Patient Survey Results for FDA Drug Development Meeting for ME and CFS, April 25-26, 2013

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Demographics:

Age *(n = 477)*

Mean = 51.0 years
Standard Deviation = 13.3

Gender *(n = 475)*

Female	84.6%
Male	13.7%
Other / Prefer Not to Answer	1.7%

Length of Illness *(n = 444)*

Mean = 17.9 years
Standard Deviation = 10.9

Race *(n = 473)*

White	96.2%
Asian / Pacific Islander	1.7%
American Indian / Alaska Native	1.5%
Prefer Not to Answer	1.3%
Black / African American	0.6%

How Sample Participated in FDA Meeting *(n = 363)*

Solely through this survey	49.0%
Submitted responses to FDA questions	18.2%
Completed CFIDS Association survey	41.9%
Attending FDA meeting	4.1%

Symptom Significance:

Percent Indicating Symptom is *Major* Problem *(n = 427)*

Exhaustion after mild physical / mental activity	92.7%
Fatigue / Extreme tiredness	90.1%
Increase in symptoms after mild physical / mental activity	86.6%
Sleep problems	82.2%
Memory / Concentration issues	74.2%
Pain	65.2%
Temperature intolerance	58.4%
Sensitivities	57.9%
Stomach problems	55.7%
Cardiovascular problems	54.3%
Flu-like sypmtoms	43.2%

Percent Including Symptom in Top 5 Most Significant *(n = 397)*

Fatigue / Extreme tiredness	67.8%
Exhaustion after mild physical / mental activity	60.2%
Increase in symptoms after mild physical / mental activity	53.1%
Pain	50.4%
Sleep problems	51.4%
Memory / Concentration issues	52.1%
Sensitivities	24.2%
Stomach problems	30.5%
Cardiovascular problems	29.0%
Flu-like sypmtoms	16.6%
Temperature intolerance	14.6%

Impact of Illness:

Illness Course *(n = 417)*

Improving	1.0%
Persisting	17.0%
Getting worse	28.5%
Relapsing / Remitting / Fluctuating	53.5%

Percent Indicating Illness Has Affected Daily Activities *(n = 415)*

Household tasks	100.0%
Work / School activities	99.5%
Social / Family activities	98.6%
Personal care activities	88.8%

Maximum Activity Level on *Best* Days *(n = 415)*

Bedridden	3.1%
Can walk around house	18.8%
Can do light housework	54.2%
Can only work part-time/do some household tasks	13.5%
Can only work full-time; nothing else	5.5%
Can only work full-time plus household tasks	3.9%
No limitations	1.0%

Maximum Activity Level on *Worst* Days *(n = 418)*

Bedridden	60.8%
Can walk around house	32.5%
Can do light housework	3.8%
Can only work part-time/do some household tasks	1.7%
Can only work full-time; nothing else	1.0%
Can only work full-time plus household tasks	0.2%
No limitations	0.0%

SF-36 Physical Functioning Score *(n = 400)*

Mean = 24.9
Standard Deviation = 19.7
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]

Work Status *(n = 474)*

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%

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

Tests:

Results of Testing

Test	# Tested	Abnormal	Normal	Not Sure
Tilt table	132	79.5%	15.9%	4.5%
Natural killer cell activity	172	70.3%	7.0%	22.7%
Repeated CPET	153	63.4%	31.4%	5.2%
Neuropsychological test	172	53.5%	30.8%	15.7%
Brain imaging	216	45.8%	48.6%	5.6%

Treatments:

Sleep Treatments:

Treatment	# Tried	Improved	Worsened	No Effect
Benzodiazepines	174	77.0%	9.2%	13.8%
Zolpidem	170	63.5%	20.6%	15.9%
OTC medications	232	56.5%	9.5%	34.1%
Tricyclic Antidepressants	179	52.0%	19.6%	28.5%
Eszopiclone	78	51.3%	24.4%	24.4%
CPAP	63	50.8%	17.5%	31.7%
Trazodone	125	49.6%	23.2%	27.2%
Melatonin	250	46.4%	8.0%	45.6%
Zaleplon	40	42.5%	27.5%	30.0%
Quetiapine	39	41.0%	35.9%	23.1%
Mirtazapine	35	37.1%	31.4%	31.4%
Sleep hygiene changes	326	35.0%	6.4%	58.6%
SSRI	131	13.0%	38.9%	48.1%
Ramelton	29	6.9%	37.9%	55.2%

General Treatments*:

Treatment	# Tried	Improved	Worsened	No Effect
Pacing	346	69.4%	3.8%	23.1%
Rintatolimod	25	40.0%	20.0%	16.0%
Informal exercise plan	319	27.6%	42.6%	24.1%
Antibiotics	162	27.2%	16.7%	45.1%
Inosine Pranobex	46	26.1%	6.5%	50.0%
Antivirals	149	24.2%	14.1%	30.9%
Etanercept/Anakinra	11	18.2%	18.2%	9.1%
Rituximab	6	16.7%	33.3%	16.7%
Formal exercise plan	219	15.1%	61.6%	13.7%
Inflaximab/Adalimumab	11	9.1%	18.2%	27.3%

Pain Treatments*:

Treatment	# Tried	Improved	Worsened	No Effect
Short-acting opioids	185	68.6%	2.7%	9.2%
Ibuprofen	333	63.1%	1.5%	24.3%
Long-acting opioids	83	62.7%	8.4%	12.0%
Biofeedback/Meditation	218	56.0%	3.2%	39.9%
Chiropractor	198	53.5%	12.6%	29.3%
Acupuncture	185	50.8%	8.1%	32.4%
Cyclobenzaprine	152	50.7%	6.6%	27.0%
Tramadol	139	46.8%	6.5%	28.8%
Acetaminophen	306	43.1%	2.3%	49.7%
Pain doctor	109	42.2%	10.1%	44.0%
Other NSAID	72	41.7%	4.2%	44.4%
Physical therapy	205	40.5%	27.3%	29.3%
Celecoxib	88	37.5%	6.8%	38.6%
Low dose naltrexone	93	36.6%	9.7%	37.6%
Anticonvulsant	173	36.4%	9.8%	30.1%
Acetylsalicylic acid	235	33.6%	1.3%	51.5%
Duloxetine/Milnacipran	125	30.4%	14.4%	32.8%
Tricyclic Antidepressants	147	21.1%	6.1%	50.3%

Cognitive Treatments*:

Treatment	# Tried	Improved	Worsened	No Effect
Behavioral measures	333	71.2%	1.2%	24.3%
Caffeine	312	48.7%	8.0%	32.4%
Thinking exercises	274	40.5%	17.9%	36.9%
Amphetamine salts	59	35.6%	16.9%	20.3%
Modafinil/Armodafinil	105	24.8%	21.9%	32.4%
Methylphenidate	67	23.9%	22.4%	35.8%

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

Effects of Treatments:

Overall Effect of Current Treatments *(n = 372)*

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

Effect of Current Treatments on Activity Level *(n = 368)*

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%