



A complex system approach towards REsilient and CONNECTED vulnerable European communities in times of change

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Abbreviations

AUDIT-C	Alcohol Use Disorder Identification Test Concise
BCOPE	Brief COPE scale
BSCI	Brief Sense of Community Index
CD-RISC	Connor Davidson Resilience Questionnaire
DPA	Data processing agreement
DMP	Data-Management plan
EMA	Ecological Momentary Assessment
FAIR	Findable, Attainable, Interoperable, Reusable
GDPR	General Data Protection Regulations
GHQ-12	General Health Questionnaire-12
GQOL	Global Quality of Life Scale
LSNS	Lubben Social Network Scale
MDSS	Multidimensional Digital Stress Scale
MHLQ	Mental Health Literacy Questionnaire
MIMIS	Mainz Inventory of Microstressors
MRR	Metatheory of Resilience and Resiliency
OSF	Open Science Framework
PMRF	Pairwise Markov Random Field
PSS	Perceived Stress Scale
PSQ	Psychosis Screening Questionnaire
PU	Public
RPWBS	Ryff's Psychological Wellbeing Scale
SASSY	Six Americas Super Short Survey
SAE	Serious Adverse Event
SES	Socioeconomic status
STAI-SF	State-Trait Anxiety Inventory Short Form

1. Summary

The first RECONNECTED study (CEMA) aims to gain a better understanding of the relation between global societal developments and mental health in different vulnerable populations in Europe. A cross-sectional cohort study will be conducted in 9 populations across Europe (Denmark, Finland, France, Germany, Kosovo, the Netherlands, United Kingdom, Spain, Switzerland). Participants will complete an online (cross-sectional) survey (30-45 minutes), followed by 14 days of completing five smartphone-based ecological momentary assessments (EMAs) a day. This report describes the study initiation package consisting of (1) the study protocol, (2) ethics approval, (3) study registration.

2. Introduction

Europe is in transition with a fourth industrial revolution on the rise, a changing population due to urbanisation, ageing, and migration flows, and several global societal challenges (e.g. climate change, digitalisation, geopolitical conflict) that threaten citizens' feelings of safety and wellbeing [1-5]. These developments have a major impact on Europe's economies, industries, cultures, public health, and the daily life of European citizens [6-10]. Although these developments bring new opportunities such as global connections and flexibility in work and learning, there are also cognitive and emotional challenges including information and connection overload related to urban life and digitalisation, worry about the future in relation to the social, environmental, and economic consequences of these developments, and identity problems instigated by, for example, social media use or migration. Not surprisingly, there are diverse groups of citizens that have difficulties adjusting to these changes, which puts them at risk of developing mental health problems. Crucially, research has suggested that the mental health of several marginalised and vulnerable citizens in Europe, such as people with low socioeconomic status, immigrants, youth, and elderly, are affected the most by these developments [11-13].

Global societal challenges may affect vulnerable citizens in Europe in different ways dependent on their phase of life, personal characteristics, and social- and environmental circumstances. For instance, regarding digitalisation, research has shown that people over 55 with low education or low living standards are vulnerable regarding workplace digitalisation [14]. Youth mental health is more likely affected by social media use and continuous connectivity [15,16]. Additionally, geographical location is important. For example, because of climate change, earthquakes have challenged Kosovo and Albania, heat-related problems hit southern European countries, and some other countries face threats of flooding or sea level rise. The war in Ukraine likely affects countries in the close

vicinity most, by causing increased threat of violence and incoming refugees [17-22]. Notably, there already exists an unmet need for mental health support among socially disadvantaged groups due to stigma, poor mental health literacy, and the high costs of treatment [23-25]. To not leave citizens behind, it is key to have a society that is aware of and responsive to these problems, and citizens that are resilient in a rapidly changing society.

The RECONNECTED project (www.reconnected-project.eu) involves a consortium of 11 European partners and was initiated in response to these global societal developments that may have direct or indirect consequences for mental health. The ultimate goal of the RECONNECTED project is to provide vulnerable citizens in Europe with a digital support system, with intervention tools, to improve resilience and connect citizens with the aim to protect their mental health. However, it is not well-known how current global societal developments impact the daily life and mental health of European citizens and what risk and protective factors are involved. To inform the development of the digital support system, a first step in the project is to gain a better understanding of the complex interplay between risk and protective factors, and mental health of various vulnerable populations in Europe (e.g. those with low socio-economic status, youth, migrant populations, elderly) in the context of global societal developments. This first RECONNECTED study (CEMA) is described in the current protocol.

