

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Assessment of patient-reported outcomes after polytrauma: protocol for a systematic review
AUTHORS	Gnass, Irmela; Ritchel, Michaela; Andrich, Silke; Kuske, Silke; Moschinski, Kai; Herrmann-Frank, Annegret; Metzendorf, M; Flohé, Sascha; Sturm, Johannes; Windolf, Joachim; Icks, Andrea

VERSION 1 – REVIEW

REVIEWER	Steven Ferree UMCU the Netherlands
REVIEW RETURNED	15-May-2017

GENERAL COMMENTS	<p>Page 8 L34-35: the authors state “polytrauma (at least two injuries, ISS>15, AIS≥3)”</p> <p>Do the authors mean 2 injuries or do they mean injuries to at least 2 body regions (head, face and neck, thorax, abdomen and extremities)? Definitions for polytrauma vary according to which source is used. An ISS of 16 and higher is usually used. However some authors adhere to the definition that not only should the ISS be 16 or higher but also that it should be the result of injury in more than 1 region.</p>
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REVIEWER	Martin Mueller Rosenheim University of Applied Sciences, Faculty of Applied Health and Social Sciences, Germany
REVIEW RETURNED	17-May-2017

GENERAL COMMENTS	<p>The protocol is well written, follows the scientific standards and reports on an important issue in the research on patients with polytrauma.</p> <p>However, there is one important issue within the manuscript that has to be clarified. The authors provide 3 different aims (in abstract, strengths and limitations and in the main text) and it is not evident, why they differentiate between aim 1 (collect instruments on PROs) and aim 3 (collect other relevant PROs). It is not clear, when outcome measures are classified into the respective groups, in particular, in the light of the given examples (ADL and social participation are an example in both classes).</p>
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	<p>Further minor remarks:</p> <p>Abstract:</p> <p>p. 3</p> <p>I. 41/42: You may want to rethink using qol here and replace it by a more general expression, such as "their lives".</p> <p>I. 45ff (aims): see comment above.</p> <p>p. 4, Strength and limitations:</p> <p>You may want to rewrite the 1st bullet point because there are two studies that analysed the use of outcome measures in poly or multiple trauma: Grill E. et al. Unfallchirurg. 2010 Jun;113(6):448-55 and Hoffman K et al. PLoS One. 2014 Jul 22;9(7):e103082</p> <p>Again (as in aims in the abstract) you distinguish between PROs (1) and further relevant PROs (3rd bullet point). Again, the decision for this differentiation is not transparent here.</p> <p>Intro, I. 41/42: You should add a "usually" in this sentence if there are other possible indicators for trauma severity than ISS. You should also add a reference to prove that the ISS is the standard instrument here.</p> <p>48/49: Please provide an estimate for incidence rather than the absolute numbers for Germany to make this fact more accessible and comparable for international readers.</p> <p>p. 5 (Aims)</p> <p>See general comment</p> <p>p. 6, I. 35: It is not necessary to specifically name RCTs here because the list already includes quantitative studies. Perhaps an expression like "all kinds of original empirical research" would be more clear.</p> <p>p. 7, discussion: The discussion again reflects the unclear differentiation between (core?) PROs and other PROs. Maybe the clarification is that the authors want to differentiate between QoL and other PROs.</p> <p>Remarks:</p> <p>Since you may want to give a suggestion on which instruments should be used to comprehensively cover the patients' perspective, you may want to consider performing a content analysis using e. g. the WHO's ICF as a reference. The methodology is described in detail by Cieza et al. in J Rehabil Med. 2005 37(4):212-8. There are several papers that report on such research.</p>
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VERSION 1 – AUTHOR RESPONSE

Referee: 1

Comments to the Authors

Paragraph 1

Page 8 L34-35: the authors state "polytrauma (at least two injuries, ISS>15, AIS≥3)"

Do the authors mean 2 injuries or do they mean injuries to at least 2 body regions (head, face and neck, thorax, abdomen and extremities)? Definitions for polytrauma vary according to which source is used. An ISS of 16 and higher is usually used. However some authors adhere to the definition that not only should the ISS be 16 or higher but also that it should be the result of injury in more than 1 region.

Response: We did not point out that the injuries must occur in different regions of the body. We made changes on page 6 to clarify this: “[...] injuries involving at least two different areas of the body or organ systems [...].”

Referee: 2

Comments to the Authors

Paragraph 1

The protocol is well written, follows the scientific standards and reports on an important issue in the research on patients with polytrauma. However, there is one important issue within the manuscript that has to be clarified. The authors provide 3 different aims (in abstract, strengths and limitations and in the main text) and it is not evident, why they differentiate between aim 1 (collect instruments on PROs) and aim 3 (collect other relevant PROs). It is not clear, when outcome measures are classified into the respective groups, in particular, in the light of the given examples (ADL and social participation are an example in both classes).

