Letter: The Choice of Control Conditions in Animal-Assisted Intervention Research

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We read with interest the review by Holder et al[1] on animal-assisted interventions (AAI) in oncology and agree with the conclusion that more randomized controlled trials (RCTs) are needed. We wish to draw attention to an important consideration in RCT design that is particularly relevant and complex for AAI studies: the choice of a control condition. Holder et al. noted that few AAI studies in oncology had control groups, and those that did faced practical challenges. Bias reduction, feasibility, and ethical considerations are among the many factors that influence the choice of control condition. Critical to the validity of the trial, the choice of a control condition should reflect the underlying study question. Our goal in this letter is to highlight the range of control conditions that may be appropriate for AAI in oncology and the rationale for using different controls.

Different scientific questions require different types of trials.[2] For nonpharmacological complementary and integrative health interventions, these types include efficacy, explanatory, effectiveness, pragmatic, noninferiority, comparative effectiveness, or three-arm trials.[2] The behavioral and integrative medicine literature has much to offer the field of AAI with respect to control condition methodology.[2,3] Control conditions used in these studies include placebo/sham, active comparators, attention controls, usual/standard care controls, and dismantling controls. For example, whereas a non-inferiority study would compare a new intervention to one already used in practice, a pragmatic trial seeking to determine whether AAI is better than usual care would use usual care as the control condition. A mechanistic study seeking to determine the importance of the interaction between patients and animal handlers might compare an AAI intervention that allows for interactions between the patient and handler to one that does not (ie, a dismantling control).

As the body of literature in AAI in oncology grows, we expect that many studies will seek to use attention controls and usual care controls for efficacy and effectiveness/pragmatic questions, respectively. The goal of an attention control group is to account for everything but the active ingredient of the intervention.[2] Interactions with healthcare providers are not considered active ingredients of medications and should thus be controlled for in pharmacologic studies. In contrast, interactions with the handler in AAI studies may be an active ingredient of the AAI intervention.[4] The handler is more than a conduit for the patient to interact with the animal. Thus, in AAI efficacy and effectiveness/pragmatic studies, it may make sense to control for attention from researchers but not for the human interaction that is part of an AAI session.

In effectiveness and pragmatic studies with usual care control groups, it is also important to note that "usual care" may differ across settings and studies.[5] An AAI intervention could be effective in a setting where usual care includes few other supportive care offerings but less effective in a setting in which patients without AAI receive other forms of supportive care. Therefore, studies should carefully describe what usual care entails to provide the context necessary for evaluating whether results are likely to be transportable to other settings. Testing an intervention in multiple healthcare settings can mitigate this concern.

We have noted some important considerations in selecting control conditions for AAI research in oncology. There is no single correct control condition. Rather, the choice should reflect the scientific question of interest and incorporate ethical and feasibility considerations. We recommend that AAI researchers follow and adapt design

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principles that have been outlined by others in behavioral and integrative medicine and frame the choice of control conditions in terms of the scientific question of interest.

Studies that use different control conditions should not be expected to yield identical results. Thus, we also recommend that systematic reviews group studies based on type (eg, mechanistic, efficacy, effectiveness, comparative effectiveness) and generally avoid meta-analyzing results across groupings.

In summary, we thank Holder et al. for highlighting the need for well-designed, controlled studies of AAI in oncology. Selecting control conditions is just one of many important aspects of study design that AAI researchers should attend to in order to rigorously test the benefits and safety of AAI for cancer patients.

Declaration of Conflicting Interests

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