



What qualitative research can contribute to a randomized controlled trial of a complex community intervention



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ARTICLE INFO

Article history:

Received 21 July 2015

Received in revised form 16 October 2015

Accepted 17 October 2015

Available online 21 October 2015

Keywords:

Complex community interventions

Randomized controlled trial

Qualitative, narrative research

Homelessness

Housing First

ABSTRACT

Using the case of a large-scale, multi-site Canadian Housing First research demonstration project for homeless people with mental illness, At Home/Chez Soi, we illustrate the value of qualitative methods in a randomized controlled trial (RCT) of a complex community intervention. We argue that quantitative RCT research can neither capture the complexity nor tell the full story of a complex community intervention. We conceptualize complex community interventions as having multiple phases and dimensions that require both RCT and qualitative research components. Rather than assume that qualitative research and RCTs are incommensurate, a more pragmatic mixed methods approach was used, which included using both qualitative and quantitative methods to understand program implementation and outcomes. At the same time, qualitative research was used to examine aspects of the intervention that could not be understood through the RCT, such as its conception, planning, sustainability, and policy impacts. Through this example, we show how qualitative research can tell a more complete story about complex community interventions.

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1. Introduction

In 2008, the Canadian government embarked on an unprecedentedly large-scale social experiment to address the needs of chronically homeless people with mental illness and addictions. At Home/Chez Soi was a research demonstration project that used the promising Housing First¹ approach, developed in the United States. It was funded for \$110 million for five years by the federal government through the Mental Health Commission of Canada², and was implemented in five communities across Canada with over 2000 participants. HF was combined with either Assertive Community Treatment³ for those with high needs, or Intensive Case Management⁴ for those with moderate needs, and compared with Treatment as Usual⁵. Although the study was a randomized controlled trial⁶, there was recognition on the part of the research team that HF is a complex community intervention⁷ [10,53], and that the RCT research could not capture the complexity of this CCI [54]. As Trickett

[53] has argued, CCIs are more about the creation of a setting than the implementation of technocology.

Qualitative research was incorporated into all phases of the RCT. Rather than assume that qualitative research and RCTs are incommensurate, a more pragmatic mixed methods approach was used [15]. However, the qualitative, narrative approach that we adopted went beyond the typical focus of mixed methods evaluation research on implementation. The narrative approach was used to examine aspects of the project that are typically not studied in RCTs or mixed methods evaluations, such as how this initiative came about, how stakeholders in five Canadian communities were mobilized to plan and implement HF programs and the research, how the programs were or were not sustained, and what the policy and practice legacy of this project was. The purpose of this paper is to provide an illustration of what qualitative, narrative research can contribute to a RCT study of a CCI. We assert that only qualitative research can be used to understand the storied nature of RCT studies of CCIs [10].

2. Complex community interventions and qualitative, narrative research

2.1. What is a complex community intervention?

While many health and social problems, such as mental illness and homelessness, are complicated in that they are rooted in multiple systems [57], they are also complex in that the different parts interact

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¹ HF = Housing First.

² MHCC = Mental Health Commission of Canada.

³ ACT = Assertive Community Treatment.

⁴ ICM = Intensive Case Management.

⁵ TAU = Treatment as Usual.

⁶ RCT = randomized controlled trial.

⁷ CCI = complex community intervention.

with one another in ways that are uncertain and emergent. Recently, concepts from complexity theory [43,57], systems thinking [17], and ecological theory [19,53] have been used to better understand the dynamic nature of complex problems, including recursive causal loops between individuals and programs, and the role of “tipping points” in which small changes can make a big impact on outcomes.

2.2. Current ways of understanding and evaluating complex community interventions

2.2.1. RCT research

According to the U.K. Medical Research Council guidelines for the evaluation of CCI [10], “experimental designs are preferred to observational designs in most circumstances.” In contrast, Wolff [59] questioned the appropriateness of RCTs for evaluating CCIs and recommended the use of multiple sites to help understand the role of contextual factors in producing outcomes. Riley, Hawe, and Shiell [41] have advocated for the use of qualitative methods in RCT research on CCIs, recommending both outcome and process data-monitoring committees. Similarly, Bonell, Fletcher, Morton, Lorenc, and Moore [7] argued for the use of “realist” RCTs that draw attention to the context of CCIs and incorporate the use of qualitative data. In spite of these recommendations, the incorporation of qualitative methods into RCTs of CCIs is still uncommon [26].

2.2.2. Theory of change and causality

Traditionally, a program's theory of change is visually depicted in a linear logic model in which inputs lead to program activities, which, in turn, lead to short-term and longer-term outcomes [44]. In multi-component interventions, the different program components are conceptualized as a “package” that lead to multiple outcomes [19]. In contrast, Hawe et al. [19] provided an alternative perspective on CCIs' theory of change by focusing on the context of the intervention. Interventions are seen as “a critical event in the history of a system, leading to the evolution of new structures of interaction and new shared meanings” (p. 267).

