Improving Professional Psychological Practice Through an Increased Repertoire of Research

Methodologies: Illustrated by the development of MOL.

Developing effective and efficient psychological treatments is an urgent public health priority. Mental and substance-use disorders are major contributors to the global burden of disease in developing countries (Whiteford et al., 2013). In developed countries, the contribution of these disorders to the burden of disease continues to rise. Mental health policy and practice research, therefore, is essential.

As researchers and practitioners we are concerned with the difficulties of applying the evidence accumulated in research settings through randomized controlled trials (RCTs) to clinical practice. Promulgation of the attitude that RCTs are the only legitimate way of generating an evidence-based psychological treatment has divorced research from practice. This separation has been detrimental to the field in terms of the development of effective and efficient treatments that can be readily implemented. Although problems with RCTs have been well documented, solutions to these problems have been less forthcoming. We briefly recap on some of the most important problems with RCTs and then provide an illustration of one way of solving the problem that our rigid adherence to RCT methodology has created. For a more detailed description of the problems of RCTs see Carey and Stiles (2015).

There are many aspects of psychological functioning and psychological treatment that would benefit from innovative and sustained research. Developing robust theories of change, for example, and identifying specific mechanisms are areas that are important to progress. These topics, however, are outside the scope of this paper which focusses solely on the process by which therapies are evaluated and suggests that RCTs need not be the only way to generate evidence of therapeutic effectiveness. Furthermore direct comparisons of the effectiveness of one therapy relative to another therapy is another important area of research but, again, one that is beyond the scope of this paper.

Problems With Relying Solely on Randomised Controlled Trials

Evidence-based psychological treatments are a crucial component in addressing the growing mental health problem comprehensively. RCTs continue to be regarded as the "gold standard" of evidence (Carey & Stiles, 2015), even though some researchers describe the idea of a hierarchy of evidence with RCTs at the top as "fundamentally wrong" (Jadad & Enkin, 2007, p. 106). Jadad and Enkin propose that the gold standard in research is matching an appropriate methodology to an important research question.

Positioning RCTs at the top of a hierarchy has had important practical ramifications. RCTs have not served us well in the development of more effective and efficient psychological treatments. Two separate and independent meta analyses (Collins & Carey, 2015; Johnsen & Friborg, 2015) reported a linear decline in pre-post effect sizes for the psychological treatment of depression from before 1980 until 1995 when effect sizes appeared to stabilize. Given that the purpose of RCTs is to provide evidence to improve clinical practice (Salter & Louise, 2015), it is hard to understand a large *increase* in RCTs (Carey & Stiles, 2015) and a *reduction* in the effect sizes of therapies being evaluated. The efficiency of treatments is also decreasing over time. Using the studies from Collins and Carey (2015), efficiency ratios (Carey, Tai, & Stiles, 2013) were conducted on all studies that provided effect size and number of sessions data. These ratios were averaged for studies that were published in the same year. Figure one depicts a decline in treatment efficiency across these studies. While causal conclusions cannot be drawn from these associations, it does appear to be the case that, in the context of promoting RCTs as a gold standard of evidence, the dual effect of an increased separation between research and practice *and* the production of less effective and efficient treatments has arisen. In order to correct the problematic situation that has developed in the context of a sole reliance on RCTs for treatment development, it is important to be clear about some of the main difficulties with the conduct of RCTs.

Insert Figure One about here

Considering a More Complete Inference Process

There are numerous reasons as to why RCTs may not generate information required to develop increasingly effective and efficient psychological treatments (Carey & Stiles, 2015). One factor that could be fundamental is a failure to realise the entire scientific inference procedure. Although the design and conduct of RCTs has improved (e.g. greater power, enhanced recruitment, control of confounds), Piantadosi (2005) emphasises that "a clinical trial alone does not represent a scientific test of a therapy in the absence of a plausible mechanism of action for that therapy." (p. 19). Plausible mechanisms of action, however, are rarely described in specific, unambiguous terms with regard to psychological treatments. In fact, Kazdin (2007) remarks that despite decades of psychotherapy research we are unable to provide evidence-based explanations for how or why our therapies produce change.

The limits of our explanations can, perhaps, be understood in the context of the broader scientific endeavour, in which experimentation alone is not sufficient to make scientific progress (Piantadosi, 2005). Equally important to experimentation is biological theory (Piantadosi); yet, psychological treatment research in the form of RCTs is almost devoid of biological theory.

