

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Developing the Network Pain Rehabilitation Limburg: a feasibility study protocol
AUTHORS	Lamper, Cynthia; Kroese, Mariëlle; Köke, Albère; Ruwaard, Dirk; Verbunt, Jeanine; Huijnen, Ivan

VERSION 1 - REVIEW

REVIEWER	Kine Gjesdal University of Stavanger, Norway
REVIEW RETURNED	22-Oct-2018

GENERAL COMMENTS	<p>General comments: Thank you for the privilege of reviewing your manuscript. The topic in this manuscript is timely. The manuscript is well written, (apart from long sentences, please rephrase, e.g. P10 L. 48). Some of your references are old; could you please introduce literature that is more recent?</p> <p>Specific Comments:</p> <p>Abstract/Introduction/Methods: 1. Could you please provide a clearer aim of this article?</p> <p>Introduction P5, L49 Please provide reference P7, L 23 -26. How do an already set goal of improving the patients level of functioning correspond to a person- centered treatment? Living a valuable life despite pain, does it always boil down to their level of function?</p> <p>Methods P 10 Table 2 Who decides the treatment aim of the patient? What does improved functioning really mean? P 10 L 31 Why is focus groups chosen in stead of individual interviews? P10 L52 Your understanding of interdisciplinary treatment does not correspond to the usual understanding and definition of this term (IASP). Please elaborate.</p>
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REVIEWER	Carl Molander Department of Clinical Sciences Danderyd, Karolinska Institutet
REVIEW RETURNED	28-Oct-2018

GENERAL COMMENTS	This ambitious study is likely to be a very important contribution to the process of improving the organization of health care for patients with chronic pain in countries with general health care traditions and organization similar to those in the Netherlands. The project planning in phases with evaluations of each phase and the well thought of combinations of quantitative and qualitative data will improve the prospects of high quality interpretation and the following building of a more effective organization and flow charts designed to help patients with different needs.
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REVIEWER	Cornelia Rolli Salathé University of Bern, Switzerland
REVIEW RETURNED	03-Jan-2019

GENERAL COMMENTS	<p>Comments on the manuscript bmjopen-2018-025962 "Developing the Network Pain Rehabilitation Limburg: a feasibility study protocol"</p> <p>Dear Authors</p> <p>Thank you for this contribution and for letting me read and comment on it. This manuscript describes the feasibility study protocol on the development of the Network Pain Rehabilitation, a transmural network for pain rehabilitation. The topic of this manuscript is highly relevant, necessary and hopefully the study will confirm the feasibility of the network development! I am very pleased with it. However, there are rather important problems of comprehension that need to be mentioned.</p> <p>A The text is well written and understandable. Unfortunately, the abstract is less clear. When reading through the abstract, I got the impression of sentences wildly put together which makes it difficult to get started with the article. I would try to rewrite the abstract with the intention to invite the reader to your article and by clearly stating the study objective, the feasibility study, not the Quadruple Aims that you are willing to investigate in a large-scale evaluation IF the study results of this study suggest the NPRLs feasibility.</p> <p>B The research question is not clearly defined in the introduction. Again, in the last paragraph of the introduction (p. 7, lines 38-40), you mention the NPRL that will be designed to fulfill the Quadruple Aims. However, the true research question / objective of the study is described in the first two sentences in the discussion part (p. 15, lines 30-35). Please reconsider the true objective of the actual study and rewrite the passages.</p> <p>C The study design seems appropriate to answer the research question. However, I do have a problem of comprehension regarding the Consolidated Framework for Implementation Research (CFIR) which obviously is the methodological basis of the study and the study design (page 14, lines 35-43). How do they fit together? This is not clearly explained. Or, if the user-centred design is your methodological basis of the study (page 8, lines 8-13), please explain its significance.</p>
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	<p>D Overall, I can follow your descriptions in the methods section regarding the “Participants”, the “Intervention”, and the “Data collection”. All three paragraphs are clearly and sufficiently described and would allow a study replication. Unfortunately, the two paragraphs “Study design” (p. 8) and “Data Analysis” (p. 14) do not match together and these two descriptions do not allow a study replication. Please clarify.</p> <p>Taken together, I would like you to thoroughly introduce the reader into the CFIR and/or the user- centred design and to explain your thoughts on how those two methods are combined in your feasibility study. By explaining the methods more clearly, the manuscript will gain in structure and clarity.</p> <p>Thanks again for your work and the opportunity for me to review your manuscript. Good luck with your ambitious, yet very necessary project!</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Kine Gjesdal

