

Content of the document submitted on February 9, 2025 by the Association of People with Myalgic Encephalomyelitis, PEM (NGO PEM), public consultation prior to the drafting of the Royal Decree that will develop Law 3/2024, of October 30, to improve the quality of life of people with Amyotrophic Lateral Sclerosis (ALS) and other diseases or processes of high complexity and irreversible course.

Hereby, the **Association of People with Myalgic Encephalomyelitis, PEM**, a national non-profit organization, in the name and on behalf of its associates and in defense of all people with Myalgic Encephalomyelitis (hereinafter referred to as ME)

REQUESTS:

That MYALGIC ENCEPHALOMYELITIS be included in the list of diseases and processes to be included in the annex of the Royal Decree that will implement Law 3/2024, of October 30 (hereinafter, ALS Law), as it is an ailment that meets each and every one of the requirements demanded by said Law.

AND COMMUNICATES:

That the Plataforma Ciudadana Movilización Persistente, a platform that unites family members and chronic patients of PERSISTENT COVID AND MYALGIC ENCEPHALOMYELITIS from all over Spain to defend the CONSTITUTIONAL RIGHTS OF THESE CITIZENS WHO HAVE BEEN ILL, ENDORSES THE CONTENTS OF THIS DOCUMENT AND SUPPORTS IT IN ITS ENTIRETY.



Myalgic Encephalomyelitis is an organic, chronic and multisystemic disease that compromises and seriously damages the health and quality of life of the people who suffer from it and their environment and that profoundly limits their functional capacity. However, given that the pathology is deeply unknown, we have prepared this paper that justifies in detail with extensive scientific references of the highest national and international prestige why this pathology and its patients meet the requirements of the ALS Act and, consequently, should be covered by it.

In this context, the [table of contents](#) of this document is as follows:

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- A. Irreversible condition with a significant reduction in survival.
- B. Not having had a significant response to treatment, or when there are no therapeutic alternatives that improve the functional status or prognosis of these people.
- C. Require complex social and health care, centered in the home and with a high impact on the immediate environment of the affected persons.
- D. Have a rapid progression in some of these processes that requires accelerating administrative processes of assessment and recognition of the degree of disability or dependence.

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1. Introduction to ME: context and main features of the disease

A. Overview

Myalgic Encephalomyelitis is an organic, chronic, multisystemic disease that seriously compromises and damages the health and quality of life of those who suffer from it and profoundly limits their functional capacity, being incapacitating for work and disabling to different degrees.

It has been recognized by the World Health Organization (WHO) since 1969, and classified as a neurological disease, specifically under the heading "Other disorders of the nervous system", in the framework of the International Classification of Diseases, both in ICD-10, code G93.32, and in ICD-11, code 8E49.

Although there is ample scientific evidence of **countless objective alterations in this disease (immune abnormalities, inflammatory activation, mitochondrial alterations, endothelial and muscular disorders, cardiovascular and neurological alterations and dysfunction of the peripheral and central nervous systems, among others¹**, there are still **no universally accepted treatment protocols** and the etiology is not sufficiently known, which makes it very difficult to deal with this disease, both for patients and health care teams². It is, therefore, an acquired disease, with complex global dysfunctions and difficult to manage, which currently has no cure or specific treatment.

Although several promising biochemical and electrophysiological properties have been identified as potential biomarkers for ME, no quantitative biomarker with sufficient sensitivity, specificity and adaptability to provide a conclusive diagnosis is currently available. This has contributed to the trivialisation, marginalisation, psychiatrisation and misunderstanding of the disease and the use, even today, of controversial, outdated and discredited diagnostic criteria that results in patients receiving inadequate and sometimes even harmful care³.

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- 1 Komaroff, A. L., & Lipkin, W. I. (2021). Insights from myalgic encephalomyelitis/chronic fatigue syndrome may help unravel the pathogenesis of postacute COVID-19 syndrome. *Trends in Molecular Medicine*, 27(9), 895-906. <https://doi.org/10.1016/j.molmed.2021.06.002>.
 - 2 Barbeta, S. L., Martínez, M. C., Mesa, A. L., Vieira, A. D., & Díaz-Rodríguez, C. (2024). Systematic review of the methodology of treatment of chronic fatigue syndrome. *Revista Científica De La Sociedad Española De Enfermería Neurológica*, 100164. <https://doi.org/10.1016/j.sedene.2024.04.002>
 - 3 Espinosa, P., & Urrea, J. M. (2019). Decreased Expression of the CD57 Molecule in T Lymphocytes of Patients with Chronic Fatigue Syndrome. *Molecular Neurobiology*, 56(9), 6581–6585. <https://doi.org/10.1007/s12035-019-1549-7>

Numerous studies⁴ have objectified and replicated (i.e., there is evidence) multiple physiological or pathophysiological clinical alterations or abnormalities (replicated and replicable) in many body systems in people with myalgic encephalomyelitis (often associated with infections -or reactivations- by different types of viruses -enterovirus, EBV, HHV-6, HHV-7, cytomegalovirus, parvovirus B19, SARS and MERS coronaviruses, endogenous retroviruses, bacteria, fungi or parasites, chemical toxins emitted by different microorganisms -bacterial exotoxins or endotoxins, mycotoxins produced by fungi- and exposure to other chemical toxic agents - xenobiotics- or biological agents), given the **multisystemic complexity and the large and complicated biochemical disorders present in this disease**.