Response: Thank you for this important feedback. We adjusted the aims in order to clarify our review focus, and consequently made amendments in the abstract, strengths and limitations, aim of the study, data extraction and synthesis, and discussion, all of which are listed below.

Abstract (p. 3):

- i. collect instruments that assess patient-reported outcomes (quality of life, social participation, activities of daily living) during follow-up after polytrauma
- iii. investigate other relevant patient-reported outcomes that are also assessed in the included studies (pain, depression, anxiety, cognitive function).

Strengths and limitations (p. 4):

- This systematic review will report the identified instruments used to assess quality of life, social participation and activities of daily living, and describe their application.
- We will show to a lesser extent additional measures for further relevant patient-reported outcomes following polytrauma, e.g. pain, depression, anxiety, cognitive function.

Aim of the study (p. 5):

The aim of this systematic review is to:

- i. collect instruments that assess patient-reported outcomes (quality of life, social participation, activities of daily living) during the follow-up after polytrauma
- ii. describe the application of these instruments in detail (e.g. duration of period of follow-up, frequency of application, time of measurements during follow up)
- iii. investigate other relevant patient-reported outcomes that are additionally assessed in the included studies (e.g. pain, depression, anxiety, cognitive function) without reporting the application of instruments in detail

Data extraction and synthesis (p. 7):

“[...] first author and publication year, study design, country, study population (number of subjects, proportion of men, mean age with standard deviation and range, kind of injury, ISS, AIS, other characteristics), treatment, aim of the study, findings, and, furthermore, for the reported PROs

according to aim 1, applied instruments to assess these PROs, description of the instrument, data collection (method of assessment, time of measurements, length of follow-up period, quality criteria of instruments (e.g. validity, reliability) and modifications of the instruments.”

Discussion (p. 7):

“Likewise, the additional knowledge on further PROs, e.g. pain, depression, anxiety, cognitive function, might emphasise the patients’ perspectives on relevant outcomes after polytrauma and lead to its consideration in the provision of health services.”

Paragraph 2

Abstract (p. 3):

I. 41/42: You may want to rethink using qol here and replace it by a more general expression, such as “their lives”.

Response: Thank you for your helpful comment here. It gave rise to the following change: “Survivors of polytrauma experience long- and short-term burden that influences their lives.”

Paragraph 3

Abstract: p. 3

I. 45ff (aims): see comment above

I. 45ff (aims), adjustment in aims was made according to the response above (please see Paragraph 1)

Paragraph 4

p. 4, Strength and limitations:

You may want to rewrite the 1st bullet point because there are two studies that analysed the use of outcome measures in poly or multiple trauma: Grill E. et al. *Unfallchirurg*. 2010 Jun;113(6):448-55 and Hoffman K et al. *PLoS One*. 2014 Jul 22;9(7):e103082

Again (as in aims in the abstract) you distinguish between PROs (1) and further relevant PROs (3rd bullet point). Again, the decision for this differentiation is not transparent here.

Response: These articles definitely should be recognised. We therefore changed the first bullet point on page 4:

“To the best of our knowledge, there are no published systematic reviews providing an overview of assessed patient-reported outcomes after polytrauma, different instruments used to measure these as well as the application of these instruments.”

Please see Paragraph 1 regarding the differentiation between PROs.

Paragraph 5

Intro, I. 41/42: You should add a “usually” in this sentence if there are other possible indicators for trauma severity than ISS. You should also add a reference to prove that the ISS is the standard instrument here.

Response: We added “usually” and inserted a reference for approval of the ISS as the most-used scoring system for measuring severity of trauma (Lefering, 2002).

Paragraph 6

48/49: Please provide an estimate for incidence rather than the absolute numbers for Germany to make this fact more accessible and comparable for international readers.

Response: We included a study of Soreide (2009) to show the problems associated with comparing incidences of major injury due to differences in the appearance of trauma, and epidemiological data approaches. The incidence for Germany is included: “This corresponds to a cumulative incidence of

0.02% per year for Germany.” In addition we will report absolute numbers: “In 2015, according to the TraumaRegister DGU®, the number of severely multiply injured patients was 17,630 (ISS ≥16) (Lefering et al., 2016).” Please see page 4.

Paragraph 7
 p. 5 (Aims)
 See general comment

Response: We gave a response to the general comment. See above (paragraph 1).

Paragraph 8
 p. 6, l. 35: It is not necessary to specifically name RCTs here because the list already includes quantitative studies. Perhaps an expression like "all kinds of original empirical research" would be more clear.

