Pilot and Feasibility Studies in Rehabilitation: Moving into the Next Decade

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WHERE ARE WE NOW?

In 2009, *Physiotherapy Canada* described the purpose of a pilot study, shortcomings of research described as pilot studies submitted to the journal, and use of pilot study results by its readers.[1] Figure 1 shows that the number of published studies labeled as *pilot* or *feasibility* studies has been steadily increasing over time. As we launch into a new decade, methodological advances provide further clarity about pilot and feasibility studies, their design and conduct, and their application to audiences beyond those who conduct the study. In this editorial, we summarize the latest research on pilot and feasibility studies done in preparation for a future randomized controlled trial (RCT) to evaluate the evaluate the effectiveness of an intervention.

DEFINITIONS

The fundamental premise of pilot studies, the provision of important information concerning the feasibility of methods, processes, and procedures for large-scale investigations, remains the same.[1] However, research shows varied and inconsistent use of the terms *pilot* and *feasibility* studies, which introduces confusion.[2] To address this gap, an international, multidisciplinary team recently proposed definitions of pilot and feasibility studies.[2] All pilot and feasibility studies ask whether a future trial can be done; however, they focus on different aspects of the trial.

Pilot studies evaluate factors related to the intervention that will be assessed in a future RCT.[2] A randomized pilot study assesses the implementation of the future RCT, or parts of it, including randomization of patients, to see whether it can be done.[2] A non-randomized pilot study also assesses all or parts of a future RCT without randomizing patients.[2] Feasibility studies evaluate questions about whether an element of the future trial can be done, excluding the intervention to be evaluated or other processes to be undertaken in a future trial.[2] Thus, all pilot studies are feasibility studies, but not all feasibility studies are pilot studies.

WHY DO WE NEED PILOT AND FEASIBILITY STUDIES IN REHABILITATION RESEARCH?

Unlike a drug trial, in which there are relatively few steps to document intervention delivery, rehabilitation involves several considerations. Rehabilitation is a complex intervention characterized by (1) the number of interacting components in the experimental and control interventions; (2) the number and difficulty of behaviours by those delivering or receiving the intervention; (3) the number of groups or organizational levels targeted by the intervention; (4) the number and variability of outcomes; and (5) the degree of flexibility or tailoring of the intervention permitted.[3] Pilot and feasibility studies assess implementation failure rather than intervention failure. Given the complexity of rehabilitation interventions, pilot and feasibility studies are needed to evaluate whether a future trial can be implemented. If researchers do not conduct a study as planned, it is not possible to truly evaluate the effects of the intervention. By extension, because the purpose of a pilot study is to assess implementation failure, it is then beyond the scope of the research question to assess efficacy.

DESIGN, CONDUCT, AND REPORTING

The research question drives the design, conduct, analysis, and reporting of pilot and feasibility studies. Pilot and feasibility studies have specific reporting considerations: the Consolidated Standards of Reporting Trials (CONSORT) statement extension for pilot and feasibility studies[4] and recent guidelines,[5] which complement

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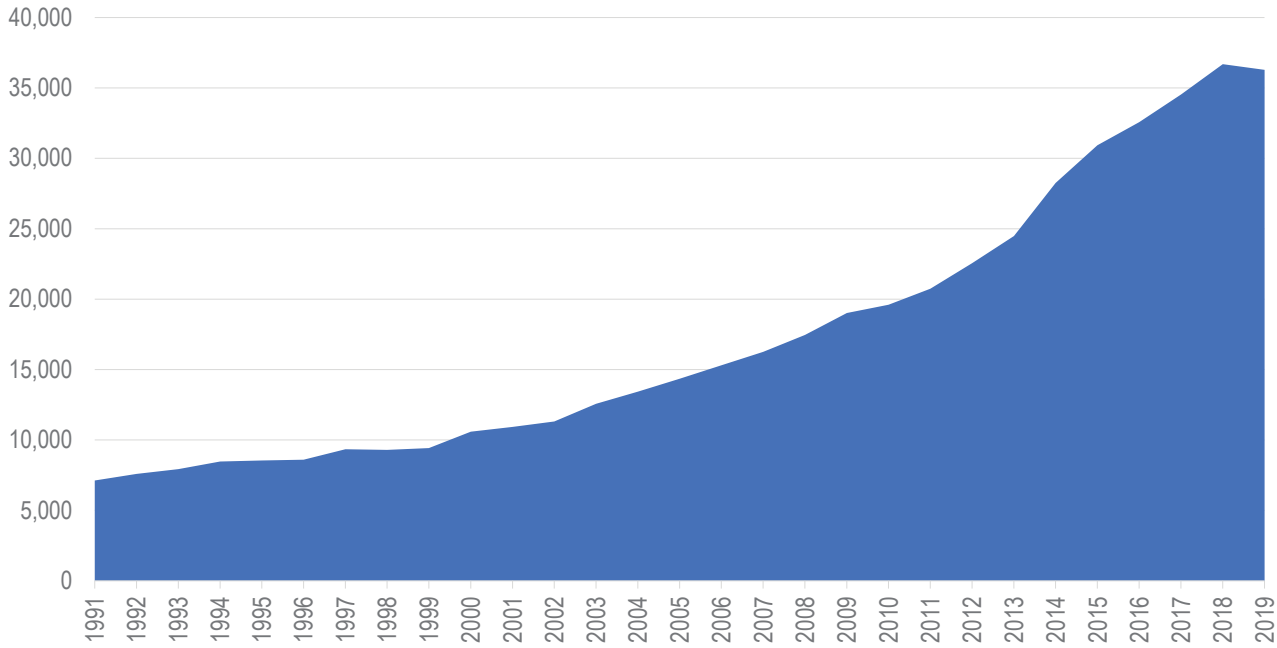

