




Enriching a randomized controlled treatment trial for anorexia nervosa by lived experience—Chances and effects of a lived experience council in the SUSTAIN study

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Abstract

Background: The development and advancement of treatment and care options is one priority in the field of eating disorders. The inclusion of persons with lived experience with eating disorders into clinical research could enrich and accelerate this endeavor, as they can add different perspectives on the disease and its treatment. Although lived experience perspectives are increasingly part of eating disorder research, they have not been widely or structurally implemented into clinical trials and there is limited information on the practice of participatory research, its framework and consequences.

Aims: The present work outlines the participatory collaboration with a lived experience council in the randomized controlled treatment trial SUSTAIN.

Materials & Methods: The manuscript is a participatory publication co-written by individuals with lived experience with anorexia nervosa and eating disorder researchers.

Results: We report on motivations for this approach, our collaboration principles, structures and shared experience of working together in the trial, the potential burdens and benefits related to participation for people with lived experience.

Discussion: We outline future directions and perspectives to integrate a participatory framework into clinical eating disorder research.

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Conclusion: The involvement of people with experiential knowledge is complex, but possible in clinical research on ED and bears huge potential for the development of more effective care.

Public Significance: Incorporating perspectives of people with lived experience into a participatory framework of mental health research bears huge potential on a societal level. This includes more relevant research topics and designs, more tailored and effective interventions, and facilitated implementation, as well as dissemination, higher credibility, destigmatization of mental illness, and patient empowerment. Participatory clinical research, however, needs structural anchorage within science and society.

KEYWORDS

anorexia nervosa, clinical trial, eating disorder, lived experience, participatory health research, patient and public involvement

1 | INTRODUCTION

Anorexia nervosa (AN) has a profound impact on the physical and mental well-being of patients (Button & Warren, 2001) and their families (Sibeoni et al., 2017; Whitney et al., 2005). Meanwhile, recent systematic reviews and meta-analyses show that treatment options for AN are limited (Monteleone et al., 2022; Solmi et al., 2021). Psychotherapy is the treatment of choice for AN. For younger patients, family-based treatment is recommended, whereas in adults, none of the most commonly recommended psychotherapies have shown superiority (Zipfel et al., 2015). High treatment discontinuation and relapse rates are challenges in the treatment of AN (Berends et al., 2018; Giel et al., 2021; Khalsa et al., 2017), which may in part reflect the treatment ambivalence often seen in patients with AN (Zipfel et al., 2015).

There is, therefore, an urgent need to develop, improve, and test effective interventions for patients with AN (Brockmeyer et al., 2018; Monteleone et al., 2022; Solmi et al., 2021; Zipfel et al., 2015). This may require research projects with an innovative approach. One aspect potentially contributing to enriching the development of treatment and care options, and to increasing treatment motivation in AN, could be a stronger inclusion of the perspectives of persons affected by eating disorders (ED) in clinical research. People with lived experience have different perspectives on the disease and its treatment than researchers, which could significantly influence the development of interventions, particularly in terms of how best to meet patient needs, how to tailor treatments to specific patient characteristics or disease stages, or how to better integrate different levels of care. The inclusion of persons with lived experience could also facilitate the implementation of clinical research into standardized care. A review of mental health intervention studies conducted by the United Kingdom Mental Health Research Network in 2013 shows that studies which included lived experience perspectives were more successful in meeting their recruitment targets, than those which did not (Ennis & Wykes, 2013).

1.1 | Participatory health research (PHR)/patient and public involvement (PPI)

Research projects with participatory elements are becoming increasingly important in research and society. They are conceptually anchored in the “citizen participation,” “citizen science,” and “action research” movements (Adelman, 1993; Hecker et al., 2018). In citizen science projects, citizens actively contribute to the research process and the generation of scientific knowledge (Hecker et al., 2018). Citizen science is characterized by a social component and thus exhibits transdisciplinary characteristics (Senabre Hidalgo et al., 2021). A central characteristic of transdisciplinary research is its application, orientation and social relevance. Citizen science projects, therefore, hold great potential for research with societal impact (e.g., von Gönner et al., 2023). Different concepts have been developed in the various research disciplines to describe this process. In medical and health research, for example, the terms PPI and PHR are commonly utilized.