Its diagnosis is made through clinical examination as there is still no specific molecular, cellular and/or imaging biomarker for this purpose, and the 2011 International Consensus Criteria should be used for this purpose, as well as for research⁵. However, there is hardly any training on it in the medical career, let alone updated, and at the clinical level, **patients take between 5 and 10 years to achieve a diagnosis and it is estimated that 90% of them are still undiagnosed⁶**. This delay in diagnosis has a negative influence on the prognosis of patients.

The pre-pandemic prevalence rate of COVID-19 is between 0.2% and 2.6% of the world population. **Despite its significant prevalence, ME remains being one of the least studied and misunderstood diseases in modern medicine⁷.**

Myalgic encephalomyelitis occurs in all age groups (including children and adolescents), although it **mainly affects young adults between 20 and 45 years of age**, and in all ethnic groups and social classes, with **women being the main sufferers (up to 75-80% of cases)**. Also, **between 75% and 80% of those affected are unable to work under normal conditions** and to maintain a regular schedule and **25% live confined to their homes and even, in many cases, confined to bed, needing a wheelchair to move around and with continuous assistance/attention even for Basic Activities of Daily Living (hereinafter BADL)**.

ME is included in the EUHealthSupport Consortium's 2023 European Commission report on diseases that place a high burden on the patient and society but are under-researched⁸.

4 Komaroff, A. L., and Lipkin, W. I. (2021). Insights from myalgic encephalomyelitis/chronic fatigue syndrome may help unravel the pathogenesis of post-acute COVID-19 syndrome. Insights from myalgic encephalomyelitis/chronic fatigue syndrome may unravel the pathogenesis of post-acute COVID-19 syndrome. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8180841/>

5 ME_IC_Primer Spanish Translation 2022.pdf. (n.d.). Google Docs. <https://drive.google.com/file/d/14BwTIDvpQmxeqjwUjX--0Xj2fXl7VrI6/view>

6 Clayton, E. W. (2015). Beyond Myalgic Encephalomyelitis/Chronic fatigue syndrome. JAMA, 313(11), 1101. <https://doi.org/10.1001/jama.2015.1346>

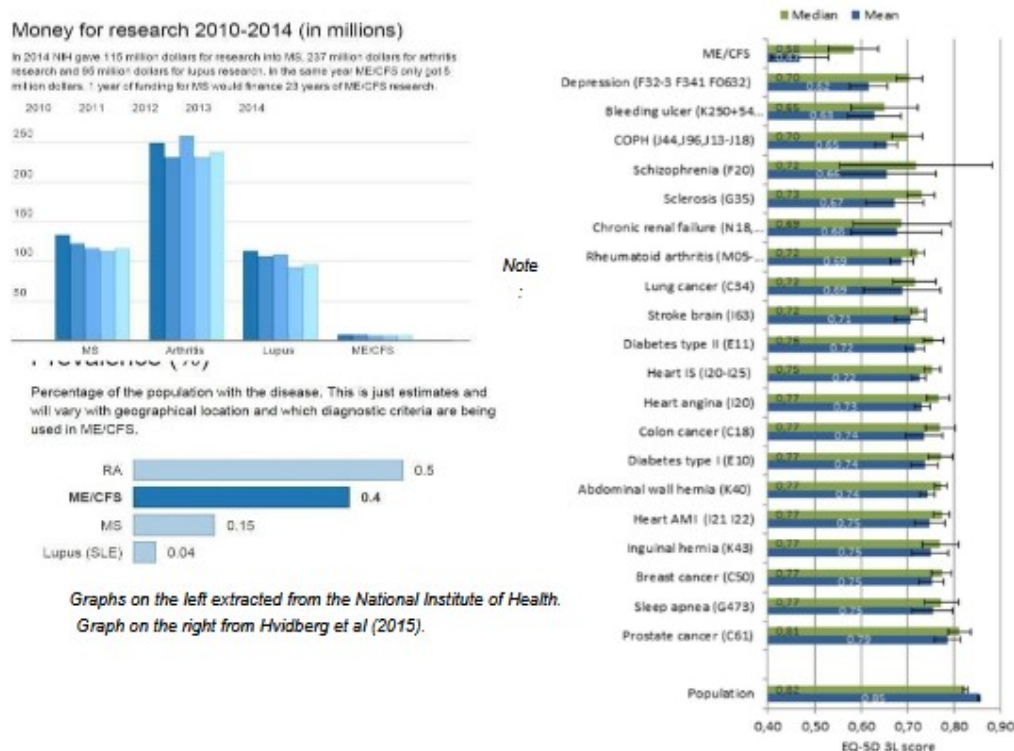
7 Arron, H. E., Marsh, B. D., Kell, D. B., Khan, M. A., Jaeger, B. R., & Pretorius, E. (2024). Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: the biology of a neglected disease. Frontiers in Immunology, 15. <https://doi.org/10.3389/fimmu.2024.1386607>

8 Publications Office of the European Union (2023). Scoping study on evidence to tackle high-burden under-researched medical conditions : discussion paper. Publications Office of the EU.

