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Collaborative Development and Validation of an Enhanced Seizure eDiary for Clinical Trials

Objective

To create an innovative seizure electronic diary (eDiary) using lessons learned from prior studies to enhance data quality and user-friendliness for patients, caregivers, and investigators (figure 1, table 1).
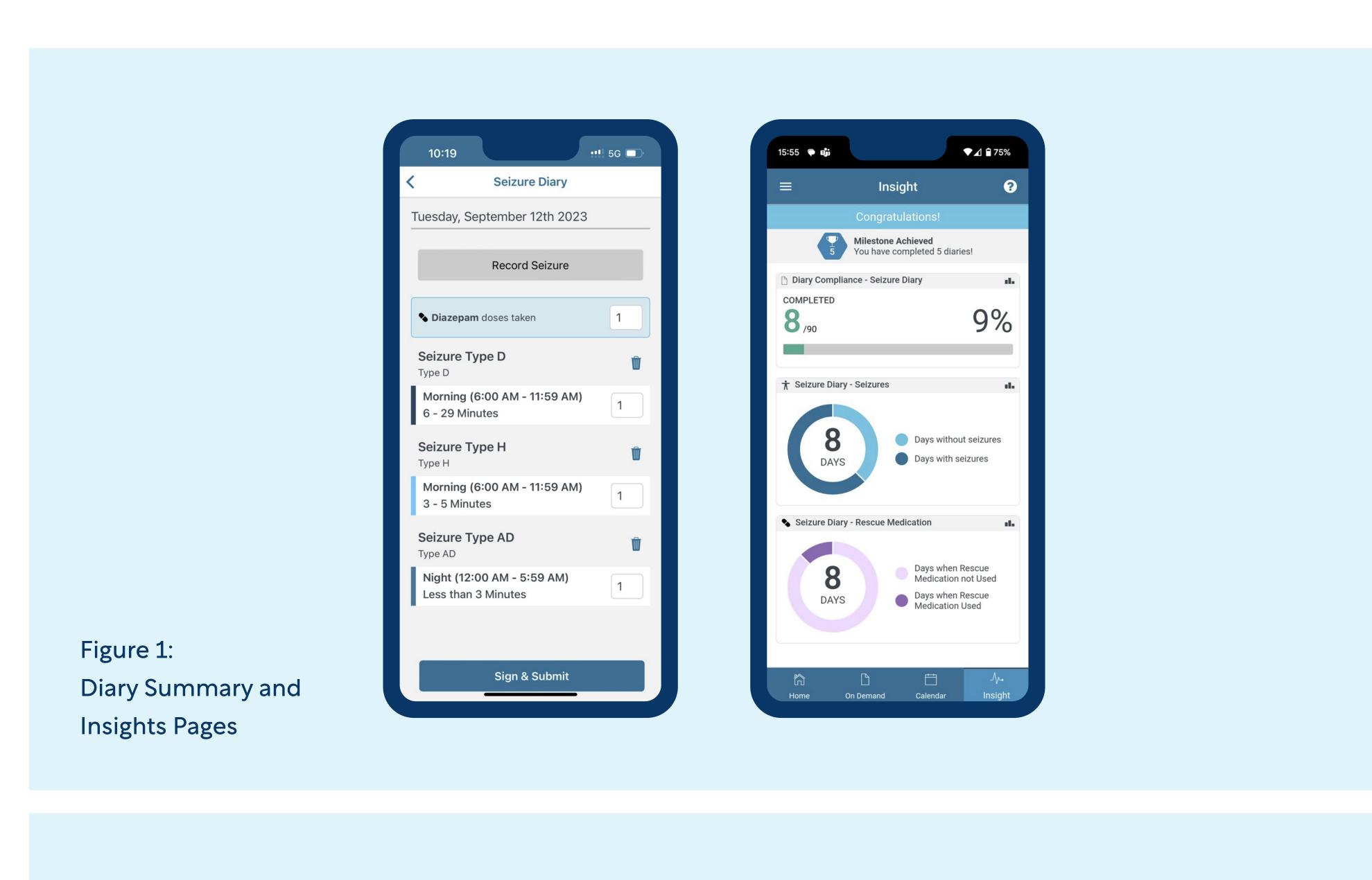
Design

