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## Components of complex interventions for healthcare: A narrative synthesis of qualitative studies

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### ABSTRACT

**Objective:** Qualitative research on therapeutic components is necessary to evaluate the efficacy of complex interventions in healthcare. As few qualitative syntheses have been conducted, this study aimed to derive a new conceptual framework for understanding the components of complex interventions and provide evidence for the implementation and evaluation of complex healthcare interventions.

**Methods:** A systematic search of seven databases was conducted to identify qualitative studies that explored components of complex healthcare interventions. Meta-ethnography was used to analyze the data and thematic analysis was used to build the conceptual framework.

**Results:** Of the 35 included studies, most complex interventions were non-pharmacological, with cancer accounting for 22%, mental health for 14%, and stroke for 8%. Half of the studies were conducted in the United Kingdom. Three main categories emerged: what should healthcare workers do? what qualifications should they have? and what should patients do? Five main themes were identified: psychological, biological, cognitive and behavioral, environmental, and social support.

**Conclusion:** This analysis provides a reference for designing components of complex interventions in further studies.

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### Introduction

There is no precise definition for complex interventions. Campbell et al described them as healthcare interventions that include several active separate critical components.<sup>1</sup> Complex interventions are widely used in healthcare, and often include education, transport, and housing; all which affect health.<sup>2</sup> Complex interventions have also been defined as interventions with several interacting components, and many problems have been uncovered when evaluating their impact on health.<sup>2</sup> In 2000, the United Kingdom Medical Research Council published guidelines for the development of robust, complex interventions that highlighted testing and appraising the effectiveness of components of complex interventions.<sup>1</sup> In 2008, these guidelines were revised in response

to the limitations encountered with the framework.<sup>3</sup> Since the first guidelines were published, various studies on complex interventions have been conducted, which resulted in some interventions being implemented. According to these guidelines, the first step is to identify evidence on the potential effect of the intervention, which is known as the preclinical or theoretical phase. The second step defines the specific components of the intervention. Qualitative testing through focus groups, preliminary surveys, or case studies was suggested as a method which could help to define components. Many researchers have explored the components of different complex interventions through qualitative methods.<sup>4</sup> However, the significance of intervention elements and how to research active components and interactions within a complex intervention remain ambiguous.

The main objective of this synthesis was to derive a new conceptual understanding of the components of complex interventions. There are no standard methods for conducting syntheses of qualitative research. However, Miles and Huberman<sup>5</sup> identified possible methods within an overall approach to qualitative data analysis that they classified as cross-case analysis.<sup>6</sup>

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Originally described by Noblit and Hare,<sup>7</sup> meta-ethnography is a method involving three major strategies: reciprocal translational analysis, refutational synthesis, and lines of argument synthesis. In developing the grid further, Schutz's notion of first and second order constructs were used by Britten and colleagues.<sup>8</sup> These explanations and interpretations were used to develop a "third order interpretation". The working definition of first order constructs reflected interpretations of experience, interpretations of interpretations of experience of second order constructs, and interpretations of interpretations of interpretations of experience of third order constructs.<sup>9</sup>

We used thematic analysis to identify important or recurrent themes in the literature, and organize or structure the findings of different studies with thematic headings.<sup>10</sup> The aim of this study was to employ the concepts of first, second, and third order constructs to synthesize the components of complex interventions for healthcare, and use thematic analysis to frame the findings to provide evidence for the implementation and evaluation of complex interventions in the health field. This intended to clearly show a new conceptual understanding of the components of complex interventions. It was hoped that this would contribute to achieving more effective complex interventions, by improving the behavior of practitioners and patients through highlighting the need to pay attention to valuing the active components of complex interventions and their therapeutic components.

## Materials and methods

### Literature search and eligibility criteria

The bibliographic databases searched to identify relevant studies were: PubMed, Embase, Cochrane Library, China Network Knowledge Infrastructure (CNKI), WanFang Data, Chinese Scientific Journals Database (VIP Database), and SinoMed. These databases were searched from inception to July 2019. The reference lists of the identified studies were also screened for further relevant studies. Literature published in English and Chinese was eligible for inclusion. Combinations of MeSH terms, Emtree terms, and keywords were used, including "empirical research," "qualitative research," "grounded theory," "complex intervention," "complex interventions," "whole systems," "holistic," "complex systems," "integrative medicine," "integrative support," and "integrative care."