Response: Thank you for the helpful comment. We used it to amend the wording here.

Paragraph 9
 p. 7, discussion: The discussion again reflects the unclear differentiation between (core?) PROs and other PROs. Maybe the clarification is that the authors want to differentiate between QoL and other PROs.

Response: We are pleased that you should mention this crucial point regarding the unclear differentiation in our aims, and hope to have made it clearer. Please see Paragraph 1.

Paragraph 10
 Remarks: Since you may want to give a suggestion on which instruments should be used to comprehensively cover the patients' perspective, you may want to consider performing a content analysis using e. g. the WHO's ICF as a reference. The methodology is described in detail by Cieza et al. in J Rehabil Med. 2005 37(4):212-8. There are several papers that report on such research.

Response: Thank you very much for your suggestion regarding a content analysis based on the WHO ICF as reference. Our focus is on the application-oriented description of applied instruments. A content analysis is beyond the scope of our review. Hence, we decided not to perform a content analysis.

Thank you for considering our systematic review protocol for publication.

VERSION 2 – REVIEW

REVIEWER	Martin Mueller Rosenheim University of Applied Sciences, Faculty of Applied Health and Social Sciences, Germany
REVIEW RETURNED	06-Nov-2017

GENERAL COMMENTS	The clarity of the manuscript has improved a lot. However, there are still some minor issues that have to be resolved before publication. Paragraph “Strengths and limitations” 1st bullet point: You may want to rephrase the sentence to clarify the content, because the second information (“different instruments used to measure these”) is - from my point of view - already included in the
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	<p>first aspect (“overview of assessed PROs after...”), e.g.: To the best of our knowledge, there are no published systematic reviews providing an overview of assessed patient-reported outcomes after polytrauma and their details of application.</p> <p>3rd bullet point: The phrase “to a lesser extent” is not necessary.</p> <p>Introduction, p. 4, l. 24: please explain TraumaRegister DGU, e.g. “... the TraumaRegister DGU®, a German registry that cover patients with...”</p> <p>Introduction, p. 5, l. 7.: “capturing a patient’s views” seems to be wrong in terms of singular/plural. Please review.</p> <p>p. 5, l16-18: See comments on 1st. bulletpoint in “Strengths and limitations”</p> <p>Methods, p.6, l. 19-20: “all kinds of original empirical research” summarizes “original qualitative, quantitative, mixed-methods studies”, therefore you can delete the latter.</p> <p>Methods, p. 7, l. 1: In my opinion, the phrase “the two latter” is not correct. You may want to use “systematic reviews and meta-analysis” instead.</p>
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VERSION 2 – AUTHOR RESPONSE

Referee: 2

Comments to the Authors

Paragraph 1

Paragraph “Strengths and limitations”

1st bullet point:

You may want to rephrase the sentence to clarify the content, because the second information (“different instruments used to measure these”) is - from my point of view - already included in the first aspect (“overview of assessed PROs after...”), e.g.:

To the best of our knowledge, there are no published systematic reviews providing an overview of assessed patient-reported outcomes after polytrauma and their details of application.

Response: Thank you for your recommendation. We would like to maintain our wording, as we believe that the meaning of the phrase would be changed when we implement the proposed adjustments. We focus deeply on the different instruments, so that it is important to stress this point.

3rd bullet point:

The phrase “to a lesser extent” is not necessary.

Response: We deleted the phrase “to a lesser extent” in the 3rd bullet point.

Paragraph 2

Introduction, p. 4, l. 24:

please explain TraumaRegister DGU, e.g.

“... the TraumaRegister DGU®, a German registry that cover patients with...”

Response: Thank you for your helpful comment here. We added an explanation on p. 4.

Paragraph 3

Introduction, p. 5, l. 7.:

“capturing a patient’s views” seems to be wrong in terms of singular/plural. Please review.

Response: We agree absolutely and have changed into the singular form “capturing a patient’s view”. Please see p. 5.

Paragraph 4

p. 5, l16-18:

See comments on 1st. bulletpoint in “Strengths and limitations”

Response: Please see our comment in Paragraph 1 regarding the change of phrase.

Paragraph 5

Methods, p.6, l. 19-20:

“all kinds of original empirical research” summarizes “original qualitative, quantitative, mixed-methods studies”, therefore you can delete the latter.

Response: Thank you very much - we have made the changes accordingly. Please see p. 6.

Paragraph 6

Methods, p. 7, l. 1:

In my opinion, the phrase “the two latter” is not correct. You may want to use “systematic reviews and meta-analysis” instead.

Response: We added systematic reviews and meta-analysis on p. 7.

Thank you for considering our systematic review protocol for publication.