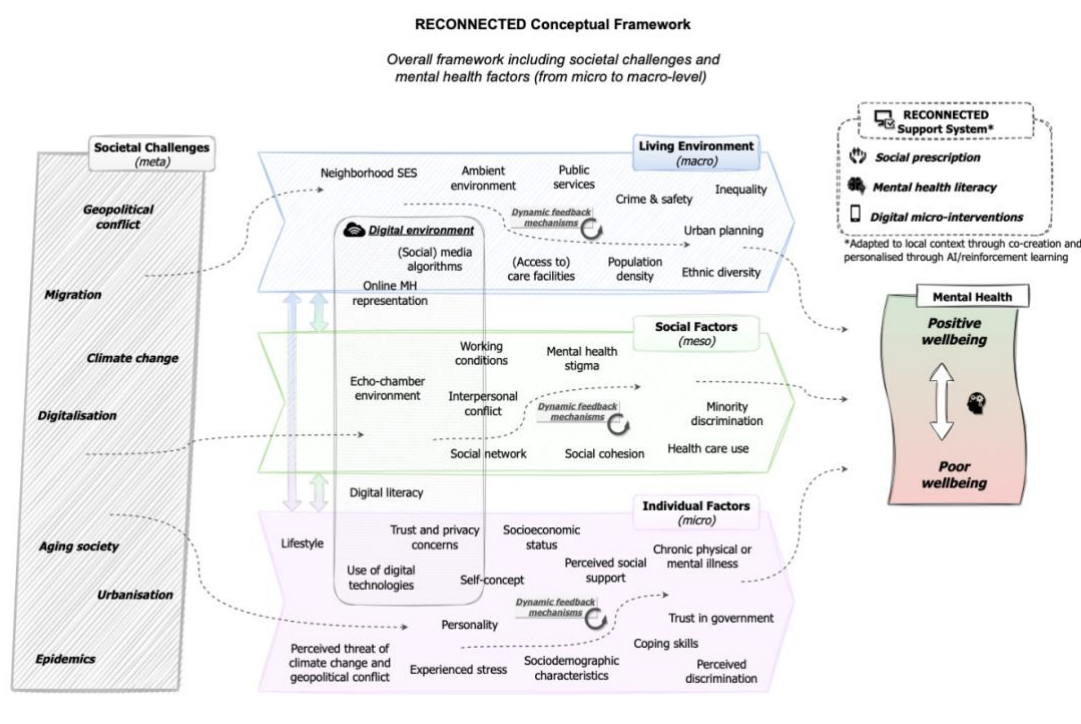


Figure 1 RECONNECTED Conceptual framework

To guide the CEMA study, an integrative conceptual framework was developed first (see Figure 1). This framework is based on an existing framework for urban mental health developed by one of the consortium partners [26] and extended for the RECONNECTED project to include global societal developments. The framework uses a complex system perspective which considers mental health as the outcome of the interplay between different risk and protective factors that can act at different levels of description ranging from the societal (meta), physical environmental (macro), social environmental (meso), and individual (micro) level. In line with a complex system perspective, the framework is based on four principles [26]: 1) the factors and outcomes involved operate as dynamically interacting elements within a complex system, 2) factors are affected by meta-factors at the societal level, 3) interactions between explanatory factors and common mental disorders occur over different time scales, and 4) outcomes can affect explanatory factors (feedback loops). Interest in the conceptualisation of mental health and its determinants as a complex system has grown over the past decade with the introduction of the network theory of psychopathology [27]. This theory assumes that psychopathology represents a complex system of interconnected symptoms that are active agents and play a causal role [27]. These symptoms can be seen as a set of nodes (elements) that are connected through edges (the associations between nodes). For example, when psychological symptoms such as depressed mood and sleep problems (nodes) are highly connected (association between nodes), an increase in one symptom will also increase the other. Conversely, if there is a weak connection between symptoms, an increase in one symptom will hardly increase the other.

In the RECONNECTED conceptual framework, global societal challenges are seen as meta-level factors that can impact mental health either directly (for example a climate disaster) and indirectly by their impact on environmental, social, and individual risk and protective factors. An example of such an indirect effect is migration (a meta factor), which may lead to job insecurity and low social participation. Dependent on individual factors, such as coping, this may lead to feelings of social exclusion, low self-esteem, and low mood if a maladaptive coping strategy such as avoidance is applied, which will further decrease social participation and the chances of finding a job. However, if an active approach to deal with the situation is applied, it may lead to increased efforts to engage in the community which may increase mood and self-esteem and, in turn, the chances of finding a job.

Resilience is a key concept in the RECONNECTED project and is defined as the process of maintaining mental health or a quick recovery when exposed to significant stressors or challenging life events that require adaptation [28,29]. Over the years, research on resilience has shifted from a trait-oriented approach -with a focus on resilient factors that

help people deal with adversity such as being optimistic- to a process-oriented approach that explains how people adapt to stressors [29]. The metatheory of resilience and resiliency (MRR) [28] integrates the trait- and process approach and fits very well with the RECONNECTED conceptual framework by (1) emphasising the interaction between the individual and their environment in managing and recovering from stressful life events and (2) offering guidance on how to intervene in this process. In this theory, resilience is considered the *process* of coping with adversity, change, or opportunity in a manner that results in the identification, fortification, and enrichment of *resilient factors* [28]. In short, the idea is that stressors (or other life prompts) can cause disruptions in people's life that threaten existing biopsychospiritual homeostasis. The (mental health) outcome of the disruption depends on the reintegration or coping process and can be resilient reintegration (e.g. with acquired new skills and qualities), back to homeostasis (e.g. to get past the disruption), reintegration with loss (e.g. by giving up motivation and hope), or dysfunctional reintegration (e.g. by using maladaptive coping strategies). Resilience processes determine for a large part how people respond to change such as those instigated by global societal developments and are influenced by risk and protective factors at the micro-, meso-, and macro level.

3. Objective

The objective of this deliverable is to present the study initiation package of the RECONNECTED CEMA study. The study initiation package consists of the CEMA study protocol (chapter 4), ethical approval (chapter 5), and study registration (chapter 6).

