



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

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Abbreviations

AI	Artificial Intelligence
CDRS-10	Connor-Davidson Resilience Scale-10
CFIR	Consolidated Framework for Implementation Research
CSQ-I	Client Satisfaction Questionnaire-I
DMP	Data Management Plan
FAIR	Findable, Accessible, Interoperable, and Reusable
GAD-7	Generalised Anxiety Disorder-7
GDPR	General Data Protection Regulation
JCA	Joint Data Processing Agreement
MHC-SF	Mental Health Continuum Short Form
MHLQ SVa	Mental Health Literacy Questionnaire Short Version for Adults
MHLI	Mental Health Literacy Intervention
MI	Micro-Interventions
MI+ML	Micro-Interventions with Machine Learning Algorithm
MOST	Multiphase Optimization Strategy Framework
MRR	Metatheory of Resilience and Resiliency
PHQ-8	Patient Health Questionnaire-8
PSS-4	Perceived Stress Scale-4
SA	Social Activation
SAE	Serious Adverse Event
SES	Socioeconomic Status
SUS	System Usability Scale
TAM	Technology Acceptance Model

1 Summary

This deliverable describes the design of a series of full factorial trials to examine a digital support system with culturally adapted and personalised intervention tools that will be delivered to various populations in Europe (i.e. youth, people with low SES, migrant populations, and older adults). The digital support system targets both individual and social factors simultaneously (i.e. mental health literacy, psychological resilience and social connectedness) to maximise health benefits. The trial will be conducted in 9 populations across Europe. This report describes the study initiation package consisting of (1) the study protocol, (2) ethics approval, (3) study registration.

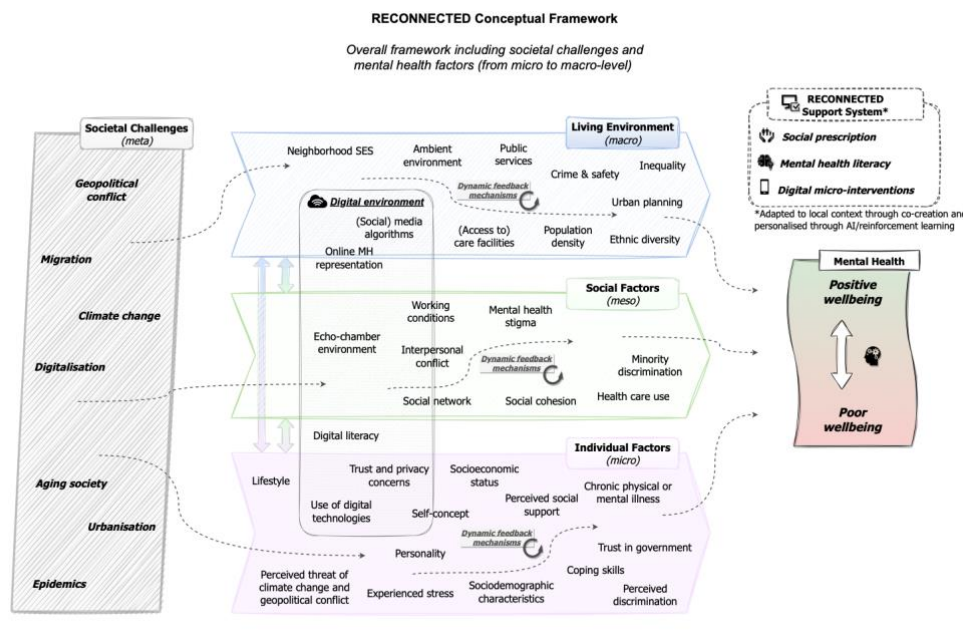
2 Introduction

Europe is experiencing a rapid transformation, driven by digitalisation, changing demographics due to urbanisation, ageing, and migration, as well as global developments such as climate change and geopolitical instability (European Commission, 2023). While developments bring new opportunities, such as greater global connectivity and increased flexibility in work and education, they also introduce cognitive and emotional challenges (Molua, 2024; Romanello et al., 2021). These challenges include, among others, identity struggles shaped by factors such as migration and social media, as well as information overload and social disconnection resulting from urbanisation and digitalisation (Saiphoo & Vahedi, 2019). Research has shown that not all citizens adapt equally well to these changes. It is suggested that vulnerable citizens in Europe, such as people with low socioeconomic status, immigrants, youth, and elderly, are affected the most by global societal developments (Benevolenza & DeRigne, 2019; Molua, 2024; Vasilescu et al., 2020). Hence, putting vulnerable citizens at higher risk for lower mental wellbeing.

Increasing mental wellbeing in vulnerable citizens

Psychosocial interventions offer a valuable means of empowering individuals to gain greater control over their lives, enhance their capacity to adapt to stressful events, and promote mental health and wellbeing (World Health Organization, 2021). Importantly, these interventions extend beyond a narrow focus on individual behaviour by incorporating social and environmental components that influence mental health outcomes (World Health Organization, 2021). This broader, multilevel perspective is consistent with the RECONNECTED project, which adopts a complex systems approach to mental health and wellbeing (Mitchell, 2009). Within this framework, mental health is understood as the product of interacting risk and protective factors operating across multiple levels, including societal challenges (meta), living environments (macro), social factors (meso), and individual characteristics (micro) (see Figure 1 for the integrated conceptual framework developed within the RECONNECTED project). Given the interconnected nature of these determinants, maximizing mental health benefits requires interventions that address risk and protective factors across multiple levels simultaneously. In line with this approach, the RECONNECTED project delivers a digital psychosocial intervention tailored to vulnerable populations across Europe. The intervention combines culturally adapted and personalized tools targeting three key domains: mental health literacy, social connectedness, and psychological resilience.

Figure 1. RECONNECTED Conceptual framework



Mental health literacy is a central component of many psychosocial interventions. It refers to the knowledge and understanding that enable individuals to recognize mental health problems, maintain good mental health, and seek appropriate support when needed (Jorm, 2015; Jorm et al., 1997). Evidence suggests that improvements in mental health literacy can increase awareness of mental health issues, reduce stigma, and foster more positive attitudes toward help-seeking and mental healthcare utilization (Brijnath et al., 2016). However, mental health literacy is not equally distributed across populations. Vulnerable groups, including individuals with lower income and educational attainment, generally report lower levels of mental health literacy than those with higher socioeconomic status (Soria-Martínez et al., 2024). This disparity is particularly concerning given that limited mental health literacy is considered a major contributor to the persistent treatment gap between individuals who need mental healthcare and those who actually access it (Tambling et al., 2023).

