A Commentary on the Role of Randomized Controlled Trials in Massage Therapy

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KEY WORDS: research methods; efficacy; effectiveness

INTRODUCTION

The number of research studies investigating massage therapy (MT) has increased significantly in the past thirty years.[1] Despite this growth, the field of MT research is still emerging. Much of the research to date investigates the efficacy of MT. Efficacy is how well an intervention, such as massage therapy, performs in ideal situations.[2,3] Randomized control trials, or randomized clinical trials (RCTs), are considered the 'gold standard' for evaluating efficacy.[2,4]

Why is there a focus on efficacy and randomized controlled trials? Perhaps because MT researchers and stakeholders value the design of RCTs to produce results about causation. But, as Worrall[5] states, "…no one believes, do they?, that randomization inevitably guarantees similar groups and hence that a positive result in a properly randomized trial is *sufficient* for a treatment to be declared effective. Well actually I think lots of people in medicine *do* believe this, because this is what they think they are being told by the experts."[5] Many of the RCTs investigating MT, rather than 'proving' efficacy, have been met with criticism. One such criticism is the application of reductionist principles on a complex treatment.[1] The focus of this article is to discuss the limitations of RCTs as the focus of massage therapy research, and offer additional designs for consideration.

A Primer on Randomized Controlled Trials

RCTs are a type of 'true experimental' design.[6] They fall under the broad umbrella of quantitative methods and are usually informed by a reductionist or positivist mindset. Some of the fundamental values of a positivist paradigm are: the belief in one reality, the concept of objectivity, and a reliance on numbers as data.[7] This underlying philosophy supports some of the key features of RCTs: random allocation of participants to groups, strict inclusion and exclusion criteria, a control group against which the intervention is tested, blinding of evaluators and participants, and standardization of the study protocol.[4]

Randomization

Randomization is one of the easiest features of RCTs to achieve. During the random allocation of participants to the study groups, each participant must have an equal opportunity to be assigned to either the intervention group or the control group. Randomization can be accomplished through random number generation or similar process, which has been done in MT studies. The purpose of randomization is intended to ensure that all of the factors thought to affect the outcomes of interest, as well as unknown factors, are equally represented in both groups.[8] Worrall,[5] as stated above, suggests this is not sufficient to determine efficacy.

Strict inclusion and exclusion criteria

When researchers are recruiting members of the public to participate in a study, inclusion and exclusion criteria determine with what the participants must present, such as the diagnosis of a given medical condition (inclusion criteria), and with what they cannot present, such as a condition that would affect the outcome of interest (exclusion criteria). These criteria are set to limit the factors that could affect the internal validity of the study. Internal validity is the extent to which the researchers can be confident that the results they have found are directly caused by the intervention and not some other factor.[9] Strict inclusion and exclusion criteria can be, and has been, done in MT studies.

The criticism of strict inclusion/exclusion criteria in RCTs is that the results are limited in their 'real world' applicability. Sometimes, those who are excluded in these types of studies are exactly the patients who present in practice with complex health conditions. While strict inclusion/exclusion criteria are not 'required' in RCTs, they are often used for the reasons mentioned above.[4]

Lack of suitable control

The use of a control in a RCT is proposed to isolate the potential therapeutic effects of the intervention and other non-specific effects that may influence the

outcome of the study.[9] The value of control lies in the ability to blind the participant to which group they have been randomized, thereby reducing selection bias.[5] The control is typically a non-therapeutic version of the intervention, such that the participant cannot tell which they are receiving.

But, what is a suitable control for massage? RCTs often compare MT to standard care or other treatments such as rest, relaxation therapy or another type of bodywork.[10,11] With each of these, the participants can easily determine whether they are in a control/comparison group or are in the intervention group. Authors of one study have tried a sham massage control and believe they have successfully developed a light-touch control; however, it is unclear whether the control might have therapeutic benefits of its own.[10] Similarly, attention from an individual overseeing the comparison may have therapeutic benefits.[8]

Inability blind participants and therapists

Without a true placebo control, MT researchers are often unable to blind participants to the arm of the study to which they have been assigned. Blinding is when the participants do not know whether they are in the intervention group or the control group.[9] In addition to an inability to blind participants, MT researchers are also unable to blind therapists to which group they are administering the treatment or control. The only people involved in MT research that often can be blinded are assessors, or those who collect data from participants. While this is good, it does not relieve the concern of bias mitigated by blinding of the participant and therapist.

Issues with standardization of the study protocol

The study intervention is one aspect of an RCT that is usually standardized. This is done to ensure, to the extent possible, that the results of the study can be directly attributed to the study protocol used.[12] In massage therapy, different techniques have a variety of names and uses depending on the jurisdiction. To combat this, sometimes researchers use common techniques or create their own protocols that the practitioners are then trained to use for the study.[10] In one study, practitioners commented that, even though they were given a protocol to follow, the application of the standardized protocol felt different on each participant.[13] They also noted the challenge for practitioners to resist focusing on what they found during treatment, such as an area the participant noted as painful or as tension in the muscles. Aspects of massage therapy treatment that are challenging to standardize include depth of pressure and the rate and rhythm of application.

The extension for the CONSORT statement applied to trials of non-pharmacological treatments calls for researchers to report the experience and training of the provider of massage, as does the adaptation of CARE guidelines for MT case reports.[14,15] The inherent variability in the administration of the intervention described above threatens the internal validly of RCTs for which they are known.

