

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)	Long-term effectiveness of rehabilitation services delivery for Wenchuan earthquake survivors with impairments over a four year period: a prospective cohort study
AUTHORS	Reinhardt, Jan; Zhang, Xia; Chen, Shi; Li, Jianan; Zhou, Mouwang; Khan, Fary

VERSION 1 – REVIEW

REVIEWER	Shapiro, Lauren University of Miami
REVIEW RETURNED	15-Dec-2021

GENERAL COMMENTS	<p>It is essential to share program evaluations of disaster rehabilitation programs such as these, and this one is particularly comprehensive and useful, as there was a natural control group. The statistical analysis is extremely complex for such a report, and I would recommend specialist statistical review. There are scattered punctuation errors throughout the report. A table clarifying the types of fractures cared for would be helpful, as one would expect different needs for rehabilitation services and outcomes depending on fracture type/location. The figures are missing on page 20 but are found later in the draft manuscript.</p>
-------------------------	---

REVIEWER	Takahashi, Shuko Nagasaki Daigaku Daigakuin Ishiyakugaku Sogo Kenkyuka, International Health
REVIEW RETURNED	13-Jan-2022

GENERAL COMMENTS	<p>This manuscript compared the effectiveness of rehabilitation services between two intervention groups and the control group after the 2008 Wenchuan earthquake. The early and late rehabilitation groups significantly improved physical function than the others. There was a substantial effect of rehabilitation on pain only in the early rehabilitation group while there was no significant effect of rehabilitation on post-traumatic stress disorder among groups.</p> <p>This article might provide important findings of the effectiveness of the early implementation of rehabilitation after natural disasters, in particular, some clues for policymakers to prepare countermeasures in catastrophic natural disasters. However, there are several uncertainties concerning the study and the description of the study in the manuscript.</p> <p>Major comments.</p>
-------------------------	--

	<p>1. My main concern is an interpretation of the authors' results. The authors explained the learning effect regarding implementation about more efficient in terms of a greater improvement overtime in the later implementation of the NHV program (page 15 line 287 to line 289). Could the authors explain more "learning effects" in this survey? I recognized that staff including nurses and physical therapists treated patients in each hospital, i.e., there was no exchange of staff or personnel between hospitals. Are there any other explanations for the authors' findings?</p> <p>2. I understood that this survey started the different time points among three areas and noted that patients were taken on community-based rehabilitation after discharge. On the other hand, did patients get any other types of rehabilitation after & after implementation of rehabilitation in hospitals among three groups? For example, people with NHV-L were taken some kinds of rehabilitation such as weight-bearing exercise before implementing NHV.</p> <p>3. The victims in Shifang county could not take the NHV program in the Introduction section, but the authors took informed consent from patients in patients in Shifang. What kinds of informed consent did the authors take in Shifang area? Did authors get IC before the survey or after the survey? If they got IC before starting this survey, it would be ethically permissible to conduct this study when rehabilitation was not possible due to accidental effects. However, if rehabilitation was not intentionally introduced, it would be an ethical problem.</p> <p>4. Author should explain the geographic characteristics among three areas in the 2008 Wenchuan earthquake such as the number of dead or missing, a situation of damage, the distance from a seismic center, and so on. In addition, are there any differences in baseline characteristics among the three counties?</p> <p>5. Authors pointed out a scientific reason about the association between a lower incidence of PTSD and rehabilitation referring to an article written by Ni et al. Could the authors add some comments about mechanisms between PTSD and implementing rehabilitation in the Introduction section?</p> <p>6. Mental care for phycological problems is important when victims lost family or close relatives in the disaster. If the NHV program included mental care or psychotherapy, the author should describe it in the manuscript.</p> <p>Minor comments</p> <ol style="list-style-type: none"> 1. "CBR" should not be used in abbreviations. It brings unnecessary effort for the reader. 2. There are some unnecessary "double periods" or comma in this manuscript, for example, page 15 line 298. The author should review the draft from a grammatical point of view. 3. (page 16 line 325 to 327). Please check this sentence grammatical point of view. 4. (page 16 line 312 to 313). What sub-groups indicate?
--	---

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Lauren Shapiro, University of Miami

Comments to the Author:

It is essential to share program evaluations of disaster rehabilitation programs such as these, and this one is particularly comprehensive and useful, as there was a natural control group.

Thank you for the positive feedback.

1. The statistical analysis is extremely complex for such a report, and I would recommend specialist statistical review.

We have added explanations as to why this statistical analysis strategy was chosen. In the end, the fixed effects part of the models can be interpreted analogously to regular OLS regression. However, for estimation of standard errors (and thus p-values) models account for specific features of the data such as clustering of participants in counties, upper and lower scale limits, etc. We hope this is clearer now. We have added:

“Rehabilitation effectiveness on primary and secondary outcomes was analyzed with longitudinal, mixed-effects regression models. In contrast to ordinary least squares regression, mixed-effects models account for clustering of participants in counties and correlation of repeated measurements within subjects.” (lines 163-165)

“Primary outcomes: The MBI and VAS pain scales[19] have known ceiling and floor effects, that is a non-negligible proportion of participants assumes values at the scale maximum or minimum. For example, if a participant reaches the scale maximum of 100 for the MBI further improvement can no longer be measured. Longitudinal Tobit regression was used to model these outcomes to account for this issue.” (lines 170-173)

2. There are scattered punctuation errors throughout the report.

We have carefully reviewed the MS for any punctuation, spelling, and grammatical errors.