It is estimated that **ME places an economic burden of €40 billion per year in Europe** in lost productivity and medical costs⁹ and **between \$18 billion and \$51 billion in the United States** in medical expenses and lost income¹⁰.

Also, in 2020, **the European Parliament published a resolution¹¹ urging all Member States to adopt with determination the measures necessary to ensure due recognition of ME.** For the time being, Spain has not implemented this initiative and the ALS law is a unique opportunity to comply with the European mandate.

In short, when compared to other similar diseases, **research on Myalgic Encephalomyelitis is critically scarce while the prevalence is similar or higher than others and the affectation to the quality of life of patients is clearly higher**, as can be seen in the following graphs:



<https://op.europa.eu/en/publication-detail/-/publication/eae32303-96e3-11ed-b508-01aa75ed71a1/language-en>

9 Pheby, D. F., Araya, D., Berkis, U., Brenna, E., Cullinan, J., De Korwin, J., Gitto, L., Hughes, D. A., Hunter, R. M., Trepel, D., & Wang-Steverding, X. (2020). The Development of a Consistent Europe-Wide Approach to Investigating the Economic Impact of Myalgic Encephalomyelitis (ME/CFS): A Report from the European Network on ME/CFS (EUROMENE). *Healthcare*, 8(2), 88. <https://doi.org/10.3390/healthcare8020088>.

10 ME/CFS Basics (2024, May 10). Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. <https://www.cdc.gov/me-cfs/about/index.html> and Jason, L. A., Benton, M. C., Valentine, L., Johnson, A., & Torres-Harding, S. (2008). The Economic impact of ME/CFS: Individual and societal costs. *Dynamic Medicine*, 7(1). <https://doi.org/10.1186/1476-5918-7-6>

11 Application for funding for biomedical research on myalgic encephalomyelitis (2020). Official Journal of the European Union. <https://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=CELEX:52020IP0140>

B. Main symptoms

Myalgic Encephalomyelitis affects the body's ability to produce the energy necessary for cellular activity and causes a wide variety of disabling and incapacitating symptoms, with the cardinal and mandatory diagnostic feature being Post-Exertional Neuroimmune Exhaustion (PNE), also called Post-Exertional Malaise (PEM) or Exacerbation of Post-Exertional Symptoms. ANPE is defined as an abnormal response to minimal amounts of physical and/or cognitive exertion, as profound and rapid physical and/or cognitive fatigue occurs in response to low-intensity exertion (or activity). Post-exertional exhaustion may appear immediately after the activity or may be delayed for up to 72 hours. The patient's recovery process and the loss of functional capacity that occurs during ANPE may take days, weeks, months or even result in permanent loss of functional capacity. Depending on the severity of the disease, it may affect even the most basic activities of daily living and the patient may take days, weeks or even months to overcome ANPE.

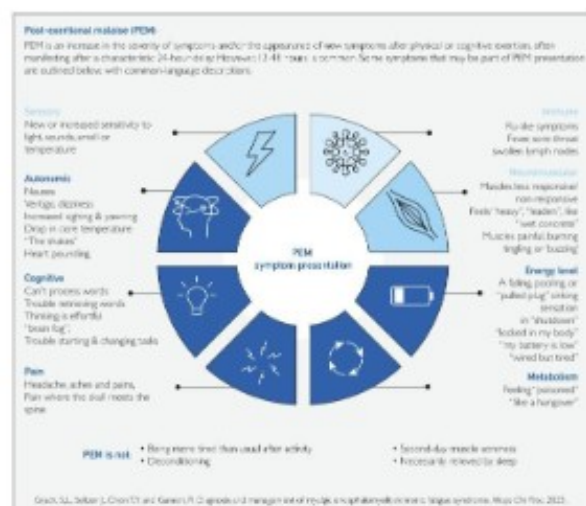
Additionally, there are more than 60 symptoms described in relation to Myalgic Encephalomyelitis. Among them are the following:

A.- Neurological dysfunctions: neurocognitive deficits, significant pain of various types, sleep disturbances and neurosensory, perceptual and motor disturbances, among others.

B.- Immune, digestive and genitourinary dysfunctions: flu-like manifestations, susceptibility to viral infections, with slower recovery times, digestive and genitourinary disorders and hypersensitivity to food, drugs, alcohol, odors and/or chemical products, among others.

C.- Dysfunctions of cellular energy metabolism and ion transport: cardiovascular and autonomic problems, respiratory problems, abnormal thermoregulatory responses and intolerance to extreme temperatures, among others.

