

**Developing and testing intervention theory by incorporating a views synthesis into a
qualitative comparative analysis of intervention effectiveness**

Short title: Incorporating a views synthesis into QCA

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Abstract

Qualitative comparative analysis (QCA) was originally developed as a tool for cross-national comparisons in macrosociology, but its use in evaluation and evidence synthesis of complex interventions is rapidly developing. QCA is theory-driven and relies on Boolean logic to identify pathways to an outcome (e.g. is the intervention effective or not?). We use the example of two linked systematic reviews on weight management programmes (WMPs) for adults—one focusing on user views (a ‘views synthesis’) and one focusing on the effectiveness of WMPs incorporating dietary and physical activity—to demonstrate how a synthesis of user views can supply a working theory to structure a QCA analysis. We discuss how a views synthesis is especially apt to supply this working theory because user views can: a) represent a ‘middle-range theory’ of the intervention, b) bring a participatory, democratic perspective, and c) provide an idiographic understanding of how the intervention works that external taxonomies may not be able to provide. We then discuss the practical role that the views synthesis played in our QCA examining pathways to effectiveness: a) by suggesting specific intervention features, and sharpening the focus on the most salient features to be examined; b) by supporting interpretation of findings, and c) by bounding data analysis to prevent data dredging.

Keywords. Systematic review, qualitative metasynthesis, qualitative comparative analysis, intervention theory

Introduction

Qualitative comparative analysis (QCA) was originally developed as a tool for cross-national comparisons in macrosociology.¹ QCA relies on Boolean logic to develop an understanding of the potential causal ‘recipes’ that lead to an outcome. These causal recipes are composed of conditions, or generally binary statements about the properties of a specific case.² Unlike traditional quantitative methods that are variable-oriented in nature, QCA is case-oriented, and it relies on deep knowledge and understanding of the cases at hand.^{2,3} QCA has two key variants: crisp-set QCA, in which all conditions are binary, and fuzzy-set QCA, in which conditions can take on any truth value between 0 and 1, where 1 is a completely clear instance of the condition and 0 is a completely clear instance of the condition not being met. We focus here on crisp-set QCA.

QCA has been used in realist evaluation⁴ and as part of more ‘traditional’ systematic reviews of interventions.^{5,6} Its application for evidence synthesis of complex interventions in particular has developed quickly.³ Building on germinal texts describing the value of QCA generally² and in systematic reviews more specifically,³ this paper explores its value for this purpose by considering two related systematic reviews that tackle the public health challenge of obesity. The background to these reviews is described further below. First, we consider the attributes of QCA that suggest its potential use for developing and testing intervention theory when intervention complexity is present. After discussing the focal systematic reviews, we review how systematic reviews of user views (or ‘views synthesis’ may be especially probative in developing intervention theory for QCA, and then offer a specific example of how we used a views synthesis to structure our QCA.

QCA as a tool in reviews of complex interventions

Relevant properties of QCA. In the case of synthesis of complex interventions, QCA offers several attractive opportunities that meta-regression methods, which are traditionally

used to understand heterogeneity in intervention effectiveness, do not. First, QCA's focus on configurations of conditions may better reflect specific properties of complex interventions that cannot be captured in meta-regression. For example, intervention components may combine to form tipping points or threshold effects. Second, because QCA focuses on causal recipes, it also acknowledges that there may be multiple pathways to intervention effectiveness, or least effectiveness. Most systematic reviewers will be interested in causal recipes, or pathways, for most effectiveness, though pathways to least effectiveness are also instructive.³ Analogously, policy customers may be interested in identifying several possible, similarly effective causal recipes for effective interventions, as well as avoiding possibly 'toxic' combinations of features, or decommissioning valuable intervention features. Third, QCA does not require causal 'symmetry', in which the presence of a characteristic is associated with the presence of an outcome, and vice versa. Instead, causal recipes are designated as either necessary or sufficient. In necessary causation, all instances of the outcome are characterised by the causal recipe. In sufficient causation, which is more often addressed in QCA, all instances of the causal recipe are characterised by the outcome.

