COMMENTARY 10th August 2023

Treatment of ME/CFS and Long COVID in Finland and from a broader perspective

Abstract

The treatment of Long COVID and ME/CFS based on the biopsychosocial approach in Finland has raised international criticism. There is no scientific evidence of this approach, and it does not represent the current guidelines.

Long-term, systemic diseases following viral infections is not a new phenomenon. At least 10 000 Finnish people suffer from ME/CFS and at least 35 000 from Long COVID. Around 10% of adults with SARS-CoV-2 infection will develop Long COVID, a disease with pathophysiology and symptoms very similar to ME/CFS. A proportion of Long COVID patients meet the diagnostic criteria for ME/CFS, so the number of ME/CFS patients will increase in Finland and worldwide. WHO encourages increasing research on Long COVID and the new Finnish Government program states that ME/CFS patients' access to benefits and rehabilitation should be promoted.

According to international scientific consensus and guidelines, Long COVID and ME/CFS are physical, multisystemic, long-term diseases that significantly limit patients’ ability to perform activities of daily living, not functional disorders. There is no known cure for either disease, but symptoms can be alleviated and functional ability in everyday life can be supported. Patients with Long COVID and ME/CFS benefit from treatment methods which are based on the same principles.

Guidelines have been updated due to new evidence. When developing guidelines systematic literature reviews have shown that the quality of the trials evaluating the effects of the GET, CBT or FND or other methods based on the biopsychosocial approach for ME/CFS has been poor or very poor of quality and therefore the results do not support the recommendation of any of these methods. Current guidelines recommend symptom titrated pacing. The revised NICE guideline is in line with Duodecim and with all major guidelines and globally supported by experts and patients. All major Long COVID guidelines are also in line with ME/CFS guidelines, including WHO and CDC guidelines and more than twenty guidelines from the Health Information and Quality Authority review.

The striking similarities of ME/CFS and Long COVID and the importance of using the knowledge gained from ME/CFS and other post-viral diseases for improving the treatment of Long COVID have been highlighted in numerous research papers, reports and guidelines. Unfortunately, Long COVID and ME/CFS patients often do not receive treatment and rehabilitation in line with current guidelines, as the implementation of the guidelines has been slow.

These under-recognized diseases should be taken seriously by all health and social care sectors, and we should ensure that patients have access to evidence-based care that is in line with guidelines.

Introduction

This commentary will focus on the treatment of ME/CFS and Long COVID patients in Finland and from a broader perspective.

Finland's largest Swedish-language newspaper, **Hufvudstadsbladet (HBL)**, published 6th June an article on the treatment of ME/CFS (chronic fatigue syndrome/myalgic encephalomyelitis) and Long COVID (Post COVID-19 Condition) patients and the difficulties they have in receiving treatment and rehabilitation according to guidelines, as well as benefits such as sick pay, in Finland. The title of the article *Maija måste vila 20 timmar om dygnet men får ingen sjukpeng – vården erbjöd henne positivt tänkande* (*Maija must rest for 20 hours a day but does not get sick pay – Health care offered her positive thinking)* describes very well the situation of these patients in Finland.

For the article, HBL journalist **Jenny Bäck** interviewed a patient suffering from severe ME/CFS, Markku Sainio, Chief Physician from Helsinki University Hospital (HUS), Janne Leinonen, Chief Physician of the Social Insurance Institution of Finland (Kela), Risto O. Roine, Chairman of the national Long COVID expert group, appointed by the Ministry of Social Affairs and Health, Professor of Neurology, and Hanna Markkula, physiotherapist, and member of the Finnish ME/CFS guideline expert group. Samuli Tani and Kaisa Metsämäki from the Finnish ME/CFS Associations were also interviewed.

Long-term, systemic diseases following viral infections is not a new phenomenon

Viruses causing various post-viral diseases is not a new phenomenon. At least 10 000 Finnish people suffer from ME/CFS and at least 35 000 from Long COVID. However, it is likely that the number of ME/CFS and Long COVID patients in Finland is significantly higher. Around 10% of adults with SARS-CoV-2 infection will develop Long COVID, a disease with pathophysiology and symptoms very similar to ME/CFS. A proportion of Long COVID patients meet the diagnostic criteria for ME/CFS after six months, so the COVID-19 pandemic will also increase the number of ME/CFS patients in Finland and worldwide.

WHO has classified ME/CFS as a neurological disease since 1969. In the ICD-11, ME/CFS (code 8E49) is an exclusion for Bodily Distress Disorder (code 6D20). According to the Theodoro et al. systematic review, there is no evidence that Long COVID is a functional disorder. The European Union COVI Committee's seminar report states that Long COVID and ME/CFS are serious somatic diseases with biological causes, not psychosomatic diseases, and that considering ME/CFS and Long COVID as psychosomatic has slowed down research and clinical development of treatments in Europe and worldwide.