PPI refers to the participation of members of the public in the research process and means that research is conducted with members of the public, not just “to,” “about,” or “for” them (Bagley et al., 2016). PartNet, the authoritative network for PHR in German-speaking countries, defines PHR as follows: “Participatory health research (PHR) is a scientific approach that understands the conduct of research as a co-production of different actors. In the entire research process, the aim is to achieve maximum participation of the people whose areas of life are being researched (...). The goal of PHR is to gain new insights and initiate changes that contribute to the promotion of people's health and well-being and to strengthen health equity” (Netzwerk Partizipative Gesundheitsforschung, 2023). Two methodological key aspects can be identified in PHR: (a) Community research, in which options for action to improve the situation of people or communities are developed, and (b) practice-based research, wherein laypersons undertake actions themselves to improve their own situation. The participatory and patient-centered approach has also gained importance in clinical research, where PPI is increasingly

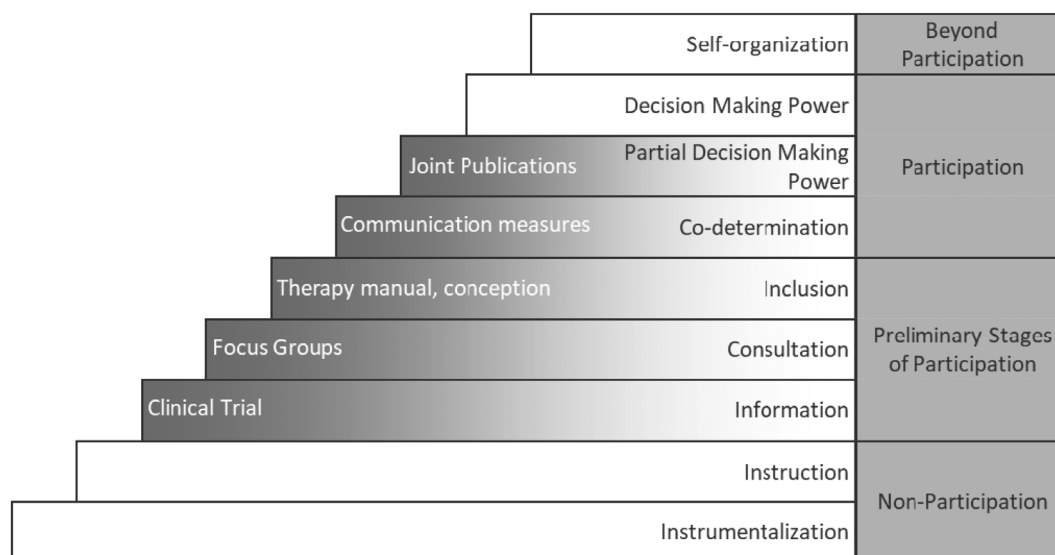


FIGURE 1 Classification of the various elements of the SUSTAIN Study (7) (gray) into the nine-stage Participation Model proposed by Wright, 2010 (19). *Instrumentalization*—involvement of people in research without consideration of putative negative effects; *Instruction*—obligation of people involved in research to act according to expectations of the research team; *Information*—detailed information of people involved in research about background, aims and procedures of the research project; *Consultation*—exchange with people involved in or affected by the research topic (e.g., self-help representatives); *Inclusion*—structured and formal dialogue process with people involved in or affected by the research topic; *Co-determination*—formal cooperation with people involved in or affected by the research topic who have direct influence on research (e.g., formal cooperation between research team and self-help institution); *Partial decision-making power*—formal cooperation with people involved in or affected by the research topic who directly lead parts of the research process, for example, recruitment, data assessment or data analysis; *Decision-making power*—people involved in or affected by the research topic decide equally with the research team about all steps and processes involved in the research process; *Self-organization*—research is completely initiated and conducted by the people involved in or affected by the research topic.

required by government research funding agencies (Price et al., 2022). The type and intensity of participation in the different stages of the research process show a wide spectrum. Various models have been developed to minimize the risk of pseudo-participation, that is, “token” inclusion of lived experience individuals. The degree of an individual’s participation can be defined on the basis of the nine-stage model developed by Wright (see Figure 1 which also includes an adaptation of the model to the SUSTAIN trial) for health promotion and prevention (Wright, 2010) which differentiates instrumentalization and instruction as “non-participation,” information, consultation and inclusion as “preliminary stages of participation,” co-determination, partial and full decision-making power as “participation,” and self-organization as “beyond participation.”