3. A table clarifying the types of fractures cared for would be helpful, as one would expect different needs for rehabilitation services and outcomes depending on fracture type/location.

We agree that rehabilitation service needs and outcomes depend on more than broad injury category and fracture locations and type need to be considered for example. The same holds also true for type of spinal cord injury (complete, incomplete, lesion level, etc.), brain injury (initial Glasgow coma scale, etc.), amputations (location) and so on. Unfortunately, more detailed information than the major type of injury was not available from the data on the program evaluation provided to us. We now discuss this as a limitation.

“Third, details on types and locations of fractures, spinal cord injury, amputations, etc. were not available to us from the data we were provided with for this secondary analysis. While one would expect different needs for rehabilitation services and outcomes depending on detailed type and location of injury, baseline scores in function and pain were similar across groups; imbalance between groups in this regard is thus unlikely to have influenced average outcomes.” (lines 360-364)

4. The figures are missing on page 20 but are found later in the draft manuscript.

We assume that this is related to how the pdf proof for your review of the MS has been created by the submission website. The figures have been submitted as separate files as requested for submission.

Reviewer: 2

Dr. Shuko Takahashi, Nagasaki Daigaku Daigakuin Ishiyakugaku Sogo Kenkyuka, Iwate Ika Daigaku - Yahaba Campus

Comments to the Author:

This manuscript compared the effectiveness of rehabilitation services between two intervention groups and the control group after the 2008 Wenchuan earthquake. The early and late rehabilitation groups significantly improved physical function than the others. There was a substantial effect of

rehabilitation on pain only in the early rehabilitation group while there was no significant effect of rehabilitation on post-traumatic stress disorder among groups.

This article might provide important findings of the effectiveness of the early implementation of rehabilitation after natural disasters, in particular, some clues for policymakers to prepare countermeasures in catastrophic natural disasters. However, there are several uncertainties concerning the study and the description of the study in the manuscript.

We thank you for helpful comments which we addressed as below indicated.

Major comments

1. My main concern is an interpretation of the authors' results. The authors explained the learning effect regarding implementation about more efficient in terms of a greater improvement overtime in the later implementation of the NHV program (page 15 line 287 to line 289). Could the authors explain more "learning effects" in this survey? I recognized that staff including nurses and physical therapists treated patients in each hospital, i.e., there was no exchange of staff or personnel between hospitals. Are there any other explanations for the authors' findings?

Thank you for this important comment. We have now clarified that there was partial exchange of staff as some of the external volunteers deployed by Jiangsu Province Hospital, Nanjing, China were transferred to the late intervention setting, training programs for local health professionals had also been updated based on previous experience. Moreover medical overall supervision (our co-author Jian'an Li) and coordination of service delivery (our co-author Xia Zhang) was the same. A learning effect is thus likely. An alternative explanation is survival and selection bias, that is we cannot exclude that initial survivors with very severe injuries in the late setting had passed away after one year or were transferred to other care settings such as nursing homes or the academic level III hospital in the capital of Sichuan Chengdu.

We have revised the passage as follows:

"The later implementation of the NHV program was even more efficient in terms of a greater improvement over time. As some of the external rehabilitation volunteers who were involved in the implementation of NHV-E were transferred to the late intervention setting and overall medical supervision and coordination of service delivery was the same, a learning effect is conceivable. Moreover, the training programs for local health professionals had been updated based on previous experience. An alternative explanation is survival and selection bias. We cannot exclude that initial survivors with very severe injuries in the late setting had passed away after one year or were transferred to other care settings such as nursing homes or the academic level III hospital in Chengdu, the capital of Sichuan. Baseline scores of function and pain, however, did not differ significantly between early and late intervention setting." (lines 325-333)

2. I understood that this survey started the different time points among three areas and noted that patients were taken on community-based rehabilitation after discharge. On the other hand, did patients get any other types of rehabilitation after & after implementation of rehabilitation in hospitals among three groups? For example, people with NHV-L were taken some kinds of rehabilitation such as weight-bearing exercise before implementing NHV. "

No rehabilitation services were provided before the program implementation in both the NHV-E and the NHV-L setting. After hospital-based rehabilitation home-based exercise programs were prescribed for patients by responsible doctors and therapists if indicated. Moreover assistive devices were provided. CBR workers also inspected people's homes and adaptations were made where needed. Within, the CBR program patients were furthermore visited by therapists who provided advice and consultations and modified home-exercise if needed. This is now clarified in the MS:

We made more clear in inclusion criteria that patient should not be or have been involved in any other rehabilitation program.