The eDiary's initial specifications were shaped through collaborative sessions between a team of industry and technological experts and the Epilepsy Study Consortium, Inc. (ESCI) Working Group, consisting of epilepsy clinical trial experts and pharmaceutical representatives. Input from the Working Group guided the creation of initial eDiary mockups, followed by iterative feedback cycles. Focus sessions with patients with epilepsy provided insights into eDiary functionality. ESCI clinicians and the Working Group tested the eDiary, leading to further iterative refinements. Post-initial development, semi-structured interviews were conducted with ten patients and ten patient caregivers. Cognitive debriefing and usability testing was conducted in alignment with regulatory focus on patient input and Patient-Reported Outcome (PRO) best practices. Cognitive debriefing evaluated the eDiary's clarity and user comprehension. Usability testing assessed ease of user interaction (figure 2, table 2).
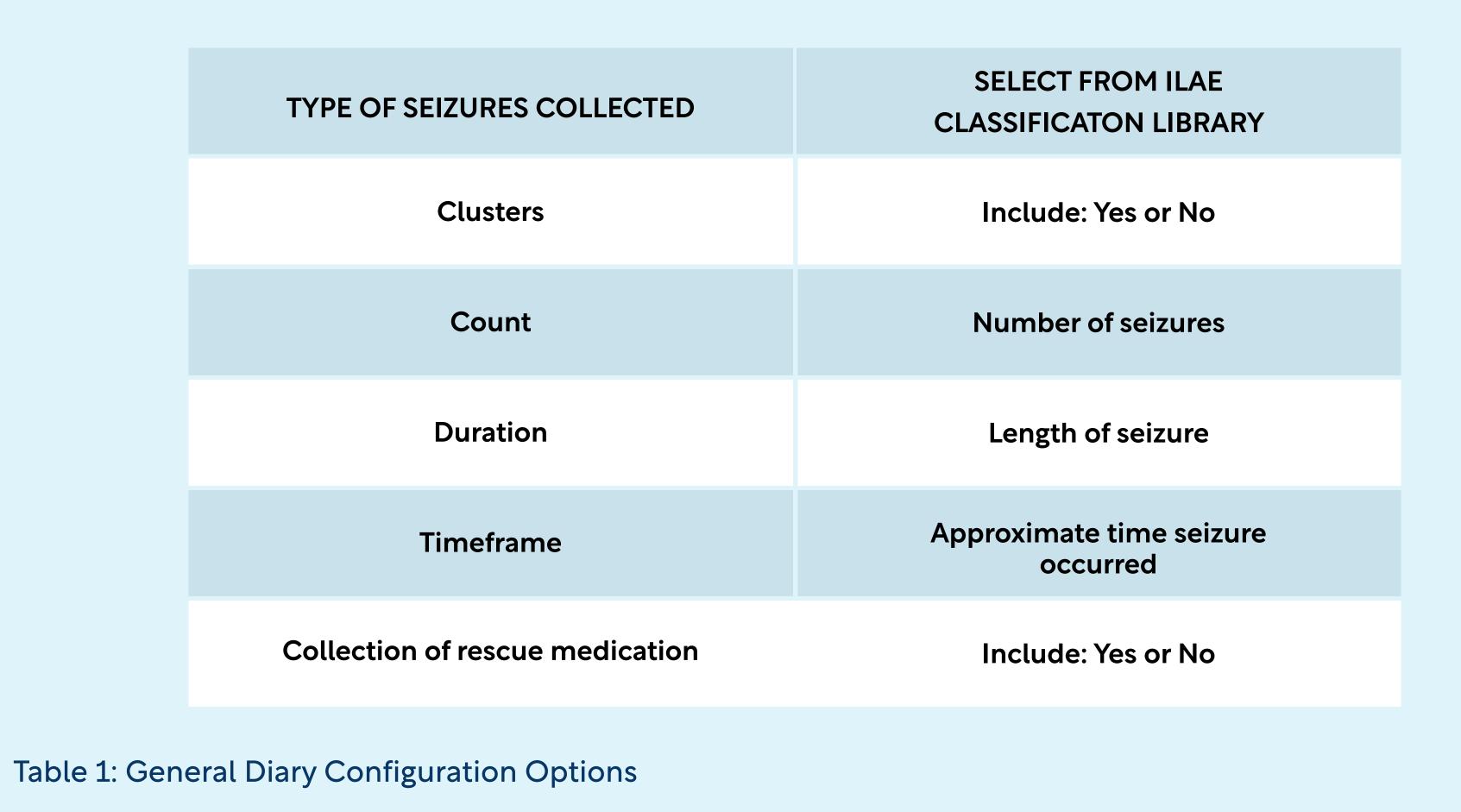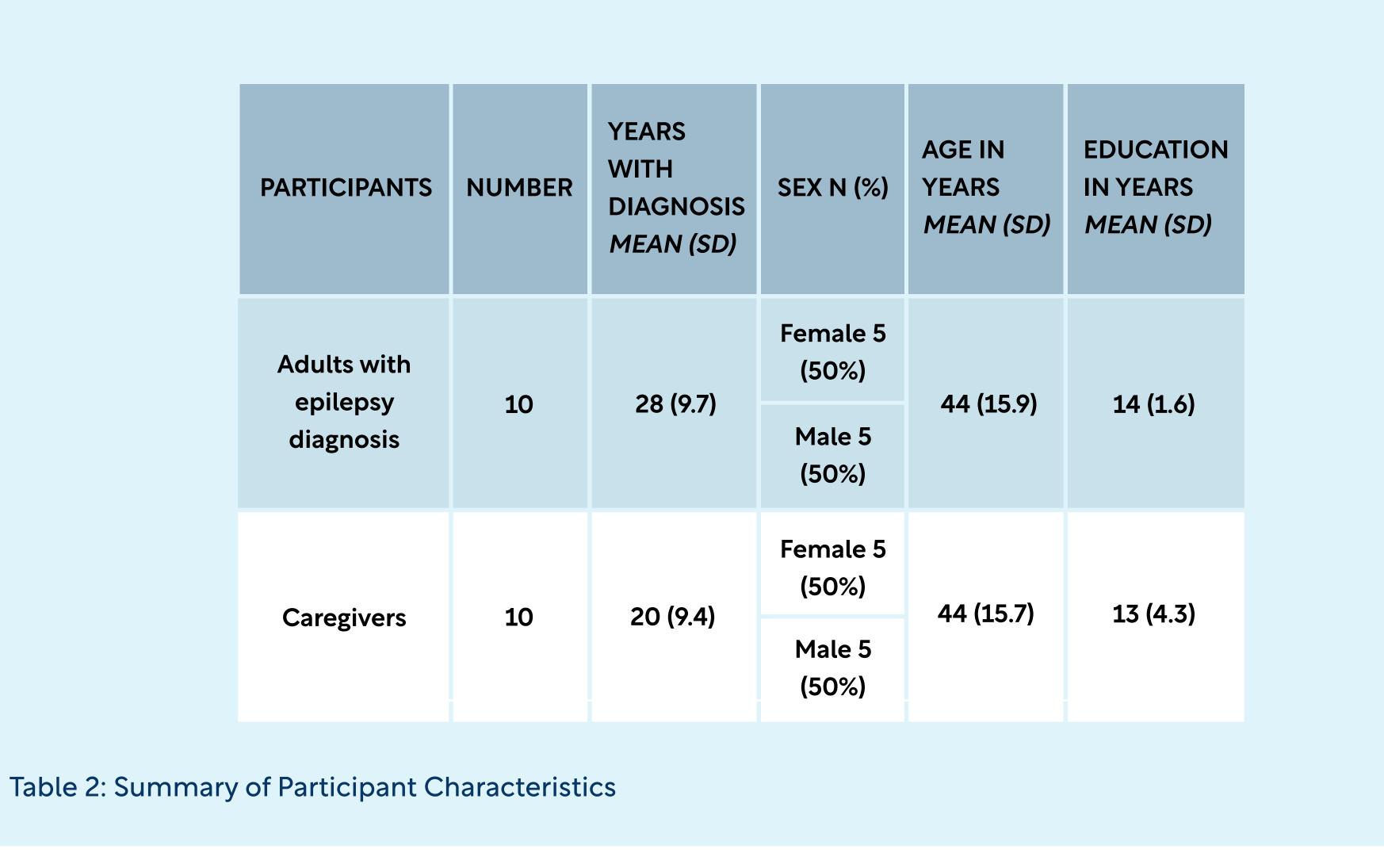
Results