Implementation Problems with Treatments that are Disorder-Specific

Key to increasingly effective and efficient psychological treatments will be connecting therapeutic programs more directly with biological mechanisms. Addressing the way in which therapies are developed is equally important. The current standard procedure is to develop psychological treatments in research settings for specific mental health disorders and then to evaluate them using RCTs. The advantage of an RCT is the strong internal validity that randomization creates (Booth & Tannock, 2014). The strong internal validity created by homogenous groups and standardised manuals has been good for RCT research but has seriously compromised psychological practice where people in clinical settings are not homogenous and treatments need to be flexible and responsive rather than rigid and consistent. For example, a study of 2316 primary care patients in Belgium demonstrated that every psychiatric classification was detected, including

19% with any of the various anxiety disorders, 14% with major depression, 18% with a somatoform

disorder, and 10% with probable alcohol abuse or dependence (Ansseau et al., 2004).

In routine clinical practice, comorbidity is typical; generally conforming to a rule that approximately

half of the individuals meeting diagnostic criteria for one disorder concurrently meet criteria for a second

disorder, half with two disorders meet criteria for three, and so on (Newman, Moffitt, Caspi, & Silva, 1998).

Even common disorders, such as major depression, are not homogenous conditions. Fried and Nesse (2015)

analysed symptom profiles for 3703 outpatients enrolled in the STAR*D trial and identified 1030 unique

symptom profiles with each of 501 profiles being endorsed by only one individual.

Significant heterogeneity and comorbidity usually requires practitioners, at the very least, to train in

multiple protocols covering different diagnostic conditions. If RCT recommendations are followed directly,

this would entail dozens of protocols. Practitioners understandably feel the need to modify evidence-based

treatment protocols in order to be effective; for example, to treat separate comorbid diagnoses sequentially

(Connor-Smith & Weisz, 2003). Consequently, a large gap exists between research and practice

environments compromising the extent to which evidence-based practice can legitimately be claimed.

In some ways, discussions about internal and external validity are "yesterday's news" with regard to

RCTs. Although the problem is well recognised, however, the misnomer of the RCT being at the top of the

methodological hierarchy p. Moreover, influential decision makers such as grant funding bodies and journal

reviewers are, for the most part, firmly wedded to the primacy of the RCT making it difficult for other

approaches to gain traction. One of the main motivations for this paper, in fact, is to demonstrate an

alternative and equivalent approach so that researchers and practitioners might have tangible examples to

develop further.

Greater scientific progress could be achieved by developing treatments in routine clinical practice that are delivered responsively and flexibly according to patients' presenting problems and that accommodate the different perspectives of the patients. Treatments should also be informed by a biological theory specifying plausible mechanisms of action. It is likely that a range of different methodologies would be most helpful in generating a comprehensive account of the evidence-base for such a treatment. From the available evidence, it seems reasonable to conclude that an effective treatment should be: flexible; transdiagnostic; efficient; open-ended; and delivered according to the perspective of the patient.

One therapy that has the characteristics that appear to be important for therapeutic effectiveness is the Method of Levels (MOL; Carey, Mansell, & Tai, 2015). MOL is a transdiagnostic cognitive therapy that is based on the principles of Perceptual Control Theory (PCT; Powers, 2005). MOL is a flexible and responsive therapy in which the perspective of the patient determines the content of the therapeutic conversation. Each session is regarded as a discreet problem solving exercise so clients are able to vary the intensity of the treatment they receive by accessing more sessions if they require more intense treatment and fewer sessions if they achieve their goals with a less intense treatment. In each session, the mobility of the client's awareness along with their cognitive reorganizing capabilities are harnessed simultaneously to scrutinise the details and structure of the client's distress so that new perspectives, insights, and possibilities are generated.

For the remainder of this paper the development and evaluation of MOL is described to illustrate a psychological treatment building approach that is different to the standardised RCT strategy. MOL has been developed and researched in routine clinical practice. This model of therapy research demonstrates one possibility for generating effective and efficient psychological treatments and progressing professional psychology research and practice.

Development of the Method of Levels

As a transdiagnostic cognitive therapy, MOL focusses on the psychological distress underlying symptom presentations rather than the symptoms themselves (Carey et al., 2015). MOL is based on three fundamental principles described in PCT: control, conflict, and reorganization (Carey et al.). Clients regulate the intensity of their MOL treatment by scheduling more sessions if they require increased intensity. MOL was initially developed in routine primary care practice in the National Health Service (NHS) in rural Scotland. In this section we begin by describing the important theoretical principles underpinning MOL and then describe some of the research used in testing the theory and developing the therapy.