1.2 | Lived experience and experiential knowledge

Participatory approaches such as PPI in medical/clinical research are motivated by increasing the legitimacy of such research projects, as well as their quality and social relevance through the use of specific knowledge and experiences that patients acquire as a result of their illness. The term “experiential knowledge” (Caron-Flinterman et al., 2005) reflects this specific perspective. In health contexts, it can refer to the lived experiences of individuals with their illness and corresponding therapy. Experiential knowledge arises when these experiences are consciously or

unconsciously transformed into personal insight (Caron-Flinterman et al., 2005). The experiences of carers further contribute to this knowledge resource. Ideally, experiential knowledge complements the expertise of researchers and provides new perspectives. As is the case with participatory approaches in general, most studies employing experiential knowledge are in relation to health care or prevention, however, few clinical studies report on integrating this approach. Experiential knowledge can be applied in different formats and at different levels. One such example is the analysis of qualitative interviews, for which there are several examples in AN research (e.g., Sibeoni et al., 2017). There are currently few quantitative studies in the field of ED which have explicitly included experiential knowledge.

1.3 | Research and practice gaps regarding the incorporation of experiential knowledge into clinical research

PPI is gaining importance in the field of mental health, additionally fostered by funding institutions which demand PPI in clinical research (Sangill et al., 2019). Implementation of PPI differs between countries and research systems: while the UK clinical research field has a PPI tradition, Germany has just started to establish PPI in mental health research (Dziobek et al., 2022; Giel et al., 2023). Similarly, in ED research, the inclusion of persons with lived experience is increasing.

For instance, there is a body of research on involving carers in ED research and treatment (Batchelor et al., 2022). However, there is little scientific exchange about the concrete practice of participatory research, its framework and its consequences. This gap has been specifically highlighted for the field of ED research (Musić et al., 2022). In a recent article published in *The Lancet*, individuals with lived experience with different mental health disorders highlighted an evidence gap, particularly regarding the impact of PPI engagement on people with lived experience (Richmond et al., 2023).

This paper aims to address this gap in research. It not only reports on the implementation of participatory aspects into clinical research in the ED field but is a participatory work in itself as it was co-created and co-written through a participatory process by a group of authors consisting of both individuals with lived experience with AN and ED researchers. As a practical example to illustrate an implementation approach, we report on our shared experience of working together as part of the randomized clinical effectiveness trial SUSTAIN (Giel et al., 2021). Within the SUSTAIN trial, a lived experience council (LEC) has been established consisting of persons affected by AN themselves or as family members. The LEC is part of the study over its entire duration.

We outline the work principles of the LEC and report on (a) motivation and expectations as well as (b) outcomes of the LEC work, including potential related benefits and burden, with a focus on LEC member perspectives. Finally, we discuss future directions and perspectives to integrate PPI in ED research.

2 | METHOD

2.1 | Recruitment of the lived experience council

The SUSTAIN research team undertook several activities from October 2019 to February 2020 to recruit participants for the newly established LEC. Advertisement material was distributed in various ways

throughout Germany, for example, to specialized counseling centers and clinics, as well as to former patients and their relatives. E-mails were also distributed via the mailing lists of the University of Tübingen and the Medical University Hospital Tübingen. The aim of the research team was to recruit a diverse group of LEC members from all over Germany with regard to age, gender, and in relation to AN, that is, to include both acutely ill persons and persons who have recovered, as well as different types of relatives (e.g., parents, siblings, or children of people with AN experience). Members of the LEC received compensation for their travel costs, however, no additional remunerations were provided.

2.2 | Composition of the lived experience council

Eighteen people initially expressed interest in joining the LEC. Of these, 15 people signed the declaration of consent for the LEC work. One person ended her participation due to time constraints, while two additional persons joined the LEC later, so 16 persons are currently participating. According to self-reports, five participants are currently affected by AN, four are previously affected persons, and seven are relatives (one daughter, five mothers, and one father).

Twelve members completed an online questionnaire on baseline characteristics at the beginning of the LEC work. Eleven board members are female. The average age is 43.8 years. Eight persons have a university degree. On a Visual Analogue Scale ranging from 1 to 100, AN currently plays a medium role ($M = 44.4$) in the lives of the LEC members.