Comment 1: Thank you for the privilege of reviewing your manuscript. The topic in this manuscript is timely. The manuscript is well written, (apart from long sentences, please rephrase, e.g. P10 L. 48).

> We thank Ms. Kine Gjesdal for reviewing our manuscript and her comments. We have rephrased some long sentences.

For example: P.10 L.48; For clarification we added a numeration to the different treatments for clarification:

Depending on the level of disability and biopsychosocial factors involved, this will either include; 1) education only and no further treatment, 2) monodisciplinary treatment in primary care, 3) interdisciplinary treatment in primary care (collaboration between GPs, primary care therapists, and mental health practice nurses in assessing and treating patients with CMP who need mental support besides physical exercise), 4) multidisciplinary treatment in secondary or 5) multidisciplinary treatment in tertiary care.

And P10. L28; we split the sentence in order to make the sentence more clear:

Moreover, a sample of approximately 10 patients, who finished a treatment according to the protocol of NPRL, will be recruited for a focus group. In this focus group more information about barriers and facilitators from a patient perspective will be collected.

And P11. L19; we split the sentence in order to make the sentence more clear:

To support the healthcare professionals in their decision making for problem mapping and treatment selection, two evidence-based objective assessment tools will be used. These tools will support the assessment of complexity of the pain problem; one tool for GPs and primary care therapists and one tool for RPs.

Comment 2: Some of your references are old; could you please introduce literature that is more recent?

> We have changed two old references to a newer reference.

Vlaeyen JW, Kole-Snijders AM, Boeren RG, et al. Fear of movement/(re)injury in chronic low back pain and its relation to behavioral performance. *Pain* 1995;62(3):363-72.

To:

Vlaeyen, JW. and Linton SJ. Fear-avoidance model of chronic musculoskeletal pain: 12 years on. *Pain* 2012;153(6):1144-1147.

And: Roy R, Thomas M, Matas M. Chronic pain and depression: a review. *Compr Psychiatry* 1984;25(1):96-105.

To:

Bair MJ, Robinson RL, Katon W, et al. Depression and pain comorbidity: a literature review. *Arch Intern Med* 2003;163(20):2433-45. doi: 10.1001/archinte.163.20.2433 [published Online First: 2003/11/12]

And; Köke AJA, van Baalen B, Remerie SC, et al. Eindrapportage Revalidatie Nederland. Implementatie en uitbreiding Nederlandse Dataset Pijnrevalidatie. Hoensbroek: Adelante Kenniscentrum, 2012.

To:

Koke AJ, Smeets RJ, Schreurs KM, et al. Dutch Dataset Pain Rehabilitation in daily practice: Content, patient characteristics and reference data. *Eur J Pain* 2017;21(3):434-44. doi: 10.1002/ejp.937 [published Online First: 2016/09/17]

Comment 3: Abstract/Introduction/Methods: Could you please provide a clearer aim of this article?

> > We thank Ms. Kine Gjesdal for this comment. We agree that the aim was not well described in the Introduction of the manuscript. Therefore, we adjusted the last paragraph of the introduction.

The Network Pain Rehabilitation Limburg (NPRL), a transmural integrated healthcare network for CMP rehabilitation, will be designed to ultimately fulfil the Quadruple Aim in the province of Limburg, the Netherlands.^{46 47} The aim is to provide integrated care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach for all involved healthcare professionals. As a first step a feasibility study will be performed. This study provides insight into the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability of the NPRL. This paper describes the study protocol of the feasibility study of NPRL for adults with CMP.

