DOI: 10.1590/1413-812320182310.23792016

Traditional Complementary and Integrative Medicine: challenges in constructing an evaluation model of care

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Abstract *The complexity and diversity of what is proposed in Traditional and Complementary Medicine constitute a challenge for those seeking evidence of its effectiveness. Its growth, offer and, use justify the need to build more complex and more appropriate methodological frameworks to explicit the uniqueness of this approach to healthcare and the diversity of its techniques. Based on a narrative review of the recent literature, this article aims to contribute to the construction of an evaluation model, focused on understanding the uniqueness and diverse dimensions of this specific care, seeking to reflect on the challenges and evidences of successful therapy. The proposed model is based on qualitative healthcare approaches, in which the experiences of the involved agents (professionals and users) in the therapeutic process become central. Assessing their effectiveness means recognizing the interconnected processes and their multiple dimensions: host practices, dialogue, diagnosis, action, and outcomes achieved.*

Key words *Process and outcome evaluation, Traditional medicine, Practice*

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Introduction

The complexity and diversity of what is proposed under the nomenclature of Traditional Complementary and Integrative Medicine (TCIM) in the world, and Integrative and Complementary Practices in Health (ICPH), in the Unified Health System (SUS) constitute a challenge for professionals and decision makers interested in evaluating their effectiveness. The increase in their offer and use has stimulated the debate about the safe and effective use of these practices[1,2], besides the introduction of new evaluative approaches that contribute with some criteria for its incorporation[3-6] which are methodologically useful to the practice of managers and health professionals, and that are beyond the scope of normative evaluation.

Recent studies[1,3-7] show the need for evaluations which emphasize the complexity of intervention processes and the intersubjective dimensions related to TCIM, because it deals with the uniqueness of symptoms and subjectivities that need to be included in order to understand or to measure their therapeutic success. Therapeutic interaction and the health professional-user dialogue are often carried out from a set of strategies and processes with specific characteristics that influence their outcomes[6,8]; and would need to be included in the evaluation proposals beyond the traditional models[6,7,9].

There are few studies on TCIM's offer and the possible effects of its use and its costs[1,4,10-12], which would justify the need to construct methodological frameworks for its evaluation. Thus, the purpose of this article is to propose elements for the construction of an evaluation model that contributes to the plurality and reach of TCIM in diverse dimensions of health care.

It is assumed that the effectiveness of TCIM cannot exclusively be focused on behavioral changes and biomedical patterns. It is understood that the evidences that attest to the therapeutic success can be constructed from the experiences, practices, and narratives of the relationship between users and professionals, besides the evidence about the reversal of symptoms and the impact on the possible health risk factor . Thus, a theoretical study was carried out with the following assumptions: 1) in spite of the diversity contained in the TCIM name, there are similar characteristics in the way of understanding care[13-14]; 2) the heterogeneity of contexts and the complexity of care require dialogue with a pluralistic theoretical framework, such as the evaluation of health promotion[15-16] with the support of theory of complex systems[17-18]; 3) care can be understood as practice[19-20] and source of evidence for the evaluation[21]; 4) care takes place through a unique relationship between professionals and users.

Complexity of Care in Traditional Complementary and Integrative Medicine

The growth of the TCIM´s offer in the Health Systems of several countries[22-24],

including in Brazil[25], has been accentuated in the last decades. Several factors have contributed to the increase in its supply and use, largely related to the structural and behavioral changes that contemporary societies are experiencing. These changes are responsible both for the occurrence of syndromes and disorders related to anxiety, insomnia, chronic pain, stress and depression, attention deficit, amongst others; as well as an enhancement of longevity of the population, which responds, in large part, to the prevalence of chronic degenerative diseases[1]. Moreover some other important factors that are shown are dissatisfaction with conventional care and the desire for more sophisticated and expanded forms of listening and caring[26-28]; the increasing pressure and interest of the market around the health sector[1,3] and the desire of health professionals to implement other modes of care[26].

In Brazil, although TCIM has been offered in public health services since the 1980s, it has been officially recognized in the last decade under the name of integrated and complementary practices with the implementation of the policy of the PICS[25]. It is worth mentioning that part of this offer stems from successful initiatives and the diversity of experiences in different realities[25,29]. Recent offer and production analysis, recorded in the information systems of the SUS[25] evidenced the limits in gathering what has been offered in the local contexts and the mismatch between what is accomplished in the daily life and what is informed to the Ministry of Health, besides the difficulty of characterizing the type of care in each context.

