

obi Obi Trial: Pre-Screen Questions

INSTRUCTIONS: Explore these questions and topics with the client, family, ATP, and treating clinician to help inform the benefit-risk assessment for the patient and determine whether participation in the Obi trial may be appropriate.

MY CLIENT HAS THE:

1	Cognitive ability to reliably understand cause and effect (i.e., activate a switch to perform a function)?	☐ Y ☐ N	 Understands → Activates switch
2	Any visual / visual-processing impairment (e.g., CVI)? If so, what type — and how might it affect their ability to use Obi safely and effectively?	☐ Y ☐ N	 Visual acuity
3	Ability to control their head (extension, flexion, rotation)?	☐ Y ☐ N	 Head control
4	Ability to reliably clear (strip) food from a stationary spoon placed in front of the mouth?	☐ Y ☐ N	 Clear Spoon?
5	Level of excessive movement (tone / spasticity). Can they maintain consistent access to a stationary mounted switch?	☐ Y ☐ N	 Tone / spasticity
6	Ability to maintain a sufficient upright position during a typical meal duration?	☐ Y ☐ N	 Upright posture Full meal
7	The client's level of age-appropriate behavior (any self-injurious / combative behavior)?	☐ Y ☐ N	 Behavior
8	Level of dysphagia (oral-motor, breath, or swallowing impairment)?	☐ Y ☐ N	 Oral-motor Breath Swallow
9	Other known or foreseeable risk / challenge that may compromise benefit / safety?	☐ Y ☐ N	 Other risk?

QUESTIONS FOR FAMILY (Optional)

Completed by family / caregiver — may help flag high-priority trials

	5 Strongly Agree	4 Agree	3 Neutral	2 Disagree	1 Strongly Disagree
1 Restoring self-feeding is a top priority for my loved one (the patient).					
2 Do you feel that, because of the time you spend with your relative, you do not have enough time for yourself?					
3 Do you feel stressed between caring for your relative and meeting other responsibilities for your family or work?					
4 Do you feel your health has suffered because of your involvement with your relative?					
5 Overall, how taxed do you feel in caring for your relative?					

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For additional information on Obi, please refer to the Obi Instructions for Use (IFU). This document is intended to supplement, not replace, the IFU or a comprehensive clinical evaluation.