Moreover, the sentence about the UK Medical Research Council framework is shifted to the Methods > study design section.

Comment 4: Introduction: P5, L49 Please provide reference;

> We have added the following reference:

17 Committee on Education of the EFIC (European Federation of IASP Chapters). The Pain Management Core Curriculum for European Medical Schools, 2013:33.

Comment 5: Introduction: P7, L 23 -26. How do an already set goal of improving the patients level of functioning correspond to a person- centered treatment? Living a valuable life despite pain, does it always boil down to their level of function?

> In Network Pain Rehabilitation Limburg (NPRL) we educate the healthcare professionals in such a way that they map the whole biopsychosocial profile of a patient before referral to a treatment.

In pain rehabilitation, the main aim is to improve functioning despite pain. And therefore, patients with chronic musculoskeletal pain that need help to improve functioning in order to reach a better quality of life will be treated in NPRL [Table 2]. Practitioners in NPRL will support the patient to find the best place for help in the region. Patients that need support to improve their quality of life without specific needs for help on the level of daily functioning will also be supported, but this will be outside NPRL.

Comment 6: Methods: P 10 Table 2 Who decides the treatment aim of the patient? What does improved functioning really mean?

> The patient decides the treatment aim when he visits a healthcare professional. In case this is necessary, the practitioner will support the patient in setting functional goals. The healthcare professional will support the patient, or in case further support is needed, will refer patients with an aim to improve functioning despite pain to a treatment within Network Pain Rehabilitation Limburg (NPRL).

In the treatments of NPRL the focus is not on pain reduction but on improving the level of functioning. This means that at the end of the treatment the patient must be able to participate in more activities compared to at the start of the treatment, despite having pain. For example: the goal of a grandmother is to walk with her grandchild at the end of the treatment.

P12 > Integral focus on treatment content and duration: treatment protocols > after the 1st sentence:

The patient decides the treatment aim when he visits a healthcare professional. In case this is necessary, the practitioner will support the patient in setting functional goals.

Comment 7: Methods: P 10 L 31 Why are focus groups chosen instead of individual interviews?

> We have added this explanation for the choice for a focus group after the sentence at P.10 L32:

In this way patients are able to react to each other which will illuminate various perspectives which leads to a faster data saturation about each topic, which is an advantage above interviews (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2642503/>) .

Comment 8: Methods: P10 L52 Your understanding of interdisciplinary treatment does not correspond to the usual understanding and definition of this term (IASP). Please elaborate.

> We thank the reviewer for the comment about the understanding and definition of the term interdisciplinary treatment. We agree that the terms interdisciplinary and multidisciplinary treatment are used in the wrong order.

We defined multidisciplinary as healthcare professionals from different disciplines work separately with their own therapeutic aim and have some team meetings. Interdisciplinary means that healthcare professionals from different disciplines work closely together and have regular team meetings.

Therefore we have changed the term interdisciplinary to multidisciplinary for primary care and, multidisciplinary to interdisciplinary for secondary and tertiary care.

Depending on the level of disability and biopsychosocial factors involved, this will either include; 1) education only and no further treatment, 2) monodisciplinary treatment in primary care, 3) multidisciplinary treatment in primary care (collaboration between GPs, primary care therapists, and mental health practice nurses in assessing and treating patients with CMP who need mental support besides physical exercise) or, 4) interdisciplinary treatment in secondary or 5) interdisciplinary treatment in tertiary care.

Reviewer: 2

Reviewer Name: Carl Molander

Comment 1: This ambitious study is likely to be a very important contribution to the process of improving the organization of health care for patients with chronic pain in countries with general health care traditions and organization similar to those in the Netherlands. The project planning in phases with evaluations of each phase and the well thought of combinations of quantitative and qualitative data will improve the prospects of high quality interpretation and the following building of a more effective organization and flow charts designed to help patients with different needs.

> We thank Mr. Carl Molander for reviewing our manuscript and his compliments on our manuscript.