Social connectedness, social support, and a sense of belonging are fundamental human needs that play a crucial role in mental health and wellbeing (Baumeister & Leary, 1995; Wickramaratne et al., 2022). Strong social networks foster feelings of belonging and serve as important protective factors by providing emotional and practical support, strengthening self-worth, and offering access to diverse perspectives and resources (Keim-Klärner et al., 2023; Steinhoff & Reiner, 2024). Conversely, social isolation and limited social support are associated with an increased risk of anxiety, depression, and other forms of psychological distress (Baumeister et al., 2007; Rutenfrans-Stupar et al., 2019; Wickramaratne et al., 2022). As a result, social connectedness is widely recognized as a key determinant of overall wellbeing and psychological resilience, particularly during periods characterized by elevated stress, adversity, and uncertainty (Rutenfrans-Stupar et al., 2019).

Resilience is commonly defined as the capacity to adapt to, withstand, and recover from adversity. One influential framework for understanding resilience is the Metatheory of Resilience and Resiliency (MRR) (Richardson, 2002), which aligns closely with the RECONNECTED conceptual framework. The MRR emphasizes that resilience emerges from the dynamic interplay between individuals and their environments in the face of adverse life events. Accordingly, resilience should not be viewed solely as an individual characteristic (micro level), but rather as a process shaped by factors operating across multiple levels, including social support networks (meso level), access to community resources (macro level), and broader societal developments (meta level) (Hall et al., 2023; Liu et al., 2017; Patel et al., 2017). This perspective is particularly relevant for vulnerable populations, who often face cumulative disadvantages that can undermine resilience and increase susceptibility to the negative consequences of adversity (Siriwardhana et al., 2014). Strengthening resilience may therefore enable individuals to better cope with stressors, enhance emotional adaptability, and maintain psychological wellbeing despite challenging circumstances (Siriwardhana et al., 2014).

One promising approach to strengthening resilience is through micro-interventions: brief, targeted strategies designed to influence specific psychological or social processes in everyday life (Fuller-Tyszkiewicz et al., 2019). Unlike traditional interventions, which often address broad clinical outcomes over an extended period, micro-interventions focus on immediate, situational challenges with minimal time and effort required from participants (Baumel et al., 2020; Elefant et al., 2017). Although primarily intended to produce short-term benefits, these interventions can cumulatively contribute to longer-term improvements in wellbeing and resilience (Fuller-Tyszkiewicz et al., 2019). Their low-cost, accessible, and scalable nature also makes them particularly suitable for reaching vulnerable populations and overcoming common barriers to mental health support, such as limited time and accessibility (Lee et al., 2025).

Digital solutions

Despite their potential, psychosocial interventions often fail to reach those most in need due to limited cultural adaptation, language barriers, and a lack of personalization. These challenges are further exacerbated by stigma, low mental health literacy, and intervention costs, disproportionately affecting socially disadvantaged groups (Dobalian & Rivers, 2008; Jorm, 2012). Digital interventions offer a promising way to address these barriers by enhancing self-management while improving scalability, affordability, accessibility, and safety (Aschentrup et al., 2024; Muñoz, 2010; Stark et al., 2022). A growing body of evidence supports the effectiveness and acceptability of digitally delivered health promotion and prevention interventions, including mental health literacy programs, social connectedness initiatives, and micro-interventions (Muñoz, 2010). For example, digital mental health literacy interventions have demonstrated effects comparable to face-to-face approaches (Yeo et al., 2024), while digital platforms can facilitate social connectedness through on-demand access and centralized activity information (Lee et al., 2023; Patel et al., 2021). In addition, digital delivery enables features such as automated monitoring, reminders, and integrated messaging, which can enhance engagement and are difficult to implement in traditional offline formats (Baumel et al., 2020).

To address barriers related to accessibility and engagement, the RECONNECTED support system combines cultural adaptation and personalization. Cultural adaptation ensures that intervention content aligns with the languages and cultural contexts of diverse European populations (Bernal et al., 1995; Nagayama et al., 2016), whereas personalization tailors intervention delivery to individuals' needs and circumstances (Cohen et al., 2021). Such tailoring can be supported by machine-learning approaches that help identify the most appropriate intervention content and timing for each user (Abd-Alrazaq et al., 2023; Baumel et al., 2020; Moshe et al., 2021).

3 Objective

The objective of this deliverable is to present the study initiation package of the RECONNECTED Factorial trial. The study initiation package consists of the Factorial trial study protocol (chapter 4), ethical approval (chapter 6), and study registration (chapter 7).

4 Factorial trial study protocol

4.1 Study aim

The *primary objective* of this trial is to determine whether adding personalized micro-interventions and social activation to a mental health literacy intervention yields additional improvements in wellbeing. These effects will be evaluated in nine full-factorial trials conducted across nine European countries. A *secondary objective* is to assess whether machine learning-enhanced personalization improves the effectiveness of micro-interventions compared with standard personalization, using pooled data from all trial sites. *Third*, a process evaluation will examine the feasibility of the digital support system, including its usability, perceived usefulness, user satisfaction, engagement, and potential adverse effects.

4.2 Methods

4.2.1 Study design

The current study consists of nine 2×2 factorial randomised controlled trials ($n=256$ in each country, total $n=2,304$) conducted across various vulnerable populations in Europe (Denmark, Finland, France, Germany, Kosovo, the Netherlands, the United Kingdom, Spain, and Switzerland). To examine the first objective, 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 (see Table 1).

To answer objective 2, 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). See Table 1.

All outcomes will be assessed online at four time points: baseline (t₀), six weeks (primary endpoint, t₁), three months (t₂), and six months (t₃) after baseline, with each assessment taking a maximum of 30 minutes to complete. After completion of the six-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.

Table 1. Experimental conditions of the full factorial design.

Condition	Mental health literacy	Social activation	Personalised interventions	micro-	Anticipated n
1	Yes	No	No		64
2	Yes	Yes	No		64
3	a b — Yes	No	Yes: MI		32
			Yes: MI+ML		32
4	a b — Yes	Yes	Yes: MI		32
			Yes: MI+ML		32

Note. MI: Micro-interventions without machine learning algorithm, MI+ML: Micro-intervention with machine learning algorithm

4.2.2 Study population

This study involves healthy 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 (see Table 2 for an overview of populations in each country). The selection of these populations ensures comprehensive coverage across different age groups. Furthermore, we have opted for countries with diverse geographical and socioeconomic characteristics. Alongside the cohort-specific inclusion criteria (Table 2) there are some general in- and exclusion criteria.

4.2.3 Recruitment and Procedure

Recruitment procedures are country-specific but follow a common sequence of steps. Information about study participation is provided on local study websites, where prospective participants can register their interest by submitting their contact details. Following registration, individuals are enrolled on the CASTOR platform, which is used for screening and data collection, and receive access to the online participant information sheet and informed consent form. The consent form explains that participation is voluntary and may be discontinued at any time without providing a reason. It also includes optional consent to be contacted for a follow-up semi-structured interview as part of the process evaluation. After providing informed consent, participants proceed to the screening and baseline assessment. Prospective participants who do not meet the eligibility criteria are informed of their ineligibility, and the survey is terminated. In countries where electronic consent is not feasible, written informed consent is obtained prior to registration in the CASTOR platform.

