**Title**: A novel Program Acceptability Tool for Telehealth (PATT) to assess patient-reported acceptability among caregivers of children with neurogenetic conditions.

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**Introduction**: Assessing treatment acceptability is important to understanding patient experiences in clinical trials, particularly as telehealth-based programs have increased in the wake of the COVID-19 pandemic. However, the use of patient-reported acceptability outcomes in tele-mental health focused trials has been mixed, with most published studies relying on objective behavior (e.g. dropout rates) or fit-for-use measures, rather than instruments rooted in a specific theoretical model (Sekhon et al., 2022). Furthermore, current measures omit other factors that participants experience across a clinical trial, such as project staff interactions, paperwork, and cultural aspects of the participant’s experience (Isreal et al., 2017). These gaps limit understanding of how to best improve clinical services to meet the needs of diverse patient populations. Here, we describe the initial development and validation of a novel assessment tool designed to capture patient-reported acceptability in telehealth-based trials, the Program Acceptability Tool for Telehealth (PATT), which was specifically designed to meet the needs of caregivers of children with neurogenetic conditions (NGC) enrolled in a telehealth clinical trial.

**Method**: 123 NGC caregivers completed the 41 items related to acceptability during an ongoing clinical trial, Project WellCAST (*Supporting the WELLbeing of CAregiverS via Telehealth*). Participation in Project WellCAST included completing a support program focused on caregiver well-being (e.g. tele-mental health therapies, live behavioral-parenting training, self-guided resources). The initial development and validation of the PATT was conducted across three stages. *Stage 1; Item generation and evaluation.* Items were rated by 5 staff NGC caregivers to evaluate the clarity of questions. Items were removed if a majority of raters rated an item as “Unclear”. PATT qualitative responses were also coded by 3 study team personnel (2 research assistants, 1 community member) to identify new concepts. New items were considered if >5% of respondents discussed a new concept not already represented. *Stage 2; Scale organization and evaluation.* Items were sorted into categories and assigned scorings. Items were tested for internal consistency using both item-scale correlations and Cronbach’s alpha. *Stage 3; Convergence validation.* To validate the PATT against other metrics of acceptability, PATT scores were compared to both patient-reported engagement and clinician-observed session attendance by conducting t-tests and Pearson correlations.

**Results**: *Stage 1.* All PATT items were rated as “Clear” overall. After coding 1,103 qualitative responses provided by 106 participants, coders determined no new items needed to be added. Items were reduced based on redundancy and parsimony. *Stage 2.* Following pre-registered thresholds, Cronbach alpha was high (0.92) in the initial 24-item pool, with item-scale correlations from 0.08-0.80. Twelve items were omitted due to low item-total correlations or redundancy with other items. The final 12-item PATT had high internal consistency (α = 0.82–0.90). *Stage 3.* PATT total scores were higher among highly engaged participants, *t*(119)=-3.32, *p*=.001, and those who self-reported completing at least 50% of sessions, *t*(119) = -4.03, *p*<.001. The number of sessions attended converged with self-rated attendance on the PATT (n=96, rho=.71, p <.001) and was positively associated with PATT total score (n=96, rho=.20, p=.048), supporting PATT validity.

**Discussion:** Our findings suggest that the 12-item PATT is a feasible, reliable, and valid tool for capturing patient-reported acceptability.A strength of the PATT is its alignment with a novel theoretical framework for measuring acceptability that considers a focal program in the context of broader practical considerations and impact. Indeed, if a participant’s experiences with a trial’s procedural and cultural elements are not isolated from the acceptability measures focused on the program itself, program acceptability scores may be obscured by these external aspects of acceptability. The PATT offers a novel ecological standard for measuring patient acceptability, potentially improving our understanding of how patients perceive domains of program, process, and impact. Although additional work is needed to validate the PATT in large, diverse cohorts and contexts, standardizing a brief, cross-cutting measure setsthe foundation for more rigorous evaluation of programs, as well as more impactful, acceptable clinical outcomes for patients.

**References:**

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