Perceptual Control Theory: A Biological Theory Specifying Mechanisms of Action.

PCT (e.g., Powers, 2005) is a biological theory explaining how organic control works. We describe PCT as a biological theory because it based upon known, physical, biological processes such as the process of negative feedback that produces homeostasis. Negative feedback is central to the process of control making negative feedback an ideal candidate for the mechanism underpinning a genuinely biopsychosocial model of functioning (Carey, Mansell, & Tai, 2014). Control is regarded as the basis of everyday functioning for living things. From a PCT perspective, conflict is the primary means by which control is chronically disrupted and psychological distress is subsequently generated. Reorganization is a simple yet powerful inherited biological learning mechanism that resolves conflict and restores control. The putative biological mechanisms of PCT have been articulated in some detail (Powers, 2005), with emerging evidence for their basis in contemporary behavioral neuroscience research (Barter, Sukharnikova, Rossi, Bartholomew, Yin, 2015; Pellis & Bell, 2011).

PCT represents exactly the kind of biological theory that can complement clinical trials to provide a complete, comprehensive, and scientific test of psychological therapies. PCT is an explanation of the process of control and control is assessed by disturbing the state of a variable and monitoring whether or not the disturbance is removed by the actions of an individual. If these corrective actions occur, we would

conclude that that particular variable was being controlled by the individual. The central principles of PCT have been rigorously tested using model building research, which are summarised later. The basic principles of PCT are clearly evident within the psychotherapeutic and psychopathology literature, although not usually discussed from a PCT perspective.

Control. Control is recognized throughout the psychopathology literature. Dobson and Dozois (2001), for example, suggest that a self-control model has potential as a general model of psychopathology and the aspects of control such as the need to control or loss of control have been described as important in disorders such as obsessive-compulsive disorder (Gwilliam, Wells, & Cartwright, 2004), panic disorder (Hedley, Hoffart, & Sexton, 2001), and psychotic disorders (Morrison, Nothard, Bowe, & Wells, 2003). Given the importance of control to psychopathology it would seem that a theory which operationally defines control and describes how control works would be extremely useful. From a PCT perspective, control is defined as "achievement and maintenance of a preselected perceptual state in the controlling system, through actions on the environment that also cancel the effects of disturbances" (Powers, 2005, p. 296). Control is the process of achieving an intended result such as developing a relationship, or building a career, or obtaining a particular emotional state. A control system maintains a current, ongoing perception of what is being controlled; the current state of the perception is compared to the intended state; and action is taken to ensure the perception matches the intention (Powers, 2005). Negative feedback minimises the difference between the intended and the perceived state (Carey et al., 2014). Homeostasis is an example of control whereby variables such as body temperature, blood plasma glucose concentrations, sodium concentrations, and neurotransmitter concentrations are maintained at appropriate levels (Carey et al.)

Conflict. Since control is regarded as the state of routine functioning, for a problem to occur, control must be disrupted in some way. Psychologically, chronic disruption of control most commonly results through conflict (Powers, 2005). Conflict is a situation where two incompatible states are

simultaneously specified; such as wanting the approval of others but also wanting to speak freely or wanting to drink to feel socially at ease but not wanting to drink because it creates relationship difficulties. According to Powers "conflict *itself*, not any particular kind of conflict, represents the most serious kind of malfunction of the brain short of physical damage" (p. 265).

Convergent evidence across the social and clinical psychology literature demonstrates that conflict, particularly between important personal goals or ideals, is associated with mental health problems and reduced well-being (Kelly, Mansell, & Wood, 2015). For example, Wells (2005) suggested that people with Generalised Anxiety Disorder (GAD) are in "two minds about worrying" (p. 110). Therapies such as Motivational Interviewing (Bell & Rollnick, 1996) and Acceptance and Commitment Therapy (ACT; Strosahl, Hayes, Wilson, & Gifford, 2004) also invoke the concept of conflict. Psychological problems might arise in ways other than conflict so the professional psychologist practicing from a PCT perspective would approach therapy with the attitude of "psychological distress as conflict" as an hypothesis that they evaluate during the therapeutic conversation.

