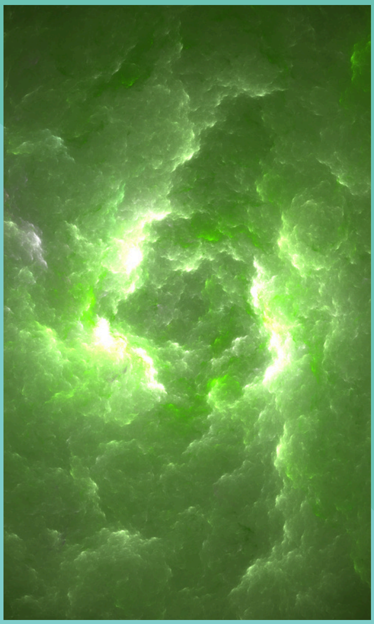
Moving Beyond the Participant Role

Mental Health Support in Trials



White paper on Mental health in clinical trials – the patients' perspective. Findings and Recommendations from a Patient and Caregiver Discussion.

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This project was sponsored by H. Lundbeck A/S.
Designed and delivered independently by PiCC United

Mental Health Support in Trials

Participants: The discussion group comprised seven participants (two women and five men); one woman and four men had prior trial experience. The group included both patients and caregivers, such as a parent representing a child who had participated in a clinical trial. Participants represented diverse health conditions and national contexts.

Clinical trials influence not only those enrolled as participants but also their caregivers. Despite this, mental health support remains an often-overlooked dimension of trial participation. This patient-led dialogue convened a diverse panel to address two central questions:

- **What are the key challenges?**
- **What actions are required?**

Lisbeth Oxholm Snede, Project Lead

Key Findings

The Problem

Stress and Anxiety: uncertain outcomes, overwhelming practical demands, potential side effects.

Impact of mental health needs reduces wellbeing and willingness to stay in the trial.

Gaps exist in trials for managing emotional stress, providing holistic care, and a personalised approach.

Patient Experience

Impact of participation: focus is on the medical condition, nothing else. You're on your own. No support when trials fail, lack of follow-up, and negative impact on wellbeing. Information is crucial, but rarely given.

Timely support: support needs will change before, during and after trial.

Designed support features needed: focus on whole-person approach, consistent communication, human touch, peer support, support/contact resources, and a tailored approach to each individual.

Recommendations

Integrate mental health support into **trial design**, with a whole-person approach. Recognise participants as partners – not just test subjects.

Involve patients: so that you can ask for help when predicting and understanding broader needs.

Build in tailored support systems: including a dedicated contact person, hotline, and psychological support.

Design for context: Especially if people have chronic or incurable condition(s).

Introduction

Mental health is a critically overlooked dimension of clinical trial participation, whether the trials target mental or physical health conditions. The uncertainties, potential side effects, practical and logistical demands, can all lead to significant emotional stress and anxiety. This directly reduces participant and carer well-being and their willingness to continue in the trial.

Through pre-meeting questionnaires and an in-depth discussion with patients and caregivers from across Europe, PiCC United identified themes of emotional stress, an unmet need for built-in whole-person support approaches and systems, a lack of human-touch and personalised approach, poor communication, and a gap in acknowledging mental health needs that is created by a complete focus on the primary medical condition being researched. Patients are unique individuals – not just trial subjects.

This report aims to distill these lived participant experiences into a clear characterisation of the problem, current experiences, and then recommendations for improvement. An overview of the report sections is below.

Listening to patients: How was it done?

Background Research

We set out to explore how patients and caregivers perceive mental health in the context of clinical trials. To support this, a pragmatic literature review was conducted spanning 2015–2025, including 14 scientific articles and three guidance documents, drawing on academic publications, websites, reports, policies, and regulations.

In parallel, a patient-led discussion was held with seven participants (two women and five men). Among them, one woman and four men had prior trial experience. The group included both patients and caregivers, representing multiple conditions and countries.

