Applying Meta-Theory to Qualitative and Mixed-Methods Research: A Discussion of Critical Realism and Heart Failure Disease Management Interventions Research

Saleema Allana¹ and Alexander Clark¹

Abstract
Meta-theory refers to broad perspectives, which make claims regarding the nature of reality. Meta-theories philosophically underpin research and practice. Despite this centrality of meta-theory to research and practice, research studies seldom have a strong articulated philosophical basis. There are persuasive philosophical arguments for invoking meta-theory in qualitative and mixed-methods research. We argue that selecting and applying a particular meta-theory is a matter of personal expression and historicity. In this article, we describe the meta-theory of critical realism (CR), which underpins our research around complex heart failure disease management interventions. CR posits that reality is mind independent and views this reality via a stratified ontology. Its explanatory focus, generative logic, multifactorial and open systems approach, and its openness to a variety of methods make it a viable meta-theory for research in a variety of disciplines, utilizing qualitative, quantitative, and mixed methods. CR hermeneutics, ethnographies, grounded theories, mixed-methods studies, and critical realist reviews follow the meta-theoretical assumptions of CR; these are extremely useful in exploring complex interventions holistically, including their components, contexts, and mechanisms.

Keywords
meta-theory, critical realism, qualitative and mixed-methods research, complex intervention research, heart failure disease management interventions

What Is Already Known?
Critical realism (CR) has been known as a meta-theory that underpins research and practice. Its assumptions of open systems, generative logic, agency and structure-related factors, and its methodological eclecticism have been widely acknowledged and appreciated. Health researchers have begun utilizing the meta-theoretical underpinning of CR.

What This Paper Adds?
What is missing in the literature is how a meta-theoretical orientation is developed. This is the first article to present reflexive accounts of the authors as to how their meta-theory evolved, which would help novice researchers to reflect over their meta-theoretical orientation. In relation to CR, a gap persists in the literature as to how different research methods operate under the meta-theory of CR. This article discusses in detail various qualitative methods, mixed methods, and critical realist reviews, underpinned by the assumptions of CR.

Applying meta-theory to qualitative research is important, yet challenging. This article illustrates how a meta-theory can be applied to qualitative and mixed-method research using the example of CR. The article will demonstrate for others, how to apply meta-theory to their work and appreciate more the nuances, compromises, and tensions in doing so.

¹ Faculty of Nursing, The University of Alberta, Edmonton, Alberta, Canada

Corresponding Author:
Saleema Allana, Faculty of Nursing, University of Alberta, Edmonton Clinic Health Academy, Edmonton, Alberta, Canada T6G 1C9.
Email: smallana@ualberta.ca
**Meta-Theories: What They Are and Why They Matter**

Meta-theory refers to broad perspectives, which make claims regarding the nature of reality. Meta-theories overarch many other theories, notably mid-range theories. Well-known meta-theories include Marxism, constructivism, positivism, and postpositivism. As such, meta-theory addresses fundamental beliefs about the world that guide an individual’s actions and can be termed to be paradigms or worldviews (Lor, 2011). Accordingly, meta-theories philosophically underpin research, practice, and substantive theory in any field of study (Sousa, 2010).

In qualitative methods, theory is a common concept invoked both in terms of types of knowledge that can be generated (notably through grounded theory) or to inform how phenomena are understood and to guide procedures around literature reviews, data collection, analysis, and knowledge translation. Meta-theory can also be used to underpin practice—for example, in relation to health care. The meta-theoretical orientation provides the health researchers with a particular ontology and epistemology, for investigating their research questions (Lor, 2011). Despite this centrality of meta-theory to research and practice, research studies seldom have a strong articulated philosophical basis (Prestwich et al., 2014). This raises the issue about how researchers can incorporate meta-theory in their research. Is invoking meta-theory in research a matter of personal expression or practical choice? How can and should meta-theory be expressed in the specifics of research? First, we will consider, is meta-theory necessary to be addressed in qualitative and mixed-methods research?

**Meta-Theory and Research: A Matter of Choice?**

There are persuasive philosophical arguments for invoking meta-theory in qualitative and mixed-methods research. Aspects of our past and our real selves shape our lens of viewing the world, which leads us to relate well to a particular meta-theory. This argument, based on Heidegger’s notion of historicity, views our past as uniquely attached to our “being” or our “self”, and has the potential to influence our future choices (The Blackwell Dictionary of Western Philosophy, 2004). Therefore, it is extremely important for the researchers to be reflexive about their past experiences, their values, and beliefs, so that they can explore the meta-theory that best fits with their way of looking at the world. This article is the first to report the exploration of a meta-theoretical orientation by us as researchers; the article also illustrates how the meta-theory of CR guides qualitative and mixed-methods research around complex heart failure disease management interventions (HFDMIs).

It is important too, to specify the tenets of any particular meta-theory that one intends to use. While we frame our research around complex HFDMIs, CR appears to be the most appropriate meta-theory for underpinning our research, philosophically. To illustrate this, we will describe the philosophical assumptions and key tenets of the meta-theory of CR. We then present our reflexive accounts in search of our own “historicity” that has led us to this meta-theoretical orientation. We then describe the philosophical underpinning provided by CR to shape our intervention research around HFDMIs. Finally, we discuss the qualitative and mixed methods that can be utilized to study complex HFDMIs, using the meta-theory of CR.