All this symptomatology implies a permanent state of illness, of continuous and disabling general discomfort, which can increase in intensity/severity after any minimum physical, cognitive, orthostatic, sensory, environmental or emotional stressor (bodily stressor).



C. Degrees of the disease

The condition of patients suffering from myalgic encephalomyelitis is usually classified into four levels of severity: mild, moderate, severe/severe and very severe/very severe¹², although in reality all levels involve a significant reduction in the functional capacity of the person.

- In cases of **mild** ME, a person can still attend work or school and perform light tasks. However, they are likely to experience mobility difficulties and their social life is affected. In milder cases, functional capacity is reduced to 50%.
- In the **moderate** degree, people experience reduced mobility and are most likely unable to go to work or school, are unable to perform activities alone, have reduced sleep quality and need frequent rest.
- People with severe or severe ME are usually confined to their homes. They have functional capacity ranging from 5% to 15% of normal functioning, experience cognitive difficulties and are hypersensitive to external stimuli.
- Finally, people with a very severe or very severe degree are confined to bed and have a functional capacity of less than 5%. These individuals are often completely dependent on others for self-care, require tube feeding, are unable to complete personal hygiene and are very sensitive to sensory stimuli.

Patients (especially those of severe/severe or very severe/very severe degree) have to deal with devastating symptoms, such as repeated paralysis, gastroparesis (requiring feeding tubes or parenteral or intravenous nutrition), living bedridden without the ability to get up, needing total isolation from any kind of stimuli, and requiring continuous assistance and monitoring for the most basic tasks of daily living such as eating, drinking, talking, thinking or moving.

The disease can lead to the collapse of several of the body's systems and even in some severe and very severe cases to death, which will rarely be recorded on a death certificate, as the final cause of death is usually a symptom of the condition, such as cardiovascular dysfunction/failure.

12 Arron, H. E., Marsh, B. D., Kell, D. B., Khan, M. A., Jaeger, B. R., & Pretorius, E. (2024). Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: the biology of a neglected disease. *Frontiers in Immunology*, 15. <https://doi.org/10.3389/fimmu.2024.1386607>

D. Quality of life

The quality of life of people with myalgic encephalomyelitis is significantly below average and the lowest of all conditions compared in relevant scientific studies (see graph on page 5)¹³. People with ME have a poorer quality of life than other serious diseases such as multiple sclerosis, stroke, chronic renal failure, lung or breast cancer¹⁴. ME is a highly debilitating disease with a major negative impact on the quality of life of patients and their caregivers¹⁵.

The following data can be highlighted:

- In the mildest cases, the physical and cognitive capacities of the sick persons are reduced and, therefore, their level of activity is reduced by 50% (the capacity to carry out all types of activities: professional/work, educational, leisure, personal, etc.).
- 75%-85% are unable to work and are totally or partially dependent: Statistically, countries such as the UK and the US recognize that only 16% are able to work partially or full-time¹⁶.
- 25% suffer from it in severe/severe or very severe/very severe form, being housebound and even confined to bed¹⁷, needing a wheelchair to move around and daily assistance for years or decades (for life), not only for shopping, housework, meal preparation, etc., but even for BADL, such as getting up (if possible), toileting, eating, etc.
- The most severely ill people, apart from being permanently bedridden, are even paralyzed, intubated, on parenteral nutrition, in dark rooms and isolated from all kinds of sensory stimuli that could trigger a relapse, and are totally dependent for their basic needs, i.e., for ADLs.

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- 13 Hvidberg, M. F., Brinth, L. S., Olesen, A. V., Petersen, K. D., & Ehlers, L. (2015). The Health-Related Quality of Life for Patients with Myalgic Encephalomyelitis / Chronic Fatigue Syndrome (ME/CFS). *PLoS ONE*, 10(7), e0132421. <https://doi.org/10.1371/journal.pone.0132421>.
- 14 Hvidberg, M. F., Brinth, L. S., Olesen, A. V., Petersen, K. D., & Ehlers, L. (2015). The Health-Related Quality of Life for Patients with Myalgic Encephalomyelitis / Chronic Fatigue Syndrome (ME/CFS). *PLoS ONE*, 10(7), e0132421. <https://doi.org/10.1371/journal.pone.0132421>
- 15 Nacul, L. C., Lacerda, E. M., Campion, P., Pheby, D., De L Drachler, M., Leite, J. C., Poland, F., Howe, A., Fayyaz, S., & Molokhia, M. (2011). The functional status and well being of people with myalgic encephalomyelitis/chronic fatigue syndrome and their carers. *BMC Public Health*, 11(1). <https://doi.org/10.1186/1471-2458-11-402>
- 16 Anderson, J. S., & Ferrans, C. E. (1997). The quality of life of persons with chronic fatigue syndrome. *The Journal of Nervous and Mental Disease*, 185(6), 359–367. <https://doi.org/10.1097/00005053-199706000-00001> y Medicine, I. O. (2015). Beyond Myalgic Encephalomyelitis/Chronic fatigue syndrome. In National Academies Press eBooks. <https://doi.org/10.17226/19012>
- 17 Pendergrast, T., Brown, A., Sunnquist, M., Jantke, R., Newton, J. L., Strand, E. B., & Jason, L. A. (2016). Housebound versus nonhousebound patients with myalgic encephalomyelitis and chronic fatigue syndrome. *Chronic Illness*, 12(4), 292–307. <https://doi.org/10.1177/1742395316644770>