Table 2 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	Youth aged 18 from the general population	The recruitment targets young people from the general population who are liable for military service. The invitation to the study will be sent together with the call-up notice that is sent to each man liable for military service. Recruitment ads (with QR codes) may also be displayed at the locations for the call-ups.
France	Adults aged 18 or older residing in low SES cities	Audio-visual content (videos and posts) on social media, local newspapers, public posters, leaflets and flyers distributed in targeted neighborhoods. These materials are also placed in strategic locations such as community and social centers, solidarity grocery stores, and spaces frequented by residents of the target areas, including pharmacies, libraries, among others.
Germany	Children aged 12-16 in secondary education	Recruitment primarily through brief presentations and leaflets within secondary schools.
Kosovo	Adults aged 18 or older also residing in low SES geographical areas	Open recruitment strategy through community centres, social work, mental health services, and social media among others. Posters and Leaflets.
The Netherlands	Adults aged 55 or older	Open recruitment strategy through community centres, social work, and public libraries.
The United Kingdom	Non-western migrants aged 18 or older	Open recruitment strategy through e.g., NGOs, migrant support organisations, faith groups, trained community connectors. Online and in-person.
Spain	Migrants aged 18 or older from a Latin-American background	Open recruitment strategy through community centres, social workers, mental health services, and social media among others.
Switzerland	German-speaking adults aged 55 or older who feel lonely	Open recruitment strategy through community centres, flyers, reports and interviews in newspapers, internet forums, and social media, among others.

Note: SES = Social Economic Status

Table 3 General in- and exclusion criteria

Criterion	Assessment method
Inclusion criterion	
Mental wellbeing (languishing or moderately healthy)	Prospects will be included if they are classified as languishing (defined as scoring “never” or “once or twice” on ≥ 7 of the 14 items, including at least one item from the emotional well-being cluster) or moderately mentally health (defined as individuals who do not meet the criteria for either languishing or flourishing) on the MHC-SF questionnaire.
Informed consent	Prospect gives (electronic or in-person) consent.
Exclusion criterion	
Severe mental illness	Self-report screen: “Do you currently have any of the following mental disorders diagnosed by a psychologist, psychiatrist, or other mental health professional?” (checklist includes schizophrenia, bipolar, psychosis, severe depression with hospitalisation).
Mental health treatment	Self-report screen: “Do you currently receive psychological treatment for a mental disorder?” “Have you started taking prescribed medication for psychological or psychiatric problems (e.g., anxiety, depression, sleep problems) within the past four weeks?” (yes/no)
Inability to Commit to Engagement	Self-report screen: “Are you able and willing to use the digital tool weekly for the next 6 weeks and complete 4 surveys?”
Insufficient language comprehension	Basic comprehension check. Part of (electronic or in-person) consent procedure: prospect can read and understand the study information.

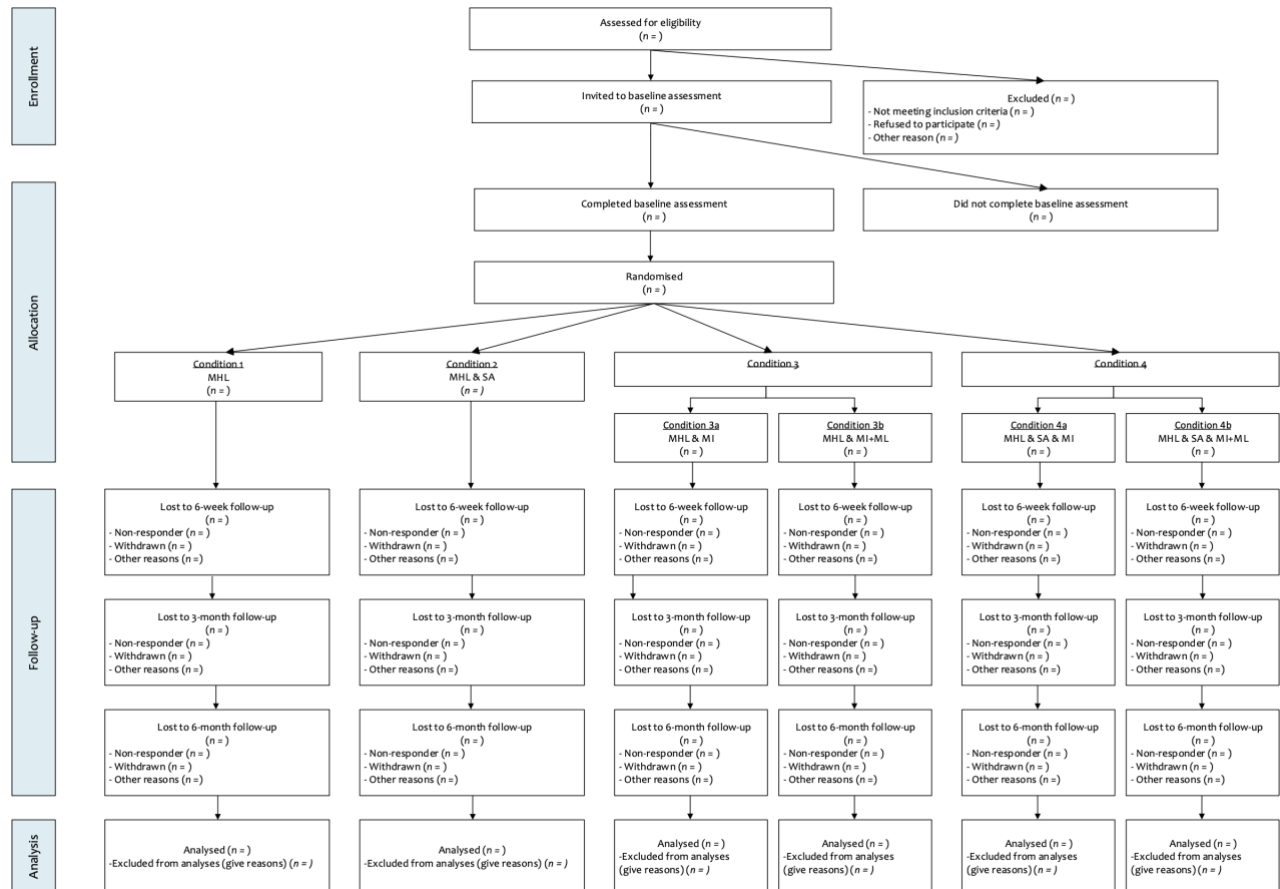
Note: MHC-SF = Mental Health Continuum Short Form. Please see refer to the section ‘Primary outcome’ for an explanation of this criterion.

A core set of baseline questionnaires will be administered across all study sites and is expected to require approximately 30 minutes to complete. Study sites may supplement this core assessment with additional questionnaires relevant to their local target population or research objectives, provided that the total assessment time does not exceed 45 minutes.

