

PEER REVIEW HISTORY

BMJ Paediatrics 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

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| TITLE (PROVISIONAL) | Characteristics of intervention studies on family-centred care in neonatal intensive care units: a scoping review of randomised controlled trials |
| AUTHORS | Lazzerini, Marzia Bua, Jenny Vuillard, Cecilia Laure Juliette Squillaci, Domenica Tumminelli, Cristina Panunzi, Silvia Girardelli, Martina Mariani, Ilaria |

VERSION 1 – REVIEW

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| REVIEWER | Karen M. Benzies |
| REVIEW RETURNED | 27-Dec-2023 |

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| GENERAL COMMENTS | <p>Dear Authors,</p> <p>Thank you for the opportunity to review this interesting manuscript reporting a scoping review describing a scoping review of family centered care interventions in neonatal intensive care units (NICUs). Given the diverse models of family centered in NICUs this scoping review is extremely important.</p> <p>Early in the Introduction, please define levels of neonatal intensive care. I am unfamiliar with "semi-intensive care". Does mean level II NICU?</p> <p>What is meant by "ancient" concepts? Please provide a reference. Please provide citations for other two scoping reviews, if published.</p> <p>Please state the scoping reviews cannot be registered in PROSPERO.</p> <p>Please be consistent in the order of interventions. For example, the order of the first list and the list on page 13/74 are not the same. Categories are very useful and reflect interventions. The California model (Franck et al) added an app to their intervention (no group differences). There is also an app in UK. Please consider addressing digital supports for education and family support.</p> <p>Please clarify whether excluding single interventions that this scoping review is focusing on multi-component interventions. Typically, scoping reviews include grey literature. Please justify why only RCTs were included?</p> |
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| | <p>Please carefully consider your statement about "key principles of FCC." This idea constitutes a philosophy or ethos of family centered care, which is difficult to operationalize and measure. Well defined, multi-component models of care with tools and strategies to support implementation are more likely to generate measurable outcomes and be sustainable over time. See Zaroni et al 2021 about implementation doi:10.1136/bmjopen-2021-054938 and Wasylak et al 2022 about sustainability DOI: 10.1097/NAQ.0000000000000552 .</p> <p>The authors may wish to explore Chamber and Norton's Adaptome related to tailoring interventions to context. Penny Hawe (2015) provides an interesting perspective on function (characteristic of interventions that should not be adapted) and form (can be adapted to local context including delivery format; sequence of multi-component intervention delivery) of interventions. Application of an implementation science framework such as Damschroder's CFIR increases efficiency of implementation. In our experience, we moved from an idea scratched on a napkin at lunch to a RCT to scale and spread, to sustainable funding in the health system in just 8 years. Supplementary files are very informative.</p> <p>Editorial</p> <p>Check manuscript for spelling (e.g., page 6/74, line 3 should be "rising" and page 9/74 line 39, should be "previous").</p> <p>Check for awkward sentence structure (e.g., page 8/74 line 23). Please change to "caregiving" from "care-taking".</p> <p>Page 16/74 lines 14-20, check for duplicate sentence.</p> <p>Please use number of decimals consistently.</p> <p>Page 27/74 please clarify the use of asterisk at line 15, table note.</p> <p>Please explain yellow highlighted sections in page 29/74.</p> |
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| REVIEWER | Dr. Rahel Schuler Justus Liebig Universitat Giessen, Department of General Pediatrics and Neonatology, Universities of Giessen and Marburg Lung Center (UGMLC), Member of the German Center for Lung Research (DZL), Justus-Liebig-University Giessen, Giessen, Germany |
| REVIEW RETURNED | 12-Jan-2024 |

