Generic full factorial Study protocol

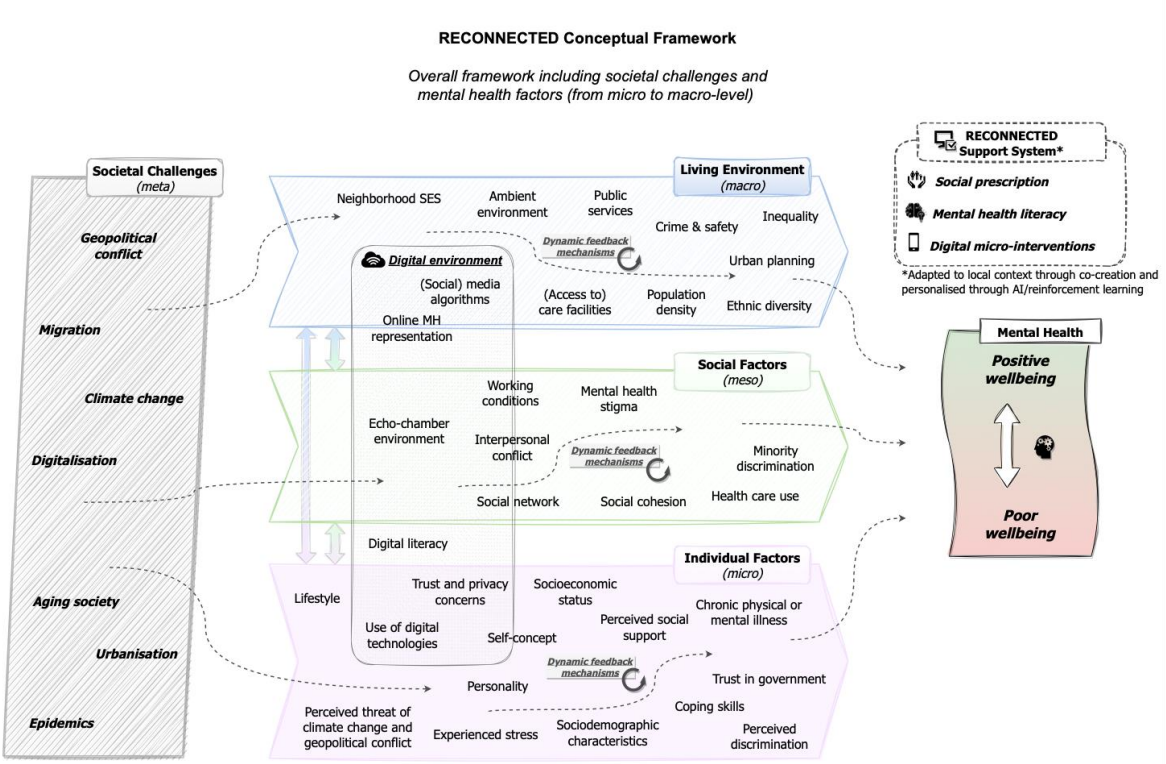
(WP4, lead VUA)

History of changes		
Version	Publication date	Change
1.0		New

Background

Europe is experiencing a period of 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, amongst others, identity struggles, shaped by factors such as migration and social media, and information overload and social disconnection due to 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 (Benevolenza & DeRigne, 2019; Molua, 2024; Vasilescu et al., 2020).

Figure 1. RECONNECTED Conceptual framework



Increasing mental wellbeing in vulnerable citizens

Psychosocial interventions are a viable way to empower individuals to gain more control over their life, learn how to adapt to stressful events and promote mental health and wellbeing (World Health Organization, 2021). They often extend beyond a sole focus on individual behaviours, incorporating a broader range of social and environmental interventions (World Health Organization, 2021). This multilevel perspective aligns with the RECONNECTED project that adopts a complex system perspective (Mitchell, 2009) on mental health and wellbeing that takes into account risk and protective factors at different levels of description: societal challenges (meta), living environment (macro), social factors (meso), and individual factors (micro) (see Figure 1 for an integrated conceptual framework that was developed in the RECONNECTED project). To maximise mental health benefits, it is suggested that interventions need to address various risk and protective factors across multiple levels (e.g., meso and micro). In the RECONNECTED project, we offer a digital psychosocial intervention with culturally adapted and personalised intervention tools to various vulnerable populations in Europe. This is a multicomponent intervention that targets mental health literacy, social connectedness, and psychological resilience.