After completing the baseline assessment, participants will be randomly assigned to one of six study conditions (see Table 1 and Figure 2). Randomization will be conducted at the individual level using the CASTOR platform. Participants will be allocated in a 2:2:1:1:1:1 ratio, with block randomization and variable block sizes ranging from 8 to 16. The allocation sequence will be accessible only to an independent researcher. Blinding is not feasible, as both participants and researchers will be aware of the intervention components included in the digital support system.

The study will be managed through CASTOR, a certified Health and Life Sciences research management platform (<https://my-researchmanager.com>). A single study project will be established within CASTOR by the coordinating institution (Vrije Universiteit Amsterdam, VUA). To ensure data security and site autonomy, each participating site will be provided with a dedicated user account granting access only to its local trial data and study procedures.

Figure 2. CONSORT flowchart of participants through the trial.



Note: MHL: Mental Health Literacy, SA: Social activation, MI = personalised micro-interventions, MI+ML = personalised micro-interventions accompanied by machine learning algorithm.

4.2.4 Sample size and power estimates

Nine factorial trials will be conducted, one in each participating country. The sample size for each trial was determined to ensure adequate power to detect meaningful component effects. Calculations were performed using the SAS Macro Factorial Power Plan (Dziak et al., 2013) in SAS (SAS Institute). Assuming a pre-post correlation of 0.60, inclusion of the baseline measure as a covariate, 80% power, an alpha level of 0.10, and a component effect size of 0.25 for each of the two intervention components, the required sample size was estimated at $n = 256$ per trial. The component effect size of 0.25 was selected as the smallest clinically meaningful effect. An alpha level of 0.10 was chosen in line with recommendations for component selection experiments, as it reduces the risk of prematurely excluding potentially effective intervention components while balancing both Type I and Type II errors.

To address the second research aim, data from all nine countries will be pooled, resulting in a total sample of 2,304 participants ($n = 256$ per country). Of these, 1,152 participants will receive micro-interventions, with half allocated to the standard version (MI; $n = 576$, conditions 3a and 4a) and half to the machine learning-enhanced version (MI+ML; $n = 576$, conditions 3b and 4b). This pooled sample provides sufficient statistical power to detect a small effect size ($d = 0.20$) when comparing the two micro-intervention conditions.

4.2.5 Digital support system

The digital support system targets mental health literacy, social connectedness, and psychological resilience. To ensure relevance across diverse vulnerable populations the content has been culturally and contextually adapted. All participants begin with a mandatory mental health literacy module, which includes onboarding to the digital support system. Upon completion, participants gain access to the social activation and personalized micro-intervention components. Participants may engage with these components according to their preferences and needs, although the intervention is designed for use over a six-week period. The digital support system is accessible via both computers and smartphones, with the micro-interventions delivered exclusively through the smartphone application.

4.2.5.1 Mental health literacy

Mental health literacy (MHL) is a brief introductory module that aims to enhance users' knowledge and understanding of mental health, including the recognition, management, and prevention of common mental health problems (Jorm et al., 1997; Kutcher et al., 2016). The module consists of approximately 10 pages of educational content covering key topics such as the distinction between mental health and mental illness, stigma, and available sources of mental health support (Brijnath et al., 2016). In addition to providing practical tips and advice, the module includes reflective exercises and optional resources for users who wish to explore the topics in greater depth. The module takes about 10-30 minutes to complete.

4.2.5.2 Social activation

Social activation consists of four modules of approximately 10 pages each and requires 10 to 30 minutes per module to complete. The component aims to strengthen social connectedness by promoting a sense of belonging, fostering supportive social networks, enhancing feelings of appreciation, and encouraging engagement with diverse perspectives. In Module 1, participants explore the concept of social connectedness and map their social network in relation to their personal values. Module 2 introduces practical strategies for strengthening existing social relationships. Module 3 focuses on identifying meaningful opportunities for community engagement, while Module 4 develops skills for building and maintaining supportive and mutually beneficial relationships.

The social activation component is grounded in evidence demonstrating the importance of social connectedness for mental wellbeing (Antonucci et al., 2014; Baumeister & Leary, 1995; Wickramaratne et al., 2022). It integrates principles of value-based behavioral activation, encouraging participants to engage in meaningful social activities aligned with their personal values (Dimidjian et al., 2011; Lejuez et al., 2011; Pepin et al., 2021), and social prescribing, by helping individuals identify opportunities for community engagement and access relevant community resources (Chatterjee et al., 2018; Cooper et al., 2022). The component emphasizes that social connectedness can be actively developed and provides a structured framework for change through goal setting, action planning, and progress monitoring, while recognizing individual differences in preferences and needs. To support engagement and skill development, the modules incorporate practical exercises, relatable personas, and tailored tips for navigating common social situations.

4.2.5.3 Personalised micro-interventions

The micro-interventions are designed to provide immediate benefits and promote resilience and mental wellbeing. They are structured into seven evidence-based mechanisms (Boniwell et al., 2023; Chmitorz et al., 2018; Schetter & Dolbier, 2011), each with 5 to 17 micro-interventions. Before starting with the micro-interventions, participants complete a self-assessment on resilience-related constructs. Based on a decision tree, the system then recommends two mechanisms to focus on, which participants can either accept or adjust. After three weeks, the assessment is repeated, resulting in an updated recommendation. The micro-interventions take between 1-15 minutes and are delivered in various formats (e.g., text-based exercises, audio recordings, videos, and interactive tasks). At the end of each micro-intervention, participants evaluate its emotional impact and perceived usefulness by answering two questions. Daily use typically involves 3 to 5 micro-interventions. Additionally, participants always have access to the micro-interventions from the 'Grounding skills' mechanism, regardless of which two mechanisms they focus on.

As part of this component, participants will also receive notifications prompting them to complete brief questionnaires. The questionnaires are used to monitor, e.g., current stress, anticipated stress, expected coping, and self-efficacy. They are assessed three times a day (morning, afternoon, evening) and take less than a minute to complete each time.

4.2.5.4 Micro-interventions + Machine Learning (MI+ML)

The algorithm developed to support the micro-interventions optimizes its delivery across three functionalities:

- **Format selection:** Various micro-interventions are available in multiple formats (i.e., text, video, or audio). The algorithm predicts the most suitable format for the participant at that specific timepoint and delivers it.
- **Grounding skills:** If the algorithm predicts stress, the system recommends the participant accessing the micro-interventions from the 'Grounding skills' mechanism.
- **Motivational messages:** The participants receive motivational messages that are designed to encourage engagement with the micro-interventions. There are three types of motivational messages: informative, affirming, or motivating (Mol et al., 2018; Provoost et al., 2020). Participants receive up to three motivational messages per day, which are combined with the questionnaire notifications whenever possible to minimize burden. The algorithm determines which type of automated motivational message is most desirable (or if no message is better). The selected message is then rewritten using a large language model to personalize tone and content based on user characteristics of the target group (e.g., age).

The stress prediction model was pre-trained using data collected in the RECONNECTED CEMA study. In contrast, the algorithms used to personalize intervention formats and motivational messages are trained and continuously refined during deployment. These algorithms update their predictions over time based on data from participants' brief daily assessments and their interactions with the digital support system, such as questionnaire completion and intervention engagement.