In this study, care is understood as an interaction, a construction of mediations, in which happiness projects are considered, not being restricted to health interventions[20,30]. According to Ayres[20] care can be seen *as a designation of health care immediately concerned with the existential sense of the experience of becoming physically or mentally sick, and therefore also of practices that*

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could promote, protect or recover health. Hence, care is built in the connectedness of the user and the professional, with objective to listen the human need of care to produce happiness[20].

This perspective has a correspondence in TCIM, since its *modus operandi* is aimed at understanding the diversity of meanings of the process of becoming ill, and how to intervene effectively in it, requiring a subjective interrelationship so that the motives or causes of suffering are elucidated. Thus, care is understood as a process, practice, with the use of various therapies of TCIM, with the exchange of experiences and knowledge between users and professionals.

Care at TCIM involves medical rationalities, such as homeopathy and traditional Chinese medicine[13], and other practices such as meditation, massage, *reiki*[31], floral, chiropractic; moreover, it also depends on the context in which they are inserted[1]. Despite the diversity of rationalities and therapeutic possibilities, its praxis presents as main characteristics: a) singularity (the focus of care is on the person, not the disease); b) flexibility (adaptation of care to the user and their context); c) complexity (the process of sickness encompasses the imbalance in the vital dynamics, in the being, besides the physical, chemical and biological realms) and d) integrality (the intervention and its evaluation contemplate objective and subjective results, it is not enough to cure the disease).

Such characteristics are evidenced in peculiar dimensions which deserve to be highlighted. In the first dimension, the focus is the individualized care, without disregarding the complexity of the socio-environmental and cultural contexts in which professionals and users live and work. It is in the process of listening, dialoguing and exchanging knowledge between those who care and those who are being cared for, that the understanding of the illness process and satisfactory results are sought. The reading or diagnosis of the illness process takes into account the flow of energy, emotions, food intake, activities, relationships, expressions, symptoms, physical characteristics and cultural and social contexts. This singularity allows that the illness can be understood as a process and an experience, which differs from the traditional definition of health as the absence of disease. It considers that each individual has not only their own constitution and psychosocial circumstances but also different reactions to the symptoms, diseases and treatments. Therefore, people with the same disease can receive different care[1], as in the Chinese medicine[5,13,32] or in the homeopathy[29,33]; and obtain responses or react distinctively to each intervention.

This conception implies a second dimension: the complexity of the illness. Illness is not only the result of biological and biochemical imbalances but the way the individuals position themselves and interact with their context, how they relate to themselves and to the illness. In this sense, the disease understood as a natural process of evolution that can be seen as an imbalance of vital breaths in the Chinese rationality[13,32], of the vital dynamics in homeopathic rationality[33], imbalance of Prana in the Ayurvedic rationality or energy polarization in the floral therapy. The imbalances and disharmonies reflect the third dimension: the complexity of care, which is not confined to a specific disease, but to the process of illness. Care is not restricted to a single therapy, it can be given through a set of interventions (herbal prescription, body practices, changes in diet, massage, meditation)[1]. Even the Reiki (positioning with hands) seeks to interfere in the physical, mental and energetic plans, values and ways of life[31]. Care, when transposing standardized protocols, builds a routine for each individual, respecting their uniqueness for the desired effectiveness. The fourth dimension concerns the process of care that is relational and interactive, built at each encounter between the user and the health professional. Its effects are evaluated during the process and both the diagnosis and the therapeutic objectives can be reformulated and reassessed, as in the Chinese medicine[13] and in the homeopathy[32-34], among others, since the TCIM professional tends to take into account the demands of the user. It contemplates a professional action with a participatory attitude of those who are being taken care of. As a last dimension, we highlight the integrality of the results. To the extent that intervention is not limited to disease, cure or cessation of symptoms, which are not the only goals to be achieved. For example, in the Chinese medicine, if the cure of a disease is accompanied by worsening of emotional symptoms, this indicates that the treatment would need to be reviewed. The healing process can be defined as a trajectory of self-knowledge and growth. The results are analyzed taking into account other evidences, such as the expansion of the feeling of well-being and happiness after the intervention, and the relationships that the individual can build or reconstruct with the social, cultural and natural environment[7].

