VOICE

PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT WITH PEOPLE AT ULTRA-HIGH RISK FOR PSYCHOSIS (UHR)

A „How to“ Guide for Researchers

PREFACE TO THIS GUIDE

As a researcher by experience from the "VOICE" project, a study that focused on gaining new perspectives on the condition of "ultra-high risk for psychosis", I want to share some insights about patient involvement in the project, taking into account the learnings and observations of my fellow researchers by experience. By doing so I hope to demonstrate the importance of PPIE research projects given that they take place in the right conditions.

Before the project started, we were patients or former patients of an early psychosis unit. The involvement in "VOICE" not only provided us with new information and perspectives on our shared condition but also allowed us to reposition ourselves entirely in the structures of thinking and talking about mental health. Beyond the role of patients, often so firmly constructed that most people fail to view it as a role, we assumed the position of researchers by experience, as which we were encouraged to see eye to eye with health care professionals, when discussing a topic that connected and separated us at the same time. The connection being that "ultra-high risk for psychosis" is a field that undoubtedly has an importance for all of us, the separation that some of us have been affected by it personally while others treat the subject (in both senses of the term) in a professional/academic context. The aim was not to eliminate these differences, as would have been impossible, but to profit from them through tearing down traditional structures of communication between these two groups, which implied having to search for and define new ways of interacting.

Corresponding to our level of involvement we joined the study at different stages. What we all shared beforehand, besides similar experiences, was a sense of nervousness about what was to come. We were not sure what would await us in such a setting, since this was for all of us, our first time being involved in a PPIE research project. It was therefore crucial to take enough time to collaborate on setting up clear conditions for interaction (such as respecting others' experiences and opinions and instating ways of barrier free communication), that would put to action the principles of the project ideals. This is fundamental, since giving a patient the name of "researcher by experience" alone, will not have a great impact on their involvement if the research conditions do not reflect this name, thus, not allowing it to become a real role.

As "VOICE" proceeded, the group dynamic within the core team and the study advisory group jointly developed in a very favorable way, laying the foundation for a productive climate to engage in, that was perceived by researchers by experience and health care professionals alike. Respectful communication and showing appreciation for the others' point of view was key in this development. In alignment with the overall search for new perspectives, many researchers by experience also reported being interested in gaining a more profound understanding about their condition from a scientific point of view.

This expectation was met by the individuals in the study group that represented academia. In turn, being able to share their personal journeys with the research subject with health professionals and among each other provided researchers by experience with a sense of empowerment and helped them to grow individually. Some even expressed viewing the study as an important part in the process of dealing with "ultra-high risk for psychosis". The possibility to connect and relate to other people that have made similar or diverging experiences with a shared phenomenon is a fundamental human need that is hindered when certain experiences become stigmatized or

even unspeakable. Projects like "VOICE" have the potential to create a safe environment for these experiences to be shared, allowing concerned individuals to connect with each other.

This research project was transformative for all of us, since its process was not only limited to finding new outlooks on the scientific status quo of a certain subject, but also entailed challenging the very structures in which such research takes place. Bearing this in mind, it is crucial for a scientific practice that considers itself democratic to not only strive to open new doors but also to consider the house, which these doors are part of and who might be excluded from having a say in it. Especially when it comes to mental health, research should avoid reproducing the isolation and power hierarchy that societies often inflict on individuals with psychiatric conditions or symptoms.

From a VOICE Co-Researcher with lived experience

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1 PUBLIC AND PATIENT INVOLVEMENT AND ENGAGEMENT (PPIE)

1.1. WHAT IS PPIE?

The importance of involving patients and other stakeholders in health-related research has grown worldwide (Coulter, 2011) and is a driver of innovation processes in the European research landscape (Mazzucato, 2018). It holds the potential to democratize research processes and introduce a shift of power and ownership towards citizens (Bonney, Phillips, Ballard, & Enck, 2016; Irwin, 1995), and generates new forms of impact (Gordon, Franklin, & Eltringham, 2018; Minogue, Boness, Brown, & Girdlestone, 2005). Involving patients in research activities and thereby learning from other experiences empowers individuals and impacts the quality of research (Staley, 2009). Studies showed that patients and the public are able to contribute to specific problems and find innovative solutions that make a difference to the individual affected. This leads to the commonly reported outcomes of involvement – improved study design, delivery, and dissemination – and over time, the wider impacts of a changed research culture and agenda (Staley, 2018),

Definition of PPIE

Patient and Public involvement and engagement (PPIE) involves citizens and patients actively and meaningfully in research processes – from generating the research question to disseminating results. According to the definition of the National Institute of Health Research (NIHR, 2023),

- 'user or public and patient involvement in research means doing research 'with' patients and the public so they are not just participants in the research.
- This requires users to have a say in the decisions made about research, so that the methods and outcomes are more appropriate to research participants and patients.'

Level of involvement

Citizens and patients can be involved in different research activities, at various stages and starting as early as possible in the process. Public involvement describes different ways of participation of citizens and patients in research (NIHR, 2023):

- **PARTICIPATION**
  Activities where citizens and patients take part in research studies (e.g., clinical trials and studies). Patients and citizens participate passively as study subjects providing data.
- **ENGAGEMENT**
  Activities where citizens and patients receive information and knowledge about research and dissemination. This one-way communication might include, e.g., the distribution of research results in newsletters and via (social) media, and engaging in science festivals and open campus.
- **INVOLVEMENT**
  Activities that actively involve citizens and patients in research undertakings as equal partners or co-researchers and in decision-making. This might include, e.g., the representation of patients in project steering boards and co-lead of projects, involving them in prioritizing research topics and generating research questions, co-creating content for data collection, interpreting results as well as involving them in the dissemination of results, e.g., co-presentation at conferences and co-authorship in publications.