4.2.5.5 Moodbuster 2.0 platform

The digital support system runs on the Moodbuster platform which, for the purpose of this study, has been redesigned as a progressive website. Moodbuster is co-owned by consortium partners VUA and INESC TEC (non-profit) (Kleiboer et al., 2016; van de Ven et al., 2017; Warmerdam et al., 2012). The digital support system will be tested for usability and effectiveness before full-scale deployment during the trial.

4.2.6 Study parameters

An overview of the measures and time of assessment is provided in Table 7. All surveys are completed online.

4.2.6.1 Primary outcome

The main study parameter is improvement in (mental) wellbeing as assessed with the Mental Health Continuum Short form (MHC-SF) (Keyes, 2002). The MHC-SF is a 14-item self-report questionnaire designed to assess positive mental health during the past month. It includes three subscales: emotional wellbeing (3 items), social wellbeing (5 items) and psychological wellbeing (6 items). Each item is rated on a 6-point Likert scale from 0 ('never') to 5 ('every day'). The instrument has both a continuous scoring system (summing total scores, range 0-70) and a categorical system (mental wellbeing status). In the categorical system, individuals can be categorized as flourishing, languishing, or moderately mentally healthy based on their responses. To be classified as flourishing (i.e., in a state of thriving, high level of subjective well-being, optimal level of psychological and social functioning), a person must report a score of 4 ('almost every day') or 5 ('every day') on at least seven of the 14 indicators. At least one of these indicators must come from the emotional well-being subscale (e.g., feeling happy, interested in life, or satisfied). Conversely, those who report a score of 0 ('never') or 1 ('once or twice') on at least seven indicators, including at least one from the emotional well-being subscale, are considered languishing (i.e., apathy, sense of restlessness or feeling unsettled, reduced interest). Individuals who do not meet either threshold are categorized as moderately mentally healthy. The MHC-SF demonstrates strong psychometric properties, including high internal consistency ($\alpha > .80$) and has been validated across diverse populations (Iasiello et al., 2022; Lamers et al., 2011, 2012).

Table 7 Overview of measures

Variable	Instrument	t0	t1	t2	t3
Primary outcome					
Wellbeing	Mental Health Continuum – Short Form (MHC-SF)	X	X	X	X
Secondary outcomes					
Mental Health Literacy	Mental Health Literacy Questionnaire - Short version for adults (MHLQ-SVa)	X	X		
Resilience	Connor-Davidson Resilience Scale - 10 (CDRS-10)	X	X	X	X
Social connectedness					
Loneliness	UCLA-9 Loneliness Scale	X	X	X	X
Social isolation	Lubben Social Network Scale (LSNS)	X	X	X	X
Initiating activities	Self-composed on social engagement	X	X	X	X
Depression	Patient Health Questionnaire-8 (PHQ-8)	X	X	X	X
Anxiety	Generalised Anxiety Disorder-7 (GAD-7)	X	X	X	X
Perceived stress	Perceived Stress Scale-4 (PSS-4)	X	X	X	X
Other assessments					
Demographics	Standard questions	X			
Feasibility (process evaluation)					
Perceived usefulness	Questions addressing usefulness and relative advantage		X		
Usability	System Usability Scale (SUS)		X		
Overall satisfaction	Client Satisfaction Questionnaire – I (CSQ-I)		X		
Unintended negative effects	Symptom deterioration (MHC-SF); Self-composed questions on e.g., adverse events, emotional burden and intervention fatigue		X		
Engagement	Log files				

4.2.6.2 Secondary outcomes

Mental Health Literacy

Mental Health Literacy is measured with the Mental Health Literacy Questionnaire – Short Version for Adults (MHLq-SVa) (Campos et al., 2022). The MHLq-SVa is based upon the validated MHLq-ya, originally designed for young adults (Campos et al., 2016). This self-report tool assesses four key aspects of mental health literacy: Knowledge of mental health problems, erroneous beliefs/stereotypes, first-aid skills and help seeking behaviour, and self-help strategies (Campos et al., 2022). Participants respond to 16 statements, rating their agreement on a five-point Likert scale, ranging from 1 (‘strongly disagree’) to 5 (‘strongly agree’). Psychometric and validation analyses across American, Portuguese, and East-Asian populations, confirmed the scale's strong psychometric properties and adaptability for cross-cultural applications (Campos et al., 2022).

Resilience

The Connor-Davidson Resilience Scale – Brief Version (CD-RISC-10) is assessed to measure resilience. The CD-RISC-10 consists of 10 selected items from the original CD-RISC (Campbell-Sills et al., 2009; Connor & Davidson, 2003) and evaluating an individual's ability to cope with and thrive despite adversity during the past month. Responses are rated on a five-point Likert scale, ranging from 0 (‘not true at all’) to 4 (‘true nearly all the time’).

This scale has demonstrated strong psychometric properties when assessing trait resilience across European community samples (Notario-Pacheco et al., 2011; Wollny & Jacobs, 2023).

Loneliness

The UCLA-9 Loneliness Scale is used to measure loneliness (Luhmann et al., 2016). The UCLA-9 is a shortened version of the revised 20-item UCLA Loneliness Scale (Russell et al., 1980). The nine items are rated on a 4-point Likert scale, ranging from 1 ('never') to 4 ('always'). Total scores range from 9 to 36, with higher scores indicated higher levels of loneliness. The UCLA-9 captures three dimensions of loneliness: intimate connectedness, relational connectedness, and collective connectedness. The validity and reliability of the UCLA-9 is comparable with those of the (revised) 20-item version (Bo et al., 2025; Liu et al., 2025), and works reliably well across different ages (Panayiotou et al., 2023)

Social Isolation

The Lubben Social Network Scale – 6 (LSNS-6) is used to assess social isolation (Lubben, 1988). The LSNS-6 is a shortened and widely applicable adaptation of the original LSNS tool, specifically designed to assess an individual's level of social engagement within two central areas: connections with family and friends. It consists of six items rated on a 6-point scale, ranging from 0 ('none') to 5 ('nine or more'). Scores can range from 0 to 30, with a value of 12 or below often considered indicative of potential social isolation. Studies reported that the LSNS-6 has high levels of internal consistency, indicating stability and validity (Lubben et al., 2006). Moreover, the stable factor structure and significant correlations with criterion variables measures support LSNS-6 as a robust instrument for evaluating levels of social isolation and social connectedness.

Depressive symptoms

The PHQ-8 is a self-report instrument that evaluates the frequency of depressive symptoms over the past two weeks (Kroenke et al., 2001). It comprises eight items that correspond to eight of the nine diagnostic criteria for major depressive disorder as outlined in the DSM-IV. Respondents rate each item on a four-point Likert scale ranging from 0 ('not at all') to 3 ('nearly every day'), resulting in a total score ranging from 0 to 24. Commonly used cut-off scores are 5, 10, 15, and 20, which indicate mild, moderate, moderately severe, and severe levels of depression, respectively (Kroenke et al., 2001). The PHQ-8 has demonstrated strong psychometric properties across diverse populations and settings, including high internal consistency and good construct validity (Arias de la Torre et al., 2023; Kroenke et al., 2001, 2009, 2010).