2.3 | Structure and content of the lived experience council work

The SUSTAIN research team and the LEC are in continuous exchange, as seen in Figure 2. The research team reports regularly on the current

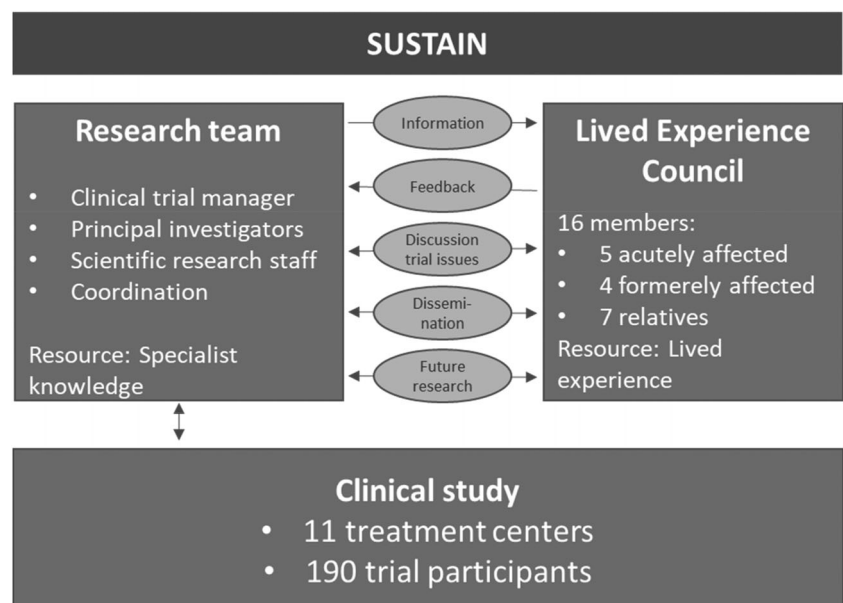


FIGURE 2 Schematic representation of the organizational structure of the SUSTAIN study, which is led by scientists in the “research team” and is guided by the Lived Experience Council on the basis of experiential knowledge.

TABLE 1 Involvement of LEC members in different stages of the SUSTAIN trial.

Stage of the SUSTAIN trial	Description of LEC involvement
Study design and funding acquisition	N/A (LEC not yet established)
Trial preparation	<ul style="list-style-type: none"> • Participation in study team trainings • Advice on patient-friendly wording of study materials • Perspectives on defining relapse and recovery • Feedback on content of treatment manual
Recruitment, data assessment and treatment	<ul style="list-style-type: none"> • Advice on improving recruitment rate • Support in communication to patients and the public, for example, by providing feedback on website content or participating in media communication
Data analysis	<ul style="list-style-type: none"> • Support in interpreting data and results • Advice on patient-friendly preparation of reporting • Co-creation of further research questions
Publication and dissemination of results	<ul style="list-style-type: none"> • Support in disseminating trial results with a focus on communication outside the science community/to people affected and their carers • Participation in publications

progress of the study, while the LEC provides feedback in the form of questions, suggestions and recommendations, for example, on the design of the therapy manual or increasing recruitment. Annual half-day (5 h) in-person meetings serve as a forum for intensive exchange and collaboration. The LEC members receive travel reimbursement. Shorter online meetings (1 h each) are held in between. The research team assesses preferences for timing and setting for meetings based on the evaluation of each in-person meeting and bypolls before each online meeting. Topics relevant to the current study, such as aftercare or digital psychotherapy, are discussed at these meetings in various formats including focus groups. Table 1 provides an overview on LEC member involvement and goals for LEC participation for each of the trial stages of SUSTAIN.

2.4 | Assessment methods investigating LEC processes

Initially, the members of the LEC were provided with information about the background of the SUSTAIN study and a detailed telephone interview was conducted with each LEC member by a member of the study team with the aim of getting to know each other and exchanging information about experiences with AN. The telephone interviews were semi-structured and based on an interview

schedule. In addition, a short online survey was conducted to collect sociodemographic data and the motivation of the LEC members for participation.

To date, three in-person LEC meetings have been held which were evaluated via questionnaire at the end of each meeting to assess satisfaction with the meeting location, content, methods, and the overall meeting on a visual analog scale of 0 (very dissatisfied) to 10 (very satisfied).