Active involvement of patients in research may ultimately maximize learning opportunities, increase the likelihood of actual impact, and help to achieve the goal of improved services to the affected community. To avoid tokenistic involvement of patients in research, it is therefore crucial to first determine "why" and "who" should be involved in research (Staley, Elliott, Stewart, & Wilson, 2021), followed by what expertise is needed in the respective project, and in which phases meaningful involvement is needed. To support the implementation of research projects, several guides for researchers (Hayes, Buckland, & Tarpey, 2012; Kaisler & Missbach, 2019; Kaisler & Missbach, 2020) explain the principles of involvement and collaboration between researchers and patients as co-researchers. Therefore, Kaisler and Missbach (2019) distinguish between following levels of involvement:

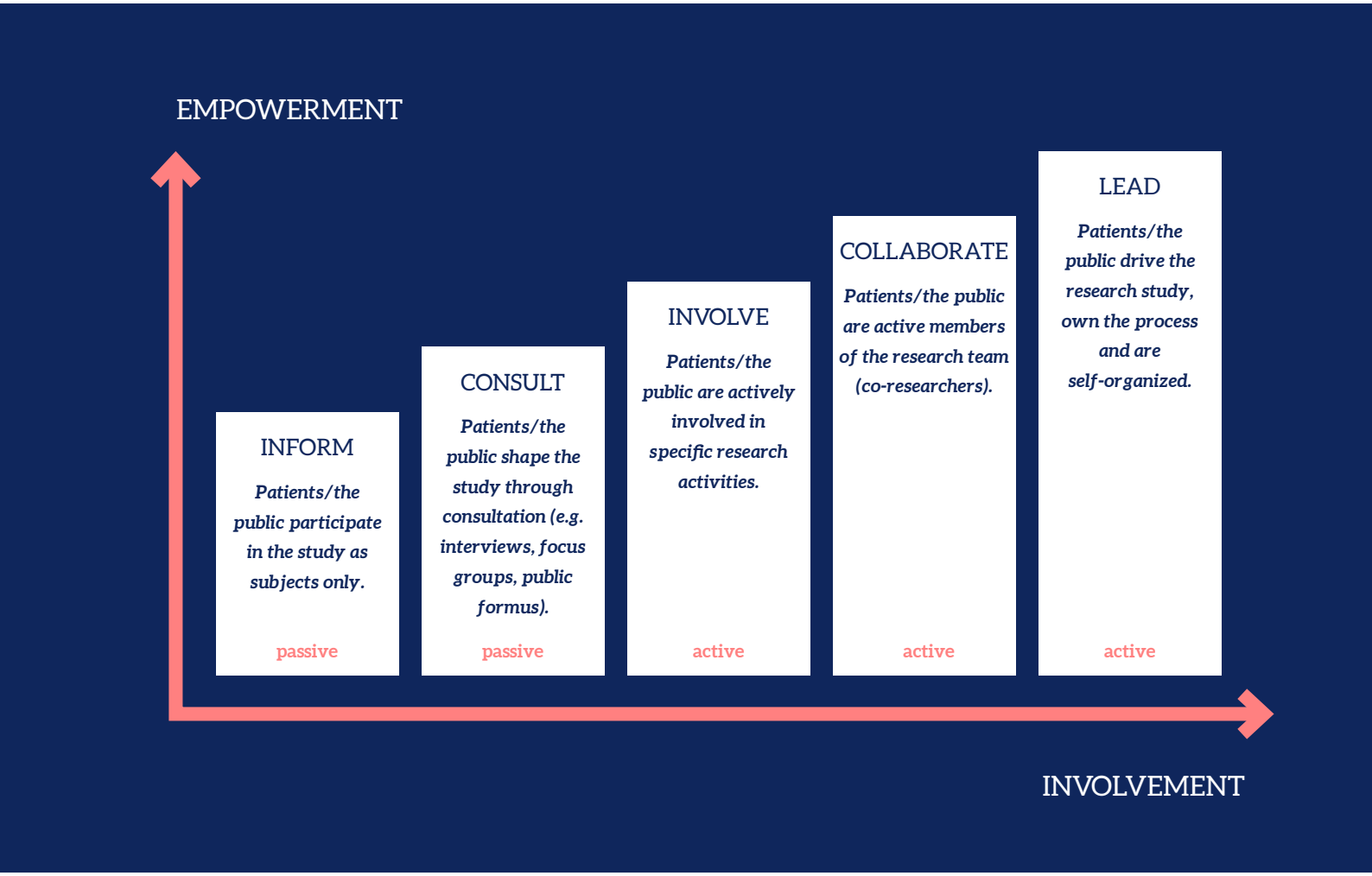

FIGURE 1: Levels of involvement.
Modified from Kaisler and Missbach (2019)

1. 2. PPIE IN MENTAL HEALTH

Involvement of individuals with lived experience into mental health research, also known as service user involvement, has started approximately 25 years ago (Wallcraft & Nettle, 2009): While some service users begun as individual researchers and became academics by making sense of their own lived experience (O'Hagan, 1993), others worked together in groups developing methods for participatory research and contributing together in participatory research surveys (Campbell, 1989; Prager & Tanaka, 1979; Smith & Ford, 1986; Tosh, Ralph, & Campbell, 2000).