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| GENERAL COMMENTS | <p>Thank you for the possibility to review this manuscript. As FCC studies and the studied interventions are very diverse this comprehensive overview of published interventions is valuable. To increase clarity and improve the manuscript I ask you to provide some minor revisions:</p> <p>P3 Line 17 The term is semi-intensive care units, please use this term throughout the manuscript.</p> <p>P3 Line 48 1 RCT, not 1 RCTs</p> |
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| | <p>P5 line 35 A focus for further studies should also be fathers as they need different support and there are few publications on fathers.</p> <p>P5 line 38- please use the terms consistently throughout the paper: semi- intensive care units</p> <p>P7 Line 28- please mention the main elements of FCC as readers may not be familiar with it.</p> <p>P8 Line 4, "possible", all possible interventions are difficult to summarize, do you mean all published intervention studies?</p> <p>P8 Line 8 It makes more sense to list the outcome after the intervention.</p> <p>P 8 line 19-28 please check the English language</p> <p>P17 line 58 do you mean semi intensive care unit? Neonatal ward is not mentioned in the results section, please specify.</p> <p>p26 line 45- the 146 RCTs included semi- intensive care units and possibly also neonatal wards, please be specific.</p> <p>P27 Line 51-P28 line 3, very long sentence, please check English language.</p> <p>P28 Line18-22 Based on the evidence of the manuscript the ideal study design cannot be suggested. This review cannot answer the question which study design is the best to generate evidence. It did not compare different study designs regarding patient outcomes or other results. FiCare studies have been successfully conducted in very different countries (China, Canada) and also multi- country with important results.</p> <p>Please check that RCT and RCTs is used correctly throughout the manuscript.</p> |
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VERSION 1 – AUTHOR RESPONSE

Dear Authors,

Thank you for the opportunity to review this interesting manuscript reporting a scoping review describing a scoping review of family centered care interventions in neonatal intensive care units (NICUs). Given the diverse models of family centered in NICUs this scoping review is extremely important.

*** Many thanks for your appreciation

1)Early in the Introduction, please define levels of neonatal intensive care. I am unfamiliar with "semi-intensive care". Does mean level II NICU?

*** We acknowledge that different countries use different wording to describe levels of care. Yes, we meant NICU level II, therefore the title has been simplified by removing the wording "semi-intensive care". In the inclusion criteria we clarified that we included NICU of all levels (as reported by the author).

2) What is meant by "ancient" concepts? Please provide a reference.

***Thank you for your inputs, we have clarified this point and added references.

3) Please provide citations for other two scoping reviews, if published.

***We received by the editor a request to highlight the cross reference in the text. Therefore, these are reported in the text, currently on page 19 (last paragraph).

4) Please state the scoping reviews cannot be registered in PROSPERO.

***Thank you for your inputs, this has been added.

5) Please be consistent in the order of interventions. For example, the order of the first list and the list on page 13/74 are not the same. Categories are very useful and reflect interventions.

*** We checked carefully but could not find a list on page 13/74.

6) The California model (Franck et al) added an app to their intervention (no group differences). There is also an app in UK. Please consider addressing digital supports for education and family support.

***Thank you for your inputs, the 2nd systematic review is covering a detailed description of the interventions, including digital App

7) Please clarify whether excluding single interventions that this scoping review is focusing on multi-component interventions.

*** This comment is not completely clear to us. We guess the referee wanted us to clarify if we have excluded single interventions. We have clarified this point in the METHODS section.

8) Typically, scoping reviews include grey literature. Please justify why only RCTs were included?

***Thank you for your point, this has been clarified in the METHOD section.

9) Please carefully consider your statement about "key principles of FCC." This idea constitutes a philosophy or ethos of family centered care, which is difficult to operationalize and measure. Well defined, multi-component models of care with tools and strategies to support implementation are more likely to generate measurable outcomes and be sustainable over time. See Zanoni et al 2021 about implementation doi:10.1136/

bmjopen-2021-054938 and Wasylak et al 2022 about sustainability DOI:

10.1097/NAQ.0000000000000552 . ***We totally agree, thank you for this valuable input, we have integrated it in the text. We have also added the following reference to the manuscript:

Zanoni P, Scime NV, Benzie K, McNeil DA, Mrklas K; Alberta FICare in Level II NICU Study Team; Alberta FICare™ in Level II NICU Study Team. Facilitators and barriers to implementation of Alberta family integrated care (FICare) in level II neonatal intensive care units: a qualitative process evaluation substudy of a multicentre cluster-randomised controlled trial using the consolidated framework for implementation research. *BMJ Open*. 2021 Oct 18;11(10):e054938. doi: 10.1136/bmjopen-2021-054938.

