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

Horizon Europe HLTH-2022-STAYHLTH-01-two-stage

Grant agreement NO: 101081020

Deliverable information	
Project start date	01-06-2023
Duration of project	54 months
Due date	01-06-2024
Work package	D3.1
Lead partner for deliverable	MHRTC
Dissemination level	PU
Author(s)	Kathrin Schopf (MHRTC)
Reviewer(s)	Annet Kleiboer (VUA)

Table of Contents

Abbreviations

CONSORT	CONsolidated Standards Of Reporting Trials
PHR	Participatory Health Research
PU	Public
PRODUCES	PRoblem Objective Design Users Co-creation Evaluation Scalability

1. Introduction

The RECONNECTED project's main objective is to provide several vulnerable groups in Europe (youth, elderly, people with low socioeconomic status, migrant population) with a secure, safe, and easy-to-use digital support system to promote resilience and to protect their mental health during times of significant global societal developments (e.g. climate change, digitalization, geopolitical conflict, a changing population). The RECONNECTED digital support system will consist of several intervention tools that target mental health literacy, individual resilience, and community participation.

Public health interventions like the RECONNECTED digital support system are typically developed using a top-down approach wherein academics control all major decisions based on relevant literature. However, when complex factors are targeted that vary between individuals and settings, systematic involvement of stakeholders using participatory research methodology is highly recommended to ensure that actionable insights and intervention tools are relevant, acceptable, and ethical to end-users and other stakeholders (Greenhalg et al., 2016). Co-creation, as a participatory research methodology, has the potential for "moving beyond the ivory tower" and represents a major opportunity to improve translational (mental) health research. More importantly, literature points to increased adherence and effectiveness of co-created interventions due to a better-tailored end-product (Greenhalg et al., 2016).

In the RECONNECTED project, co-creation will be applied in the development of the intervention tools to ensure that the digital support system fits with the needs and preferences of the local vulnerable target populations. There is no consensus on the definition of co-creation. We have adopted the definition of Leask and colleagues who define co-creation as "collaborative public health intervention development by academics working alongside other stakeholders" (Leask et al., 2019). In the project, end-users and other important stakeholders such as mental health service providers and community workers will be actively involved and will work alongside academic project members in the development and adaptation of the intervention tools. The same co-creation process will be applied in each of the nine target populations. However, each co-creation process may result in different outcomes locally, as the needs and preferences of the various populations may differ. Thus, the final digital support system may differ between target populations.

2. Objective

This participatory research protocol describes the co-creation process between researchers and stakeholders that will be applied to develop the content of the RECONNECTED digital support system in different populations and settings. The protocol is guided by the framework of Leask and colleagues (2019) that is developed to make the process of co-creation systematic and reproducible. The protocol can be considered a blueprint that can be used by communities that want to adapt the RECONNECTED support system to a new local context after the project phase.

3. Participatory Research Protocol

The framework of Leask and colleagues (2019) includes the following steps: 1) planning the purpose of the co-creation, 2) conducting, what activities can be used during co-creation and how commitment of co-creators can be ensured, 3) evaluation of the co-creation process and the outcomes (i.e., how to know that the process and the outcome are valid and effective), and 4) reporting of the co-creation process and the outcomes (i.e., how to report the findings).

3.1 Planning

Framing the aim of the study (principle 1)
In this step, the aim of the study and the appropriate sampling strategy will be defined. To clearly frame the aim of the study in a systematic way, the proposed PRODUCES-framework, will be utilized. PRODUCES stands for **PR**oblem, **O**bjective, **D**esign, **U**sers/**C**o-creators, **E**valuation, and **S**calability. A summary of how this framework has been used in the RECONNECTED-project is visible in Table 1.

Within the RECONNECTED-project, the theoretical background (i.e., **PRoblem**) is the current accumulation of global societal challenges (e.g., climate change, digitalization, geopolitical conflicts, a demographically changing population), which may threaten the mental health of vulnerable individuals. These societal developments may be associated with cognitive and emotional challenges as well as difficulties in adjusting to these developments. Research has suggested that the mental health of several marginalised and vulnerable citizens in Europe, such as people with low socioeconomic status, immigrants, youth, and elderly, are affected the most heavily by these developments (Benevolenza et al., 2019; Hallingberg et al., 2022; Kantamneni et al., 2020).