Three authors (SSM, NL, SJZ) independently selected the studies for inclusion in the review according to pre-stated eligibility criteria, as follows.

**Inclusion criteria:** (I) Topic specifying the components of a complex intervention; (II) Qualitative research or methods used in grounded theory.

**Exclusion criteria:** (I) Therapy might be a complex intervention, but the topic did not specify the components of the complex interventions (e.g., patients' attitudes to complex interventions); (II) Complex intervention that was unrelated to medicine (e.g., healthcare policy); (III) Study protocol or review.

Disagreements were resolved by discussion and adjudicated by another author (JPL). Decisions about inclusion and exclusion were based on the entire content of the study. Study quality was evaluated by the first author (SSM) and confirmed by the co-first author (HY) using the Criteria Appraisal Skills Programme (CASP) (<https://casp-uk.net/#!casp-tools-checklists/c18f8>). Disagreements were discussed and adjudicated by another author (JPL). The results of the quality appraisal of each study of the CASP checklist are shown

in Supplementary Data 1.

### Data extraction and analysis

Two authors (SSM, NL) independently extracted data using a pre-designed data extraction form that included the complex intervention, the elements of the complex intervention, patients, research setting, sample size, data collection method, data analysis, and outcomes. Next, we used thematic analysis to pool the qualitative data and form the conceptual framework.

First, participants' initial views, quotations, accounts, and interpretations were considered as first order constructs. Second, the components of the complex interventions and the original authors' own words (or paraphrasing) were listed as second order constructs. Finally, studies were translated into one another, which required comparison of the second constructs. See Supplementary Data 2 for the translation grids.

A grid in Microsoft Excel (Office Professional Plus 2016, Microsoft, Redmond, WN) was created for translating the second order constructs across the included studies. The translation grids were drafted by the first author and distributed to the other authors for confirmation; any differences were resolved by discussion. The first order constructs, second order constructs, and description of each second order construct in each paper were extracted by the first author. A translation of each second order construct was made across all included studies. After completing these steps, codes were derived from the second order constructs and translation codes obtained.

## Results

### Study characteristics

In total, 35 studies<sup>4,11–44</sup> were identified that satisfied the inclusion/exclusion criteria (Fig. 1). The characteristics of the included studies are shown in Supplementary Data 3. Most of the complex interventions were non-pharmacological interventions; for example, case management interventions,<sup>27</sup> a baby milk intervention,<sup>4</sup> or information aids.<sup>28</sup> One study focused on traditional Chinese medicine (TCM) interventions,<sup>38</sup> and three studies focused on acupuncture.<sup>40,42,44</sup> The qualitative data collection methods were individual interviews, focus groups, and observation.

The 35 identified studies were categorized into 12 groups according to different diseases. Of these studies, cancer accounted for 20%, mental health for 14%, and stroke for 8% (Supplementary Data 4 for classification of the included studies based on disease). Three types of interventions were identified according to intervention delivery: self-help, peer-support, and healthcare worker (Supplementary Data 4 for classification of the included studies based on intervention type). Healthcare worker interventions referred to: nursing, supporting caregivers, providing information/communication, interpersonal relationships with patients, skills for promoting rehabilitation, preventing obesity, individual interventions, and complementary and alternative medicine. The health workers in our review were defined as doctors, healthcare practitioners, general practitioners (GPs), nurses, and informal caregivers.

Overall, 55% of the studies reported interventions for supporting human interrelationships rather than treating disease. Of the interventions, 11% were complementary and alternative medicine and 17% were aimed at preventing obesity or promoting rehabilitation. The remaining 8% were nursing interventions. The included studies were mainly conducted in the UK (50% of the sample). The remaining studies were conducted in Italy, Sweden, Germany, Ireland, the USA, France, Chile, Canada, China, Spain, and Belgium.