Pre-meeting survey

A pre-meeting survey was conducted online. Two women and five men participated, who were patients and caregivers. The purpose of this survey was to gather input from people who had experience with clinical trials (as well as those who had been rejected from a clinical trial), to understand which topics, questions, and support options were most important to them. After reviewing survey answers, questions were written to guide the discussion.

Listening to patients: How was it done?

Patient & Carer Discussion

These questions were then addressed in an online group discussion between our project lead and all of the participants. Participants agreed for the discussion to be recorded, including a transcript of the conversation to be documented. Questions were based on the topic 'The Perception of Mental Health in Clinical Trials' and the survey completed. Participants were guided throughout the meeting, using the pre-written questions.

Authoring this report

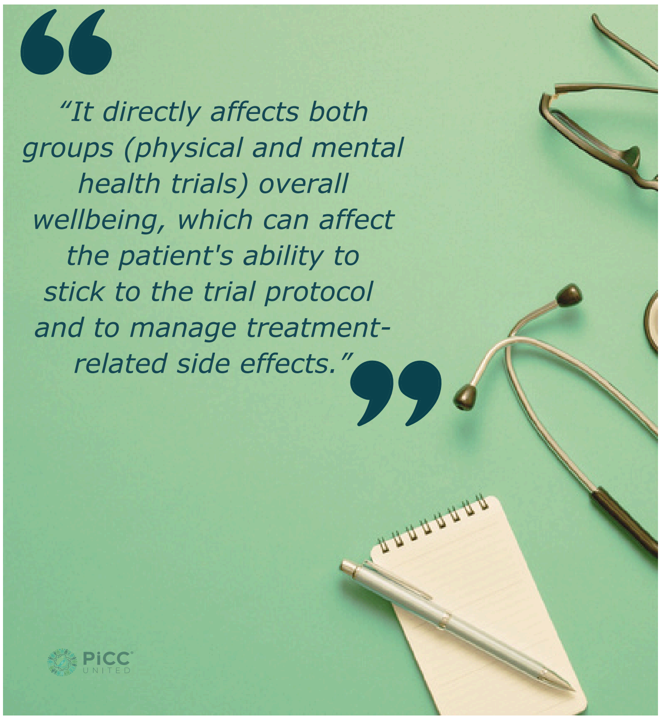
This report aims to inform different stakeholders about how patients and caregivers feel about mental health in clinical trials, and provide actionable points to be considered for future trials. Three emerging themes were identified: 'Understanding the Problem', 'Patient Experiences', and 'Improvement Recommendations'. Following this, the report was shared with those involved in this project for comments.

Action

To researchers/sponsors: *Researchers and sponsors should integrate mental health support into trial design from the outset.*

To patients and caregivers: *It's okay to talk about this – awareness and mutual support are essential.*

Understanding the problem



> *"It directly affects both groups (physical and mental health trials) overall wellbeing, which can affect the patient's ability to stick to the trial protocol and to manage treatment-related side effects."*

Trials themselves can impact on participant mental health

All trials need improved approaches but this may look different depending on what is being researched:

Trials where psychological or mental health is the condition being studied:
Focus on psychological safety, continuous support, trust and relationship with staff

Trials where a non-psychological condition is being studied:
Focus on side effects and consequences, practical logistics, physical outcomes, and their impact on mental health.

Impact on participants

Elements of a trial that either reduce the wellbeing of patients or their carers, or miss an opportunity to support them when their wellbeing is lowered, will reduce people's willingness to continue.

> *"We had a lot of anxiety and trauma and emotions throughout the day whilst trying to go through the process of just starting the trial."*

Stress and Anxiety

> *"I stood outside the door – I had to support, but I wasn't allowed to be informed."*

Joining a clinical trial adds to people's stress and anxiety over uncertain outcomes, all the practical and logistical demands that now must be met (in addition to normal life), and coping with the extra side effects they may or may not get.

Identified gaps

Everyone is unique and caring for the whole person is important. Building in links with other care functions beyond the trial is essential.
Having a human touch, and reaching out to connect are essential.