Powers (2005) is not the first to link conflict with psychological distress with the work of Miller (1944), Mowrer (1960), and others providing important insights into approach and avoidance conflicts. Powers' contribution, however, is to explain with a functional model how conflict can have its devastating effects. Moreover, by integrating conflict into a coherent theory, Powers is able to articulate what the conflict-free state of an individual might be and how this state can be achieved through the process of reorganization.

Reorganization. Powers (2005) proposed a primitive yet powerful inherited learning mechanism as the candidate for growing and developing the network of control systems that produces a mature organism. This reorganizing mechanism is based on a process of random change and error reduction. When chronic error threatens the ongoing integrity of the system, random changes to the system are generated. If

the effect of a change reduces error, that change persists until error increases at some time in the future

(Powers). If error does not reduce, another random change is generated and the effect on error is monitored.

The ultimate criterion, is the effect of the change on error (Marken & Carey, 2015).

This process of random change and error reduction is considered to be the primary means of

chronic conflict resolution (Carey et al., 2015). MOL, therefore, seeks to promote reorganization. Because

reorganization is a random process it is important to appreciate that conflicts remit according to variable

time frames. Also, the best solution might not be the first solution generated, so some patients' problems

might appear to deteriorate before they improve (Carey et al.). Understanding therapeutic change as a

process of reorganization fosters an appreciation of how new insights, perspectives, and beliefs are

generated and also enables therapists to accommodate the idiosyncratic nature of the reorganizing process.

Research to Test the Theory and Develop the Therapy

In PCT, the methods used to test important aspects of the theory are quite different to theory

building research in other areas of psychology. The model building research used to test the theory will be

described first in this section followed by research that has been used to develop the therapy.

Research testing the theory. PCT theorists and scientists rely on simulation model building rather

than statistical models to test important theoretical principles robustly and empirically. In PCT, a model is a

"precise quantitative proposal about the way some system operates in relation to its environment" with the

model being "stated in a way that can be used to calculate behavior as a function of moment-by-moment

variations in the independent variable" (Bourbon & Powers, 2003, p. 141). Because of the way the

principles of control, conflict, and reorganization have been tested through building simulation models,

researchers and clinicians are confident that these principles are sturdy and broadly applicable to designing

psychological treatments.

Simulation models can open the lid on a "black box" that could otherwise not be explained. A

model, however, should not hold primacy over experience. If a model disagrees with experience then the

model should be reconsidered. Yet when models do agree with experience they provide a powerful mode of

explanation. Combining model building methodology with other research approaches such as qualitative

methods, therefore, should provide the most robust of all evidence (Marken & Carey, 2015).

   Tests of hierarchical control. One example of model building research testing the PCT model of

behavior is a computer simulation of a hierarchy of control systems described by Marken (1990). The

simulation demonstrated that all control systems at all levels of the hierarchy could successfully control their

perceptual inputs without conflicting with each other. This control occurred despite continuously varying

disturbances to the environmental correlates of the perceptions under control.

   Successful control in a hierarchy requires that higher level systems act more slowly than lower level

systems. This fact provides a basis for empirical tests of the hierarchical control model using reaction time

methods. One of the earliest such tests demonstrated that the seemingly simple action of a person

maintaining arm position involves a hierarchy of control systems; where slower, higher level relationship

control systems act to revise the arm's relationship to the body (Powers, Clark, & McFarland, 1960). This is

highly relevant information for professional psychologists who may find it helpful to learn that a high level

goal such as being a confident person will take longer to change and achieve than a lower level goal such as

meeting a friend for coffee.

   More precise tests of the hierarchical control model using reaction time experiments have been

described by Marken (1993) and Marken, Khatib, and Mansell (2013) demonstrating that lower level

perceptions (e.g. shape) can be controlled at a faster rate of presentation than higher level perceptions (e.g.

sequence). This has also been tested by comparing people's behavior to that of computerised hierarchical

control models performing the same tasks (Marken & Powers, 1989a). For example, a series of

computerised tracking experiments where participants were signalled to change the phase relationship

between cursor and target showed an almost perfect match between the behavior of the participants in the study and that of a two level control model performing the same task (Marken & Powers).

Tests of reorganization. Model-based research on reorganization has mostly tested the efficiency of the proposed random trial-and-error method of optimizing control systems (Marken & Powers, 1989b). It has been demonstrated, for example, that a random trial-and-error process where the rate of random change is proportional to the difference between current and goal state will reach the goal state almost as efficiently as it would had it been able to move directly toward the goal (Marken & Powers). This process of reorganization is now called the *E. coli* method since it resembles the biased random walk navigation process of the *E. coli* bacteria (Koshland, 1980).