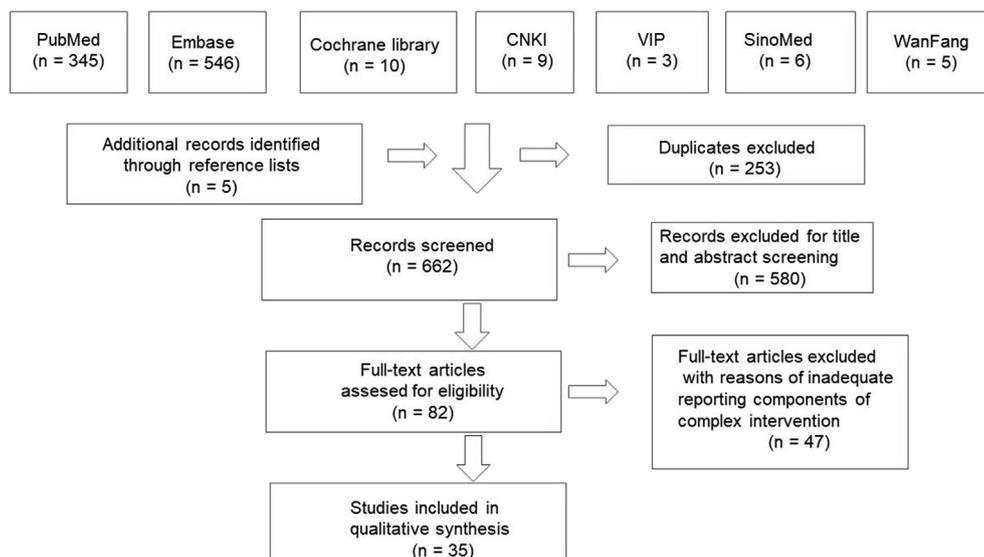


Fig. 1. Flow chart of study search and selection.

As shown in Supplementary Data 4 (cross analysis between disease and complex interventions), the interventions identified for mental health were self-help, peer support, interpersonal relationships with patients, and individual interventions. Self-help interventions, TCM, and acupuncture played important roles in dealing with chronic diseases. Peer support was considered important for children or patients with mental disorders. If the diseases were associated with a physical and psychological burden to family and society, interventions for supporting caregivers were essential. Some researchers also focused on interventions for interpersonal relationships for mental or psychological diseases.

#### Conducting the synthesis

Finally, three categories were developed: what should healthcare workers do? what qualifications should they have? and what should patients do? Five main themes were developed from the components synthesis: psychological support, biological support, cognitive and behavioral support, environmental support, and social support. Sixteen subcategories emerged from these codes. An additional theme, humanistic care, also emerged. Fig. 2 shows the flow chart of the data extraction and analysis.

Most of the complex interventions were a series of behavior rules, which meant the components of the complex interventions were internalized in implementation. The theory embodied by complex intervention elements was developed for components synthesis. This theory highlights that in addition to biological support, people need psychological support, cognitive and behavioral support, social support, and environmental support; all five aspects run through the implementation of complex interventions.

#### Categories of the components

For the elements of implementation of complex interventions, two perspectives were identified: healthcare workers and patients. In the implementation of complex interventions, two vital subcategories were “what should healthcare workers do?” and “what qualifications should they have?” Healthcare workers (i.e., doctor, nurse), family members, and other caregivers should: “assess the condition,” “set goals,” “provide drug or expertise-based interventions,” “give patients advice or guidance,” “time the delivery of the intervention,” “identify the setting for the intervention,”

“monitor and supervise the process,” “coordinate situations and relationships,” “evaluate and document the process,” and “tailor the intervention.”

What should healthcare workers do?

**Assessing the condition** Before implementing a complex intervention, a review of the complex intervention strategies and an assessment of the patients’ condition should be conducted. Healthcare workers assessed the health of their patients through clinical judgment and standard screening tools.<sup>26</sup> To support clinical judgment, healthcare workers searched for information about the healthcare system and got to know the patient, such as “what to eat” and “how to exercise.”

Getting to know the patient focused on “evaluating patients’ symptom burden” and “what they were concerned about.” Evaluating patients’ symptom burden contained “evaluating level of risk,” “physical function,” “nutritional status,” “activities of daily living,” and “communication and swallowing.” For example:

*“FP47: I think that the most useful part is the detection of risk factors and that you can discuss to a certain extent where the fundamental risk factor is.” (first order construct; Moreno-Peral et al., 2019)*

Getting to know “what were they concerned about” means “understanding the way I feel.” Sometimes this needed the collection of biographical data. These biographies were documented in writing, sometimes with the help of photographs to obtain an extensive impression of the patients’ lives. This information was useful to understand patients’ behavior and validate their life themes.<sup>21</sup>

**Goal setting** Setting a goal is an effective way to implement an intervention. Some complex interventions set graded tasks. Easy tasks were set that increased in difficulty until the target behavior had been performed.