- Children and adolescents can also develop severe or severe forms, which, in most cases, prevent them from attending the school, institute or educational center in question.
- Some sick people die due to the complications derived from the disease and others, unfortunately, due to the severity and the very hard and disabling nature of their symptoms and their lack of quality of life and also, of course, to the lack of understanding, abandonment and lack of protection by the health, social-health, labor, family and/or social system, are forced to opt for euthanasia (which in very few countries can actually exercise this right) or suicide.

2. Framework of the ME in Law 3/2024, of October 30 (ALS Law)

A. Irreversible condition and with a significant reduction in survival

With regard to irreversibility it is worth mentioning:

- To date, myalgic encephalomyelitis is a disease with no cure and no approved specific treatment. Only treatments of disparate efficacy exist to alleviate certain symptoms¹⁸.
- ME has a poor prognosis with prospects of recovery around 5% with subsequent relapse in the vast majority, i.e. the vast majority of patients will see their functional capacity and quality of life significantly reduced during the course of the disease¹⁹.
- According to a study published in France in 2022, improvement rates are only of 4.8%²⁰.
- The symptoms of the disease persist for life, because it a chronic disease and there is still no effective treatment for them (it is merely a symptomatic treatment, with few favorable results) and even less any specific treatment has been developed for the disease, since its etiopathogenesis is unknown.

18 Arron, H. E., Marsh, B. D., Kell, D. B., Khan, M. A., Jaeger, B. R., & Pretorius, E. (2024). Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: the biology of a neglected disease. *Frontiers in Immunology*, 15. <https://doi.org/10.3389/fimmu.2024.1386607>

19 Montoya, J., Dowell, T., Mooney, A., Dimmock, M., & Chu, L. (2021). Caring for the Patient with Severe or Very Severe Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. *Healthcare*, 9(10), 1331. <https://doi.org/10.3390/healthcare9101331>

20 Ghali, A., Lacout, C., Fortrat, J., Depres, K., Ghali, M., & Lavigne, C. (2022). Factors Influencing the Prognosis of Patients with Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. *Diagnostics*, 12(10), 2540. <https://doi.org/10.3390/diagnostics12102540>

There is also scientific literature to support reduced survival. For example:

- In ME patients, early mortality is related to cardiovascular problems, cancer, and suicide as shown by several studies conducted in the United States. The findings suggest that ME patients have a significantly higher risk of early all-cause (M= 55.9 years) and cardiovascular disease-related (M= 58.8 years) mortality, and had a directionally lower mean age of death from suicide (M= 41.3 years) and cancer (M= 66.3 years) compared to the general US population [M= 73.5 (all causes), 77.7 (cardiovascular), 47.4 (suicide) and 71.1 (cancer) years of age]"²¹. In the same , another study states that the mean age of ME patients who die of heart failure is 58.7 years. This is significantly lower than the 83.1 years of age of those dying from heart failure in the general population of the United States."²²
- A recent study (January 2025)²³ showed a significant association ME and Cardiovascular Disease (CVD). Study participants diagnosed with ME had a more than 3-fold increase in the odds of cardiovascular disease indicating that ME is a significant independent risk factor for cardiovascular disease after adjusting for age, sex, race, diabetes, hypertension, dyslipidemia, muscle mass index category, and smoking status.
- The risk of death by suicide in patients with Myalgic Encephalomyelitis is 7 times higher than in the general population²⁴. Several factors may contribute to a with ME having suicidal thoughts or actions and the development of depression-like symptoms, including: lack of treatment options and low recovery rates; increased levels of pain and disability; greatly diminished quality of life; stigma and beliefs sometimes held by family, friends and even physicians that the disease is not real or is just depression; loss of employment and subsequent poverty."²⁵
- Malnutrition in ME especially in severe and very severe patients can lead to nutrition and hydration problems that can end up being fatal. The reasons may be inability to swallow, severe gastrointestinal problems tolerating food, or patient being too weakened to eat and drink. Some patients with very severe ME will require tube feeding, either enteral or parenteral.