With regard to program activities, Hawe, Shiell and Riley [18] have made a distinction between the form and function of an intervention. Form refers to the specific program activities that are carried out with participants, while function refers to the principles that underlie the particular activities and are theorized as being critical for achieving intended outcomes. Rather than follow a very prescribed, “cookie cutter” approach (form), the intervention can and should be adapted to the context, while adhering to the underlying principles of the intervention (function). Similarly, fidelity evaluation should focus on implementation of the broad principles of the intervention, rather than specific, prescribed program activities.

Evaluators espousing a complexity orientation [7,19,21,43] have suggested several qualities of causation in a theory of change for CCIs. First, causation should be characterized by recursive causal loops, rather than uni-directional causal arrows that link activities with outcomes. Second, the impacts of program components should be viewed as synergistic rather than as additive. Underlying this synergy lies the important role of collaboration among stakeholders, including staff, researchers, administrators, and funders. Third, since complex systems are dynamic and outcomes are uncertain, unintended outcomes should be anticipated, not just hypothesized outcomes. For example, HF is predicted to lead to housing people with mental illness and addictions, but if the person brings her or his substance-abusing friends into the home, this may lead to the unintended side-effect of problems with one's landlord, which may lead to eviction, and then a new cycle of interventions with the individual to re-house her or him. Fourth, similar to the previous point, causality should be viewed as contextually bound rather than as universal. Thus, it is important to examine what works for whom under what circumstances.

2.3. An alternative: qualitative, narrative approaches to understanding and evaluating complex community interventions

2.3.1. The storied nature of interventions

Narrative analysis provides another way of thinking about RCT studies of CCIs. Narratives can facilitate understanding and create meaning for human behavior [40]. Narratives include several components: a temporal sequence (a beginning, a middle, and an end), a cast of characters, a plot, and, often, a moral or lessons that are passed on to readers and listeners. As Rappaport [40] noted, narratives span levels of analysis, such that there are both personal stories of individuals and larger programmatic or community narratives, which mutually influence one another. In the context of permanent supportive housing for formerly homeless people with mental illness, Kirkpatrick and Byrne [23,24] illustrate this distinction in their description of the personal stories of individuals and the larger housing program narrative from which the individuals derived meaning.

According to Trickett et al. [54], telling the “full story” of CCIs goes beyond the evaluation of outcomes to an analysis of the processes that enabled the research and intervention to come into being, the “brokering” work necessary for academic and community partners to negotiate the nature of the intervention, and the tensions that have to be negotiated to successfully implement, evaluate, and sustain the intervention. Trickett et al. [54] argue that capturing this sort of “relational” knowledge in specific cases is useful in informing the implementation of CCIs in other contexts.

2.3.2. Embedding qualitative research within RCT studies of complex community interventions

While the value of qualitative research for informing mental health programs [14] and policy [12] has received some currency, there has recently been more attention paid to embedding qualitative research in RCTs [7,20,41]. In particular, qualitative research has found a particular niche in process evaluations of CCIs under the rubric of “implementation science” [11]. Qualitative methods have been used either alone [6, 25] or with quantitative methods using mixed methods approaches [18, 20,38] to study implementation.

Currently, mixed methods approaches to program evaluation provides a very circumscribed role for qualitative methods in their focus on implementation. We believe that qualitative research can play an even larger role in RCT evaluations of CCIs by adopting a narrative approach. In addition to the focus on implementation, qualitative research lends itself to the study of personal and program narratives [40], and thus can be used to tell the “full story” of RCT studies of CCIs. A qualitative, narrative approach can reveal the complexity of RCTs by focusing on the story of a CCI from the beginning to the end of the project and on multiple ecological levels of analysis, spanning from individual participants and staff to programs to social policy. A qualitative, narrative approach is akin to what Kidder and Fine [22] have called a “big Q” approach to qualitative research, in contrast to the more limited “small q” approach to the more typical use of qualitative methods in mixed methods approaches to implementation evaluation. More detail on the mixed methods approach to the design of the current study can be found in the following paper [28].

3. Housing First for homeless persons with mental illness

3.1. At Home/Chez Soi

At Home/Chez Soi was modeled after the Pathways to Housing program in New York City. The Pathways HF program stands in contrast to “treatment first” approaches, by rapidly providing housing to homeless people with mental illness rather than offering housing as a reward for progress in treatment [55]. HF is based on the following principles: consumer-driven services, including choice over one's housing, separation of housing and clinical treatment, a recovery orientation, and an

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