*“Monthly contact to encourage mothers to set small achievable goals and revise them. Review of personal feeding plan (PFP) to revise goals.” (first order construct; Lakshman et al., 2014)*

Sometimes a specific or individualized goal was needed. For example, in the process of the baby milk intervention, a specific

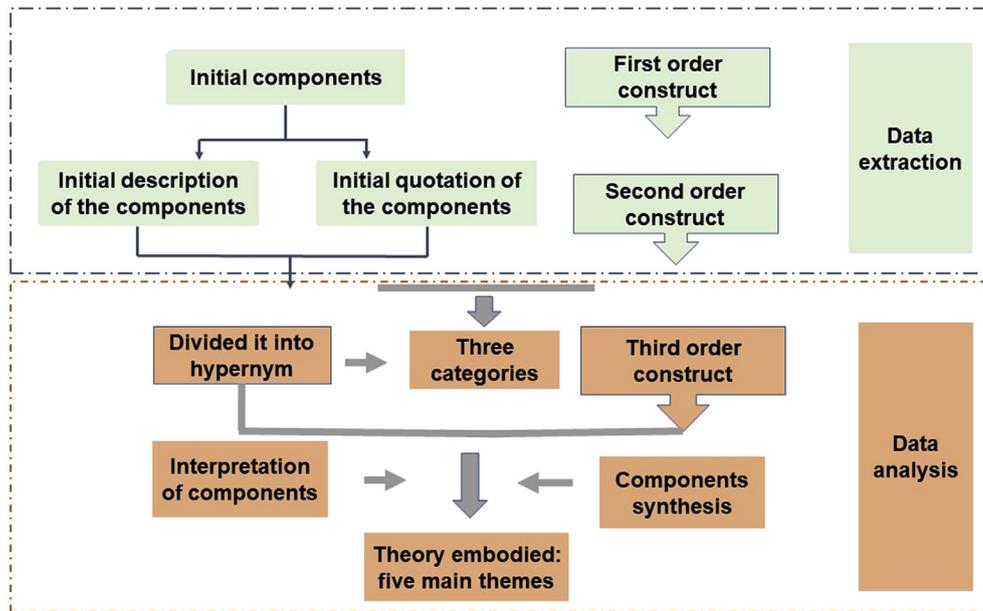


Fig. 2. Flow chart of the data extraction and analysis.

goal involved “detailed planning of what the mother would do, including a definition of the behavior specifying frequency, intensity, or duration and specification of at least one context, that is, where, when, how, or with whom.”<sup>4</sup>

**Herbal or expertise-based interventions** In our study, herbal or expertise-based interventions indicated TCM and acupuncture, respectively, which involved the delivery of physical treatment for patients by practitioners.

**Advice or guidance** During the process of the complex interventions, advice or guidance was not only provided for patients, but also for healthcare workers. “Counseling,” “education,” and “role modeling” were the main elements of this subcategory.

Providing healthcare worker counseling contained “providing instruction to patients” and the “method of providing healthcare worker counseling.” These components were “providing or planning professional symptom support,” “lifestyle advice,” “social interaction,” “inviting and sharing information,” “psychosocial advice,” “helping patients to make sense of their condition,” and “acupuncture concepts and the role of congruent explanations in the provision of advice.”

Providing or planning professional symptom support meant preparing patients to deal with side effects and offering self-care advice on possible side effects. “Inviting and sharing information” reflected the importance of two-way communication between practitioners and patients. “Acupuncture concepts and the role of congruent explanations in the provision of advice” were described within acupuncture care. It was argued that identifying the nature of the diagnosis was central to helping explain the diseases, and suitable terminology could help translate professional concepts into plain language. “Acupuncturists were explicit about the use of coherent and consistent explanations, referring to the Chinese medical model and a general ‘explanatory model,’ both built on concepts from acupuncture theory.”<sup>42</sup>

The methods of healthcare worker counseling included “face-to-face communication,” “meeting between the patient and intensive care unit consultant,” “telephone counseling,” “outreach counseling,” and “tips for counseling.” The tips focused on the simplicity of the language or questions.

Relevant codes were classified into educational content and

tools. Educational content indicated in both patient-education and healthcare worker-education. Education could be targeted at patients, staff, or even patients’ relatives. Education aimed to train healthcare workers to identify and respond, train family physicians to improve qualifications or communication skills. In addition, education was helpful for mental health and for patients’ understanding of their disease.

