

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

Submission date 07/02/2026	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 09/02/2026	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 09/02/2026	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

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