PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

Title (Provisional)

Carer strain in post-stroke emotionalism: a cross-sectional analysis

Authors

Broomfield, Niall; Walters, Matthew; West, Robert M

VERSION 1 - REVIEW

Reviewer	**1**
Name	**Hinwood, Madeleine**
Affiliation	**The University of Newcastle, School of Medicine and Public Health**
Date	**22-Feb-2024**
COI	**None to declare**

Abstract is well-written and a good summary

I like the strengths and limitations section; it is well written and acknowledges the limitations of this study.

Introduction-

This study is contrasted with the Colamonico survey to provide a rationale, but I do wonder whether the justification for the current study could be stronger. You note that the specific psychological impact of caring for people with emotionalism after stroke is not known, however it would be useful if you can justify why a separate evaluation in stroke may be required (i.e. what is unique about stroke compared to other neurological conditions that such an assessment is worthwhile?)

Post-stroke emotionalism is a symptom I have heard little about. Some more expansion around this term, what outcomes it has been associated with (in stroke and other cohorts), may be useful to readers. I think it is well defined, but the potential clinical meaningfulness of exploring this area of stroke care could be better elucidated.

Methods-

The paper needs a review for grammar- there are some minor errors throughout (e.g. in the sample size section: 'N=102 had informants at 6-month follow up reporting carer strain data').

More info about carer recruitment required. ‘For each participant, an informant (spouse or closest relative) was recruited.’ Were these definitely the primary caregiver for the stroke survivor? Patient/carer dyads appeared to be recruited in the acute phase of stroke, but the interview for this study did not occur until month 6- what if there was a change in carer or similar over this time?

Results-

Please define all scales used in footnotes to tables- for example, I am unsure what a social deprivation score of 2600 versus one of 2966 means, or what the stroke classifications are.

You claim no difference between respondents and non-respondents to MCSI. I find that difficult to believe, particularly as you did not include carer characteristics. The response to this survey may be more likely to differ by carer characteristics than by patient characteristics. Regardless, even though statistical significance was not reached, there are also differences between these patient groups (e.g. sex, social deprivation, stroke classification). The selection bias is in two stages- those who initially agreed to participate, and then of this group, only those with a non-missing MCSI were included. I think this needs to be acknowledged.

Are the percentages correct in Table 1? Some sum to more than 100% in the groups I believe make sense (e.g. stroke classification)- this may be because patients could fall into more than one category, but needs to be clarified in a footnote to the tables.

I prefer not to perform variable selection by using those which are statisticially significantly associated with the outcome, but rather select covariates based on prior knowledge/expert opinion. Otherwise, the descriptive exploration of the association between PSE and carer strain seems reasonable.

Discussion

P12 ‘the findings offer a longitudinal analysis’- please revise as this term typically refers to study design features not present in this study

Limitations well acknowledged

Reviewer 2

Name Pappadis, Monique R.

Affiliation University of Texas Medical Branch School of Health Professions, Division of Rehabilitation Sciences

Date **24-Feb-2024**

COI **None.**

Thank you for the opportunity to review the authors' work and contributions to the literature on post-stroke emotionalism. The main objective of this study was to examine the differences in carer strain by whether an individual is a carer of someone with post-stroke emotionalism (PSE) or not. Additionally, the study explored the relationship between carer strain and characteristics of the care recipient. The study of PSE is very interesting and additional work is needed. Overall, limited research has explored PSE; however, there is much evidence available related to the relationship of carer strain and the characteristics of the care recipient, which lowers the novelty of the work. Given the focus is on PSE, the authors' work focuses more on carer strain then PSE. Several studies that have explore PSE either quantitatively or qualitatively have not been included in the authors' work and should be considered. There are also significant grammatical errors that should be addressed. Additional specific comments are included below:

Abstract

It would be helpful to modify the Abstract by using BMJ's structured abstract format for original research: Objectives, Design, Setting, Participants, primary/secondary outcome measures, Results, and Conclusions.