Principles for service user research involvement are published in *The SURGE Guidance for Service user Involvement in the Mental Health Research Network* (Surge, 2005) and *The Ethics of Survivor Research* (Faulkner, 2004).

Service users involved in research are often referred to as "service user researchers", "experts by experience" "peer specialists" and "academic user researcher".

In this guide, we refer to them as "co-researchers with lived experiences" – a term which was agreed upon within the co-creation research group of our VOICE project.

Referring to previously published guidelines (Surge, 2005; Faulkner, 2004), the following principles are important in the context of service user involvement:

- CLARITY & TRANSPARENCY
- RESPECT
- FLEXIBILITY
- ACCESSIBILITY
- EMPOWERMENT
- A COMMITMENT TO CHANGE
- UNDERLYING THEORETICAL APPROACH
- ACCOUNTABILITY
- DIVERSITY
- EQUAL OPPORTUNITIES
- PROTECTION FROM HARM

1. 3. ABOUT THIS GUIDE

This 'How-to' Guide supports researchers and co-researchers with lived experience of ultra-high risk (UHR) for psychosis setting up participatory research projects that actively involve patients as co-researchers in their work. It supports readers to apply PPIE principles, especially, when working with individuals at UHR. It is intended to guide readers through each step of a research project, provides principles and considerations as well as checklists and specific recommendations of involving co-researchers with UHR-experience in research.

While publications on service user involvement in mental health research in general (Faulkner, 2004; Wallcraft, Schrank, & Amering, 2009) as well as participatory research with patients from specific target groups (Prebeg et al., 2023) already exist, to our best knowledge, no guideline exists for participatory research including co-researchers with lived co-researchers with UHR-experience" experience.

2 THE VOICE PROJECT

2. 1. THE CONCEPT OF "ULTRA-HIGH RISK FOR PSYCHOSIS" (UHR)

The concept of "ultra-high risk for psychosis" (UHR) aims to detect a risk for developing a later psychosis in help-seeking and symptomatic individuals at an early stage. Within the UHR-concept, distressing experiences below the threshold of manifest psychotic symptoms are defined as "attenuated psychotic symptoms" (APS) and "brief limited psychotic symptoms" (BLIPS) with respect to intensity or frequency criteria (Yung et al., 2003).

Besides treating specific symptoms and any associated difficulties in psychosocial functioning in affected individuals, reducing the duration of untreated psychosis in case of transition to manifest psychosis, as well as potential prevention of the latter and of further functional decline are essential aspects of early intervention in individuals at UHR.

2. 2. AIMS AND OBJECTIVES OF VOICE

The VOICE project aimed to create new perspectives on diagnosis, treatment and research concerning the condition of "ultra-high risk for psychosis" by including individuals with lived experiences as co-researchers. By reflecting on current evidence-based guidelines on detection and treatment, unmet needs were identified and new insights into this state gained. The aim of VOICE was to include co-researchers with lived UHR-experience during all steps of the project process from drafting the project proposal to the distribution of results, co-authoring papers and co-presenting our results at stakeholder and scientific conferences. By doing so, we wanted to empower co-researchers with lived experience through meaningful involvement and by leading the discussion, rather than being discussed about.

VOICE also aimed to impact the current scientific discourse by stimulating the research community, especially by giving a new impetus on "how to" actively involve individuals with lived UHR-experience as co-researchers.

Other important outcomes of VOICE were acquiring and sharing the perspectives and perceptions of co-researchers with lived experience concerning UHR-terminology and definitions, treatment and diagnostic procedures. With this, new streams of research and improvement of clinical procedures of clinical procedures concerning individuals at UHR were the objective of VOICE.

2. 3. THE CO-CREATION PROCESS OF VOICE

2. 3. 1. Before the project

Co-researchers with lived UHR-experience were recruited at the early psychosis outpatient clinic specialized in early recognition and treatment of psychosis risk states at the Clinical Division of Social Psychiatry, Medical University of Vienna. Co-researchers with lived UHR-experience (recent or lifetime) as defined per international criteria applied at the outpatient clinic and who were stable with respect to their current mental health status were included without any further specifications for in- or exclusion. Psychiatrists experienced in research and clinical work on psychosis risk from within and outside of the Clinical Division of Social Psychiatry were sought out for participation. Aiming for cooperation on a par from the start, the study proposal was co-authored by one co-researcher with lived UHR-experience as well as two psychiatrists specialized in the treatment of individuals at risk of developing a psychosis.

The VOICE Core Team (Project Steering Committee) for governance consisted of two co-researchers with UHR-experience and two psychiatrists experienced in research and clinical work on psychosis risk. While one co-researcher with lived experience was already involved in the ideation phase in co-writing the project's proposal, the second co-researcher of the Core Team was recruited after funding approval. The project was funded by the Ludwig Boltzmann Gesellschaft, Open Innovation in Science Center, PPIE Call 2021.

Further, the Study Advisory Group (SAG) was formed with a total of eight individuals including four individuals with lived UHR-experience and four psychiatrists experienced with clinical high-risk states for psychosis.

2. 3. 2. During the project

The process consisted of four Core Team meetings and four co-creative workshops. The workshops were designed by the supervising consultant together with Core Team members in an iterative and process-oriented manner. Therefore, the content was open-ended and followed the outcomes and discussion points of each workshop.