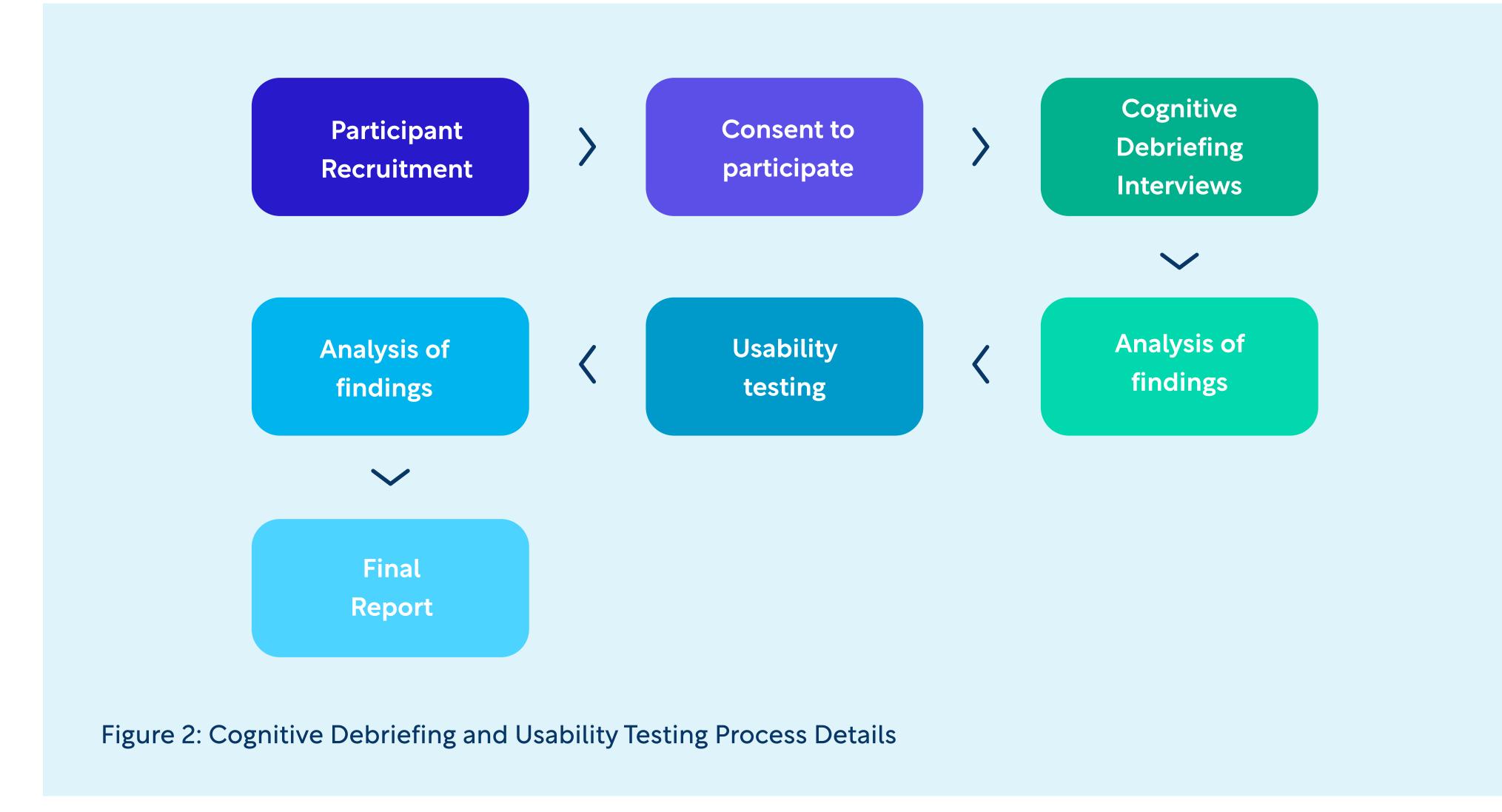Patients found the eDiary instructions and content relevant. Cognitive Debriefing results include twenty-one suggested minor modifications. Eighteen were implemented, two will be addressed in