4. CEMA study research protocol

4.1 Study aim

The overall objective of this study is to gain a better understanding of the relation between global societal developments and mental health in different vulnerable populations in Europe. More specific aims are:

1. To describe stressors, other risk- and protective factors at different levels of description, and mental health and wellbeing of different vulnerable populations in Europe.
2. To examine -cross-sectionally- to what extent mental health and wellbeing are related to several risk- and protective factors at the individual-, social-, and environmental level.
3. To investigate the resilience process (stress-regulation strategy-outcome) dynamically in people's daily life using ecological momentary assessments to identify adaptive and maladaptive regulation strategies to deal with daily life stressors.

Research aims 2 and 3 are approached from a complex system perspective and use network models to test the association (edges) between elements (nodes) in the network. These networks will be examined within the various vulnerable populations and compared across vulnerable populations; research aim 2 mainly to generate hypotheses and identify potential actionable target points and research aim 3 to test hypotheses. Factors related to global societal developments will be integrated in the models (e.g. perceived stress due to climate change, digital distress, urbanisation grade).

4.2 Methods

4.2.1 Study design

The study is a cohort study in 9 populations across Europe (Denmark, Finland, France, Germany, Kosovo, the Netherlands, United Kingdom, Spain, Switzerland). Participants will complete an online (cross-sectional) survey (30-45 minutes), followed by 14 days of completing five smartphone-based ecological momentary assessments (EMAs) a day.

4.2.2 Study population

This study involves people from the general population including vulnerable populations (i.e. individuals with an increased susceptibility to developing mental health problems in response to current global societal developments due to their age, minority status, or socioeconomic status). The cohorts represent specific populations from nine different European countries (see Table 1). Furthermore, we have opted for countries with diverse geographical and socioeconomic characteristics. Alongside the cohort-specific inclusion criteria (Table 1), a general inclusion criterion is access to a smartphone with Internet connection that participants can use for the duration of the study. There are no additional inclusion or exclusion criteria.

Table 1. Country-specific target populations and recruitment procedures.

Country	Target population	Recruitment procedure
Denmark	Youth aged 16-25 from the general population	Posters at relevant educational institutions and social media posts.
Finland	Young adults aged 18-20 from the general population	Through educational institution mailing lists.
France	Adults aged 18 or older residing in low socioeconomic status (SES) geographical areas based on postal code on the outskirts of Paris	Open recruitment through announcements on social media and in local newspapers, public posters,

		and flyers distributed in targeted neighborhoods. These materials are also placed in strategic locations such as community and social centers, solidarity grocery stores.
Germany	Children aged 12-16 in secondary education in North-Rhine Westphalia, Germany	Mainly open school-based recruitment, additional open recruitment at youth sports clubs and youth recreational clubs.
Kosovo	Adults aged 18 or older, residing in various SES neighborhoods (in low and other SES neighborhoods) in Pristina municipality and surrounding area.	Open recruitment strategy via advertisement through social media, university libraries and social work centres, by distributing posters, flyers and landing page website link, to attract potentially interested participants.
The Netherlands	Adults aged 55 or older living in urban areas	Open recruitment strategy through social media, community centers, social work, and public libraries.
The United Kingdom	Non-western migrants aged 18 or older who live in the United Kingdom	Open recruitment via, community workers, email, social media posts, newsletters, university platforms and other local channels, such as cultural centres.
Spain	Migrants aged 18 or older from a Latin-American background in Spain	Open recruitment strategy through, among others, community centers, social workers, and mental health services.

Switzerland	German-speaking adults aged 55 or older from the general population who live in Switzerland	Open recruitment strategy through community centers, social workers, and mental health services, social media, newspaper interviews, among others.
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4.2.3 Procedure

A local study website will contain all information about study participation. Prospects apply for participation on the website by submitting their contact details and completing a short questionnaire screening for in- and exclusion criteria. Those eligible to take part will be registered on the Moodbuster Platform (which is used for data collection) and receive a link to the online informed consent form. When informed consent is provided, participants will be invited to complete the online (cross-sectional) survey and subsequently to complete 14 days of ecological momentary assessments (EMA) on their mobile phone. A standard set of questions for the baseline survey will be identical across all study sites. Local sites may supplement that with additional questionnaires of particular interest for the local target group or research group, provided that the total set of questionnaires will take no more than an average of approximately 45 minutes to fill out. After completing the baseline survey, the participants will complete daily smartphone-based ecological momentary assessments (EMAs). EMA is a structured diary technique to measure subjective experiences in daily life [29]. In the EMA study, the participants will be prompted to complete small, specific, and easy items five times per day within 5 temporal windows (they will be prompted randomly in the first 30 minutes of the window and, if not responsive, again during the final 30 minutes of the window): a morning assessment, three assessments during the day, and an evening assessment. The standard set of items will comprise 13 items during the morning assessment, 15 during the day assessments, and 21 items during the evening assessment. As with the baseline survey, local sites may supplement the fixed set of EMA questions with additional items, provided that the EMAs will not take more than 3 minutes to complete. Participants are instructed to complete the EMAs as soon as possible after receiving the prompt (notification on their smart phone). However, the notification will remain visible for two hours beyond the time slot. We opted not to set a very short timeframe for completing the EMAs, as is sometimes done, because we recognize that not all participants can respond immediately due to contextual factors. For instance, some may only have access to their phones during breaks from school or work. All EMA measures will be time stamped.