9) The authors may wish to explore Chamber and Norton's Adaptome related to tailoring interventions to context. Penny Hawe (2015) provides an interesting perspective on function (characteristic of interventions that should not be adapted) and form (can be adapted to local context including delivery format; sequence of multi-component intervention delivery) of interventions.

Application of an implementation science framework such as Damschroder's CFIR increases efficiency of implementation. In our experience, we moved from an idea scratched on a napkin at lunch to a RCT to scale and spread, to sustainable funding in the health system in just 8 years.

*** Sincere thanks for all these advices, we have read with interest all the suggested literature. Since we already have 67 references in the manuscripts, we have opted not to add to the references these additional (very interesting) papers, however, we'd like to thank again the referee for pointing them out.

10) Supplementary files are very informative.

*** Many thanks for your appreciation

Editorial

1) Check manuscript for spelling (e.g., page 6/74, line 3 should be "rising" and page 9/74 line 39, should be "previous").

***Corrected

2) Check for awkward sentence structure (e.g., page 8/74 line 23).

***Corrected

3) Please change to "caregiving" from "care-taking".

***Corrected

4) Page 16/74 lines 14-20, check for duplicate sentence.

***Corrected

5) Please use number of decimals consistently.

***Corrected, we always use 1 decimal, except for the p values

6) Page 27/74 please clarify the use of asterisk at line 15, table note.

***Corrected

7) Please explain yellow highlighted sections in page 29/74.

*** We have been requested by the editorial office (see email below) to highlight cross reference in the text and in the letter to the editor we specified that cross references of the EPINICU supplement were highlighted in yellow in the text (note that the yellow text in the PDF Proof is on page 30). Here is the text of the email received from Henry Spielberg: *"You can add cross-references to the other papers in the collection - use the first author name (and et al) and title of the paper. Please ensure these are clearly highlighted in the text so the production editor can update with the correct citation when the papers are published online."*

Reviewer: 2

Dr. Rahel Schuler, Justus Liebig Universität Giessen

Comments to the Author

Thank you for the possibility to review this manuscript.

As FCC studies and the studied interventions are very diverse this comprehensive overview of published interventions is valuable.

*** Many thanks for your appreciation

To increase clarity and improve the manuscript I ask you to provide some minor revisions:

1) P3 Line 17 The term is semi-intensive care units, please use this term throughout the manuscript.

***Corrected

2) P3 Line 48 1 RCT, not 1 RCTs

***Corrected

3) P5 line 35 A focus for further studies should also be fathers as they need different support and there are few publications on fathers.

***Totally agree, added

4) P5 line 38- please use the terms consistently throughout the paper: semi- intensive care units

***Corrected

5) P7 Line 28- please mention the main elements of FCC as readers may not be familiar with it.

***Thanks for pointing this out, we have added this in the previous paragraph (3^o paragraph in the INTRO).

6) P8 Line 4, "possible", all possible interventions are difficult to summarize, do you mean all published intervention studies?

***Corrected

7) P8 Line 8 It makes more sense to list the outcome after the intervention.

***Corrected

8) P 8 line 19-28 please check the English language

***Corrected

9) P17 line 58 do you mean semi-intensive care unit? Neonatal ward is not mentioned in the results section, please specify.

***Corrected

10) p26 line 45- the 146 RCTs included semi- intensive care units and possibly also neonatal wards, please be specific.

*** We checked, only 2 studies made explicit that they included a maternity ward. None made explicit that a neonatal ward was included, in addition to intensive newborn care unit.

11) P27 Line 51-P28 line 3, very long sentence, please check English language.

***Corrected

12) P28 Line18-22 Based on the evidence of the manuscript the ideal study design cannot be suggested. This review cannot answer the question which study design is the best to generate evidence. It did not compare different study designs regarding patient outcomes or other results. FiCare studies have been successfully conducted in very different countries (China, Canada) and also multi- country with important results.

***Corrected

Please check that RCT and RCTs is used correctly throughout the manuscript.

***Corrected

VERSION 2 – REVIEW

None

VERSION 2 – AUTHOR RESPONSE

None