**CR and Its Outlook of Life**

CR posits that reality is mind independent and views this reality via a stratified ontology which depicts three distinct but interconnected layers of reality, the realms of the real, actual, and empirical (Schiller, 2016). The real domain pertains to causal powers and potentialities that have the potential to generate observable or unobservable events in the actual domain. These underlying powers can explain events and outcomes in the world and they have existence and power independent of the human thought and awareness (Bhaskar, 1998). Mechanisms in the real domain are not directly observable but exist and can exercise power independent of human perception (Schiller, 2016). In the actual domain, events occur, whether or not these effects are experienced by humans. Events take place in the actual domain and have existence irrespective of whether these are perceived by humans (Schiller, 2016). The realm of the empirical refers to human perception and social processes, including seemingly formal inquiries, such as scientific investigation and processes. Humans are only capable of inhabiting the empirical domain—and as such their claims to knowledge are always fallible, that is, these can never be certain (Clark, Lissel, & Davis, 2008).

To illustrate the ontological assumptions of CR, let us consider an example. For instance, an HFDMI designed for the HF patients resulted in improved clinical outcomes. Since improvement in clinical outcomes is a perceptible experience, this may be considered as a part of the empirical domain. Now, as per the CR ontology, though events are experienced in the realm of the empirical; however, they actually occur in the actual domain, whether or not these are perceived by humans. When this particular HFDMI was explored further, it was identified that it actually motivated the patients significantly to be compliant with their medications and prepared them well for continuous symptom monitoring and management. This was the event that probably occurred in the realm of the actual domain, and whether or not the patients were aware about this motivation and preparedness, it led them to take better care of themselves. Another assumption of the CR ontology suggests that all these events taking place in the actual and the empirical domains are a result of the causal mechanisms existing in the real domain. Process evaluation of this intervention revealed that the one-on-one communication of the health professionals with the patients, and their prolonged engagement, likely led to enhanced motivation and preparedness to deal with the symptoms. Thus, one-on-one communication of patients with health providers and prolonged engagement are the underlying
mechanisms that took place in the real domain, which led to motivation and preparedness of patients in the actual domain, eventually leading to observable improvement of clinical outcomes in the empirical domain.

Key Tenets of CR

Explanatory Focus
CR seeks primarily to explain outcomes—it is an explanatory ontology. This reflects the focus of CR primarily on aspects of the real—thus called, because powers and potentialities in the realm of the real exist and exert a real influence on outcomes in the realm of the actual, irrespective of whether this is known or not. Relatedly, CR is appropriate to explore research questions related to “why” phenomena occur. In intervention research, this means moving beyond merely measuring outcomes—whether an intervention works or not—to understand why interventions have the outcomes that they do. In short, why interventions work (Pawson & Tilley, 1997). As we will see, this is not only useful but also ontologically justified.

Successionism Versus Generative Logic
CR views causality as being generative rather than, like positivism, successionist. A successionist approach to conceptualizing causality implies a linear approach, which suggests that an intervention produces a particular outcome, without any reference to the context in which the intervention occurs or the mechanisms through which its effects are realized. A successionist approach is more apt for the experiments in physical science where experimental controls are in place to exclude or control the numerous factors that can affect causality in a particular situation. However, given complex health interventions are delivered, enacted, and received in social contexts, these situations cannot be artificially controlled (Pawson & Tilley, 2001). In contrast to successionism, CR’s generative model of causation suggests that social and health interventions are always embedded in sociocultural contexts in which outcomes are generated by the complex interplay of factors associated with the people providing and receiving the intervention, the place(s) in which the intervention is provided, the components and mechanisms of the intervention (Clark, MacIntyre, & Cruickshank, 2007; Pawson & Tilley, 2001). Usually, small changes in one or more factors within this generative conception could lead to very large changes in outcomes. Subsequently, a health or social intervention alone, without any reference to its context, cannot be deemed effective or ineffective. Therefore, studies guided by the meta-theory of CR should seek to explore and account for the wide range of individual, intervention, and contextual factors associated with the intervention.

Explanations Rooted in an Interplay of Agency and Structures
This generative model of causation posits that both agency and structural factors can influence outcomes (Clark et al., 2008). Agency refers to the more microfactors that reside primarily in individuals; while, structures imply external contextual factors outside of individuals, such as cultural and social norms, places, or structures that may oppress particular groups, such as women, ethnic minorities, or those of low-socioeconomic status. CR proposes that events or outcomes occur because of an interplay between individual factors such as attitudes, beliefs, and values, and contextual factors such as social processes, cultural norms, and so on (Clark et al., 2008). This has important implications for social and health sciences research, which must explore a wide range of individual and contextual factors, in order to determine from a critical realist perspective, as to what influences outcomes from an intervention? (Clark et al., 2007).