Thus, considering the care taken at TCIM, its evaluation should take into account the following aspects:

a) the interventions in the TCIM share some intrinsic dimensions, deriving from the vital paradigm, despite their diversity[13,32];

b) care can be defined as practice[19,20] because it involves collective and individual aspects aimed at interaction, dialogue and experiences exchange between the health professional and the user. It is built taking into account the technical knowledge, the living experiences, and the understanding from different medical rationalities;

c) care has a *modus operandi* in understanding the process of illness and a unique interaction with the resources of biomedicine, as it seeks to integrate physical symptoms, emotional aspects and the context of life, without necessarily eliminating the biomedicine care strategies. TCIM is a diverse set of modes of care, and its complexity challenges the traditional models of health evaluation[6-7]. Both the process of illness and the care present different subjectivities, emotions, values and sociocultural perspectives between user and professional that interfere in the success of the process[35]. In this case, methodological plurality and the emphasis on qualitative studies are necessary. Thus, the meanings of efficacy or effectiveness should not be limited to the expectations of the professional but should welcome the senses and meanings of those who are receiving care.

These dimensions imply the recognition of the uniqueness of care as the central object of the evaluation of TCIM, which suggests the search for other sources of evidence and new evaluative approaches.

Challenges for the construction of an evaluation of care model in the TCIM

Although randomized trials are essential for validating the efficacy of specific drugs and therapies in the biomedicine, they are not sufficient to assess interventions and complex practices[7] in uncontrolled contexts, and facing the individual and single processes, as in the TCIM[13,17,36].

Evaluations aimed at simplifying the reality and having limited focus on evidence from experimental studies, in which strictly techno-scientific criteria are established both in policy and in health actions, have been criticized by researchers in the field of health promotion[15,16]. However, such criticisms did not reverse the hegemony of these studies, since this perspective also subsidizes other interests and disputes in the field of health.

Authors of the field of evaluation, especiallySchwandt[21] and Patton[37], inspired the search for qualitative approaches to health assessment in the face of an understanding of the plurality of interactions, contexts, and meanings that permeate health care and practices, as well as the difficulty in reproducing unique situations from one context to another[38], or even, to account for the complexity of processes and their effects[21,38]. These authors define the object of evaluation as an open and complex system in which multiple strategies are used in the face of the plurality of contexts and meanings attributed by the agents involved. Causal models would be inadequate[38] insofar as programs, interventions, and practices involving interdependent and reflective social processes and interactions between, for example, professionals and users, or between programs and communities. Likewise, what is at stake is an evaluative perspective in which the main contribution would be understanding 'how', 'why', 'for whom' and 'in what contexts' the interventions, strategies and processes for health promotion or recovery work[15,38].

Schwandt[21] contributes to this debate by redefining evaluation as action based on the problematization of the object to be evaluated and the very meaning of the evaluation. From the methodological perspective, the evaluation can no longer be seen as an objective and neutral study, while mere collection and analysis of data and information[21]. Pioneering authors in this debate[15,16,37] understand the evaluation as a reflexive activity: the evaluator interprets and understands facts, events and actions developed that depend on the interaction of the agents in a given context. The representations and categories of agents' perception are central to the success of the interaction and to the success of the care, as well as the effort and methodological rigor of the evaluator to capture such processes in the environment or context in which they occur. The approach proposed by Schwandt[21] is appropriate to evaluate care in TCIM insofar as it understands the users and professionals involved in interdependent processes and practices in which the point of view or the perception of the agents directly involved in the actions is crucial. Processes of changes and practices in health depend on the motivation, the engagement and the established relationship between professionals and users, and the choice between the various therapeutic techniques. The evaluation, in this sense, is reflexively contextualised, that is, with a focus on the relationship between users and professionals, between the institutional environment, the social context and health practices and actions.

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There would be a repositioning of practice as a central element in the evaluation, which would define its focus as: a) activities, actions and interrelationships among the main agents that structure the practice; b) interaction of institutionally circumscribed agents to a context of norms, responsibilities and regulations with the so-called normative evaluations; c) organized reflexivity among social agents capable of providing subsidies for changes[21].

In the TCIM, care understood as practice has its own dimensions, associated with an extended understanding of the process of illness and healing. Thus, other evaluative methods would need to be constructed, since classical evaluative studies and clinical trials are insufficient. In the case of homeopathy, for example, a medicine that is proposed as effective for asthma may not be effective for all individuals who have the disease. Care, in this case, is not to administer the homeopathic medicine as if it were a "magic" pill. It is not it alone which is effective. The same is true with acupuncture. It is not only a matter of simply inserting the needle at a specific point for a particular symptom or disease, as the effect will be different in each individual. Hence the difficulty in establishing and measuring effects of complex interventions or care whose evidence is built on the basis of the classical experimental method.

