

Minimum data elements for research reports on CFS.

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Table 1: Minimal Data Elements

Study design

- Type of study (e.g. case-control; case-only; cross-sectional; longitudinal)
- Recruitment method, site and time-frame
- Dates and time intervals of data collection
- Randomized protocol (when employed)
- Primary and secondary outcomes
- Language(s) used to collect data
- Statistical methods
- Ethical review

Demographics of study population

- Age, race, ethnicity, sex
- Educations, socioeconomic status
- Body mass index
- Marital status, children, living arrangements
- Employment/disability status
- Mode of onset of illness (e.g., acute, gradual; definition used to determine)
- Duration of illness
- Factors that exacerbate or trigger illness (desirable)

Case definition

- Specify case definition used for enrollment and methods used to apply definition
- Cite reference for questionnaires and scoring, or provide copies and scoring algorithm in supplementary material

Symptom Inventory

- Include all case defining symptoms, frequency and severity
- Sleep
- Pain
- Include reference to questionnaire and scoring method, or provide copy in supplemental material

Medical and psychiatric exclusions and co-morbidities

- Screening laboratory tests and cut-off values for exclusion
- Exclusionary medical and psychiatric conditions - method of ascertainment
- Methods used to evaluate controls for medical/psychiatric conditions
- List of co-morbid conditions in study population
- Current medications

Self-reported functional impairment/levels of activity

- Specify instrument/questionnaire used, and method of scoring; validated options include:
 - Medical Outcomes Survey Short Form-36
 - Short Form-12
 - Sickness Impact Profile
 - International Physical Activity questionnaire
 - The Seven-day Physical Activity Recall Questionnaire
 - Tune logs such as Activity Record (ACTRE) (Gerbrand Furst, 1992)

Table 2: Additional Elements

Functional Assessment

- Maximal or submaximal exercise test
- Actigraphy, pedometers

Cognition

- Cambridge Neuropsychological Test Automated Battery

Allostatic load

- Body mass index, waist-hip ratio
- Blood pressure
- Heart rate variability
- Interleukin 6 (IL-6)
- Serum Aldosterone,
- 24 h urinary cortisol

Hypothalamic-Pituitary-Adrenal axis activity

- Morning or diurnal salivary cortisol curve
- ACTH
- FSH and LH (follicular or luteal phase of menstrual cycle)
- Prolactin

Immune functioning and allergies

- Natural killer cell function
- Plasma cytokines
- Soluble mediators (cytokine receptors, Neuropeptide Y)
- EBV early antigen or IGM EBV, CMV
- IGE or skin test measures for inhalant allergens (pollen, mold, dust mites, animal dander)

Sympathetic activity

- Salivary amylase (surrogate for blood catecholamine levels)
- Heart rate variability

Coping

- Locus of control
- Beliefs towards illness
- Other coping questionnaires

Genomic and transcriptomic studies

- Genome-wide association studies (GWAS)
- Whole-genome sequencing studies (WGS)
- Transcriptional analysis (mRNA) studies
- Epigenetic studies

Proteomic studies

- Identify as possible disease-defining biomarker, disease-activity biomarker, prognostic biomarker or therapeutic biomarker
- Identify as type 0, 1 or 2 biomarker as defined in Frank and Hargreaves (2003)
- Describe methodology used (e.g. high-performance LC-MS/MS, accurate inclusion mass screening 11 (AIMS), stable isotope dilution (SID)-MRM-MS (Addona et al., 2011))