In order to analyze possible effects of the LEC work, an electronic census was conducted among all LEC members 2.5 years after the project started. For this purpose, a questionnaire was designed by a subgroup of LEC members and the study team. The questionnaire consisted of 14 questions and inquired about attitudes and perceptions of LEC work related to feelings, knowledge transfer, and social issues, as well as personal developments in the area of one's own AN or coping with the AN of relatives. LEC participants were asked to assess the effects of the LEC work on 4-point unipolar Likert scales (e.g., not at all—very strongly) or 5-point bipolar Likert scales (e.g., negative—neutral—positive). The assessment was anonymous.

2.5 | Ethical aspects

Research related to the LEC was approved by the Ethics Committee of the Medical Faculty of the Eberhard Karls University of Tübingen and the University Medical Hospital Tübingen, Germany (project number 127/2020BO2).

3 | RESULTS

3.1 | Motivation and expectations of lived experience council members

The motivation and expectations for participating in the LEC were diverse. Examples compiled from the telephone interviews and online survey (assessed at the very beginning of the project) are presented in Table 2.

During reflection for the present participatory writing project, one LEC member and co-author describes her motivation like this:

“My motivation to serve on the lived experience council for the SUSTAIN study is based on our experiences of our daughter's discharge from inpatient treatment. Our 15-year-old daughter was an inpatient in an adolescent psychiatric unit for four months and was fortunate enough to receive a day hospital placement for two more months. After six months of clinical treatment, she had achieved neither a normal weight nor self-responsible eating behavior (...). The structure of inpatient/day hospital care with its many therapeutic offers was followed

TABLE 2 Overview of the motivation for participation on the Lived Experience Council and the expectations of participation on the Lived Experience Council according to telephone interviews and online survey conducted at the inception of the Lived Experience Council.

	Motivation for participation in the lived experience council	Expectations for participation in the lived experience council
Personal interest/self-development	<ul style="list-style-type: none"> • General interest in participatory research and psychotherapy research 	<ul style="list-style-type: none"> • Networking with other affected persons and the study team
	<ul style="list-style-type: none"> • Finding a way to deal with own helplessness 	<ul style="list-style-type: none"> • Contribution of own ideas, thoughts and experiences • Learning more about research in the field of AN and its treatment • Confrontation with the disease • Benefiting from new treatment approaches
		<ul style="list-style-type: none"> • Being able to better understand and help those affected
Providing assistance	<ul style="list-style-type: none"> • Helping others—both those affected and their relatives • Being a role model to others by sharing personal experiences and providing hope 	
Improving the system/research	<ul style="list-style-type: none"> • Opportunity to influence the advancement of treatment and understanding of AN • Viewing the topic from different perspectives 	<ul style="list-style-type: none"> • Improving care for patients with AN • Thinking outside the box, providing food for thought
	<ul style="list-style-type: none"> • Educate society 	
	<ul style="list-style-type: none"> • SUSTAIN study concept very successful 	

by everyday life at home with one therapy session per week (...). She was given a place in a therapeutic residential housing after six months at home and had to be readmitted as an inpatient four months later due to severe weight loss.”

Another LEC member shares her experience and motivation like this during the writing process:

“When I heard about SUSTAIN, I immediately had the impulse to join the lived experience council. My primary motivation was to share my experiences (...) in the hope that these could aid both future research and patients. I felt the need to help and to give something back. Another motivation for joining (...) was to make a positive contribution to the current choice of therapies. (...) SUSTAIN is a step in the right direction towards better care for patients—especially therapies with sustainable and long-term effects. In addition, (...) I was looking forward to getting to know other (...) people affected by the disease. (...) I find it very beneficial that all members can contribute at any time and that the feeling arises that everyone can contribute something valuable through his/her experience and perspective. I find it very interesting to gain insights into current research, even though I have no professional contact with it myself.”

3.2 | Motivation and Expectations of the study team

The study team wished to establish a direct connection with persons affected by AN through the LEC and to receive direct feedback to ensure that the procedure and contents of the SUSTAIN Study are understandable and meaningful for patients. In addition, the LEC in combination with the SUSTAIN study allows the study team to have a direct positive impact on the treatment of and clinical practice around patients with AN, and to address the issues that are often perceived as difficult by affected individuals.

3.3 | Evaluation and feedback

A short questionnaire was distributed among participants of each of the three meetings held so far, so as to evaluate the meeting. Participants evaluated the meetings as very positive, with a mean value of 8.6 regarding overall satisfaction at the first meeting, 9.5 at the second meeting, and 9.6 at the third meeting.