Mental health literacy is a core component of most psychosocial interventions. It aims to increase knowledge and understanding about mental health and illness and how to get support if needed (Jorm, 2015; Jorm et al., 1997) and has demonstrated the ability to increase mental health awareness, reduce stigma, and change attitudes towards mental health and mental health seeking behaviours (Brijnath et al., 2016). Research has shown that vulnerable populations, such as individuals with lower income and educational levels, tend to have lower mental health literacy compared to those with higher socioeconomic status (Soria-Martínez et al., 2024), which is important considering that low mental health literacy is one of the primary reasons for the treatment gap between those who need help and those who seek help (Tambling et al., 2023).

Social connection, social support, and a sense of belonging are fundamental human needs (Baumeister & Leary, 1995; Wickramaratne et al., 2022). Strong social networks foster belonging and act as protective factors for mental well-being by providing support and resources, enhancing self-worth, and broadening perspectives (Keim-Klärner et al., 2023; Steinhoff & Reiner, 2024). Social isolation, on the other hand, is associated with increased risks of anxiety, depression, and other psychological distress (Baumeister et al., 2007; Rutenfrans-Stupar et al., 2019; Wickramaratne et al., 2022). Therefore, social connectedness is particularly crucial for overall wellbeing (Rutenfrans-Stupar et al., 2019) especially when people experience high level of stress and uncertainty.

Resilience is commonly defined as the capacity to adapt to and recover from adversity. A theoretical approach to understand resilience, is the 'metatheory of resilience and resiliency' (MRR) (Richardson, 2002), which aligns well with the RECONNECTED conceptual framework. MRR emphasizes the dynamic interaction between individuals and their environment in managing and recovering from adverse life events. Resilience is thus not simply an individual trait (micro) but is influenced by external factors, such as social support (meso) and access to resources (macro) (Hall et al., 2023; Liu et al., 2017; Patel et al., 2017). Being a vulnerable citizen has been found to be associated with decreased resilience, making them more susceptible to the negative effects of adversities (Siriwardhana et al., 2014). By fostering resilience, individuals can develop greater emotional adaptability and coping mechanisms to navigate stressors more effectively (Siriwardhana et al., 2014). One way to enhance resilience could be through micro-

interventions. Micro-interventions target specific social and psychological processes and alter the way that people think, feel, or behave in their daily lives (Fuller-Tyszkiewicz et al., 2019). Micro-interventions conceptually differ from standard and brief interventions in their scope, objectives, and time frame (Baumel et al., 2020; Elefant et al., 2017). They are narrower in focus, with a clear and targeted goal, and a timely approach, reducing the effort needed for completion. Unlike traditional interventions that often target broad clinical outcomes (e.g., reducing social anxiety), micro-interventions are designed to address more immediate and situational challenges, such as reducing stress before an exam or overcoming hesitation to attend a social event (Baumel et al., 2020). While their initial focus is to generate short-term positive effects, they contribute incrementally to longer-term goals like enhancing overall well-being (Fuller-Tyszkiewicz et al., 2019). In addition, micro-interventions offer greater scalability by being low-cost and overcoming common barriers to access, such as time constraints and scheduling difficulties (Lee et al., 2025).

Digital solutions

Existing interventions psychosocial interventions do not always reach those in need due to limited cultural adaptation, language barriers, as well as lack of personalisation. These challenges are further reinforced by stigma, low mental health literacy and the high costs of interventions, which particularly affect socially disadvantaged groups (Dobalian & Rivers, 2008; Jorm, 2012). Digital interventions present a promising solution to bridge this gap by empowering individuals' self-management and enhancing scalability, affordability, accessibility, and safety of interventions (Aschentrup et al., 2024; Muñoz, 2010; Stark et al., 2022). Furthermore, empirical evidence supports the efficacy, effectiveness, and acceptability of digital health promotion and prevention tools (Muñoz, 2010). Moreover, evidence has shown that mental health literacy interventions, social activation, and micro-interventions can also be delivered digitally effectively. For instance, a meta-analysis of digital mental health literacy interventions reported large effect sizes for improving literacy and medium effect sizes for mental health outcomes, comparable to face-to-face interventions (Yeo et al., 2024). Similarly, digital interventions focusing on increasing social connectedness offer enhanced usability by enabling on-demand access and consolidating activity information in one platform, making it

more user-friendly than traditional pen-and-paper methods (Lee et al., 2023; Patel et al., 2021). Moreover, digital delivery of micro-interventions provides unique advantages, such as automatic monitoring, notifications, and integrated messaging tools, which are not feasible in offline formats (Baumel et al., 2020)