Reorganization research can help clinicians understand more clearly the nonlinear and unpredictable nature of psychological change (Marken & Carey, 2015). Periods where things seem to be getting worse along with sudden leaps forward, as well as plateauing, can all be explained through the process of reorganization. Understanding reorganization as a process of random change and error reduction can provide professional psychologists with a new approach to supporting clients who are behaving in peculiar and perhaps even apparently counterproductive ways.

Research developing the therapy. While model building research has been the method du jour for investigating the important biological principles and mechanisms underpinning MOL, different methodologies have been used to both complement some of the model building work in areas that are directly relevant to the treatment as well as investigating other aspects of the treatment such as treatment effectiveness and efficiency. In particular, qualitative methods have been used to explore the change process through semi-structured interviews with clients accessing different therapies. Additionally, patients and GPs have provided their assessment of the implementation and experience of MOL (Carey & Mullan, 2007).

Investigating the change process. A series of studies have considered different aspects of the

change process, including reports by people who experience change through psychotherapy as well as individuals who experience change without psychotherapy (Buchan, Galbraith, & Carey, 2013; Carey et al., 2007; Gianakis & Carey, 2011; Higginson & Mansell, 2008). These studies established that people describe a similar change process regardless of whether it happens with or without psychotherapy (Carey et al., 2015). The change process involved both sudden and gradual components. Participants in these studies did not describe change occurring in an orderly, linear series of stages or steps. This qualitative change research produced results that complement the reorganization research mentioned above.

These studies demonstrated that participants could not identify *how* change occurred even though they were emphatic *that* change occurred. While this might sound counterintuitive at first, it makes sense that people might be aware of their state prior to change and also aware of their state after change but not be able to describe the transition from prior to after. This is consistent with anecdotal experience where people recalling a name they have forgotten find that, at some later point; the name "pops" into their mind. The experience of the name appearing is undeniable but how it came to be there is much more difficult to articulate. The indescribable nature of the change process might explain why descriptions of change in psychotherapy actually report the consequences of change rather than the change process itself.

Impact of the therapy. In the development of MOL, practitioner researchers considered it important to ascertain how the therapy was experienced by patients. People who attended sessions of MOL were asked to describe their experiences of the therapy and also of the way in which they were able to schedule appointments as they required them (Carey, Carey, Mullan, Spratt, & Spratt, 2009; Carey & Mullan, 2007). GPs were asked about their perspective of the way in which patients were able to access therapy. These qualitative investigations accompanied quantitative assessments using standardised questionnaires, which demonstrated that patients, on average, showed decreases in self-reported symptoms.

In general, patients reported experiencing MOL positively and described the benefits they derived from the MOL conversations (Carey & Mullan, 2007). Patients were surprised at the "depth" they reached within therapy sessions. GPs were extremely positive about the approach.

The importance of a sound theory to make sense of different results was, again, highlighted in these studies. Some patients, for example, described feeling confused at the time they were interviewed (Carey & Mullan, 2007). At the time of being interviewed, however, not all patients will have finished attending MOL sessions and the confusion may have been a normal manifestation of the reorganization process beginning to generate random changes. From a theoretical perspective, therefore, reorganization, would not necessarily be considered a problematic occurrence. This point provides a more granular illustration of the importance of including theoretical principles as part of empirical investigations.

Trials of MOL. Given the way in which MOL has been developed in routine clinical practice, trials evaluating its effectiveness do not look similar to trials conducted in research settings. It is not the setting or the presence of a control group, however, that distinguishes experimental from nonexperimental work (Piantadosi, 2005). The defining feature of an experiment is the degree to which the scientist controls the treatment under investigation (Piantadosi). MOL trials have typically been conducted in health services where the entire population of people referred for psychological treatment is administered the treatment.

Replication instead of randomisation. Rather than randomisation in research settings, MOL researchers have chosen replication in routine practice as a means of maintaining the rigor of their work. Replication is standard in many areas of scientific research but relatively uncommon in RCT research (Carey & Stiles, 2015). MOL researchers, however, have replicated their findings with different clinicians in different primary care settings across different time frames as well as different health services such as secondary care (Carey et al., 2009). They have also replicated this work in different health systems such as

from the Scottish NHS to the Australian public mental health service (Carey et al., 2013). Effect sizes of

0.80 (Carey & Mullan, 2008); 0.77 and 1.36 (Carey et al., 2009); and 1.45 (Carey et al., 2013) are reported.

