

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Sense of coherence and physical health-related quality of life in Italian chronic patients: The mediating role of the mental component
AUTHORS	Galletta, Maura; Cherchi, Manuela; Cocco, Alice; Lai, Giacomo; Manca, Valentina; Pau, Martina; Tatti, Federica; Zambon, Giorgia; Deidda, Simona; Origa, Pierangelo; Massa, Elena; Cossu, Efsio; Boi, Francesco; Contu, Paolo

VERSION 1 – REVIEW

REVIEWER	Roald Pijpker/Lenneke Vaandrager Wageningen University, Department of Social Sciences, Health & Society
REVIEW RETURNED	16-Mar-2019

GENERAL COMMENTS	<p>The authors address a significant research gap within the field of health promotion and salutogenesis. Although there is an accumulating body of evidence supporting the relationship between Sense of Coherence (SOC) and health development in patients with chronic illness, much less is known about how a strong SOC influences their health-related quality of life. The authors aimed to test the mediating effects of the mental component of quality of life (MC) within the relationship between SOC and the physical component of quality of life (PC). The study found that the MC could explain – to a certain extent – the associations between a strong SOC and the PC in patients with a chronic illness. The results are hence worthwhile publishing as this study captures both scientific and practical relevance. However, a major revision is necessary to enhance the quality of the study, in particular, the mediation analysis. Overall, the contribution of the authors to the lesser-researched part within the salutogenic model is highly appreciated, just as its relevance for health promotion practice.</p> <p>Major issues Introduction: the independent variable is SOC, the dependent variable is the PC of quality of life, and the mediating variable is the MC of quality of life. However, this is not clear in the study aim (lines 37-42 – page 6). Therefore, I suggest that the authors redefine their aim more concisely as “quality of life” is not the dependent variable of the study, but the PC of quality of life is the dependent variable. I also suggest to explain what is meant by a mediating (i.e., explaining) variable; this is not always clear for people who are not familiar with using quantitative approaches. Line 19 - page 4: it is not only about using resources, but also the ability to identify and (re)use resources “in a health-promoting way”. I suggest rephrasing those lines.</p>
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Lines 35-47 – page 4: SOC is about being able to identify and (re)use their resources to deal “with the tension raised by stressors effectively (e.g., stressful events)”. Being able to deal, overcoming, or avoiding tension raised by stressors is something different than ‘dealing’ with stressors. The authors should emphasise this to prevent that SOC becomes a personal trait/psychological coping skill; it is an underlying resource enabling effective coping strategies.

Lines 32-37 page 5: it is not clear what the authors mean with activating their resilience resources. SOC refers to the ability to identify and (re)use resources from their internal or external environment. Also, I suggest giving some examples of what is meant with internal/external resources.

Methods: the sampling procedure and inclusion criteria are well justified. The data collection, however, lacks clarity. What is meant by completed questionnaires and directly returned to the researchers (lines 21-23 – page 7) ?. Does that imply that non-completed questionnaires were excluded for the data-analysis and that the researchers conducted the interviews face-to-face?

The statistical procedure (lines 12-31 page 8) does not enable other researchers to replicate the analysis. PROCESS is indeed suitable to test for mediating effects of variables; however, Model 4 is not explained. I suggest describing the underlying assumptions of the conceptual diagram.

Results: the results are well described, but not complete nor answering the research question. Moreover, the most critical analysis is missing (i.e., Model 4; the mediation analysis), which makes it impossible to retrace the results. Table 3 claims to present the mediation analysis, but the coefficient (.66) is nowhere to be found within this table. For now, Table 3 refers to a multiple regression analysis, and not a mediation analysis. I suggest using a diagram to show the effects/coefficients of the variables for each path. An example can be found in the paper of Pijpker et al., (2018) who also used PROCESS (Model 4) to test for mediating effects. Finally, clarity about how the correlations analysis was conducted is lacking (e.g., what test did the authors use?; a two or a one-sided test?).