To realize the potential of digital interventions, they need to be tailored to the specific needs and cultural context of the target population. Cultural adaptation means alignment of interventions with the cultural context of the target population. This may include language adjustments and the use of culturally meaningful metaphors, such as symbols and sayings (Bernal et al., 1995; Nagayama et al., 2016). Personalisation, on the other hand, means adjustment of intervention with the individual's (current) needs and characteristics. This means that, based on these factors, a specific intervention may or may not be offered (Cohen et al., 2021). Persuasive technologies, such as machine learning algorithms, can support personalization by predicting an individual's psychological state and informing decisions about whether, when, and which intervention to offer (Abd-Alrazaq et al., 2023; Baumel et al., 2020; Ciharova et al., 2024; Moshe et al., 2021).

Objective

This full factorial trial is part of the RECONNECTED project (www.reconnected-project.eu). RECONNECTED involves a consortium of 11 European partners responding to global societal developments affecting mental wellbeing of vulnerable citizens. The project will offer a digital support system with culturally adapted and personalised intervention tools to various vulnerable populations that are understudied and difficult to reach with regular mental health interventions (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 main aim of this trial is to examine if personalised micro-interventions and social activation add wellbeing benefits to mental health literacy. The additional effects of personalised micro-interventions and social activation to mental health literacy will be tested through nine full factorial trials in nine European countries. The second objective is to evaluate whether integrating a machine learning algorithm into personalised micro-interventions

improves the effectiveness of the personalised micro-interventions compared to the standard version. This analysis will be conducted using pooled data from the nine trial sites. The third objective is to conduct a process evaluation to assess the feasibility of the digital support system, including usability, perceived usefulness, overall satisfaction, potential unintended negative effects, and engagement.

Methods

Study design full factorial trial

This study is part of the RECONNECTED project (www.reconnected-project.eu). The current study consists of nine 2×2 factorial randomised controlled trials (*n*=256 in each country, total *n*=2,304) across various vulnerable populations in Europe (Denmark, Finland, France, Germany, Kosovo, the Netherlands, the United Kingdom, Spain, and Switzerland). To study the first research aim, all participants will be randomised to receive the mental health literacy intervention; with no or a maximum of two additional components (i.e., personalised micro-interventions and social activation). The full factorial design allows to assess the additional effect of each component, both individually and in interaction (see Table 1).

Two answer research aim 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) follow-up, with each assessment taking a maximum of 30-45 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 micro-interventions	Anticipated *n*
1	Yes	No	No	64

2		Yes	Yes	No	64
3	a	Yes	No	Yes: MI	32
	b			Yes: MI+ML	32
4	a	Yes	Yes	Yes: MI	32
	b			Yes: MI+ML	32

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

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.

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	People aged 18-20 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 geographical areas based on postal code on the outskirts of Paris	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 in the area of Bochum	Recruitment primarily through brief presentations and leaflets within secondary schools.
Kosovo	Adults aged 18 or older also residing in low SES geographical areas based on postal code in Pristina	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 living in Urban areas	Open recruitment strategy through community centres, social work, and public libraries.
The United Kingdom	Non-western migrants aged 18 or older in Greater London	Open recruitment strategy through e.g., NGOs, migrant support organisations, faith groups, trained community connecters. Online and in-person.
Spain	Migrants aged 18 or older from a Latin-American background in the Valencia province	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 and live in Switzerland	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.

Recruitment participants and procedure

Recruitment procedures are country specific but generally follow the following sequence of steps. A local study website will contain all information about study participation. Prospects apply for participation on the website by submitting their contact details. Prospects will be registered on the CASTOR platform (which is used for screening and data collection) and receive a link to the online information sheet and informed consent form. The informed consent form includes amongst other things that participants are free to discontinue their participation at any time, without having to give a reason and may determine for themselves the extent to which they engage with the intervention. Additionally, it includes a specific request for consent to be contacted for a follow-up semi-structured interview as part of the process evaluation. Once informed consent is provided, they will be directed to the screening survey. They will complete a short questionnaire screening for in- and exclusion criteria. Those who do not meet the criteria will be notified that they are ineligible to participate in the study. Those who meet the criteria will be directed to the baseline survey. In some countries, informed consent may need to be provided via pen and paper. If this is the case, informed consent will be obtained before prospects are registered on the CASTOR platform.