Multifactorial Causation in an Open System
Invoking agency and structural factors in this interplay and generating model yields an ontology that is natural, multifactorial, and multilevel. In short, it is complex. Pawson and Tilley (2001) label this conception to be that of an open system—in contrast to the closed system approach that dominates both the physical sciences and the randomized controlled trials. These closed system approaches assume that interventions have positive effects in accordance with regular, law-like regulatories. Interventions work or don’t work—and the benefits of interventions that work well in some setting should be transferable to other settings. This follows because context is assumed to be controlled for or irrelevant in the closed system, while interventions are assumed to be inherently effective or ineffective. Conversely, CR assumes an open systems approach in which context has the potential to influence outcomes, interventions are enacted in systems involving multiple factors associated with the intervention, context, and people involved. These factors can themselves influence each other in generating ways to be creative and unexpected but powerful effects on outcomes (Clark, 2012). Because systems are open, fluidity and change is usually common in these systems. Interventions that are found to be effective in one setting may not demonstrate similar benefits in another setting, because intervention effects don’t just depend on the nature of interventions, but also the people involved and aspects of context (Clark, 2012). Intervention research adopting this open systems approach should explore the nature of interaction of these multiple factors, as to know what (intervention) works best for whom (populations), where (settings), and why (mechanisms).

Openness to Multiple Methodologies and Interdisciplinary Research
Thus far, these tenets are ontological—referring to aspects of being rather than of method. Indeed, as a meta-theory, CR is more an ontology than methodology: It focuses primarily on the nature of reality and does not firmly prescribe how to capture or know that reality. A key benefit of CR associated with this primacy on ontology is in the meta-theory’s ability to
accommodate diverse research methods, notably qualitative and quantitative research, including mixed methods.

The explanatory focus, that defines CR, necessitates an openness to quantitative, qualitative, and mixed-methods data and study designs (Clark et al., 2008). Given reality is independent of the mind, different methods can be used to try to capture complexities of that reality—without the proviso that because the realm of the actual and real can never be truly known, all data (and indeed science) can only ever be seen as being an account of reality—and cannot be equated with reality itself.

CR research methods should be guided by the research questions and the complex phenomena being explored (Pawson & Tilley, 2001). This diversity in methods is due to CR’s search for explanations of outcomes in complex systems, which requires various methods of data collection and analysis, to understand the dynamics of an array of contributing factors and mechanisms. As CR does not esteem any one data type over another (Clark et al., 2008), both qualitative and quantitative data can be used in CR inquiries.

Further still, given the primacy of reality to CR inquiry, the meta-theory implies that reality takes precedence over disciplinary positions—which may serve to distort, impoverish, or otherwise narrow accounts of reality (Sayer, 2000). As such, CR encourages researchers to focus on the complexity of the phenomena they are exploring beyond the disciplinary perspective(s) they may have (Clark et al., 2008). This is termed to be a postdisciplinary approach (Sayer, 2000).

CR in Context

The two opposite philosophical orientations about the nature of reality have been positivism and constructivism. On the one hand, positivism claims for the absolute truth, regularities, and causal laws, whereas, on the other hand, constructivism argues for the reality which is relative to one’s position within the social system (Cruickshank, 2012). CR found its way in between the two extremes of objective, mind independent and subjective, mind-dependent nature of reality assumed by positivism and constructivism, respectively. It assumes that the world is a stratified open system where unobservable events interact to produce the observable events (Cruickshank, 2012). The beauty of CR is in its assumption about the nature of reality, that is, though it assumes that the reality is mind independent, however, it also acknowledges the value of social explanation (Clark et al., 2008). Although the dual and sliding nature of CR’s ontology has been critiqued (Cruickshank, 2004); however, this ontology makes CR adaptable for those who are interested in explaining the events, utilizing science and perceptions (Cruickshank, 2012). This means that CR can successfully accommodate the hermeneutical perspectives associated with constructivism and the mind-independent reality, traditionally ascribed to positivism (Elder-Vaas, 2012).

Reflexivity for Explaining Meta-Theory Underpinning Our Research

Meta-theories should not only be ontologically defensible but should also be a product of the historicity of the researchers involved. For example, feminist researchers may ground themselves in this meta-theory because of personal, ethical, or practical reasons related to emancipation of women.

To clarify what this historicity looks like, in this section, we demonstrate as to how our personal selves (our past experiences, beliefs, and values) led to our meta-theoretical orientation.

Reflexive Account by Author 1

For me, CR carries a deep meaning and a long history. I realized the importance of explanations at quite an early age. I remember being in a school initially, where knowledge was transferred to us to be remembered, but our whys were never attended to. As I moved to Grade eight, I fortunately got a teacher who knew the importance of answering the whys of her students. I distinctly remember her encouraging each of us, to not only get contented with the description of phenomena, rather, to go beyond and ask why did this happen or why did this not happen? Her encouragement to seek for explanations ignited my curiosity to understand every phenomenon in depth with its underlying mechanisms. As I grew up, I kept on looking for explanations of the phenomena encountered in everyday life, ranging from “why is it sunny some days and not on other days?” to “why are people settling out of the country so rapidly?”

Our meta-theoretical orientation is not only influenced by our personal values, but these are also shaped up by our professional values. My ability to look for the underlying mechanisms behind the events grew even more while working as a nurse at a coronary care unit. At each step, while dealing with my patients, I utilized my explanatory thinking to understand and to make others understand as to why this happened or why did this not happen? Sometimes it was as simple as looking for the explanation behind a phlebitis or a fall, the other times, it was as complex as identifying the underlying reasons for an unsuccessful cardiopulmonary resuscitation or an ineffective mechanical ventilation.

