Author’s response to reviews

Title: Interprofessional collaboration in nursing homes (interprof): Development and piloting of measures to improve interprofessional collaboration and communication: A qualitative multicentre study

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Author’s response to reviews:

Dear Louise Symmons,

thank you very much for your mail from June 28th, in which you required our pilot study to be registered in a clinical trial register/database.

The authors would like to invite you to reconsider the need for registration. On the ICMJE homepage we read the definition of a clinical trial:

“any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”
Some trials assign health care providers, rather than patients, to intervention and comparison/control groups. If the purpose of the trial is to examine the effect of the provider intervention on the health outcomes of the providers' patients, then investigators should register the trial. If the purpose is to examine the effect only on the providers (for example, provider knowledge or attitudes), then registration is not necessary.

In our pilot study we did not evaluate any effects on health outcomes of the residents. The goal of the qualitative interviews was to get an impression on feasibility and acceptance of our provider intervention (implementation of measures to improve interprofessional communication). We were mainly interested in the process of the implementation and the interviewees' experiences and attitudes. In this context we only asked very briefly if respondents perceived a benefit for the residents. No health outcome data on resident level were collected at all (no data on illnesses, medication, hospitalisation, etc.). We only conducted one interview with a resident and one with a relative, focusing on if and how the implementation was perceived.

Our ethical review board did not classify the study as a clinical trial, and did not require registration. We currently prepare a randomized controlled trial on the implementation of the measures with the primary outcome: reduction of hospitalization of residents. This clinical trial is funded by the Innovationsfond and we will register it according to ICMJE definitions.

2. The requirements concerning the consents are added to the Declarations section (line 9-17 Page 22).

We hope that you deem the manuscript appropriate for publication anyway, and look forward to your reply.

Kind regards

Christiane Müller