

The How, Why, and for Whom Mindfulness-based Programs and Practices Produce Change in the General Population: A Scoping Review Protocol

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Abstract

Background: Despite growing evidence for the salutary effects of mindfulness-based programs (MBPs), there is limited understanding of the how, why, and for whom these programs work in the general population. To better understand these questions, one must implement design and data-analytic approaches that can elucidate potential mediators, mechanisms, and moderators. These variables explain the processes through which treatments, such as MBPs, produce change (mediators/mechanisms) and illuminate in which contexts these programs work best (moderators). The extant literature has investigated these variables predominately in pre-post analyses of MBPs. However, there are other ways to explore these processes or 'pathways of change.' One option is to implement dismantling trials and investigate the effects of core components of MBPs (e.g. mindfulness practice). Understanding how key elements operate in isolation will help specify 'active ingredients' and how the MBP framework works on the whole. The primary objective of the current scoping review will be to comprehensively evaluate studies that have explored pathways of change in MBPs and individual mindfulness practices to further our understanding of how to best adapt these programs and maximise benefits across the general population.

Methods: Five electronic databases (PubMed, PsycINFO, Embase, Scopus, and the Cochrane Central) will be systematically searched for eligible studies. Studies will be included if they investigate a MBP or practice in the general population (adults aged 18 and over). Eligible studies must evaluate a proposed mediator, mechanism, or moderator of a MBP or practice. The following information will be extracted for charting: (a) Name of author(s), (b) year of publication (c) sample characteristics (d) sampling method (e) reported mediators, mechanisms, and moderators, (f) design approach, (g) data-analytic approach, (h) adherence to methodological requirements, (i) description of MBP or practice, (j) treatment dosage, (k) delivery mode, (l) effect sizes and outcomes. A qualitative narrative summary of the results will be described in accordance with the information extracted for charting.

Discussion: The results from this review will help inform mindfulness teachers, researchers, and health-care professionals who intend to adapt MBPs or practices.

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Background

Mindfulness, defined as bringing moment-to-moment awareness of one's thoughts, emotions, and bodily sensations in a non-evaluative and accepting way, was introduced as a secular practice in mainstream settings in the late 1970's when Jon Kabat-Zinn developed the mindfulness-based stress reduction (MBSR) program to help relieve chronic pain symptoms (1, 2). Mindfulness-based cognitive therapy (MBCT), an adaptation which includes elements of cognitive therapy, was created in the early 2000's as a treatment for depression (3). MBSR/MBCT are mindfulness programs traditionally formatted as eight-week courses with weekly group sessions guided by a trained mindfulness instructor (1, 3). Some of the

strongest evidence for these mindfulness-based programs (MBPs) is in the context of recurrent depression (4, 5) and chronic pain (6), but there is also scope for investigating several adaptations of these programs in wider populations.

A population-based strategy can be adopted to investigate the effects of MBPs in the general population. According to this approach, most conditions fall on a continuum in that there are few 'highs' and 'lows' and many values that fall somewhere in between (7). In the context of mental well-being, you may find that a smaller proportion of the population experiences a 'high' well-being state and a 'low' well-being state and that a larger proportion experiences a range of different states between the two ends of this distribution (see Figure 1). Melzer et al. (2002) (8) examined this approach in the context of common mental health conditions and found that symptoms were widely distributed and followed a continuous model. To date, the majority of mindfulness research seems to pertain to the effects of MBPs on these 'lows' or 'highs' which dismisses the proportion of the population that may be at a moderately elevated risk. It is important that future research examines the effects of MBPs across the entire population distribution of mental well-being to understand the extent to which these programs can produce entire population shifts in therapeutic outcomes. This work will also pave the way to better understand how community wide factors (e.g. mindfulness experience, history of anxiety or depression) within the general population may impact the direction and magnitude of these potential population shifts.

Research that has investigated the effects of MBPs across the entire general population is currently underexplored. In a previous meta-analysis conducted by Khoury and colleagues (2015) (9), the overall effects of included studies (n = 29) demonstrated large improvements on stress and moderate improvements on anxiety, depression, and quality of life in pre-post analyses of MBSR in the context of 'healthy individuals,' yet only four studies specifically indicated general population samples. Other reviews (10-12) have included non-clinical samples but it is unclear how they operationalize this definition in regards to symptom count within the general population. Without clear definitions of participant samples, it is difficult to know where on the population distribution curve of specific outcomes (e.g. well-being, stress, anxiety, depression, etc.) MBPs demonstrate effects. Moreover, without this information, we cannot fully understand the *how*, *why*, and *for whom* these programs work best. The authors of this review have defined the "*why*" as the mediators and mechanisms through which change is produced and the "*how*" (e.g. sustained mindfulness practice) as the explanatory medium through which these mechanisms are targeted. The "*for whom*" is understood as the moderators (e.g. individual characteristics) that impact both how and why the treatment works.