A group workshop was a common form of education. Educational was delivered via educational handouts, a manual, patient information brochure, a curriculum, educational DVD, and other education materials. In the process of education, psychoeducation techniques, communication and behavior change skills, or even simple content all contributed to the implementation process. For example, “talk down” was a component of the “Safewards intervention.”<sup>18</sup> This included de-escalation techniques, which were summarized in poster format. Staff members who were expert in techniques for conflict and containment spent some time explaining the poster.<sup>18</sup>

Patients were usually actively accompanied by peers who themselves suffered from diseases. An expert could show the person how to correctly perform a certain behavior; for example, in a class or on video. In this way, peers, formal or informal carers, or the expert served as a role model. As noted in the Baby Milk Intervention, this “models or demonstrates the behavior”; in this intervention, this involved demonstrating the correct method for formula-feeding.<sup>4</sup>

**Timing** The analysis revealed that timing was a component concerned with when to intervene (e.g., the phases of complex interventions, long- or short-term, early or late) and the frequency of implementation. As noted by a clinical social worker, “caregivers should receive long-term support from the beginning to the end.”<sup>17</sup>

**Setting** The setting indicated the place the complex interventions were implemented. All interventions required a physical environment. Some interventions were community-based complex interventions. A neutral, flexible, convenient, and private setting is considered to facilitate the implementation of complex interventions and communication between those involved. A suitable setting could facilitate the creation of social bonds. As Villeval reported, “choosing a neutral setting for the intervention to

foster a mix of populations from different territories.”<sup>20</sup>

**Monitoring and supervision** Some complex interventions needed “monitoring or supervision,” such as monitoring a care plan, monitoring symptoms, monitoring side effects, self-monitoring, or making guidelines for reflective supervision. One study reported that to prompt self-monitoring, participants were encouraged to record amount fed in a personal feeding plan.<sup>4</sup>

**Coordination** Complex interventions generally involved coordination of two aspects: coordination of care and coordination of interpersonal relationships. Care coordination emphasized establishing a coordination mode or structure of the complex intervention (e.g., liaison with ward-based staff to ensure equipment and community referrals were in place before discharge home).<sup>26</sup>

The relationship between patients and healthcare workers could be divided into three subcategories: relationship between patients and healthcare workers, relationship between healthcare workers, and relationship between patients. In addition to building a therapeutic relationship, healthcare workers also aimed to build trusting, harmonious, and supporting relationships, which helped to promote patient adherence. To achieve these goals, healthcare support and peer support were necessary.

Factors identified for healthcare support were social skills, including: “staff and patients knowing each other,” “clear mutual expectations and mutual help,” “communication skills,” “positive attitude of staff toward patients,” “conflict resolution,” “focal person support,” “reflection of counselor,” “perspective adoption skills” (i.e., the ability to analyze and structure the complex caregiver situations and guide the client through the process in an appropriate way), “engagement with their patients’ attitudes,” “capitalizing on immediate treatment effects,” “social media support,” and “support patient continuously and conveniently.”

For peer support, sharing experiences or recovery stories and playing a role model were the main methods to help patients. During the interaction with peers, social comparison was used, in which patients compared their experiences with those of mentors and other patients. Through this comparison, patients could develop a better understanding of their disease, which could also reassure patients because they could find emotional resonance with other people who had the same experience. As Stewart reported, many youths said they now realized “how a lot of people have it a lot worse” because of the support program.<sup>37</sup> Even adolescents who participated in that program only a few times affirmed that they benefited from comparing themselves with others.

**Evaluation and documentation** Some complex interventions emphasized evaluation and documentation. For example, the Baby Milk Intervention needed parents to provide feedback on their behavior, which included providing data about recorded behavior, as well as evaluating performance based on set criteria or the performance of others.<sup>4</sup> Documentation was a component of “Integrative Validation Therapy,” which indicated the nursing record of each resident contained their biography.<sup>21</sup> Some interventions did not highlight in the documentation of components reflecting their objective. For example, additional information about the impact of a critical illness on a patient is needed to provide to GPs as a form of a discharge summary, which was completed by the generic rehabilitation assistant.<sup>26</sup>

**Individual or tailored interventions** Complex interventions usually focused on each patient’s condition and treatment programs specifically designed for those patients. People felt strongly that programs should be tailored to the individual rather than taking a “one size fits all” approach. That meant goal setting was individual, and the information was specific. It also meant that adjustment was inevitable. For example, “adjusting one’s voice in volume, tone and pitch to the individual situation” or “adapting the

validation techniques to the individual abilities of the person.”<sup>21</sup> In this way, each patient’s requirement could be met:

*“Residents who require more time normally start lunch around half an hour earlier, thus allowing for individual support ...” (first order construct; Palese et al, 2018).*

*What qualifications should they have?*

**Practitioners’ personality traits** As patients were often in a low mood, they were keen to be understood, supported, and respected. Practitioners needed to put themselves in their patient’s shoes to understand the person. This required practitioners’ “unconditional appreciation of and respect for people,” “accepting patients’ subjective reality,” “normalization,” “preparedness for unexpected reactions (flexibility),” “keeping congruence,” “empathy,” “patient and equanimity,” and “providing general encouragement.”

These personality traits were helpful for understanding patients’ concerns, promoting a sense of normality, reducing stigma, and managing emotion, which acted to encourage, comfort, and reassure patients or break isolation. For this reason, these codes were categorized as psychological support. As noted by Krieger, some personality traits are needed to successfully implement and improve acceptance of caregiver support, such as appreciation, empathy, tolerance, and open mindedness.<sup>17</sup> Normalization meant that when patients recognized other people had the same problem, they tended to sense they were normal thereby reducing stigma.<sup>37</sup> Congruence (genuineness) meant to be honest with patients and therefore avoid the “therapeutic lie.”<sup>21</sup>

**Skills and capabilities** To successfully implement complex interventions, healthcare workers’ skills and capabilities were also important. “Diagnostic and needling skills,” “self-incentives,” “behavior for comfort/reassurance,” and the “perception of healthcare workers” were identified as skills and capabilities.

Perception of healthcare workers was one of the most important abilities. It contained “perception of feelings and motivation,” “observation of symptoms and behavioral disturbance,” “recognition of other diseases and symptoms,” “generalizing feelings and motivation,” and “search attitude of residents.”

*What should patients do?*

**Patient preferences** Patients were the host of the disease and therefore important subjects of medical treatment. Patients owned self-preference, self-value, and power to defeat diseases. Some complex interventions emphasized individual or tailored intervention. Considering patients’ preference meant offering patients choices so their wishes could be respected. Practitioners should also know what patients focus on and the patient-centered goals they want to achieve or their expectations of the effects. As highlighted by Lewis, program users should have the ability to choose from a menu of options on delivery and guidance to suit their preferences.<sup>34</sup>

**Patients’ adherence** Patients’ adherence was reflected in compliance with doctors’ orders, which was manifested in compliance with the process of treatment to promote the effectiveness of the treatment.

*“Most patients have good compliance. Sometimes some patients who have kidney disease should behave properly, that is to say, they must pay attention to it. But some of them don’t pay attention to it. In fact, they suffer a lot.” (first order construct; Palese et al., 2018)*

**Self-care and support** “Self-care and support” meant facilitating the active engagement of patients in their own recovery, including planning, design, implementation, and evaluation.

“Empowering patients” meant giving patients the right to know, to participate and to manage, which contained self-help and involved in the decision-making. It was shown by the components of “prompts intention formation” or encouraging the person to decide to act or set a general goal, “enhancing the population’s participation at all intervention stages,” “engaging patients to actively take up lifestyle advice,” “facilitating the active engagement of patients in their own recovery,” “engagement with their patients’ attitudes,” and “changes to behavior and lifestyle.” In other words, empowering participants could arouse people’s initiative and enthusiasm for fighting disease.

**Patients’ self-value** Patients were also willing to provide support to others. A study about an online peer support intervention indicated that providing support to others seemed to increase adolescents’ confidence and self-esteem.<sup>37</sup> This reflected that patients not only seek help from others, but can also help others, which was a way for them to realize their personal values. The components of “reciprocity of support,” “hope held in the work aspect of the role,” and “enhancing self-efficacy and self-worth” demonstrated this demand by patients.