Strengths/ Limitations

These should only focus on the methodology and not the results. Please modify bullets.

Background

Overall, the Background would benefit from a more detailed review of PSE. Several recent quantitative and qualitative studies are not included in the Background. Also, there have been several studies that have explored stroke survivors' characteristics with carer strain or burden that were not included.

Aim 3 should be emphasized and included in the Abstract. (Page 5, Line 54)

Methods

Typo page 6, Line 13, Line 16

Limitation noted is that carer information was not obtained. Page 7, Lines 3-6.

What was the reliability of the MCSI in this study? Page 7, Line 39

More details should be included on the TEARS-IV used to examine PSE. Page 7, Lines 46-51

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Please consider modifying the paragraph to explore reasons for such findings or relate the findings to existing literature. Page 12, Lines 11-32.

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Other than the study by Colamonico, there was not detailed discussion on how the studies results either corroborate with or contradict existing literature.

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VERSION 1 - AUTHOR RESPONSE

Reviewer: 1

Dr. Madeleine Hinwood, The University of Newcastle

Comments to the Author:

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Thank you.

Introduction-

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Thank you. We have added specific text explaining the importance to focus specifically on emotionalism after stroke, strengthening the justification for the current study (page 5)

Post-stroke emotionalism is a symptom I have heard little about. Some more expansion around this term, what outcomes it has been associated with (in stroke and other cohorts),

may be useful to readers. I think it is well defined, but the potential clinical meaningfulness of exploring this area of stroke care could be better elucidated.

Thank you. We have expanded the Background to offer a more detailed commentary on PSE including relevant review articles, emphasising recent quantitative and qualitative work on PSE, noting associated outcomes and setting out the importance clinically of exploring this area of stroke care (page 4).

Methods-

The paper needs a review for grammar- there are some minor errors throughout (e.g. in the sample size section: 'N=102 had informants at 6-month follow up reporting carer strain data').

Thank you. We have carefully re-read the manuscript and corrected all identified typographical and grammatical errors, including the above correction.

More info about carer recruitment required. ‘For each participant, an informant (spouse or closest relative) was recruited.’ Were these definitely the primary caregiver for the stroke survivor? Patient/carer dyads appeared to be recruited in the acute phase of stroke, but the interview for this study did not occur until month 6- what if there was a change in carer or similar over this time?

Thank you. We have clarified that our CRF and site training required the TEARS research nurses to complete MCSI for all patients “…by interviewing the nearest relative/carer”. WE also clarify the MCSI instructional set states: “…Here is a list of things that other caregivers have found to be difficult. Please put a tick in the columns that apply to you.” (page 7)

We note we did not collect data on the relationship between the patient and the caregiver, nor on the caregivers themselves. We assume but do not definitely know that respondents were the primary caregiver. It could be that an individual who escorted the patient to the six-month appointment was a significant caregiver (e.g. a daughter), but not the primary caregiver (e.g. the spouse). We have clarified this in Methods (page 7) and added text in the Limitations section of Discussion (page 14).

Results

Please define all scales used in footnotes to tables- for example, I am unsure what a social deprivation score of 2600 versus one of 2966 means, or what the stroke classifications are.

Thank you. We have added footnotes to all three Tables, defining the scales used (page 18-20), including the Oxford Stroke Classifications. We have amended the text in Measures and Procedure, clarifying that the social deprivation measure used was the Scottish Index of Multiple Deprivation rank provided by the Scottish Government based on 6976 data zones. A rank of 1 corresponds to the most deprived area or data zone and 6976 the least deprived.

You claim no difference between respondents and non-respondents to MCSI. I find that difficult to believe, particularly as you did not include carer characteristics. The response to this survey may be more likely to differ by carer characteristics than by patient characteristics. Regardless, even though statistical significance was not reached, there are also differences between these patient groups (e.g. sex, social deprivation, stroke classification).