2. 3. 2. 1. Core Team meetings

A constituent meeting of the Core Team took place in May 2022 (Kick-Off). It aimed at getting to know each other and building trust among the Core Team members, discussion forms of collaboration within the team:

- anonymity, data protection, and informed consent
- communication structure and availability of team members
- documentation of workshops and briefing documents for workshops
- dates for team meetings

Further, the Core Team explored ideas of collaboration in the project (e.g., safety plan, no-gos, and the remuneration of co-researchers) as well as responsibilities and decision-making processes to be discussed with the SAG in the first workshop.

Monthly Core Team meetings took place in-person or online before and after each co-creation workshop to reflect the process and follow-up tasks discussed in the workshops.

2. 3. 2. 2. Co-creation workshops

Four full-day co-creation workshops, thereof three thematic workshops, took place between June and November 2022. A facilitator, who was familiar with PPIE principles, designed the workshops in coordination with the Core Team. The design of workshops incorporated the following elements:

- providing information in form of short inputs (20 minutes) to specific topics
- one-to-one or small group interactions between clinicians/researchers and co-researchers sharing experiences and fostering mutual learning
- co-creation of content to specific topics in small groups using methods such as the open space method, world café (group discussion), gallery walk
- and group discussions to reach consensus about certain topics.

The workshops always started with a report from the Core Team addressing updates and open topics. Participants were encouraged to document the discussion points in small groups on post-it's and flip charts. A second facilitator documented the workshops by summarizing the discussion points and output of each workshop and providing a photo protocol of all produced materials by the participants to the documentation.

Workshop 1:

ORIENTATION & COLLABORATION

The first co-creation workshop aimed at orienting the entire project group consisting of the Study Advisory Group and the Core Team and discussing forms of collaboration in the project. After initial introductions and getting-to-know each other, the Core Team presented their first considerations for possible collaboration within the group. The group discussed following topics:

- Confidentiality, anonymization and informed consent
- Decision-making, safety plan, communication structures
- Roles and tasks of the Core Team and the SAG

The second part of the workshop aimed at pointing out expertises and experiences of the group. Participants expressed their interest, experiences, motivation and engagement in the project, and expectations for the project. Further, the group discussed the vision of the project exploring added value and benefits for different stakeholder groups (e.g., clinicians, patients, family members, the general public) and defined the aims and output of the project. Last, they discussed ways to evaluate the workshops considering PPIE elements for evaluation.

Workshop 2:

PROJECT AIMS & DIAGNOSIS

The first part of the second workshop followed-up the discussion and open points from the first workshop. Participants prioritized project aims and outputs that should be generated within the project period displayed in an action plan:

- website and social media page
- VOICE logo
- jour fixe: regular meetings for persons with UHR-experience
- journal: individual reflexions of the process in a diary
- publications: scientific publications and a 'how to' guide for clinicians and researchers

The second part of the workshops addressed diagnostics of UHR in help-seeking individuals. First, the UHR concept was introduced in a brief presentation in order to foster further discussions and an exchange of personal experiences in small groups consisting of clinicians and co-researchers. Individuals shared highlights of small-group discussions with the whole group and framed general consideration for UHR diagnosis. Second, a brief presentation of diagnostic instruments used to assess for UHR criteria was given to open a discussion in small groups exploring thematic clusters and questions of the tool. Afterwards the groups shared their insights and the whole group agreed on important and missing topics in the diagnostic tool.

Workshop 3:

TERMINOLOGY

The third workshop aimed to explore terminology of psychosis risk-related terms and definitions. After a short input, participants first reflected own experiences and meaning of familiar terms (a list of terms used in psychiatric consultations was provided beforehand) individually and posted their insights on a grid:

- helpful and tolerable
- stressful but endurable
- not endurable and burdensome
- not endurable but helpful

The group agreed on terms positioned on the grid and marked terms that were perceived differently. This exercise supported the following task to co-create informational material (e.g., flyers) for help-seeking individuals with UHR using adequate wording and explanations of UHR conditions that can be used in psychiatric consultations at the clinics to explain and inform about UHR and its options.

Workshop 4:

TREATMENT & DEBRIEF

The fourth and last workshop addressed existing treatment options and recommendations for treatment of persons with UHR-experience. Starting with a short input, participants discussed their own experiences from the perspective of lived-experience and clinical practice in small groups and shared their discussion points with the whole group. Afterwards participants discussed topics where more research is needed from the following clusters:

- psychopharmacology
- symptoms
- digital applications for treatment
- psychoeducation

The second part of the workshop investigated data analysis of the diary reflections ('journal'). To familiarize participants with qualitative content analysis, the facilitator introduced the method in exercises, e.g., clustering clothes and song texts according to their similarities, differences, and overarching topics. After these introductory exercises, the participants analyzed the diaries' text in pairs of two and clustered the content in (sub-)categories. The group agreed on categories and subcategories creating a coding tree for further comparative analysis.

Last, the group discussed further steps and implementation of the project output outlined in the action plan. The debrief included individual reflections of the co-creative experience and journey and take home messages for researchers/clinicians and co-researchers.

2. 3. 2. 3. Evaluation of co-creation workshops

At the end of each workshop participants filled in a questionnaire assessing the collaboration between researchers and co-researchers and the event. The 'Participation check' questionnaire is freely available at https://ois.lbg.ac.at/ois-resources/tools/.

