Youth Well-being digital mental health platform;

2) Treatment group 2 will have access to the Youth Well-being digital mental health platform plus peer support;
3) The control group will receive general information about standard care.

Our main analysis will compare the pooled treatment groups (comprising both, Youth Well-being platform-only and platform-plus-peer) with the control group across all severity groups to maximize statistical power.

The Youth Well-being Digital platform
Treatment groups will have access to a 10-week, digital, transdiagnostic mental health intervention grounded in cognitive behavioural therapy. The transdiagnostic approach addresses multiple mental health problems simultaneously. The Youth Well-being platform, co-designed with young beneficiaries and staff of the Renta Joven program, comprises six modules: motivational interviewing, behavioural activation, problem-solving, interpersonal effectiveness, sleep strategies, and PTSD symptom management. Additionally, an emotional regulation toolbox is available for flexible use as needed. All modules and tools rely on and are inspired by components of protocols tested in comparable populations.

Peer support
Peer support is aimed to clarify any questions regarding the platform's tools and to motivate participants to remain engaged with the platform. Peers are trained to provide relatable guidance and emotional encouragement to enhance user engagement, help participants navigate the resources available in the platform, and ensure the sustainability of the intervention. Peers will have contact with participants through personalized messages on the platform.

Procedure and assessment
Participants will go through the following procedure and assessment:
1) Screening survey: All eligible Renta Joven participants will be invited to complete a screening survey to assess consent, ability and means to participate in the study.
2) Baseline survey: Participants who meet eligibility criteria, consent to the study and complete the screening survey will be invited to take part in the baseline survey, which assesses a range of variables including mental health symptoms with three internationally recognized standard scales, all of which have been validated in Colombia: The Patient Health Questionnaire-9 (PHQ-9), designed to measure depressive symptoms; the Generalized Anxiety Disorder-7 (GAD-7), which evaluates symptoms of anxiety; and the Primary Care Posttraumatic Stress Disorder (PTSD) for DSM-5 (PC-PTSD-5), which assesses symptoms of PTSD. Participants will be classified into mild, moderate or severe levels of symptoms based on routinely used categorizations for each scale. Asymptomatic participants will be excluded.
3) Exclusion of participants at acute risk of suicide: Participants identified as having a risk of suicide and requiring emergency treatment will be excluded from the intervention and directed to a safety protocol and local services.
4) Randomization: Participants will be randomly allocated to the control (50%) or treatment group (50%). Stratified randomization by overall severity level (mild, moderate, severe) will be carried out using STATA. Fifty percent of participants within each severity group will be randomly allocated to the control group (usual care) and fifty percent to the treatment group (digital platform), with comparisons between these groups used to test our primary hypotheses. Participants with mild symptoms in the treatment group will access the Youth Well-being platform. Those in the treatment group with moderate or severe symptoms will be further randomized into two equal subgroups: 50% to platform-only and 50% to platform-plus-peer support.
5) Follow-up Assessments: We will conduct three follow-up surveys of effectiveness and

implementation outcomes at 3, 6 and 9 months after the intervention begins. Data on user engagement will also be routinely collected automatically through the Youth Well-being digital platform. For participants who consent, government administrative data will also be used to assess educational and employment outcomes.
Semi-structured interviews and focus groups will also be conducted with programme participants and peers to assess their experiences with the intervention and identify enablers and barriers to successful implementation.

Intervention Type
Behavioural

Primary outcome measure
1. Mental health, measured using the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) index, a composite measure of depression and anxiety derived from the summed scores of the PHQ-9 and General Anxiety Disorder-7 (GAD-7) scales, at baseline, 3, 6 and 9 months
2. Enrolment continuity, measured through the survey by assessing whether participants interrupted their program or dropped out, at baseline, 3, 6 and 9 months
3. Academic performance, measured based on participants' grade point average (GPA) assessed through survey questions at baseline, 3, 6 and 9 months, complemented with government administrative data