Table 2 Inclusion process

Advertisement of study information....	-> Landing page with study info and sign-up option (name, e-mail, eligibility e.g. via Qualtrics)	-> If eligible, participant is entered into Moodbuster system and login details will be e-mailed by the research team....	-> The e-mail will provide instructions for installing the app and completing the survey...	-> Participants fill out the survey and proceed to the app for 14 days of EMA....	-> When finished a notification is send to the local site (automated from INESC-TEC)....	-> Local study team will send reimbursement.

4.2.4 Sample size and power estimates

There is no good guidance on the a-priori sample size calculation for network analyses. Our sample size calculation is based on a rule of thumb based on simulation data, which showed that a sample size of 250-350 is generally sufficient to observe moderate sensitivity, high specificity, and high edge weights correlation with about 20 nodes (unpublished data). As we want to base conclusions on locally collected and pooled data, we aim for a sample size of 350 participants in each of the 9 cohorts, leading to a total sample of 3,150 participants.

4.2.5 Study parameters

The selection of study variables is guided by the RECONNECTED conceptual framework and the intervention tools that will be developed in the project and target psychological resilience, social participation, and mental health literacy. An overview of the survey questions and EMA items is provided in table 3 and 4 respectively. In addition to the questions completed by participants we collect information from registries based on area of living.

4.2.5.1 Survey

Mainz Inventory of Microstressors (MIMIS)

The *Mainz Inventory of Microstressors* (MIMIS) [33] is a self-report instrument aimed at comprehensively assessing individual microstressors. In this study we slightly adapted the MIMIS to include 46 potential daily stressors (instead of 58) that are rated twice, once for how many times a stressor occurred in the past fourteen days (instead of 7 days as the original scale proposes) on a four-point Likert scale from 0 (“Did not happen”) to 3

(“Nearly every day”) and once for perceived severity stressor rated and five-point Likert scale from 0 (“not at all straining”) to 4 (“very straining”). High correlations were found between scores and momentary assessment for microstressor occurrence ($r \geq .69-.83$) and for mean perceived microstressor severity ($r \geq .74-.85$). Underlining strong validity for use of MIMIS as past-week stressor assessment [33].

Perceived Stress Scale (PSS) 4 items

The *Perceived Stress Scale* (PSS) 4-item version [34] is a widely used instrument for assessing an individual's perception of stress in their life. Respondents are asked to recollect their feelings and thoughts over the past month and answer accordingly on a five-point Likert scale ranging from 1 (“Never”) to 5 (“Very often”). Studies have shown that higher scores on the PSS are associated with greater psychological distress, poorer physical health outcomes, and reduced quality of life [34,35]. The PSS 4-item version has repeatedly shown acceptable psychometric properties upholding its validity as a reliable short version of its 14-item counterpart [34,35,36]. Brevity and ease of administration make the PSS an efficient instrument for assessing perceived stress levels and informing interventions aimed at reducing stress and improving overall well-being.

Six Americas Super Short Survey (SASSY)

The *Six Americas Super Short Survey* (SASSY; [37]) assesses individuals' levels of concern regarding climate change. Designed with four questions answered using tailored Likert scales, the survey categorizes individuals into six distinct groups based on their attitudes and concerns about climate change, ranging from “Alarmed” to “Dismissive”. The 4-item version of SASSY has demonstrated good validity, test-retest reliability, and predictability of climate change concern, with average classification accuracy ranging from 77 to 94 percent [37,38]. Additionally, in European subsamples, the Six Americas Short Survey successfully determined German climate change attitudes [39], underscoring its usability for the present study.

Multidimensional Digital Stress Scale: Connection Overload

The connection overload subscale of the Multidimensional Digital Stress Scale [40], serves as a robust tool for assessing stressors related to excessive connectivity and engagement with social media platforms. The questionnaire comprises six statements regarding negative concerns about media use. A five-point Likert scale ranging from 1 (“Never”) to 5 (“Always”) is used to assess frequency of the statements during the past week. Hall et al. (2021) demonstrated that the subscale exhibits good internal reliability and strong associations with overall digital stress, thereby providing a solid foundation for its standalone use.

Table 3

Domain	Variable	Instrument Used	Items
Participant characteristics	Gender, age, relationship status, education, employment, children, household composition	n/a	8
Health	Previous and current mental health disorders	n/a	5
	Current medical conditions	n/a	1
	Hospitalized for severe Infection	n/a	1
Digital skills	Use of devices	n/a	3
Area of living	Residential Area Indicator (Postal Code or Other Indicator)	n/a	1
	Residential Area at Birth Indicator (Postal Code or Other Indicator)	n/a	1
Migration	Country birth, years living in country, country birth parents	n/a	6
Stress(ors)	Micro-Stressors	Mainz Inventory of Microstressors (MIMIS)	max 46
	General Perceived Stress	Perceived Stress Scale (PSS)	4
	Concern about Climate Change	Six Americas Super Short Survey (SASSY)	4
	Connection overload	Multidimensional Digital Stress Scale (MDSS)	6
	Geopolitical Unrest	STAI-SF re Geopolitical Unrest	3
Mental health	General Mental Health	General Health Questionnaire-12 (GHQ-12)	12
	Psychological Well-being	Ryff's Psychological Well-being Scale (RPWBS)	18
	Psychotic Symptoms	Psychosis Screening Questionnaire (PSQ)	5
	Quality of Life	Global Quality of Life Scale (GQOL)	1
Individual Factors	Mental Health Literacy	Mental Health Literacy Questionnaire (MHLQ)	16
	Resilience	Connor Davidson Resilience Scale (CD-RISC)	10
	Coping Skills	The Brief COPE Scale (BCOPE)	28
	Physical Activity		2
	Tobacco, Illegal Drug, Recreational Medication		3
	Alcohol Use	Alcohol Use Disorders Identification Test (Audit-C)	3
Social Factors	Sense of Community	Brief Sense of Community Index (BSCI)	8
	Social Isolation	Lubben Social Network Scale (LSNS)	6
	Loneliness	n/a	1