The Participation check assessed following closed-ended questions on a 5-point scale ('not at all satisfied' – 'very satisfied' or 'does not at all apply' – 'very much applies'):

Demographic data:

- age
- gender
- In what role did you participate today?
- In which organization do you perform this role?
- To which area would you assign your expertise?
- If you are participating as an academic researcher: Please indicate your current position.

Please provide an impression of the atmosphere of today's event. How did you experience the event?
(7-point semantic differential)

- boring – exciting
- unclear – clear
- meaningless – meaningful
- inefficient – efficient
- unpleasant – pleasant
- discouraging – motivating
- isolating – connecting
- useless – useful

How satisfied are you with the following aspects of today's event?
(5-point scale)

- Selection of participants
- Organization before the event (invitation, pre-communication, etc.)
- Comprehensibility of language
- Atmosphere/mood in the group

To what extent do the following statements apply to this event?
(5-point scale)

- The participants were easy to follow.
- I was able to influence the content and results of the event.
- I was able to influence the procedure and design of the event.
- Whenever I voiced an opinion, I was taken seriously.
- The atmosphere allowed for raising objections and voicing opposing opinions.
- My expectations towards the event were met.

What do you take away from this event?
(5-point scale)

- Interesting contacts
- Knowledge, know-how
- Ideas/inspiration for my day-to-day life
- Ideas/inspiration for my paid or voluntary work
- Other: (open-ended)

All in all, how satisfied are you with the event?
(5-point scale)

Please indicate to what extent the following statements about co-creation apply.
(5-point scale)

- The work in the co-creation workshop was solution-oriented.
- The co-creation workshop was well facilitated.
- Participation in the co-creation workshop helped me in my work.
- I enjoyed participating in the co-creation workshop.
- I will continue to use the results of the co-creation workshop.
- I will refer others to the co-creation workshop.

What else would you like to tell us? Any feedback or criticism is welcome!
(open-ended)

2. 3. 3. After the project

After the project, the project's outcomes and the project process were disseminated through communication activities (e.g., project homepage, social media accounts) and presented at scientific and non-scientific conferences (e.g., stakeholder conferences). We further make the project outcomes and the project process freely available via open repositories (Zenodo, Open Science Framework) and open access publication. The results and learnings from our research process continue to be embedded in ongoing clinical work and learnings shared in scientific lectures and seminars and internal training sessions. Findings will especially feed into our work at the Department of Psychiatry and Psychotherapy of the Medical University Vienna.

3 HOW TO SET UP A CO-CREATIVE PROJECT

with patients at UHR as co-researchers with lived experience?

Firstly, the recommendations given in this chapter and in chapter 4 were compiled within the participatory research process of our project VOICE together with co-researchers with lived UHR-experience. Further, previously published publications and guidelines on participatory research and service user involvement in mental health (Cooley & Lawrence, 2006; Faulkner, 2004; Involve, 2010; Prebeg et al., 2023; Wallcraft et al., 2009) were adapted for participatory research with co-researchers with lived UHR-experience:

3. 1. RECRUITMENT OF CO-RESEARCHERS WITH LIVED UHR-EXPERIENCE

- Define the target group of co-researchers with respect to current or past lived experience of a specific condition you want to include in your research project (e.g., only co-researchers with specific psychiatric diagnoses or only those with experiences of psychiatric hospitalization).
- Consider pros- and cons of recruiting in your own patient population versus patients treated elsewhere.
- Define in- and exclusion criteria for co-researchers with lived experience (e.g., being psychopathological stable and well enough for regular participation).
- Be aware of the stage of recovery or existing psychiatric symptoms co-researchers with lived UHR-experience might be in.
- Start recruitment of co-researchers from the conceptual stage of the project.
- Include a minimum of two co-researchers with lived experience already when writing the project proposal as well as for specific tasks within the project in case of absence or illness.
- Projects benefit from diversity (e.g., age, background, experience, gender etc.). Be aware when recruiting.

3. 2. ADMINISTRATIVE ISSUES: PAYMENT AND COMPENSATION OF CO-RESEARCHERS, FUNDING

Payment of co-researchers with lived experience involved in research is considered as good clinical practice (Cooley & Lawrence, 2006; Involve, 2010). Payment and financial compensation value their time, skills and knowledge and help to reduce potential power imbalances between professionals and co-researchers with lived experience. The amount of payment should be appropriate to the level of involvement and should not be tokenistic. Co-researchers can be employed on a full- or part-time basis, self-employed, appointed as consultants or on a work contract basis or can receive honoraria or vouchers. Payment depends on preferences of the co-researchers and external factors (e.g., conditions of the associated institution through which the project takes place).

- Clarify type and amount of compensation according to the type of involvement at the beginning of the project taking preferences of co-researchers and limitations through external factors into account.
- Inform co-researchers who receive state-support (due to unemployment, inability to work, etc.) or other financial benefits about potential effects on the latter through additional income with paid involvement. If necessary, support them in getting information to avoid any financial disadvantages or loss due to additional payment.

- Communicate with the financial department and human resources department of your institution about paid involvement of co-researchers with lived experience.
- Plan project budgeting and potential funding before the project starts.
- Besides adequate remuneration for co-researchers with lived experience, calculate budget for meeting venues, travel and conference costs, external supervision and publication fees.

3. 3. TASKS AND RESPONSIBILITIES

In research collaborations between professionals, such as clinicians, and co-researchers with lived experience, every project participant might contribute with different expertise and experience to the project.

