

# Development and Validation of Brain Fog Questionnaire in Patients and Healthy Volunteers

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## Introduction

- Brain foginess (BF) encompasses a constellation of neurocognitive symptoms that remain poorly characterized, in part due to its multidimensional symptoms.
- They are increasingly seen in gastroenterology patients, particularly those with gas, bloating and distension.
- We developed and psychometrically tested a 19-item questionnaire that described symptoms of importance to both patients and clinicians (Tetangco et al, ACG 2020).
- After due input from patients and clinicians, weightage analysis and item reduction, a 15-item new BF questionnaire (BFQ) was developed.
- Our aim here was to perform a preliminary comparative analysis of BFQ in patients with BF and healthy controls.

## Methods

- In this Phase II questionnaire study, patients with unexplained abdominal gas, bloating, distension, and symptoms of BF for  $\geq 3$  months completed the 15-item BFQ using a visual analogue scale, and a 10-item Gas and Bloating validated questionnaire at baseline and 2-weeks.
- The patients also completed Montreal Cognitive Assessment (MoCA) and Digital Symbol Substitution test (DSST).
- Healthy controls were invited to complete the aforementioned questionnaires.
- Data were compared for test-retest reliability, and between the two groups.

## Results

- Ten patients (8 females, mean age 44.4 years), and 12 healthy controls (5 females, mean age 42.8 years) participated.
- The most severe visual analogue scores for BF symptoms that were reported by patients included feeling sleepy ( $5.8 \pm 0.9$ ), being easily distracted ( $5.8 \pm 1.0$ ), and having difficulty focusing ( $5.5 \pm 0.9$ ).
- The patients had a significantly higher BFQ total score compared to healthy controls ( $65.6 \pm 9.0$  vs  $9.8 \pm 4.1$ ,  $p < 0.001$ ), with all 15 BFQ items significantly higher than healthy controls on BFQ (Table 2).
- There were no significant difference in DSST scores ( $42.8 \pm 6.6$  vs  $61.5 \pm 17.6$ ,  $p = 0.065$ ) or MoCA scores ( $25.6 \pm 0.9$ , vs  $24.9 \pm 3.3$ ,  $p = 0.957$ ) between the two groups.
- The BFQ had a good test-retest reliability ( $ICC = 0.78$ ,  $p = 0.017$ ) for 9/15 BFQ items.

## Table

Brain Fog Questionnaire	Patients				HV's	p value (Pts vs HVs)
	Baseline	2-week	ICC	p value		
I am forgetful and/or experience short-term memory loss	4.5±0.9	4.4±0.7	0.50	0.16	1.0±0.5	<0.01
I have difficulty thinking	4.4±0.6	4.8±0.7	0.84	<b>0.01</b>	0.7±0.4	<0.01
I have difficulty focusing	5.5±0.9	5.2±0.7	0.82	<b>0.01</b>	1.1±0.7	<0.01
I feel cloudy and/or spacey	5.4±1.0	5.3±0.9	0.88	<0.01	0.6±0.4	<0.01
I have difficulty finding the right word(s) to communicate	3.8±0.9	3.6±0.6	0.67	0.06	0.6±0.3	<0.01
I have difficulty understanding what others say	2.8±0.6	3.0±0.7	0.36	0.26	0.2±0.1	<0.01
I feel mentally fatigued and/or exhausted	5.3±1.0	5.0±1.0	0.76	<b>0.02</b>	0.9±0.3	<0.01
I feel that I am slow	3.6±0.9	3.5±0.8	0.78	<b>0.02</b>	0.6±0.4	<b>0.01</b>
My mind goes blank	4.4±0.9	4.2±0.9	0.17	0.39	0.9±0.5	<0.01
I am easily distracted	5.8±1.0	4.9±0.9	0.85	<0.01	1.3±0.7	<0.01
I have difficulty understanding words that I have read	3.5±0.9	2.6±0.7	0.87	<0.01	0.2±0.1	<0.01
I experience confusion	4.0±1.1	3.9±0.9	0.88	<b>0.02</b>	0.2±0.1	<0.01
I feel sleepy	5.8±1.0	5.4±0.8	0.75	<b>0.03</b>	0.8±0.3	<0.01
I feel that my thoughts are moving too quickly	3.3±0.9	3.6±1.0	0.46	0.18	0.2±0.2	<0.01
I go somewhere to do something, but cannot remember why	3.8±0.9	4.4±1.0	0.27	0.32	0.7±0.3	<0.01
Brain Fog Questionnaire total score	65.6±9.0	63.7±8.1	0.78	<b>0.02</b>	9.8±4.2	<0.01

Table: Comparison of brain fog questionnaire responses in patients (baseline vs week 2), and healthy volunteers. On BFQ, patients recorded the overall severity of each item on a 10 cm long horizontal line, with 0 indicating absence of the symptom and 10 indicating severe symptoms.

## Conclusions

- The 15-item BFQ comprehensively captures key symptoms of BF and significantly differentiates healthy controls from BF patients.
- Also, the lack of difference in MoCA and DSST scores between BF patients and healthy controls suggests that these patients do not have cognitive impairment.
- The BFQ has good test-retest reliability, but therapeutic responsiveness requires further study.