# PEER REVIEW HISTORY

## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | Evaluation of a complex integrated, cross-sectoral psycho-oncological care program (isPO): a mixed-methods study protocol |
| **AUTHORS** | Jenniches, Imke; Lemmen, Clarissa; Cwik, Jan Christopher; Kusch, Michael; Labouvie, Hildegard; Scholten, Nadine; Gerlach, Alexander; Stock, Stephanie; Samel, Christina; Hagemeier, Anna; Hellmich, Martin; Haas, Peter; Hallek, Michael; Pfaff, Holger; Dresen, Antje |

## VERSION 1 – REVIEW

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| **REVIEWER** | Ozgur Tanriverdi<br>Mugla Sitki Kocman University Faculty of Medicine, Turkey |
| **REVIEW RETURNED** | 27-Oct-2019 |

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| **GENERAL COMMENTS** | Dear Author<br>The integration of psychooncology in palliative care is very important in cancer patients and their relatives and therefore the project seems to be able to meet this deficit. However, in which period palliative care is to be integrated or at what stage of cancer will be the main strength of this project. Palliative care begins at the time of diagnosis in cancer patients and continues until the last moment of life. It also contributes to patients' relatives during the mourning period. In this project it is necessary to ensure that this definition of palliative care fully meets. It should also be determined whether integrative oncology approaches (music therapy, hobbies, yoga, plates, etc.) are included in the project variables in patients with a psychooncological approach or psychiatric treatment.<br>I think it is an important project for the future both in terms of palliative care approach and management.<br><br>Best regards |

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| **REVIEWER** | Luciana Neamtiu<br>European Commission<br>Joint Research Centre<br>Italy |
| **REVIEW RETURNED** | 27-Nov-2019 |

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| **GENERAL COMMENTS** | The protocol is very interesting and well presented. However, there are some issues which are not detailed. The study has the ethical approval and it seems to be compliant with the GDPR. Patient consent is required for participation to the study, but there are no details about data collection legal basis. Is explicit consent to process (collect, store, analyse) the data obtained also from the patients? What about linking data? The scope of the cancer |

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| | registry collection is different. I would suggest clarifying more this aspect.<br>In the line 37 page 3, instead of incidence (which usually is expresses as rate), "new cancer cases" would be more appropriate as number of cases is reported.<br>Line 34, page 7, for a reader without knowledge about the certification program of German Cancer Centers, it is not clear what is the difference between hospitals and certified cancer centers. A brief explanation would help. |

## VERSION 1 – AUTHOR RESPONSE

**Reviewer 1:**

Remark:

*“The integration of psycho-oncology in palliative care is very important in cancer patients and their relatives and therefore the project seems to be able to meet this deficit. However, in which period palliative care is to be integrated or at what stage of cancer will be the main strength of this project. Palliative care begins at the time of diagnosis in cancer patients and continues until the last moment of life. It also contributes to patients' relatives during the mourning period. In this project it is necessary to ensure that this definition of palliative care fully meets. It should also be determined whether integrative oncology approaches (music therapy, hobbies, yoga, plates, etc.) are included in the project variables in patients with a psycho-oncological approach or psychiatric treatment.*

*I think it is an important project for the future both in terms of palliative care approach and management.”*

Answer: Thank you very much for your constructive and helpful remarks. We agree with the reviewer, that the integration of psycho-oncology in palliative care is very important in cancer patients and their relatives. The project isPO indeed is not primarily geared towards palliative care. With isPO a pilot project started with a focus on the integration of psycho-oncological care into biomedical cancer treatment during 12 months from cancer diagnosis according to a stepped-care approach. But upon successful acceptance into the standard health care we are with the reviewer, that a definition of palliative care and the associated integration of the several oncology approaches will be very necessary and important for the cancer patients and their relatives. To address this point accordingly, we have amended the protocol.

**Reviewer 2:**

Comment 1:

*“The study has the ethical approval and it seems to be compliant with the GDPR. Patient consent is required for participation to the study, but there are no details about data collection legal basis. Is explicit consent to process (collect, store, analyse) the data obtained also from the patients? What about linking data? The scope of the cancer registry collection is different. I would suggest clarifying more this aspect.”*

Answer: Thank you very much for your important ethical considerations. The explicit consent to process the data obtainded is given by all patients. Therefore, the study information for patients is accompanied by a written consent. Without this consent, no data will be collected, stored or processed. This also includes the data linkage. In this context, the cancer registry collection provides additional information on the medical status of the patients included. This dataset will include clinical measures such as the tumor state, medical procedures or the type of chemotherapy or radiotherapy. From the scope of cancer registry data, group differences will be extracted, for example, in terms of age, entities or gender. The analyses will provide further insights into the influence of biomedical treatment or the severity of the disease on the effectiveness of psycho-oncological treatment. To describe this point in more detail, we have added further details to the consent in the chapter "ethical considerations".

Remark:

*“In the line 37 page 3, instead of incidence (which usually is expresses as rate), "new cancer cases" would be more appropriate as number of cases is reported.”*

Answer: Thank you very much for this specification. We changed the terms.

Comment 2:

*“Line 34, page 7, for a reader without knowledge about the certification program of German Cancer Centers, it is not clear what is the difference between hospitals and certified cancer centers. A brief explanation would help.”*

Answer: Thank you very much for this comment. Contrary to hospitals, that provide the basic medical cancer care, oncology centres bundle competences in the areas of treatment, cooperation and research. A certified oncological centre is a network of qualified and jointly certified, multi- and interdisciplinary, trans-sectoral and, if necessary, cross-locational facilities (hospitals, physicians, rehabilitation facilities) which best cover the various care areas for patients as far as possible. To meet the rapidly growing need for comprehensive, holistic, multidisciplinary and integrative oncological care of the population, these oncology competence centers have emerged. We have added this explanation to our study protocol.