It was within cardiology nursing practice that I realized the power of context in shaping up and explaining health outcomes. I came across patients who presented with massive myocardial infarctions but survived, as they presented to the hospital timely, versus those who presented with relatively less serious infarctions but could not survive, due to delayed arrival to the hospital. When explanations were sought through my master’s thesis, many contextual realities seemed to play their part such as the time taken to report the symptoms, if the patient went to a general physician (GP) before coming to the hospital, if the GP identified the heart attack symptoms immediately and referred the patient to the hospital, if the ambulance was available at the GP’s clinic, if the patient was accompanied by
someone who could help him in reaching the hospital, if there
was heavy traffic while the patient was being transported to the
hospital, and so on.

My career as a nurse academic enhanced my explanatory
thinking further and gave me an opportunity to understand the
contextual factors and their effects on outcomes even better. I
taught about 100 students in each class, and each of these
students performed differently. When I got to analyze their
academic performance, I looked for the underlying explana-
tions. There were always some interacting factors that led the
student to perform in a certain manner, such as their relation-
ship with parents and siblings, their relationship with peers, the
peer pressure, their personality type, their motivations and
aspirations, and their intellectual abilities. I used to get amazed
at the influence of the context in determining the students’
academic outcomes. Very soon, it became an important profes-
sional value for me to look at situations within the broader
context in which they existed, whether it be student-related
or patient-related situations, and to look for the contextual
influences that affect the outcomes.

Reflexive Account by Author 2

I grew up in a house dominated by science. My father was and
is an avid scientist—having previously worked as a nuclear
safety physicist for his career in Scotland. In nuclear safety,
the existence of a mind-independent reality is essential. Believ-
ing a nuclear power station is safe and ensuring it is via good
science are two distinctive claims to knowledge. If calculations
are flawed and a radiation leak occurs—whether we believed
the reactor to be safe or not is incidental. Further, radioactivity
is real—even when we cannot readily perceive this radiation
with our senses. This suggests that there is indeed a hidden
world beyond our perceptions that has an existence irrespective
of whether we believe or recognize this. Reflecting his scien-
tific leanings, our house was overflowing with books on sci-
ence, engineering, and technology. While this background
could have rendered me into a hard positivist—I was also
drawn to the social sciences—an appreciation of the cultural
and the social—of the messy and the complex. A hard view of
science struggled to capture the ambiguity and diversity of
social, economic, and cultural aspects of the world. My early
career in nursing reinforced to me that as a professional—bio-
logical realities were mind independent—tumors existed in
patients’ bodies irrespective of whether they knew or believed
this—but also that social, cultural, and personal aspects were
important too. The framing, perceptions, and beliefs individu-
als had influenced their anxiety, stress, and behaviors. Nursing
offered the perfect axiom to draw the biological, social, and
cultural together via its holism. Nursing assumed that emanci-
pation was possible, and accordingly that the individual, if
given the right support and resources, could successfully trans-
cend difficult circumstances. CR aligned with my professional
values and could adequately subsume biological, social, and
cultural factors influencing health outcomes—and avoided the
more dogmatic and narrow natural conclusions of the positions
of constructivist and positivist alternatives.

Role of CR in Shaping Our Research Around
Complex HFDMIs

What then are the full implications of this CR meta-theory for a
focused program of research? Our current research explores the
effectiveness of HFDMIs. Heart failure (HF) is the most costly
chronic condition affecting high-income countries, affecting
around 10% of all people aged over 65 years and up to 40% of
people aged >85 years (Blair, Huffman, & Shah, 2013). The
syndrome is characterized by the heart’s inability to meet the
demands of the body. This insufficiency reduces the perform-
ance of all the body’s systems and results in symptoms of
breathlessness, fatigue, fluid retention, and cognitive impair-
ment. The wide prevalence of HF is related to the relative
commonality of its causes: in high-income countries, the syn-
drome results from myocardial infarction (or heart attack) or
chronic hypertension (high blood pressure). People with HF
can live longer and better lives if they consume appropriate
medications at the right dosages and frequency and engage in
effective self-care.

HFDMIs refer to the interventions provided to people with
HF to promote effective self-care. Typically, these interven-
tions are composed of different components. HF self-care inter-
ventions, reflecting past research, focus on promoting effective
management around medications, alcohol/fluid restriction,
weight management, smoking cessation, physical activity, and
timely help seeking (Buck et al., 2018). All these strategies
reduce the size of demands the heart places on the body,
increase the heart’s performance, or promote rapid support
during the early stages of symptom exacerbation.

HFDMIs are very diverse: they vary widely in type and
context: from interventions provided in-person in hospitals or
clinics, to those provided in the home remotely via telephone,
e-mail, Internet, text messages, or apps. Interventions can be
provided by a wide range of different health professionals such
as nurses or physicians or by multidisciplinary teams. From a
CR perspective, the outcomes of these interventions are gener-
ated not only by the interventions (such as via the interaction
between intervention components) but also by their interaction
with the “context” of intervention delivery and the providers
and recipients of the interventions (Clark & Thompson, 2010).