Discussion: the authors reflect on their findings, limitations and implications of public health and communities. Most parts are sound and make sense when looking at the cross-sectional research design and the overall aim of the study. At the same time, the claims made about the mediating effects of MC are not supported by data and hence not valid (see previous comments). Also, I do not agree with the researcher’s claim that SOC becomes relatively stable in adulthood (lines 51-53 page 11). SOC has shown to increase with age, reaching its highest levels at older ages. Since age has shown to be a possible confounder in Table 3, I encourage to reflect what that means for the conclusions drawn.

Conclusions: because the mediation analysis is missing in the methods and results, the conclusions are not valid nor supported by data.

In summary, explaining, and reporting the mediation analysis, will enhance the internal validity claims of the study in such a way the results should be published.

	<p>Minor issues</p> <p>Use of English: I suggest that the authors consult a native English speaker to correct for grammar and spelling throughout the manuscript.</p> <p>References: the reference list also needs a rigour revision as references are reported inconsistently (e.g., use of capital letters).</p> <p>An example of how to report a mediation analysis (model 4 of PROCESS): Pijpker, R., Vaandrager, L., Bakker, E. J., & Koelen, M. (2018). Unravelling salutogenic mechanisms in the workplace: the role of learning. <i>Gaceta Sanitaria</i>, 32(3), 275-282.</p>
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REVIEWER	Geir Lorem UiT The arctic university of Norway
REVIEW RETURNED	05-Apr-2019

GENERAL COMMENTS	<p>Thank you for an interesting article. Despite its limitations (x-section and limited sample) your article contains relevant findings for clinical practices. The article also discuss its limitations in a sound and self-critical manner but should include a power analysis. I also like the utilization of mediation analysis and the manner you communicate its results.</p> <p>My remarks are thus minor, but I think they will strengthen the argument of the article.</p> <p>P2 l7. SOC is not defined at first introduction of the abbreviation</p> <p>P2 l28-30 and P9 l12ff: You say that SOC score of the study sample was equivalent to that of general population (mean difference = -2.7, 95% CI = -4.8-.00). However, you do not discuss this analysis in the methods or limitations. Since the sample is small, you need a power calculation. What was the statistical power? What is a clinical significant difference? And do you have statistical power to examine this difference?</p> <p>P5 l40ff. The literature review can be improved. Health related quality of life and Self-reported health is an interesting concept and there are more research that examines the dynamics between known disease, mental health and perceived health. Here are two examples of studies that examines similar dynamics.</p> <p>I generally do not suggest own work in reviews, but we published a similar study examining the dynamics between known disease, mental health and SRH in 2016. We not only found the associations but also point to the fact that somatic disease has increased its significance from 1994 to 2008 partly because of its strong association with mental health. Although our study is based on a general population and do not include SOC, it indicates a similar dynamics in a general population and concurs with your study. I leave it to your discretion and literature review but I think the article would benefit from a broader literature review and a few references that contextualize your research into the ongoing research on SRH and HRQOL.</p> <p>P7 l 28: Are the diagnosis self-reported or based on the patient journals? The section should also clearly indicate which variable that were outcome, independent variables of interest, and which that were considered as confounders for the sake of the analysis.</p> <p>P9 l23: "mediation analysis was performed via PROCESS macro" You need to explain the principles and steps of this analysis. Moreover, what does model 4 look like? The article needs to include a directed acyclic graph of your conceptual model as well as its transition into a statistical model.</p>
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	<p>P10 I35: “The results are in line with theoretical purpose by showing that SOC is mainly correlated to MCS ($r = .52$) and then to PCS ($r = .35$).” Moreover, MCS and PCS was 0.73. Consider to include a remark on this in-text, too.</p> <p>P11 I16: “... findings support that SOC is a psychological process that affects patients’ mental health status, which in turn affects their physical health.” It is not possible to draw this conclusion from x-sectional data. You don’t have access to the timeline, and consequently have a problem with reversed causality. Moreover, longitudinal studies also suggest that impaired mental health may follow physical illness. Please, revise the statement.</p> <p>P13 I16. Include power analysis, as suggested above.</p> <p>p12 I25 I would also like to see the total effect, and subsequently also calculations of the relative effectsizes of the direct and mediated effects in relation to the total effect. It could be included in the DAG diagram.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1

