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Physical Restraints: Consensus of a Research Definition Using a Modified Delphi Technique

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物理约束：研究定义的共识：使用修改后的Delphi技术

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目的：开发一个国际上接受的研究物理约束定义。

设计：全面文献检索后，采用基于网络的、多轮、修改后的Delphi技术进行审查和反馈。

环境：临床护理环境。

参与者：由14个国家的48名专家组成的国际小组，他们已经对临床护理领域的物理约束研究和临床应用做出了持续贡献。

测量：数据收集使用在线调查程序和一次面对面会议。在线调查结果和会议结果用于后续轮次，直到达成定义共识。共识定义为90%的参与专家同意所提出的物理约束定义。

结果：在文献检索期间，共识别了34种不同定义，作为多轮Delphi技术的起点。在三轮后，45（95.7%）的47名剩余专家同意新提出的定义：“物理约束是指任何动作或程序，防止一人自由的身体运动到意愿的位置和/或正常访问其身体的使用任何方法，附着或相邻于他/她不能控制或轻易移除的身体。”

结论：一个多学科、国际代表性的专家小组达成了对老年人物理约束的定义共识。这是一个必要的步骤，以改善比较跨研究和国家的物理约束使用率。

KEY WORDS: definition; physical restraint; Delphi technique

Over the past 4 decades, the use of physical restraints in persons in clinical care has received significant attention from researchers, clinicians, policy-makers, and advocacy organizations. Physical restraints are pervasive and widely used around the world in long-term and acute care settings. Most studies have focused on reduction1–6 or prevention of the use of physical restraints7–9, nursing staff attitude or perception toward their use10–14 and prevalence of their use.15–21 Estimates of physical restraint prevalence vary widely (6–70%) from country to country.17,22 This is attributed to differences in data collection methods but is mainly due to varied conceptual and operational definitions.23 Thus, it is difficult to compare outcomes across studies. For example, a systematic review of studies concerning use of physical restraints in adults in long-term and acute settings found that some studies had included the use of bedrails as a restraint but that other studies did not.24 Because of this measurement bias, prevalence rates of physical restraint use cannot be easily compared. Furthermore, the interpretation of results from physical restraint clinical research would benefit from a consistent definition to better conduct comparative effectiveness research. Therefore, the aim of the current study was to develop an internationally accepted research definition of physical restraint in clinical care settings such as nursing homes and hospitals.

METHODS

设计

The current study first involved a comprehensive literature search followed by a web-based, three-round, modified Delphi technique. The modified Delphi technique consisted...
of three rounds of reviews and feedback in which data were collected using an online survey program and one in-person meeting.

Literature Search
A comprehensive literature search was conducted between June and September 2011 to identify existing definitions of physical restraints. A three-step search strategy was used. Search terms included physical restraints, definition, nursing homes, residential care facilities, acute care, intensive care unit (ICU), incidence, prevalence, elderly, and older persons. The electronic databases MEDLINE, CINAHL, Cochrane Library, and Embase were first searched to identify additional definitions. Finally, a wider Internet search for sources of “gray literature” was conducted. All types of publications were included in the search procedures (e.g., governmental, educational and other institutional reports, research organization sites, conference proceedings and papers, dissertations). Thirty-four different definitions were identified and used as a starting point for the modified Delphi technique (definitions available from the corresponding author upon request).

Delphi Technique
The Delphi technique is a widely used method to assess consensus in the opinions of experts.\textsuperscript{25,26} It is a group-facilitated interaction process that is directed in a series of structured questionnaires or “rounds” of opinion collection and feedback.\textsuperscript{27} The Delphi technique is based on the principles of structuring information flow, anonymity, and regular feedback. All information flows from a chairperson (central facilitator) enabling structured and anonymous participation.\textsuperscript{28} It is not a method for creating new knowledge but rather a process for making the best use of available information.\textsuperscript{29} In this study, the traditional Delphi technique was modified by adding an additional round of in-person discussion among some of the experts.

Participants
As part of the literature search within the three-step strategy, researchers and clinicians who have made sustained contribution to research and clinical application in the field of physical restraint use in the care of older persons were identified as experts. Researchers were considered experts when they had credibility according to the target audience, indicated by authorship of at least one publication (in English) on physical restraints in a peer-reviewed journal in the last 3 decades. Experts were also recruited from the networks of the authors identified in the search. Experts were contacted through an e-mail invitation including a brief introduction of the study aim and purpose and were asked to participate in the Delphi survey. This e-mail included an invitation to a face-to-face meeting during the 2011 Annual Scientific Meeting of the Gerontological Society of America in Boston, Massachusetts. Experts participating in Round 1 were also asked to suggest other experts in the field who could be added to Round 2 of the Delphi survey.

Data Collection and Analysis of the Survey
All experts who had agreed to participate in the Delphi survey received an e-mail in September 2011 that included a link to complete the online Round 1 survey. Participants were asked to complete each round within 2 weeks and were sent a reminder e-mail if they did not do so. After each round, a feedback report with a summary of the main results of the previous round was sent to the experts. During the first round, all 34 definitions identified in the literature were presented, as well as questions regarding the expert respondents’ professional characteristics (e.g., country in which they practiced, role, background). The experts were asked to choose the three most-appropriate definitions from among the 34 listed and rank them in order of preference. The experts were also asked whether their chosen definitions met their criteria of what could be considered to be physical restraints and to provide suggestions to enhance these definitions.

The face-to-face meeting was then conducted during the November 2011 Annual Scientific Meeting of the Gerontological Society of America to provide an opportunity for open discussion among those attending. The results of the online survey and the in-person meeting were then used for distribution in subsequent rounds until consensus on an agreed-upon definition was reached. Consensus was defined as 90% of the participating experts agreeing with the proposed definition of physical restraint.

