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A randomised control study: evaluating the RECONNECTED digital mental health intervention in Kosovo

Submission date 07/02/2026	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 09/02/2026	**Overall study status** Ongoing	
Last Edited 09/02/2026	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Study information

Scientific Title
A complex system approach towards REsilient and CONNECTED low socioeconomic status people in times of change: a full factorial randomized controlled trial

Acronym
RECONNECTED

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/12/2025, Ethics Committee Alma Mater Europaea Campus College Rezonanca (Glloku te Shelgjet ”Veternik”, Prishtina, 10000, Kosovo; +383 (0)38 544 754; info@rezonanca-rks.com), ref: AD-6197/25

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Factorial

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Mental wellbeing

Interventions
This full factorial trial is part of the RECONNECTED project. The project will offer a digital support system with culturally adapted and personalized intervention tools to various vulnerable populations. The digital support system targets both individual and social factors simultaneously (i.e. mental health literacy, psychological resilience and social connectedness) to maximize health benefits. The main aim of this trial is to examine if personalised micro-interventions and social activation add wellbeing benefits to mental health literacy. The additional effects of personalised micro-interventions and social activation to mental health literacy will be tested through full factorial trial. The other objective is to conduct a process evaluation to assess the feasibility of the digital support system, including usability, perceived usefulness, overall satisfaction, potential unintended negative effects, and engagement. To study the first research aim, all participants will be randomised to receive the mental health literacy intervention; with no or a maximum of two additional components (i.e., personalised micro-interventions and social activation). The full factorial design allows to assess the additional effect of each component, both individually and in interaction. To study the second

research aim, participants who receive the micro-interventions (conditions 3 and 4) are further randomized to receive either the standard micro-intervention (MI; conditions 3a and 4a) or micro-interventions supported by a machine learning algorithm (MI+ML; conditions 3b and 4b).

All outcomes will be assessed online at four timepoints: baseline (t0), 6 weeks (primary endpoint, t1), 3 months (t2), and 6 months (t3) follow-up, with each assessment taking a maximum of 30-45 minutes to complete. After completion of the 6-month follow-up assessment, all participants are granted access to the full digital support system, including components not previously available due to randomization. This access remains available until trial completion.

This study involves healthy individuals with an increased susceptibility to developing mental health problems in response to current global societal developments due to socioeconomic status. Adults aged 18 years or older also residing in low SES geographical areas in Kosovo. The selection of these populations ensures comprehensive coverage across different age groups.

Intervention Type
Behavioural

Primary outcome(s)
1. Well-being measured using Mental Health Continuum – Short Form (MHC-SF) at baseline (t0), 6 weeks (primary endpoint, t1), 3 months (t2), and 6 months (t3) follow-up

Key secondary outcome(s)
1. Mental health literacy measured using Mental Health Literacy Questionnaire - Short version for adults (MHLQ-SVa) at baseline (t0), 6 weeks (primary endpoint, t1)

2. Resilience measured using Connor-Davidson Resilience Scale - 10 (CDRS-10) at baseline (t0), 6 weeks (primary endpoint, t1), 3 months (t2), and 6 months (t3) follow-up

3. Social connectedness measured using UCLA-9 Loneliness Scale; Lubben Social Network Scale (LSNS) and Initiating activities -Self-composed on social engagement at baseline (t0), 6 weeks (primary endpoint, t1), 3 months (t2), and 6 months (t3) follow-up

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Mental wellbeing (languishing or moderately healthy) on the MHC-SF questionnaire scores
2. Informed consent (electronic and/or in person).
3. Can understand, write, and speak Albanian
4. Has a smartphone
5. Resides in Kosovo

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Severe mental illness
2. Mental health treatment
3. Inability to commit to engagement
4. Insufficient language comprehension

Date of first enrolment
01/04/2026

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
Kosovo

Sponsor information

Organisation
Për Mendje Të Shëndoshë

Funder(s)

Funder type

Funder Name
HORIZON EUROPE Framework Programme

Alternative Name(s)
Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon, Horizonte Europa

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available