Secondary outcome measures
1. Standardized scores for depression (PHQ-9), anxiety (GAD-7), and PTSD (PC-PTSD-5)
2. Changes in clinical thresholds for depressive symptoms (measured with the PHQ-9), anxiety symptoms (measured with the GAD-7), and PTSD symptoms (measured with the PC-PTSD-5), at baseline, 3, 6 and 9 months
3. Courses completion, measured by questions on how many courses or modules they took in the prior semester, how many they expect to take, whether failing courses and how many, at baseline, 3 and 6 months
4. Study efforts: measured by questions about hours of self-study and engagement with study programme, at baseline, 3 and 6 months
5. Work and income, measured by questions about work (for all participants) and income (only for participants that completed their studies) during the last academic period, assessed at baseline, 3, 6 and 9 months
6. Future orientation, comprising measures of: a) Patience, assessed through a 10-point Likert scale asking, "Compared to others, do you consider yourself a person willing to give up something today in order to benefit from it in the future?"; b) time discounting, measured through a series of two hypothetical binary choices between immediate and delayed financial rewards; c) self-Control, measured by the BSCS scale, a short 13-item self-report format measure of the general self-control construct; assessed at baseline, 3 and 6 months
7. Employment outlook, measured by questions about aspirations and expectations on their employment and earning six months after graduation, assessed at baseline, 3 and 6 months
8. Education aspirations and expectations, measured through questions about the extent to which they expect to continue and complete their study programme, and aspirations about their studies, assessed at baseline, 3 and 6 months
9. Additional educational and employment outcomes from administrative data, particularly retention and continuity with study programme and compliance with Renta Joven conditions, as well as earnings from formal employment.
10. Quality of life, measured with the EQ-5D scale and used to assess intervention cost-effectiveness; measured at baseline and 9 months

Overall study start date
01/09/2022

Completion date
12/01/2026

Eligibility

Key inclusion criteria
1. To provide informed consent
2. Registered in the Renta Joven programme
3. 18 years and older
4. Mild, moderate or severe symptoms of depression, anxiety and/or PTSD (excluding individuals with high risk of suicide, who will be offered a safety protocol)
5. Access to a smartphone, PC, tablet or other device with internet
6. To answer positively to a question about their willingness to use a digital platform for mental health and well-being
7. To complete the baseline survey in no less than 4 minutes

Participant type(s)
Learner/student

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
11250

Total final enrolment
14881

Key exclusion criteria
Participants identified through the baseline survey as having a risk of suicide. These participants will be contacted by a project psychologist and offered psychological first aid, crisis management, and assistance in identifying and accessing local mental health services. The psychologist will track their progress and verify their access to the identified resources.

Date of first enrolment
27/01/2025

Date of final enrolment

09/03/2025

Locations

Countries of recruitment
Colombia

Study participating centre
Santa Fe de Bogota Foundation [orignal name: Fundacion Santa Fe de Bogota]
Carrera 7 B No. 123-90
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
https://www.unisante.ch/

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Sponsor type
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Website
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ROR
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Sponsor type
Government

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Funder(s)

Funder type
Research organisation

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

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

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication of main study findings as well as additional publications of secondary findings in peer-reviewed journals

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
All individual participant data collected via surveys and the co-designed platform will be pseudo-anonymized (coded) using unique participant ID numbers. Administrative data, owned by the Social Prosperity Office of the Colombian government, will be added to the survey database in a pseudo-anonymized manner based on an explicit data-sharing agreement. Identifiable information contained within the surveys will be removed and securely stored in a separate link file, which includes participant names, national ID numbers, consent forms, and corresponding IDs. This link file will be stored in a separate physical and secure location beyond the completion of the study, ensuring participants can be invited to participate in any future research initiatives related to the study.

Audio recordings of qualitative semi-structured interviews and focus groups, which contain identifiable data, will be destroyed as soon as the transcripts are finalised.

During the data collection phase, pseudo-anonymized data will be shared exclusively with partner institutions as defined in the collaboration agreement. All data will be treated as confidential and will not be shared with external researchers without prior written consent from all collaborating institutions. In cases where external researchers or institutions request access, a formal data-sharing agreement must be completed prior to the release of de-identified data.

Upon project completion, the pseudo-anonymized datasets will be stored in Unisanté's data repository (https://data.unisante.ch/home), which provides long-term storage and facilitates access to research datasets. To ensure data security and allow time for initial analyses, the data will be subject to a two-year embargo period before becoming openly accessible. After the embargo, quantitative datasets will be made openly available to researchers worldwide. Qualitative data will also be stored, but will not be publicly available, and instead shared upon request, due to the sensitive and context-specific nature of the qualitative data.
Consent forms and data will be retained for a minimum of 5 years after the last publication. Following this period, the principal investigators will evaluate whether to retain the data further, considering its relevance to national and international researchers at that time. Throughout data storage and sharing, we will ensure adherence to the FAIR principles (Findable, Accessible, Interoperable, and Reusable) to maximize the utility of the data for future research.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 1	07/06/2025	09/06/2025	No	No
Statistical Analysis Plan	version 2	11/06/2025	11/06/2025	No	No