

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Prevalence and characteristics of Chronic fatigue syndrome/Myalgic encephalomyelitis (CFS/ME) in Poland: A cross-sectional study
AUTHORS	Slomko, Joanna; Newton, Julia; Kujawski, Sławomir; Tafil-Klawe, Małgorzata; Klawe, Jacek; Staines, Donald; Marshall-Gradisnik, Sonya; Zalewski, Pawel

VERSION 1 - REVIEW

REVIEWER	Zack SHAN Griffith University, Australia
REVIEW RETURNED	11-Jun-2018

GENERAL COMMENTS	<p>This study investigated the presence and characteristics of chronic fatigue syndrome (CFS) in Poland. The authors confirmed that fatigue is a common symptom experienced by the Polish population and that CFS is an under recognized syndrome in this group. This type of prevalence study is essential to establish a research program. The study made good contributions to the body of knowledge in the CFS literature. However, the paper need to be largely revised as a scientific manuscript, I only listed revisions in the abstract for illustration as minor concerns. The author may want to revise the rest of the manuscript more carefully. In addition, I have the following major concerns.</p> <p>Major concerns</p> <ol style="list-style-type: none">1. One of the hallmarks of CFS is the cognitive deficits. Therefore, 36-Item Short Form Survey (SF-36), which includes both physical component summary (PCS) and mental component summary (MCS), is increasingly used for CFS evaluation. The Chalder fatigue scale does not separate these two components.2. As a prevalence study suggested by title, using Fukuda criteria is not enough given availabilities of diagnostic criteria recommended for CFS by The Institute of Medicine (IOM) and CFS International Consensus Criteria (ICC).3. Evaluation of autonomic functions is great, however, its significance is diminished without a comparison with normal controls. <p>Minor concerns:</p> <p>The manuscript need to be largely revised as a scientific paper, here I just listed revisions in the abstract.</p> <ul style="list-style-type: none">• Line 1, CFS. The abbreviation need to be defined in the first usage.• Line 7, participants. How the participants represent general population. If not, described it.
-------------------------	--

	<ul style="list-style-type: none"> • Line 13, COMPASS 31. Define it before using it. • Line 15, The majority, the majority of what? What is the criteria of “majority”? • Line 16, Compass 31, keep the terminology consistent. • Line 16, 50%, 50% of what? • Line 20, (mean (SD) QQLS score 64(11)), too clumsy.
--	---

REVIEWER	Killian Welch NHS Lothian UK
REVIEW RETURNED	03-Jul-2018

GENERAL COMMENTS	<p>The main potential criticism of the study is obviously the manner in which patients were identified. This could have led both to patients seeking a diagnosis (which is of course essentially made on subjective symptom reporting) and led to a biased sample. Sampling bias could have occurred in various directions. Recruitment via media could have resulted in a greater likelihood of identification of unemployed patients (with more severe symptoms), conversely the need to attend a research centre may have excluded that who were more severely affected (and therefore bedbound). This research is difficult however – the alternative approach of identification through primary care may have yielded very few patients, particularly if there is little recognition of the condition in Poland. It is my view therefore that the approach used by the authors was reasonable given the current state of the evidence base in Poland. A further criticism would be the switch from contact by telephone to website when numbers became overwhelming. This clearly will have selected for patients with internet access (who were tech-literate), and potentially introduced bias to younger, more affluent and/or educated patients. Again however I think this was a pragmatic response by the researchers; it simply emphasises that the sample obtained may not be representative of the broader population of CFS patients in Poland. Such sampling bias may also explain differences in clinical characteristics from other cohorts, and the authors should probably be more explicit about this. Again however, as the primary purpose of the study was to establish if CFS existed as a clinical entity in Poland I don't think this means the research does not have value.</p> <p>I was impressed by the comprehensive manner in which the identified cohort was characterised.</p> <p>Other issues I have are that I can't see any supplementary data (this is referred to in the text) and I don't see any details of ethics committee approval for the study. Additionally there is no description of the statistical methods employed to make group comparisons. There are also multiple analyses without correction for multiple comparisons, which also needs to be acknowledged or corrected for. While I don't think the statistical issues necessarily necessitate specialist statistical review (they seem pretty straightforward), there does need to be discussion of these issues by the authors.</p>
-------------------------	--

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Zack SHAN

Institution and Country: Griffith University, Australia

Please state any competing interests or state 'None declared':

None declared

Answer:

Thank you for that comments.

We used Chalder Fatigue Scale to measure the extent and severity of fatigue. Reliability coefficients for the CFQ 11 have been high in studies of CFS/ME patients. We agree with the reviewer that cognitive function tools are missing in this article, and this could one of the limitation of this study.

It was the first epidemiological study in Poland and that's why, with prof. Julia Newton recommendation we used Fukuda criteria to indicate CFS/ME patients. In the future research we will try to compare other diagnostic criteria recommended for CFS/ME in Polish cohort.

Hemodynamic and autonomic parameters were automatically measured at rest and in a tilted position with a Task Force Monitor. The Task Force Monitor consists of electrocardiography, impedance cardiography, oscillometric, and continuous BP measurement. We decided that more interesting will be classified the cohort according to predominance of sympathetic or parasympathetic function. That's why we decided to compare this two phenotypes, without normal controls.

All mistakes in the abstract has been corrected.

Reviewer: 2

Reviewer Name: Killian Welch

Institution and Country: NHS Lothian, UK

Please state any competing interests or state 'None declared': None declared

Answer:

Thank you for all valuable remark.

We agree with the reviewer that the main potential limitation could be the manner in which patients were identified. However conducting CFS/ME epidemiological study in Poland is very difficult because in this country chronic fatigue syndrome is diagnosed very rarely, which may be associated with the fact that the aetiology of the disease is still poorly known, and with diagnostic problems resulting from a lack of detailed and uniform guidelines allowing an unambiguous diagnosis and initiation of effective treatment in CFS/ME patients.

We added details of ethics committee approval for the study.

We apologize if 'result' section wasn't clear enough, we have reorganize this section and added 'statistical analyses' section.

VERSION 2 – REVIEW

REVIEWER	Zack SHAN Griffith University
REVIEW RETURNED	16-Nov-2018

GENERAL COMMENTS	The authors addressed appropriately all the issue raised, the paper may be published.
-------------------------	---

REVIEWER	killian welch NHS Lothian, UK
REVIEW RETURNED	13-Nov-2018

GENERAL COMMENTS	I do think the paper reads much better now. The issues i raised have been addressed.
-------------------------	--