Co-researchers with lived experience might specifically contribute to the project

- by sharing experiences concerning symptoms (e.g., UHR symptoms) and treatment
- by sharing the individual course of specific symptoms
- by sharing what helps and what hinders during treatment
- which clinical recommendations are subjectively helpful and which do not help at all
- by sharing one's own handling of distress and symptoms
- by sharing gaps identified in psychiatric treatment and research
- by helping to identify unmet needs for specific symptoms and disorders

Psychiatrists might specifically contribute to the project

- by sharing knowledge concerning psychiatric symptoms and disorders, diagnosis and treatment (e.g., concerning UHR states, psychotic disorders, early recognition of psychoses)
- by sharing experiences of clinical work with patients with different psychiatric symptoms/disorders
- by connecting medical institutions, co-researchers with lived experience and the public
- by contributing with their own experience of psychiatric symptoms/disorders

Concerning tasks and responsibilities during involvement of co-researchers with lived UHR-experience, the following recommendations are given:

- Clarify tasks and responsibilities for all researchers at the beginning of the project. Nevertheless, be flexible to adapt tasks and methods during the course of the project.
- Acknowledge lived experience as an expertise of highest value!
- Avoid restricting co-researchers with lived UHR-experience to one specific task or engagement. Again, be flexible for adapting existing plans.

3. 4. GOVERNANCE AND PROJECT OVERSIGHT

Implementation of successful research involvement of co-researchers with lived UHR-experience needs appropriate organizational structures.

To actively involve individuals with lived UHR-experience into participatory research, the following governance structures are given: Core Team, Study Advisory Group (SAG), and supervision.

3. 4. 1. CORE TEAM

- The Core Team (Project steering board) should include at least two co-researchers with lived UHR-experience.
- A balanced Core Team should include approximately the same number of co-researchers with lived UHR-experience and professionals/clinicians.
- Project-related decisions will be decided consensually.
- For every substantial decision within the Core Team, consensus has to be reached among all Core Team participants. All members should have the same decision-making rights.
- If disagreement evolves, a supervising consultant should be approached and asked for mediation. With this, equal distribution of power among the Core Team members should be guaranteed.
- The Core Team is responsible to ensure safety for any decline in psychiatric conditions via a dedicated safety plan prepared in a first kick-off meeting of co-researchers with lived experience.
- When problems arise during co-creation processes (e.g., safety issues, organizational problems, conflicts), these issues should be documented and addressed within Core Team meetings. After a consensual decision on the issue, the ones affected will be informed and decisions will be transparently communicated.
- The Core Team should determine time and type of communication and schedule meetings and dates (e.g., for workshops).
- The Core Team reflects on previous project processes (e.g., workshops), decides on consecutive agenda and monitors the project development.
- The Core Team members should communicate regularly on their agreed-upon way of communication (e.g., email, phone) and within project steering committee meetings (e.g., every second month).

3. 4. 2. STUDY ADVISORY GROUP (SAG)

- The Study Advisory Group (SAG) should be established before the project starts.
- A balanced research team of co-researchers with lived UHR-experience and professionals/ clinicians is recommended.
- The SAG and the Core Team members both participate and cooperate within the research process (e.g., participation in workshops, reflection, publication and presentation of results).
- The SAG gives advice to the Core Team on a regular basis.
- The SAG members can contribute to different tasks within the participatory process on an agreed-upon basis.

3. 4. 3. Supervision

- An external consultant/supervisor experienced with team building and, ideally, participatory research should be included for coaching, process reflection, workshop design and facilitation.

- General complaints related to the project process should be appointed to the external consultant.

3. 5. INTERACTIONS WITH CO-RESEARCHERS WITH LIVED EXPERIENCE

Interaction between co-researchers with lived experience and clinical experts is a key element in participatory research projects. Therefore, developing agreed-upon rules for interactions is important at an early stage during co-creative projects.

3. 5. 1. Collaboration between clinicians and co-researchers

Collaboration and active involvement of co-researchers with lived experience is possible within every step of the co-creation process from the very beginning of the process (e.g., co-writing the project proposal, project design and methods, data collection, co-writing publications, dissemination of results).

Secrecy and anonymization

In participatory research processes between co-researchers with lived UHR-experience and clinicians, certain rules on secrecy and anonymization must be agreed upon at the beginning of the project by all participants.

- A consent form for confidentiality, anonymization and informed consent should be signed by all project participants at the beginning of the project. Rules concerning confidentiality, anonymization and informed consent should be made clear for all participants.
- The rules of the general data protection regulation must be complied with by all project participants.
- No details concerning treatment of co-researchers with lived experience should be discussed during the co-creation process.
- Co-creation processes (e.g., workshops, meetings) are not intended as psychological treatment or supervision.
- Participants of the co-creation process decide for themselves which information is shared within the research team.
- The contents discussed in the co-creation process will not be passed on to third parties.
- Participants must consent to the publication of names in the event of a planned publication or congress participation.
- The option for an anonymous publication or publication within the framework of a consortium should be possible if a co-researcher with lived experience does not want to be named in a publication.

Do's and Don'ts for interaction and collaboration

- Decide within the research team in which form co-researchers with lived experience and clinicians prefer to be addressed during the co-creation process if relevant (e.g., to be on a first-name basis or to be addressed more formally)
- Determine rules for interaction within the research team and together conclude on "No Go's" during the participatory research process.
- Provide recommendations on general behavioral rules regarding communication and interaction (e.g., hearing others out during conversations, preserving boundaries of others and leading a respectful interaction with each other).
- Clarify in the beginning the importance of the work setting and also agree on other "No Go's" related to the collaboration process (e.g., participating under the influence of drugs, unreliability, lack of cancellation in case of absence).
- Provide learning activities for the research team (conferences, workshops, short presentations during workshops etc.) during the project process; tailor the learning activities to the interest of the co-investigators and be flexible!