Underpinning each of these benefits is an understanding of causation as generative or configurational, rather than successionist. That is to say, instead of understanding interventions merely as an event that temporally precedes an outcome, QCA understands interventions as generative of outcomes through the 'falling into place' of key interventional and contextual aspects. The goal of QCA, then, is to identify what needs to fall into place for interventions to be most, or least, effective.

QCA meets systematic reviews. A key trend in the development of research synthesis methods for complex interventions is the juxtaposition of multiple related systematic reviews to develop knowledge that one review alone would not have been able to generate.⁷ A germinal example of this is the use of a systematic review and qualitative

synthesis of children's views on school nutrition programmes to understand heterogeneity in the effectiveness of school programmes to promote consumption of fruit and vegetables. Programmes in which messaging matched children's views that fruits and vegetables were 'tasty' were more successful than those that labelled fruits and vegetables as 'nutritious', a label that the synthesis of children's views suggested would not be popular.⁸

Various synthesis devices for juxtaposing (rather than combining) qualitative and quantitative studies, such as integrative grids,⁹ have been proposed. But to our knowledge, only one previous project has used a systematic review and synthesis of qualitative studies to inform a QCA of intervention effectiveness.⁵ Because the use of QCA in intervention synthesis is still in its infancy, we offer here a rationale and a framework for using a systematic review and synthesis of qualitative studies that explore service users' views (what we call hereafter a *views synthesis*) to structure the use of QCA in analysing intervention effectiveness throughout the lifecycle of the analysis. We demonstrate this framework throughout with our recent views synthesis¹⁰ and QCA¹¹ on tier 2 weight management programmes (WMPs) for overweight and obese adults. Both the views synthesis¹⁰ and the QCA¹¹ have been published elsewhere; here we provide an account of the methods we used to integrate these two syntheses.

Background to our reviews

Obesity is a pressing issue in public health, and England has one of the highest rates of overweight and obesity in the developed world.¹² In 2015, the Department of Health for England commissioned an evidence review to identify the critical features of successful WMPs in order to inform policy and commissioning decisions in the UK. Tier 2 WMPs, which address both diet and exercise, are delivered in the public, private and voluntary sector. However, while these interventions are broadly effective for helping individuals to lose weight (that is, the pooled effect across trials suggested a significant and clinically meaningful

difference), they are heterogeneous in content and in approach. In 2013, the National Institute for Health and Care Excellence released guidance on these tier 2 WMPs that was based on three systematic reviews, including a synthesis of intervention effectiveness,¹³ a related synthesis to explore how components of interventions were associated with their effectiveness,¹⁴ and a synthesis of qualitative studies.¹⁵ While all three reviews met high standards of rigour in conduct and reporting, the components analysis yielded mixed results. Though it found that interventions with diet and exercise together were more effective than diet-based WMPs and exercise-based WMPs alone, a validated taxonomy of behaviour change components did not explain heterogeneity in intervention effectiveness.

Our work took as a starting point the reanalysis of the systematic reviews that informed the NICE guidance. To develop the views synthesis, we used a variety of methods including database searching and citation chasing to update searches from the 2013 review. Having identified 21 studies on service users' views, we subsequently analysed the data using thematic synthesis.¹⁶ Themes identified at this stage included perceptions of: a) the relative importance and utility of different features of WMPs; b) the best approaches for delivering each of the features; and c) the mechanisms through which the different features influence behaviour change. Findings from our views synthesis are reported in depth elsewhere.¹⁰ To develop the QCA of intervention effectiveness, we examined trials included in the NICE 2013 review on the primary outcome of mean kg difference in weight loss between intervention and control arm. We selected the ten most effective and the ten least effective interventions and used these as the basis for our QCA models. We 'sampled' these trials for several reasons. First, this approach created a strong contrast between most effective and least effective interventions, similar to MSDO/MDSO (most similar, different outcome/most different, similar outcome) designs used especially in macrosociology to identify potential causal factors.¹¹ Second, and by corollary, this strategy filtered out the 'noise' that could obscure

differences between most and least effective WMPs. Findings for our QCA model are also reported in depth elsewhere.¹¹

The value of views syntheses to supply ‘theory’ in QCA

Qualitative comparative analysis was originally intended to form a ‘third way’ between the challenges to generalisability that qualitative and case-based research exhibit and the quantitative, ‘net effects’ thinking of statistical methods in social research.^{1,2} It is a theory-led, abductive method of research that is structured and guided by deep knowledge of the field of inquiry and of the relevant theoretical constructs in that field. However, because QCA was developed in the theoretically rich field of cross-national macrosociology, it is not immediately obvious what the relevant ‘theory’ should be when using QCA to analyse intervention effectiveness. In addition, many intervention evaluations are not developed using an explicit theory, and these theories, where they exist, are frequently poorly reported.¹⁷ This means that identification of a suitable theory to structure QCA in synthesising interventions is not obvious.