The **Objective** of the RECONNECTED project is to provide vulnerable citizens in Europe with a digital support system with intervention tools to protect their mental health. The intervention tools will target mental health literacy, foster community participation, and enhance individual resilience by offering micro-interventions that teach individual coping skills. To ensure that the intervention is acceptable, relevant, and ethical to the local target populations; local end-users and other stakeholders (e.g., citizens, mental health service providers, community workers) will be involved as co-creators in the intervention development.

The participatory health research (PHR) paradigm will be used to **Design** the co-creation process. This paradigm highlights participation as the defining principle throughout the research process (International Collaboration for Participatory Health Research (ICPHR), 2013).

The end-**Users** of the RECONNECTED digital support system are people from different vulnerable target populations: low socioeconomic status communities in France and Kosovo, people aged 55 and older living in the Canton of Bern (Switzerland) or in Urban environments (Netherlands), adult migrant population living in greater London (UK) or

Valencia (Spain), youth 16-25 in Denmark, males in mandatory military service (Finland), and adolescents aged 12-16 in secondary education in the area of Bochum (Germany).

Co-creators will be members of the local target populations themselves, service providers or stakeholders of the target populations such as mental health experts, mental health professionals, and public health authorities. For example, within the RECONNECTED-project one vulnerable group includes youth (adolescents and young adults). For the group of adolescents, co-creators may be students (adolescents) with different socio-demographical backgrounds, teachers, school social workers, youth welfare office specialists, child and youth psychotherapists, school administration office, and local politics. An overview of co-creators per consortium partner is provided in Deliverable 18 (D5.1).

A full factorial randomized controlled trial will be utilized to **Evaluate** the effectiveness of the RECONNECTED digital support system in the different target populations (9 trials in total). In addition, the co-creation process will be evaluated during the intervention development process and alongside the trials. During the development of the intervention content, a protocol will be completed by researchers after each co-creation meeting, which includes the contents, the outcomes, and the conclusions of the sessions. In addition, co-creators will be asked to complete brief anonymous evaluation forms regarding satisfaction with the meeting, the work atmosphere, the level of participation, and eventually the degree to which the intervention is representative of the co-creators' opinions. Alongside the trials, process evaluations will be conducted including assessments on engagement, acceptability, feasibility and satisfaction with the support system.

Scalability refers to how the intervention can be scaled to a population level. The scalability model in RECONNECTED combines aspects of the distributed and cascade model described by Leask and colleagues (2019). We develop one generic digital support system in collaboration with end-users and stakeholders from different local populations. Dependent on the outcome of the local co-creation process, the digital support system will be adapted and evaluated in the nine vulnerable populations. Dependent on the outcome of the evaluation of the digital support system in a local target population, the system will be optimized, and specific implementation scenarios will be developed for each target population by researchers and stakeholders. The optimized support system can be used for upscaling.

Table 1: The PRODUCES framework to the RECONNECTED-project		
PRODUCES	Definition	RECONNECTED-project
PRoblem	Specific health behaviour or concern and population.	The risk of global societal challenges to the mental health of vulnerable populations in Europe (e.g., youth, elderly, migrants, etc.).
Objective	Specific mechanism within the problem to be targeted, and how.	Improve mental health literacy, foster community participation, and enhance individual resilience to improve mental health.
Design	Participatory methodology to be used in co-creation.	Participatory Health Research (PHR)
(end-)Users	Target population of the intervention.	Dependent on each local site: youth, elderly, people with low socioeconomic status, and migrant population.
Co-creators	All actors engaged in the co-creation process.	Academic researchers (consortium member staff), target end-users, and other stakeholders: service providers or stakeholders of the target group, mental health experts or mental health professionals, and public health authorities
Evaluation	Evaluation procedure of the co-creation process and effectiveness of intervention itself.	The co-creation process will be evaluated by both the research team and the co-creators. Researchers will complete an established protocol and co-creators will complete an anonymous feedback form. The intervention will be evaluated through a factorial randomized trial with a process evaluation alongside.
Scalability	How the intervention will be scaled up to population level.	Distributed model and cascade model