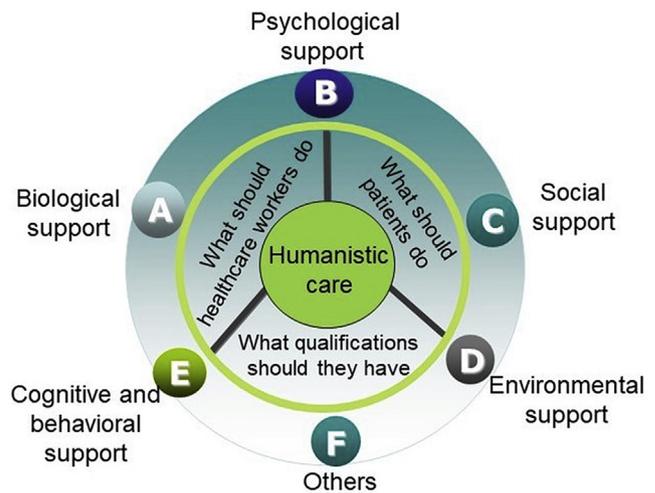


Fig. 3. Model for components of complex interventions.

*Components synthesis: theory embodied by complex intervention components*

When it came to components synthesis, five possible themes emerged: biological support, psychological support, cognitive and behavioral support, social support, and environmental support. Table 1 shows a summary of the main themes, definitions, and description identified in the studies included in the synthesis. However, as Fig. 3 shows, these themes were not always independent; they were interconnected and sometimes intertwined. In the healthcare domain, psychological support, cognitive and behavioral support, social support, and environmental support all

served for biological support. Cognitive and behavioral support for patients or healthcare workers was always reflected at all stages of the implementation. Fig. 3 shows the model for components of complex intervention.

Cognitive and behavior support, environmental support, and social support often interacted. As stated by Wade, the social communication of human beings, either with people or objects, is goal oriented.<sup>46</sup> In the social context, a person observes the behaviors of other people and interprets the meaning of these behaviors based on the role they played and interaction with others at that moment. The person had their own preference when they

**Table 1**  
Summary of the main themes, definitions, and descriptions identified in the studies included in the synthesis.

Main theme	Definition	Description	Papers that refer to main theme
Biological support	Components related to patients’ physical health.	“Acupuncture” or “Chinese medicine herbs” were main components for biological support. “Providing or planning professional symptom support,” “lifestyle advice,” “capitalizing on immediate treatment effects” and “diagnostic and needling skills” were also considered as biological support.	3, 29, 31, 33, 35
Psychological support	Components related to persons’ psychological health.	“Psychosocial advice,” “psychoeducation” and “practitioner’s personality traits” were obvious for psychological support. “Health workers’ initiative” was considered as psychological support for its “self-incentives” of health workers.	7, 8, 11, 12, 15, 18, 25, 28
Social support	Components related to the relationships build in medical process.	Relationships building involved communication or coordination between people. Components reflecting communication or coordination were categorized into social support, such as “counseling method,” “inviting and sharing information,” “care coordination” and “interpersonal relationships”.	2, 5, 6, 7, 8, 10, 12, 16, 17, 18, 20, 23, 27, 28, 30, 32, 33
Environmental support	Setting of the complex intervention.	All interventions require physical environment. Even some interventions are named as community-based complex interventions. After all, choosing a neutral, flexible, convenient and private setting facilitates the implementation of complex interventions.	2, 4, 7, 10, 32, 33
Cognitive and behavioral support	Patients or healthcare’s comprehension about diseases, or participants’ behavioral changes for health-well.	“Tips for counseling,” “helping patients to make sense of their condition,” “acupuncture concepts and the role of congruent explanations in the provision of advice,” “patient education,” “healthcare worker education,” “perspective adoption skills,” “evaluation,” “perception of healthcare workers” and “patients’ self-value” all could promote patients or healthcare’s comprehensible for diseases. “Patient preference” was included as preference was closely related to humans’ cognition. “A role model,” “tailoring intervention,” “behavior for comfort/reassurance,” “patients’ adherence” and “self-care and support” were correlated with changing behavior.	1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 16, 17, 19, 21, 22, 23, 24, 25, 26, 27, 28, 29, 31, 33, 34
Other components	Components that cannot be categorized into the above five themes.	Such as “assess the condition,” “goal setting,” “documentation” and “monitoring and supervision,” were part of the implementation process. It was not appropriate to classified them into the above five main themes.	1, 3, 4, 7, 11, 14, 16, 17, 18, 26, 30

exercised choices or evaluated the quality of life based on their actions. They had their own standard of measurement (e.g., social position, money, interpersonal relationships).<sup>45</sup> Interpersonal relationships were also important in the area of healthcare. One acupuncture practitioner explained the contribution of immediate treatment effect to building a harmonious relationship:

*“The simplest way to get that is to deliver results, so that the patient feels different after your treatment, they know something’s happened, they think well this is interesting, this is really going to help and that immediately creates a big amount of bonding, but that’s I think the sort of strongest factor, a successful relationship evolves out of successful treatment.” (first order construct; MacPherson, Thorpe, & Thomas, 2006)*

The theory embodied by complex intervention components reflected the importance of “treating patients as human beings, not just people who got sick,” which is advocated by humanistic care.