The complexity of the interventions, the diversity of strategies and contexts refer to different methodological approaches, revitalizes the field of health assessment and proposes the use of more complex[18] and realist[16] models, which would make possible to open a the so-called "black box" of the process of care[7,37]. It is a matter of understanding the role of qualitative approaches in evaluation, recognized within the tradition of the social sciences. An assessment focused on the complexity of health care would open an innovative way to identify the evidence for its effects. For example, the outcome of caring for users with diabetes would not restrict their focus on checking the glucose profile and anthropometric measures, but to understand the process of illness from the context of life and to understand what meanings the user would attribute to their disease and its causes. It would provide strategies for sharing knowledge and awareness of the user about self-care and its various therapeutic strategies, as well as renowned measures to improve nutrition, the routine of physical activities among others. The evaluation, in this case, would be aimed at understanding the interpersonal action in which care is carried out: the modes of action, the techniques or therapies used, the dialogue and the stimuli raised, as well as the responses and reactions of the user. The elements of the context, capable of influencing care, could be systematized to generate useful learning and evidence of its effectiveness. This reflexively shared knowledge would be useful to the user as it enables the understanding of how to deal with the complexity of the illness process vis-à-vis the risk factors present in his/her context and lifestyle.

Care as a practice in Traditional Complementary and Integrative Medicine

Care, understood as practice[20,21] socially construed, is central in the reflection on the evaluation process. It implies recognition of the importance of interaction and interdependence among the agents involved. Care presupposes the technical knowledge of professionals and the ability to discern and make judgments from the set of their experiences, familiarity and accumulated knowledge, but their implementation depends necessarily on the uniqueness of those who are receiving care. Thus, care is not confined to the standardized responses and technical rationalities of a consultation, it includes both the reflexivity inherent to the uniqueness of the agents and the limits imposed by social organizations and structures. It is important to emphasize that this process is built by the agents in their interrelationship, which allows understanding care as a practice[21]: an action impregnated with senses and subjectivities. In addition, the practice presupposes both the knowledge that agents have and the ability to trigger knowledge and situational understanding that guide the choices and decision making of professionals. This perspective advances to understand the interaction between professionals and users from the organized rationality and the reflexivity present in the practice of care. Both the experience and the singularity of illness are at stake, as well as the capacity of the institutionally situated professional to make technical decisions.

Care understood as practice involves the diversity of knowledge and experiences, in an interaction between caregiver and caretaker. It concerns an organized reflexive action, that is, subject to regulation and institutional evaluation, but focused on a more comprehensive understanding of the complexity of the process of illness and suffering; that is, an experience of illness and /

or distress suffered by single individuals. It seeks dialogue and balance between the experience of the professional and the user with the techniques and rationalities available. The practice, when being problematized in this perspective, is no longer seen as an automatic and linear response[39] in the face of a situation or a problem and becomes a process evaluated in its complexity, as a chain of events and unique temporal sequences with a high degree of unpredictability, and which result from the way agents understand their action and interact circumstances[21].

The assessment here needs to be seen as a reflexive activity[21]. That is, the evaluator interprets and understands facts, events and actions developed that depend on the interaction and experience of the agents. The representations, perceptions and experiences of the agents are central to the evaluation of care and to seek evidence about the therapeutic success. In this evaluation, the qualitative approaches are fundamental, since *it* seeks evidence of the effectiveness of care from the point of view of the agents involved. The evaluation tries to systematize useful knowledge that can subsidize professionals and institutions.

Contribution to a model of evaluation of care in TCIM

The theoretical model is employed in the field of health assessment as one of the first steps for evaluation. It aims to elaborate a representation of the fundamental dimensions of policies, programs and interventions[16]. In short, it seeks to identify the problem vis-à-vis the desired situation or change, the target population, the conditions of the context, the process, and the necessary and sufficient attributes to produce, in isolation or in an integrated manner, the effects.

Evaluating the effectiveness of care in TCIM means understanding the chain of processes involved in the action: reception, dialogue, diagnosis, intervention, exchange, outcomes of each meeting and goals achieved. Turning almost always to the uniqueness of the caregiver-caretaker relationship, the experience of care in TCIM often expresses the use of various rationalities, including biomedical. They are also considered more subjective dimensions such as capacity, predisposition and quality of dialogue, communication, interaction and involvement, as well as the willingness and motivation of both the caregiver and the caretaker.

In this direction, a model of evaluation of care in TCIM would articulate the following interdependent dimensions: a) significant aspects of the context (social and institutional); b) the care (practice) with emphasis on the interactions between the agents and their unfolding, and the techniques and therapeutics used; c) the agents (professionals and users); d) the outcomes as the possible evidence of therapeutic success.