Sampling strategy (principle 2)
The sampling strategy serves two purposes: First, it should ensure that a representative sample of end-users will be recruited, so the outcome is relevant, acceptable, and ethical for that group. Second, it should ensure there is a representation of all necessary expertise from relevant stakeholder groups. With regard to the co-creator sampling strategy, the RECONNECTED-project will employ **purposive sampling**, aiming for diversity and variation in demographic characteristics and expertise of co-creators. The number of co-creators invited may vary depending on the specific task of the meetings. Generally, a total of between 3-10 co-creators per activity is desirable. Each consortium partner will recruit **at least** 3-5 stakeholders for co-creation sessions. Relevant stakeholders are for example: citizens, mental health service providers, community workers, academics, and public health authorities. A co-creator contact database will be established, from which a balanced set of co-creators representing different areas, expertise and interests will be invited to the co-creation meetings. Consortium partners may choose which co-creators to invite. The representation of co-creators may be dynamic, as members may fluctuate (e.g., due to personal circumstances or interests).

3.2: Conducting

In this section, the principles, procedures, methods, roles, and responsibilities regarding the co-creation process will be defined (*principle 4*). Also, the aims and agenda of the co-creation sessions will be summarized. In addition, measures will be defined to enhance the manifestation of psychological ownership (i.e., the feeling that something is yours; *principle 3*), which may enhance creativity and commitment among co-creators.

Within the RECONECTED-project, approximately **six to ten** co-creation sessions with each local target population will take place within one year (May 2024 to May 2025), with an approximate bimonthly workshop frequency. The sessions will typically be conducted as 90-minute workshops including a short break. The workshop duration may be extended by consortium partners to 120 minutes, depending on the needs of the specific group (e.g., elderly, immigrants). The workshops will generally be held in-person. An online workshop format is considered less favourable but may be used if needed. Workshop dates will be announced in a timely manner (preferably at least 1-2 months in advance) and a subsample of co-creators may be invited to each workshop, depending on the aim. Workshops will be prepared, moderated, and documented by a research team member, guided by the present participatory research protocol. PowerPoint slides and supporting materials will be provided in print version at the beginning of each workshop. A digital version of all materials will also be made permanently accessible to co-creators (e.g. using a file hosting/cloud service). Co-creators will receive an adequate incentive for their time. The specific amount may vary between countries and characteristics of co-creators and will be determined locally by each consortium partner. In Germany, for example, adolescent students will receive a total of 50 euro per workshop, while professionals/public sector employees (e.g., teachers, social workers) will receive a total of 100 euro per workshop. Informed consent regarding the terms and conditions of the co-creation process will be obtained from co-creators verbally or in written form. If co-creators are minors, written informed consent will additionally be obtained from parents/guardians.

All co-creation workshops will be conducted according to the following structure: **Before** each workshop, a workshop schedule will be prepared by research team members (guided by the present participatory research protocol) including the aims, contents, and methods of the workshop. Generally, all workshops will be supported by a visual presentation (e.g., PowerPoint presentation), created by research team members. All co-creators will receive a short reminder approximately one week before the workshop including a short preparatory notice regarding the aim and content. **At the beginning** of each workshop, if applicable, the main findings from the previous meeting will be briefly summarized (e.g., a short report will be presented including amendments made in response to the co-creators feedback). Also, the aims and schedule for the current meeting will be outlined. In the **main part** of the workshop, co-creators and researchers will work together with researchers on a predefined task in accordance with the aims of the meeting. Typically, there will be a theoretical introduction to the topic of the meeting (e.g., social prescribing, mental health literacy, psychological interventions) prepared by researchers to up-skill co-creators and to provide fundamental information in order to complete the task of the meeting. **At the end** of a workshop, a documentation form will be completed by researchers including the content, and results of the workshop. Furthermore, all co-creators will complete a brief anonymous evaluation form including satisfaction with the meeting, the work atmosphere, and the level of participation. There will always be some flexibility with regard to the agenda, especially in case of questions, need for clarification, or other urgent group-related matters. In case of insufficient time to complete a certain task, a solution will be discussed between researchers and stakeholders (e.g., postponing a certain topic, providing information at another time, extending the meeting, etc.). An additional meeting to continue or resume a certain task may also be scheduled, if needed. In case of individual needs, there will be a contact person for concerns or requests of group members.

