Needed: post-trial access in exercise interventions

Drs Kass Gibson and Paul Gorczynski outline post-trial access in both moral and policy terms and provide key considerations for researchers considering undertaking clinical trials of exercise.

Rhetoric regarding the contribution of physical activity to health and well-being outcomes is longstanding and amplifying. A key strategy from researchers to encourage health officials and governments to take the health benefits of physical activity more seriously has been to use medicine as both foil and metaphor for being active (Sallis, 2009). The former promotes the supposedly side-effect-free nature of physical activity, as well as cost effectiveness of being active compared to pharmaceutical and surgical treatments. The latter is a credence-seeking strategy used to promote physical activity as an important health-care practice, rather than leisure pursuit (Smith, 2016). Such promotion of physical activity as a crucially important cornerstone of individual health-care practice and public health strategy also draws on an extensive, robust, and further developing evidence base, particularly clinical trials, where exercise, a purposeful and repetitive form of physical activity, is evaluated.

As physical activity researchers, University ethics committee members and Health Research Authority (HRA) Research Ethics Committee vicechairs, we have witnessed an increase in both published literature and proposed research for clinical trials that evaluate exercise. Concomitantly, we have noticed researchers are giving insufficient thought and planning in trial design for post-trial access to their exercise interventions. Especially compared to clinical trials of medical and surgical interventions. If researchers take the exercise as medicine metaphor - and research practices of medicine - seriously, we argue post-trial access needs far greater consideration in research design. Below we outline post-trial access in both moral and policy terms before providing key considerations for researchers considering undertaking clinical trials of exercise. What, then, is post-trial access?

Post-trial access is most commonly understood as making necessary arrangements to provide access to the study intervention should it prove beneficial. In its most simple terms, post-trial access includes making a treatment available to study participants, particularly those in the control arm of a trial, to ensure participants who necessarily expose themselves to risks and inconveniences through research participation are able to realise some benefit. In the context of clinical trials of exercise, post-trial access to the specific intervention is relatively simple, albeit not without costs. Strategies can include, for example, cross-over or stepped-wedge designs and/or trial extensions (Sofaer & Stretch, 2011). However, post-trial access becomes more complicated when we consider research context and benefit more broadly (Cho *et al.*, 2018).

Complications arise when research participants may realise a health benefit by continuing with the study intervention. For example, many clinical trials of exercise provide interventions such as structured training programmes, tracking devices or facility access for participants to engage in exercise. Yet, those interventions - which usually increase one's level of activity - are removed at the completion of the study. If these interventions enable participants to realise health benefits by increasing levels of activity, we argue there is a moral obligation for researchers to continue to support participants' exercise behaviours, especially when ceasing exercise would be harmful.

Post-trial access is a well-established concern within international ethics guidelines. For example, the Declaration of Helsinki, published by the World Medical Association (2008) requires: "At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits." For research that recruits populations considered as disadvantaged or vulnerable, the Declaration states that such research is justified only "if there is a reasonable likelihood that this population or community stands to benefit from the results of the research." (Article 17).

Similarly, the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) guidance (2008) states:
"Even if research addresses a question that has social value for the community or population where it is carried out, the community or population will not benefit from successful research unless the knowledge and interventions that it produces are made

available to them." CIOMS (2002) identifies the study sponsor as having the obligation "to make a beneficial intervention or product developed as a result of the research reasonably available to the population or community concerned." While post-trial access has strong moral imperatives and clear instruction from ethical frameworks, it is nonetheless complex and contested. Especially defining what might be considered "reasonably available." For example, obligations become more complicated when participants perceive benefit, contrary to research findings; and becomes more compelling when research participants are from vulnerable groups (Sofaer & Stretch, 2011). Reasonable conditions for denying post-trial access are explained by the HRA in the United Kingdom (HRA, 2012).

In our experience as HRA Research Ethics Committee vice-chairs, researchers most often cite limited resources as the reason why post-trial access cannot be provided. While such logistical challenges are frustrations for researchers and intuitively obvious, we argue a case needs to be made not only why post-trial access would be an inappropriate use of resources but also whether conducting the trial in the first instance is an appropriate use of resources (Gorczynski *et al.*, 2019; Williams & Gibson, 2018). In other words, it might be time to devote less research effort to establishing a clinical evidence base for exercise and, instead, address access to exercise.

Ultimately, as a field, insufficient attention is devoted to post-trial access as an ethical consideration in clinical trials of exercise. Researchers must consider health need and not just evidence need in their study design. More specifically, researchers must articulate in research protocols conditions for post-trial access, including if this is dependent on study success, however success may be defined. Further, researchers must clearly explain to potential participants what post-trial access is available, for which participants, and under what circumstances. ■

Dr Kass Gibson

Kass is a Senior Lecturer at Plymouth Marjon University and Vice-Chair of the NHS Health Research Authority South West - Cornwall and Plymouth Research Ethics Committee.

Dr Paul Gorczynski

Paul is a Senior Lecturer at the University of Portsmouth and Vice-Chair of the NHS Health Research Authority London - Bloomsbury Research Ethics Committee.

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