Beyond questions of efficacy

As a result of the criticisms described above, RCTs have limited usefulness in a practice that strives to be evidence-informed. The very strategies that are used to enhance internal validity are the ones that reduce external validity or the ability to generalize the findings of a study to the realities of practice. That RCTs provide a useful research foundation cannot be disputed; however, to understand the complex treatment that is massage therapy, additional research methods are needed to explore important questions about the effectiveness of massage therapy in the real world.

Additional Research Methods to Investigate Massage Therapy

If the profession of massage therapy is interested in understanding the effectiveness of MT in real practice settings and with patients with complex health conditions, it is worthwhile for MT researchers and other stakeholders to consider other ways of exploring MT in addition to RCTs, including effectiveness studies, convergent parallel mixed methods, and case reports.

Effectiveness studies

Studies that seek to understand how an intervention performs in real world settings are effectiveness studies, or pragmatic trials.[2,3,7] The argument for effectiveness studies is that treatments that are not possible to implement in practice have little use.[2] Because effectiveness studies are as close to usual care with more heterogeneous patients,[3] there are many uncontrolled variables that introduce questions about internal validity. As mentioned previously, RCTs have limited external validity due to the strict inclusion/exclusion criteria used to recruit participants to the study and standardized treatments.[3] This is usually less of a concern in effectiveness studies, as all patients who would normally receive treatment are able to participate. Effectiveness studies use treatments that are pragmatic and approximate regular practice.[3] As a result, effectiveness studies must report the exact treatment provided, the setting in which it was provided, and the qualifications of who provided it.[2] This allows the reader to analyze whether the results of the study fit their practice and patients. In summary, effectiveness studies focus less on internal validity and more on external validity.[2]

Convergent parallel mixed methods

Mixed methods research (MMR), where qualitative and quantitative methods are combined in various ways depending on the research question, is becoming recognized for the potential to investigate

complex questions. One such design, convergent parallel mixed methods, is worthy of consideration in MT research.[16] In this design, a qualitative study is conducted alongside another quantitative study, such as a RCT. With this design, researchers can explore qualitatively the outcomes experienced by the participants or seen by the practitioners. This type of design combines the best parts of the RCT along with qualitative design, such as qualitative description,[17] to enhance the data collected and, subsequently, the results from such a study. This is just one example of how MMR might be beneficial to explore MT.

Clinical case report

A clinical case report is when a clinician researcher reports on the outcomes of treatment for one person.[18] This form of evidence is often criticized for the lack of internal and external validity and may be dismissed as anecdotal.[7] However, clinical case reports can be very useful in practice and in a body of research. First, information about harmful incidences or novel approaches to treatment can be described in a clinical case report.[7,19] In these instances, clinical case reports become a structured way in which to communicate anecdotal evidence that is important for practice. Second, while clinical case reports may not have high population generalizability, they do have high case generalizability. In other words, a clinical case may not speak to a course of treatment for a population of people with a given condition but, when the presentation of the individual in case is closely aligned to the presentation of another individual, the course of treatment may have similar outcomes to those seen in the clinical case report. Finally, novel approaches to treatment that demonstrate benefits in clinical case reports may stimulate other types of research studies, such as efficacy studies, convergent parallel mixed methods, or even a RCT.

CONCLUSION

No type of research method is without its limitations. Despite the prestige given by positivists to RCTs, they too are limited in the evidence they provide. Evidence hierarchies suggest that practitioners should accept the results of RCTs, or the systematic review of RCTs, as the highest forms of evidence.[20] Worrall[5] states that hierarchies of evidence overrate RCTs, and comments that those using evidence must appraise research as part of its consumption. This idea has also been discussed by Finch[21] in his presentation of the evidence funnel. Privileging one methodology over another does not recognize the benefits of the multiple approaches to the available research.[22] This may also mean that stakeholders will trust the results from one study over a body of work, which is important when considering the differing results of subsequent trials and the tendency for a popular study to be frequently quoted while other studies are overlooked.[23]

The answer is not to throw out the randomized controlled trial, but rather to ask questions that are of interest to the profession and its stakeholders. It is hypothesized that these questions would go beyond: "Does massage therapy have an effect on [an outcome] in patients with [a given condition and strict inclusion and exclusion criteria], when compared to [a control group that may also have therapeutic effects]?" Currently, MT researchers do not know what outcomes are of interest to patients or practitioners. Using a convergent parallel mixed methods study would be one way to capture that information within an already planned RCT.

Designs that maintain ecological validity, or the realities of practice, are criticized for their lack of internal validity and lack of ability to show causation. This is true. Designs such as effectiveness studies and case reports are limited in their internal validity. But, their relevance to practice cannot be overlooked. Researchers should consider whether there are methodologies, other than RCTs, that allow for rigorous investigation of massage therapy in a way that would be useful for stakeholders. Consider this: Wouldn't a body of literature, built from answering authentic questions from different perspectives with rigorous methods, be more useful than any number of systematic reviews of RCTs? The answer may depend on your worldview, but it is worth further discussion.

ACKNOWLEDGMENTS

The author would like to acknowledge the comments made by the anonymous reviewer and editor, which significantly improved the focus of this article.

CONFLICT OF INTEREST NOTIFICATION

The author declares there are no conflicts of interest.

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