However, several possibilities exist. For example, the ‘theory’ used to lead a QCA of interventions could be a hypothesised theory of change for a class of interventions, or a health promotion theory like the Theory of Reasoned Action. Here, we suggest that views syntheses may be especially apposite in guiding QCA. There are several reasons for this. First, a synthesis of users’ views, when developed interpretively, can present third-order constructs that both encompass and reinterpret the findings in primary studies to go beyond any one study.^{18,19} Originally developed in the qualitative synthesis method of meta-ethnography, third-order constructs are higher-level concepts developed through the synthesis of qualitative studies that account for the content of individual studies, but that also offer a higher level of generalisability and interpretation than any one study might offer.²⁰ Methods to synthesise qualitative studies such as thematic synthesis,¹⁶ lines-of-argument synthesis²⁰ and grounded

theory-based approaches²¹ all rely on constant comparison to develop interpretive understandings of the social processes at play in the phenomenon of interest. The findings of a views synthesis can thus be understood as a lay ‘middle-range’ theory of the intervention. A middle-range theory sits between a grand theory, which has a high level of abstraction and seeks to explain a range of phenomena, and individual programme theories, which are specific to particular interventions and contexts. Thus, a middle-range theory, with its balance between generality to a class of interventions and specificity to the particular phenomena embedded in this class, can provide the theoretical and substantive point of departure for QCA.

Second, and by corollary, a views synthesis that focuses on user views foregrounds the experiences and concerns of those most proximally affected by the intervention of interest. This is important from a democratic, participatory perspective, which is increasingly recognised as being of value in systematic reviews.²² It also serves to discipline the analytic process by preventing the analysts straying from the perspectives of users. Especially in situations where time or resources do not allow for an extensive consultation process throughout the systematic review, or in situations where there is a need for greater analytic generalisability beyond a specific context, a views synthesis can help ‘voice’ service users. It is also possible to integrate the views of providers or commissioners, for example, though we did not undertake to do this here.

Third, and also related to the first point, views syntheses can provide, via a middle-range theory, an idiographic understanding of heterogeneous complex interventions in ways that externally imported theories and taxonomies cannot. In fact, QCA was originally developed to target and focus causal explanation of social phenomena in the face of theories that can ‘develop only general lists of potentially relevant causal conditions’.²³ Middle-range theories may be more informative for understanding interventions than ‘grand theories’ of

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health promotion and human behaviour, as middle-range theories will, by definition, reflect an understanding of the intervention that is more proximal to how the intervention actually works.²⁴ As noted above, an externally validated taxonomy for behaviour change components was unable to meaningfully account for heterogeneity in intervention effectiveness. Because a views synthesis comes from within the intervention and the experiences of users, it may have greater relevance to the complex interventions under examination and specific analytic power to account for variations in effectiveness. The next section illustrates how a views synthesis might be incorporated into a QCA, with reference to the synthesis of views described above.

Views syntheses as a tool to structure QCA

Step 1: using a views synthesis to construct a data table. The first step in QCA is the construction of a data table. The data table consists of one row per intervention, with relevant conditions and the outcome in the columns. Because we selected the ten most and ten least effective interventions, coding on the outcome was straightforward.

However, determining which conditions should be included was less obvious. We developed a coding framework based on the findings of the views synthesis. The views synthesis identified seven domains, within which 38 subordinate themes that had been translated across studies were included. These themes reflected features of WMPs that users valued and felt were relevant to their success within WMPs. For example, one of the domains identified was 'delivery format'. Within delivery format, themes that emerged included the value of group sessions as an important social tool, and high-intensity programming to 'hook' participants into the programme.