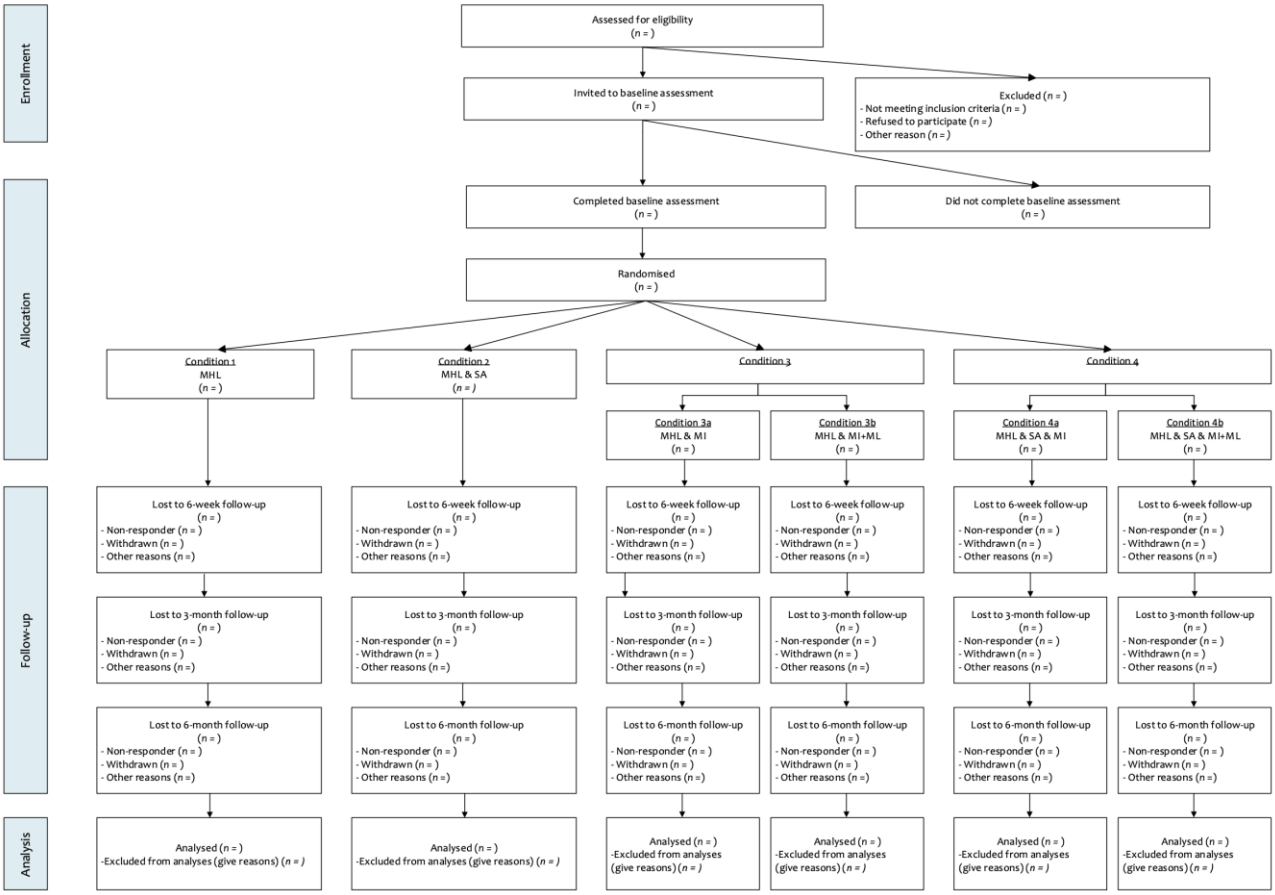
A standard set of questions for the baseline assessment will be identical across all study sites (approximately 30 minutes to complete). Local sites may supplement that with additional

questionnaires of particular interest for the local target group or research group, provided that the total set of questionnaires will not take more than 30-45 minutes to fill in.

Once participants completed the baseline assessment, they will be randomly allocated to one of the six conditions (see Table 1 or Figure 2). Randomisation will take place at the individual level, stratified by country. The process will be conducted in CASTOR using an allocation ratio of 2:2:1:1:1:1 (Please see Table 1 and Figure 2). Block randomisation will be used with variable block sizes that vary between 8 and 16. The allocation scheme can only be accessed by an independent researcher. Blinding for group allocation is not possible as both the researchers and participants will know if/what components will be added to the digital support system.