train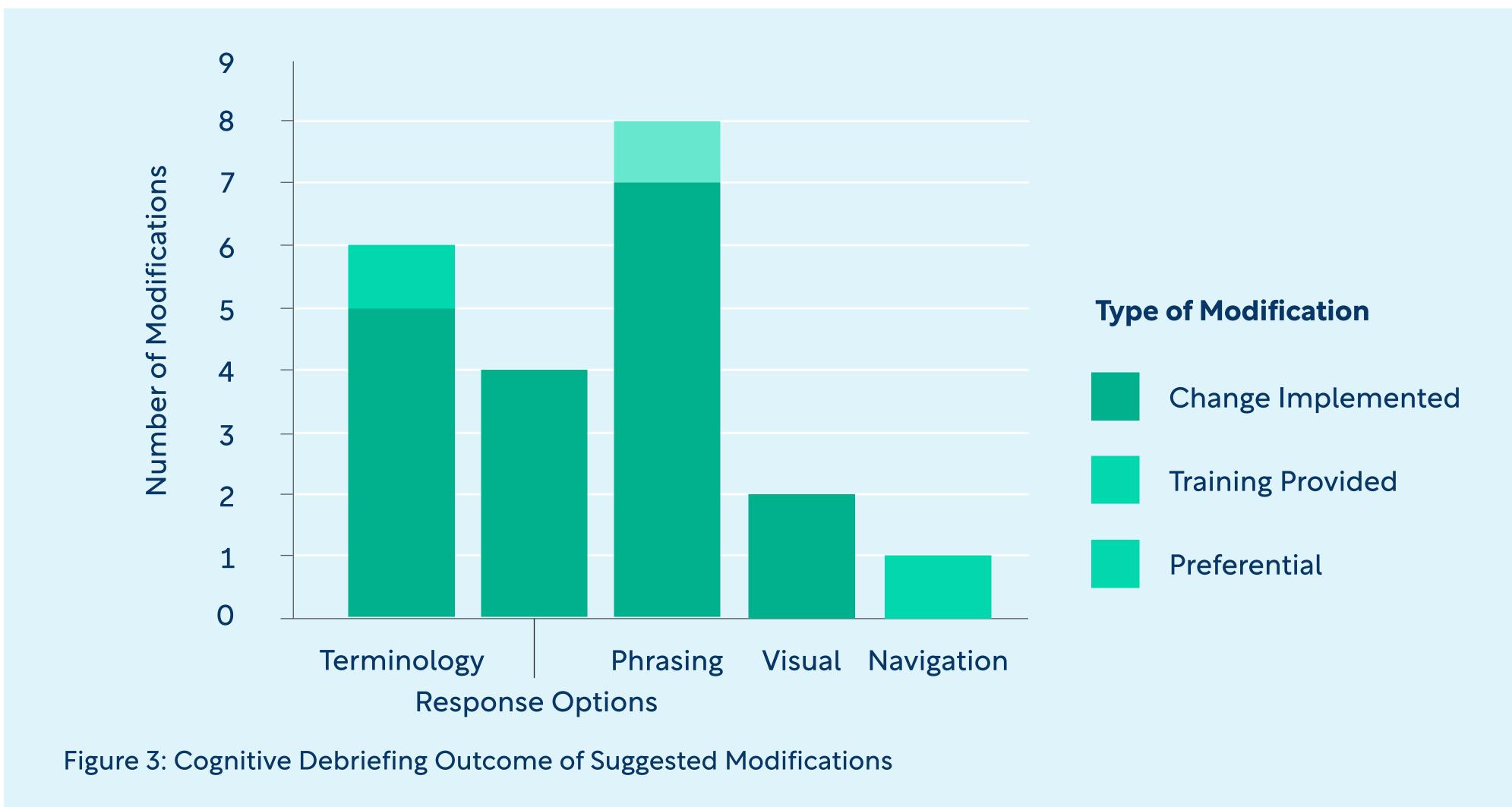ing and a remaining one was preferential. Usability testing results include six suggested minor modifications, three will be addressed in training and three are preferential (figures 3-6).