Reviewer: 3

Reviewer Name: Cornelia Rolli Salathé

Comment 1: Dear Authors. Thank you for this contribution and for letting me read and comment on it. This manuscript describes the feasibility study protocol on the development of the Network Pain Rehabilitation, a transmural network for pain rehabilitation. The topic of this manuscript is highly relevant, necessary and hopefully the study will confirm the feasibility of the network development! I am very pleased with it. However, there are rather important problems of comprehension that need to be mentioned.

> We thank Mrs. Cornelia Rolli Salathé for reviewing our manuscript and her compliments on our manuscript.

Comment 2: The text is well written and understandable. Unfortunately, the abstract is less clear. When reading through the abstract, I got the impression of sentences wildly put together which makes it difficult to get started with the article. I would try to rewrite the abstract with the intention to invite the reader to your article and by clearly stating the study objective, the feasibility study, not the Quadruple Aims that you are willing to investigate in a large-scale evaluation IF the study results of this study suggest the NPRLs feasibility.

> We have rewritten the abstract:

Introduction: Patients receiving a rehabilitation treatment for chronic musculoskeletal pain (CMP) face challenges as mismatches often exist between the complexity of patient's pain problem and the treatment offered. This can result in less efficient care for the patient and increased medical shopping. The Network Pain Rehabilitation Limburg (NPRL), a transmural integrated healthcare network, will be designed to improve daily care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach given by all involved healthcare professionals. A feasibility study will be performed which will give insight into the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability of the NPRL.

Methods and analysis: This is a feasibility study with a three-phase iterative and incremental design, based on key principles of an user-centred design. It will examine the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability for further development and refinement of the NPRL. Mixed methods will be used in which healthcare professionals, as well as patients involved in the NPRL, will participate. The results of each phase will be analysed following the Consolidated Framework for Implementation Research (CFIR) and will be used to refine NPRL in daily practise.

Ethics and dissemination: Informed consent will be obtained from all participants. The results of this feasibility study will form the basis for refinement of NPRL and planning of a large-scale process and effect evaluation of the Quadruple Aim outcomes. Dissemination will include publications and presentations at national and international conferences. Ethical approval for this study was granted by the Medical Ethics Committee Z, the Netherlands, METC 17-N-133.

Comment 3: The research question is not clearly defined in the introduction. Again, in the last paragraph of the introduction (p. 7, lines 38-40), you mention the NPRL that will be designed to fulfill the Quadruple Aims. However, the true research question / objective of the study is described in the first two sentences in the discussion part (p. 15, lines 30-35). Please reconsider the true objective of the actual study and rewrite the passages.

> We thank Mrs. Cornelia Rolli Salathé for this comment. We agree that the research question was not well described in the Introduction of the manuscript. Therefore, we adjusted the last paragraph of the introduction.

The Network Pain Rehabilitation Limburg (NPRL), a transmural integrated healthcare network for CMP rehabilitation, will be designed to ultimately fulfil the Quadruple Aim in the province of Limburg, the Netherlands.^{46 47} The aim is to provide integrated care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach for all involved healthcare professionals. As a first step a feasibility study will be performed which will provide insight into the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability for further develop and refinement of the NPRL. This paper describes the study protocol of the feasibility study of NPRL for adults with CMP.

Moreover, the sentence about the UK Medical Research Council framework is shifted to the Methods > study design section.

Comment 4: The study design seems appropriate to answer the research question. However, I do have a problem of comprehension regarding the Consolidated Framework for Implementation Research (CFIR) which obviously is the methodological basis of the study and the study design (page 14, lines 35-43). How do they fit together? This is not clearly explained. Or, if the user-centred design is your methodological basis of the study (page 8, lines 8-13), please explain its significance.

> This study is a feasibility study with an iterative and incremental design, based on key principles of user-centred design. This is the methodological approach as used of the study.

The qualitative data which will be analyzed using The Consolidated Framework for Implementation Research (CFIR). This framework will guide the data analysis and will help to give an overview of barriers and facilitators in the three steps of the iterative design (exploration of context, implementation, transferability).

In the methods > study design section we have added a sentence to clarify this.

