

Supplementary Materials

Methods: Subject inclusion and exclusion criteria

Table S1 Subject inclusion and exclusion criteria

Inclusion criteria
Subject signed and dated a written informed consent form
Subjects were aged ≥ 18 years
Subjects had a clinician-confirmed diagnosis of IBS-D (mild, moderate, or severe) and symptoms for ≥ 6 months prior to diagnosis
Subjects had experienced recurrent abdominal pain or discomfort associated with at least two of the three following features for ≥ 3 days a month, for the previous 3 months: (1) improvement with defecation; (2) onset associated with a change in frequency of stool; and (3) onset associated with a change in form (appearance) of stool.
Subjects must have experienced loose (mushy) or watery stools (Type 6 or 7 on the Bristol Stool Form Scale ^{1,2}) in $\geq 25\%$ of bowel movements and hard or lumpy stool in $< 25\%$ of bowel movements in the absence of anti-diarrhea medication or laxative use, in the previous 3 months
Subjects had to be fluent in English, and willing and able to participate in a face-to-face, 90-minute interview
Subjects had to have a device (smartphone or tablet) with an Android or iOS operating system and be willing to download a mobile application or have it done for them
Exclusion criteria
Subject had an organic disease or functional gastrointestinal syndrome, other than IBS-D, potentially affecting the digestive tract passage or colonic function, including structure, obstruction, or ileus

Subject had bowel movement characterized as an Astellas Stool Scale Form ³ ≤3 in the previous 7 days
Subject had benign polyps or colonic diverticulosis judged to have an influence on the digestive tract passage or colonic function
Subject had a history of surgical resection of the stomach, small intestine, or large intestine (excluding resection of appendix or benign polyps)
Subject had a history of ischemic colitis
Subject had a history of unexplained blood passage from the rectum
Subject had uncontrolled lactose intolerance, or was receiving radiotherapy for abdominal disease
Subject had cardiovascular, pulmonary, endocrine, metabolic, hematological, neurologic, or gastrointestinal (excluding IBS-D) disease
Subject had a history of thyroid dysfunction
Subject had any condition or situation that would put the subject at significant risk, could confound the study results, or could interfere significantly with the subject's involvement in the study
Subject had a cognitive impairment or disorder that would interfere with his or her ability to participate in a face-to-face interview
References: <ol style="list-style-type: none"> 1. Lewis SJ, Heaton KW. Stool form scale as a useful guide to intestinal transit time. <i>Scand J Gastroenterol</i>. 1997;32(9):920-924. 2. Heaton K. Understanding your bowels. 3rd ed. Banbury, UK Family Doctor Publications 1999. 3. Lasch K, Delgado-Herrera L, Tesler Waldman L, et al. Development of a new instrument to assess stool form and consistency in irritable bowel syndrome with diarrhea. <i>Gastroenterol Hepatol: Open Access</i>. 2016;4(1).

Methods: Recruitment targets

Table S2 Recruitment targets

Patient characteristics		Target, n (%)
Severity of disease	Mild	8–9 (~33)
	Moderate	8–9 (~33)
	Severe	8–9 (~33)
Age	18–64 years	20 (80)
	≥65 years	5 (20)
Sex	Male	10 (40)
	Female	15 (60)
Education	High school or less	10 (40)
	Some college or higher	15 (60)
Race	Caucasian	15 (60)
	Non-Caucasian	10 (40)
Electronic device	Android	13 (~50)
	iOS	13 (~50)

Interim results

Subjects in wave 1 (n=7), wave 2 (n=8), wave 3 (n=10) interviews reported no issues with interpreting the items similarly between the pen-and-paper and mobile application formats. However, subjects reported some difficulty with interpreting items in the Report History section of the mobile application (**Tables S3, S4, and S5** for waves 1, 2, and 3, respectively). Modifications made after wave 1 and 2 interviews are also presented in **Tables S3 and S4**, respectively).

Table S3 Summary results for wave 1 (n=7), along with modifications made to the mobile application

