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Regression-based statistical mediation and moderation analysis in clinical research: Observations, recommendations, and implementation

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A R T I C L E I N F O

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A B S T R A C T

There have been numerous treatments in the clinical research literature about various design, analysis, and interpretation considerations when testing hypotheses about mechanisms and contingencies of effects, popularly known as *mediation* and *moderation* analysis. In this paper we address the practice of mediation and moderation analysis using linear regression in the pages of *Behaviour Research and Therapy* and offer some observations and recommendations, debunk some popular myths, describe some new advances, and provide an example of mediation, moderation, and their integration as conditional process analysis using the PROCESS macro for SPSS and SAS. Our goal is to nudge clinical researchers away from historically significant but increasingly old school approaches toward modifications, revisions, and extensions that characterize more modern thinking about the analysis of the mechanisms and contingencies of effects.

Clinical research is about more than establishing that an effect exists, such as whether a new form of therapy is more effective than existing methods for treating certain conditions, or whether people who have certain experiences in life such as psychological trauma are more likely to suffer later in life from certain symptoms such as posttraumatic stress. It is just as important to understand how such effects operate and the boundary conditions of those effects. The former refers to the mechanism by which an effect is transmitted, whereas the latter speaks to the circumstances, contexts, or types of people for whom an effect exists and for whom it does not. Establishing boundary conditions is particularly important in application, because such understanding provides insight into the types of people for whom a particular therapeutic method works or does not, or what dispositions or attitudes might influence how much a life experience has an effect positive or negative down the road. There have been numerous treatments in the clinical research literature (e.g., Breitborde, Srihari, & Pollard et al., 2010; Kraemer, 2016; Kraemer, Wilson, Fairburn, & Agras, 2002; Magill, 2011) of various design, analysis, and interpretation considerations when testing hypotheses about mechanisms and contingencies of effects, popularly known as *mediation* and *moderation* analysis, respectively.

Given the importance of understanding the mechanisms and contingencies of effects, and the diverse perspectives in the methodology literature about how to test questions about mediation and moderation, we were asked by guest editors of *Behaviour Research and Therapy (BRaT)* to write a pedagogically-oriented overview of the practice of mediation and moderation analysis, so as to provide authors and reviewers some guidance on how to implement the advice offered by methodologists who think about these questions for a living. We took this as a challenge, and started by scanning the pages of the last five years of this journal to see what researchers are actually doing, noting in particular the kinds of designs researchers use and how they go about analyzing their data so that we could make an informed assessment of the conventions and procedures used by researchers in this area.

It didn't take us long to appreciate that the task we were invited to perform was next to impossible. There is too much diversity and complexity in method and design in the pages of this journal for us to provide a coherent treatment of best practices and current recommendations. We could have exhausted our entire page budget discussing just one specific method (e.g., mediation analysis) and one specific type of design (e.g., longitudinal), but doing so would have limited the value of this paper to only those who use such

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designs. Yet most of the methods used by clinical researchers in the pages of *BRaT* have one thing in common, and that is their reliance on linear modeling principles. Given that many of the published examples we found in our perusal of the journal are based on straightforward linear regression analysis (as discussed by, say, Baron & Kenny, 1986), yet sometimes seemed to reflect a lack of appreciation for or awareness of current advances and changes in thinking, we decided to keep things simple and focus our treatment on the fundamentals applied with ordinary least squares (OLS) regression with continuous outcomes. Restricting our discussion to this simpler problem also allowed us to broaden the audience while shaving off material that would have been required to bring the typical reader up to speed on a more complex method. Still, many of the recommendations we offer in the OLS regression context generalize to more complex methods used by clinical researchers. To satisfy the request for a pedagogical treatment, we have kept the mathematics to a minimum when possible and discuss implementation of some of these methods using the PROCESS macro available for SPSS and SAS (Hayes, 2013) that has become widely used by researchers interested in testing hypotheses about moderation and mediation.

Throughout we provide references to examples of some of the things we have seen, most published in the pages of *BRaT*, illustrating points we make or things we recommend doing or not doing. It is not our intention to finger-wag when we cite examples of things we suggest avoiding or that represent outdated thinking. We recognize that substantive researchers doing meaningful clinical research have more important things to do than staying up to date on recent innovations, nuances, and updates in methodology, and that there is always a time lag between movements in methodology and implementation by those doing the substantive work of the business. Our goal is to nudge clinical researchers a bit in a particular direction rather than question the quality or value of the work being done by contributors to this journal.