We restated each of these themes into conditions and operationalized them so as to be able to code the interventions for the presence (1) or absence (0) of these specific conditions. Thus, to follow on from above, we examined interventions for the presence of group work and high intensity. We specifically operationalised high intensity by looking for interventions

with a high number of sessions (≥ 48 sessions) delivered at high frequency (fortnightly or more often) and over a long duration (≥ 12 months). Two reviewers independently assigned interventions to the different conditions before reaching agreement regarding the coding, similar to best practice for data extraction in systematic reviews. The final data table is included in Online File 1.

Step 2: using views syntheses to construct and refine truth tables. The second step in QCA is the construction of a truth table. This involves examining the consistency and coverage of combinations of conditions on the outcomes. The identification of conditions for a QCA model is best guided by theoretical and substantive knowledge of the field.^{1,3} Views syntheses can help construct and refine truth tables by identification of overarching themes and by suggesting ways to refine truth tables when initial findings are hard to interpret.

In this specific case, we were faced with a surfeit of possible conditions that we had identified from our views synthesis. It was clear that we would be unable to analyse all 38 conditions we identified in one QCA model. Moreover, the findings of such a model would have been difficult to interpret. Thus, we examined our views synthesis for overarching patterns in the results that would guide the construction of more targeted truth tables. Two key themes emerged with sufficient evidence on relevant conditions. The first was the importance of provider support, and the second was the importance of peer relationships. We used the views synthesis to construct truth tables examining how conditions relating to provider support and peer relationships combined to form pathways to most effectiveness and least effectiveness. For example, when we examined provider support we looked not only at whether 1) opportunities to develop supportive relationships with providers were present, but also if the intervention provider had 2) set energy intake goals (e.g. calorie prescription), 3) energy expenditure goals (e.g. exercise), 4) weight loss goals for participants, and 5) directly provided exercise, and whether the intervention was 6) high intensity and 7) featured a

graduated exit (i.e. a gradual, planned shift from initial intensive WMP support to a less intensive approach). In a separate truth table for peer relationships, we also initially examined whether 1) group work was included, and whether the intervention was 2) population group-targeted (e.g. to men only) or 3) health risk group-targeted (e.g. to people at high risk for cardiovascular disease).

While examining our initial truth table for provider support, we realised that findings were difficult to interpret. Upon examining the data table and after group discussion, we instead identified two related processes under the overarching theme of provider support: provider ‘directiveness’, or the degree to which the provider supported the user by setting clear goals and following up on them, and provider-user alliance, or the degree to which the intervention fostered a therapeutic alliance. This led us to construct still more targeted truth tables corresponding to these two processes and using the seven conditions originally included. The final three truth tables are presented in Table 1.

Step 3: using views syntheses to resolve contradictory configurations. After construction of truth tables, the next step is to examine and resolve contradictory configurations, or combinations of causal conditions that are not completely consistent. Views syntheses can discipline the resolution of these contradictory configurations by suggesting new lines of inquiry—and by ‘bounding’ the analysis to prevent data dredging, or the quest for results that are particularly newsworthy or that fit the research team’s preconceptions.

Our truth tables for provider directiveness and provider-user alliance did not have any contradictory configurations. This is demonstrated in Table 1, where all configurations with cases in both of these truth tables include either only most effective or only least effective interventions. However, our truth table for peer relationships did include contradictory configurations, as two configurations included a mix of least effective and most effective interventions. As we sought to understand these contradictions, we noticed that findings in the

views synthesis relating to peer relationships referred to users' views on their similarity to each other in population terms, rather than by health risk group. That is, users in a WMP targeted at middle-aged men who were football fans were more likely to report the importance of peer relationships than were users in a WMP targeted at people with elevated cardiovascular disease risk. As a result, we dropped health risk group targeting from our model. The final truth table for peer relationships is shown in Table 1.

Findings from the subsequent model still presented contradictory configurations. Though interventions with both population targeting and group work were completely consistent for high effectiveness and interventions with neither were completely consistent for least effectiveness, both configurations with one but not the other were contradictory. In these situations, it is recommended to return to knowledge of the cases and of the relevant theory to understand additional conditions that may help resolve contradictions. But when we revisited the views synthesis, we were unable to find a reasonable explanation grounded in the data that would help us to resolve this configuration. We thus did not continue trying to resolve the contradictory configurations in this table.

