

Patient Survey Results for FDA Drug Development Meeting for ME and CFS, April 25-26, 2013
 For more information, contact Lily Chu (lilyxchu@gmail.com)

Demographics

Age (*n* = 623)

Mean = 51.2 years
 Standard Deviation = 12.9

Gender (*n* = 616)

Female	86.2%
Male	12.8%
Prefer not to answer	1.0%

Education (*n* = 623)

Less than high school	1.0%
Some high school	1.9%
High school degree / GED	6.7%
Partial college	23.3%
College degree	35.6%
Graduate / Professional degree	31.1%
Prefer not to answer	0.3%

Race (*n* = 618)

White	96.1%
American Indian / Alaska Native	1.6%
Asian / Pacific Islander	1.6%
Prefer not to answer	1.1%
Other	1.1%
Black / African American	0.5%

Length of Illness (*n* = 617)

Mean = 17.9 years
 Standard Deviation = 11.1

How Sample Participated in FDA Meeting (*n* = 482)

Solely through this survey	49.4%
Submitted responses to FDA questions	19.7%
Completed CFIDS Association survey	41.3%
Attended FDA meeting	4.6%

Symptom Significance

Percent Indicating Symptom is Major Problem (*n* = 561)

Exhaustion after mild activity	92.5%
Fatigue	90.0%
Increase in symptoms after mild activity	86.1%
Sleep problems	82.5%
Memory / Concentration issues	75.9%
Pain	66.7%
Sensitivities	61.1%
Temperature intolerance	58.7%
Stomach problems	55.9%
Cardiovascular problems	52.7%
Flu-like symptoms	43.8%

Percent Including Symptom in Top 5 Most Significant (*n* = 475)

Fatigue	71.4%
Exhaustion after mild activity	63.2%
Memory / Concentration issues	58.7%
Increase in symptoms after mild activity	58.3%
Pain	57.7%
Sleep problems	54.9%
Stomach problems	30.9%
Cardiovascular problems	30.7%
Sensitivities	28.0%
Flu-like symptoms	18.3%
Temperature intolerance	17.1%

Impact of Illness:**Illness Course (n = 551)**

Relapsing / Remitting / Fluctuating	54.4%
Getting worse	27.4%
Persisting	17.1%
Improving	1.1%

Maximum Activity Level on Best Days (n = 549)

Bedridden	3.3%
Can walk around house	18.9%
Can do light housework	53.2%
Can only work part-time or on some household tasks	13.7%
Can only work full-time; nothing else	6.2%
Can only work full-time plus household tasks	3.6%
No limitations	1.1%

SF-36 Physical Functioning Score (n = 522)

Mean = 25.2

Standard Deviation = 19.9

This sample's mean is lower than means of individuals with congestive heart failure, chronic lung disease, and osteoarthritis with hypertension

General Population Mean = 84.15 (SD = 23.28)¹

1: Ware, J., Snow, K., Kosinski, M., Gandek, B. (2000). *SF-36 Health Survey®: Manual and Interpretation Guide*. Lincoln, RI: QualityMetric Incorporated.

Percent Indicating Illness Has Affected Daily Activities (n = 553)

Social / Family activities	99.8%
Household tasks	99.6%
Work / School activities	99.4%
Personal care activities	88.8%

Maximum Activity Level on Worst Days (n = 551)

Bedridden	61.0%
Can walk around house	31.8%
Can do light housework	4.7%
Can only work part-time or on some household tasks	1.3%
Can only work full-time; nothing else	1.1%
Can only work full-time plus household tasks	0.2%
No limitations	0.0%

Work Status (n = 620)

Disability due to CFS or ME	53.4%
Unemployed due to CFS or ME	21.9%
Retired	9.9%
Disability (other medical reason)	8.0%
Working part time	7.0%
Working full time	5.7%
Homemaker	4.0%
Student	2.3%
Other	2.1%
Unemployed (other reason)	1.3%

Effects of Treatments:**Overall Effect of Current Treatments (n = 491)**

Not helpful	22.8%
Slightly helpful	49.5%
Moderately helpful	23.9%
Very helpful	3.8%

Effect of Current Treatments on Activity Level (n = 487)