STAI-SF Related to Geopolitical Unrest

The *State Scale* of the Spielberger State—Trait Anxiety Inventory Short Form (STAI-SF) [41], designed to assess individuals' current levels of anxiety, including those influenced by external stressors such as geopolitical unrest. This abbreviated version consists of three items targeting feelings of worry, tension, and upset, with responses scored on a seven-point Likert scale ranging from 1 (“does not describe my current state of mind at all”) to 7 (“describes my current state of mind perfectly”). Both the State Anxiety Scale and its condensed form have demonstrated strong internal consistency, reliability, and content validity across various study populations [41,42,43,44]. Recent research by Celuch, Savolainen, Oksa, & Oksanen [45] highlights the association between heightened anxiety related to the Russo-Ukrainian war and increased psychological distress.

General Health Questionnaire-12 (GHQ-12)

The *General Health Questionnaire-12* (GHQ-12), as validated by Goldberg, Gater, Sartorius, Ustun, Piccinelli, Gureje, & Rutter [46], is a shortened version of Goldberg's scale [47]. It functions as a screening tool aimed at identifying psychiatric disorders within both community and non-psychiatric clinical settings. The questionnaire consists of 12 items that probe respondents about recent experiences of specific symptoms or behaviors. Responses are rated on a four-point Likert scale, ranging from "Not at all" to "Much more than usual". Goldberg et al. [46] demonstrated the GHQ-12's reliability and adequate validity. However, it's important to exercise caution when using it as a screening tool, as suggested by Schnirtz [48] and Romppel et al. [49]. Specifically, single-item assessments should be conducted carefully, and a unidimensional model should be maintained.

Ryff's Psychological Well-being Scale (RPWBS): Six Subscales

The *Ryff's Psychological Well-being Scale* (RPWBS) [50] is an 18-item shortened version of the initial scale proposed by Ryff & Keyes [51]. The subscales provide a nuanced understanding of individuals' overall well-being by exploring dimensions such as autonomy, environmental mastery, personal growth, positive relations with others, purpose in life, and self-acceptance. Each subscale comprises three reflective statements, which respondents rate on a 7-point Likert scale, ranging from "Strongly agree" to "Strongly disagree". Ryff & Keyes [50] demonstrated statistically significant correlations, ranging from .70 to .89, between the shortened RPWBS and its validated parent scale [51]. While the scale exhibits high test-retest reliability and internal consistency across multiple studies, its six-factor structure has been met with varying degrees of success [51,52,53].

Psychosis Screening Questionnaire (PSQ)

Bebbington & Nayani's [54] Psychosis Screening Questionnaire (PSQ), aims to identify psychotic symptoms. Comprising five targeted probe questions supplemented by detailed responses in cases of affirmative responses, the PSQ provides a structured framework for systematically evaluating potential indicators of psychosis. Bebbington & Nayani [54] reported high predictive value for the questionnaire, underlining its validity when used as a screening instrument.

Global Quality of Life Scale (GQOL)

The *Global Quality of Life Scale* (GQOL), introduced by Hyland and Södergren [55], comprises a single item designed to assess overall perceived quality of life. Participants indicate their response by selecting a number between 0 and 100 on the self-coined Hyland (H) scale, where 100 represents "Perfect quality of life" and 0 represents "No quality of life," with intermediate values displayed as well. This single-item index has demonstrated strong correlations with other quality of life measures and has exhibited acceptable psychometric properties [55,56].

Mental Health Literacy Questionnaire (MHLQ)

The *Mental Health Literacy Questionnaire* - short version for adults (MHLq-SVa). Based on the validated MHLq-ya (for young adults), this self-report questionnaire measures four dimensions of mental health literacy: Knowledge of mental health problems, erroneous beliefs/stereotypes, first-aid skills and help seeking behavior, and self-help strategies [57]. 16 statements are presented which participants rate on agreeableness by a five-point Likert scale ranging from 1 ("Strongly disagree") to ("Strongly agree"). Campos, Dias, Costa, et al. (2022) conducted psychometric and validation testing across American, Portuguese, and East-Asian populations. The scale demonstrated good psychometric properties after translation and across different cultures, indicating its flexibility for cross-cultural adaptations.

Connor Davidson Resilience Scale (CD-RISC)

The *Connor Davidson Resilience Scale* - brief version (CD-RISC-10) comprises 10 items from the original CD-Risc [58,59]. The CD-RISC-10 has shown good psychometric properties when used to measure trait resilience across European community samples [60,61]. Items consist of ten statements regarding one's ability to navigate and thrive in the face of adversity. Responses are scored on a five-point Likert scale ranging from 0 ("Not true at all") to 4 ("True nearly all the time").