> *No one rings me outside. Sorry, nobody rings me to ask me how are you doing?*

Understanding the problem

Two trial types – different support needs.

Mental health trials: Require strong focus on psychological safety, trust and continuity with staff, clear crisis access, and peer-to-peer support. Engagement should start early, with frequent check-ins maintained throughout and after the trial.

Physical health trials: Need precise medical communication, clear logistics, and strong support in managing side effects. The most critical support is during treatment phases, with structured post-trial follow-up to ensure continuity of care.

Impact on participants

At a time when patients and their carers are discussing clinical trials they are already under a lot of stress and are likely to be in an unprecedented situation for them.

The process of even trying to join a trial can be profoundly impactful, even for those who are successful.

> “Several participants felt abandoned once the trial ended, describing themselves as ‘disposable’. You know, you're disposable. And patients want to know, even if it hasn't worked... what's happened with this clinical trial?...what's going to happen next? And it just seems such an awful way of treating people.”

For those not eligible, they are dropped. One participant shared their experiences of their child being rejected from a trial due to difficulties collecting a blood sample

> *"Line drawn under it. See you later. Best of luck next time."*

Even when trials go wrong, such as in cases of severe adverse effects, a complete lack of support is often felt. It seems like industry sponsors start "lawyering up" and locking down communication with patients.

Patient experiences

Impact of participation

Participants expressed frustration that patients are often treated as “disposable” once their contribution is made. Communication quickly reduces, leaving people without updates, personal contact, or even a simple check-in to ask how they are doing. At the same time, patients and their caregivers are already under significant stress and often face unprecedented situations when considering or joining a trial. Even the process of trying to participate can be profoundly impactful, regardless of whether they are ultimately accepted.

> *“Support is needed when a trial does not go well and leaves participants without a way forward. But support is equally important when a trial proves successful yet offers no access afterwards. In both cases, participants are left without continuity, highlighting the constant need for ongoing support...”*

> *“They then got to this point where the industry sponsors lawyered up, locked down, nobody would speak to anybody about anything. So then you have a family whose child has gone through a clinical trial, has had a really bad thing. But again, there's no. No support after it all went horribly wrong.”*

> *“An awful lot of effort has to be put in the beginning... If you can't be bothered at that initial stage to kind of really think about what's bothering me, then why would I be in your trial even if I wanted to be?”*

To address this, participants emphasised the need for clear and consistent dialogue throughout the entire trial process. Both patients and caregivers require clarity at every step, supported by trusted peer-to-peer connections that provide accurate information, reassurance, and shared experience. For those not eligible, rejection was described as abrupt and distressing. Sensitive communication – with clear reasons and guidance on possible next steps – is essential to reduce feelings of abandonment.

Patient experiences

Support needs by study steps

The need for a clear, consistent dialogue throughout the whole trial process was highlighted many times. Patients and caregivers emphasised the importance of clarity at every step, supported by trusted peer-to-peer connections that provide accurate information, reassurance, and shared experience.

Before the trial

Who: Clear identification of a contact person/people for both practical and emotional support.

What: Explanation of the trial process, expectations, possible scenarios, commitments, and side effects.

How: Locations, logistics, relevant departments, and help to plan the trial process.

Peer-to-peer: Connect with an experienced participant (buddy/alumni) to share real-life insight and reassurance.

During the trial

Who: Clear identification of roles for different contact people (e.g. medical, side effects, logistics).

What: Agreed communication channels, response times, and referrals.

How: Support beyond trial visits, little touch points (such as a 5 minute call), feedback on progress, acknowledging that this is terrifying for some, listening and then working together to create personalised support.

Peer-to-peer: Maintain access to peers with similar experiences to reduce anxiety and foster trust.

After the trial

Who: Contact for post-trial follow-up and emotional support. Make sure that people are proactively called to see how they are doing.

What: Explanation of results, next steps, options, treatments, smooth and integrated transition into next treatment step. Ongoing support from previous participants and peers to help with this transition.