No improvement in any area	56.8%
Improvement in personal care abilities	31.0%
Improvement in household task abilities	24.5%
Improvement in cognitive abilities	16.3%
Improvement in social life	14.4%
Improvement in work/school life	6.5%

Treatments:**Sleep Treatments:**

Treatment	# Tried	Improved	Worsened	No Effect
Benzodiazepines	232	76.3%	8.6%	15.1%
Zolpidem	232	64.7%	18.5%	16.8%
Tricyclic antidepressants	238	54.6%	18.5%	26.9%
OTC medications	315	53.0%	10.2%	36.8%
CPAP	84	52.4%	19.0%	28.6%
Eszopiclone	105	50.5%	22.9%	26.7%
Melatonin	333	47.4%	9.3%	43.2%
Trazodone	164	47.0%	24.4%	28.7%
Mirtazapine	50	42.0%	30.0%	28.0%
Zaleplon	60	40.0%	21.7%	38.3%
Quetiapine	47	38.3%	34.0%	27.7%
Sleep hygiene changes	429	34.7%	7.2%	58.0%
SSRI	174	13.2%	40.8%	46.0%
Ramelton	42	7.1%	38.1%	54.8%

General Treatments*:

Treatment	# Tried	Improved	Worsened	No Effect
Pacing	451	71.0%	3.8%	21.5%
Rintatolimod	33	33.3%	21.2%	15.2%
Informal exercise plan	424	28.8%	41.5%	21.9%
Antibiotics	232	28.4%	15.5%	41.4%
Antivirals	198	27.8%	13.1%	30.8%
Inosine Pranobex	58	27.6%	12.1%	46.6%
Etanercept/Anakinra	16	18.8%	18.8%	12.5%
Formal exercise plan	293	16.4%	63.5%	11.3%
Rituximab	14	14.3%	35.7%	21.4%
Inflximab/Adalimumab	14	7.1%	21.4%	21.4%

*An additional category of participants (not shown) indicated that treatment had mixed effects or were unsure of treatment's effect

Pain Treatments*:

Treatment	# Tried	Improved	Worsened	No Effect
Short-acting opioids	245	64.9%	4.1%	7.3%
Ibuprofen	440	62.0%	1.6%	25.0%
Long-acting opioids	110	60.9%	7.3%	10.9%
Biofeedback/Meditation	305	53.8%	3.9%	38.0%
Chiropractor	264	53.0%	12.5%	28.0%
Cyclobenzaprine	199	49.7%	6.5%	27.1%
Acupuncture	246	46.3%	8.5%	32.5%
Tramadol	181	43.6%	6.6%	29.3%
Physical therapy	272	41.9%	25.0%	27.6%
Acetaminophen	407	41.8%	2.5%	49.4%
Other NSAID	100	40.0%	3.0%	41.0%
Pain doctor	142	39.4%	8.5%	43.7%
Anticonvulsants	234	38.5%	10.7%	29.5%
Celecoxib	117	36.8%	7.7%	37.6%
Low dose naltrexone	117	36.8%	9.4%	38.5%
Acetylsalicylic acid	319	34.2%	1.6%	51.7%
Duloxetine/Milnacipran	169	32.0%	14.2%	27.8%
Tricyclic antidepressants	197	24.9%	7.1%	46.2%

Cognitive Treatments*:

Treatment	# Tried	Improved	Worsened	No Effect
Behavioral measures	441	71.2%	0.9%	24.0%
Caffeine	413	47.7%	9.0%	31.7%
Thinking exercises	371	39.6%	18.1%	36.1%
Amphetamine salts	76	32.9%	21.1%	19.7%
Methylphenidate	91	25.3%	20.9%	33.0%
Modafinil/Armodafinil	143	23.1%	23.1%	34.3%

Tests:**Results of Testing**

Test	# Tested	Abnormal	Normal	Unsure
Tilt table	171	77.2%	17.5%	5.3%
Natural killer cell activity	228	73.2%	5.7%	21.1%
Repeated CPET	204	60.8%	34.3%	4.9%

Results of Testing (continued)

Test	# Tested	Abnormal	Normal	Unsure
Neuropsychological test	226	50.9%	30.5%	18.6%
Brain imaging	288	45.8%	47.9%	6.3%