The qualitative data collected during the study will be analysed using The Consolidated Framework for Implementation Research (CFIR).

Comment 5: Overall, I can follow your descriptions in the methods section regarding the “Participants”, the “Intervention”, and the “Data collection”. All three paragraphs are clearly and sufficiently described and would allow a study replication. Unfortunately, the two paragraphs “Study design” (p. 8) and “Data Analysis” (p. 14) do not match together and these two descriptions do not allow a study replication. Please clarify.

> We thank Mrs. Cornelia Rolli Salathé for this comment. In the paragraph Study design we made changes as described at comment 4. In the paragraph Data Analysis we adjusted the first part of the paragraph with a description of the iterative design with key principles of user-centred design.

In this iterative design with key principles of user-centred design, the results will be gathered in daily practice from the healthcare professional and patient perspective. The results of each phase will be used to adapt the intervention for the next phase. The Consolidated Framework for Implementation Research (CFIR) protocol according to Damschroder et al⁵⁵ will be used to develop this feasibility evaluation and analysis plan of the results. This explanatory framework with theory-based constructs and mechanisms will be used to explain whether an implementation may or may not succeed and to identify barriers and facilitators.

Comment 6: Taken together, I would like you to thoroughly introduce the reader into the CFIR and/or the user-centred design and to explain your thoughts on how those two methods are combined in your feasibility study. By explaining the methods more clearly, the manuscript will gain in structure and clarity.

> In the paragraph Data Analysis we adjusted the first part of the paragraph with a description of the iterative design with key principles of user-centred design. And in the methods > study design section we have added a sentence to clarify the use of the Consolidated Framework for Implementation Research (CFIR).

Comment 7: Thanks again for your work and the opportunity for me to review your manuscript. Good luck with your ambitious, yet very necessary project!

> We thank Mrs. Cornelia Rolli Salathé her compliments on our project.

VERSION 2 – REVIEW

REVIEWER	Kine Gjesdal University of Stavanger, Norway
REVIEW RETURNED	20-Mar-2019

GENERAL COMMENTS	The article is well-written and deals with a timely topic. A bit more problematizing about how different professions (GPs, nurse (RNs), physiotherapist, occupational therapist) in an interdisciplinary team will develop a common understanding (biopsychosocial) and approach towards pain management is not thoroughly discussed.
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REVIEWER	Cornelia Rolli Salathé Institute for Psychology, University of Bern Switzerland
REVIEW RETURNED	31-Jan-2019

GENERAL COMMENTS	<p>Dear Authors Thank you for working so thoroughly on your manuscript “Developing the Network Pain Rehabilitation Limburg: a feasibility study protocol”. It has greatly improved.</p> <p>However, I still believe that the Abstract is the weakest part of your manuscript. I still do not completely agree with the “Methods and analysis” paragraph, it could need some more step by step clarity. Especially the second phrase “It will examine the barriers...” is redundant since you exactly wrote the same phrase in the paragraph “Introduction” above. Please rewrite.</p> <p>Also, when stating the research question (p. 6, lines 38ff), you keep reformulating the “transmural integrated healthcare network...” and still mention the Quadruple Aim. Please avoid obvious redundancies and stay with the main research question regarding the feasibility study.</p> <p>Taken together, the manuscript improved with regard to the first version, but I still would appreciate if you could – once again – work on the abstract and the research question by avoiding redundancies.</p> <p>Thanks again for your work and the opportunity for me to review your manuscript. Again, good luck with your ambitious, yet very necessary project!</p>
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VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Kine Gjesdal

Comment 1: The article is well-written and deals with a timely topic.

> We thank Ms. Kine Gjesdal for reviewing our manuscript again and her positive comment.

Comment 2: A bit more problematizing about how different professions (GPs, nurse (RNs), physiotherapist, occupational therapist) in an interdisciplinary team will develop a common understanding (biopsychosocial) and approach towards pain management is not thoroughly discussed.

> P 10. L22 (Methods). We have added some extra explanation about the development of a common understanding.