Figure 1:
Diary Summary and Insights Pages

Table 1: General Diary Configuration Options

TYPE OF SEIZURES COLLECTED	SELECT FROM ILAE CLASSIFICATON LIBRARY
Clusters	Include: Yes or No
Count	Number of seizures
Duration	Length of seizure
Timeframe	Approximate time seizure occurred
Collection of rescue medication	Include: Yes or No

Table 2: Summary of Participant Characteristics

PARTICIPANTS	NUMBER	YEARS WITH DIAGNOSIS MEAN (SD)	SEX N (%)	AGE IN YEARS MEAN (SD)	EDUCATION IN YEARS MEAN (SD)
Adults with epilepsy diagnosis	10	28 (9.7)	Female 5 (50%) Male 5 (50%)	44 (15.9)	14 (1.6)
Caregivers	10	20 (9.4)	Female 5 (50%) Male 5 (50%)	44 (15.7)	13 (4.3)

Figure 2: Cognitive Debriefing and Usability Testing Process Details

Figure 3: Cognitive Debriefing Outcome of Suggested Modifications

Figure 4:
Cognitive Debriefing Suggested Change and Outcome

Additional text for clarity

Removed mathematical symbols

Corrected category numbering

Figure 5: Usability Testing Outcome of Suggested Modifications

- Some participants did not notice or know to click on the light-yellow ribbon to report multiple seizure-free days
- Suggestion was to change color of ribbon, font size or wording
- Additional training, with a visual, will be provided to ensure this functionality is evident to the participants