A systematic review shows that only about 5% of patients fully recover. The prognosis of Long COVID is unclear, but 85% still reported symptoms one year after their symptom onset and neuropsychiatric symptoms can persist for up to two years after an acute infection.

The cardinal symptom of ME/CFS is post-exertional malaise/post-exertional symptom exacerbation (PEM/PESE), i.e., the worsening of symptoms after even minor physical, mental, social, or cognitive exertion, typically within about 12–48 hours of exertion. PEM/PESE may also occur immediately during/after exertion or with a longer delay. Recovery from PEM/PESE usually requires bed rest. In the worst case, the decline in functional ability can be permanent. PEM/PESE is not psychosomatic and is not associated with fear, avoidance behavior or deconditioning.

PEM/PESE occurs in all patients with ME/CFS and in most patients with Long COVID. Other common symptoms of Long COVID and ME/CFS include fatigue, cognitive difficulties, dysautonomia/PoTS, reduced tolerance to physical and/or cognitive exertion, brain fog, unrefreshing sleep, pain and immune system symptoms.

Access to benefits and rehabilitation should be promoted

The new Finnish Government program states that ME/CFS patients' access to benefits and rehabilitation should be promoted.

According to the statement by Dr **Hans P. Kluge**, WHO Regional Director for Europe in June nearly 36 million people across the European Region may have developed Long COVID over the first three years of the pandemic. That is approximately 1 in 30 Europeans. 1 in 30 who may still be finding it hard to return to normal life and who is suffering in silence, left behind as others move on from COVID-19. WHO is encouraging more research to be undertaken, because unless comprehensive diagnostics and treatment for Long COVID is developed, we will never truly recover from the pandemic.

Patients with Long COVID and ME/CFS benefit from treatment methods which are based on the same principles. The core components are multidisciplinarity, people-centered care and shared decision-making, individuality, symptom-specificity, continuity, coordination of care and accessibility.

The Finnish Medical Society Duodecim published the Finnish ME/CFS Good Practice Consensus Guideline in February 2021. The Finnish guideline for treatment on Long COVID has not yet been published so patients could be treated using the WHO Clinical management of COVID-19: Living guideline until the national treatment guideline is published.

According to the HBL article, two years after the publication of the Duodecim guideline, the Finnish ME/CFS associations are very disappointed. Access to treatment is still random and most patients remain without benefits. The fundamental issues are still missing, starting with the recognition of ME/CFS as a severe disease, says **Samuli Tani**, President of the Finnish Medical ME/CFS Association (SLME) in the HBL article. **Kaisa Metsämäki**, President of the Finnish ME/CFS Association (SMEY) says that patients are given unreasonable and unrealistic demands for recovery.

The biopsychosocial approach is the basis of treatment in Finland

The treatment of ME/CFS patients in Finland is organized mainly in the HUS Outpatient Clinic for Functional Disorders and Long COVID patients mainly in the HUS Outpatient Clinic for Long-Term Effects of COVID-19. In both outpatient clinics the biopsychosocial approach is the basis of treatment. In addition to patient care, the outpatient clinics have played an important role in nationwide education and development of care. According to the HUS press release in June, these clinics will merge in the beginning of August, and the new clinic's name will be Rehabilitation Outpatient Clinic for Persistent Symptoms.

The treatment of Long COVID and ME/CFS based on the biopsychosocial approach in Finland and the HUS international biopsychosocial Long COVID symposium in March 2023 have raised international criticism for example here, here , here and here. The keynote speakers of the symposium included Professor **Michael Sharpe**, Professor **Paul Garner** and Professor **Gerd Kvale**.

There is no scientific evidence of the biopsychosocial approach. Therefore, its use as a scientific theory has been criticized for example here and here.

The Lancet editorial in March highlights that *long COVID is often easily dismissed as a psychosomatic condition. Given what we now know about the effects of long COVID and its biological basis, it must be taken seriously.*

In the consensus recommendations from the U.S expert panel the biopsychosocial approach is presented as an outdated standard of care for ME/CFS: *In the past, CBT and GET were studied and recommended for ME/CFS on the basis of the disease theory that "the symptoms and disability of CFS/ME are perpetuated predominantly by unhelpful illness beliefs (fears) and coping behaviors (avoidance [of activity])," leading to considerable deconditioning. However, GET and CBT studies have been widely criticized for their methodology, inadequate tracking of harms, and a disease theory that conflicts with the evidence of multisystem biologic impairment.*

Professor **Juhani Knuuti**, MD, explores the scientific basis of brain reprogramming in his blog, stating that there is no scientific evidence that brain reprogramming can "retrain" brain structures such as the amygdala or insula. The method is used at HUS to treat ME/CFS and Long COVID patients.