Evaluations of HFDMIs—including those from randomized
trials—have been found to be consistently inconsistent—in
both trials and meta-analyses of trials (Clark, Savard, &
Thompson, 2009; Clark & Thompson, 2010; Savard, Thomp-
son, & Clark, 2011). Meta-theories such as positivism struggle
to subsume such demonstrable inconsistencies—and usually
attribute the wide variability in findings to issues around
method—notably intervention fidelity, study differences in
populations, outcomes, and comparison groups (Clark et al.,
2009). Seldom is ontology invoked. This may be because to
do so would undermine the ontological basis that has buttressed
past research efforts; if interventions cannot be assumed to be
inherently effective, this undermines the careers, guidelines, and practices built of this very basis (Clark & Thompson, 2010). However, the data do appear to suggest that interventions do have markedly different effects across contexts. Merely, carrying out more trials on the same flawed meta-theoretical basis is unlikely to yield markedly different conclusions. Instead, a different focus on a different basis is needed. Via its explanatory focus on complexity, CR is well placed to do this.

Given the presence of complex interactions within and around HFDMIs, CR is a highly appropriate worldview and it provides the most appropriate meta-theoretical underpinning, for exploring this research question.

CR’s Methodological Eclecticism and Research Around Complex HFDMIs

What then methodologically does research into HFDMIs grounded in CR look like? As explained earlier, CR can embrace diverse research methods and realizes their value in explaining complex phenomena. We now explore how CR can guide qualitative, quantitative, and mixed-methods research to understand the complex HFDMIs and their effectiveness.

Qualitative Studies Uncover the Mechanisms Underlying Complex Phenomena

Qualitative studies seek to understand the complex phenomena through the participants’ experiences and thus can explicate the perceived explanations, mechanisms, and the complex relationships that may not otherwise be identified through quantitative research (McEvoy & Richards, 2006). This is because these phenomena may be unknown unknowns—which go unmeasured due to lack of knowledge or known unknown—factors that are not measured because these are immeasurable.

Qualitative research can be used to understand many aspects of the complexity of HFDMIs: from understanding more about the patients’ involvement in HFDMIs to the influence of context. Yet qualitative research has not been widely utilized in complex health intervention trials. A systematic review of complex health interventions revealed that only some of the investigators utilized qualitative components along with the trial, to explore more about the intervention qualitatively. Their findings also indicate that those qualitative studies lacked theoretical underpinning and there were issues with the methods. Also, the qualitative findings were not properly triangulated with the quantitative findings of the trial (Lewin, Glenton, & Oxman, 2009).

When qualitative research is underpinned by the meta-theoretical assumptions of CR, this makes it different from the qualitative research, which is underpinned by constructivism. Based on the CR’s notion of stratified ontology and mechanisms that operate in the real domain to produce events that can be experienced in the empirical domain, CR qualitative research aims to explore the mechanisms that make complex interventions effective for the patients. This is different from the qualitative studies rooted in constructivism that are more interested in describing participants’ experiences. Also, underpinned by the CR’s assumptions, health care is understood as an open system where many different factors interact to produce patient outcomes. Some of these factors are agency related, that is, individual factors, whereas others are structure-related factors such as culture, organizational norms, resources, setting, and so on. Under these assumptions, the CR qualitative studies seek to understand both agency- and structure-related factors that affect intervention outcomes. Patients’, health-care professionals’, and family members’ experiences and observations help in qualitatively understanding these factors in the open system of health care. This characteristic of CR qualitative studies indicates toward the generative logic, that is, understanding the complex interplay of contextual factors, which is at the heart of CR.

Hermeneutics. While CR views reality as being mind independent, this is entirely compatible with recognizing the existence of hermeneutical dimensions of human existence and a constructivist vent (Elder-Vass, 2012). As such, constructivism itself ceases to be the only alternative to positivist meta-theory because constructivism is also compatible with CR meta-theory. CR hermeneutic studies seek to understand the mechanisms deriving phenomena that have been experienced by the participants rather than merely understanding their experiences (Danermark, Ekstrom, Jakobsen, & Karlsson, 2005). It is different from constructivist hermeneutic studies, which emphasize understanding human experiences as a whole. Research into health interventions can benefit from hermeneutics, mainly because of the hermeneutics’ focus on understanding the phenomenon through people’s experiences (Thirsk & Clark, 2017). Therefore, in case of complex HFDMIs, hermeneutics can be extremely useful to understand these interventions and their complex mechanisms of delivery, through the experiences of the patients for whom the intervention is intended, and the experiences of the health professionals who are involved in intervention delivery (Thirsk & Clark, 2017). CR hermeneutic research could, for example, focus on what can be learnt about the intervention and its mechanisms by utilizing the participants’ experience of going through the intervention?