	Reviewer’s comment	Author’s response
	<p>Introduction: the independent variable is SOC, the dependent variable is the PC of quality of life, and the mediating variable is the MC of quality of life. However, this is not clear in the study aim (lines 37-42 – page 6). Therefore, I suggest that the authors redefine their aim more concisely as “quality of life” is not the dependent variable of the study, but the PC of quality of life is the dependent variable.</p>	<p>Thank you for this suggestion. Now, in Page 6, last sentence, we specified that our dependent variable is physical health-related quality of life.</p>
	<p>I also suggest to explain what is meant by a mediating (i.e., explaining) variable; this is not always clear for people who are not familiar with using quantitative approaches.</p>	<p>Thank you, we agree it is important to be clearer for readers. We integrated an explanation of mediator variable in Page 9, within the statistical analysis section.</p>
	<p>Line 19 - page 4: it is not only about using resources, but also the ability to identify and (re)use resources “in a health-promoting way”. I suggest rephrasing those lines.</p>	<p>Thank you. We reworded the sentence and now it sounds as follows: “The concept relies not only on using resources (e.g., economic, social, healthy lifestyles, self-esteem, experience, knowledge resources, etc.), but also on the ability to identify and (re)use resources in a health-promoting way.” (Page 4, top paragraph).</p>
	<p>Lines 35-47 – page 4: SOC is about being able to identify and (re)use their resources to deal “with the tension raised by stressors effectively (e.g., stressful events)”. Being able to deal, overcoming, or avoiding tension raised by stressors is something different than ‘dealing’ with stressors. The authors should emphasise this to prevent that SOC becomes a personal</p>	<p>We agree with reviewer. We reworded that sentence by emphasizing SOC as a resource enabling coping strategies. Now the sentence sounds as follows “This depends on whether they are able to deal with, overcome, or avoid the tension generated by stressors (e.g., stressful events) effectively by identifying and (re)using resources.⁴ The</p>

	<p>trait/psychological coping skill; it is an underlying resource enabling effective coping strategies.</p>	<p>ability to identify and (re)use resources to effectively cope with stressful events and promote health would positively influence one's own health condition.¹ It can be explained by the sense of coherence concept,^{5 6} which is an underlying resource enabling effective coping strategies that forms the basis of the salutogenic model." (Page 4, bottom paragraph).</p>
	<p>Lines 32-37 page 5: it is not clear what the authors mean with activating their resilience resources. SOC refers to the ability to identify and (re)use resources from their internal or external environment. Also, I suggest giving some examples of what is meant with internal/external resources.</p>	<p>Thank you. We reworded the whole part and gave some examples of internal/external resources (Page 5). "The literature indicates that SOC is related to an individual's ability to identify and (re)use resources from his/her internal (e.g., cognitive, emotional, and behavioral strategies) or external (e.g., social support, social fairness, relationships, outdoor life, culture) environment to cope with difficulties and maintain good health.^{10 11 12 13} According to Antonovsky,^{4 6} individuals with high SOC perceive stressors as challenges, and thus anticipate events and the resources available to modify their perception of life and move from a condition of illness to one of health. High SOC strengthens resilience and promotes an individual state of well-being.^{1 4}"</p>
	<p>Methods: the sampling procedure and inclusion criteria are well justified. The data collection, however, lacks clarity. What is meant by completed questionnaires and directly returned to the researchers (lines 21-23 – page 7) ?. Does that imply that non-completed questionnaires were excluded for the data-analysis and that the researchers conducted the interviews face-to-face?</p>	<p>Thank you. We specified that all the patients completed the questionnaire autonomously and then returned it directly to the researchers (Page 7, "data collection" section). Also, in the instrument section, we explained that questionnaires were self-reported but the demographic part was completed by the physician via patient interviews. Demographic and self-reported parts of the questionnaire were then matched via coding scheme to guarantee patients' privacy (Page 7, bottom, and page 8, top paragraph).</p>
	<p>The statistical procedure (lines 12-31 page 8) does not enable other researchers to replicate the analysis. PROCESS is indeed suitable to test for mediating effects of variables; however, Model 4 is not explained. I suggest describing the underlying assumptions of the conceptual diagram.</p>	<p>Thank you for the suggestion. We explained Model 4 and added the conceptual diagram (Page 9 and Figure 1,).</p>
	<p>Results: the results are well described, but not complete nor answering the research question. Moreover, the most critical analysis is missing (i.e., Model 4; the mediation analysis), which</p>	<p>Thank you for suggesting Pijpker et al., (2018)'s article. We rewrote the results in the text, and re-structured Table 3 with mediation results for Model 4. Also, we integrated a</p>