	Heading	Interview summary	Modifications made
IBS-D Daily Symptom Diary Report History	'# of times passed gas past week' chart and summary	<ul style="list-style-type: none"> Overall, subjects misinterpreted the vertical axis of the chart as number of times gas passed rather than the categorized frequency of episodes of passing gas in the past week (ie, 4=all of the time, 3=most of the time, 2=some of the time, 1=a little of the time, 0=none of the time) Specifically, misinterpreted: <ul style="list-style-type: none"> Chart vertical axis as representing the number of episodes of passing gas (n=2) Number of times passed gas on Wednesday on chart as referring to the number of episodes of passed gas rather than 'some of the time' (n=5) Results in chart summary as referring to the number of episodes of passed gas rather than 'some of the time' 	Heading revised to: 'How often passed gas past week'
	'# of accidents past week' chart	<ul style="list-style-type: none"> Overall, subjects could not tell the number of days with accidents represented by the pie chart as they did not understand that the chart represented the number of days with and without accidents Additionally, interpreted the chart as number of accidents in the past week (n=2) 	Chart to display the actual number of days with and without accidents
	'Total IBS-D pain, cramping,	<ul style="list-style-type: none"> Overall, subjects expressed confusion and difficulty understanding the composite score 	Heading revised to: 'Summary of IBS-D symptoms (pain,

	and pressure score over the past week' chart	<ul style="list-style-type: none"> Subjects misinterpreted: <ul style="list-style-type: none"> Composite score as an average of all the previous charts/questions (n=2) Their pain tolerance level (n=1) Number of days with symptoms (n=1) 	cramping, and pressure) over the past week'
	'Total IBS-D pain, cramping, and pressure score over the past week' chart summary	<ul style="list-style-type: none"> Overall, subjects expressed confusion as to the meaning of the 'total score' in the summary Subjects misinterpreted: <ul style="list-style-type: none"> Total score as an average of all the previous questions (n=1) Their pain tolerance level (n=1) Could not provide a response (n=1) 	Heading revised to: 'Summary of IBS-D symptoms (pain, cramping, and pressure) over the past week' Summary screen to indicate that the summary score is a rating out of 10 (ie, '6/10')
IBS-D Symptom Event Log	'# of bowel movements today'	<ul style="list-style-type: none"> Difficulty in interpreting 24-hour time format (n=2) 	Revised summary screen to display time in 12-hour clock format
Report History	'Immediacy of need today' chart	<ul style="list-style-type: none"> Difficulty in interpreting the vertical axis of the chart (n=1) 	
	'Immediacy of need today' summary	<ul style="list-style-type: none"> Difficulty interpreting the average immediacy of need number (n=1) 	
Usability of mobile application		<ul style="list-style-type: none"> Overall, subjects found the mobile application easy to use Difficulty downloading and/or installing the application onto their mobile devices (n=4) 	

		<ul style="list-style-type: none">• On some screens the font size was small, making it difficult to read clearly (n=2)• Suggestion that the mobile application buttons could be made to stand out more clearly (n=1)• Difficulty in knowing which questionnaire section was referred to by the 'Daily Symptom Diary' and 'Symptom Event Log' mobile application buttons (n=1)	
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Table S4 Summary results for wave 2 (n=8), along with modifications made to the mobile application

	Heading	Interview summary	Modifications made
IBS-D Daily Symptom Diary Report History	'# of times passed gas past week' summary screen		'How often passed gas past week'
	'# of accidents past week' chart	<ul style="list-style-type: none"> Overall, subjects expressed hesitation in telling the number of days with accidents represented by the pie chart. Additionally, interpreted chart as number of accidents in the past week rather than number of days with accidents in the past week (n=2). 	'# of days with accidents past week'
	'# of accidents past week' summary screen	<ul style="list-style-type: none"> Misinterpreted the summary as reporting the number of accidents in the past week rather than the number of days with accidents (n=2) 	'# of days with accidents past week' and added the word 'days' to the right of the number in the circle at the top of the screen
	'Summary of IBS-D symptoms (pain, cramping, and pressure) over the past week' chart	<ul style="list-style-type: none"> Misinterpreted the composite score as an average of all the previous charts/questions (n=3) 	Revised headings to 'Average severity of IBS-D pain, cramping, and pressure over the past week' and added the word 'severe' to the key at the bottom of the chart

	<p>Summary of IBS-D Symptoms (pain, cramping, and pressure) over the past week' summary screen</p>	<ul style="list-style-type: none"> • Misinterpreted the total score as: <ul style="list-style-type: none"> – Percentage of time in which they experienced symptoms (n=1) – Number of symptoms experienced (n=1) – Average of all of all the previous charts/questions (n=1) 	<p>Revised headings to 'Average severity of IBS-D pain, cramping, and pressure over the past week' and added the word 'severe' to the key at the bottom of the summary screen.</p> <p>Revised the summary screen so that the key for the 0 to 10 rating appears directly below '6/10'</p>
Usability of mobile application		<ul style="list-style-type: none"> • Overall, subjects found the mobile application easy to use. • Difficulty downloading and/or installing the application onto their mobile devices (n=4) • Font size was small, making it difficult to read clearly (n=4) • 'Back' buttons on the mobile application screens were too small and did not work as intended when pressed (n=1) 	

Table S5 Summary results for wave 3 (n=10)