Time 1 and time 2 instead of pre and post. Additionally, with patient-led appointment scheduling,

standard pre and post trials are not possible. Instead Time 1 and Time 2 trials are conducted. Outcome

measures are administered at every appointment so that when Time 2 occurs, the patient's last outcome

score is used to compare with their Time 1 score. Essentially, this means that the results achieved with MOL

trials may be underestimates of the actual effect size because some people will not record the progress at the

time of the comparison that they will eventually go on to make beyond Time 2 (Carey et al., 2013).

Benchmarking, the efficiency ratio, and treatment length. Another methodological innovation has

been the use of benchmarking to establish different comparison groups (Carey et al., 2013). In one study,

evaluations of routine clinical practice published in the peer-reviewed literature were located and their

relevant statistics were derived. Whilst benchmarking, like any methodology, has disadvantages, it also has

some significant strengths. In an RCT, the standard procedure compares the therapy being developed with a

Treatment as Usual group or some other control group which the researcher expects will not perform as well

as the therapy being investigated. In a benchmarking study, however, the therapies under investigation are

the preferred therapies of different researchers and clinicians. These therapies are compared across studies

according to particular statistics. In this study, effect sizes as well as reliable and clinically significant change

statistics were compared (Carey et al.). Furthermore an efficiency ratio was developed and used as an

additional statistic for benchmarking purposes.

In the context of finite financial resources and the growing mental health burden in public health,

the efficiency of treatments requires serious consideration. There is a significant disconnect with the delivery

of psychological treatments in that most treatments are designed to be longer than ten sessions, yet most

patients attend for fewer than ten sessions (Carey et al., 2015). The evidence for treatment length has been

largely accumulated through RCTs. While an RCT demonstrates *that* a certain number of sessions can be effective in reducing psychological distress, they have never demonstrated that a certain number of sessions is *necessary* for treatment effectiveness.

Using RCTs to provide information they are unable to deliver has resulted in the development of treatment guidelines that are out of step with clinical practice. For example, in the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) recommends that, "For all people with depression having individual CBT, the duration of treatment should typically be in the range of 16 to 20 sessions over three to four months" (Nice, 2009, p. 28). However, the first year evaluation of the Improving Access to Psychological Therapies initiative in the United Kingdom, reported that the "numbers of treatment sessions were surprisingly low" (Glover, Webb, & Evison, 2010, p. 23). In this study only 1.38% of the 7,825 patients for whom data were available attended 16 or more treatment sessions with the median number of appointments being less than 10. We would argue that the only reason this result would be "surprising" is because RCTs have created a misleading picture regarding treatment duration.

Designing treatments to be longer than patients need is inefficient. MOL is designed to be delivered within the timeframe of individual clients. The benchmarking exercise indicates that MOL is an efficient treatment compared to other studies of treatments delivered in routine clinical practice (Carey et al., 2013).

Limitations and research context. The approach to therapy research and development described here is similar in many ways to routine outcomes monitoring and client feedback. In the approach we have outlined, however, the data obtained through monitoring and feedback have been used in conjunction with robust theoretical principles to develop and evaluate a new therapy rather than monitoring the effects of an existing therapy. Moreover, these data have been collated across different clinicians and different services to investigate areas such as efficient methods of appointment scheduling.

Every research method has strengths and limitations and this approach to therapy research and development is no exception. The approach we have articulated would not necessarily be the best approach, for example, to compare the relative effectiveness of different therapies directly. As we suggested at the beginning of this paper, the gold standard should not be ascribed to a particular research method. Rather, the gold standard should be the *process* of matching an appropriate research method to an important research question. From this perspective, all research designs, including RCTs, can be considered to be useful and relevant designs depending on the questions being asked. Throughout this paper we have emphasised that different research methods should be considered complementary rather than oppositional to provide a more complete understanding of the area under investigation.

Implications and Applications

In order to have a sustained impact on the increasing burden of disease created by mental health problems it is important to develop creative and innovative solutions that do not compromise scientific rigor. We are not suggesting that RCTs have no place in the development of effective and efficient psychological treatments but, rather than a mountain top, RCTs might be better situated on a level playing field. From this field the most appropriate methodology or methodologies for the questions to be answered can be selected. Isolating RCTs as the preferred method of treatment development and evaluation has thwarted the progress of professional psychological practice.

