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Beyond the Protocol:

Using Qualitative Research to Strengthen Clinical Trials and Center Patient Perspectives

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Agenda

- Why go beyond the protocol?
- PRO-ACTIVE Pilot Trial: post-intervention qualitative interviews
- PREEMPT Trial: qualitative interviews to determine next steps
- Takeaways

Going Beyond the Protocol

Clinical trials tells us what happened, but not always why

Traditional Clinical Trial Data	Questions Participants Can Help Answer
Did the intervention work?	What was this experience like?
How much?	What made participation easier or harder?
Was it safe?	What did participants value?
Did participants complete the intervention?	What outcomes mattered to them?
What were the measures outcomes?	Would they participate in a future study?

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Qualitative Data in Clinical Trials

Where does it fit?



Before: Understand patient priorities / barriers, where are the gaps?

During: Understand participation and implementation

After: Understand participant experience / contextualize findings

Between studies: Inform the design of the next trial / intervention

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PRO-ACTIVE Pilot Study

Acceptability & Feasibility of Digital Interventions to Help Address Symptoms for Patients Undergoing Radiation for Breast Cancer



Bi-weekly symptom ePROs



Fitbit Sleep and Activity Monitoring



Virtual Exercise Program (IM@Home)

- **Study Participants:** n=40 (29 from UW/FH, 11 from community clinic), enriched enrollment
- **Post-intervention qualitative interviews:** n=13 (9 academic, 4 community)

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PRO-ACTIVE Study

What can quantitative data tell us?

- **96.4%** ePRO completion
- **90%** Fitbit uptake
- **19.7 hrs/day** mean Fitbit wear time
- **55%** enrolled to IM@Home
- **2.38 classes/week** mean attendance

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PRO-ACTIVE Study

What answers can qualitative data tell us?

Quantitative Finding	Question Qualitative Interviews can Answer
96.4% ePRO completion	How did survey cadence impact likelihood of completion?
90% Fitbit uptake	What made Fitbit easy/hard to use?
19.7 hrs/day mean Fitbit wear time	What motivated you to keep wearing the device?
55% enrolled to IM@Home	Why did some choose to participate while others did not?
2.38 classes/week mean attendance	What made attendance feasible?

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Qualitative Interview Guide

PRO-ACTIVE Pilot Study

What were the *challenges* you faced using Fitbit? What helped you remember or *feel motivated* to wear it?

What was your *experience* with the recorded exercise content? What about live classes?

How did being a part of the study *affect your experience* going through radiation treatment?

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Qualitative Interviews: Best Practices

Ask open-ended, non-leading questions

Instead of: “Did you find the Fitbit helpful?”

Ask: “What was your experience using the Fitbit?”

Use probes to go deeper

Examples: “Can you tell me more about that?” OR “What did you mean by…?”

Listen more than you talk

Give participants time to think and embrace silence; make eye contact

Stay curious and neutral

Don’t agree/disagree, or react in a way that could influence responses

Follow the participant, not just the interview guide

The guide is a roadmap, not a prescription

Interviewing: DOs & DON'Ts



Qualitative Findings & Themes

Fitbit is an **easy-to-use tool for tracking physical activity** and providing **real-time feedback** to motivate users.	• *"[Fitbit] offered a layer of accountability…being able to set attainable goals and have a quantifiable measure of achievement." – S13*
Exercise classes provided **valued opportunities for community and connection during cancer treatment**.	• *"It really helped to have the online classes, especially right after the radiation treatment, because I really wasn't gonna go to the gym for that recovery period." – S30*
Participants **gained insight into their movement and fatigue** while finding purpose in helping others.	• *"I just feel like I just sailed through radiation. Staying active definitely help me sleep." – S04*