Figure 6:
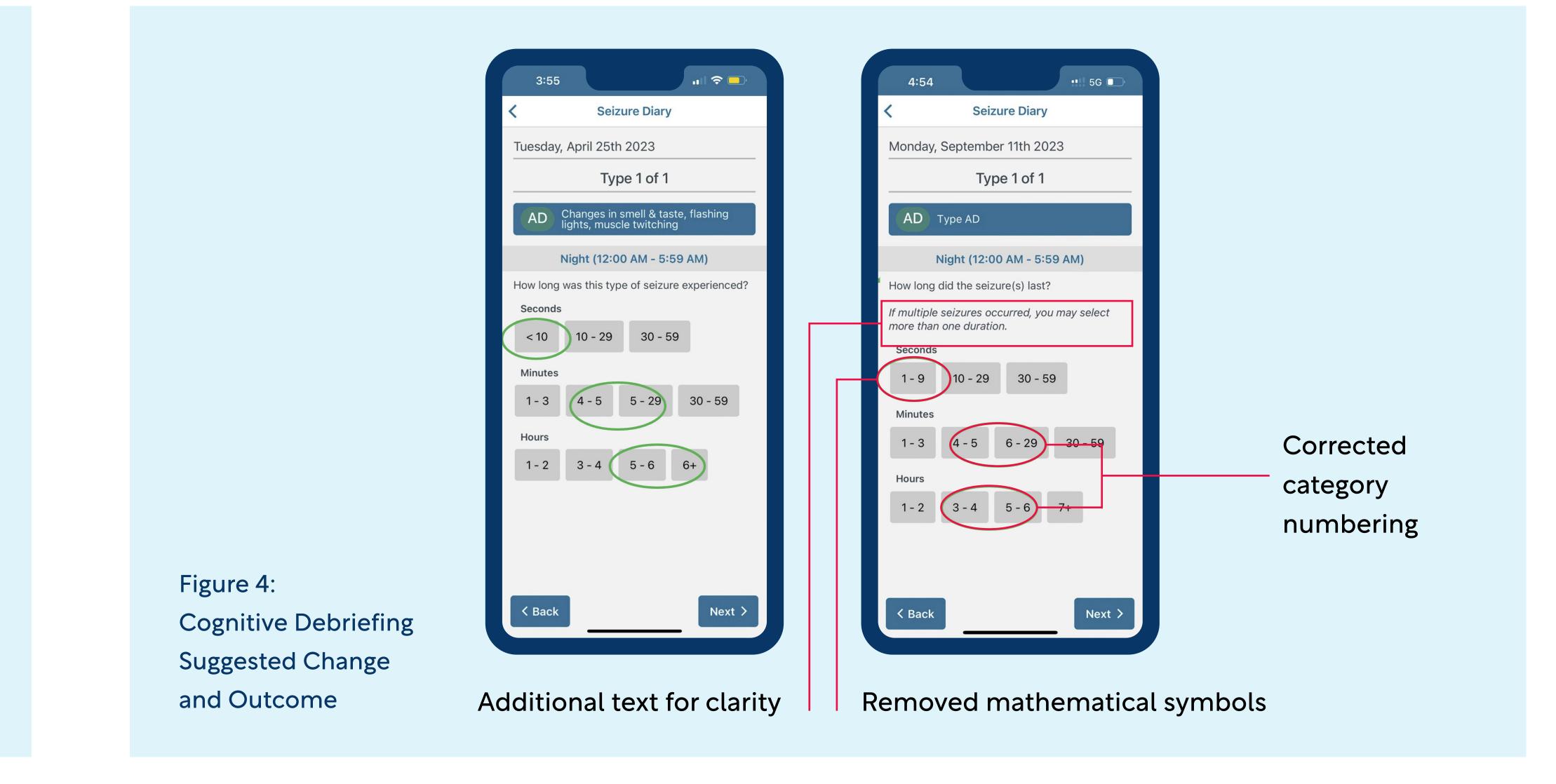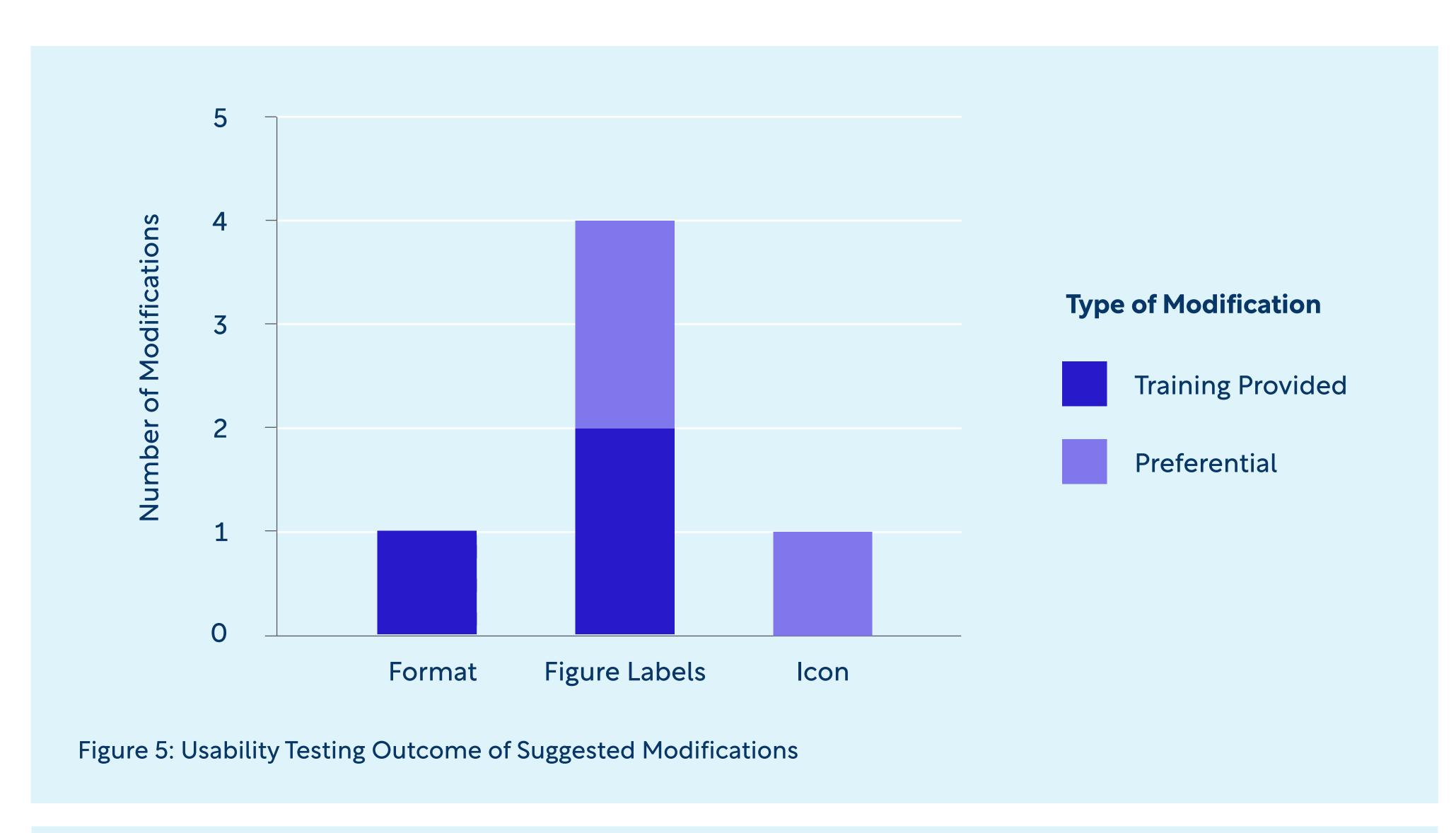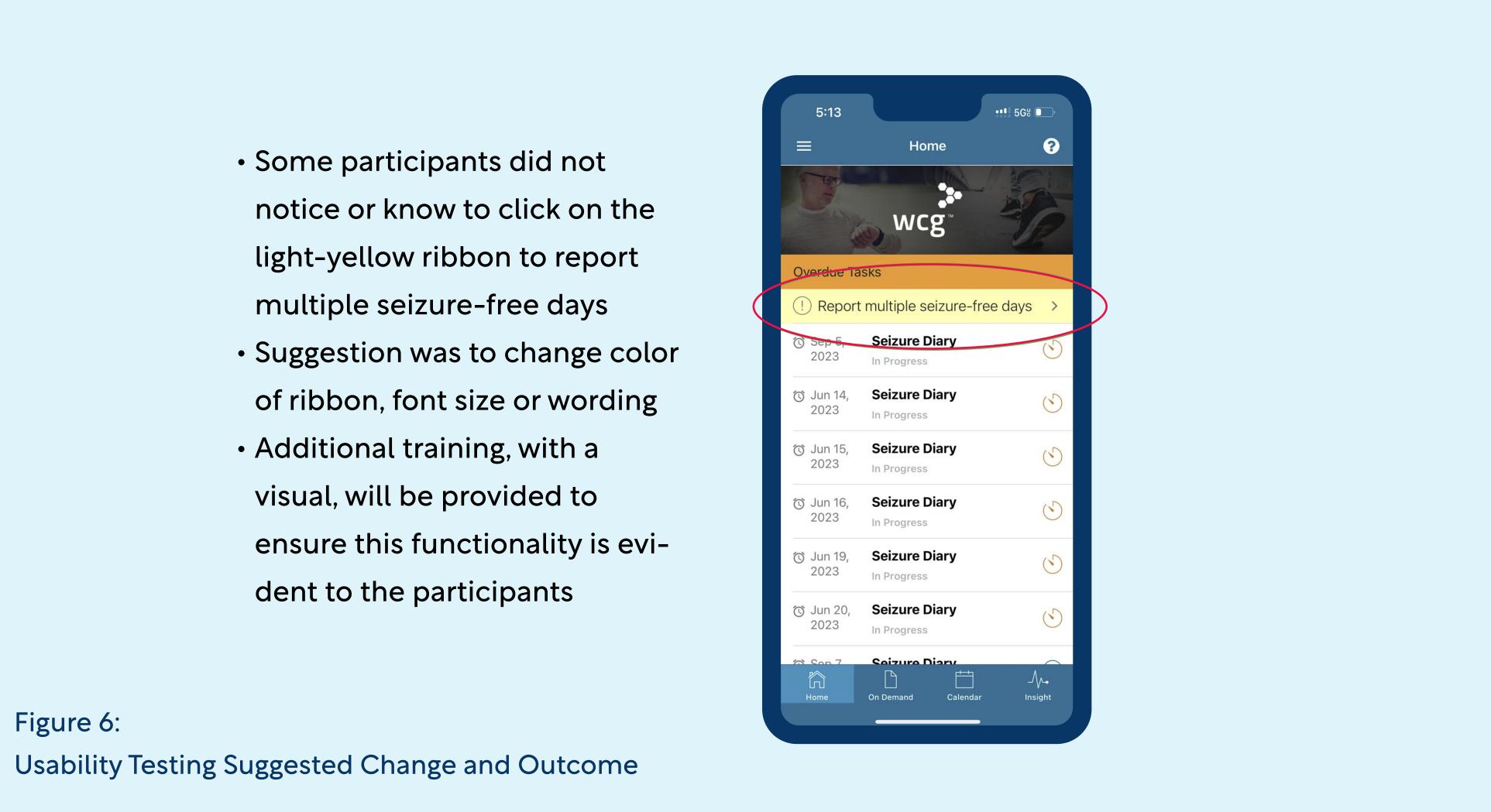Usability Testing Suggested Change and Outcome

Conclusion

Patients found the eDiary instructions and content relevant. Cognitive Debriefing results include twenty-one suggested minor modifications. Eighteen were implemented, two will be addressed in training and a remaining one was preferential. Usability testing results include six suggested minor modifications, three will be addressed in training and three are preferential.