Figure 1 Number of PubMed-indexed studies published in 1991–2019 based on the search terms *pilot* OR *feasibility* AND *rehabilitation*.

the existing guidance. Next, we highlight two examples of physiotherapy pilot and feasibility studies.

Example 1

Consider a 2-centre, pilot RCT that informed the 56-centre, international A Very Early Rehabilitation Trial (AVERT) for patients post-acute stroke.[6,7]

1. *Interacting components:* Patients were randomized within 24 hours of stroke onset, and each centre needed to coordinate very early mobilization in addition to usual care or usual care within a stroke unit.
2. *Difficulty of behaviours:* Those providing rehabilitation required clinical expertise in acute care; patients receiving the intervention could be medically unstable.
3. *Groups and organizational levels:* The intervention involved physiotherapy and nursing, with blinded outcomes occurring at 7 and 14 days and at 3, 6, and 12 months.
4. *Outcomes:* The primary safety outcome was death at 3 months, and the primary feasibility outcome was difference in mobilization dose between groups.
5. *Flexibility:* Interventionists integrated clinical judgment to apply the intervention protocol. Investigators demonstrated no difference in death at 3 months, and mobilization dose in the intervention group was double that of the control group (167 vs. 69 minutes).

Example 2

Extensive pilot and feasibility research informed an ongoing 17-centre, international CYCLE RCT evaluating the effectiveness of early in-bed cycle ergometry with mechanically ventilated patients (ClinicalTrials.gov Identifier NCT03471247). A non-randomized pilot study suggested that in-bed cycling could safely start within the first 4 days of mechanical ventilation and throughout a patient's intensive care unit stay.[8] A 7-centre randomized pilot study demonstrated a future RCT was possible, but a larger RCT would require additional physiotherapist resources.[9] A feasibility study of physiotherapists participating in the CYCLE pilot RCT identified concerns about providing equitable care to all patients on their caseload, in addition to trial participants.[10]

WE URGENTLY NEED WELL-DESIGNED PILOT AND FEASIBILITY STUDIES IN REHABILITATION

Pilot and feasibility studies are fundable by any funding agency. These studies produce valuable information to inform the design and accelerate the conduct of large-scale rehabilitation trials. They are an integral part of reducing research waste to focus on evaluating the most relevant, effective interventions to improve patient outcomes.

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Les études pilotes et les études de faisabilité en réadaptation : la prochaine décennie

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OÙ EN SOMMES-NOUS?

En 2009, *Physiotherapy Canada* a décrit l'objectif d'une étude pilote, les lacunes des recherches soumises à la revue sous le nom d'études pilotes et l'utilisation des résultats de ces études par les lecteurs[1]. La figure 1 démontre que le nombre d'études publiées sous le nom d'*études pilotes* ou d'*études de faisabilité* a augmenté régulièrement depuis. À l'aube d'une nouvelle décennie, les progrès en matière de méthodologie permettent de préciser le mode de conception et de tenue des études pilotes et des études de faisabilité, de même que leur adoption par d'autres auditoires que ceux retenus à l'origine. Dans cet éditorial, les auteures résument les recherches les plus récentes sur les études pilotes et les études de faisabilité réalisées en vue d'un essai aléatoire et contrôlé (EAC) pour évaluer l'efficacité d'une intervention.

DÉFINITIONS

La prémisse fondamentale des études pilotes, soit l'obtention d'information importante sur la faisabilité des méthodes, des processus et des marches à suivre de recherches à grande échelle, n'a pas changé[1]. Cependant, les recherches révèlent une utilisation variée et contradictoire des termes études *pilotes* et études *de faisabilité*, ce qui suscite la confusion[2]. Pour corriger cette lacune, une équipe multidisciplinaire internationale a récemment proposé des définitions des études pilotes et des études de faisabilité[2]. Ce type d'études évalue la possibilité de réaliser un futur essai, mais s'attache à des aspects différents de cet essai.

Les études pilotes évaluent des facteurs liés à l'intervention qui seront examinés dans un futur EAC[2]. Une étude pilote aléatoire évalue la mise en œuvre de l'intégralité ou d'éléments d'un futur EAC, y compris l'aléation des patients, pour établir si cet EAC peut être réalisé[2]. Une étude pilote non aléatoire évalue également l'intégralité ou des éléments du futur EAC, mais sans aléation des patients[2]. Les études de faisabilité évaluent des questions sur la possibilité d'effectuer un élément du futur essai, à l'exclusion de l'intervention évaluée ou d'autres processus qui seront entrepris dans ce futur essai[2]. Ainsi, toutes les

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