3.4 | Effects of the lived experience council work

Table 3 provides an overview of the effects of the LEC work for its members, according to an anonymous survey. The frequencies of each item from the survey are presented as histograms in a supplementary file (Figures S1–S14). The results show that members personally

TABLE 3 Descriptive results regarding the impact of the Lived Experience Council on its members.

For me, the lived experience council means...	N	Min	Max	Mode	M	SD
1. Satisfaction–disappointment (1–5)	10	1	3	2	1.7	.68
2. Motivation–frustration (1–5)	10	1	2	1; 2	1.5	.53
3. Relief–burden (1–5)	10	2	4	3	3.2	.63
4. Pressure to perform: none–very much (1–4)	10	1	2	2	1.6	.52
5. Appreciation: very much–none (1–4)	10	1	3	2	2.0	.82
6. Influence: very much–none (1–4)	10	2	3	3	2.9	.32
7. Knowledge gain: very much–none (1–4)	10	1	4	2; 3	2.5	.84
8. Assumption of responsibilities: very much–none (1–4)	10	1	4	3	2.9	.99
9. Inclusion of personal experiences: very much–none (1–4)	10	1	3	3	2.4	.70
10. Making social connections: very much–none (1–4)	10	3	4	4	3.6	.52
11. Stigmatization: much stronger–much less (1–5)	10	2	5	3	3.6	1.1
12. Feelings of being at the mercy of the disease: much stronger–much less (1–5)	10	2	5	3	3.4	.84
13. For Affected persons: stabilization–Destabilization (1–5)	6	2	3	3	2.7	.52
14. For Relatives: Support of affected persons: much stronger–much less (1–5)	3	2	3	2	2.3	.58

affected by AN, as well as carers, are high to very highly motivated to participate in the LEC's work and believe the work of the LEC to be satisfactory. The workload and the pressure to perform are rated as neutral by all members, while feedback from those currently and formerly affected by AN shows a somewhat wider range. Members note the appreciation by the study team and rate the increase in knowledge and the inclusion of personal experiences as strong. They feel that they have “some” influence on the SUSTAIN study. The question whether LEC work improved the ability to take responsibility for one's own living environment triggered different feedbacks. While those affected by AN stated that they experienced very strong or strong improvements, carers mainly saw “some” improvements. Especially currently and formerly affected persons reported making increased social connections as a result of the LEC work. While most carers stated that the LEC work had not changed the perceived stigmatization of the disease, formerly affected persons reported “much less stigmatizing,” while one currently affected person felt that the stigmatization of the disease has increased since the time before the LEC. The members affected or formerly affected by AN did not report any destabilization as a result of the LEC work, in fact, two currently affected members even saw themselves somewhat stabilized by it. The question directed exclusively at carers as to whether they were better able to support affected persons as a result of the LEC work was answered by two persons with “somewhat better,” while one person saw no change.

Experienced benefits of the LEC work have been summarized by one member and co-author like this during the writing process:

“The benefit of being an advisory board member is being able to support research with my own experiences and thus make a positive contribution. It is interesting to see what topics are currently being

researched and how treatment offers are developing. At the same time, it is nice to come into contact with people who have had experiences with anorexia nervosa in various forms. This creates a sense of connection.”

The work of the LEC not only has an individual impact on the members of the LEC, but also on the SUSTAIN research team. From the perspective of the research team, the LEC makes a significant contribution to ensuring that the SUSTAIN study is directly related to the patients and their carers, that is, that research is not conducted “about” the patients, but “with” them. This helps enormously to not lose sight of the patients' well-being during research. In addition, by revising the study and therapy materials, LEC members helped to keep them comprehensible and relevant. Another point that deserves special emphasis is that numerous suggestions and ideas contributed by the LEC members pointed out criticisms and misunderstandings in the treatment of AN, thus contributing to the improvement of treatment and innovation of new research projects. For future phases of the project, when efficacy trial data are available, the results will be jointly interpreted, evaluated, communicated, and disseminated.

4 | DISCUSSION

This article outlines the participatory work of a LEC with the research team in a clinical trial on AN treatment. Particularly in German-speaking countries, participatory and collaborative research approaches are rarely applied in the field of mental health research, although PHR/PPI has a high democratic and emancipatory potential (Clar & Wright, 2020; Dziobek et al., 2022; von Peter et al., 2020;

Wright, 2021). Even internationally, the direct involvement of people with experiential knowledge does not seem to be widely established yet in the field of ED (Musić et al., 2022). The SUSTAIN trial includes perspectives of LEC members and the study team, and the goal of establishing a LEC for the SUSTAIN study was to incorporate experiential knowledge into clinical research.