Convergence of Qual & Quant

A More Complete Picture of Participant Experience

Quantitative Engagement (WHAT)	Qualitative Finding (WHY)
90.0% (36/40) agreed to wear a Fitbit; mean wear time 19.7 hours/day (SV 4.4 hours)	Fitbit-enabled self-monitoring, promoted accountability, goal setting, and symptom awareness through real-time activity and sleep feedback
96.4% PRO completion rate across biweekly assessments (range: 90-100%)	ePRO reporting was manageable, timely, and meaningful for symptom communication
55% (22/40) enrolled in virtual mind-body program; mean attendance of 2.38 classes/week	Virtual mind-body programming was acceptable and provided a flexible, accessible source of supportive exercise during treatment

PRO-ACTIVE: Results Dissemination

ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Patient experiences with digital supportive care interventions during breast radiation therapy: A mixed-methods analysis from the PRO-ACTIVE pilot study.

Chelsea Blanes
University of Washington Department of Radiation Oncology, Seattle, WA

Accepted abstract for poster presentation at 2026 ASCO Quality Care Symposium (Oct 2026, Boston, MA)

What if we ask patients BEFORE we design the next trial?



PRO-ACTIVE Study: We listened AFTER participation.

Can patient insights and feedback help with clinical trial study design?

NRG-CC014 PREEMPT Study

Phase III National Clinic Trial

- Objective: Determine whether **prophylactic radiation therapy** (RT) to high-risk asymptomatic bone metastases **decreases occurrence of skeletal-related events (SREs)** compared to standard of care (SOC)
  - n=280
  - Accrued in 11 months (vs anticipated 29 months)

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NRG-CC014 PREEMPT Study

What's Next?



What should the next trial look like?



What would make a future clinical trial **meaningful, acceptable, and feasible** for patients?



Who should help answer that question?

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PREEMPT Follow-up Study

Eligibility ≠ Participation

WHAT MATTERS?	• Which outcomes are most important to patients? • What benefits do they value?
WHAT'S ACCEPTABLE?	• How much treatment burden is acceptable? • What side effects or tradeoffs would they tolerate?
WHAT'S FEASIBLE?	• How many visits? How much follow-up? • What study requirements fit into their lives?

Patient insights → Study design decisions → Patient-centered clinical trial

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Planned Qualitative Study

Population: Adults with polymetastatic solid tumors (>5 sites of metastatic disease) who have high-risk, asymptomatic bone metastases

Semi-structured interviews

- Risk perception
- Preventative treatment and palliative care
- Patient priorities: Staying independent? Avoiding hospitalization? Remaining active? Maintaining quality of life?

Bottomline: What would make a future study worth participating in?

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Qualitative Research in Clinical Trials

	PRO-ACTIVE	Next Phase of CC014
When?	After participation	Before next trial
Who?	Trial participants	Patients eligible for future research
Purpose	Understand experience	Inform future design and outcomes
Questions	What worked? What didn't?	What would patient want?
Impact	Improve intervention delivery	Shape future protocol/outcomes

Ask patients. Listen to what they tell us. Act on it.

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Beyond the Protocol

What qualitative research adds

Qualitative research can help us:

- **Explain**: Why did we see the quantitative findings we saw?
- **Improve**: How can we improve intervention delivery and participant experience?
- **Prioritize**: Which outcomes matter most to patients?
- **Design**: What study designs are acceptable and feasible?
- **Partner**: How can patients become partners in research (not simply participate)?

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Practical Considerations

You don’t need a HUGE qualitative study

Potential approaches:

- Small number of post-intervention interviews
- Semi-structured interviews
- Focus groups
- Open-ended questions embedded in surveys
- Patient advisory groups / patient advocates

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Key Takeaways

- Quantitative data tells us WHAT happened; qualitative research helps us understand WHY.
- Patient experiences can identify opportunities to improve trial delivery.
- Patient input can shape the next trial, not just evaluate the last one.
- “Patient-centered” means more than reducing burden.
- Patients can be partners in research, not just participants.

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QUESTIONS?

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