Safety plan

When collaborating with co-researchers with psychiatric symptoms/psychiatric disorders, setting up a safety plan in case of a psychiatric deterioration or crisis is very important. For specific considerations on a safety plan in participatory research with co-researcher with lived UHR-experience see **4.1.1. Dealing with crisis: safety plan.**

Communication and decision-making processes

- Build a trustful, open and non-hierarchical basis for communication within the participatory research team (e.g., do not use academic jargon, do not use academic degrees in communication)
- If possible, do meet at a neutral place and do not wear a lab coat.
- Determine how decisions should be made within the research team (e.g., consensus) and if a right to veto should be given during the co-creation process.
- Decide on agreed upon rules for communication between personal meetings (e.g., emails, by phone).
- Stay in regular contact within the research team to make project updates visible for them. Make sure that there is enough information available on the topic for all researchers without piling them up with material.
- Don't forget to inform co-researchers about changes and adaptations based on their involvement and even more so, if independent from their involvement.

3. 5. 2. Roles and shared responsibilities

Roles in the project

- Determine agreed-upon roles and responsibilities of all participants at the beginning of the project for each step of the process. Nevertheless, be flexible on adapting the roles of co-researchers based on their own preferences, skills and capacities.
- Adapt roles and responsibilities with possible opt-in/opt-out options for different tasks.
- Allow movement of co-researchers with lived experience and clinicians between roles.
- Incorporate the feedback of co-researchers and, accordingly, adapt tasks and the level of involvement.

Shared responsibilities

- If possible, co-present results together with co-researchers with lived UHR-experience, e.g., at scientific, non-scientific and stakeholder conferences.
- Co-author funding applications, publications, folders with co-researchers with lived experience.
- Make the co-researchers' contribution clear for the public (e.g., as consortium on publications if individuals don't want to be named)

3. 5. 3. Expertise and expectations

- Clarify the expectations of co-researchers with lived UHR-experience and clinicians associated with the project (e.g., aims, project visions, personal expectations)
- Clarify which expertise is brought along by co-researchers on an individual level.
- Discuss individual levels of engagement depending on the time and resources of all participants.

3. 5. 4. Alignment of the project goals

Vision of the project

To successfully implement a participatory project involving multiple perspectives, all participants need to have a common vision of the project.

- Explore the added value and benefit for different stakeholder groups (e.g., patients, clinicians, family members, the general public).
- Map potential scientific and societal impact for these stakeholder groups.
- Derive project aims from potential impacts.
- Discuss potential output and outcome for different stakeholder groups.

Prioritization of project goals

Make sure that the project's goals and expected output align with co-researchers expectations and possible contributions in the beginning of the project. These contributions may vary in the course of the project depending on the time and resources of co-researchers.

- Prioritize aims of the projects (e.g., until the end of the project, for follow-up projects).
- Build a ranking list of activities according to interests and project goals.
- Agree on an action plan for activities: **who** is doing **what** until **when**.
- Discuss if support is needed to fulfill the task(s).

Project evaluation

The project evaluation is necessary to assess the quality of the project and level of involvement of co-researchers. Quality assessment should involve at least two dimensions: the assessment of PPIE activities and project outcomes.

- Discuss how the team will know whether the project goals are achieved by
  - defining concrete goals and milestones,
  - define concrete tasks for project members,
  - reflecting the status of outputs in between and at the end of the project.
- Investigate how these goals can be assessed with quantitative and qualitative measures (e.g., questionnaire, interviews, focus groups etc.) or other innovative methods.

The assessment of PPIE activities should measure

- impressions of the collaborative atmosphere (e.g., inspiration, motivation, usefulness, excitement, efficiency),
- satisfaction with the activity (e.g., organization, selection of participants, comprehensibility of language, atmosphere/mood in the group),
- the overall satisfaction of the collaboration between academic researchers/ clinicians and co-researchers,
- takeaways from the activity (mutual learning), and
- the level of co-creation of the activity (e.g., influence of the content and design, being heard by others, being able to decide, meet expectations).

4 RECOMMENDATIONS AND CHECKLISTS OF PPIE ACTIVITIES IN UHR

4. 1. SPECIFIC CONSIDERATIONS FOR PPIE ACTIVITIES WITH CO-RESEARCHERS WITH LIVED UHR-EXPERIENCE

4. 1. 1. Dealing with crisis: safety plan

Setting up an appropriate safety plan at the beginning of the project process is highly important when working with co-researchers with UHR-experience with and without other psychiatric comorbidities. In general, all measures must be taken to create a secure and trusting basis for cooperation for all involved researchers during all stages of the process. Co-researchers with lived UHR-experience have an increased risk for developing a manifest psychosis. Individuals at UHR may experience unusual thought content or perceptions that are not perceived by others. Communication problems can result in difficulties in social contexts. Thus, clinical experts (psychiatrists, psychologists) with expertise in UHR states should be included in participatory research projects involving individuals with lived UHR-experience and co-creation processes should be individually based on patients' needs. The clinical awareness should be on any deterioration of pre-existing UHR symptoms such as non-bizarre and bizarre ideas or perceptual abnormalities, changes of speech or a decline in functioning as well as manifest psychotic symptoms such as hallucinations.