Ethnography. Ethnographic methods involving prolonged engagement in the selected setting can be very useful for the process evaluation of health interventions (Morgan-Trimmer & Wood, 2016). Ethnographic data collection methods, notably observations, are powerful tools to explicate the context of intervention delivery, and the causal pathways that make those interventions work—that is, the cultural and contextual factors that affect the effectiveness of interventions and the perceptions of participants about the intervention. For instance, ethnographic work could observe the interactions between health professionals and patients during intervention delivery, family members’ participation in intervention delivery, or patient’s beliefs that may affect their participation in the intervention.
This would help evaluate interventions holistically, along with the generative effects produced by an interaction of agency-related (patient and family related) and structure-related (health system and health professionals related) factors, rather than measuring intervention effects in isolation. These interactions are important to be explored because these determine participants’ motivation and thus whether they continue their participation in the intervention or not. For instance, a cardiac patient who has strong family support and whose family motivates him to participate in the cardiac rehabilitation intervention will be more motivated to attend the rehabilitation than someone who lacks strong family support. Similarly, a patient who has experienced positive and therapeutic communication by health professionals during the health education sessions will be more motivated to attend these sessions, versus someone who has had negative experiences with health professionals.

Indeed, CR ethnographies, underpinned by the meta-theoretical assumptions of CR, are based on the tenet that culture is an integral part of the real world of open systems, which manifests itself in the empirical world in different forms (Barron, 2013). Thus, there is an underlying culture, which may not be seen or heard explicitly; however, it is deriving many observable events in the empirical domain of the world. For instance, in a certain culture, women hold the belief that they should respect their elder-in-laws in any circumstances; since this is a belief, it cannot be observed. However, what is observable are the effects that this cultural belief leads to. A woman from such a culture may even quietly tolerate violence by her in laws, without raising her voice against it. CR ethnography is therefore intended to explore the apparent and the underlying culture. The strategies that critical realist ethnographers can adopt for the exploration of this underlying culture are photography; dialogue with participants; observations of participants and their surroundings; analysis of text, observations, and photographs; and reflexivity (Barron, 2013). Through these research strategies, the underlying cultural mechanisms can be explored that make HFDMIs effective or ineffective. For instance, one of the underlying mechanisms in the open system of health-care culture is that of dealing with the patients with dignity. This mechanism is brought to the effect with the generative effects of structural factors such as health professionals’ behavior with patients, institutional policies, procedures, and practices. A critical realist ethnography can be extremely helpful in exploring if and how a health system’s culture promotes patients’ dignity.

**Grounded theory.** Grounded theory seeks to generate theory grounded in data (Corbin & Strauss, 1990). Grounded theory can explicate why interventions work when they work, and why they don’t when they don’t. This ability arises from the ability of grounded theory to explain patterns and variations; this reflects the similar broader explanatory focus of CR. An example of a grounded theory study to understand the barriers for effective diagnosis and management of HF is the one by Fuat, Hungin, and Murphy (2003).

CR grounded theory fulfills emancipatory goals by focusing on understanding the underlying generative mechanisms, in comparison to the traditional constructivist grounded theory, which focuses on mere surface description (Oliver, 2011). For example, many a times, beneath the observables are the human motivations and frustrations, which interact with the structural factors to produce events (Oliver, 2011). The above example of patients’ participation in health interventions is appropriate for a CR grounded theory as well. Since attrition rate is high for health interventions, it is important to understand the underlying motivations and frustrations that determine whether the patient continues to participate or discontinues participation in the intervention. In case of HFDMIs, a critical realist grounded theory can be used to understand the process of decision-making utilized by the patients to actively participate in the disease management programs offered to them, or to understand the thinking processes that lead them to leave a particular disease management program in between. This approach will identify what generative mechanisms are responsible for proper or underutilization of HF disease management programs.

Reflecting the fallibility that CR always subsumes, CR allows for tentativeness of the findings of grounded theory, assuming that the emerging theory is modifyable (Oliver, 2011). Another feature that CR brings to grounded theory is its openness to embrace several research methods. Therefore, a CR grounded theory can utilize various qualitative and quantitative data collection methods to develop a theory (Oliver, 2011). Rather than the purely inductive approach that is pursued by constructivist grounded theory, a CR grounded theory takes an abductive approach. The researcher begins the research process with some preconceived ideas and has some assumptions about the phenomenon to be explored (Oliver, 2015). This acknowledges that the researcher has a particular lens and encourages the researcher to be upfront about their preconceived assumptions, and to consider them as tentative and subject to change during the research process (Oliver, 2011).

**Mixed Methods Can Be Extremely Useful in Evaluating Complex Interventions**

Mixed methods provide the best opportunity to triangulate the findings obtained through qualitative and quantitative methods, to be able to reach to the most robust and conclusive evidence (McEvoy & Richards, 2006). This is because mixed methods develop a comprehensive understanding of the phenomenon under investigation; the ability of the mixed methods to explore health conditions through multiple dimensions makes it more effective for complex health intervention research (Chiang-Hanisko, Newman, Dyess, Piyakong, & Liehr, 2016). There are three basic purposes of triangulation: confirmation of findings through various methods, ensuring completeness of findings through the use of multiple methods, and exploring retroductive inferences (McEvoy & Richards, 2006). Therefore, mixed methods can serve to provide confirmed, complete,
and retrodictively inferred explanations for the health interventions’ effectiveness, which aligns with the intent of CR well.

