

Evaluation of a Self-Administered Smart Phone-Based Application as a Wellness Measure in a Clinical Trial of Zanubrutinib

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Introduction

Self-administered assessments via smart phone-based applications (apps) can gather patient wellness data; however, data regarding app utilization in clinical trials are limited. This study evaluated engagement with a self-administered wellness app as a supplemental tool to assess quality-of-life (QoL) in study BGB-3111-215 (NCT04116437), which included patients with B-cell malignancies treated daily with oral zanubrutinib.

Methods

This exploratory analysis evaluated the feasibility of using a voluntary device-based, self-administered activity and QoL questionnaire app (Medable, California, USA) in clinical-trial patients. Feasibility was measured by rates of consent, utilization, and compliance. Consent was assessed by the percentage of patients who agreed to app use. Utilization was assessed by percentage of patients who engaged with the app. Compliance was assessed by actual versus scheduled engagements. The app also included passive activity tracking and a 6-minute walk test.

Results

As of 1 September 2022, 78 patients had enrolled in the study (median age 71 years), 20 consented (consent rate, 26%). Eleven patients (median age 65 years) engaged with the app at least once (utilization rate, 14%; n=11, questionnaire; n=7, walk test). Questionnaire engagement occurred a median of 2 times (range, 1-17) and a median of 7 times (range, 1-15) for the walk test. Four patients engaged with the questionnaire and 6 patients engaged in the walk test beyond week 12. Passive activity was collected for 8 patients beyond week 12. Among patients who engaged the QoL questionnaire and walk test, compliance rates were 18% and 21%, respectively.

Conclusions

This initial study showed that a subset of patients was willing to participate in the self-administered QoL questionnaire and activity tracker. Further comparison of app results and clinical trial findings are ongoing to explore factors affecting utilization and compliance rates.