How: Make sure that at the end of the trials the next diagnostic and/or treatment department is prepared to integrate patient into the next stage of their care and hand over care together. Provide post-traumatic support when required as a standard activity. Confirm department readiness to integrate the patient into the next stage of care.

Patient experiences

Desired support needs

Patients and caregivers repeatedly stressed the importance of clarity and continuity at every step of the trial. This must be supported by trusted peer-to-peer connections, accurate information, and a human touch. The needs identified are summarised below.

Whole person

Design approach to make sure that the whole person, not just the disease, is considered. Connect dots between physical effects and what you're asking of people (of the disease, of side effects, of challenges with study requirements) and mental health impact.

Tailored Approach

Build in support mechanisms so the approach can be tailored with each unique person. Involve psychological support for diverse mental health needs.
There may be different requirements for psychological and physical health clinical trials.

Peer Support

Connection with others who have lived similar experiences can provide reassurance and trust. This can be facilitated through local access within clear boundaries (non-clinical), buddy systems, and patient points of contact. In-person meetings are highly valued when possible.

Dedicated Contacts

Single point of contact for all initial questions.
Access to professionals for getting answers.
Knowing how to handle situations and who to contact is essential from the start.

Information

Provide clear explanations in everyday language, with personalised outcome feedback supported by visuals when helpful. Ensure a human touch, not just clinical detail, and be consistent and transparent about research results.

Resources

Show genuine interest in people as partners, not just as trial subjects. Maintain contact through newsletters, postcards, online tools/apps (accessibility checked), hotlines, and phone calls between visits.

As an optional extra, offer supportive practices such as mindfulness or relaxation for those who may find it helpful.

Improvement recommendations

For all clinical trials

- **Integrate mental health support** during the trial design stage.

  How: *Build psychological safety measures into trial protocols from the outset.*

- **Patient involvement throughout.** Identify areas of action and solve together, for a longer and better participant experience.

  How: *Engage patients early in co-design workshops and keep them involved at key decision points.*

- **Caregiver inclusion:** Proactively include named relatives in communication and updates (with consent), and signpost support resources tailored for caregivers.

  How: *Provide optional caregiver briefings, information packs, and direct contacts for support.*

- **Tailorable support systems.** Dedicated contact person and stability in the core team delivering the trial. Psychological support, improved communication, and peer support.

  How: *Assign one consistent site contact per patient, and integrate peer-to-peer buddy options.*

- **Illness specificities:** For patients living with chronic and/or incurable conditions, the considerations and support needs may be complex. Take time to consider this during the design stage.

  How: *Include condition-specific patient advisors when drafting protocols and support systems.*

Improvement recommendations

For all clinical trials

- **Training for clinical trial staff:** Train clinical trial staff on a whole-person approach, maintaining connection, communication methods, and tailoring support with patients and carers.

  How: *Run mandatory training modules with patient input, including role-play on sensitive communication.*

- **Address practical barriers** by reducing participation burden through travel reimbursement, flexible scheduling, and remote/online options where feasible.

  How: *Offer digital visits where possible, reimburse transport costs promptly, and adapt visit times to participants' daily lives.*

Sponsor responsibility: *Embedding mental health support must be the responsibility of trial sponsors from the outset. External patient organisations and support groups may complement this (e.g. peer support), but meaningful integration must be designed and resourced within the trial itself*.

For psychological trials

Communication Style
Use communication styles that reduce stigma and fear of judgment.

Peer-to-Peer Role
Build peer-to-peer connections into the trial process.

Timing of Support
Engage participants early, before the trial begins.

For physical health trials

Communication Style
Explanation to patient understanding.

Peer-to-Peer Role
Sharing real-life experiences.

Timing of Support
Strong focus during the trial itself.

Improvement recommendations

For all clinical trials

For physical health trials

Communication Style

Explanation focused on patient understanding. Gentle, consistent, and person-centred. Use communication styles that reduce stigma and fear of judgment.

