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Pilot and feasibility studies in Sports Medicine

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Over recent years, there has been an increasing emphasis on the importance of preliminary work prior to the organisation of large-scale, publicly funded randomised controlled trials. Many large public funding bodies now expect substantial work to have been done prior to the main bid for money to fund a large trial or indeed any large study. The value of preliminary work is now recognised and researchers are encouraged to carry out feasibility and pilot studies before a major trial and to publish both the protocol and the results of their work in advance of the main trial. There is a new journal, *Pilot and Feasibility Studies,* which publishes the results of such studies.

Similar to a randomised controlled trial, a pilot trial should have clear objectives and a priori criteria for success. It should be designed, conducted and reported using the same standards as any high-quality randomized controlled trial. Pilot and feasibility studies are important in that they can ensure that scarce research money and researcher efforts are being invested in efficient trials that can provide definitive answers to important research questions. Guidelines for reporting pilot trials as part of an extension of the CONSORT statement have been published [1,2]

A recent review of physical activity trials comments on some of the feasibility issues that are more common in this area [3]. These include: the challenge of blinding of group allocation, retaining interest of the comparison group, participant and instructor fidelity, and being able to recruit people who are not already active enough, but interested enough in becoming active to sign up for the study. A second review in sports medicine reported on five journals which published over five articles which related to randomized pilot trials between 2012 and 2015 [4] The authors found that reporting and understanding of pilot and feasibility studies in studies of physical activity was poor, with few providing sufficient explanation. Over half of the studies did not have feasibility objectives which corresponded with previous research findings, so that these findings were not being disseminated effectively to researchers in the field of physical activity. The low standard of reporting across most of the reviewed articles

and the fact that the extended CONSORT 2010 statement was ignored by the journal editors highlights the need to actively disseminate these guidelines to ensure their impact. The authors also reported that journal editors in this area will rarely publish pilot and feasibility studies, but this might be because the studies are generally of poor quality and an objective of this paper is to encourage better design and reporting in the area of physical activity trials.

Current Definitions

There are several papers that clarify the various distinctions in pilot and feasibility studies and these are summarised in the Box. [2,5,.6]

Box here

Researchers should view feasibility as an overarching concept, with all studies done in preparation for a main study open to being called feasibility studies, and with pilot studies as a subset of feasibility studies. Authors should describe their feasibility objectives and methods well and in accordance with the guidelines [1], reporting clearly if their study is in preparation for a future RCT to evaluate the effect of an intervention or therapy. A pilot study should address the main uncertainties that have been identified in the development work in order to plan a main trial or other major piece of research.

The CONSORT statement and the Horne review [1,4] only apply to *randomised external* pilot trials (See Box). An internal pilot study will have a trial monitoring committee which will make suggestions as to whether the trial should be abandoned at that stage or extended either in length or eligibility of participants and possibly suggest revising the sample size upward to accommodate unanticipatedly large variability in the outcome variable. An external pilot trial may suggest, for example, that an individually randomised trial is not possible and so the team may consider a cluster trial as the main trial. The results from the pilot may suggest the main outcome variable may be difficult to measure accurately, so other outcomes measures might be proposed. Note that changing the outcome variable from what is proposed in the protocol to that which appears in the main trial report often highlights major generalisability

issues with the trial and so it is better to identify the main outcome variable whilst planning the trial. [7]

Examples

Haines aimed to describe the feasibility of an exercise intervention (reduced-exertion, high-intensity interval training REHIT) in nondiabetic hyperglycaemia patients [8]. The study intended to recruit 40 participants but achieved only 6. It revealed several issues including patient eligibility, challenges to recruitment, patient consent, and poor clinician engagement. The process of accurately screening and case finding eligible patients was problematic. The author concluded that a trial in its current form is not feasible, but made suggestions as to changes that could occur in future studies.

An excellent trial in sports medicine that, nevertheless, might have benefited from piloting is the INSPIRE (INtervention Study on Prevention of Injuries in Runners at Erasmus MC) Trial [9]. This study with 2378 participants aimed to reduce running injuries in recreational runners by providing evidence-based online advice on modifying known risk factors. It not only failed to show an effect, but the point estimates were in the wrong direction to that expected. It also had a high drop-out rate (28% compared to 5% expected). A feasibility or pilot study might have highlighted the drop-out rate, giving the authors a chance to try and make completion of the outcome questionnaire more attractive. It may also have suggested that the intervention as it stands would be unlikely to be beneficial to the participants, leading to an opportunity for modifying the intervention. However, it is good that such a large, negative trial was published, because *a priori* the hypothesis was worth testing.

We hope that this article will encourage more researchers to think about a pilot or feasibility study before the main trial, and to publish the results. Even if the authors themselves do not plan on a subsequent major study, the information will help other researchers in the field to plan future studies.

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Box : Feasibility and Pilot Studies

A *feasibility* study asks whether something can be done, should the investigator proceed with it, and if so, how.

A *pilot* study asks the same questions but also has a specific design feature. A pilot study replicates a future study, or part of one conducted on a smaller scale.

An *internal* pilot study is simply the first part of the main trial. For an internal pilot trial, the design is fixed and decisions will be made (after a year say) as to whether recruitment to the full trial is possible in the time postulated.

In an *external* pilot trial, the subjects are not expected to be included in the main trial, and more radical changes to the design may be made, such as changing the outcome variable.

Feasibility studies include all preliminary work prior to a main study, and pilot studies are a subset of this.

To facilitate their identification, these studies should be clearly identified using the terms ‘feasibility’ or ‘pilot’ as appropriate, including feasibility studies that are largely qualitative.

Investigators should report appropriate objectives and methods related to feasibility; and give clear confirmation whether their study is in preparation for a future randomised controlled trial designed to assess the effect of an intervention.