For the conduct of the study, we will make use of CASTOR - an approved Health and Life Science platform for research management support (see https://www.castoredc.com/). For the study, one project will be created within CASTOR by the PI organization (VUA), but each site will receive its own login with access only to their local trial.

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.

Sample size and power estimates

To address research aim one, the trials will be analysed separately for each country. Therefore, the sample size calculation was conducted to ensure sufficient statistical power to detect reliable effects within each country. The sample size was calculated using a free version of SAS (SAS, n.d.) and the SAS Macro 'Factorial Power Plan' (Dziak et al., 2013). Assuming pre-post-design (pre-post-correlation) of 0.6, pre-test as covariate, a power of 0.8, a component effect size of 0.25 for each of the two independent components, and an alpha of 0.1, the calculated sample size is *n* = 256. The component effect size was set to 0.25 assumed to be the smallest Meaningful Clinical Important Difference (MCID). An alpha of 0.1 is recommended for component selection experiments to decrease the risk to prospectively rule out potentially active components (i.e., decrease risk of type 1 and type 2 error).

To answer research aim two, data from all nine countries will be pooled (*n*=256

participants per country, total sample of 2,304 participants). Of these, 1,152 receive micro-interventions: half the standard version (MI, *n* = 576, conditions 3a and 4a) and half the version supported by a machine learning algorithm (MI+ML, *n*=576, conditions 3b and 4b). This sample provides sufficient power to detect a small effect size of 0.20.

Digital support system

The digital support system is a new model of community care that addresses both individual and social level factors (i.e., mental health literacy, social connectedness, and psychological resilience) to maximise health benefits. The specific content of the digital support system is adapted to suit various vulnerable communities (e.g., youth, elderly, migrants, and people with low SES). All participants will start with the mandatory mental health literacy module, which includes a brief onboarding to the digital support system. After completion of this module, the app opens access to the other two components, social activation and personalized micro-interventions. Participants are free to use the interventions however works best for them, but it is designed to be used for approximately 6 weeks. The app can be accessed on a computer and smartphone, however, the micro-interventions are smartphone based.

Mental health literacy

Mental health literacy (MHL) is a brief introductory module designed to provide users with basic knowledge about mental health and strategies to address common challenges associated with detection, management or prevention of mental health (Jorm et al., 1997; Kutcher et al., 2016). This module includes ~10 pages of educational content designed to address explain differences between mental health and illness, and covers topics such as stigma and how to access mental health resources if needed (Brijnath et al., 2016). The module offers tips and advice, reflection tasks, and additional readings for those who are interested.

Social activation

Social activation comprises four modules of 10 pages that take about 20-30 minutes to complete. It is designed to encourage people to take action in strengthening social connectedness by fostering a sense of belonging, building supportive networks, feeling

appreciated, and broadening perspectives. In the first module, participants explore the concept of social connectedness more deeply and identify their own social network in relation to their personal values. In module 2, participants learn practical strategies to strengthen their social connections. Module 3 focuses on finding meaningful ways to engage with their community. In module 4, participants develop skills to build and maintain supportive relationships. The social activation component builds on the literature that describes the benefits of social connectedness for wellbeing (Antonucci et al., 2014; Baumeister & Leary, 1995; Wickramaratne et al., 2022). It uses principles of value-based behavioural activation by encouraging people to engage in value-based social activities in a structured way (Dimidjian et al., 2011; Lejuez et al., 2011; Pepin et al., 2021) and social prescribing by identifying individual needs for community engagement and offering resources to connect with the community (Chatterjee et al., 2018; Cooper et al., 2022). The module empowers participants by highlighting that social connections can be actively strengthened. It provides structured steps for implementing change such as goal setting and action planning, while encouraging individual differences in needs and values. The module also includes structured exercises, relatable personas, progress monitoring and offers practical tips and advice for handling specific situations.

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. For detailed information on the micro-interventions please refer to Appendix 1.

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 has been trained beforehand based on data from the RECONNECTED CEMA-study. The algorithms for personalising the format selection and the motivational messages are trained during deployment. These algorithms refine their predictions over time using input from short daily questionnaires and participant activity data

from the digital support system (e.g., adherence to the short daily questionnaires).

Moodbuster 2.0 platform

The digital support system runs on the Moodbuster 2.0 platform, consisting of a web application and a smartphone application. Personalised therapeutic modules can be created, and it can be used as a stand-alone intervention or with a therapist portal for blended or guided self-help. The platform is available in Albanian, Dutch, Danish, English, Finnish, French, German, Polish, Spanish, Portugese, and Ukrainian. Moodbuster is co-owned by consortium partners VU Amsterdam and INESC-TEC Portugal (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.