The Brief COPE Scale (BCOPE)

The Brief COPE scale (BCOPE) is a 28-item short version of the original 60-item COPE scale [62], which was theoretically based on various models of coping. Utilizing a Likert scale with four response categories ranging from 1 (“I haven’t been doing this at all”) to 4 (“I’ve been doing this a lot”), this scale enables individuals to report on their coping mechanisms in the face of stressors and challenges. Research indicates that the BCOPE demonstrates adequate to good psychometric properties across various populations, including those experiencing normal stress levels and highly stressed environments [62,63,64,65]

Physical activity 2-item

For the present study, two individual items were chosen to measure physical activity. The first measure enquires about the frequency of engaging in physical activity sufficient to elevate breathing rate over a specified recall period of last week. Answers are given on an open-response scale with valid responses ranging from 0 to 7 days. Those reporting zero days of activity are classified as ‘inactive’, those reporting between 1 and 4 days are considered ‘fairly active’, and those reporting 5 days or more are considered ‘active’. Good psychometric values for the single-item measure were found [66] and it has been determined that the item is a valid screening tool to determine whether respondents are sufficiently active to benefit their health [67]. If the participant answers the first item regarding physical activity as four days or less, they are then prompted to respond to a second item. This second item presents a closed question, asking whether the participant has been physically active for at least two and a half hours (150 minutes) over the past week. Originally, this tool was designed to assess whether respondents met the physical activity recommendation outlined by the British Department of Health, which recommend engaging in at least 30 minutes of moderate-intensity physical activity on five or more days of the week [68]. (Department of Health, 2004). Research conducted by Milton, Engeli, Townsend, Coombes, and Jones [69] demonstrated that a combination of these two items yielded the best kappa agreement when compared to longer, more comprehensive questionnaires.

Screening for substance use

Three questions are used to gain information on tobacco use, illicit drug use and the use of non-medical prescription medication in the past 12 months. The answer options are assessed on a 5-point likert scale (never, less than monthly, monthly, weekly, daily or almost daily).

Alcohol Use Disorders Identification Test (Audit-C)

The Alcohol Use Disorders Identification Test-Concise (AUDIT-C), introduced by Bush, Kivlahan, McDonell, et al. [70], is a brief alcohol-screening instrument designed to reliably identify individuals who are hazardous drinkers or have active alcohol use disorders. It comprises the first three questions of the AUDIT focusing on alcohol consumption [71], all scored on a five-point Likert scale with higher scores indicating more consumption and higher dependency. While the full AUDIT may perform better when used for screening purposes, studies have shown that the AUDIT-C still meets the necessary thresholds to be considered a valid primary care screening test [70].

Brief Sense of Community Index (BSCI)

The 8-item *Brief Sense of Community Scale* (BSCS) [72] was developed to assess the sense of community (SOC) dimensions of needs fulfillment, group membership, influence, and shared emotional connection in a resident's community. The items were based on the dimensions as defined in the McMillan and Chavis [73] model and created primarily by McMillan's underlying theory. In addition, all BSCS items were designed to reference respondents' neighborhood and used a 5-point Likert-type response option format ranging from strongly agree to strongly disagree. The overall BSCS and its subscales were also found to be correlated as expected with community participation, psychological empowerment, mental health, and depression.

Lubben Social Network Scale (LSNS)

The 6-item Lubben Social Network Scale (LSNS-6) [74], represents a condensed and more broadly applicable version of the original LSNS [75]. This scale aims to evaluate social engagement across two key domains: 'Family' and 'Friends'. Participants provide responses using a 6-point Likert scale, ranging from "None" to "Nine or more", with total scores falling between 0 and 30. A clinical cut-off score of 12 or lower indicates a risk of social isolation for the individual. Lubben et al. [74] reported high levels of internal consistency, indicating the stability and reliability of the measure. Additionally, the stable factor structure and significant correlations with criterion variables support LSNS-6 as a robust tool for assessing social isolation and connectedness.

Loneliness single item

The loneliness single item [76] is developed and validated as a screening instrument for subjective experience of loneliness in large population-based samples. The item asks about the experience of feeling alone and having few contacts on a 5-point Likert scale ranging from 0 ("no, does not apply") to 4 ("yes, it applies, and I suffer strongly").

4.2.5.2 Ecological momentary assessments

Based on a review of evidence-based interventions on resilience [e.g., 77-80], several mechanisms to foster resilience were established. Consequently, specific EMA items were selected to cover some of the identified mechanisms: stress anticipation, stressful events and their impact, positive and negative affect, emotion regulation and received social support. Throughout the day, stressors and adverse situations will be assessed to evaluate stress resistance, including their impact on protective mechanisms and the ability to maintain homeostasis and stable adaptive functioning despite adversity (e.g., “Did you experience a stressful event or problem since the last prompt?”) [81]. Resilience pertains not only to major life events but also to minor stress events [82], which can influence daily health behaviors such as sleep patterns and physical activity, as well as long-term well-being [83]. Therefore, daily assessment of stressors will provide a dynamic view of the resilience process. Furthermore, physical activity and sleep quality were assessed [84].