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- 21 McManimen, S. L., Devendorf, A. R., Brown, A. A., Moore, B. C., Moore, J. H., & Jason, L. A. (2016). Mortality in patients with myalgic encephalomyelitis and chronic fatigue syndrome. *Fatigue Biomedicine Health & Behavior*, 4(4), 195–207. <https://doi.org/10.1080/21641846.2016.1236588>
- 22 Maes, M., & N. M. Twisk, F. (2009, December). Why myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) may kill you: Disorders in the inflammatory and oxidative and nitrosative stress (IO&NS) pathways may explain cardiovascular disorders in ME/CFS. Research Gate. Retrieved February 9, 2025, from <https://www.researchgate.net/publication/200704601>
- 23 Denu, M. K. I., Revoori, R., Eghan, C., Kwapong, F. L., Hillman, A., Normeshie, C. A., Berko, K. P., Aidoo, E. L., & Buadu, M. a. E. (2025). Association between chronic fatigue syndrome/myalgic encephalomyelitis and cardiovascular disease. *Scientific Reports*, 15(1). <https://doi.org/10.1038/s41598-025-86609-4>
- 24 Kapur, N., & Webb, R. (2016). Suicide risk in people with chronic fatigue syndrome. *The Lancet*, 387(10028). <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2816%2900270-1/fulltext>
- 25 McManimen, S. L., Devendorf, A. R., Brown, A. A., Moore, B. C., Moore, J. H., & Jason, L. A. (2016). Mortality in patients with myalgic encephalomyelitis and chronic fatigue syndrome. *Fatigue Biomedicine Health & Behavior*, 4(4), 195–207. <https://doi.org/10.1080/21641846.2016.1236588>

Often, there may be a significant delay in implementing this, due to professional judgment, resulting in the patient suffering severe malnutrition. Healthcare professionals may fail to recognize that the problems are a direct consequence of very severe ME²⁶.

B. Not having had a significant response to treatment, or when there are no therapeutic alternatives that will improve the functional status or prognosis of these persons.

As stated earlier in this document, Myalgic Encephalomyelitis (ME) is a complex, acquired, multisystemic disease in which there is a severe disruption of the neurological regulatory system resulting in impaired communication and interaction between the CNS and major body apparatus and systems, particularly the immune and endocrine systems, dysfunction of cellular energy metabolism and ion transport, and cardiac disorders.

Its cardinal manifestation consists of a pathologically low threshold of fatigability, characterized by an inability to produce sufficient energy when needed²⁷.

To date, there is no cure or specific treatment for ME. Treatment can only be offered to alleviate some of the symptoms, but, unfortunately, with little or no effectiveness²⁸.

C. Require complex social and health care, centered in the home and with a high impact on the immediate environment of the affected persons.

People with myalgic encephalomyelitis lead a life subject to enormous limitations and renunciations. Their various symptoms prevent them, in most , from working, socializing, doing housework, taking care of their families, traveling, etc., and even performing ADLs such as personal hygiene, dressing, cooking, etc.

People with a severe or very severe degree of impairment (25% of the total) live bedridden, suffer intolerance to external stimuli such as light or sound and need assistance for daily living, even requiring external support for oxygen therapy and/or feeding²⁹. These patients are housebound and confined to bed³⁰, needing a wheelchair to move around and daily assistance for ADLs such as getting up (if possible), toileting, eating, etc.

26 Baxter, H., Speight, N., & Weir, W. (2021). Life-Threatening malnutrition in very severe ME/CFS. *Healthcare*, 9(4), 459. <https://doi.org/10.3390/healthcare9040459>

27 ME_IC_Primer Spanish Translation 2022.pdf. (n.d.). Google Docs. <https://drive.google.com/file/d/14BwTIDvpQmxeqjwUjX--0Xj2fXl7VrI6/view>

28 NICE. (2021, October 29). Overview | Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management | Guidance | NICE. <https://www.nice.org.uk/guidance/ng206>

29 Diptico SEMG_PEM_ENCEFALOMIELITIS_MIALGICA.pdf. (n.d.). Google Docs. <https://drive.google.com/file/d/1K-tXzN5XpR-iygLNodwl9a9pCRucFY24/view>

The most severe degrees, apart from being permanently bedridden, are even paralyzed, intubated, on parenteral nutrition, in dark rooms (in semi-darkness) and isolated from all types of sensory stimuli that could trigger a relapse, and are totally dependent for their basic needs, that is, for BADL.

In particular, severe and very severe patients have a higher prevalence of comorbidities common to ME (e.g., mast cell activation syndrome, postural orthostatic tachycardia syndrome) and/or complications of being homebound or bedridden (e.g., osteoporosis, constipation, pressure ulcers, aspiration pneumonia, depression and deconditioning) which may further aggravate their situation and complicate their management, eventually requiring total care³¹.

Patients with severe or very severe ME have difficulty adequate medical care because they are unable to travel to doctors' offices³². The most severely affected patients are bedridden, are very uncomfortable in the upright position for more than a few seconds or minutes, have general weakness and lack of stamina, and periods of rest may be necessary during clinical evaluation as the patient becomes visibly tired and shows signs of increasing cognitive difficulty³³.