Ideally, the LEC is a representative selection of the relevant stakeholder groups. For this reason, an attempt was made to create a diverse composition of members with regard to characteristics such as place of residence, gender, age, and so forth. The proportion of the three subgroups in the current LEC is roughly equal, with a slight preponderance of carers (40% vs. 30% each). However, selection bias could not be avoided. Representativeness is unlikely to be fully achieved in practice (Lander et al., 2019), but is a limitation and must be considered in analyses.

The LEC accompanies a clinical study with experiential knowledge. To classify the SUSTAIN approach into a participation model, the nine-stage model of Wright (2010) was used (Figure 1). Considering the purely clinical part of the SUSTAIN study with direct patient reference, level 3 (information), is clearly achieved, however, the ethical and legal framework of a strictly controlled clinical trial clearly limits the participation possibilities here. The elaboration of directly trial-related or further topics in focus groups can be assigned to level 4 (consultation). level 5 (involvement) was achieved in the elaboration of the therapy manual by members of the LEC. Onwards from level 6 of the participation model, direct and formal influence on the project is achieved. In the SUSTAIN project, this applies, for example, to the definition of communication measures of the study team and the LEC. In the case of joint publications, even level 7 (partial decision-making authority), is reached.

An analysis of participants' reported motivation for serving on the LEC shows predominantly intrinsic motivations. This seems to be a good prerequisite for a multi-year volunteer commitment (Phillips et al., 2019). In fact, the drop-out rate during the SUSTAIN study has been low. The different motivations can be clustered into three categories: personal interest and development, helping those affected, and improving the health care system/research. This is consistent with project analyses from applied health research (Tarpey, 2006).

The evaluation of the collaboration to date, particularly during the LEC meetings, was extremely positive. In particular, the atmosphere and the opportunity for discussion were emphasized. Suggestions for further topics of the LEC were an exchange with patients of the SUSTAIN study and increased public relations.

Participation projects in medicine have a special position in the research landscape: They do not investigate objects from nature and technology but focus on human beings and their experience with disease as the object of study. Laypersons involved are usually directly affected persons or their carers. Therefore, dealing with ethical aspects plays a special role so as to minimize impairment of the involved persons (Schaefer & Narimani, 2021), especially in ED research (Musić et al., 2022).

It is also worth taking a look at the perceptions and effects which the study has on the LEC members in order to identify positive

effects, but also putative risks, especially, of involving acutely ill individuals.

Our evaluation draws a positive picture of the LEC work overall, with no major adverse effects: Motivation, satisfaction and a feeling of appreciation predominate. Moderate strain and pressure to perform were indicated in particular by those (formerly) affected. A certain degree of stress is not surprising, since coming to terms with one's own illness requires personal resources. The perceived pressure to perform is also typical for patients with AN (Cassin & von Ranson, 2005). In any case, the work of the LEC did not destabilize the (formerly) affected persons. Through the work of the LEC, additional knowledge could be built upon, which, in addition to personal gain, is also important against the backdrop of the dialogue function of a participatory project. The fact that personal lived experience is included in the project was confirmed; at the same time, the desire for greater opportunities to exert influence became clear. Most participants felt that their self-efficacy was strengthened by the LEC work, that they were somewhat less at the mercy of others, and that the LEC work had a destigmatizing effect. This underscores the importance of such study formats with regard to the social problem of stigmatization of mental illness. In this regard, the results of our analysis are broadly consistent with recent reports from PPI mental health stakeholders from the UK that do not focus specifically on ED (Richmond et al., 2023). This analysis of perceptions and impacts certainly does not allow any general statements to be made on the basis of 10 data sets. However, it does indicate a tendency that does not appear to necessitate any countermeasures to impairments that arise but rather permits a continuation of the LEC work in this form or further development.

In order to minimize putative risks when involving currently ill and recovered individuals in ED research, ethical approval is important as well as an evaluation of LEC involvement effects. When starting LEC collaboration, it should be clarified how to give feedback on putative adverse experiences associated with LEC work and how to get help in this case. The research team should be ready and capable of offering help and support if a LEC member approaches them.