	Heading	Interview summary
General		<ul style="list-style-type: none"> Subjects were unable to identify which questionnaire results they would be viewing if they selected 'Daily Symptom Diary' or 'Symptom Event Log' (n=7)
IBS-D Daily Symptom Diary Report History	'Severity of abdominal pain past week' chart	<ul style="list-style-type: none"> Misinterpreted the vertical axis and point on the chart as the days of the week rather than severity (n=2)
	'Severity of abdominal pain past week' summary screen	<ul style="list-style-type: none"> Misinterpreted the summary screen as the day of the week rather than severity (n=2)
	'How often passed gas past week' chart and summary screen	<ul style="list-style-type: none"> Overall, subjects misinterpreted the vertical axis of the chart as the number of episodes of passed gas rather than the categorized frequency of episodes of passing gas in the past week (ie, 4=all of the time, 3=most of the time, 2=some of the time, 1=a little of the time, 0=none of the time) Misinterpreted results in the chart summary as referring to number of episodes of passed gas rather than 'some of the time' (n=4)
	'# of days with accidents past week' chart and summary screen	<ul style="list-style-type: none"> Overall, subjects could not tell the number of days with accidents represented by the pie chart as they did not understand that the chart and summary represented the number of days with and without accidents
	'Average severity of IBS-D pain, cramping, and pressure over the past week' chart	<p>Overall, subjects continued to express confusion and difficulty understanding the composite score.</p> <p>Misinterpreted the composite score as:</p> <ul style="list-style-type: none"> Average of all the previous charts/questions (n=1) Level of tolerance to the symptoms (n=1) Number of accidents in the previous week (n=1)

		<ul style="list-style-type: none"> – Average intensity and frequency of all the previous charts/questions (n=1)
	'Average Severity of IBS-D pain, cramping, and Pressure over the past week' summary screen	<ul style="list-style-type: none"> • Overall, subjects expressed confusion understanding the summary composite score. • Misinterpreted the summary score as: <ul style="list-style-type: none"> – Experiencing symptoms 6/10 days (n=3) – Average of either all the previous charts/questions (n=2) or only two of the previous charts/questions (n=2) – Experiencing symptoms 60% of the time, average level of symptom tolerance, number of episodes of cramping, or experiencing 6 out of 10 symptoms (n=1) – Unable to understand the meaning of the summary composite score (n=1)
	'Past month' and 'past 3 months' charts	<ul style="list-style-type: none"> • Misinterpreted the horizontal axis of the charts as the lowest level of the symptoms represented by the chart (n=3) or as the level of pain tolerance (n=1)
IBS-D Symptom Event Log	'# of bowel movements today' chart	<ul style="list-style-type: none"> • Misinterpreted the chart as bowel movement severity (n=1)
Report History	'Bowel movement appearance today' chart and summary screen	<ul style="list-style-type: none"> • Overall, subjects misinterpreted the meaning of the vertical axis in the chart and the average shown on the summary screen. • Misinterpreted the vertical line in the chart as the quantity of bowel movements (n=2) • Misinterpreted the summary as representing bowel movement appearance over 5 days (n=1) or a week (n=1) • Unable to understand the meaning of the summary average bowel movement appearance (n=1)
	'Feeling of complete	<ul style="list-style-type: none"> • Misinterpreted the chart as the number of bowel movements (n=1)

	emptying today' chart	
Usability of mobile application		<ul style="list-style-type: none"> • Overall, subjects found the mobile application easy to use. • Difficulty downloading and/or installing the application onto their mobile devices (n=4) • Font size was small, making it difficult to read clearly (n=3) • Font was difficult to read when on a gray background (as on a mobile application button) (n=1)

Table S6 Interpretation of response options for conceptual equivalence across formats
for the IBS-D Daily symptom Diary

	Response	Conceptual equivalent, n %			Data not collected, n (%)
		Yes	No	Unclear	
Item 1: Abdominal pain	0 – No	24 (96)	0 (0)	1 (4)	0 (0)
	10 – Most severe	24 (96)	0 (0)	1 (4)	0 (0)
Item 2: Abdominal cramps	0 – No	23 (92)	0 (0)	2 (8)	0 (0)
	10 – Most severe	25 (100)	0 (0)	0 (0)	0 (0)
Item 3: Abdominal pressure	0 – No	24 (96)	0 (0)	1 (4)	0 (0)
	10 – Most severe	25 (100)	0 (0)	0 (0)	0 (0)
Item 4: Bloating severity	0 – Not bloated	24 (96)	0 (0)	1 (4)	0 (0)
	10 – Extremely bloated	24 (96)	0 (0)	1 (4)	0 (0)
5 Item: Frequency of passing gas	None of the time	24 (96)	0 (0)	1 (4)	0 (0)
	A little of the time	23 (92)	0 (0)	1 (4)	1 (4)
	Some of the time	21 (84)	0 (0)	4 (16)	0 (0)
	Most of the time	24 (96)	0 (0)	0 (0)	1 (4)
	All of the time	24 (100)	0 (0)	1 (4)	0 (0)
Item 6: Accidents	Yes	20 (80)	0 (0)	5 (20)	0 (0)
	No	23 (92)	0 (0)	2 (8)	0 (0)