Whereas RCTs are expensive and require the commitment of dedicated research teams, the implications of this paper are that practitioner researchers can make good use of the data they collect in the course of their routine practice to inform the development of effective and efficient treatments. By basing treatments on sound theories with plausible biological mechanisms and through the use of a variety of methodologies, including replication, it is possible to achieve a much greater connection between research

and practice. The result will be treatments that can be applied seamlessly to a range of different practice settings and a variety of presenting problems.

In this paper we have described the development and evaluation of MOL to illustrate the way in which different methodologies can be combined to build an evidence base. MOL is perhaps the only psychotherapy informed by a biological theory which tests its foundational principles using the exacting procedures of simulation model building. MOL has been developed in routine clinical practice paying attention to elements such as patients' perspectives, the principle of replication, and benchmarking as a methodology for making comparisons.

By linking theory closely with empirical investigations and using a variety of methodologies it has been possible to develop an effective and efficient, evidence-based treatment that is flexible and responsive to the range of problems needing to be addressed in routine clinical settings. This treatment, and the approach through which it was developed and evaluated, may assist in reversing the concerning trend of an increasing burden of disease for mental health problems and may help to close the divide between research and practice.

References

Ansseau, M., Dierick, M., Buntinkx, F., Cnockaert, P., De Smedt, J., Van Den Haute, M., & Vander Mijnsbrugge, D. (2004). High prevalence of mental disorders in primary care. *Journal of Affective Disorders, 78*, 49-55. http://dx.doe.org/10.1016/S0165-0327(02)00219-7

Barter, J. W., Li, S., Sukharnikova, T., Rossi, M. A., Bartholomew, R. A., & Yin, H. H. (2015). Basal ganglia outputs map instantaneous position coordinates during behavior. *Journal of Neuroscience, 35*, 2703-16. https://doi.org/10.1523/JNEUROSCI.3245-14.2015

Bell, A., & Rollnick, S. (1996). Motivational interviewing in practice: A structured approach. In F. Rotgers, D. S. Keller and J. Morgenstern (Eds.), *Treating substance abuse: Theory and technique* (pp. 266-85). New York: Guilford Press.

Booth, C. M., & Tannock, I. F. (2014). Randomised controlled trials and population-based observational research: partners in the evolution of medical evidence. *British Journal of Cancer, 110*, 551-55. https://doi.org/10.1038/bjc.2013.725

Bourbon, W. T., & Powers, W. T. (2003). Model and their worlds. In P. J. Runkel, *People as living things* (pp. 137-54). Hayward, CA: Living Control Systems Publishing.

Buchan, C., Galbraith, V., & Carey, T. A. (2013). An Interpretative Phenomenological Analysis investigation into men's experience of psychological change without psychotherapy. *Poster presented at the Counselling Psychology Annual Conference, 11-12 July, Cardiff, UK.*

Carey, T. A., Carey, M. A., Mullan, R. J., Spratt, C. G., & Spratt, M. B. (2009). Assessing the statistical and personal significance of the Method of Levels. *Behavioural and Cognitive Psychotherapy, 37,* 311-24. https://doi.org/10.1017/S1352465809005232

Carey, T. A., Carey, T. A., Stalker, K., Mullan, R. J., Murray, L., & Spratt, M. (2007). Psychological change from the inside looking out: A qualitative investigation. *Counselling and Psychotherapy Research, 7,* 178-85. http://dx.doi.org/10.1080/14733140701514613

Carey, T. A., Mansell, W., & Tai, S. J. (2014). A biopsychosocial model based on negative feedback and control. *Frontiers of Human Neuroscience, 8,* article 94. https://doi.org/10.3389/fnhum.2014.00094

Carey, T. A., Mansell, W., & Tai, S. J. (2015). *Principles-based counselling and psychotherapy: A Method of Levels approach*. London: Routledge.