Adopting a critical realist stance in mixed-methods research offers a sound ontological basis, which supports and justifies the use of diverse methods exploring the same phenomenon, philosophically (Zachariadis, Scott, & Barrett, 2013). The priority of context and of the underlying mechanisms suggested by CR, and its explanatory nature of ontology, make mixed methods ontologically coherent with the premises of CR. Utilizing the meta-theory of CR, mixed-methods research serve various purposes, which are congruent with the critical realist ontology. For instance, CR assumes a multilayered world (empirical, actual, and real), whereby the exploration of these multiple layers and the events taking place within them requires different methods that can explore both the perceptible events and the unobservable mechanisms. Thus, mixed-methods research provides complementary views over the same phenomenon, painting a complete picture of the phenomenon under study (Zachariadis et al., 2013). Also, following the retroductive approach of CR, mixed methods can be used to draw inferences using one research method, and then developing further research questions to explain those inferences, which can then be answered through other relevant research methods (Zachariadis et al., 2013).

In relation to the HFDMIs, one of the many possible examples of a mixed-methods study could be: first, identifying through a quantitative approach, the components of the HFDMIs that work the best in a particular setting and context, and later exploring qualitatively if and why the participants found those interventions to be effective and inclusive. The triangulated findings of this mixed-methods study will provide a complete understanding of the effectiveness of those interventions. These triangulated findings are important, so that effectiveness of interventions can be linked with the contextual factors that made those interventions effective. Without this exploration, the intervention may yield different outcomes when applied in different contexts, since we would not have any information about which characteristics of health professionals, health setting, and resources made that intervention work for the patients.

**Quantitative component of mixed-method research.** By virtue of its meta-theoretical assumptions, CR does not underpin randomized controlled trials (RCTs), which are based on successionism and linear relationship between the intervention and the outcomes (Marchal et al., 2013). It has been argued that the traditional RCTs can predict cause and effect relationships in closed systems, but they miss onto the most important contextual factors that intervene in an open system—like health care. Alternatively, studies underpinned by CR explore, not only the effects of the intervention but also the organizational structure and culture, resources, and the actions of the people involved, to understand how these factors affect intervention effects (Porter & O’Halloran, 2012). Quantitative components of mixed-methods studies, which are underpinned by CR, intend to find associations between the participants’ contextual factors, that is, their socioeconomic and educational background, their level of understanding, their support systems, and their participation in the complex health interventions (McEvoy & Richards, 2006).

An example of such a study would be the one that identifies the association of participants’ socioeconomic and educational status, their clinical condition (blood pressure and heart), and their level of family cohesion, with the participants’ involvement in the intervention and with the intervention outcomes. All these data refer to the participants’ context and can help in understanding participants’ level of involvement in a particular intervention. Thus, this cross-sectional study is guided by CR as the data, obtained through this study, explain why a certain intervention would work for some people and not for the others.

**Critical Realist Reviews**

CR can also underpin studies using secondary data. A CR review focuses on reviewing literature related to complex social interventions, processes, and practices. Looking through the critical realist lens, such a review seeks to unpack the complex social phenomena in terms of their components, the interactions between components and with the context, and the mechanisms involved in determining outcomes. This approach covers the complexity of social phenomena in complete breadth and depth (Edgley, Stickley, Timmons, & Meal, 2016). A CR review approach works best for evaluating health service interventions such as HFDMIs, which work within complex social systems. These interventions are usually composed of several interacting components, and these are greatly affected by contextual factors. Thus, a critical realist review of these interventions is an attempt to unpack: what works the best for whom, where, how, and why? One of the examples of a critical realist review is our upcoming synthesis, which will utilize network meta-analysis, a sophisticated approach, to identify the key components of interventions, the interactions between those components and with the context of intervention delivery.

**Conclusion**

In conclusion, health research needs to be adequately grounded in meta-theoretical assumptions. Meta-theories are better articulated and reflected in research methods when these are selected by the researchers, considering their historicity, beliefs, and values. Our research around HFDMIs is grounded in CR, which is characterized by seeking explanations through generative logic and multifactorial causation. The beauty of CR is in its methodological eclecticism, drawing from quantitative, qualitative, and mixed methods, in an attempt to explain why things happen the way they do. The article illustrates CR’s openness to the various research methods using examples from the research around complex HFDMIs, so as to explore which HFDMIs work the best for whom, where, how, and why?
Declaration of Conflicting Interests
The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding
The author(s) received no financial support for the research, authorship, and/or publication of this article.

References
Barron, I. (2013). The potential and challenges of critical realist ethnography. *International Journal of Research & Method in Education*, 36, 117–130.

Bhaskar, R. (1998). Philosophy and scientific realism. In M. Archer, R. Bhaskar, A. Collier, T. Lawson, & A. Norrie (Eds.), *Critical realism: Essential readings* (pp. 16–47). Oxford, England: Routledge.

Blair, J. E., Huffman, M., & Shah, S. J. (2013). Heart failure in North America. *Current Cardiology Reviews*, 9, 128–146.

Buck, H. G., Stromberg, A., Chung, M. L., Donovan, K. A., Harkness, K., Howard, A. M.,… Evangelista, L. S. (2017). A systematic review of heart failure dyadic self-care interventions focusing on intervention components, contexts, and outcomes. *International Journal of Nursing Studies*, 77(1), 232–242.