Figure 1 illustrates a conceptual example of a population distribution of mental well-being pre-post a MBP in the general population. This figure is inspired by Geoffrey Rose's population-based strategy (7) and the findings of Melzer et al. (2002) (8). The authors of this review define the general population as the full distribution curve rather than the largest proportion of the population (e.g. the blue shaded region). The general population may include a smaller proportion of 'lows' and 'highs' in terms of individuals that have a low mental well-being and high mental well-being. The largest proportion of the general population may include individuals with state values that range between these highs and lows. It

should be noted that this figure is not based on actual data and is only used to help describe a more nuanced framework of this approach, which recognises that mental well-being may fall on a continuum and that, through increased mindfulness training, individuals may experience increased well-being.

To uncover *how* and *why* specific treatments such as MBPs have an effect on a particular outcome, Kazdin (13) argues that one must elucidate the mechanisms of change. These variables explain how a treatment (T) impacts change in a specific outcome (O) by illuminating the 'interim processes' between the treatment and the outcome (TàO). The ultimate goal with uncovering a mechanism of change is therefore to understand this relationship (TàMechanismsàO) from 'beginning to end' (13). There are methodological requirements put forth that help elaborate a mechanism of change. These requirements involve establishing the mediator (M), which demonstrates the relationship (TàO) statistically and is therefore an intermediate step in establishing a causal relation and mechanism of change [see Figure 2a for simple mediation]. Once all or most of the requirements are met and the relationship has been demonstrated by a series of studies, then one can argue for a mechanism of change (13) [see Kazdin (2007) for full criteria]. It is important to note that the distinguishing factors between a mediator and mechanism are discrete in that both attempt to uncover the same processes yet a mediator is established at an earlier stage of research whereas a mechanism is uncovered after extensive replication studies. Mediators can be understood as unrefined mechanisms that require further investigation to determine whether the methodological requirements are met and the finding has been supported in numerous studies.

In addition to understanding how MBPs effect change, it is also important to ask *for whom* they are more and less effective. Moderators are variables that effect the presence or absence, as well as the 'direction or strength,' of the relationship between the treatment (T) and outcome (O) [TàO] (13) [See Figure 2b for simple moderation]. In the context of mindfulness research, these variables are of interest to not only help refine the mediators and mechanisms that explain *how* and *why* MBPs work but also to help uncover *for whom* these programs work best. By elucidating these characteristics along with mediators and mechanisms, MBPs can be thoughtfully adapted and applied to specific populations and contexts (14, 15). It is important to note that there are different methods that can be used to evaluate these mentioned pathways of change and each method has their own strengths and limitations.

The existing literature on the *how* and *why* MBPs work in the general population is sparse and typically does not meet all the methodological requisites set out above by Kazdin (2007) (13). Gu et al. (2015) (16) identified twenty papers, in a systematic review and meta-analysis, that examined mediators of MBCT and MBSR on mental health and wellbeing outcomes in clinical samples (e.g. adults with symptoms of depression) and non-clinical samples (e.g. students and individuals with limited or no previous mindfulness training). The main results indicated strong evidence for cognitive and emotional reactivity, moderate evidence for mindfulness and repetitive negative thinking, and weak evidence for self-compassion and psychological flexibility as potential mechanisms through which MBPs produce change (16). However, it is unclear how representative these clinical and non-clinical samples are of the general population and most of the included studies have methodological shortcomings when it comes to

establishing a mechanism of change according to Kazdin's requirements (13, 16). For example, most studies did not report on temporal ordering to establish that change in the proposed mediator occurred before change in the outcome variable of interest (16). Research on the *for whom* MBPs work best in the general population is also limited. A comprehensive meta-analysis found that therapist training in mindfulness, rather than clinical training, moderated clinical outcomes (10). However, there were few studies that reported on this variable and it is still unclear how each sample (clinical versus non-clinical) is defined in the context of the general population.

This lack of evidence on the *how, why, and for whom* MBPs work in the general population seems to be attributed to a failed agreement on how to best define and operationalize population samples. One aim of this review is to help reach some consensus on these definitions and operationalizations and to further explore the extent to which relevant studies have met the requirements put forth by Kazdin (2007) (13) in establishing moderators, mediators and mechanisms of change.