Anxiety symptoms

Anxiety symptoms will be measured using the GAD-7 (Spitzer et al., 2006). The GAD-7 is a self-report questionnaire designed to assess the severity of generalised anxiety symptoms over the past two weeks. It consists of seven items, each rated on a four-point Likert scale ranging from 0 ('not at all') to 3 ('nearly every day'), yielding a total score between 0 and 21. Cut-off scores of 5, 10, and 15 are used to classify mild, moderate, and severe anxiety, respectively (Spitzer et al., 2006). The GAD-7 has demonstrated strong psychometric properties, including high internal consistency and good criterion validity across clinical and general populations (Löwe et al., 2008; Spitzer et al., 2006)

Perceived stress

Perceived stress is measured with the perceived Stress Scale - 4-item version (PSS-4) (Cohen et al., 1983). The PSS-4 evaluates an individual's perception of stress in daily life. Individuals reflect on their thoughts and emotions over the past month and respond using a five-point Likert scale, ranging from 0 ('never') to 4 ('very often'). Sum scores range from 0 to 16, with higher scores corresponding to more stress. Studies have shown that higher scores correlate with greater psychological distress, poorer physical health, and diminished quality of life (Cohen et al., 1983; Karam et al., 2012). The PSS-4 has consistently demonstrated strong psychometric properties, reinforcing its validity as a concise yet reliable alternative to the original 14-item version (Cohen et al., 1983; Karam et al., 2012; She et al., 2021).

Initiating activities

Initiative to engage in social activities is assessed using two self-composed items assessing whether participants' social engagement in the past week. One item focuses on group-based activities (e.g., hobbies, religious events), while the other addresses one-on-one contact (e.g., with a friend or family member). Participants indicate their level of engagement on a four-point scale, capturing stages ranging from no intention, intention but no action, preparatory steps, to actual participation.

4.2.6.3 Other assessments

Demographics

These include amongst others gender, age, relationship status, education, employment, children, household, and postal code.

Motivation for participation

Participants are asked to indicate whether they wish to engage with the digital support system in order to increase their awareness of mental health, expand their social network and/or enhance their resilience. Multiple responses can be selected.

4.2.7 Administrative aspects and data collection

The RECONNECTED project has a data-manager located at the PI institute VUA 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 Findable, Accessible, Interoperable, and Reusable (FAIR) principles are applied. A data-management plan (DMP) following the DMP template for Horizon Europe was drafted for the purpose of the RECONNECTED project and will be updated regularly.

Data collection and processing

Upon being included in the study, participants receive a participant number based on the site and subsequently the order of entry in the study. A separate table (i.e., coding scheme) is kept locally in which participant numbers are linked to a random study participant code. Personal data allowing direct identification that is used for administrative purposes (i.e., name, email, address) is encrypted and stored separately from the data obtained in the study and includes the participant number. In the study itself, only the study participant codes will be used. The assessments will be collected centrally using the CASTOR platform.

To ensure compliance with GDPR and national data protection legislation, the project has implemented a comprehensive data governance framework including a Joint Controller Agreement (JCA) among participating consortium partners. Processed pseudonymized data will be pooled and stored securely with restricted access on Research Drive at VU Amsterdam. The file containing directly identifying personal data will be stored locally in local department's archive in line with the requirements of the local ethical committee. Access to the file linking participant numbers to direct identifiers will be strictly limited to authorized study personnel and will be destroyed once data verification and necessary administrative follow-up are complete. Meta-data will be published in the Open Science Framework after the main study results have been published.

Timeline

All trial protocols have been approved by local scientific and ethical committees and will be (or are) registered in a WHO approved clinical registry prior to inclusion of participants. The inclusion period will run from August 2026 to March 2026. Varying slightly between trial sites. This means that all data will be collected by September 2027 (giving the fact that the follow-up period is 6 months). Data cleaning and analyses will be performed from April 2027 to December 2027.

4.2.8 Statistical analyses

A detailed statistical analysis plan is completed and described in a separate deliverable (D14/D4.2). To examine the additional effects of personalised micro-interventions and social activation to mental health literacy, a series of linear mixed models according to the intention-to-treat principle will be estimated at site level. The primary outcome is a change in mental wellbeing which will be analysed from baseline (t₀) to six weeks (primary endpoint, t₁), three months (t₂), and six months (t₃) after baseline. Both main effects and interaction effects will be estimated. Main effects refer to the impact of each individual component on the primary outcome, while the interaction effects refer to how the interaction between components influence the primary outcome.

4.2.9 Process evaluation

4.2.9.1 Participants and procedure

The process evaluation will be conducted alongside the full factorial trial and will employ a mixed methods approach. Quantitative measures will be collected as part of the standard set of questionnaires administered at the post-intervention assessment (thus, $n=256$ per site). To gain a more in-depth understanding of the digital support system's feasibility, semi-structured interviews will also be conducted ($n=24$ per country). For this, a purposive sampling strategy will be applied: six participants from condition 1, six from condition 2, six from conditions 3a & b, and six from conditions 4a & b. This results in a total of 12 participants per component (i.e., social activation and personalised micro-interventions), providing sufficient qualitative depth while maintaining feasibility. Additionally, of the six participants recruited within each condition, three participants will be included who actively engaged with the digital support system and three who initiated but discontinued early. The sampling strategy is guided by methodological literature on information saturation in homogeneous subgroups, which indicates that approximately 12 interviews per category are typically sufficient to capture key thematic patterns (Guest et al., 2006; Hennink & Kaiser, 2022).

4.2.9.2 Recruitment for the semi-structured interviews

Participants who provided prior consent to be contacted for a follow-up interview, via the informed consent form completed at trial entry, will be approached for participation in a qualitative interview. As part of the screening process, participants will be asked to indicate which of the follow statements best applies to them: “*I actively participated in the digital support system*”, “*I started using the digital support system but discontinued early*”, and “*I never started using the digital support system*”. The semi-structured interviews will last approximately 45-60 minutes and will be conducted via videoconferencing or in-person. Participants are reimbursed for their time, in accordance with site policies, with compensation typically ranging between €30 and €50.

4.2.9.3 Measures

The quantitative measures are outlined below. Topic guides for the semi-structured interviews have been developed (see Appendix 1). This guide offers structured examples of tailored questions on, for example, participants’ experiences with an intervention.

Perceived usefulness

This refers to the extent to which participants perceive the digital support system as beneficial. To assess this, participants are asked to rate (1) how useful they found the intervention in improving their mental well-being, based on an item adapted from the Technology Acceptance Model (TAM) (Davis, 1989), and (2) how they position this digital support system relative to other services or forms of support they are familiar with based on an item adapted from the Consolidated Framework for Implementation Research (CFIR) topic guide (Brooke, 1996; Damschroder et al., 2009, 2022). Each item is answered on a 5-point Likert scale.