The aims and agenda of the co-creation sessions will be defined in advance. As co-creation is an iterative process, the aims and agenda of the individual co-creation sessions may be subjected to change throughout the co-creation process. The overall aim of the co-creation process is to co-develop a digital support platform including intervention components on mental health literacy, social prescribing, and psychological micro-interventions which fit the needs and the daily life of different vulnerable populations. Therefore, generic evidence-based psychological content will be selected and/or created by researchers based on reviews of the scientific literature and input/feedback from co-creators. A major task of the co-creation process will be to adapt/tailor the generic intervention content to fit the needs and everyday life of the target population and to make it appealing and easily-consumable (e.g., choosing examples, use of graphics/illustrations, selection of format, etc.) At the beginning of the co-creation process, the following aims are considered fundamental: Welcome and introduction, overview of the RECONNECTED-project, overview of terms and conditions of the co-creation process, and providing informed consent to the terms and conditions. Throughout the co-creation process, the following aims will be pursued: 1) validation and enrichment of the conceptual framework of the RECONNECTED-project, 2) generating

ideas for contents as well as enrichment and adaption of evidence-based contents provided by researchers on social prescribing, mental health literacy, and psychological micro-interventions, 3) co-design of the digital intervention tools with regard to format, appearance, and navigation (i.e., overall user-friendliness), 4) validation of digital intervention tools by pilot testing the digital support platform. An overview of the preliminary aims and agenda per co-creation session is presented in Table 2.

With regard to activities and methods of the co-creation process, the RECONNECTED-project will mainly rely on consultative workshops with high-quality discussions, based on knowledge transfer between researchers and stakeholders. While researchers will provide co-creators with scientific and psychological knowledge in order to make well-informed decisions, co-creators will provide researchers with their lived experiences and opinions in order to inform the intervention development. Researchers will moderate group discussions using common conversation techniques (e.g., asking open questions, active listening, summarizing information, redirecting to another topic, etc.). Possible methods that will be used are brainstorming sessions (compiling ideas as a group), developing scenarios (identifying needs of end-users in different contexts), and prototyping (pilot testing of the intervention tool). In addition, supportive software (e.g., Power Point, Mentimeter) will be used to enhance knowledge exchange by creating interactive presentations including feedbacks, votings, and brainstorming.

The following roles and responsibilities of co-creators and researchers were defined within the co-creation process of the RECONNECTED-project. Co-creators will contribute their ideas, knowledge, preferences, and experiences in accordance with the aims and research questions. All contributions are considered equally important, co-creators need to share their knowledge and perspectives to create equality. Researchers will prepare, moderate, and document the stakeholder workshops; researchers will provide, prompt, and summarize content-related input in accordance with the aims and research questions. Researchers will also ensure adherence to the task objectives and the general rules of the co-creation process.

The following rules will apply to the co-creation process of the RECONNECTED-project: Group rules include being on time with regard to the start and end time of the workshop, active participation of all participants, respectful communication (e.g., no interrupting), equity of opinions (no hierarchies), tolerance for all opinions, and adherence to the agenda and aims as much as possible. Co-creators will also be informed that there are no right or wrong answers and encouraged to seek clarification if necessary. To ensure confidentiality, co-creators will be asked to keep confidential regarding research-related matters, which may not be communicated to third parties. Additionally, they will be asked to keep confidential regarding personal matters of group members (e.g., personal information or personal experiences). Finally, co-creators will be given the possibility to add rules themselves. All relevant procedures will be made transparent to co-creators. They will be outlined and discussed during the first workshops and repeated at later time points if necessary. Terms and conditions will also be provided in written form, for example

as a handout. Consortium partners may also choose to ask their co-creators to sign an informal contract including the terms and conditions.