The biopsychosocial approach does not represent the guidelines

According to international scientific consensus and guidelines, Long COVID and ME/CFS are physical, multisystemic, long-term diseases that significantly limit patients' ability to perform activities of daily living, not functional disorders. There is no known cure for either disease, but symptoms can be alleviated and functional ability in everyday life can be supported.

CDC emphasizes that *patients should talk with their doctors about all potential therapies because many treatments that are promoted as cures for ME/CFS are unproven, often costly, and could be dangerous.* NICE states that *ME/CFS symptoms can be managed but there is currently no cure (non-pharmacological or pharmacological) for ME/CFS.*

According to the report of the European Commission it is not yet known what are the effective treatments for Long COVID.

The biopsychosocial approach does not represent the guidelines for ME/CFS or Long COVID. The guidelines from CDC, NICE, BMJ Best Practice, Clinical Coalition, Mayo Clinic, Euromene, Duodecim no longer recommend graded exercise therapy (GET) or similar treatment methods or cognitive behavioral therapy (CBT) or any other method as curative or the use of functional neurological disorder (FND) methods based on the biopsychological approach. All major Long COVID guidelines, including WHO and CDC guidelines and more than twenty guidelines from the Health Information and Quality Authority review, are also in line with major ME/CFS guidelines.

Considering ME/CFS as a functional disorder is also contradictory to the Finnish Duodecim ME/CFS guideline, which states that functional disorders should be excluded when establishing the diagnosis.

The key components of treatment recommended in the guidelines is avoidance/ minimization of PEM/PESE with symptom titrated pacing, adequate rest, and integration into daily activities. The patient should be given information about the disease and its impact on everyday life. Pacing targets all physical, cognitive, mental and social activities that require exertion. The focus is on finding energy-saving strategies to carry out everyday activities, avoid "push-and-crash cycles" and optimizing functional capacity in everyday life by staying within the individual energy envelope.

Unfortunately, Long COVID and ME/CFS patients often do not receive treatment and rehabilitation in line with current guidelines, as the implementation of the guidelines has been slow.

Treatment based on the current guidelines and the pathophysiological mechanisms of Long COVID and ME/CFS were discussed at the international conference in Finland in October 2022. Keynote speakers included Professor **Ronald W. Davis**, Professor **Risto O. Roine**, Associate Professor **Manoj Sivan** and **David M. Systrom**, MD.

The guidelines have been updated due to new evidence

All major ME/CFS guidelines have been updated due to new evidence. When developing guidelines systematic literature reviews have shown that the quality of the trials evaluating the effects of the GET, CBT or FND or other methods based on the biopsychosocial approach for ME/CFS has been poor or very poor of quality and therefore the results do not support the recommendation of any of these methods.

Current guidelines recommend symptom titrated pacing, according to the *"do no harm"* principle, because it has been shown to cause the least harm and the most benefit to patients.

CDC states:
Best practice: prevent harm! In the past, patients have been advised to be more active without any precautions about PEM. However, studies have demonstrated a lowered anaerobic threshold in patients with ME/CFS, suggesting impaired aerobic energy metabolism. Increased activity can thus be harmful if it leads to PEM.

The PACE trial has provoked strong scientific criticism. Studies have also highlighted harms for patients resulting from the use of GET, CBT and Lightning Process or similar methods. Our review shows that more patients are unable to work after treatment than before treatment *with CBT and GET. It also highlights the fact that both treatments are unsafe for patients with ME/CFS. Therefore, questioning the recovery behaviour of patients with ME/CFS is pointless. This confirms the conclusion from the British National Institute for Health and Care Excellence (NICE), which has recently published its updated ME/CFS guideline and concluded that CBT and GET are not effective and do not lead to recovery. Studies on CBT and GET for long COVID have not yet been published.*

Tschopp et al states: *Graded Exercise Therapy (GET) was perceived as harmful by patients, whereas pacing, complementary/alternative medicine, and dietary supplements and medications to alleviate symptoms were reported to be helpful to varying degrees.*

It is also important to note that the Wright et al study found that physical activity caused worsening of symptoms for 75% of Long COVID patients. The researchers therefore recommend symptom titrated pacing for Long COVID patients with PEM/PESE.

The NICE guideline is in line with all major guidelines

The NICE ME/CFS guideline represents the international scientific consensus. All major ME/CFS guidelines are in line with the NICE guideline and it is globally supported by experts and patients.

NICE's revised guideline has been criticized by the biopsychosocial school of practice. A very small number of the UK's more than 100 Medical Associations, seven of which are members of the Royal College of Physicians, have withdrawn from the NICE guideline. The Lancet critique of the NICE guideline and the latest NICE critique by White et al was also written by physicians who strongly represent the biopsychosocial school of practice. The authors have extensive conflicts of interest. All authors are or have been professionally involved in providing or promoting treatments that have been removed from the new guidelines.

