

COMMENTS RESPONSES

IMPORTANT DEVIATIONS FROM STUDY PROTOCOL

To the Editor: As authors of a guideline¹ and a systematic review on interventions for preventing and reducing physical restraints (PR) in long-term geriatric care,² we eagerly awaited the publication by Koczy and colleagues³ on the Redufix trial that had been completed 5 years before. Since then, without public access to the final results, the intervention has been promoted throughout Germany as a successful method of reducing physical restraints, with a number of follow-up projects supported by the German Federal Ministries. We read the article with great interest but find it difficult to judge the intervention's efficacy because a number of questions arise concerning methodological and reporting issues.

The study has not been registered in a public trials registry. Thus, the reader cannot assess the investigators' adherence to their original planning, but Koczy and colleagues have published a study protocol in German.⁴ Comparison of the protocol and the *Journal of the American Geriatrics Society* (JAGS) article indicates several post hoc changes, most important the redefinition of the primary endpoint. The protocol defines the primary endpoints as "number of persons with PR and number of hours of application," whereas in the JAGS article, the main outcome is "complete cessation of PR use in residents 91 to 93 days after the start of the intervention," which means that the planned end point, "reduction in the number of residents with PR", was changed to "increase in the number of residents without PR." This reflects a completely different perspective on the results, because different populations are considered. Originally, the authors assumed a relative risk reduction of 50% (5% of residents with PR in the control group (CG) and 2.5% in the intervention group (IG)) referring to the use of PR in the whole population of residents. Using the altered end point and the redefined reference population, the results show 83.2% of residents with PR in the IG, compared with 91.2% in the CG (a relative risk reduction of 9%). The assumed and the actual results cannot be compared. As in the JAGS article, there is no information on the use of PR in the whole population, so it is not possible to judge on the magnitude of the effect.

Based on the original end point, the required sample described in the protocol is 54 clusters with 100 residents each. Surprisingly, the JAGS article does not report an adapted power calculation despite the altered end point and the smaller sample size of only 45 clusters.

The definition of PR also differs from the protocol. In the JAGS article, only belts and fixed tables were considered to be PR, whereas the protocol also includes other measures, including braked wheelchairs near a table and "protective sheets." In our view, bedrails should not be excluded from PR, even if this is in accordance with other studies in the field. At least the number of residents with bedrails should be reported to judge possible unwanted effects of the intervention and a possible shift of PR toward bedrails.

Unsatisfactorily, analyses have not taken the cluster design into account, indicating a unit-of-analysis bias and further deviation from the study protocol. We are not con-

vinced by the rationale now given by Koczy and colleagues³ for the avoidance of cluster adjustment. It remains unclear how the 1.5% variance has been calculated. The pronounced sex distribution difference between the study groups further points out the necessity of cluster adjustment. The authors should have provided at least a cluster-adjusted sensitivity analysis. Use of proper cluster adjustment would most likely have resulted in loss of statistical significance of the primary end point because the lower limit of the confidence interval is already at the brink (odds ratio = 2.16, 95% confidence interval = 1.05–4.46).

Not only does the article's internal validity remain difficult to assess, but its external validity must also be contested. The study is a further example of lack of reporting of details on the development and evaluation of complex interventions, including insufficient reporting of the underlying theory, modeling of components, piloting of feasibility and acceptability, and standardized introduction of the intervention throughout different centers.

In conclusion, we would have expected the authors to adhere to the study protocol even if this would have led to a nonsignificant result. Rather than "fishing for *P*-values," analyses of strengths and weaknesses of the program would have been of great significance even if not "statistically significant."

Considering the complexity and effort of the program, transparent and comprehensive reporting of the study results with adequate statistical methods would have been an important step toward the development of future programs to reach the imperative goal of avoiding PR use in nursing home residents. Unfortunately, this is not the case.

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Conflict of Interest: As authors of a guideline on physical restraint reduction in nursing homes and of a Cochrane review on this topic, we asked Koczy and colleagues several times for access to the unpublished data. Koczy and colleagues denied access to their unpublished data. Thus, we could not exclude our personal conflict of interest.

Author Contributions: GM and SK discussed the article by Koczy and colleagues and jointly prepared this letter.

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RESPONSE LETTER TO MEYER AND KÖPKE

To the Editor: Meyer and Köpke raise questions about the planning and conduct of our study on the reduction of physical restraints (PRs) in long-term care.¹ Their discussion points also require attention because they are controversial in the majority of observational and intervention studies. We had to learn most of these lessons while piloting the intervention for feasibility and acceptability, which then led to some modifications from the application.² There were no post hoc changes in the conduct of the study. We strongly encourage an international consensus process on endpoints and measures of restraint studies similar to the Prevention of Falls Network Europe consensus publication on fall prevention.³ Measures must be particularly robust, feasible, and acceptable to residents, caregivers, and nursing homes. The planning of our study is registered and accessible with the state board of physicians (registration number 221-04). Meyer and Köpke had access to the results during shared symposia for at least 2 years, including the official report to the ministry (<http://www.reduffix.de/cms/website.php>). From the lessons learned in the pilot, we restricted our analysis on the robust measures such as belt restraints, although we are aware that social disengagement and neglect might be just as harmful. Bedrails are just one example of many that can be assistive devices or PRs depending on their use. Chairs, depending on their ergonomics and functional capacity, can be PRs or supportive.

A debatable question is whether we should consider the prevalence of PR-free individuals at the end of the study in a given time frame (e.g., 72 hours) or the time without PRs over the study period as the best primary end point. We registered 80,000 data points to document restraint prevalence during the study period. To observe more than 5,000 persons without PRs at the beginning would have inflated the data set to more than 1 million observations, which would have undermined the feasibility of the study. This was one major reason why we decided to report the results based upon the number of restrained residents at baseline and not the percentage of restrained and unrestrained residents.

We disagree with the statement that the study was underpowered because we could only recruit 45 nursing homes. The original power analysis assumed PR prevalence to be 5% and that we would recruit 100 restrained residents in each arm. The higher prevalence of 7.7% led to a much higher number of residents ($n = 333$) completing the study. This is described in the consort diagram. Other limitations

of our study have been described in the article, including the imperfect fit of the intervention and control groups.

The statistical analysis has been part of the review process. The proportion of total variance contributed by nursing homes (between-cluster variance) was estimated using multilevel analyses in an unconditional means model (PROC MIXED). Potential confounding according to sex imbalance between study groups was addressed by adjusting for sex in all models on an individual level. The statistical methods used in the article were an a priori decision based on the unconditional means models. A post hoc calculation using a multilevel analysis for the primary endpoint shows an odds ratio of 2.20 (95% confidence interval = 0.97–5.04, $P = .06$). It is correct that using a multilevel model adjusting for clustering results in borderline significance.

It was our intention to conduct a PR reduction study in high-use nursing homes under realistic circumstances. The ultimate goal in this setting is to eliminate PRs completely. It has been demonstrated that some countries such as the United Kingdom have achieved this by cultural norms. Other countries such as the Netherlands recently responded with new legislation forbidding the use of restraints in long-term care. The results of our study have led to normative changes in several states in Germany. We are awaiting the results of these measures on the use of inappropriate treatment for older persons with dementia.

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