## Discussion

This study synthesized the components of three kinds of complex interventions in healthcare: self-help interventions, peer-support interventions, and healthcare worker interventions. Three categories of components were developed and five main themes emerged from the components’ synthesis. These five themes were interrelated and inseparable. This study indicated that when constructing complex intervention elements, researchers should consider both implementation and humanistic characteristics, including biological, psychological, social, cognitive behavioral, and environmental support.

The transformation of the medical model from the biomedical model to biological-psychological-social-environmental-spiritual model emphasized personality, social attributes, and the interaction between humans and their environment. Individual differences determined the individualization of diagnosis and treatment. Individual differences were embodied in biological differences (genetic characteristics, metabolism, and physiology) and differences in personality, psychology, and values.<sup>45</sup>

Healthcare workers understand that health and diseases are influenced by biological, psychological, and social factors.<sup>46</sup> The biopsychosocial model has been widely accepted in research on complex interventions.<sup>46</sup> This model is closely related to health psychology, which examines the interaction between psychology, behavioral, biological, and social factors.<sup>47</sup> It may also help physicians to better understand their patient from a holistic perspective, which includes “psychological and medical aspects” and “psychological and sociological well-being.”<sup>47</sup>

Because the themes we extracted were interrelated and inseparable, the codes were movable and flexible. For example, positive social interactions not only played an important role in psychological health, but were also essential to biological health. As humans are complex organisms, human health should also be considered across multiple dimensions. This reflects the essence of humanistic or patient-centered care.

In addition, the outcomes for complex interventions were also of concern, as only a few studies reported outcomes. In addition to biological indicators, psychological and social benefits of the intervention were recorded, such as patients becoming active participants in their care and improved quality of life<sup>14</sup> and self-efficacy,<sup>16</sup> how participants perceived the intervention,<sup>19</sup> or participants’ satisfaction in general.<sup>21</sup> However, it is important to note that although we discussed criteria for adequate metaphors (themes) and the appropriate form of translations, the interpretive paradigm means that any interpretation, metaphor, or translations

was only one possible reading of that studied. Other investigators would have other interpretations.<sup>7</sup>

As this study incorporated all types of complex interventions, this model can only be a reference for clinical implementation or clinical trials of complex interventions. The specific application should be determined according to the type, location, and environment of interventions.

This study was a part of a project to evaluate the efficacy of complex interventions, which followed the methodological standards established by UK Medical Research Council. This paper was an attempt to synthesize the therapeutic components of the complex interventions in healthcare. The potential audiences who are interested in this synthesis are practitioners, clinical investigators, and social medicine researchers in conventional or alternative medicine. For practitioners, the components of complex interventions identified here could help ensure their clinical practice is comprehensive. For clinical investigators interested in evaluating complex interventions, in this study offers a biological-psychological-social-environmental-cognitive behavior model for developing complex interventions. Social medicine researchers may be interested in the social factors that influence health we described. This study represents the first steps in exploring the definition of complex intervention elements.

This study incorporated all types of complex interventions and heterogeneity was inevitable in terms of diseases and components of interventions.

## Conclusion

There are a range of complex interventions in healthcare. We showed that the components of complex interventions embodied the biological-psychological-social-environmental-cognitive behavior medical theory, which may affect the development of outcomes for testing these interventions. Further systematic research on the outcomes of complex interventions is needed.

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## Declaration of competing interest

The authors declare that they have no conflict of interest.

## CRediT authorship contribution statement

**Sisi Ma:** Conceptualization, methodology, data curation, formal analysis, and writing – original draft. **He Yu:** Conceptualization, methodology, formal analysis, and writing – review & editing. **Jianping Liu:** Conceptualization, project administration, supervision, and funding acquisition. **Ning Liang:** Data curation and validation, and writing – review & editing. **Sijia Zhu:** Data curation, software, and validation. **Xun Li:** Software, formal analysis, and methodology. **Nicola Robinson:** Methodology, funding acquisition, and writing – review & editing.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jtcms.2020.04.003>.

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