In addition to exploring these variables in MBPs, there is also an opportunity to explore the *how, why, and for whom* in mindfulness-based practices. Kazdin (2007) (13) argues that one way to identify possible mediators and mechanisms of change is by conducting dismantling trials that isolate individual components of a treatment to explore how they bring about change in isolation rather than in combination of each other. Applying this idea to secularized mindfulness programs, one way to dismantle a MBP (e.g. MBCT) is to isolate individual meditation practices (e.g. body scan, mindful movement, etc.) within the program and to explore pathways of change (mediators, mechanisms, and moderators). Mindfulness practices are regarded as a core component of MBPs (3, 15) and conceptual frameworks (17) along with early research (18-20) suggests that these individual meditation practices can effect change on outcomes without being nested within a formal MBP. However, future research needs to address the change processes to better understand the particular aims and skills of individual mindfulness meditation practices.

Past research (18, 19) seems to highlight practices that are derived from the general framework of mindfulness-based programs, but the Crane et al. (2017) (15) definition is not implemented which makes it difficult to pin-point whether or not these practices originate from MBSR/MBCT and their adaptations. Sauer-Zavala et al. (2012) (20) compared three different meditation practices (sitting meditation, mindful yoga, and body scan) and found greater improvements in psychological well-being in mindful yoga compared to the other practices, and more change in emotion regulation difficulties in the mindful yoga condition compared to the body scan condition. Graduate students who led the practices followed scripts from MBSR/MBCT curricula. This helps clarify the effects of these practices within these frameworks, but it is important to note that practice adherence was not measured. Without this measurement, it is difficult to fully understand how change is produced (20).

Research on the mediators and mechanisms through which mindfulness-based practices produce change is in its early stages. Kok and Singer (2017) (21) suggest that each meditation practice has a 'phenomenological fingerprint' or rather a unique subjective experience. For instance, it was observed that

the body scan meditation brought about greater changes in interoceptive awareness (the ability to use the body as a barometer for one's thoughts and emotions) compared to a breathing, loving-kindness, and observing-thought meditation. Britton and colleagues (2018) (22) tested two 'active ingredients' of MBCT by dismantling this program and creating two structurally equivalent curricula that either implemented focused attention (FA) elements or open-monitoring (OM) elements and compared these curricula to a formal MBCT intervention in individuals with mild to severe affective disturbances. One interesting result indicated that individuals that took part in the OM program demonstrated greater improvements in nonreactivity whereas participants in the FA program experienced more change in attentional control. However, given that there was no 'business as usual' control, it is difficult to understand whether changes in outcome were as a result of practice-specific effects or non-specific effects (22). Overall, future research needs to further explore potential mediators and mechanisms (e.g. interoceptive awareness, nonreactivity, and attentional control) of mindfulness-based practices within the general population.

Several moderators of brief mindfulness interventions (ranging between one single session to two week sessions) were examined by Schumer, Creswell, and Lindsay (2017) (19). Type of mindfulness training exercise (focused breathing, multiple exercises, body scan, or other) was explored as a potential moderator and the results suggest that the 'other' practice type accounted for more change in negative affectivity outcomes ($g = .30, p < .001, n = 27$) compared to the other practice types. This implies that the characteristics of these 'other' practices may predict greater improvements in outcome. However, without a clear description of these 'other' practices, it is difficult to understand which qualities or skills of these practices may account for such change (19). Moderation analyses conducted by Blanck et al. (2018) (18), suggest that total amount of practice and delivery mode (face to face versus online) may have an effect on outcome yet the results were non-significant. Taken together, there is evidence that demonstrates positive effects of these different mindfulness practices on a range of outcomes (18-21) but the evidence-base on the *how, why, and for whom* these practices work best is still in its infancy and requires clear delineation of both the mindfulness practices and conceptual framework, with clear definitions of key constructs (population, moderator, mediator, mechanism, treatment, and outcome). So far, and to the knowledge of the authors, there is no review that has comprehensively examined these pathways of change in practices derived from MBSR/MBCT and their adaptations. In light of the limited evidence on the change processes of both MBPs and the practices derived from these programs across the general population, the rationale for this review is to provide a summary of the current evidence to inform future research studies and stakeholders in the field who would be interested in adapting these programs and practices in contexts for the general population.

Objectives

The primary aim of the current scoping review is to examine the *how, why* and *for whom* MBPs and practices operate in the general population. Due to the novelty and breadth of this research topic, the authors decided to follow the stages and methodology of a scoping review.

The objective of this scoping review is to explore the following questions: (a) Through which mediators, mechanisms, and moderators do MBPs and practices produce change in the general population of adults? (b) Which design approaches (e.g. RCT, quasi-experimental, dismantling trials, etc.) are used to evaluate mediation, moderation, or a mechanism of change? (c) Which data analytic approaches (e.g. multiple regression, path analysis, etc.) are used to evaluate mediation, moderation, or a mechanism of change? (d) To what extent have the identified papers met the formal recommendations laid out by Kazdin (2007) (13) in establishing pathways of change? The key elements of these research questions include the general population (population), mediators, mechanisms, and moderators (concept), and MBPs and practices (context). Several established and accepted frameworks (23-25) will be used to drive the methodology and stages of the scoping review. This review protocol adheres to the PRISMA-P checklist along with the PRISMA extension for Scoping Reviews (PRISMA-ScR) checklist (26, 27). See Additional File 1 and 2 for completed check-lists.

Methods

Eligibility criteria

Participants

Studies will be included if they evaluate a MBP or practice in the general population. The general population has been defined (See Figure 1) as the full population distribution, which includes the 'highs,' 'lows,' and the full range of values in between. Thus, studies will not be excluded if they include clinical samples, as this would be representative of the 'high' symptom-counts that fall on the population distribution curve. Participants must be adults (aged 18 or above).

Context

Eligible studies must include MBPs, defined by Crane and colleagues (2017) (15) as predominately MBSR and MBCT and any adaptation of these programs, or mindfulness-based practices that derive from these programs. The rationale for focusing on these programs and practices is because this is where the evidence-base is strongest. Mindfulness-informed programs (e.g. Acceptance and Commitment Therapy, Dialectical Behavior Therapy, and Mindful Self Compassion) will be excluded because sustained mindfulness training is not a core component of these therapies and inclusion of these studies would therefore contradict our aim to identify studies that have evaluated mindfulness-based practices. Second-generation mindfulness programs will also be excluded because the evidence-base is still underdeveloped and the range of programs is more heterogeneous (15).

As discussed, eligible studies will include mindfulness practices derived from MBPs. Due to heterogeneity of terms used for mindfulness practices, a content analysis was conducted to determine the extent that different terms in the literature related to the same or different practices. Two reviewers developed this analysis and were in agreement. According to four key curricula for MBCT and MBSR (1, 3, 28, 29), formal practices are key ingredients of the MBP approach as they allow for deeper engagement whereas

informal practices are used to cultivate mindfulness specifically during daily activities. For the scope of this review, eligible studies will examine formal practices because the evidence-base is stronger and they have clearer operational definitions and parameters compared to informal practices. Future studies will need to investigate informal practices in addition to other practice-related components of MBPs (e.g. silent retreats, orientation sessions, home-based versus in-class practices).

The existing literature on a definition or set criteria for formal practices is sparse and inconclusive. Crane and colleagues (2014) (30) operationalize formal practices as approximately 40 minutes in duration and as a practice that is engaged with at least three times each week on average (which was also used by Perich et al. 2013 (31)). Moreover, Hawley et al. (2013) (32) argue that guidance is provided for formal practices and that these practices are engaged with for a specific amount of time whereas there is less structure and no required length or time for informal practices. One thing to keep in mind is that these studies formulated these operational definitions in the context of recurrent depression. Therefore, there might be scope for a more flexible operational definition.

The content analysis adopted to clarify the eligibility criteria for formal practices rests on the assumption that practices used across all four key MBP curricula (1, 3, 28, 29) are core to the MBP approach and regarded as formal meditation practices. This process began by hand-searching these texts to compile a list of all the practices implemented across these MBCT and MBSR curricula. In addition to having two reviewers, experienced mindfulness instructors were also consulted to help match these practices across each curriculum based on the intentionality or theme behind the practice. From there, a list of key characteristics, shared between all these practices, was gathered. The determined key elements (listed below) were then used to clarify the eligibility criteria for studies that evaluate mindfulness practices. It is important to note that this content analysis was used to specify eligibility criteria for formal mindfulness-based practices and should be replicated in future studies to validate its usage.

In summary, a formal mindfulness-based practice must be:

- Home-based, in that the practice is predominately engaged with at home in the context of the original MBP
- Scheduled with CD or audio guidance in the context of the original MBP (supported by Hawley et al., 2013 (32))
- Practiced at least three times per week, during the appropriate weekly session, in the context of the original MBP (supported by Crane et al., 2014 and Perich et al., 2013 (30, 31))

Concept

Studies will be included if they evaluate mediators, mechanisms, or moderators of a MBP or practice. The extent to which these eligible studies adhere to the requirements laid out by Kazdin (2007) (13) in establishing pathways of change will be reported.

In an effort to fully understand the extent, range, and nature of this research activity, all studies that have evaluated a MBP or practice will be included in the review regardless of design or analytic approach, treatment dosage, delivery mode, or reported outcomes. English and Spanish publications will be included and a specific year range (1979 and onwards) will be considered. The rationale for starting with the publication year of 1979 is because this year coincides with the introduction of mindfulness into mainstream settings when MBSR was developed.

Search strategy

Five electronic databases (PubMed, PsycINFO, Embase, Scopus, and Cochrane Central) will be systematically searched for eligible studies. These databases were chosen based on their relevance to the social and medical sciences. Other sources (e.g. Web of Science conference proceedings, PsycEXTRA, or connectedpapers.com) will also be systematically searched to identify grey literature.

The primary research question ('Through which mediators, mechanisms, and moderators do MBPs and practices produce change in the general population of adults?') was broken down by population, context, and concept terms and then a list of synonyms and related terms were developed. For the search, the population terms were left open to ensure that more specific samples within the general population (e.g. nonclinical and clinical) were not excluded. Key search terms from the primary research question include: 'mediators,' 'mechanisms,' 'moderators,' and 'mindfulness.' A list of synonyms and related terms were developed by first running mock search in one electronic database (PubMed) and searching keywords in relevant papers. Experts in the field, including a research librarian, were also consulted to help refine the search terms. Moreover, the content analysis used to clarify the criteria for mindfulness-based practices (see above) was also used to specify the search terms. Specific practice terms were included as direct phrases to reduce noise and to narrow focus on practice terms specifically used in the four key MBP curricula used for guidance. Please see additional file to review an example search using PubMed (Additional File 3).

The snowballing method and PEARL citation method will be used for eligible studies to help identify other included studies. Reference lists of relevant systematic reviews and meta-analyses will also be searched by hand to locate other possible eligible studies. Corresponding authors of eligible studies will be contacted to retrieve further information, if needed. A PRISMA flow diagram (33) will be used to track sources identified through databases and other sources, number of duplicates removed, number of papers screened for eligibility, and ultimately the number of papers included for narrative synthesis. Any amendments made will be documented and provided with a rationale within the final publication. The aim is to run the search strategy in all included databases and begin screening by September 2020. The anticipated end date is October 2020.

Data extraction

EndNote software will be used to manage studies throughout the review process. Two reviewers will be responsible for screening titles and abstracts for eligibility. Any uncertainties will be discussed with a

third reviewer. Two reviewers will also read the full-texts independently to determine final inclusion. In regards to data charting, the aim is to extract the following information from each included study: (a) Name of author(s), (b) year of publication, (c) sample characteristics, (d) sampling method, (e) reported mediators, mechanisms, and moderators, (f) design approach, (g) data-analytic approach, (h) adherence to Kazdin (2007) (13) requirements, (i) description of MBP or practice, (j) treatment dosage, (k) delivery mode, (l) effect sizes and outcomes. This process will be piloted using a mock data extraction form (Additional File 4). One reviewer will be in charge of charting the data from the included sources. A second reviewer will confirm the data collected from these sources and where there is any dispute a third reviewer will help make the final decision.

Strategy for data synthesis

A qualitative narrative summary of the results will be described according to the information extracted for charting. Depending on the amount of data, the idea is to develop a conceptual framework on the *how*, *why*, and *for whom* MBPs and practices produce change in the general population. If appropriate, a schematic diagram or visual depiction will be provided to summarize the findings of the review. No specific outcomes will be prioritized.

Dissemination

The results of this scoping review will be submitted for publication in a peer-reviewed journal.

Discussion

The overarching aim of this scoping review is to examine the *how*, *why* (mediators and mechanisms) and *for whom* (moderators) MBPs and mindfulness-based practices work in the general population. To the knowledge of the authors, this scoping review will be the first to extensively examine the change processes and effects of MBPs and practices across the entire general population distribution. The hope is that the results from this review will help inform mindfulness instructors, researchers, and health-care professionals who intend to adapt MBPs or practices in a unique setting or sample within the general population.

Abbreviations

MBSR: Mindfulness-based stress reduction

MBCT: Mindfulness-based cognitive therapy

MBP(s): Mindfulness-based program(s)

RCT: Randomized-controlled trial

PRISMA-P: Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocols PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-analysis extension for Scoping Reviews

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analysis

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

All data generated or analysed during this study [along with additional files] will be included in the published article.

Competing interests

The authors declare that they have no competing interests.

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Author's contributions

SM, JMM, and WK have each made substantial contributions to the conception and design of this work. SM wrote the first draft and JMM and WK contributed to the subsequent revisions. All authors read and approved the manuscript.

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Figures

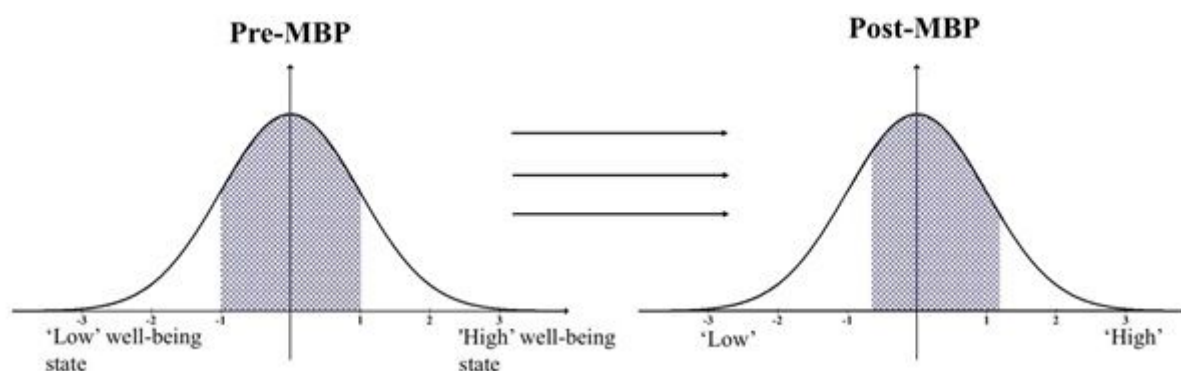


Figure 1

Population distribution of mental well-being pre-post a MBP

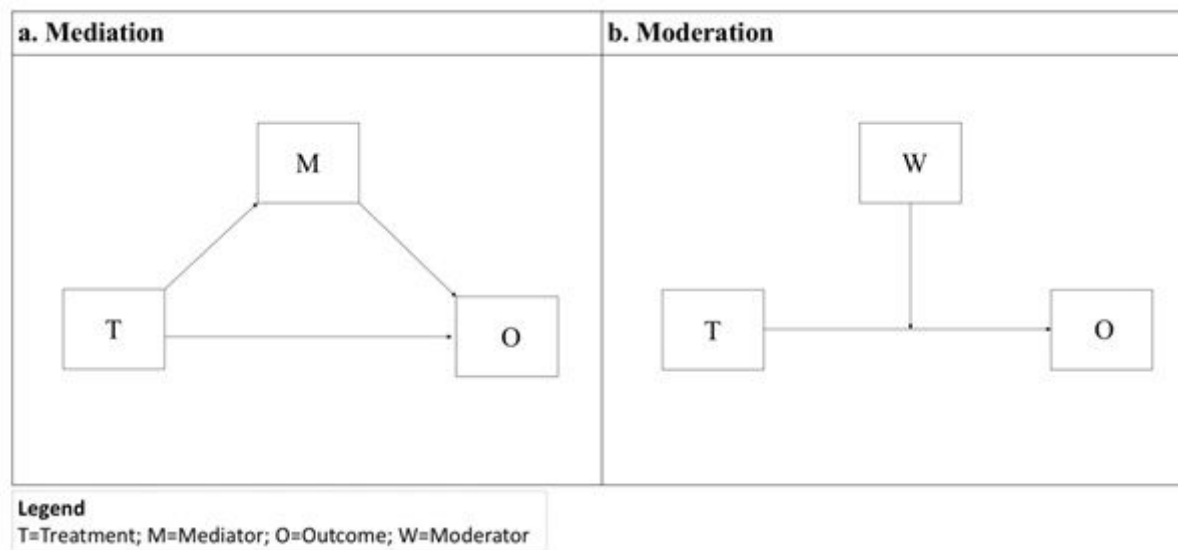


Figure 2

Conceptual models of mediation and moderation

Supplementary Files

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