

IDIOPATHIC HYPERSOMNIA SYMPTOM DIARY (IHSD): DEVELOPMENT OF A NEW PATIENT REPORTED OUTCOME (PRO) MEASURE

Authors: A. Dorenbaum¹, M.C. Lam¹, L. Lien¹, T. Roth², S.D. Mathias³

Institutes: ¹Balance Therapeutics, Inc, San Bruno, ²Henry Ford Health System, Detroit, ³Health Outcomes Solutions, Winter Park, United States

Introduction: Idiopathic hypersomnia (IH) is a rare neurological disorder characterized by a constellation of symptoms related to daytime functioning. We present initial findings on the development of a new PRO, the Idiopathic Hypersomnia Symptom Diary (IHSD), based on qualitative research with individuals with IH.

Materials and methods: Concept elicitation (CE) interviews were conducted with individuals with IH to identify the most important symptoms and impacts experienced by this population. Interview results were analyzed, and the most frequently-reported issues identified were used to develop the IHSO. The draft IHSO contained 4 items assessing the worst severity of common symptoms and impacts including mental fogginess/confusion, exhausted/tired, difficulty remembering things, and difficulty completing tasks or activities, and an overall severity of hypersomnia question.

The IHSD was then cognitively debriefed (CD). Individuals with IH were asked to complete the IHSD and were then asked questions about the meaning of instructions, items, and response options, the clarity and relevance of each item, and appropriateness of the recall period. Input from clinical experts in IH was also obtained.

All interviews were conducted in the US by telephone with individuals diagnosed with IH using semi-structured interview guides, developed specifically for this study. Verbal consent was obtained.

Results: Seven individuals completed the CE interviews (86% female, mean age = 37). The most commonly-reported symptoms and impacts were feeling tired (100%), difficulty completing daily activities (86%), brain fog/mental fogginess (71 %), sleepiness during the day/desire to sleep (71 %) and difficulty remembering things (71 %). Saturation, the point at which no new issues were mentioned in subsequent interviews, was reached by the 5th interview. Four individuals with IH (100% female, mean age:37) completed the 1st round of CD interviews. All individuals were able to accurately paraphrase each IHSD item, and most (75%) found it easy to complete. The draft IHSO was revised based on these interviews to include 2 versions of the questionnaire: one to be asked in the morning and the other to be asked in the early evening. Other revisions included reordering the items and revising some text for clarity. After the 2nd round of interviews (n=2) were conducted, very minor revisions were made to the IHSD for clarity. Clinicians reviewed the IHSD, and no further revisions were recommended. The final versions of the IHSD, to be completed twice each day, contain 4 items assessing the worst severity of mental fogginess/brain fog, difficulty starting or completing tasks or activities, difficulty remembering things, and feeling exhausted/tired, and an overall severity of hypersomnia question.

In general, the full range of responses was used for each item, and the mean time to complete the IHSD was 3 minutes.

Conclusions: This is the first IH-specific PRO measure developed for use in this population. Future research will focus on conducting additional CE and CO interviews in order to confirm the content

validity and clarity and relevance of the IHSD. Its measurement properties will be evaluated in upcoming studies.

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