Study parameters

An overview of the measures and time of assessment is provided in Table 7. An overview of the survey questions is provided in Appendix 2. All surveys are completed online.

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
Other assessments					
Demographics	Standard questions	X			
Psychopathology					
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

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				

Primary outcome

Mental wellbeing 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'). Based on their responses, 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 (α>.80) and has been validated across diverse populations (Iasiello et al., 2022; Lamers et al., 2011, 2012).

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.

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.

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.

Psychopathology The Patient Health Questionnaire – 8 (PHQ-8) and the Generalised Anxiety Disorder – 7 (GAD-7) will be assessed to measure psychopathology.

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 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).

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 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 (please see Appendix 3).

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.

Moodbuster data will be temporarily stored on INESC-TEC servers in Portugal. Although the infrastructure is not ISO/IEC 27001:2005 certified, INESC-TEC has implemented the necessary technical and organisational security measures, in accordance with GDPR requirements. A joint data processing agreement (JCA) between INESC-TEC (as data processor) and consortium partners (as joint controllers) define data processing and protection. Collected 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. Each partner will clean and process their data following a protocol provided by VU Amsterdam.

Processed pseudonymized data will be pooled and stored securely with restricted access on Research Drive at VU Amsterdam. Access to this data will be controlled with data-sharing procedures in compliance with General Data Protection Regulation (GDPR). 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. For details regarding the data management plan for RECONNECTED, please refer to Appendix 3.

Timeline

All trial protocols will be submitted to local scientific and ethical committees for approval, and all trials will be registered in a trial register prior to inclusion of participants. The local protocol will be registered in a WHO approved clinical registry prior to inclusion of participants. The inclusion period will run from April 2026 to December 2026. Varying slightly between trial sites. This means that all data will be collected by June 2027 (giving the fact that the follow-up period is 6 months). Data cleaning and analyses will be performed from June 2027 to December 2027. Results are expected for publication in the summer of 2028.

Statistical analyses

A detailed statistical analysis plan will be completed during the recruitment period (March 2026). 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) follow-up. Both main effects and interaction effect of the components will be estimated. Main effects refer to the impact of each individual component on the primary outcome, while the interaction effect refer to how the interaction between components influence the primary outcome. Specifically, separate models will be tested in which each component (social activation, micro-interventions) is included as a moderator, followed by model including the two-way interaction (e.g., social activation x micro-interventions). Component variables will be effect-coded as -1 (component absent) and 1 (component present).

Process evaluation

Participants, 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 site). 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).

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.

Measures

The quantitative measures are outlined below. Topic guides for the semi-structured interviews are still to be developed.

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 and completed exercises. Note that detailed information in terms of actual entered answers by the participants will not be used for study purposes

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 the CFIR framework by at least two researchers. A detailed analysis plan will be completed during the recruitment period (June 2026).

Burden for participants

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.

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 15 minutes, if people read all available background material, this may take up to 45 minutes. Regarding social activation, the estimated time commitment is 15 minutes for each module and about 30 minutes between modules for exercises. This sums up to a total of 75-205

minutes. This means that the for the micro-interventions (both with and without the machine learning algorithm), the estimated time commitment includes the completion of the micro-interventions (20-30 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 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) will spend approximately 20 to 23.5 hours on the digital support system.

Risk for participants

Regarding our specific context, there are no known risks. The digital support system was developed as part of the RE-CONNECTED 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.

Benefits for participants

Regarding our specific context, there are no known benefits.

Disadvantages for participants

We believe that next to the time-investment in terms of completing surveys there are no disadvantages of participation.

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.

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 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.

Information about ethical regulations concerning the machine learning algorithm of the micro-interventions, please refer to "Appendix 4: RECONNECTED AI System Ethics". The digital support system is not classified as a medical device and, as such, does not fall under the scope

of the EU Medical Device Regulation (see Appendix 5: Medical Device Regulation Rationale).

Other information

Publication policy and amendments

In case adjustments are made to the study protocol (local) amendments will be submitted. The local protocol and the results will be submitted for publication in separate papers. The usual conventions will be followed for authorship as described in the consortium agreement.

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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 Disoerder – 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.

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Appendix 1: Personalised micro-interventions

Appendix 2: Survey questions RECONNECTED full-factorial trial

Appendix 3: DMP RECONNECTED

Appendix 4: RECONNECTED AI System Ethics.

Appendix 5: Medical Device Regulation Rationale