With regard to decisional processes, the RECONNECTED-project aims for high decisional power of co-creators in order to achieve true "co-creation". A framework which outlines different levels of participation in patient and public involvement in public health care research is *The 9 Levels of Participation in Patient and Public Involvement* (Wright, 2010). These levels may help to ensure that the contribution of patients or citizens is appropriate and meaningful. The aim is to promote greater partnership and collaboration between researchers, patients, and the public, leading to more relevant and impactful research outcomes. In the RECONNECTED-project, co-creators shall have at least partly decisional power, meaning they have the right to participate in the decision-making process, while the decision-making authority is limited to certain aspects. If decisions need to be made, they will be based on consensus or a majority vote within the group of researchers and co-creators.

Within the RECONNECTED-project, the following measures will be taken to ensure buy-in, commitment, and retention of co-creators. Potential co-creators will be approached by researchers and provided with clear and comprehensive information regarding the project, the task, the conditions, and the timeline. Preferably, this information will be provided in the form of visually appealing materials (e.g., flyer, brochure). Importantly, co-creators will be offered an adequate (financial) compensation for their time, which may differ depending on legal and administrative regulations of the country or institution. Furthermore, it is considered crucial to establish a good work atmosphere during the co-creation workshops based on respect, tolerance, and transparency. Research team members will be role models and gate keepers within this regard. Researchers will also acknowledge the rights of co-creators to receive knowledge and information as well as the right to be trusted.

3.3: Evaluating (*principle 5a and b*)

In this section, it is described how effectiveness of the co-creation process *and* the digital support system will be determined in the nine vulnerable target populations.

As co-creation is an iterative process, the evaluation will be embedded throughout the process. After every co-creation workshop, a protocol will be completed by researchers, which includes the contents, methods, conclusions, and outcomes of the session. Also, any deviations from the original schedule will be noted including reasons. The validity of the outcome and the process will be guaranteed by continuously summarizing and reflecting on previous sessions. In addition, all co-creators will be asked to complete brief anonymous questionnaires to determine co-creator ownership and satisfaction with the process. Questions will include the following: "How comfortable did you feel at the meeting?", "How interesting did you find the meeting?", "To which extent were you able to contribute to the meeting?", "To which extent do you feel that your contributions were appreciated?", "How willing are you to participate in the next meeting?", "Please rate the work atmosphere of today's meeting!", and "Please rate the level of participation that

best characterizes today's meeting!". At the end of the co-creation process, co-creators will also be asked to indicate their level of satisfaction with the co-creation process and the degree to which the intervention is representative of their opinions. Moreover, retention and drop-out rates will be reported and analyzed to ascertain loyalty to the co-creation process, albeit bearing in mind the length of the process.

The evaluation of the effectiveness of the co-created intervention RECONNECTED digital support system will be through full factorial randomized optimization trials in the nine target populations. The aim of the trials is to examine whether micro-interventions to improve individual resilience (tool 1) and social prescribing to improve community participation (tool 2) add anything, either alone or in interaction, to mental health literacy education (tool 3) with respect to improvement in mental health. Detailed information on the trial design and the evaluation will be included in the factorial trial protocol. Alongside the trials we will conduct a process evaluation that will include assessments of participant satisfaction, acceptability, feasibility and usability of the digital support system

3.4: Reporting

In this section, it is described how the outcomes of the co-creation process and the digital support platform will be reported.

The co-creation process and its outcomes will be reported in an open-access research report to ensure transparency and replicability. The reporting of the intervention co-creation will be based on the reporting guidelines proposed by Leask and colleagues (2019). The report aims to further describe the co-creation process, examine differences between the original schedule and the actual implementation of sessions, and describe the outcomes of the co-creation process between consortium partners working with different vulnerable populations.

The outcomes of the multi-center randomized controlled trials evaluating the digital support platform will be published in international scientific journals. The reporting of the randomized controlled trial will be based on scientific reporting guidelines (e.g., CONSORT statement factorial trial extension). The process evaluations will be included in the outcome paper or will be published in a separate paper.