A study published in 2023 on the Impact of myalgic encephalomyelitis on the quality of life of people with ME and their partners and family members³⁴ showed that the quality of life of all of them is greatly affected, it being clear that the impact of ME goes far beyond affected person. Seventy-one percent of caregivers reported that caregiving took more than 40 hours per week

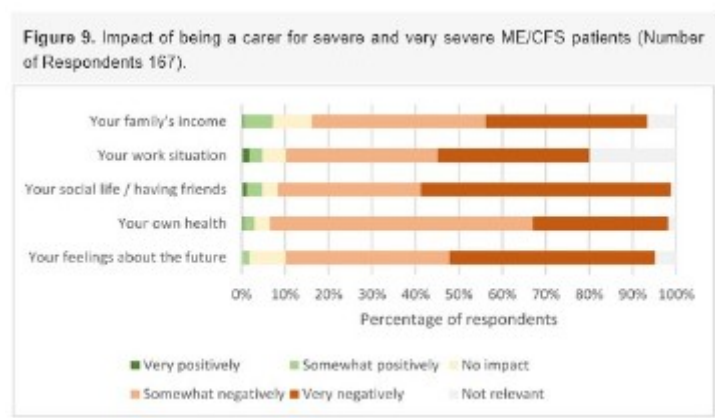
30 Pendergrast, T., Brown, A., Sunnquist, M., Jantke, R., Newton, J. L., Strand, E. B., & Jason, L. A. (2016). Housebound versus non housebound patients with myalgic encephalomyelitis and chronic fatigue syndrome. *Chronic Illness*, 12(4), 292–307. <https://doi.org/10.1177/1742395316644770>

31 Montoya, J., Dowell, T., Mooney, A., Dimmock, M., & Chu, L. (2021). Caring for the Patient with Severe or Very Severe Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. *Healthcare*, 9(10), 1331. <https://doi.org/10.3390/healthcare9101331>.

32 Kingdon, C., Giotas, D., Nacul, L., & Lacerda, E. (2020). Health Care Responsibility and Compassion- Visiting the housebound patient severely affected by ME/CFS. *Healthcare*, 8(3), 197. <https://doi.org/10.3390/healthcare8030197>.

33 Nacul, L., Authier, F. J., Scheibenbogen, C., Lorusso, L., Helland, I. B., Martin, J. A., Sirbu, C. A., Mengshoel, A. M., Polo, O., Behrends, U., Nielsen, H., Grabowski, P., Sekulic, S., Sepulveda, N., Estévez- Lopez, F., Zalewski, P., Pheby, D. F. H., Castro-Marrero, J., Sakkas, G. K., . . . Lacerda, E. M. (2021). European Network on Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome (EUROMENE): Expert Consensus on the Diagnosis, Service Provision, and Care of People with ME/CFS in Europe. *Medicine*, 57(5), 510. <https://doi.org/10.3390/medicina57050510>

34 Sommerfelt, K., Schei, T., & Angelsen, A. (2023a). Severe and Very Severe Myalgic Encephalopathy/Chronic Fatigue Syndrome ME/CFS in Norway: symptom burden and access to care. *Journal of Clinical Medicine*, 12(4), 1487. <https://doi.org/10.3390/jcm12041487>.



Another study of nearly 1,500 caregivers showed (as did the previous study) that ME had a significant impact on caregivers emotionally, economically, socially, occupationally and even on their health (sleep, eating habits and sex life). 84.7% considered it difficult to care for their relatives. Only 11.1% of participants with ME live alone, demonstrating the need for care³⁵.

D. Have a rapid progression in some of these processes that requires accelerating administrative processes of assessment and recognition of the degree of disability or dependency.

ME is an underdiagnosed disease, which even for those finally diagnosed involves a long period in search of diagnosis that takes on average 6.8 years in Europe and 8.5 years in Spain³⁶ since the patient starts reporting symptoms. As mentioned earlier in this paper, the delay in diagnosis has a negative influence on the patient's prognosis. This is why, when patients are finally identified as having ME, immediate intervention is crucial avoid worsening already very damaged health of those suffering from the disease and their caregivers.

35 Vyas, J., Muirhead, N., Singh, R., Ephgrave, R., & Finlay, A. Y. (2022). Impact of myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) on the quality of life of people with ME/CFS and their partners and family members: an online cross-sectional survey. *BMJ Open*, 12(5), e058128. <https://doi.org/10.1136/bmjopen-2021-058128>

36 European ME Alliance (2024). EMEA Survey of ME/CFS patients in Europe. In <https://www.europeanmealliance.org>. Retrieved February 9, 2025, from <https://www.europeanmealliance.org/documents/emeaeusurvey/EMEAMEsurveyreport2024.pdf>

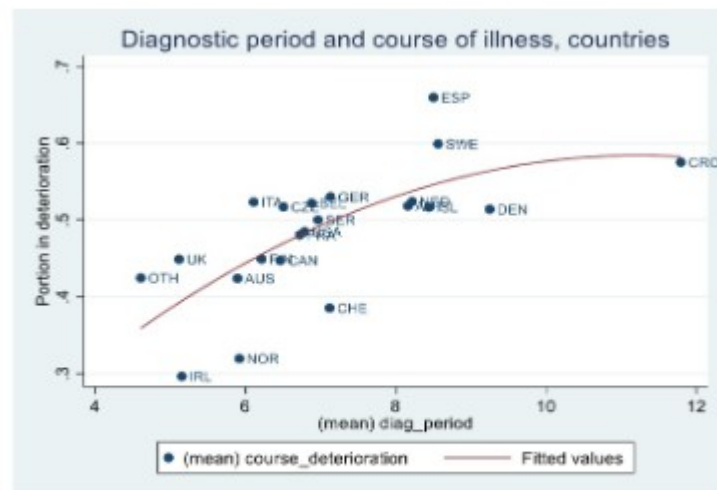


Figure 29: The relationship between diagnostic period (in years, x axis) and portion of patients with a deteriorating course of illness (y-axis), at country level (n=22).