Steps 4, 5 and 6: Boolean minimisation, consideration of logical remainders and interpretation through the lens of the views synthesis. Following construction of truth tables and resolution of contradictory configurations, the next step is Boolean minimisation, which 'crunches' the configurations into a final result. These results are then interpreted and logical remainders, or configurations with no cases, are considered as well for their plausibility. The results of Boolean minimisation for truth tables relating to provider directiveness and provider-user alliance is shown in Table 2. Strictly speaking, logical remainders should be considered before interpretation of the minimised solution. However, we present our discussion of these two steps together because we found that consideration of logical remainders helped us to finalise our interpretation, and vice versa. A views synthesis

can help to understand and interpret minimised solutions by grounding the abstract set relations in the views of users.

For example, the minimised solution for our provider directiveness model included two pathways to high effectiveness. Both included provider-set energy-intake goals and provider-set exercise goals, as well as either direct provision of exercise or provider-set weight goals. Similarly, pathways to least effectiveness were characterised by the absence of provider-set energy intake goals, alongside absence of both provider-set exercise goals and direct provision of exercise, or alongside absence of provider-set weight goals even if provider-set exercise goals and direct provision of exercise were present. Findings from our views synthesis suggested that the comprehensive nature of both pathways in prescribing behavioural directives in the context of supportive relationships initiated processes leading to self-regulation, processes that users described as being key to success in the WMP.

Similarly, when we examined the logical remainders (shown in Table 1), we looked for combinations of conditions that emphasised development of ‘comprehensive’ self-regulation. In the provider-user alliance truth table, we identified 16 possible configurations, of which seven were not present in any of the included interventions. We judged that of these logical remainders, six would be likely to lead to least effectiveness as they lacked either opportunities for the development of supportive provider relationships or did not foster self-regulation via direct exercise provisions. In contrast, the one logical remainder including supportive provider relationships alongside direct exercise provision and graduated exit was likely to be most effective.

Finally, as we sought to write up the analysis, we found it helpful to frame our QCA model findings against specific quotes from the views synthesis. This not only foregrounded the views and preferences of users, but it also gave colour and context to our abstract set relations. For example, when framing our findings about provider-user alliance, we matched

our discussion with a quote from a user, who expressed that in strong alliances, ‘You feel that somebody’s batting for you’.²⁵

Discussion

In this paper, we have described the benefits of using views syntheses to supply the relevant ‘theory’ for a QCA-based intervention synthesis, and demonstrated the ways in which a views synthesis can structure a QCA approach to synthesis of complex interventions. We have demonstrated how a views synthesis is of use throughout the life cycle of the analysis, both to guide and support new lines of enquiry, and also to discipline analyses by preventing data dredging. Because QCA derives its meaning from interpretation of a model’s minimised solution, a views synthesis can provide a powerful check as to whether results are worthwhile or meaningful.

QCA provides another opportunity to understand differences in the effectiveness of complex interventions. It tells the analyst different things than a meta-analysis or a meta-regression might. Because QCA is necessarily an abductive approach, the types of knowledge it generates may be better viewed as formalising and proposing an explanatory theory of intervention effectiveness rather than offering a predictive or inferential estimate of how different interventions may be differentially effective. It should also be noted that meta-regression cannot provide an understanding of configurational causation. In this vein, QCA can provide a powerful alternative tool to understand causal pathways to intervention effectiveness from a configurational perspective.

Moving forward, we hope that this will be one in a series of ongoing methodological advancements for the synthesis of complex interventions to yield different kinds of knowledge. For example, the role of views syntheses in fuzzy-set QCA has yet to be explored. Views syntheses may be of use in calibrating fuzzy sets, though we look to future work to attempt this. Moreover, syntheses representing different stakeholder perspectives, including

providers and policymakers, could provide a panoramic perspective as to how concerns relevant to different groups are reflected in pathways to effectiveness.

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Table 1. Three final truth tables used in analysis.