Usability

The perceived ease of use of the digital support system is evaluated with the System Usability Scale (SUS) (Brooke, 1996). The SUS consists of 10 items rated on a five-point Likert scale ranging from 0 (‘strongly disagree’) to 4 (‘strongly agree’). A total SUS score is obtained by summing the item scores and multiplying by 2.5, resulting in a score between 0 and 100. Higher scores reflect greater perceived usability, with scores above 70 generally indicating good usability (Bangor et al., 2008; Lewis et al., 2015).

Overall satisfaction

Overall satisfaction with the digital support system is measured using the Client Satisfaction Questionnaire for Internet-based Interventions (CSQ-I) (Boß et al., 2016), an adaptation of the original Client Satisfaction Questionnaire - 8 (CSQ-8) (Larsen et al., 1979). The CSQ-I comprises eight items, each rated on a four-point Likert scale ranging from 1 (‘does not apply to me’) to 4 (‘applies to me’). Scores can vary between 8 and 32, with higher totals reflecting greater participant satisfaction. Although no standardized cut-off values exist, elevated scores are generally interpreted as indicating a more positive evaluation. The CSQ-I has demonstrated strong reliability (Boß et al., 2016).

Unintended negative effects

This refers to experienced negative effects associated with the digital support system. To assess this, (1) symptom deterioration will be analysed by examining the number of participants who showed no response or experienced worsening in mental well-being during or following the intervention, as measured by the primary outcome measure (MHC-SF). (2) participants will be asked to report unintended consequences through self-composed questions addressing frustration, emotional burden, intervention fatigue, adverse events (potentially) linked to the digital support system, novel or worsened symptoms, and dependency on the system. Questions are rated on Likert-scales ranging from 1 ('strongly disagree') to 5 ('strongly agree'). An open-ended question is also added in case participants want to add anything.

Engagement

Information about engagement with the digital support system is measured with 'meta-data'. This includes for example number of logins into the platform, completed exercises, number of days active. Note that detailed information in terms of actual entered answers by the participants will not be used for study purposes

4.2.10 Analyses plan

Quantitative data will be summarized using descriptive statistics. All semi-structured interviews will be audio-recorded and transcribed verbatim. Field notes and memos will be made for analysing purposes during and after interview. Thematic analysis will be conducted according to a coding framework by at least two researchers. A detailed analysis plan is completed and described in another deliverable (D14/D4.2).

4.2.11 Burden for participants

4.2.11.1 Assessments

Participant burden involves completing online questionnaires at baseline (duration: 30 minutes), six weeks (duration: 30-45 minutes), three months (duration: 30 minutes), and six months (duration: 30 minutes). Completion of the questionnaires may be slightly distressing for some participants.

4.2.11.2 Digital support system

Participants are free to decide how much time they are willing to dedicate to the digital support system. They are allowed to use the digital support system for as long as the trial runs, but we expect participants to engage with the digital support system for a maximum of six weeks. The total time investment for the core mental health literacy intervention is estimated to be 10 minutes, if people read all available background material, this may take up to 35 minutes. Regarding social activation, the estimated time commitment is 15-30 minutes for each module. For the micro-interventions (both with and without the machine learning algorithm), the estimated time commitment includes the completion of the micro-interventions (15-30 minutes per day), evaluation of the micro-interventions (2-3 minutes per day) and brief daily questionnaires (3-5 minutes per day). This sums up to a total of 210 minutes per week, leading to total maximum of 17.5 to 21 hours if participants engage consistently over the six-week period. The group with mental health literacy and no additional components will spend approximately 30 minutes on the digital support system. In contrast, participants who receive mental health literacy, social activation and micro-

interventions (with or without machine learning algorithm) can spend up to 20 to 23.5 hours using the digital support system.

4.2.12 Reimbursement

The reimbursement is country-specific, depending on local practices. In some countries, this may be an incentive (e.g., money or voucher of approximately 30-50 Euros) for completing the questionnaires and/or participating in an interview. In other countries, receiving the digital support system itself is considered the incentive.

4.2.13 Ethics

This study protocols will be registered in WHO approved registries. Scientific approval will be obtained from local (faculty) ethical boards, if indicated. We will adhere to national Codes of Ethics for Research in Social and Behavioural Sciences, including APA Ethical Principles, Declaration of Helsinki, and good clinical practice. 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) 01/01/2021 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 (HRA, RS 810.30) 01/03/2025 in Switzerland. The project will also be conducted in line with the EU AI act Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence, and the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR).

Inclusion of first participant will be reported to the ethics committee in each country. This is a low-risk study in relatively healthy participants, and we do not expect that any serious adverse event (SAE) will occur. In the case an SAE does occur, we will report this accordance with the requirements of the ethical committee. We will also report last patient included, and data collection finished to the ethics committee in each country.

We believe that next to the time-investment in terms of completing surveys there are no disadvantages of participation. Regarding our specific context, there are no known risks. The digital support system was developed as part of the RECONNECTED project and has not been tested before. However, it is a health promotion intervention focusing on increased mental health literacy, increasing resilience, and social connectedness. There is evidence that these interventions can be effective and safe including in our target populations.

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6 Ethical approval

Ethical approval has already been obtained from all review boards.

- Denmark: De Videnskabsetiske Komitéer for Region Midtjylland, Case number 1-10-72-116-25, on 17th November 2025: Committee assessed that the project could not be considered health science research with an obligation to the Health Research Ethics Committee System, as found in Committee Act Article §14, paragraph 1.
- Finland: Ethics Committee for Human Sciences at the University of Turku, ref: TY/2005/2025
- France: The Comité de protection des personnes Ile de France II, Case number 2026-A00629-42, on 4th May 2025.
- Germany: Ethics committee of the Faculty of Psychology of Ruhr-Universität Bochum, Case Number 1069, on 2nd March 2026.
- Netherlands: Medical Research Ethics Committee of Amsterdam UMC classified the study as non-WMO research (nr. 2026.0466, July 10th 2026) consequently, formal ethical approval was not required.
- Kosovo: Ethics committee of Alma Mater Europaea Campus College “Rezonanca”, project number AD-6197/25, on 30th December 2025.
- Spain: Ethics Committee of Research in Humans of the Ethics Commission in Experimental Research of the University of Valencia, Approval Number 2024-PSILOG-3607551, approved on 21 November 2024.
- Switzerland: Gesundheits-, Sozial, und Integrationsdirektion Kantonale Ethikkommission für die Forschung, Case number 2026-00129, on 09th March 2026.
- United Kingdom: Ethics Committee of the Psychology department at St Mary's University, Twickenham, Approval Code SMU_ETHICS_2025-26_468, approved on 27 March 2026.