Medical, health and occupational intervention (if they are still able to work) or timely recognition of their occupational, social and economic incapacity are essential to mitigate the devastating consequences of this unknown and invisible disease. Sixty-one percent of patients are bedridden on their worst days, which is indicative of the need for home care and rapid support to accelerate the administrative processes of dependency and disability³⁷.

In the absence of pharmacological treatments for ME, the consensus of the scientific community has identified the need for a very careful use of one's own energy resources, strictly avoiding overload. This **energy management** is internationally known by the English term "**pacing**" and is **recognized as the only possible action to avoid worsening in patients**³⁸. **Since reducing the level of activity is critical to slowing down the development of the disease, it is essential to expedite aids such as dependency or disability that can enable patients to reduce the level of activity without physical overexertion, and financial consequences of the disease.**

A recent European study found a significant correlation between poor protection by the care and social protection system for patients and deterioration in the course of disease. Conversely, rapid access to the protection offered by the recognition of dependency and disability would reduce the worsening of ME patients³⁹.

37 Pendergrast, T., Brown, A., Sunnquist, M., Jantke, R., Newton, J. L., Strand, E. B., & Jason, L. A. (2016). Housebound versus nonhousebound patients with myalgic encephalomyelitis and chronic fatigue syndrome. *Chronic Illness*, 12(4), 292-307. <https://doi.org/10.1177/1742395316644770>

38 Sommerfelt, K., Schei, T., & Angelsen, A. (2023a). Severe and Very Severe Myalgic Encephalopathy/Chronic Fatigue Syndrome ME/CFS in Norway: symptom burden and access to care. *Journal of Clinical Medicine*, 12(4), 1487. <https://doi.org/10.3390/jcm12041487>.

39 European ME Alliance (2024). EMEA Survey of ME/CFS patients in Europe. In <https://www.europeanmealliance.org>. Retrieved February 9, 2025, from <https://www.europeanmealliance.org/documents/emeaeusurvey/EMEAMEsurveyreport2024.pdf>

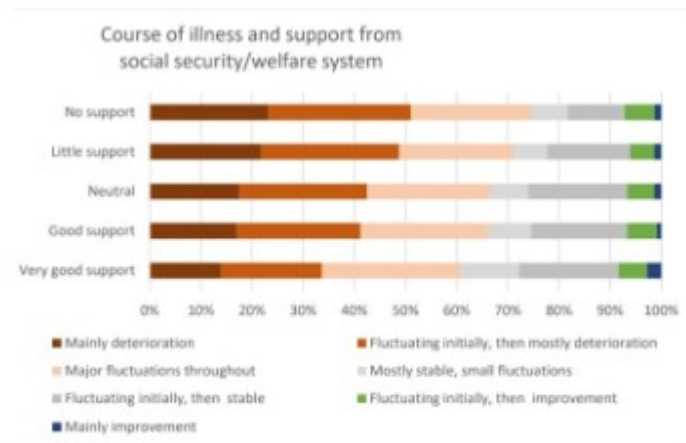


Figure 40: Course of illness and support from social security/welfare system (n=9 784).

In particular, the most severely ill ME patients are an extremely vulnerable group. Their symptoms are devastating and result in a lack of ability to eat, drink, move around or communicate independently, leading to a very poor quality of life. There are studies that illustrate this situation, as well as the need for urgent care in the most severe cases⁴⁰.

3. Conclusion

As has been proven in this writing, Myalgic Encephalomyelitis is a disease:

- Serious,
- Chronicle,
- Multisystemic,
- Highly disabling, especially in its more severe/severe degrees in which patients cannot even attend to the most basic needs of their daily life and self-care as their functional capacity is reduced by 85-95% all areas of life,
- With a significant reduction in life expectancy,
- No known treatment or cure,
- Underdiagnosed,
- Infrainvestigated,
- and, ultimately, devastating for patients and their immediate environment, both from a health point of view in the broadest sense of the term, and from the perspective of employment, social and financial stability of patients and their environment.

Attached below in section 4 is the bibliography used to support everything described in this letter, but of course, we also remain at the disposal of the Ministry of Health to provide any additional documentation or scientific references that may be of interest or that may be required to cover this **serious social emergency**, both within the framework of the ALS Act and in any other context.

40 Sommerfelt, K., Schei, T., & Angelsen, A. (2023a). Severe and Very Severe Myalgic Encephalopathy/Chronic Fatigue Syndrome ME/CFS in Norway: symptom burden and access to care. *Journal of Clinical Medicine*, 12(4), 1487. <https://doi.org/10.3390/jcm12041487>

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