Chiang-Hanisko, L., Newman, D., Dyess, S., Piyakong, D., & Liehr, P. (2016). Guidance for using mixed methods design in nursing practice research. *Applied Nursing Research*, 31, 1–5.

Clark, A. M. (2012). What are the components of complex interventions? Theorizing approaches to parts, powers and the whole intervention. *Social Science & Medicine*. doi:10.1016/j.socscimed.2012.03.035

Clark, A. M., Lissel, S. L., & Davis, C. (2008). Complex critical realism: Tenets and application in nursing research. *Advances in Nursing Science*, 31, E67–E79.

Clark, A. M., Maclntyre, P. D., & Cruickshank, J. (2007). A critical realist approach to understanding and evaluating heart health programs. *Health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine*, 11, 513–539.

Clark, A. M., Savard, L. A., & Thompson, D. R. (2009). What is the strength of evidence for heart failure disease management programs? *Journal of American College of Cardiology*, 54, 397–401.

Clark, A. M., & Thompson, D. R. (2010). What type of heart failure program is best? Wrong question, wrong assumption. *European Journal of Heart Failure*, 12, 1271–1273.

Corbin, J., & Strauss, A. (1990). Grounded theory research: Procedures, canons and evaluative criteria. *Zeitschrift für Soziologie*, 19, 418–427.

Cruickshank, J. (2004). A tale of two ontologies: An immanent critique of critical realism. *The Sociological Review*, 52(4), 567–585.

Cruickshank, J. (2012). Positioning positivism, critical realism and social constructionism in the health sciences: A philosophical orientation. *Nursing Inquiry*, 19(1), 71–82.

Dannemark, B., Ekstrom, M., Jakobsen, L., & Karlsson, J. (2005). *Explaining society: Critical realism in the social sciences*. London, England; New York, NY: Routledge; Taylor and Francis Group.

Edgley, A., Stickley, T., Timmons, S., & Meal, A. (2016). Critical realist review: Exploring the real, beyond the empirical. *Journal of Further and Higher Education*, 40, 316–330.

Elder-Vass, D. (2012). *The reality of social construction*. Cambridge, England: Cambridge University Press.

Fuat, A., Hungin, A. P. S., & Murphy, J. J. (2003). Barriers to accurate diagnosis and effective management of heart failure in primary care: Qualitative study. *BMJ*, 326, 196.

Lewin, S., Glenton, C., & Oxman, A. D. (2009). Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: Methodological study. *BMJ*, 339, b3496.

Lor, P. (2011). Preparing for research: Metatheoretical considerations. *International & Comparative Librarianship—Encyclopedia of Library and Information Sciences*, 4–15.

Marchal, B., Westhorp, G., Wong, G., Van Belle, S., Greenhalgh, T., Kegels, G., & Pawson, R. (2013). Realist RCTs of complex interventions—An oxymoron. *Social Science & Medicine*, 94, 124–128.

McEvoy, P., & Richards, D. (2006). A critical realist rationale for using a combination of quantitative and qualitative methods. *Journal of Research in Nursing*, 11, 66–78.

Morgan-Trimmer, S., & Wood, F. (2016). Ethnographic methods for process evaluations of complex health behavior interventions. *Trials*, 17, 232.

Oliver, C. (2011). Critical realist grounded theory: A new approach for social work research. *British Journal of Social Work*, 42(2), 371–387.

Pawson, R., & Tilley, N. (1997). *Realistic evaluation*. London, England: Sage.

Pawson, R., & Tilley, N. (2001). *Realistic evaluation*. London, England: Sage.

Porter, S., & O’Halloran, P. (2012). The use and limitation of realistic evaluation as a tool for evidence-based practice: A critical realist perspective. *Nursing Inquiry*, 19, 18–28.

Prestwich, A., Sniehotta, F. F., Whittington, C., Dombrowski, S. U., Rogers, L., & Michie, S. (2014). Does theory influence the effectiveness of health behavior interventions? Meta-analysis. *Health Psychology*, 33, 465–474.

Savard, L. A., Thompson, D. R., & Clark, A. M. (2011). A meta-review of evidence on heart failure disease management programs: The challenges of describing and synthesizing evidence on complex interventions. *Trials*, 12, 194. doi:10.1186/1745-6215-112-1194

Sayer, A. (2000). *Realism and social science*. London, England: Sage.

Schiller, C. J. (2016). Critical realism in nursing: An emerging approach. *Nursing Philosophy*, 17, 88–102.

Sousa, F. J. (2010). Chapter 9: Metatheories in research: Positivism, postmodernism, and critical realism. In A. G. Woodside (Ed.), *Organizational culture, business-to-business relationships, and firm networks* (pp. 455–503). Bingley, England: Emerald Group.

The Blackwell Dictionary of Western Philosophy. (2004). *Historicity*. In N. Bunnin & Y. Jiyuan (Eds.). Hoboken, NJ: Blackwell.

Thirsk, L. M., & Clark, A. M. (2017). Using qualitative research for complex interventions: The contributions of hermeneutics. *International Journal of Qualitative Methods*, 16, doi:10.1177/1609406917721068

Zachariadis, M., Scott, S. V., & Barrett, M. I. (2013). Methodological implications of critical realism for mixed-methods research. *MIS Quarterly*, 37, 855–879.