In accordance with the reported positive results regarding motivation, evaluation and effects of the LEC work by the participants, the study team of the SUSTAIN study also draws a very positive picture regarding the work. Thus, the motivation for the foundation of the LEC with regard to the support in the SUSTAIN study has been fully fulfilled and, in addition, impulses for further research projects and implementations in practice have resulted, so that currently even a continuation of the LEC beyond the SUSTAIN study and the transfer into a LEC for patients with AN is being considered.

Conceptual discussions outlined further communication measures on AN and treatment options and, for example, suggested the involvement of LEC members in a peer program in which (formerly) affected persons act as companions for patients just discharged from inpatient treatment to ease their transition from the clinic to everyday life (e.g., Pellizzer & Wade, 2023). One LEC member puts this idea as follows:

“An eating disorder is a very special illness that requires special support. In my opinion, there is a lack of ‘eye-to-eye’ support by people who have had such

experiences themselves and who have an understanding of the challenges after hospitalization and everyday life. The members of a lived experience council could work together with patients and clinics to design a program in which “peers” with relevant experience establish one-to-one contact with the respective patients during their stay in the clinic and then meet them regularly in everyday life, at least for a certain period of time. Of course, such mentors would have to be trained accordingly.”

4.1 | Summary and perspectives for future research

The SUSTAIN trial investigates a novel aftercare treatment for patients with AN, and it combines a randomized efficacy design with a participatory approach by establishing a LEC to incorporate experiential knowledge into clinical research. The present paper was established and written together in a participatory process by authors with lived experience with AN and ED researchers.

Reflecting on the SUSTAIN study in the context of participatory medical research reveals opportunities and potential, but also challenges involved on different levels (personal, structural, and societal). SUSTAIN not only investigates the efficacy of a new therapy but also aims to gather impulses for future research on a scientific level and to further develop the incorporation of lived experience on a conceptual level. The medium-term goal, in terms of increasing the level of participation, is that in subsequent projects the LEC will be involved even before the implementation phase and can contribute more experiential knowledge in defining the content and designing the project. This would allow jointly identified challenges to be addressed in a more targeted manner by the scientific community. Involving laypersons in research can also improve communication in the opposite direction, that is, from science to society. Research projects and scientists' working methods, perspectives and challenges thereby become more visible and understandable. A LEC can thus perform a dialogue function between society and research.

Mental illness, and ED in particular, is still associated with high stigma (Foran et al., 2020). The SUSTAIN study suggests that participatory research formats could help destigmatize these illnesses. On the one hand, on a superordinate level through an increased dialogue between science and society and, on the other hand, on an individual level through the effect of “patient empowerment” that can result from active participation in the research process.

The experiences of the SUSTAIN study show that the involvement of social actors with experiential knowledge is possible in clinical research on ED and that this cooperation may enrich and possibly contribute to the development of effective interventions. However, the implementation and further development of such projects are complex, require consideration of ethical aspects as well as research on LEC participation effects and risks, and cannot be carried out by the discipline alone, but requires support from, for

example, the social sciences. Participatory projects also cost additional time and resources (Price et al., 2018). The expansion of participatory research projects, which is increasingly demanded by society and funders, must therefore be supported financially and structurally (Giel et al., 2023), meaning current funding strategies must be adapted (von Peter et al., 2020). This includes the possibility of acquiring project funds for reimbursement of LEC members and for the preparatory phase of the actual study in order to collaboratively design research projects that have a practical impact and bring about sustainable improvements for the treatment of AN and other mental illnesses. Innovative study designs beyond classical RCT designs are also needed to best incorporate the enormous potential of experiential knowledge into future clinical research and care.

AUTHOR CONTRIBUTIONS

Katrin Elisabeth Giel: Conceptualization; funding acquisition; project administration; writing – original draft; writing – review and editing. **Judith Bremer:** Conceptualization; visualization; writing – original draft. **Susanne Rieß-Stumm:** Conceptualization; writing – original draft. **Bettina Gregg:** Conceptualization; writing – original draft. **Anke Fritz:** Conceptualization; writing – original draft. **Isabel Klemm:** Conceptualization; writing – original draft. **Melissa-Claire Daugelat:** Conceptualization; visualization; writing – original draft. **Kathrin Schag:** Conceptualization; project administration; writing – original draft. **SUSTAIN study group:** Writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data is available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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