	<p>makes it impossible to retrace the results. Table 3 claims to present the mediation analysis, but the coefficient (.66) is nowhere to be found within this table. For now, Table 3 refers to a multiple regression analysis, and not a mediation analysis. I suggest using a diagram to show the effects/coefficients of the variables for each path. An example can be found in the paper of Pijpker et al., (2018) who also used PROCESS (Model 4) to test for mediating effects.</p>	<p>statistical diagram (Figure 2) showing the coefficients of the variables for each path (Pages 11-12).</p>
	<p>Finally, clarity about how the correlations analysis was conducted is lacking (e.g., what test did the authors use?; a two or a one-sided test?).</p>	<p>Thank you for your advice. We specified that bivariate analysis was conducted using Pearson's correlation (Page 8 bottom, "statistical analysis" section). We also integrated information about the test in Table 2, "(two-tailed)" test.</p>
	<p>Discussion: the authors reflect on their findings, limitations and implications of public health and communities. Most parts are sound and make sense when looking at the cross-sectional research design and the overall aim of the study. At the same time, the claims made about the mediating effects of MC are not supported by data and hence not valid (see previous comments).</p>	<p>We thank you for pointing this out. As per your comment #8, we rewrote the results (e.g., Table 3 and statistical diagram) to make clear the mediation analysis results, thus making now the discussion section more coherent with the findings.</p>
	<p>Also, I do not agree with the researcher's claim that SOC becomes relatively stable in adulthood (lines 51-53 page 11). SOC has shown to increase with age, reaching its highest levels at older ages. Since age has shown to be a possible confounder in Table 3, I encourage to reflect what that means for the conclusions drawn</p>	<p>Thank you for bringing this point to our attention. We made changes in the text and integrated as follows: "research showed that SOC may increase with age, reaching its highest levels at older ages¹³. In addition, age proved to be a possible confounder in our study as it was negatively related to both the MCS and PCS components of quality of life." (Page 14, top paragraph).</p>
	<p>Conclusions: because the mediation analysis is missing in the methods and results, the conclusions are not valid nor supported by data. In summary, explaining, and reporting the mediation analysis, will enhance the internal validity claims of the study in such a way the results should be published.</p>	<p>Based on your comments #8 and #10, we have extended the method and results sections to make clear mediation analysis. In this way, conclusions are supported by data.</p>
	<p>Minor issues Use of English: I suggest that the authors consult a native English speaker to correct for grammar and spelling throughout the manuscript.</p>	<p>Thank you for your suggestion. The whole manuscript has been proofread by a professional copy-editing service.</p>
	<p>References: the reference list also needs a rigour revision as references are reported inconsistently (e.g., use of capital letters).</p>	<p>Thank you. We made a thorough check of all references and edited those that were incorrectly reported.</p>