The selection bias is in two stages- those who initially agreed to participate, and then of this group, only those with a non-missing MCSI were included. I think this needs to be acknowledged.

Thank you. We looked at respondents/non-respondent differences in case there was a bias. We did not find evidence of bias but we acknowledge there still could be. Importantly, we are not claiming there is no selection bias, rather that we looked and found none. We have added text in the Limitations acknowledging that we only measured certain respondent/non-respondent differences, and there could be sampling bias, but that we found no evidence of this (page 14).

Are the percentages correct in Table 1? Some sum to more than 100% in the groups I believe make sense (e.g. stroke classification)- this may be because patients could fall into more than one category, but needs to be clarified in a footnote to the tables.

Thank you. We have carefully checked the percentages in Table 1 for all relevant data.

I prefer not to perform variable selection by using those which are statisticially significantly associated with the outcome, but rather select covariates based on prior knowledge/expert opinion. Otherwise, the descriptive exploration of the association between PSE and carer strain seems reasonable.

Thank you. This was an exploratory analysis and we had little previous knowledge about carer strain in stroke emotionalism, as it is very under researched. The statistical approach used thus aimed to reduce the data to a parsimonious model, to avoid nuisance variables.

Discussion

P12 'the findings offer a longitudinal analysis'- please revise as this term typically refers to study design features not present in this study

Thank you. The reference to 'longitudinal analysis' on page 13 has been removed.

Reviewer: 2

Dr. Monique R. Pappadis, University of Texas Medical Branch School of Health Professions

Comments to the Author:

Thank you for the opportunity to review the authors' work and contributions to the literature on post-stroke emotionalism. The main objective of this study was to examine the differences in carer strain by whether an individual is a carer of someone with post-stroke emotionalism (PSE) or not. Additionally, the study explored the relationship between carer strain and characteristics of the care recipient. The study of PSE is very interesting and additional work is needed. Overall, limited research has explored PSE; however, there is much evidence available related to the relationship of carer strain and the characteristics of the care recipient, which lowers the novelty of the work. Given the focus is on PSE, the authors' work focuses more on carer strain then PSE. Several studies that have explore PSE either quantitatively or qualitatively have not been included in the authors' work and should be considered. There are also significant grammatical errors that should be addressed. Additional specific comments are included below:

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Thank you. We have rewritten the Abstract to ensure it is structured according to BMJ submission guidelines for research: Objectives, Design, Setting, Participants, Primary and Secondary Outcome Measures, Results, Conclusions, Trial Registration. (page 2-3)

Strengths/ Limitations

These should only focus on the methodology and not the results. Please modify bullets.

Thank you. We have amended Strengths and Limitations section, relating specifically to the methods and not to the results of the study.

Background

Overall, the Background would benefit from a more detailed review of PSE. Several recent quantitative and qualitative studies are not included in the Background. Also, there have been several studies that have explored stroke survivors' characteristics with carer strain or burden that were not included.

Thank you. We have expanded the Background to offer a more detailed commentary on PSE including relevant review articles, emphasising recent quantitative and qualitative work on PSE, noting associated outcomes and setting out the importance clinically of exploring this area of stroke care (page 4).

We have also added commentary in the Background on the prevalence of caregiver burden in stroke, and also citing literature which links stroke survivor characteristics with heightened carer strain/burden (page 4).

Aim 3 should be emphasized and included in the Abstract. (Page 5, Line 54)

Thank you. We have emphasised Aim 3 and included this in the Abstract (page 6).

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What was the reliability of the MCSI in this study? Page 7, Line 39

Thank you. Our sample size was unfortunately too small to sensibly consider computing reliability within the study. We include text as follows (page 7), highlighting the reliability of the MCSI:

“MCSI has acceptable internal (alpha=.90) and test-retest reliability (alpha=.86) basing on the Thornton and Travis sample14, and has been used previously to screen carer burden in the context of neurologic disease18,19, including stroke.20”

More details should be included on the TEARS-IV used to examine PSE. Page 7, Lines 46-51

Thank you. We have added additional text summarising the structure and diagnostic basis of TEARS-IV used to examine PSE (page 8).