- For any psychiatric deterioration or acute crisis during the project process (e.g., during workshops), a clinician experienced with UHR symptoms and psychotic disorders should be present and in charge to take care in case of distress.
- The clinician in charge should be announced at the beginning of the project process and accountability should be made known to every project participant.
- During the project period, a minimum of two co-researchers experienced with UHR symptoms and psychotic disorders should be responsible for psychiatric deteriorations IN CO-RESEARCHERS during the project period – also beyond project activities. This does not mean that they should take over the treatment of involved co-researchers in general, but they are designated as first persons of contact in case of crisis for support and further help.
- Tools for behavioral coping skills in case of distress or deterioration can be helpful for some individuals with UHR or other symptoms during the process (e.g., hedgehog ball). These tools should be made freely available for all participants during the process.

4. 1. 2. Ethical aspects

Research ethics committees are responsible that research participants are not harmed within research projects ("non-maleficence") and that research is for the common good ("beneficence") according to the Declaration of Helsinki (World Medical Association, 2001). Research ethics committees are also in charge of providing independent information to researchers, participants and funders and to inform if research proposals comply with ethical research standards. Depending on local conditions, research ethics committees will be more or less experienced and familiar with participatory research with involvement of co-researchers with lived experience.

- Since "user or public and patient involvement in research means doing research with patients and the public" (NIHR, 2023), involved co-researchers are not "just" subject of research, but actively involved collaborators within the project. Thus, some PPIE projects might not be considered medical research on individuals in the common sense by research ethics committees. Inform yourself before the project starts, whether this is the case for your project. Principal investigators are responsible for ensuring compliance with local ethics regulation.

- Be aware of time schedules of local ethics committees and plan submissions of proposals accordingly in order to avoid possible delays.

4. 1. 3. Non-disclosure agreement and data protection

Informed consent and confidentiality are of highest importance in research in general and moreover in collaboration with co-researchers with lived experience. Involvement of co-researchers with lived UHR-experience means that some co-researchers will share very personal, potentially distressing and intimate life experiences, the protection of which must be of highest priority.

- Informed consent and a confidentiality declaration concerning the project should be given in written form by all research participants at the beginning of the project.

- All research participants should be informed about different aspects of confidentiality and anonymity (e.g., being named in publications) and must have the opportunity to declare their consent to different aspects independently (e.g., being named in a publication, but not being shown on pictures in the internet).

- Provide clear written and verbal information about your project.

- Anonymity must be maintained during the whole project process regarding all public outcomes of the processes (e.g., quotations used in publications or on a webpage).

- Discuss within your research team how withdrawal from the project by a research participant should be handled.

- Declare who will have access to the research material and data and where it will be kept.

4. 2. CHECKLISTS FOR PPIE ACTIVITIES WITH CO-RESEARCHERS WITH LIVED UHR-EXPERIENCE

4. 2. 1. BEFORE THE PROJECT

- ✓ Calculate the budget for the project and inform yourself about possibilities for funding/grants.
- ✓ Inform yourself if a submission of your project proposal is necessary at the local ethics committee. If yes, set necessary steps for submission.
- ✓ Start inclusion of co-researchers with lived experience already when writing the project proposal.
- ✓ Define criteria for in- and exclusion for co-researchers with lived experience.
- ✓ Recruit a Core Team and a Study Advisory Group according to in- and exclusion criteria.
- ✓ Clarify the structures for remunerating co-researchers with lived experience.
- ✓ Communicate in advance with the financial department and the Human Resources department of your organization (e.g., concerning possibilities for payment/honoraria of co-researchers, contract of work, etc.).
- ✓ Get informed consent and a confidentiality declaration in written form by all research participants.
- ✓ Develop a clear job description with clarification of the roles of all participants of the Core Team and of the Study Advisory Group.
- ✓ Agree upon clear information about role-related tasks and responsibilities.

4. 2. 2. DURING THE PROJECT

- Build trustful and honest relationships to set up a trustworthy collaboration that overcomes hierarchical boundaries and allows an eye-to-eye collaboration.
- Co-create the project proposal and set up a safety plan with the Core Team.
- Develop a time schedule and a plan for evaluation of your project activities.
- Assign a PPIE-experienced supervisor and/or mentor for the project. Schedule regular meetings with the Core Team and the Study Advisory Group (depending on project activities: workshops, etc.).
- Inform the whole research team on agreed-upon rules for safety, communication and behavior, secrecy and anonymization.
- Provide appropriate payment or remuneration for the involved co-researchers.
- Provide training or mentoring, if necessary.
- Consult and communicate with co-researchers about priorities for research and action plans (e.g., raising awareness).
- Further co-design and co-create the project process.
- Co-develop the further project vision and project and action goals.
- Co-write publications and co-present the results and the project on scientific and non-scientific conferences.
- Monitor the project regularly (e.g., assessment of PPIE activities; monitoring of the budget, research goals and action plans).

4. 2. 3. AFTER THE PROJECT

- Disseminate research outcomes together with co-researchers with lived experience.
- Co-present the project and results at scientific and non-scientific conferences and other events (e.g., stakeholder events).
- Co-design future research projects and co-write funding applications.
- Ensure that co-researchers are informed about project outcomes and publications.
- Mark the ending of a project (e.g., with a final meeting) and reflect on the learnings gained within collaboration.

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