Set	Number of cases by effectiveness
Provider directiveness	
~direct provision * ~provider-set weight goals * ~provider-set energy intake * ~provider-set exercise goals	7 least effective
~direct provision * provider-set weight goals * ~provider-set energy intake * ~provider-set exercise goals	2 least effective
~direct provision * provider-set weight goals * provider-set energy intake * provider-set exercise goals	3 most effective
direct provision * ~provider-set weight goals * ~provider-set energy intake * provider-set exercise goals	1 least effective
direct provision * ~provider-set weight goals * provider-set energy intake * provider-set exercise goals	2 most effective
direct provision * provider-set weight goals * provider-set energy intake * provider-set exercise goals	5 most effective
<i>~direct provision * ~provider-set weight goals * ~provider-set energy intake * provider-set exercise goals</i>	0
<i>~direct provision * ~provider-set weight goals * provider-set energy intake * ~provider-set exercise goals</i>	0
<i>~direct provision * ~provider-set weight goals * provider-set energy intake * provider-set exercise goals</i>	0
<i>~direct provision * provider-set weight goals * ~provider-set energy intake * provider-set exercise goals</i>	0
<i>~direct provision * provider-set weight goals * provider-set energy intake * ~provider-set exercise goals</i>	0
<i>direct provision * ~provider-set weight goals * ~provider-set energy intake * ~provider-set exercise goals</i>	0
<i>direct provision * ~provider-set weight goals * provider-set energy intake * ~provider-set exercise goals</i>	0
<i>direct provision * provider-set weight goals * ~provider-set energy intake * ~provider-set exercise goals</i>	0
<i>direct provision * provider-set weight goals * ~provider-set energy intake * provider-set exercise goals</i>	0
<i>direct provision * provider-set weight goals * provider-set energy intake * ~provider-set exercise goals</i>	0
Provider-user alliance	
~direct provision * ~provider relationships * ~graduated exit * ~high intensity	2 least effective
~direct provision * ~provider relationships * ~graduated exit * high intensity	1 least effective
~direct provision * provider relationships * ~graduated exit * ~high intensity	5 least effective
~direct provision * provider relationships * graduated exit * ~high intensity	1 least effective
~direct provision * provider relationships * graduated exit * high intensity	3 most effective
direct provision * ~provider relationships * graduated exit * high intensity	1 least effective
direct provision * provider relationships * ~graduated exit * ~high intensity	1 most effective

direct provision * provider relationships * ~graduated exit * high intensity	1 most effective
direct provision * provider relationships * graduated exit * high intensity	5 most effective
<i>~direct provision * ~provider relationships * graduated exit * ~high intensity</i>	0
<i>~direct provision * ~provider relationships * graduated exit * high intensity</i>	0
<i>~direct provision * provider relationships * ~graduated exit * high intensity</i>	0
<i>direct provision * ~provider relationships * ~graduated exit * ~high intensity</i>	0
<i>direct provision * ~provider relationships * ~graduated exit * high intensity</i>	0
<i>direct provision * ~provider relationships * graduated exit * ~high intensity</i>	0
<i>direct provision * provider relationships * graduated exit * ~high intensity</i>	0
Peer relationships	
<i>~population targeting * ~group work</i>	5 least effective
population targeting * ~group work	3 most, 1 least effective
<i>~population targeting * group work</i>	2 most, 4 least effective
population targeting * group work	5 most effective

* = and, ~ = not, + = union set; italics indicate logical remainders

Table 2. Results of Boolean minimisation from final truth tables for provider directiveness and provider-user alliance.

Set	Outcome, consistency, coverage
Provider directiveness	
provider-set energy intake * provider-set exercise goals * (direct provision + provider-set weight goals)	Most effective, 1.00, 1.00
~provider-set energy intake * (~direct provision * ~provider-set exercise goals + direct provision * ~provider-set weight goals * provider-set exercise goals)	Least effective, 1.00, 1.00
Provider-user alliance	
provider relationships * (graduated exit * high intensity + direct provision * ~graduated exit)	Most effective, 1.00, 1.00
~provider relationships * (direct provision * graduated exit * high intensity + ~direct provision * ~graduated exit) + provider relationships * ~direct provision * ~high intensity	Least effective, 1.00, 1.00

* = and, ~ = not, + = union set