RESULTS

Consider modifying sentence for clarity: page 10, 28-31. "The Barthel Index..."

Thank you. We have amended this sentence for clarity, as follows:

“The Barthel Index was lower in PSE patients known to have PSE, suggesting emotionalism associates with greater functional dependence”

Typo Page 11, Line 33

Thank you. We have carefully read the manuscript and corrected all identified typographical and grammatical errors.

DISCUSSION

Please consider modifying the paragraph to explore reasons for such findings or relate the findings to existing literature. Page 12, Lines 11-32.

Thank you. We would note that this is the first paper to study carer strain specifically in emotionalism following stroke and so we are not aware of other studies in this area with which to compare, beyond the Calamonico paper which we do discuss (page 13).

Another Limitation is that the characteristics of the carers were not obtained or considered.

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Thank you. This is the first paper to study carer strain specifically in emotionalism following stroke and so we are not aware of other studies in this area with which to compare, beyond the Calamonico paper which we do discuss (page 13).

There is qualitative research on PSE that exists. Page 14, Lines 25-30.

Thank you. We have clarified this in the relevant text (page 14-15).

Yours Sincerely

Niall M Broomfield

VERSION 2 - REVIEW

Reviewer	**1**
Name	**Hinwood, Madeleine**
Affiliation	**The University of Newcastle, School of Medicine and Public Health**
Date	**12-Aug-2024**
COI	**None to declare**

Thank you for your resubmission of this interesting article. I have a few queries.

- I could not replicate your power calculation. It is not clear whether a 1-unit difference in means on the MCSI is clinically relevant, but regardless my calculations returned very low levels of power unless I made fairly favourable assumptions about the variance. I am not sure what standard deviation you used in your calculation; it is not reported. It is best to report this as sensitivity or achieved power- the effect size you could detect given your dataset. It's fine if the study was rather underpowered, but this should just be acknowledged.

- I think the way you have addressed missing data may be reasonable, but it should be acknowledged that there are likely to be some unmeasured differences between those who did, and those who did not, complete the follow up survey. I previously made this comment, and it has not been addressed.

- Similarly, I previously noted that I prefer not to perform variable selection by using those which are statisticially significantly associated with the outcome, but rather select covariates based on prior knowledge/expert opinion.

- Otherwise, the descriptive exploration of the association between PSE and carer strain seems reasonable.

Some of my comments regarding methods/results have not been addressed. No response to reviewer comments was included, to allow me to see why this is the case. As such, these comments still stand, as well as any of my previous, minor recommendations which were not addressed.

Reviewer	**2**
Name	**Pappadis, Monique R.**
Affiliation	**University of Texas Medical Branch School of Health Professions, Division of Rehabilitation Sciences**
Date	**19-Aug-2024**
COI	**None.**

Thank you for addressing the reviewers' comments. This manuscript has significantly improved with the additional edits made to the Introduction as well as clarification of the Methods. This work will make a contribution to the limited literature on post-stroke emotionalism.

VERSION 2 - AUTHOR RESPONSE

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Thank you. We have clarified this in the relevant text (page 14-15).

SECOND RESPONSE TO REVIEWERS (SEPTEMBER 2024)

Reviewer: 1
Thank you for your resubmission of this interesting article.

Thank you

I have a few queries. I could not replicate your power calculation.

Thank you. Please note that the standard deviation of our outcome variable MCSI was unknown to us for our target population. Hence the power calculation was based upon standardised effect size: that is, the effect size divided by the standard deviation. Please check calculations using a standard deviation of 1 to see how our calculations are derived.