Items related to affect (e.g., “At the moment I feel... sad/stressed/relaxed/energetic”) were based on the Hedonic and Arousal Affect Scale (HAAS; [85], which assesses self-reported affective experiences of high and low arousal and is suitable for ecological momentary design. Additionally, individuals will be asked about their emotion regulation abilities. These items will provide data on existing coping skills, specific emotion regulation strategies (e.g., implementation of strategies to feel better), and maladaptive use (e.g., worrying, feeling overwhelmed by emotions) [86]. Enhancing social relationships is another way to foster resilience (e.g. [87]). Social support [88,89] is negatively associated with perceived stress. Received social support (e.g., “I received social support today” or “I would have appreciated social support today”), a key protective factor against mental health problems [90], will be assessed as one of the EMA items.

4.2.5.3 Information from registries

Information about factors at the environmental (e.g., pollution, access to mental health services urbanicity, ethnic diversity of the population, green space, neighbourhood crime, neighbourhood SES, access to public services, population density, income inequality) will be taken from available information (i.e., Eurostat <https://ec.europa.eu/eurostat> and local databases).

Table 4

Core EMA items					
Domain	Concept	Question	Timetable		
			Morning	2 - 3- 4	End of day
Affect	Negative/ low arousal	At the moment I feel sad	1	1	1
	Negative/ low arousal	At the moment I feel bored	1	1	1
	Negative/ high arousal	At the moment I feel stressed	1	1	1
	Negative/ high arousal	At the moment I feel irritable	1	1	1
	Positive/ low arousal	At the moment I feel joyful	1	1	1
	Positive/ low arousal	At the moment I feel relaxed	1	1	1
	Positive/ high arousal	At the moment I feel energetic	1	1	1
	Positive/ high arousal	At the moment I feel enthusiastic	1	1	1
Lifestyle	Physical activity	Today, I have been physically active	0	0	1
Sleep	Sleep quality	I slept well last night	1	0	0
Stressor	Objective assessment stressor	Did you experience a stressful event or problem since the last prompt?	1	1	1
	Subjective appraisal (optional)	To what extent did you find this stressful event or problem mentally straining?	1	1	1
	Micro-stressor*	Which of the following stressors did you experience today?	0	0	1
Stress anticipation	Expected stressor	I expect today to be a stressful experience	1	0	0
	Confidence	I am confident I can cope with today's challenges	1	0	0
	Worry about the future	I am worried about how today will turn out	1	0	0
Coping	Social support	I received social support today	0	0	1
	Social support (optional)	I would have appreciated social support today	0	0	1
	Emotional control	Since the last questionnaire, I felt overwhelmed by emotions	0	1	1
	Strategy use	I implemented strategies to feel better (e.g. talking with a friend, having a walk, meditation)	0	1	1
	Self-efficacy	I felt I had enough skills or resources to cope with daily stressors and challenges	0	1	1
	Values/beliefs	I acted according to my values and beliefs	0	1	1
	Worrying	I have been worrying	0	1	1
	Day evaluation	Today, my day has been ...	0	0	1
Burden	Burden questionnaire	Today, I found completing the questionnaires to be burdensome.	0	0	1
Open field	Optional	Is there anything else you would like to add?	1	1	1

*Participants will receive a predetermined personalized list of up to five microstressors, selected based on their answers on the MIMIS questionnaire completed during the baseline online survey. The MIMIS survey results will determine the five microstressors most mentally straining reported by each participant. If an individual indicates experiencing fewer (or none) of these microstressors in the MIMIS survey, a reduced number (or none) of microstressors will be assessed during the EMA assessments.

4.2.6 Administrative aspects and data collection

The RECONNECTED project has a data-manager located at the PI institute VU Amsterdam who oversees the way data is collected, generated, and processed. The data manager will deal with all privacy, security and ethical issues as required and secures that the FAIR principles are applied. A data-management plan (DMP) following the DMP template for Horizon Europe is available and will be updated regularly.

Data collection and processing

Upon being included in the study, participants receive a random participant number. Personal data that allows direct identification of participants (i.e. name, email, address) will be stored separately from the data obtained in the study (locally on secure servers) and includes the participant number. Study participants can access the Moodbuster platform with credentials (username and password) provided to them by the researcher via e-mail. These credentials are connected (in a separate table) to the participant number. The Moodbuster platform does not process directly identifiable data, only pseudonomized data.

Both the cross-sectional survey and the EMA measures will be collected centrally using the web- and smartphone application of the Moodbuster 2.0 platform. The consortium partners VU Amsterdam and INESC-TEC Portugal have shared ownership of the Moodbuster platform (on a non-for-profit base). In this project, the Moodbuster data will be stored and processed on the servers of INESC-TEC situated on site in Portugal, which makes them responsible for data processing. INESC-TEC has adopted technical and organisational measures in order to meet specific security requirements. Although the technical infrastructure of the processor is not ISO/IEC 27001:2005 certified, it shall enforce the specific security guarantees by implementing all necessary security measures. A joint data processing agreement (DPA) between INESC-TEC as data processor and all consortium partners as joint controllers will cover what data will be processed and how it will be protected.

Raw data will be transferred by INESC-TEC to local consortium partners (on request by the local PI) who will receive the data using secure and password protected software. Consortium partners will clean and process their own data according to a protocol provided by consortium partner VUA. Processed pseudonymized data will be pooled and stored on Research Drive, a secure server at the institute of consortium partner VU Amsterdam. VU Amsterdam is responsible for sharing data procedures in line with general data protection regulations (GDPR) requirements. The file containing directly identifying personal data will be stored locally in each department's archive in line with the

requirements of the local ethical committee. After the study is complete and results have been disseminated, the coding schemes will be destroyed. The pseudonymized pooled study data will be stored on Research Drive on a secure server located at the PI institute VU Amsterdam with restricted access. Meta-data will be published in the open science framework after the main study results have been published.