In the social context, one must take into account the beliefs, meanings, cultural and social values and socioeconomic conditions of users. In the institutional context, the conditions for the development of care, such as physical space, investment in permanent education, inputs and sufficient financial resources. Care is understood as a process, a set of activities that can bring initial, intermediate and final outcomes and also feedback on the new processes of care. For example, increased autonomy and self-care, seen as results, interfere in the construction of the goals of care (process), which have repercussions on the autonomy and the user's awareness (outcomes) and that will lead to new goals. Thus, the model seeks to show the possible ways to search for evidence of therapeutic success in the various stages of care in view of the various techniques and therapeutics proposed by TCIM.

The components of the suggested model include the professionals' previous knowledge and experience, the way in which care is developed, the interaction process and, finally, the users' response based on their references and motivations. Care is not limited to the professionals' way of acting, but how the user welcomes the proposal.

It is important to recognize that the success of the process depends to a large extent on the training and experience of practitioners, as well as on the institutional environment in which TCM care is developed. Outcomes and effects are flexible and, to a large extent, dependent on technical training, professional responsibility and experience, as well as their understanding of the sociocultural context and the life and work of the users. But in a heterogeneous scenario, the evaluation of these outcomes would need to show whether the care taken allows the goals to be achieved by the user, which is the reason why the care was constructed, as well as evidence of the unplanned consequences or effects.

In addition, institutionally organized care (in the health services) should establish as much as possible goals to be achieved, although flexible, not subject to closed protocols. In the model, care is socially constructed from listening, meaningful and reflective interaction between users and professionals. The consequences and effects are

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constantly evaluated and re-evaluated and the goals are built together. However, the importance of external evaluations and those focused on the users' experience and perception are not ignored.

Finally, the dimensions of care in TCIM require the verification of their outcomes both from the physical manifestation and from the manner of " how the user feels". Unlike, in the biomedicine, in which the outcomes are predominantly verified from the cessation of disease symptoms.

The proposed model is in line with the literature that has been pointing to the importance and growth of qualitative approaches in health that deal, among other aspects, with understanding the practice and care in health, and in particular in TCIM. TCIM care has several specificities, as well as unique characteristics that suggest more innovative evaluation approaches and, therefore, evaluative models focused on the experience and interaction between professionals and users.

Final Considerations

Illness and care processes need to be seen as socially-constructed processes. From this perspective, a set of arguments against the growing and excessive medicalization of the disease emerges, vis-à-vis the naturalization of social problems. That is, reducing social and behavioral issues to health issues and, therefore, linking them to a purely biomedical approach. It motivates a critical perspective, capable of relativizing the hegemony of biomedical discourse and opens the way to include other rationalities present in the field of health. It is from this relativization that the TCIM is now recognized by the WHO and, in Brazil, it is a component of SUS, with significant growth in recent years. Its recent worldwide expansion makes it crucial to construct and implement evaluations that elucidate its effectiveness and also its limitations. By including and highlighting a group of characteristics of care with TCIM, the focus and object of the evaluation is redefined. Thus, the question of the effectiveness of TCIM care is incorporated beyond biomedical evidence. Embracing the complexity of the disease process implies broadening and redefining the human and social dimensions that surround the process of care, seeking new methodological references for its evaluation, as well as including new ways of defining and seeking evidences of therapeutic success.

The debate about the different theoretical references and several evaluation paradigms is relevant. In this case, the methodological assumptions for the evaluation can walk in tune with the complexity of the practice, drawing attention to the uniqueness of the interactions between the agents involved and the specificity of the contexts. The construction of models aims to contribute to a useful evaluation perspective for managers, professionals and health institutions, which cannot ignore or set aside the various rationalities that exist in the health-disease process.

Conducting the assessment from the dimensions of care and its characteristics builds up a promising path, since it is reflexively oriented to understand the complexity of interrelationships and interdependence between the agents involved.

Methodological reflection seems necessary in view of the considerable increase in the use of TCIM in the health system and the difficulty inherent in traditional evaluation models to capture the singularities and specific characteristics of the health / disease process. More appropriate and feasible models, aimed at improving the quality of practices, would need to be discussed, which presupposes the expansion of the debate that is still incipient in the country.

Collaboration

IMC Sousa has worked on the design, writing and revisions of the article; VA Hortale and RCA Bodstein in the writing and reviewing of the article.

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Article submitted 23/02/2016
Approved 06/10/2016
Final version submitted 08/10/2016