RESULTS
Round 1
Of 49 experts invited to participate in the Delphi procedure, 40 agreed to participate, one refused because of personal circumstances, and eight did not respond despite repeated invitations. The participating experts originated from 13 countries (Australia (n = 2); Belgium (n = 1); Canada (n = 5); Finland (n = 2); Germany (n = 5); Hong Kong (n = 2); the Netherlands (n = 4); Norway (n = 1); Spain (n = 2); Sweden (n = 2); Switzerland (n = 2); United Kingdom (n = 2); United States (n = 10). Thirty experts (75%) were employed as university researchers, and 28 (70%) were nurses. All 40 participants selected the three definitions that they thought were most appropriate and ranked them from 1 (best definition) to 3 in order of preference.

Seventeen (40%) of the experts participating in the first round attended the Annual Scientific Meeting of the Gerontological Society of America in Boston. In addition to discussing potential restraint definitions, the group identified a set of guiding principles. Experts concurred that consistency among researchers was the main purpose of a uniform definition. Also, the group agreed that a clear research definition would facilitate evidence-based practice change and governmental regulation. It was expected that a uniform research definition would eventually enable comparisons of restraint use across countries. The experts agreed that a restraint is a restraint, regardless of the setting or the intent of the user.

Table 1 has a summary of definitions selected in each round. Based on the survey results and the group discussion, four published definitions were selected in Round 1. All four
definitions comprised three characteristics of physical restraints, which were present in all definitions: device, material, or equipment attached or adjacent to a person’s body; cannot be easily removed; and prevents or restricts free body movement. Based on these three characteristics, a first draft definition of physical restraints was proposed as an outcome of the group meeting: “Physical restraint refers to actions or procedures that prevent a person’s free body movement to a position of choice and/or normal access to his/her body by any manual method, physical or mechanical device, material, or equipment attached or adjacent to a person’s body that a person cannot control or remove easily.”

Round 2
In Round 2, eight additional participants were added to the expert panel from Canada (n = 2), South Korea (n = 1), Spain (n = 3), the United Kingdom (n = 1), and the United States (n = 1). There was one nonresponder from Round 1, leaving 47 participants completed Round 2. Background characteristics of the participants in the expert panel were consistent with those participating in Round 1. In this round, 72% of the expert panel agreed with the definition proposed from the group meeting and the first round. The main feedback from experts regarding the definition related to the wording of “any manual method, physical or mechanical device, material, or equipment.” The experts suggested that this was too specific and that “any method” would be sufficient. Some questioned whether the definition should address whether the use of a device was deliberately applied as a restraint, but most respondents agreed that the intention of physical restraint usage was not relevant, because the consequences of physical restraint use remain the same. Finally, some experts suggested including a list of concrete items as examples of physical restraints, but such a list would never be all encompassing and was not included in the definition. In Round 3, the following final definition was proposed to the panel: “Physical restraint is defined as any action or procedure that prevents a person’s free body movement to a position of choice and/or normal access to his/her body by the use of any method, attached or adjacent to a person’s body that he/she cannot control or remove easily.”

Round 3
The same 47 experts as in Round 2 participated in Round 3. Forty-five (95.7%) of the experts agreed with the proposed definition in Round 3. The main objection of the two experts who did not agree is that this definition may be interpreted as including a wide range of treatments and medical devices.

DISCUSSION
A multidisciplinary, internationally representative panel of experts reached consensus on a research definition of physical restraints after three rounds of revisions: “Physical restraint is defined as any action or procedure that prevents a person’s free body movement to a position of choice and/or normal access to his/her body by the use of any method, attached or adjacent to a person’s body that he/she cannot control or remove easily.”

Strengths and Limitations
The inclusion of experts from 14 countries who have conducted research concerning restraints in elder populations strengthened the process. Widespread use will depend on translating the definition into various languages, with back translation to ensure validity. Another strength is that the panel included individuals from seven disciplines, which provided various perspectives. Furthermore, the face-to-face meeting provided many of the experts an opportunity for interactive discussion of opposing and similar views. It is likely that the easy-to-use online survey format and multiple email reminders resulted in the high response rate of the survey over three rounds.27,30

A limitation of this study is that participants were a convenience sample of experts based on a review of the scientific literature conducted over the past 3 decades. A few experts were not included because of nonresponse to the survey or their research was not published in English. Another limitation was that the experts were primarily researchers, although many also held a clinical appointment. Although it is likely that this definition can be used in clinical practice, it may require further operationalization and evaluation.

Implications and Future Research
Despite the focus on formulating a research definition, there are some things to consider in applying this definition in research and clinical care. For example, splints and
plaster casts may be incorrectly categorized as a physical restraint. The new definition could also be problematic within the intensive care unit setting, so medical and life-sustaining treatments are considered outside the scope of this definition. Similarly, the proximity of the restraint to the person may influence whether a physical restraint should be defined as an environmental versus a physical restraint. Finally, the next step is to operationalize physical restraint use so that it translates into a highly reliable and valid means of capturing restraint types and thus informs knowledge of the pervasiveness of physical restraints across the globe.

CONCLUSION

A multidisciplinary, internationally representative panel of experts reached consensus on an accepted research definition for physical restraints in older persons. This is a necessary step toward being able to better compare the prevalence of physical restraint use across studies and countries. The results of this study can also be used to guide research interventions aimed at reducing use of physical restraints.

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Author Contributions: Bleijlevens, Wagner, Capezuti, Hamers: study concept and design. Bleijlevens, Wagner: acquisition of subjects and data. Bleijlevens, Wagner, Capezuti, Hamers: analysis and interpretation of data, preparation of manuscript. All authors read and approved the final manuscript.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Appendix S1. List of Members of the International Physical Restraint Workgroup.

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