Reviewer 2

	Reviewer's comment	Author's response
1.	P2 I7. SOC is not defined at first introduction of the abbreviation	Thank you. Sorry for this oversight. We defined SOC in the Abstract (Page 2).
2.	P2 I28-30 and P9 I12ff: You say that SOC score of the study sample was equivalent to that of general population (mean difference = -2.7, 95% CI = -4.8-.00). However, you do not discuss this analysis in the methods or limitations. Since the sample is small, you need a power calculation. What was the statistical power? What is a clinical significant difference? And do you have statistical power to examine this difference?	Thank you for bringing this point to our attention. We introduced power analysis in Page 8, "statistical analysis" section, and reported the results in Page 10. Moreover, we added in the limitation section as follows: "However, statistical power analysis shows that our sample is representative of the general population." (Page 14).
3.	P5 I40ff. The literature review can be improved. Health related quality of life and Self-reported health is an interesting concept and there are more research that examines the dynamics between known disease, mental health and perceived health. Here are two examples of studies that examines similar dynamics. I generally do not suggest own work in reviews, but we published a similar study examining the dynamics between known disease, mental health and SRH in 2016. We not only found the associations but also point to the fact that somatic disease has increased its significance from 1994 to 2008 partly because of its strong association with mental health. Although our study is based on a general population and do not include SOC, it indicates a similar dynamics in a general population and concurs with your study. I leave it to your discretion and literature review but I think the article would benefit from a broader literature review and a few references that contextualize your research into the ongoing research on SRH and HRQOL.	Thank you for this suggestion. We found your article interesting and integrated it in our literature/reference list (Page 6).
4.	P7 I 28: Are the diagnosis self-reported or based on the patient journals? The section should also clearly indicate which variable that were outcome, independent variables of interest, and which that were considered as confounders for the sake of the analysis.	The questionnaire consisted of two sections. The first included demographic variables among which diagnosis. The Physician completed this part of the questionnaire via patient interviews. Diagnosis were based on medical record. The second section of the questionnaire was self-reported by patients. We explained that in Pages 7 and 8, "Instrument" section. Also, the information about independent, dependent and confounders variables was

		reported in the statistical analysis section, bottom paragraph, Page 8.
5.	P9 I23: "mediation analysis was performed via PROCESS macro" You need to explain the principles and steps of this analysis. Moreover, what does model 4 look like? The article needs to include a directed acyclic graph of your conceptual model as well as its transition into a statistical model.	Thank you for the suggestion. We explained Model 4 and added the conceptual diagram (Page 9 and Figure 1). Also, we integrated a statistical diagram (Figure 2) showing the coefficients of the variables for each path (Page 12).
6.	P10 I35: "The results are in line with theoretical purpose by showing that SOC is mainly correlated to MCS (r = .52) and then to PCS (r = .35)." Moreover, MCS and PCS was 0.73. Consider to include a remark on this in-text, too.	Thank you for this suggestion. We added the comment in Page 11, bottom paragraph.
7.	P11 I16: "... findings support that SOC is a psychological process that affects patients' mental health status, which in turn affects their physical health." It is not possible to draw this conclusion from x-sectional data. You don't have access to the timeline, and consequently have a problem with reversed causality. Moreover, longitudinal studies also suggest that impaired mental health may follow physical illness. Please, revise the statement.	We thank you for pointing this out. Now we reworded the statement as follows: "...these findings support the idea that SOC is a psychological process that is related to patients' mental health status, ^{11 23} which is positively associated with their physical health" (Page 13, middle paragraph).
8.	P13 I16. Include power analysis, as suggested above.	Thank you. As we carried out power analysis, we added in the limitations section as follows: "However, statistical power analysis shows that our sample is representative of the general population." (Page 14).
9.	p12 I25 I would also like to see the total effect, and subsequently also calculations of the relative effectsizes of the direct and mediated effects in relation to the total effect. It could be included in the DAG diagram.	Thank you for this advice. We reported all the results for Model 4 in a new Table 3 in which you can see all the coefficients, including total effect. Also, we added the results in the statistical diagram of Figure 2 (Page 12).