7 Study registration

All nine factorial trials will be registered in a WHO approved clinical registry. The trials below have already been registered. Procedures for the remaining sites are currently in progress.

- Finland: the study entitled "A complex systems approach towards REsilient and CONNECTED vulnerable European communities in times of change: Finnish trial" is listed on the ISRCTN registry with study registration number ISRCTN18011789 (25th February 2026)
- France: the study entitled “Improving Mental Health in Vulnerable Populations Through Micro-Interventions and Social Prescribing: A Factorial Randomized Trial (ReconnectedTRI)” is listed on ClinicalTrials.gov with study registration number NCT07697807 (9th July 2026)
- Germany: the study entitled “MOODBUSTER - mental health among students” is now listed on the DKRS registry with the study registration number DRKS00040069 (24th May 2026)
- Kosovo: the study entitled "A randomised control study: evaluating the RECONNECTED digital mental health intervention in Kosovo" is listed on the

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ISRCTN registry with study registration number ISRCTN10501523 (9th February 2026)

- Switzerland: the study entitled “RECONNECTED – Studie zur Wirkung einer digitalen Unterstützungsplattform zur Stärkung des psychischen Wohlbefindens bei Menschen ab 55 Jahren mit erhöhter Einsamkeit” is listed on the DRKS registry with the study registration number DRKS00039588 (25th March 2026).

Appendix 1 Topic guide semi-structured interviews

Interviewer instructions

- The interview consists of 7 to 9 main questions (depending on the study condition) and is estimated to take ~45 minutes.
- Q1 has a separate version for participants who discontinued early.
- Questions Q3-Q4 cover the intervention components Social Activation and Micro-interventions. These are conditional on randomisation condition.
- The guide is a structure, not a script.
- Probes are suggestions, not mandatory questions. Use them to deepen responses that are superficial or to explore constructs that have not yet been mentioned. For participants who discontinued early, some probes may be irrelevant.
- Adapt language and phrasing to the participant's background and information shared during the interview.
- If a question seems inappropriate for your target population, feel free to leave it out.
- Monitor the question order but remain flexible if a topic arises earlier than anticipated.
- Interviews can be conducted via video-conferencing or face-to-face.
- Text **highlighted in yellow** are instructions for the interviewer and should not be read aloud to the participant.
- The *grey italicised text* following each question and probe indicates the theoretical construct being assessed. This is for coding purposes and should not be read aloud to the participant.

Start of the interview

- Confirm informed consent and ask permission to record the interview
- Briefly inform the participant about the purpose and structure of the interview

Warm up: Can you briefly remind me, how often did you use the app during the study and which parts did you use?

Engagement & Motivation

Q1a For participants who actively participated in the app. Otherwise go to Q1b.

Q1a) What motivated you to use the app, and was there anything that got in the way?

(autonomous/controlled motivation)

- Did it fit naturally in your daily routine, or did it feel like something you had to make time for? (compatibility)
- **If applicable:** What got in the way when you used it less? (disengagement, amotivation).

Q1b For participants who discontinued early.

Q1b) What led you to stop using the app? (disengagement, amotivation, barriers to engagement)

- Was there a specific moment or experience that triggered it? (disengagement)
- Looking back, what would have needed to be different for you to continue? (barriers to engagement, compatibility)

Perceived Usefulness & Mechanisms of Change

Q2) What did you think of [the mental health literacy module], and what did it do for you? (perceived usefulness, mechanism)

- How clear and understandable did you find the information, and was there anything you felt was missing? (accuracy, comprehensiveness, accessibility)
- How did it connect to your own life and situation? (relevance)
- Did it change how you think or talk about mental health? If so, did anything stay with you? (mechanism)
- Do you feel like it affected your overall mental wellbeing? (mechanism)

Q3 only for participants randomized to receive the Social Activation component. Otherwise go to Q4.

Q3) What did you think of [the social activation component], and what did it do for you? (perceived usefulness, mechanism)

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If the participant has not engaged with this component at all:

- What was the reason you did not use this part of the app? (*perceived usefulness, barriers to engagement*)

If the participant at least started with this component:

- How clear and understandable did you find the information, and was there anything you felt was missing? (*accuracy, comprehensiveness, accessibility*)
- How did it connect to your own life and situation? (*relevance*)
- Did you act on the exercises? If so, did anything stay with you? (*mechanism*)
- Do you feel like it affected your overall mental wellbeing? (*mechanism*)

Q4 only for participants randomized to receive the Micro-Interventions. Otherwise go to Q5.

Q4) What did you think of [the micro-interventions], and what did it do for you? (*perceived usefulness, mechanism*)

If the participant has not engaged with this component at all:

- What was the reason you did not use this part of the app? (*perceived usefulness, barriers to engagement*)

If the participant at least started with this component:

- How clear and understandable did you find the information, and was there anything you felt was missing? (*accuracy, comprehensiveness, accessibility*)
- How did it connect to your own life and situation? (*relevance*)
- Do you feel that [the micro-interventions] helped you cope with stressors more effectively in your daily life and if so, can you give an example? (*mechanism*)
- Did you adopt any of the techniques as habits — are there any you still use now? (*mechanism*)
- Do you feel like they affected your overall mental wellbeing? (*mechanism*)

Additional probes for the MI-AI group:

- How did you experience it when the app suggested you might be experiencing stress, and did it prompt you to use the micro-interventions? (*perceived usefulness, mechanism*)
- How did you experience the motivational messages, did they make a difference for you? (*perceived usefulness*)

Unintended Negative Effects

Q5) Did using the app have any negative effects on how you felt, or on other areas of your life?

(*unintended negative effects*)

If yes:

- What negative emotions came up for you while or after using the app, and how did you handle that? (*emotional distress*)
- How did the people around you react to your use of the app, and did that have any effect on your relationships? (*social & relational harms*)

Q6) Did you have any concerns about your data or privacy while using the app? (*data and privacy concerns*)

- What made you feel safe or unsafe sharing information through it? (*data and privacy concerns*)

Usability

Q7) How easy or difficult was it to navigate and use the app, and did that change over time? (*usability*)

- Which parts were easy to use, and which were confusing or difficult? (*learnability, efficiency*)
- In what way did the design feel suited, or not suited, to your background or daily circumstances? (*community-specific barriers*)
- Did you ever get stuck or end up somewhere in the app you did not intend to, and what did you do then? (*error tolerance & recovery*)

Satisfaction

Q8) Overall, how satisfied are you with the app, and did it meet your expectations? (*global satisfaction*)

- What had you expected going in, and how did that compare to your actual experience? (*expectancy-disconfirmation*)
- What contributed most to your satisfaction or dissatisfaction? (*quality appraisal, needs fulfilment*)
- What would you change or improve? (*quality appraisal*)

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Q9) Would you recommend the app to someone in a similar situation? And why? *(recommendation intention)*

- Could you explain if you would use it again yourself if it were available after the study?
(recommendation intention)

Closing: Is there anything you would like to add that we have not covered yet?