"According to the principles of intention to treat analysis, data from all participants initially recruited into the program are included in this study in so far as they meet the following inclusion criteria: adult

Wenchuan earthquake survivor with fracture, SCI, TBI, amputation, soft tissue or crush injury caused by the disaster and residing in one of the three counties mentioned above, provided written informed consent for participation in the program evaluation, and not currently enrolled or had previously participated in another rehabilitation program for treatment of Wenchuan earthquake-related injuries.” (Lines 126-131)

3. The victims in Shifang county could not take the NHV program in the Introduction section, but the authors took informed consent from patients in patients in Shifang. What kinds of informed consent did the authors take in Shifang area? Did authors get IC before the survey or after the survey? If they got IC before starting this survey, it would be ethically permissible to conduct this study when rehabilitation was not possible due to accidental effects. However, if rehabilitation was not intentionally introduced, it would be an ethical problem.

Informed consent in Shifang was taken before the baseline survey. This was as in any other cases, personally signed informed consent or witnessed verbal consent for illiterate persons with signature provided by the witness. In all counties, informed consent procedures were repeated for follow-up surveys. The implementation of the rehabilitation program in Shifang county did not take place for reasons that were beyond control of the authors and the NGOs and health professionals responsible for program implementation. This was not influenced by the authors or other staff involved in the rehabilitation program but rather a political decision by the governmental authorities in Shifang. We now clarify this in the MS as follows:

“The same rehabilitation program was planned for implementation at Shifang county where participants were recruited and a baseline survey conducted with informed consent procedures as described in the previous section. However, due to resource constraints the county government eventually decided not to implement the program. Participants from Shifang county who had initially been deemed eligible for rehabilitation, instead served as geographical control group.” (lines 105-110)

4. Author should explain the geographic characteristics among three areas in the 2008 Wenchuan earthquake such as the number of dead or missing, a situation of damage, the distance from a seismic center, and so on. In addition, are there any differences in baseline characteristics among the three counties?

Thanks for this important comment. We have now provided a map (new Figure 1) to show the location of the counties as well as distance from epi-center. Numbers on damage and fatalities in the different counties are now also provided (see lines 111-113).

We furthermore give p-values for any baseline differences in demographics and injury types in Table 1 and explicitly state that there were baseline differences in demographics and injury types, making adjustment for these covariates necessary in analysis.

Methods: “Due to baseline imbalance in demographic characteristics and injury types as well as differences in dropout patterns (see Results, Table 1), models were adjusted for gender (referent: female), age (mean centered), marital status (referent: not married), years of formal education (mean centered) and injury type (referent: fracture).” (lines 181-184).

Results: “At baseline, groups differed significantly in terms of injury characteristics and all demographics apart from gender.” (lines 251-252)

5. Authors pointed out a scientific reason about the association between a lower incidence of PTSD and rehabilitation referring to an article written by Ni et al. Could the authors add some comments about mechanisms between PTSD and implementing rehabilitation in the Introduction section?

Thanks. This connection was indeed missing in the introduction and has been added as suggested.

“Moreover, data on other outcomes including pain and mental health had not been analyzed yet. While function and pain are primary targets of physical rehabilitation interventions in earthquake survivors, effects on mental health outcomes such as post-traumatic stress disorder symptoms are

also conceivable, with possible pathways being through improved physical activity [15] and social support[16], among others.” (lines 86-90)

6. Mental care for psychological problems is important when victims lost family or close relatives in the disaster. If the NHV program included mental care or psychotherapy, the author should describe it in the manuscript.

The inpatient rehabilitation program did not include mental care or psychotherapy but the CBR component included a peer support program as previously described. Supposed pathways for improving mental health are thus improved physical activity and social support as stated in response to your comment 5 above.

Minor comments

7. “CBR” should not be used in abbreviations. It brings unnecessary effort for the reader. Corrected.

8. There are some unnecessary “double periods” or comma in this manuscript, for example, page 15 line 298. The author should review the draft from a grammatical point of view. Corrected.

9. (page 16 line 325 to 327). Please check this sentence grammatical point of view. This has been rewritten.

“Eventually, from an epidemiological standpoint, it is important to develop strategies for drawing random samples from the total affected population in order to determine point prevalence of disability and improve generalizability of findings regarding intervention effectiveness. Pre-established and ideally pre-funded research protocols that can be activated when disaster strikes are thus desirable.” (lines 374-378)

10. (page 16 line 312 to 313). What sub-groups indicate? This has been clarified.

“Second, we provide population-averaged estimation of rehabilitation effects which may differ across sub-groups such as patients with different types of injuries.” (lines 357-358)

VERSION 2 – REVIEW

REVIEWER	Takahashi, Shuko Nagasaki Daigaku Daigakuin Ishiyakugaku Sogo Kenkyuka, International Health
REVIEW RETURNED	25-Feb-2022

GENERAL COMMENTS	The authors have satisfactorily responded to all my questions and made the necessary changes to the manuscript. I recommend that specialists in biostatisticians review these statistical analyses since we can not evaluate them sufficiently about the present study methods. When specialists decide the statistics are appropriate, then I agree with the publication of the study.
-------------------------	---