How: *Train staff to use supportive, non-judgmental language and to check for understanding in plain words*.

Peer-to-Peer Role

Sharing real-life experiences of treatment effects, recovery, and navigating trial logistics.

How: *Invite experienced patients to share their journey through peer videos, Q&A sessions, or site-based buddy systems.*

Timing of Support

Strong focus during the trial itself, especially around treatment phases and test results, with structured follow-up after the trial.

How: *Ensure trial sites plan for extra staff availability at treatment milestones, and build a standard follow-up call or visit into trial closure*

For psychological trials

Communication Style

Use communication styles that reduce stigma and fear of judgment. Explanation focused on patient understanding.

How: *Train staff to use supportive, non-judgmental language and to check for understanding in plain words.*

Peer-to-Peer Role

Build peer-to-peer connections into the trial process.

How: *Provide a buddy system or alumni network for current participants, with clear non-clinical boundaries.*

Timing of Support

Engage participants early, before the trial begins.

How: *Schedule pre-trial orientation calls, regular short check-ins, and structured follow-up appointments post-trial.*

Conclusions

This project has shown that clinical trial participation is not only a medical experience, but also an emotional and practical journey for both patients and caregivers. The discussions revealed a strong need for mental health support to be built into every stage of the trial process – before, during, and after – regardless of whether the trial focuses on physical or psychological conditions.

Participants emphasised the importance of feeling valued as people, not just as trial subjects. Too often, they described being left without updates, excluded from communication, or rejected without explanation. Caregivers, who carry much of the emotional and practical burden, also highlighted their exclusion as a key gap.

Key recommendations from this work include:

- Integrating mental health support into trial design.
- Ensuring patient and caregiver involvement throughout.
- Providing dedicated contacts, clear communication, and peer-to-peer support.
- Addressing practical barriers such as transport, flexible scheduling, and post-trial handover to regular clinicians.
- Build peer-to-peer connections with others.

By embedding these elements into clinical trial design and delivery, sponsors and research teams can improve wellbeing, reduce drop-out rates, and strengthen trust. Most importantly, they can demonstrate respect for the individuals and families who make trials possible.

Supporting patients as whole people – not just participants – is essential for ethical, effective, and sustainable clinical research.

Key Quotes

*“Just the human touch. I'm totally missing that. **It's all medical**...”*

“I stood outside the door – I had to support, but I wasn’t allowed to be informed.”

– Female caregiver

“In a cancer trial you worry about side effects and logistics. In a mental health trial, you worry about yourself – will I get worse, and will anyone catch me if I fall?”

– Male participant

”Not knowing if I was on placebo made me doubt every symptom.”

– Male participant

“Cause it [mental health support] doesn't have to be massive, it just has to be meaningful.”

“...Explain the things...We're not medical specialists, we're patients. And in many cases, there are a lot of medical language, which I can't understand fully...”

“When the trial ended, I just felt dropped. I didn’t know who to call or what came next.”

– Female participant

Project Contributors

Project Lead & Facilitation

Patient & Caregiver Contributors

- Seven participants (two women, five men) from multiple countries and conditions.
    - Five participants had previous clinical trial experience (one woman, four men).
    - Roles included both patients and caregivers.
- All contributions were recorded and transcribed with consent; findings are presented anonymously.

Project lead

- PiCC United - Project lead: Lisbeth Snede – Led and facilitated the patient and caregiver discussion, synthesised findings, drafted the report, and integrated the analysis of discussion themes and evidence base.

Research & Analysis

- H. Lundbeck A/S – Support to pragmatic literature review.
- Dr. Molly Gracey and Dr. Jenny Royle (MediPaCe) – Report drafting, analysis of discussion themes.

Design & Delivery

- PiCC United – Independent coordination, design of project, patient engagement, and report delivery.

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Listening to Patients

Mental Health Support Needs in Clinical Trials

Thanks to everyone who took part for your collaboration, honesty, and willingness to make a difference