Table S7 Interpretation of response options for conceptual equivalence across formats
for the IBS-D Symptom Event Log

	Category	Conceptual equivalent, n %			Data not collected, n (%)
		Yes	No	Unclear	
Item 1: Date and time of bowel movement	–	–	–	–	25 (0)
Item 2: Immediacy of need	No	23 (92)	1 (4)	1 (4)	0 (0)
	Slight	22 (88)	0 (0)	3 (12)	0 (0)
	Moderate	23 (92)	0 (0)	1 (4)	1 (4)
	Quite a bit	23 (92)	0 (0)	2 (8)	0 (0)
	Extreme	25 (100)	0 (0)	0 (0)	0 (0)
Item 3: Bowel movement appearance	Like marbles or hard rocks	25 (100)	0 (0)		0 (0)
	Single solid clumpy stool	24 (96)	0 (0)	1 (4)	0 (0)
	Hard, solid formed, harder to pass	24 (96)	0 (0)	1 (4)	0 (0)
	Smooth, a softer stool	24 (96)	0 (0)	1 (4)	0 (0)
	Soft chunks or clumps	24 (96)	0 (0)	1 (4)	0 (0)
	Loose, mushy stool	23 (92)	0 (0)	2 (8)	0 (0)

	Watery and muddy	24 (96)	0 (0)	1 (4)	0 (0)
	Just liquid	24 (96)	0 (0)	1 (4)	0 (0)
Item 4: Feeling of complete emptying	Yes	25 (100)	0 (0)	0 (0)	0 (0)
	No	25 (100)	0 (0)	0 (0)	0 (0)

Notes: Difference was not due to the type of format

Table S8 Interpretation of the mobile application Report History for the IBS-D Daily symptom Diary

Chart item	Interpretation parameter	Interpretation as intended, n (%)			Data not collected, n (%)
		Yes	No	Insufficient data	
Item 1: Abdominal pain severity	Horizontal axis (days of the week)	25 (100)	0 (0)	0 (0)	0 (0)
	Vertical axis (severity)	24 (96)	0 (0)	1 (4)	0 (0)
	Data point on chart	24 (96)	1 (4)	0 (0)	0 (0)
	Summary screen	22 (88)	3 (12)	0 (0)	0 (0)
Item 2: Abdominal cramps severity	Vertical axis (severity)	25 (100)	0 (0)	0 (0)	0 (0)
	Data point on chart	24 (96)	1 (4)	0 (0)	0 (0)
	Summary screen	24 (96)	1 (4)	0 (0)	0 (0)
Item 3: Abdominal pressure	Vertical axis (severity)	24 (96)	1 (4)	0 (0)	0 (0)
	Summary screen	23 (92)	2 (8)	0 (0)	0 (0)
Item 4: Bloating severity	Vertical axis (severity)	24 (96)	0 (0)	1 (4)	0 (0)
	Summary screen	24 (96)	1 (4)	0 (0)	0 (0)
Item 5: Frequency of passing gas	Vertical axis (how often)	18 (72)	6 (24)	1 (4)	0 (0)

	Data point on chart	9 (36)	14 (56)	1 (4)	1 (4)
	Summary screen	20 (80)	4 (16)	0 (0)	1 (4)
Item 6: Accidents (number of days in past week)	Difficulty interpreting chart	18 (72)	5 (20)	2 (8)	0 (0)
	Able to identify number from chart	20 (80)	5 (20)	0 (0)	0 (0)
	Summary screen	24 (96)	1 (4)	0 (0)	0 (0)
Average severity of abdominal pain, cramping, and pressure	Chart and associated summary page	12 (48)	10 (40)	3 (12)	0 (0)
	Vertical axis	20 (80)	3 (12)	2 (8)	0 (0)
	Average severity summary screen	13 (52)	12 (48)	0 (0)	0 (0)
Filters (phrases)	Past week	25 (100)	0 (0)	0 (0)	0 (0)
	Past month	25 (100)	0 (0)	0 (0)	0 (0)
	Past 3 months	24 (96)	0 (0)	1 (4)	0 (0)
	Horizontal axis	23 (92)	2 (8)	0 (0)	0 (0)