Timeline for the study

The protocol was registered in the Open Science Framework (OSF) on May 28th 2024, prior to inclusion of the first participants. The first participant was recruited on 13 September 2024. The inclusion period will run from September 2024 to April 2025 varying slightly between study sites. Data cleaning and analyses will be performed from January 2024 to September 2025 (starting with the first study site with completed data). Results are expected to be submitted for publication at the end of 2025.

4.2.7 Statistical analyses

A detailed statistical analyses plan will be completed halfway through the recruitment period (March 2025). Research question one is mainly based on descriptive statistics and univariate analyses. For research questions two and three, network analyses will be conducted based on pairwise Markov Random Field (PMRF) models. PMRF models are characterised by undirected edges between nodes that indicate conditional dependence relations between nodes. An absent edge means that two nodes are conditionally independent given all other nodes in the network. An edge indicates conditional dependence given all other nodes in the network [31]. Because our network contains a mixture of categorical and continuous variables, the Mixed Graphical Model will be used to estimate the PMRF. In order to limit the number of spurious relationships, a statistical regularisation technique will be used. Models will be compared across vulnerable populations and on the pooled data and are hypothesis generating (research aim 2) and hypothesis testing (research aim 3)

4.2.8 Reimbursement

After the study, participants will receive an incentive (approximately 30-50 Euros). The type of incentive varies per study site and can be money, a voucher, or else. The total amount that participants receive depends on the number of (EMA) questionnaires completed and participants will receive a fixed amount for completing the cross-sectional survey and an incentive for each completed EMA day.

4.2.9 Ethics

Scientific approval is obtained from local ethical review boards, and the study is registered in the OSF. We will adhere to national Codes of Ethics for Research in Social and Behavioral

Sciences, including APA Ethical Principles, Declaration of Helsinki, and GDPR. Compliance with GDPR regulations will include a Data Protection Impact Assessment to ensure data privacy protection and risk mitigation. The study falls under the Directive 95/46/EC of the European parliament and of the council of Europe dated 24th October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. The study will comply with regulations transposing this directive at the national level: Danish Data Protection Act (23/05/2018) in Denmark; Finnish data protection act (5.12.2018/1050) in Finland; RGPD (règlement général sur la protection des données) 25/05/2018 in France; German data protection act of 30/06/2017 in Germany; the DPA (Law No. 06/L-082 on data protection 03/2019) in Kosovo; the Dutch DPA (algemene verordening gegevensbescherming) 25/05/2018 in the Netherlands; United Kingdom General Data Protection Regulation (UK-GDPR) 01/01/2018 in the United Kingdom; the new law on data protection (LOPD:6/12/2018) and Garantia de Decheros Digitales (GGD) in Spain; Federal Act on Research involving Human Beings in Switzerland.

Inclusion of first participant will be reported to the ethics committee in each country. This is a low-risk study in the general population, and we do not expect that any serious adverse event (SAE) will occur. In case an SAE does occur, we will report this in accordance with the requirements of the ethical committee. We will also report the last participant included, and data collection finished to the ethics committee in each country. We believe that next to the time-investment in terms of completing the cross-sectional surveys and the EMAs, there are no disadvantages or benefits of participation.

4.3 References

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5 Ethical approval

Ethical approval has been obtained from the following review boards:

- Denmark: De Videnskabetiske Komiteer for Region Syddanmark, Case number 20232000 – 6, on 15 January 2024: Committee assessed that the project could not be considered health science research with an obligation to report to the Health Research Ethics Committee System, as found in Committee Act Article §14, paragraph 1.

- Finland: The Ethics Committee for Human Sciences at the University of Turku, Health Care Division, Case Number TY/567/06.01.01/2024, on 27 June 2024.
- France: Comité de protection des personnes Ouest III, Dossier 24.03218.000320, on 30 August 2024.
- Germany: Fakultät für Psychologie Ethikkommission of RUHR University, on 01 August 2024.
- Kosovo: Ethics committee of AAB College, Ref. nr. A5-1204/24; date 29 November 2024
- Netherlands: Vaste Commissie Wetenschap & Ethiek (VCWE): nr VCWE-20240105R1, on 11 July 2024.
- Spain: Ethics Committee of Research in Humans of the Ethics Commission in Experimental Research, University of Valencia on 21 November 2024.
- Switzerland: Ethikkommission für die Forschung am Menschen, GSI, Kanton Bern, Project-ID 2024-01346, on 26 August 2024.
- United Kingdom: Ethics Committee at St Mary's University, SMU_ETHICS_2023-24_696, on 28 October 2024.

6 Study registration

The study is registered in the Open Science Framework (OSF) in line with the information requested by WHO registries. The study was preregistered in the OSF on May 28th 2024 (with embargo). On 15th August 2024 this Embargo was released. In line with the FAIR principles that promote open science, the project was assigned a unique object identifier (DOI) : <https://doi.org/10.17605/OSF.IO/KTJ7Q>. The OSF will be used as a central place to capture different aspects and products of the research lifecycle (e.g. metadata and publications).