VERSION 2 – REVIEW

REVIEWER	Roald Pijpker Health and Society, Department of Social Sciences, Wageningen University & Research, Wageningen, the Netherlands
REVIEW RETURNED	09-Jul-2019

GENERAL COMMENTS	I want to compliment on how the authors have used the comments. The research contributes to the field of health promotion and salutogenesis and is worthwhile publishing. However, I still have some issues that should be tackled. I have listed my points below list-wise:
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	<p>1. abstract: the physical component of health-related quality of life is missing in the objective, and hence comes out of the blue in the results. I would suggest rephrasing the objective more concisely (as done in the introduction): ...mediating role of the mental component of quality of the physical component of quality of life.</p> <p>2. page 33: your findings are very much in line with SOC being a predictor of quality of life. Your study hence not only complements but also confirms previous research on SOC and health-related quality of life. The authors should highlight this strength in the discussion.</p> <p>3. page 34 and abstract: in the abstract, the authors state that better knowledge of a person's SOC and how it affects the health-related quality of life may help to plan tailoring interventions to strengthen SOC and improve health-related quality of life. Subsequently, in the discussion on page 34, the authors give multiple intervention strategies (all on the individual level) for enhancing SOC-levels. Could the authors reflect on how to strengthen external resources as well, rather than to make people more aware of their resources? SOC and resources have shown to affect (strengthen) each other in a reciprocal way and hence should, in my opinion, be both addressed. A related issue concerns what a salutogenic intervention exactly entails, see the recently published article about unaddressed knowledge gaps: Future directions for the concept of salutogenesis: a position article (Bauer et al. 2019). I suggest taking these recent developments into account.</p>
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REVIEWER	Geir Lorem UiT The arctic university of Norway
REVIEW RETURNED	05-Jun-2019

GENERAL COMMENTS	The revision clarified my questions. It is interesting work. I have no more remarks.
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VERSION 2 – AUTHOR RESPONSE

Reviewer 1

	Reviewer's comment	Author's response
	<p>1. abstract: the physical component of health-related quality of life is missing in the objective, and hence comes out of the blue in the results. I would suggest rephrasing the objective more concisely (as done in the introduction): ...mediating role of the mental component of quality of the physical component of quality of life.</p>	<p>Thank you. We specified the study aim as we done in the introduction.</p>
	<p>2. page 33: your findings are very much in line with SOC being a predictor of quality of life. Your study hence not only complements but also confirms previous research on SOC and</p>	<p>Thank you for the suggestion. We integrated a sentence in the discussion (Pages 11-12).</p>

	health-related quality of life. The authors should highlight this strength in the discussion.	
	<p>3. page 34 and abstract: in the abstract, the authors state that better knowledge of a person's SOC and how it affects the health-related quality of life may help to plan tailoring interventions to strengthen SOC and improve health-related quality of life. Subsequently, in the discussion on page 34, the authors give multiple intervention strategies (all on the individual level) for enhancing SOC-levels. Could the authors reflect on how to strengthen external resources as well, rather than to make people more aware of their resources? SOC and resources have shown to affect (strengthen) each other in a reciprocal way and hence should, in my opinion, be both addressed. A related issue concerns what a salutogenic intervention exactly entails, see the recently published article about unaddressed knowledge gaps: Future directions for the concept of salutogenesis: a position article (Bauer et al. 2019). I suggest taking these recent developments into account.</p>	<p>Thank you. This is an important suggestion because we have the opportunity to quote a very recent work on the topic.</p> <p>We added a reflection to on how to strengthen external resources (Page 13).</p>

VERSION 3 – REVIEW

REVIEWER	Roald Pijpker Health and Society, Wageningen University, Wageningen, The Netherlands
REVIEW RETURNED	02-Aug-2019
GENERAL COMMENTS	The revision clarified my questions. I have no more remarks