It is not clear whether a 1-unit difference in means on the MCSI is clinically relevant, but regardless my calculations returned very low levels of power unless I made fairly favourable assumptions about the variance. I am not sure what standard deviation you used in your calculation; it is not reported. It is best to report this as sensitivity or achieved power- the effect size you could detect given your dataset.

Thank you. Please note that our modelling was based on the transformed variable square-root of MSCI, which is more difficult to interpret. To illustrate, please consider the difference seen between those dyads with and without PSE, reported in Table 2 as 9.75 – 4.23 = 5.52 units.

First note that this relates to a standardised difference of 5.52/5.92 = 0.93. [5.92 can be calculated from Table 2 reported SDs]. So, our study has more than 90.9% power based on a *t*-test.

Now consider the clinical meaning of a difference of 5.52 units. Such a difference can only arise by differences in at least 3 of the 13 items – perhaps 2 large differences and a smaller one or differences in 5 or 6 items. There is clearly a meaningful difference in reported carer strain between these two groups. We would ths argue that a five-point difference on MCSI seen between carers of individuals with and without PSE on MCSI, as observed here, would is indeed clinically relevant, requiring response differences by carer group on at least three of the thirteen scale items, or on two items, if big differences.

It's fine if the study was rather underpowered, but this should just be acknowledged.

Thank you. In the Discussion, we now explicitly note that the study is underpowered (page 15)

I think the way you have addressed missing data may be reasonable, but it should be acknowledged that there are likely to be some unmeasured differences between those who did, and those who did not, complete the follow up survey. I previously made this comment, and it has not been addressed.

Thank you. In our initial response, we added text in the Limitations acknowledging that we only measured certain respondent/non-respondent differences, and there could be sampling bias, but that we found no evidence of this (page 15). We now also explicitly acknowledge that, as you suggest, there are likely to be some unmeasured differences between those who did, and those who did not, complete the follow up MCSI survey (page 14).

Similarly, I previously noted that I prefer not to perform variable selection by using those which are statisticially significantly associated with the outcome, but rather select covariates based on prior knowledge/expert opinion. Otherwise, the descriptive exploration of the association between PSE and carer strain seems reasonable.

Thank you. In our initial response (please see above Initial response to reviewers July 2024), we noted that this was an exploratory analysis and we had little previous knowledge about carer strain in stroke emotionalism, as it is very under researched. The statistical approach used thus aimed to reduce the data to a parsimonious model, to avoid nuisance variables.

We share your preferred approach to variable selection for situations where there is good prior knowledge. However, here the situation was that there is little established prior evidence and we thus sought to highlight the strongest associations while dropping variables with weaker associations which might just have been nuisance variables. Our approach was exploratory and we would not claim that there is no association with those variables dropped

but sought only to identify main associations. Accordingly, we have now added a sentence in Methods Statistical Analysis (page 11) underlining this position.

Some of my comments regarding methods/results have not been addressed.

We endeavoured to directly address all your very helpful comments – please see above Initial response to reviewers (July 2024)

No response to reviewer comments was included, to allow me to see why this is the case. As such, these comments still stand, as well as any of my previous, minor recommendations which were not addressed.

We are very sorry that you did not receive our initial response to reviewers document, please see above Initial response to reviewers (July 2024)

Reviewer: 2

Thank you for addressing the reviewers' comments. This manuscript has significantly improved with the additional edits made to the Introduction as well as clarification of the Methods. This work will make a contribution to the limited literature on post-stroke emotionalism.

Thank you

VERSION 3 - REVIEW

Reviewer	**1**
Name	**Hinwood, Madeleine**
Affiliation	**The University of Newcastle, School of Medicine and Public Health**
Date	**27-Oct-2024**
COI	

Once again, some of my previous comments regarding methods/results have not been addressed. As no response to reviewer comments was included, I cannot see why this is the case. As such, these comments still stand, as well as any of my previous, minor recommendations which were not addressed.

Apart from this, overall the manuscript does appear to be improved, but I do have remaining queries which have not been answered, in particular more details around the sample size calculation.