The White et al critique concluded:
the dissonance between this and the previous guideline was the result of deviating from usual scientific standards of the NICE process. The consequences of this are that patients may be denied helpful treatments and therefore risk persistent ill health and disability.

NICE responded to the critique in The Guardian:
We reject entirely the conclusions drawn by the authors of this analysis, and in particular their conclusion that NICE has not followed international standards for guideline development which has led to guidance that could harm rather than help patients.

In developing our guideline, as well as bringing together the best available scientific evidence, we also listened to the real, lived experience and testimony of people with ME/CFS to produce a balanced guideline which has their wellbeing at its heart.

ME Association responded to the critique:
It is disappointing but not surprising to find that these doctors and researchers – many of whom have devoted a large part of their professional life to trying to persuade their colleagues that ME/CFS is caused by abnormal illness beliefs and behaviours and can be successfully treated by CBT and graded exercise therapy (GET) – are still refusing to accept the recommendations in the new NICE guideline on ME/CFS.

World ME Alliance responded to the critique:
NICE guideline is robust and globally supported. Moreover, it is crucial for readers to be aware that previous studies conducted by these researchers were rated as low or very low quality by Nice. This information adds an important context to their perspectives.

Health care offered positive thinking

An ME/CFS patient interviewed with HBL can barely sit or talk. Yet, according to the authorities, she is still capable of working. Health care offered positive thinking as a solution.

The Patient was referred to the HUS Outpatient Clinic for Functional Disorders, which offered her online therapy. She says in the interview that the therapy was based on the fact that she was depressed and anxious and that the assumption was that she would fear certain things beforehand, and they would happen as a result. The advice was to think that she could do things even if they caused symptoms.

Everything was interpreted as a product of my imagination. They said I would recover if I just believed in the methods, but they don't work if you don't believe in them, the patient says in the interview with HBL.

According to the HUS website, research has shown that functional disorders are caused by sensitization of the central nervous system, with symptoms arising in response to challenges or threats, and there is no problem with the organ system itself. Often healing requires that the examination cycle be broken and on decreasing the threat of symptoms. As a result, reactivity, fear and symptom monitoring take a back seat. According to the clinic, several patients have recovered from functional disorders.

Prof. Risto O. Roine emphasizes, that Long COVID and ME/CFS are not functional disorders

Long COVID and ME/CFS are not functional disorders or mental disorders, and this is agreed by international experts. The fact that these diseases are often seen as functional in Finland is harmful and prevents patients from receiving the care and benefits to which they are entitled, says Professor **Risto O. Roine** in the interview with HBL.

Bäck also interviewed physiotherapist **Hanna Markkula**. Markkula says in the interview, that with pacing it is possible to alleviate symptoms and improve functional capacity. Most Long COVID patients also benefit from the method. Markkula emphasizes that a gradual increase in physical activity without taking into account PEM is not recommended, as it may lead to a worsening of the disease.

According to Markku Sainio, MD, everyone can be cured

Markku Sainio, MD, from HUS says in the interview with HBL that in his opinion ME/CFS is a functional disorder and that the solution is brain reprogramming. According to him, everyone can be cured, but the patient's own attitude is crucial to recovery, and it is not possible to treat a patient who is reluctant. In our opinion, patients who interpret the illness as if something in the body is broken feel unwell, Dr Sainio says in the interview.

Dr **Janne Leinonen**, MD, from Kela, says in the interview with HBL, that ME/CFS has traditionally been considered as a functional disorder and decisions on permanent benefits have not been made in cases of functional disorders.

ME/CFS and Long COVID should be taken seriously

The striking similarities of ME/CFS and Long COVID and the importance of using the knowledge gained from ME/CFS and other post-viral diseases for improving the treatment of Long COVID have been highlighted in numerous research papers, reports and guidelines.

International collaboration and patient involvement, both in the design of research trials and in the development of care pathways, is crucial. Funding is also needed for research and education in the treatment based on evidence and guidelines, so that patients receive the treatment and support services that best serve their daily lives.

Hopefully, the new Finnish Government will keep its promise to improve the situation of ME/CFS patients and will analyze the need to improve cooperation between physicians specializing in insurance benefits and those treating patients to ensure a better and fairer realization of patients' benefits.

These under-recognized diseases should be taken seriously by all health and social care sectors, and we should ensure that patients have access to evidence-based care that is in line with guidelines.

Written by:

The ME/CFS and Long COVID Network of Professionals
An international multidisciplinary network of health care professionals specializing in ME/CFS, Long COVID and related diseases. The network monitors and analyzes research and experience and collaborates internationally with professionals in the field.

Read the article by Hufvudstadsbladet here (in Swedish, behind the paywall)