All healthcare professionals with different specialisms will participate together in the meetings and education days. This ensures a common understanding of the biopsychosocial approach and rehabilitation treatment options. In order to facilitate this in daily practice, the following elements are integrated in NPRL:

Reviewer: 3

Reviewer Name: Cornelia Rolli Salathé

Comment 1: Dear Authors, Thank you for working so thoroughly on your manuscript "Developing the Network Pain Rehabilitation Limburg: a feasibility study protocol". It has greatly improved.

> We thank Mrs. Cornelia Rolli Salathé for reviewing our manuscript again and her positive comments.

Comment 2: However, I still believe that the Abstract is the weakest part of your manuscript. I still do not completely agree with the "Methods and analysis" paragraph, it could need some more step by step clarity. Especially the second phrase "It will examine the barriers..." is redundant since you exactly wrote the same phrase in the paragraph "Introduction" above. Please rewrite.

> We agree with the reviewer and have rewritten the "Methods and analysis" part of the abstract:

Introduction: Patients having chronic musculoskeletal pain (CMP) face challenges as mismatches often exist between the complexity of patient's pain problem and the rehabilitation treatment offered. This can result in less efficient care for the patient and increased medical shopping. The Network Pain Rehabilitation Limburg (NPRL), a transmural integrated healthcare network, will be designed to improve daily care for patients with CMP. NPRL focusses on improving patient's level of functioning despite pain by stimulating a biopsychosocial approach given by all involved healthcare professionals. A feasibility study will be performed which will give insight into the barriers and facilitators, perceived value, acceptability, and implementation strategies for NPRL.

Methods and analysis: This study has a three-phase iterative and incremental design, based on key principles of an user-centred design. Mixed methods will be used in which healthcare professionals

and patients involved in NPRL, will participate. In phase 1, NPRL will be developed and healthcare professionals educated. Phase 2 focusses on the implementation and phase 3 on the transferability of NPRL. In addition, preliminary data on patient's work status, general health, and participation level will be collected. The qualitative results of each phase will be analysed following the Consolidated Framework for Implementation Research (CFIR) and will be used to refine NPRL in daily practise.

Ethics and dissemination: Informed consent will be obtained from all participants. The results of this feasibility study will form the basis for refinement of NPRL and planning of a large-scale process and effect evaluation of the Quadruple Aim outcomes. Dissemination will include publications and presentations at national and international conferences. Ethical approval for this study was granted by the Medical Ethics Committee Z, the Netherlands, METC 17-N-133.

Comment 3: Also, when stating the research question (p. 6, lines 38ff), you keep reformulating the "transmural integrated healthcare network..." and still mention the Quadruple Aim. Please avoid obvious redundancies and stay with the main research question regarding the feasibility study.

> We have clarified the goal of the project and the goal of this study in the introduction. The goal of Network Pain Rehabilitation Limburg is to provide integrated care for patients with CMP in a transmural healthcare network. The Quadruple Aim will help to design and evaluate NPRL. This article describes the protocol of a feasibility study. The aim of this feasibility study is to provide insight into the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability of the NPRL

P6. L38: The Network Pain Rehabilitation Limburg (NPRL), a transmural healthcare network for CMP rehabilitation, will be designed to ultimately fulfil the Quadruple Aim in the province of Limburg, the Netherlands.^{47 48} NPRL provides integrated care for patients with CMP in order to improve their level of functioning despite pain by stimulating a biopsychosocial approach for all involved healthcare professionals. As a first step a feasibility study will be performed. This study aims to provide insight into the barriers and facilitators, perceived value, acceptability, and implementation strategies for the development, implementation, and transferability of the NPRL. This paper describes the study protocol of the feasibility study of NPRL for adults with CMP.

Comment 4: Taken together, the manuscript improved with regard to the first version, but I still would appreciate if you could – once again – work on the abstract and the research question by avoiding redundancies.

Thanks again for your work and the opportunity for me to review your manuscript. Again, good luck with your ambitious, yet very necessary project!

> We thank Mrs. Cornelia Rolli Salathé her compliments on our project.