Before diving in, we want to make our position on the role of data analysis in research clear from the outset, to avoid unnecessary confusion, overconfidence in what statistics can do by those who adopt some of our recommendations, and to preempt accusations that we are oversimplifying a complex problem in science. There are some hardliners who say that to claim the existence of cause-effect relationships (and mediation is by definition a cause-effect process), one must engage in experimental manipulation with random assignment, collect data over time or, ideally, both. Furthermore, one must meet an overwhelming number of assumptions beyond those of linear modeling that go by such names as “sequential ignorability,” “stable unit treatment value” and others, many that are quite technical in nature or hard or impossible to test. Others argue that one cannot conduct a mediation analysis with merely correlational data, that moderators must be independent of presumed causes of effects, and the list of requirements goes on and on (see e.g., Emsley, Dunn, & White, 2010; Preacher, 2015, for a discussion of many of these assumptions). We feel that if these are taken as literal requirements rather than as just ideals or recommendations, most research would not be done because most researchers cannot meet these requirements (due to resource constraints, ethics, and a myriad list of other reasons). Indeed, the use of such a high standard for causal inference would render most of the natural sciences unable to say anything about cause-effect relationships, given that experimentation, manipulation, and the various assumptions that social scientists often impose on themselves are rarely used or met in the natural sciences (c.f., Darlington & Hayes, 2017, pp. 166–168). We would rather see more imperfect work conducted and published than see research slow to a trickle because investigators don't feel that their work will satisfy all critics and pass every test for valid causal inference.

Our position is a more relaxed one reflecting our laissez-faire attitude about the role of data analysis in science (see Hayes, 2013, pp. 15–18, for a more extended discussion). Here, we don't dwell on some of the philosophical debates that one can find in the methodology literature about what cause-effect means, the limitations of various research designs for entertaining cause-effect questions, and the boundaries of the value of regression analysis and statistical control. This article is about data analysis, but we see data analysis as a tool, only one of many in a researcher's arsenal, and ultimately secondary to theory, knowledge of the literature in one's substantive area, and solid logical argument. Statistical methods are agnostic, indeed, ignorant about the origins of the data with respect to measurement and design. Inferences about substantive meaning are made not with output from routines built into statistical software, but by researchers who are attempting to make sense of and interpret that output. Inferences are products of our minds, not our mathematics. Any statistical method can be used on data regardless of its source as a tool to help guide the researchers' thinking about their data and their findings. So we don't agree that one cannot conduct a mediation analysis with correlational data, or that moderators must be uncorrelated with independent variables in order to do a moderation analysis. You can do most anything you want with your data. Most any statistical tool can provide some insight into the story you ultimately end up telling with your data.

1. Statistical mediation analysis

Mediation analysis is used when a researcher seeks to test hypotheses about or better understand how an effect of X on Y operates. The causal antecedent X could be which of two forms of therapy a client receives, or it could be an individual difference measure such as exposure to various sources of trauma, or any other conceivable variable that has some kind of causal force on a consequent outcome variable. That consequent Y could be something like frequency or severity of symptoms of some ailment, or how much satisfaction a person gets from interpersonal interactions in the course of day-to-day life. A therapeutic method (X) might affect symptoms experienced after the termination of therapy (Y) because the method influences how people interpret negative events that occur in life (M), and those interpretations then influence the extent to which symptoms are manifested. Or traumatic experiences (X) might negatively influence happiness one gets from interpersonal interactions (Y) because traumatic experiences result in the manifestation of certain behaviors that others find uncomfortable to witness (M), and this in turn produces less pleasant interactions. In both of these examples, X affects Y because X affects the *mediator variable* M, and this causal effect then transmits X's effect to Y through the effect of M on Y. Thus, a mediation model is a set of two or more causal events chained together in sequence of the form $X \rightarrow M \rightarrow Y$. So by definition, mediator variable M must be causally located between X and Y. It must be affected by X, and it in turn must affect Y.

Although mediation analysis has been around in various forms for at least 70 years or so, Baron and Kenny (1986) popularized an approach using easy-to-understand regression analysis principles. The overarching purpose of the analysis by their approach, sometimes called the *causal steps approach*, is to determine whether M can be deemed a mediator of the effect of X on Y. They described a series of analytical steps or *criteria* required to establish mediation. Whether these criteria are met is determined by estimating regression coefficients for X and M in three regression models, two with Y as the dependent variable and one with M as the dependent variable: