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COMMENTARY/POSITION PAPER

Translational behavioral medicine for population and individual health: gaps, opportunities, and vision for practice-based translational behavior change research

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Abstract

In this commentary, we propose a vision for "practice-based translational behavior change research," which we define as clinical and public health practice-embedded research on the implementation, optimization, and fundamental mechanisms of behavioral interventions. This vision intends to be inclusive of important research elements for behavioral intervention development, testing, and implementation. We discuss important research gaps and conceptual and methodological advances in three key areas along the discovery (development) to delivery (implementation) continuum of evidence-based interventions to improve behavior and health that could help achieve our vision of practice-based translational behavior change research. We expect our proposed vision to be refined and evolve over time. Through highlighting critical gaps that can be addressed by integrating modern theoretical and methodological approaches across disciplines in behavioral medicine, we hope to inspire the development and funding of innovative research on more potent and implementable behavior change interventions for optimal population and individual health.

Keywords

Precision lifestyle medicine, Practice-based translational behavior change research, Science of behavior change

Implications

Practice: Behavioral medicine has the potential to be a bedrock in clinical and public health practice; numerous barriers, however, such as an insufficient understanding of the fundamental mechanisms of behavior change on the one end and a typically one-size-fits-all implementation approach that ignores variation in contexts and settings on the other, diminish the actual impact of behavior change interventions.

Policy: We hope to inspire the theoretical development, funding, and testing of innovative research on more potent and implementable behavior change interventions for optimal population and individual health.

Research: We propose an initial vision for "practice-based translational behavior change research," defined as multi-level clinical and public health practice-embedded research on the implementation, optimization, and fundamental mechanisms of behavioral interventions.

Behavioral medicine should be a bedrock in clinical and public health practice because unhealthy lifestyle behaviors such as smoking, poor diet, physical inactivity, and lack of sleep are rampant, and they contribute to major chronic conditions and the growing multimorbidity epidemic [1, 2]. Lifestyle-related chronic diseases—mainly cardiovascular disease, cancer, respiratory diseases, and type 2 diabetes—are now the leading cause of morbidity and mortality globally [3, 4]. There are significant health and economic consequences for individuals and society. Arguably, translational behavioral medicine spanning theories of behavior change, clinical and translational behavioral research, and real-world implementation of proven behavioral interventions is an ideal discipline in which to incubate a vision for both population health and precision medicine through behavior change, or what we call "practice-based translational behavior change research."

Population health is defined as "the health outcomes of a group of individuals, including the distribution of such outcomes within the group [5]." Broadly speaking, population health aims to improve the overall health of a discrete human population and to reduce disparities across its subpopulations. Precision medicine is "an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person," as defined by the National Institutes of Health (NIH) [6]. The precision medicine movement envisages that medical treatments and health interventions will become precise, proactive, and personalized—and consequently more effective by tailoring them to (largely stable/fixed) aspects of the individual. The ultimate vision, however, goes somewhat beyond this to offer individually tailored, ecologically valid treatment

on a population level that adapts to changing conditions and contexts over time. This intersection is where precision medicine meets population health. The concept holds the potential to reshape how we can promote health and treat disease, and can be readily extended to lifestyle and behavioral interventions.

The translational promise of basic behavioral research in clinical medicine and implementation science is increasingly recognized with more targeted funding support by federal sponsors. This signals a change in research priorities from not only supporting basic behavioral research to one in which research investments demonstrate benefit to population health. To truly impact population health within a precision paradigm, new concepts, methods, and partnerships need to occur if behavioral medicine is to realize its full potential. New ways of considering how we go about the research endeavor are needed because the disciplines of basic, clinical, and implementation science in behavioral medicine, and their funding streams, appear to remain minimally overlapping; working within—rather than across—boundaries and, thus, not yet optimally harnessing the transdisciplinary potential. Numerous barriers, such as an insufficient understanding of the fundamental mechanisms of behavior change on the one end and a one-size-fits-all implementation approach that ignores variation in contexts and settings on the other, stymie innovation in the discovery-to-delivery pipeline of behavioral medicine research. The actual impact of behavior change research on clinical and public health practice has, as a result, been limited.

Herein, we propose a vision for "practice-based translational behavior change research," defined as clinical and public health practice-embedded research on the implementation, optimization, and fundamental mechanisms of behavioral interventions. This vision intends to be inclusive of important research elements for behavioral intervention development, testing, and implementation. In what follows, we discuss important research gaps and conceptual and methodological advances in three key areas along the discovery (development) to delivery (implementation) continuum of evidence-based interventions to improve behavior and health that could help achieve our vision of practice-based translational behavior change research. We expect our proposed vision to be refined and evolve over time. Through highlighting critical gaps that can be addressed by integrating modern theoretical and methodological approaches across disciplines in behavioral medicine, we hope to inspire the development and funding of innovative research on more potent and implementable behavior change interventions for optimal population and individual health.

THE TREATMENT "BLACK BOX" CHALLENGE AND POTENTIAL SOLUTIONS FOR UNDERSTANDING MECHANISMS OF BEHAVIOR CHANGE

Health behavior change research has long endured a disconnect between basic and applied science, lagging behind in basic science discoveries of the change mechanisms in behavioral interventions and leaving a "black box" phenomenon. Research funders typically do not provide mechanisms to support integrated, coordinated "basic" behavioral science research in intervention studies that could potentially address this gap. Yet, there is an increasing recognition of the need for systematic application of theory to the development and evaluation of behavioral interventions [7]. A major challenge for behavioral intervention developers and researchers is that theories of behavior change are numerous and often have overlapping constructs and underspecified definitions of constructs and their interrelationships [8].

Behavior change interventions are typically multicomponent and encompass various behavior change techniques, which are the active components or building blocks of an intervention designed to change behavior [9]. Developing truly "theory-based" interventions requires an understanding of links between behavior change techniques and theoretical mechanisms of action. Understanding such links will allow the components of a behavioral intervention to be dismantled, constructed, or parameterized differently, whether for enhanced potency in population-targeted interventions, personalized tailoring, or for improved implementability in practice settings. However, the current understanding of the mechanisms of action underlying common behavioral change techniques is lacking, although innovative research on this issue is emerging [10].

It is important to distinguish mechanisms of the effects of behavior change on health and well-being from the mechanisms of (producing) behavior change. The former is the conventional notion of treatment mechanisms in biomedical and biobehavioral research. As an example, to understand the mechanisms of a dietary intervention in heart health, a study could measure the effects of dietary changes on traditional cardiovascular risk factors and biomarkers of oxidative stress and inflammation. The latter is the foundation for the science of behavior change, which has emerged as a new discipline that aims to advance knowledge about the mechanisms of action through which behavior change occurs. In the prior example, it might be studying the active components that are the foundation of the intervention and promote dietary change. Major funding agencies now recognize the imperative of understanding mechanisms of behavior change (particularly those common to multiple behaviors and health problems). Notably, the NIH's Science of Behavior Change (SOBC) common fund

program supports studies focused on mechanism-focused, experimental medicine approach to behavior change research in order to advance basic science on the initiation, personalization, and maintenance of behavior change. The promise of this work is that understanding mechanisms will make interventions more precise and, therefore, more effective.

Several conceptual and methodological advances in the science of behavior change show great promise to transform behavioral intervention development and testing. The Obesity-Related Behavioral Intervention Trials (ORBIT) model [11] and the NIH Stage Model [12] are two exemplary conceptual models jointly developed by NIH researchers and independent investigators. Both models: (i) emphasize the importance of translational behavioral research along a continuum, from basic science through clinical science to implementation science; (ii) provide a structured but flexible and iterative progressive process of intervention development; and (iii) specify stages or phases of the process without conceiving of them as prescriptive or linear. The models also differ in important ways. They offer different but complementary conceptualizations of research on how to translate fundamental behavioral science discoveries into efficacious and implementable interventions for preventing and treating behaviorally based health problems. Importantly, the ORBIT model adopts terminology from the drug development model and focuses exclusively on the early, pre-efficacy phases of behavioral treatment development. The NIH Stage Model is a recursive, multidirectional, multistage model featuring two pillars: the principal that the behavioral intervention development process is incomplete until an intervention is optimally potent and implementable and the emphasis on examination of the change mechanisms in every stage of the process.

Behavioral intervention developers and researchers must still address the practical challenge of deciding which theory or theories to draw on and what theoretical mechanisms of action to target in the face of an abundance of behavior change theories [8]. This is increasingly being addressed by consolidated frameworks that provide guidance and systematize theory-based intervention development [9, 10, 13]. The Theoretical Domains Framework is one example of a consolidated model. It specifies 14 theoretical domains that may be relevant to understanding and changing behavior [14, 15]. Additionally, a 93-item taxonomy (BCTTv1) provides an integrated and hierarchical classification system for reliably specifying intervention components in terms of behavioral change techniques and mechanisms of action, organized into 16 groupings [9]. This approach can support and systemize efforts (e.g., the NIH SOBC program) that focus on theoretical mechanisms that need to be both measurable using reliable and valid assays, tests, or measures, and malleable through experiment or intervention. We contend that the potential of SOBC research would be substantially greater if it were integrated with clinical and implementation sciences in behavioral medicine.

THE CHALLENGE OF TREATMENT PERSONALIZATION AND POTENTIAL SOLUTIONS FOR ADVANCING PRECISION MEDICINE IN LIFESTYLE INTERVENTIONS

A pronounced limitation in effectiveness often exists because the average effects of empirically supported behavioral interventions are often modest and derived from a (perhaps sizable) fraction of the target population. Indeed, perceptions of ineffectiveness among providers, patients, and other decision-makers are a common barrier to adoption of behavioral interventions. Also, most clinicians are accustomed to titrating, augmenting, and switching medications if a patient does not respond to first-line treatments as expected. Research on how brief behavioral interventions should be sequenced, integrated, altered, or coordinated, that is, personalized, is still lacking. Without treatment algorithms for the titration and augmentation of behavioral interventions, their effectiveness and implementation potential is diminished.

The content of behavioral interventions typically includes multiple components in one "package," with limited empirical evidence for how the package may be deconstructed or assembled differently while retaining or possibly improving effectiveness. At the same time, intervention delivery often uses a single or a limited number of formats (e.g., group or individual and in-person, by phone, or electronically), with little flexibility for personalization of how and when the individual receives the intervention. The dynamic nature of personal factors (e.g., sociodemographic characteristics, physical and mental health status, and preferences) and contextual factors (e.g., social relationships and physical environments at home, school, and work) and the complex interplay of these factors with one another contemporaneously and over time create complexity and yet ample potential for precision lifestyle medicine, a concept we recently proposed [16]. Importantly, the intervention personalization (or precisioning) process can occur both at the level of persons (e.g., to relatively stable genotype, and behavioral or psychological phenotypes) and within persons over time (e.g., accounting for dynamic fluctuations in disease status, psychological and behavioral factors, and social contexts).

The treatment personalization challenge could be addressed in several ways and at several levels. Personalization processes based on relatively stable attributes and associated challenges have been fairly well described already [17, 18]. We focus on approaches that can adapt treatment to different contexts (e.g., based on attributes of a clinical care setting, patient mix) and adapt treatment within persons over time (e.g., to lack of treatment response,

other dynamic changes). There are, of course, multiple approaches to addressing these challenges and we do not presume to suggest that any one (or more) is preferable. In fact, we suspect that the greatest progress will be made when efforts are cumulated across diverse methods. We also note that this journal has devoted attention to this issue, hosting a special section more generally addressing ways to optimize behavioral interventions (see *Trans Behav Med.* 2014; 4[4]).

Several of the numerous potential methods to advancing precision lifestyle medicine in the context of implementation deserve attention. For example, there is growing use of sophisticated qualitative and quantitative approaches to determining potential moderators of treatment acceptability and feasibility. One longstanding approach is the use of variants of N of 1 designs (e.g., where an individual patient is randomly assigned to one of the possible treatments and repeatedly crossed over between two or more treatment alternatives) and related approaches to tailoring of intervention content to the individual. Although of great use clinically, this technique is highly person-centered and consequently often has little generalizability to other patients, contexts, diseases, etc., making it somewhat less useful for implementation [19]. An alternative is the single-case study, particularly as a method to enable rapid prototyping of interventions by repeatedly iterating refined treatment packages.

Multiphase Optimatization Strategy (MOST) designs are powerful tools to dismantle multicomponent intervention packages; that is, they can help discern what are the active components, optimal doses, etc. [20]. In particular, this can also help develop a portfolio of effective treatment elements, and even be validated as a function of contextual factors (e.g., attributes of clinical settings, patient mix). Additionally, a sophisticated approach that is more readily assimilable to clinical and implementation contexts is the Sequential Multiple Assignment Randomized Trial (SMART) design [21, 22]. This design provides a stepped approach to intervention delivery that allows careful testing of optimal intervention content sequencing, dose, and content changes, including stop rules and conditions for delivery of multiple treatment components. Further, a series of approaches have recently been developed—and are starting to be carefully tested—that attempt to leverage the capacity to personalize intervention delivery to dynamic aspects of patient experience [23]. For instance, just-in-time interventions attempt to match the delivery of intervention content to moments of need, such as smoking cessation tips when craving is high or relaxation techniques when stress is high. Emerging work is demonstrating that these approaches are feasible, and appear to be more effective than providing similar intervention content in nontemporally personalized ways [23]. Finally, an extension of this approach is just-in-time adaptive intervention [24], which shares the features just described but also includes dynamical features that allow the system to "learn" over time, adapting treatment (e.g., intervention content, delivery rules) over time as patient status changes. Integration of basic research on behavior change mechanisms with these innovative behavioral intervention designs would promote the development of behavioral treatment titration and personalized optimization strategies that has been largely absent in the behavioral medicine literature to date.

THE IMPLEMENTATION CHALLENGE AND POTENTIAL SOLUTIONS FOR UNDERSTANDING CONTEXTS AND SETTINGS

Even when behavior change mechanisms and treatment personalization are better understood, translating these approaches to practice-based settings remains a challenge. We have robust evidence-based behavioral interventions for a variety of health conditions, such as the Diabetes Prevention Program, the Dietary Approaches to Stop Hypertension, and the 5As for smoking cessation, to name a few. Broad adoption with careful attention to population-specific and organizationally appropriate implementation strategies could fundamentally shift risk distributions to meaningfully improve overall health and reduce disparities. Yet, the population health impact of these and other proven behavioral interventions has been limited.

The lack of effective intervention implementation commonly reflects a poor understanding of the implementation barriers faced in real-world settings and contexts or priorities between behavioral medicine researchers and practitioners. Most proven behavioral interventions are designed for and aimed at target individuals, whose behavior needs to change and/or behavior change agents or intermediaries, such as health professionals, support partners, and informal caregivers. However, implementation is a complex endeavor. For implementation to be effective, a plethora of contextual and setting factors need to be considered that encompass multiple levels of influence—including the individual, interpersonal, organizational, community, and macro-policy levels—as well as both medical and nonmedical sectors in addition to public, social, and private enterprise. Interventions deemed efficacious via highly controlled randomized trials are not able to offer recommendations on how to adapt and implement interventions into practice to ensure that contextual factors are leveraged for success. To address this gap, we need concepts and approaches that can describe and model contextual complexity in a way that is informative for integrating evidence-based approaches into practice settings and build on well-designed feasibility studies [25].

Understanding effective implementation requires considering theories and concepts that account for context, multiple levels of influence, and potential mechanisms for change from a more macro or collective perspective. Systems theory [26] and the social ecological framework derived from systems theory [27] seek to identify contextual patterns within nested levels of influence. Further, organizational theory examines how collective behavior can be facilitated via system changes that could support better implementation [28]. These theoretical approaches are advantageous because they (i) propose mechanisms of action, such as interdependence, that account for how context affects the behavior of individuals embedded in social systems, organizations, and communities [29], (ii) outline principles, such as equifinality, that suggest implementation effectiveness can be achieved through multiple implementation strategies versus a one-size-fits-all approach [27], and (iii) provide a perspective from which multilevel, multicomponent interventions can be conceptualized and designed by taking into account these mechanisms of action and principles [30].

Looking to new methods and strategies that provide a solution for addressing implementation barriers is critical. These approaches span the continuum of fine-grained analysis of potential strategies that can be used when implementing evidence-based interventions in complex practice settings [31, 32] to intervention mapping approaches that can be used to leverage theory and evidence to address ecological determinants in interventions and support stakeholder participation in intervention planning [13, 33]. Participatory and stakeholder-centered evaluation approaches that build capacity, accountability, and sustainability are proposed as central to implementation effectiveness [34, 35]. Additionally, these approaches define and operationalize ecologically valid implementation outcomes, such as acceptability or feasibility that are relevant to the implementation process [36].

The analytic approaches typically used in behavioral medicine are not well suited to testing the concepts, methods, and strategies that account for contextual complexity. Analytic approaches are needed that can provide practical recommendations for how to implement evidence-based interventions effectively and that can account for interdependence, equifinality, and/or other more macro concepts. One approach that can accommodate this challenge is qualitative comparative analysis (QCA), an analytic approach derived from Boolean algebra that identifies both necessary and sufficient conditions for implementation effectiveness [37]. It can accommodate both qualitative and quantitative data sources to define multiple pathways to implementation success. QCA can identify multiple combinations of implementation factors that signal better or worse implementation by accounting for aspects of the context and intervention attributes [38]. This analytic approach is complementary to MOST [39] in which contextual factors could be screened, identified for inclusion or exclusion in an intervention approach based on effectiveness, refined to fit a local context or problem so the optimal contextual approach is used, and confirmed via methods like QCA that can capitalize on model complexity.

PRACTICE-BASED TRANSLATIONAL BEHAVIOR CHANGE RESEARCH TO ADDRESS MECHANISMS OF BEHAVIOR CHANGE, PERSONALIZATION, AND IMPLEMENTATION

The major conceptual and methodological advances highlighted in each of the three areas above have evolved in parallel, but with little evidence of cross-fertilization so far and no well-defined funding infrastructures to support their integration. The essence of our proposed vision for practice-based translational behavior change research is an integrative, dynamic, and iterative approach to synergistically address important translational research questions in behavioral medicine. For example, how do health systems implement and sustain a pragmatic and efficacious behavioral intervention as first-line treatment to improve population health management? When implemented, how can this first-line behavioral intervention be enhanced or modified to promote treatment personalization and effectiveness for individuals? And what are the change mechanisms of the implementation strategy, the first-line intervention, and any personalization enhancing tactics? To answer these types of questions, three areas require integration and new theoretical and methodological approaches need to be considered.

We envision this integrative approach to be dynamic and self-perpetuating, in that answers to these questions from one iteration of the embedded studies would inform the questions and designs of the next iteration. We also believe that implementation strategy should be congruent with the local context, and that ideal candidates for first-line interventions and enhancement tactics should be robust and simple. The former calls for substantive and substantial engagement of key stakeholders early and throughout the implementation cycle(s). The latter implies evidentiary considerations of effectiveness, scalability (across populations and settings), and sustainability (societal trends, economic and social policies). For example, public and private health insurance coverage is now available for behavior therapy for obesity treatment [40, 41], diabetes prevention [42], and smoking cessation [43], and effective and scalable interventions are available as possible first-line choices in each of these areas.

Operationalizing our proposed integrative approach may include using various research concepts and methods, some of which we have

highlighted earlier. As an illustration, a pragmatic multicenter and multilevel project targeting obesity control, diabetes prevention, or smoking cessation given the available reimbursement policies, may involve an effectiveness-implementation hybrid design [44] (Type 1, 2, or 3 depending on the trial's relative emphasis on effectiveness and implementation); multiple geographically and contextually diverse sites of one setting (e.g., primary care practice) or different settings (e.g., primary care and public health practice); and large, racially and socioeconomically representative populations meeting broad eligibility criteria (e.g., as per practice guideline and/or reimbursement policy, if applicable). This umbrella project may embed linked studies focused on the implementation, augmentation, and/or mechanisms of a target first-line behavioral intervention, respectively.

Questions about whether and how the sites will implement the first-line intervention could be framed within the Consolidated Framework for Implementation Research [45] to identify site-specific barriers and enablers in the outer and inner settings, the characteristics of the individuals involved, the intervention characteristics, and the implementation process. The findings from mixed-methods research with relevant decision-makers and target audiences would determine site-specific implementation strategies (e.g., internal and/or external facilitation, audit and feedback, sequencing implementation strategies or required policies and procedures) for the rollout of the first-line intervention, and QCA could ascertain site variability related to effectiveness.

Additionally, all participants in this implementation study who receive the first-line intervention could be automatically enrolled in a SMART trial of behavioral treatment augmentation using brief, focused behavioral interventions. For example, problem-solving therapy [46, 47] and motivational interviewing [48] have been validated across a wide range of target physical and mental health problems, and can be delivered by typical health (para) professionals in clinical and community settings. Also, both seem to evoke mechanisms of change related to generalizable processes of human behavior, and are not limited to specific target behavior changes. As such, their conceptual compatibility with the likely first-line behavioral interventions appears high. Their brevity and focus and demonstrated effectiveness make them promising titration options for individuals who do not respond to the first-line intervention.

Finally, the first two studies would support a deep dive into change mechanisms at the setting and individual levels—and between-level interactions—to decipher how and why the implementation strategies and the first-line and augmented behavioral interventions work or do not work, and under what conditions. This embedded mechanistic study could leverage the latest advances in taxonomies of organizational and individual behavioral changes and assays of theoretical mechanisms such as self-regulation, stress, and interpersonal processes being developed within the NIH SOBC Research Network (http://scienceofbehaviorchange.org/). The pragmatic context would enhance the external validity of mechanistic understandings emerging from such a study, and equally important, it would afford researchers, implementers, and decision-makers an engaged real-world research "living laboratory." In this context, basic discoveries of fundamental mechanisms could be readily translated into intervention adaptation and implementation, and further mechanistic investigation in a dynamic, iterative, learning, and quality improvement process within actual practice.

CONCLUSION

The pivotal role of human behavior in health and chronic illness is clear. The need for optimally efficacious and implementable behavior change interventions is imperative. The potential of translational behavioral medicine in propelling the population and precision health movements is compelling. As an important step to help fulfill this potential, we presented an integrated vision of practice-based translational behavior change research. The vision draws on the notion of fusing the conceptual and methodological strengths of practice-based research and translational research within a bold science of behavior change paradigm.

We highlighted a number of conceptual and methodological advances related to fundamental behavior change mechanisms, behavioral intervention optimization, and behavioral intervention implementation. These disciplines have witnessed impressive strides, and the concepts and methods noted are not intended to be exhaustive or detailed, but only to illustrate some of the cutting-edge science in each. This illustration also underscores the continuing gaps in knowledge on both ends of the behavioral intervention development and implementation continuum, and the steps in between. There lies tremendous potential for transformation in behavioral medicine if the leading concepts and methods that have emerged independently in basic science, efficacy/effectiveness trials, and implementation science are better integrated to foster transdisciplinary behavior change research.

In particular, we call for more practice-based translational behavior change research in which transdisciplinary investigators embed rigorous mechanistic discoveries and continued intervention optimization within thoughtful designs addressing the contextual complexity affecting implementation in diverse, generalizable settings and populations. Positioned in the crossroads of traditionally disparate disciplines of behavioral medicine, this integrated line of inquiry exemplifies a synergistic, dynamic, and

iterative approach to behavior change research. This approach differs from the traditional linear research pipeline by leveraging newer hybrid effectiveness and implementation designs while also embedding basic science research. This innovative integrated approach is highly consistent with, and could be leveraged by, strategic goals and priorities of the NIH. For example, in addition to the traditional (largely discrete, stepwise) NIH funding stream (R21, R34, R01, and R18), newer funding mechanisms have been increasingly used to support large pragmatic projects, such as the NIH Health Care Systems Research Collaboratory, or pioneering projects on behavior change mechanisms and assays, such as the NIH SOBC Research Network. Novel applications leveraging these newer funding opportunities or even additional specifically targeted funding opportunities (particularly to better integrate sophisticated testing of implementation features) may be necessary to realize the vision for practice-based translational behavior change research. The expected outcomes of this vision, when fulfilled, would be refined change mechanisms, optimized effectiveness, and sustained implementation of behavioral interventions across diverse practice settings, contexts, and populations—and, thereby, improved population and individual health.

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Primary Data The authors attest that this manuscript is not being simultaneously submitted elsewhere. The manuscript is exclusively submitted to *TBM* to be considered for publication as a Commentary and it has not been previously published. It contains no primary data or original research findings. Hence, there is no primary data for review.

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Authors' Contribution All authors contributed equally to the planning and writing of this article.

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