Table 1 Overview of aims and agenda per co-creation session

Co-creation session	Aims	Agenda
1	Welcome and introduction to team Overview of project Overview of terms and conditions Informed consent Validation and enrichment of conceptual framework	Welcome and introduction round Presentation of RECONNECTED-project according du PRODUCES method Presentation of organisational matters and procedures Obtaining verbal or written consent from co-creators Brainstorming to obtain co-creators ideas regarding variables in conceptual framework (e.g., risk and protective factors, mental health variables, societal challenges)
2	Summary of last session (feedback) Knowledge exchange and content development regarding the intervention component "social prescribing"	Presentation of conceptual framework including amendments by co-creators Up-skilling of co-creators regarding the role of social participation in mental health Brainstorming or other interactive method to generate ideas regarding • social activities relevant for target group • unmet social needs and reasons for not meeting these needs • identification of obstacles/barriers for social participation and ideas to overcome them • enhancement of motivation for social activities • information of social activities in local community and finding other social activities
3	Summary of last session (feedback) Knowledge exchange and content development regarding the intervention component "mental health literacy"	Summary of session on "social prescribing" Presentation of generic intervention approach regarding mental health literacy Adaptation of generic intervention to needs, preferences and daily lives of target group using brainstorming or other interactive methods
4	Summary of last session (feedback) Knowledge exchange and content development regarding the intervention component "psychological micro-interventions"	Summary of session on "mental health literacy" Presentation of generic intervention approach regarding micro-interventions Adaptation of generic intervention to needs, preferences and daily lives of target group using brainstorming or other interactive methods
5	Summary of last session (feedback) Presentation of intervention prototype Pilot testing prototype	Summary of session on "psychological micro-interventions" Presentation of full intervention prototype created from three key components Brainstorming or other interactive method to generate feedback on intervention prototype Preparations for pilot testing of intervention prototype
6	Summary of last session (feedback) Discussion of prototype (final refinement) Feedback regarding co-creation process Closing	Summary of session on the intervention prototype Guided group discussion or other interactive method regarding results of pilot testing Feedback round on co-creation process Acknowledgements & fare-well

4. Discussion

The present participatory research protocol aimed to define the participatory research methodology in co-creating the digital support platform within the RECONNECTED-project. The protocol will ensure that the process of co-creation is systematic and reproducible. It may also be used by researchers or communities that want to adapt the digital support system or another intervention to a local context or population. The present protocol summarizes the key principles and recommendations of Leask and colleagues (2019) for participatory methodologies in the co-creation and evaluation of public health interventions and describes how these principles will be implemented within the co-creation process of the RECONNECTED-project.

5. References

Benevolenza, M, (2019). "The impact of climate change and natural disasters on vulnerable populations: A systematic review of literature." Journal of Human Behavior in the Social Environment 29.2 (2019): 266-281

Greenhalg T, Jackson C, Shaw S, Janamian T. (2026) Achieving research impact through co-creation in community-based health services: literature review and case study. Milbank Quarterly, 2016;94:392-429.

Hallingberg, B., Parker, K., Eriksson, C., Ng, K., Hamrik, Z., Kopcakova, J., ... & Badura, P. (2022). Joint Family Activities and Adolescent Health and Wellbeing: Further Considerations Following the War in Ukraine. Journal of Adolescent Health, 71(1), 132-133.

Kantamneni, N. (2020). The impact of the COVID-19 pandemic on marginalized populations in the United States: A research agenda. Journal of vocational behavior, 119, 103439.

International Collaboration for Participatory Health Research (ICPHR) (2013) Position Paper 1: What is Participatory Health Research? Version: Mai 2013. Berlin: International Collaboration for Participatory Health Research.

Leask, C.F. et al. (2019). Framework, principles and recommendations for utilizing participatory methodologies in the co-creation and evaluation of public health interventions. *Research Involvement and Engagement,* 5:2.

Wright, M.T., von Unger, H., Block, M. (2010). Partizipation der Zielgruppe in der Gesundheitsförderung und Prävention. *Partizipative Qualitätsentwicklung in der Gesundheitsförderung und Prävention,* 35-52.