Carey, T. A., & Mullan, R. J. (2008). Evaluating the Method of Levels. *Counselling Psychology Quarterly, 21,* 247-56. https://doi.org/10.1080/09515070802396012

Carey, T. A., & Mullan, R. J. (2007). Patients taking the lead. A naturalistic investigation of a patient led approach to treatment in primary care. *Counselling Psychology Quarterly, 20*, 27-40. http://dx.doi.org/10.1080/09515070701211304

Carey, T. A., & Stiles, W. B. (2015). Some problems with randomized controlled trials and some viable alternatives. *Clinical Psychology and Psychotherapy.* doi:10.1002/cpp.1942

Carey, T. A., Tai, S. J., & Stiles, W. B. (2013). Effective and efficient: Using patient-led appointment scheduling in routine mental health practice in remote Australia. *Professional Psychology: Research and Practice, 44*, 405-14. http://dx.doi.org/10.1037/a0035038

Collins, M., & Carey, T. A. (2015). Identification of real and artefactual moderators of effect size in the treatment of depression. *Multivariate Behavioral Research, 50*, 109-25. doi:10.1080/00273171.2014.963193

Connor-Smith, J. K., & Weisz, J. R. (2003). Applying treatment outcome research in clinical practice: Techniques for adapting interventions to the real world. *Child and Adolescent Mental Health, 8*, 3-10. doi:10.1111/1475-3588.00038Dobson, K. S., & Dozois, D. J. (2001). Historical and

philosophical bases of the cognitive behavioral therapies. In K. S. Dobson (Ed.), *Handbook of cognitive-behavioral therapies* (2nd ed., pp. 3-39). New York: Guilford Press.

Fried, E. I., & Nesse, R. M. (2015). Depression is not a consistent syndrome: An investigation of unique symptom patterns in the STAR*D study. *Journal of Affective Disorders, 172,* 96-102. doi:10.1016/j.jad.2014.10.010

Gianakis, M., & Carey, T. A. (2011). An interview study investigating experiences of psychological change without psychotherapy. *Psychology and Psychotherapy: Theory, Research, and Practice, 84,* 442-57. doi:10.1111/j.2044-8341.2010.02002.x

Glover, G., Webb, M., & Evison, F. (2010). *Improving access to psychological therapies: A review of the progress made by sites in the first roll-out year.* Stockton-on-Tees, UK: North East Public Health Observatory.

Gwilliam, P., Wells, A., & Cartwright-Hatton, S. (2004). Does meta-cognition or responsibility predict obsessive–compulsive symptoms: A test of the metacognitive model. *Clinical Psychology and Psychotherapy, 11,* 137–144. doi:10.1002/cpp.402

Hedley, L. M., Hoffart, A., & Sexton, H. (2001). Early maladpative schemas in patients with panic disorder with agoraphobia. *Journal of Cognitive Psychotherapy, 15,* 131–142.

Higginson, S., & Mansell, W. (2008). What is the mechanism of psychological change? A qualitative analysis of six individuals who experienced personal change and recovery following a significant life difficulty. *Psychology and Psychotherapy: Theory, Research, and Practice, 81,* 309-28. doi:10.1348/147608308X320125

Jadad, A., & Enkin, M. (2007). *Randomized controlled trials: Questions, answers, and musings* (2nd ed.). Malden, MA: Blackwell Publishing.

Johnsen, T. J., & Friborg, O. (2015). The effects of cognitive behavioral therapy as an anti-depressive treatment is falling: A meta-analysis. *Psychological Bulletin.* Advance online publication. http://dx.doi.org/10.1037/bul0000015

Kazdin, A. E. (2007). Mediators and mechanisms of change in psychotherapy research. *Annual Review of Clinical Psychology, 3,* 1-27. doi:10.1146/annurev.clinpsy.3.022806.091432

Kelly, R. E., Mansell, W., & Wood, A. M. (2015). Goal conflict and well-being: A review and hierarchical model of goal conflict, ambivalence, self-discrepancy and self-concordance. *Personality and Individual Differences, 85,* 212-229. http://dx.doi.org/10.1016/j.paid.2015.05.011

Koshland, D. (1980) *Bacterial chemotaxis as a model behavioral system*. New York: Raven Press.

Marken, R. S. (1990). Spreadsheet analysis of a hierarchical control system model of behavior. *Behavior Research Methods, Instruments, & Computers*, 22, 349-59. doi:10.3758/BF03203175

Marken, R. S. (1993). The hierarchical behavior of perception. *Closed Loop, 3*, 33-54.

Marken, R. S., & Powers, W. T. (1989a). Levels of intention in behavior. In W. Hershberger (Ed.) *Volitional Action* (pp. 409-30). North-Holland: Elsevier Science Publishers.

Marken, R. S., & Powers, W. T. (1989b). Random-walk chemotaxis: Trial-and-error as a control process. *Behavioral Neuroscience, 103,* 1348-1355. doi:10.1037/0735-7044.103.6.1348

Marken, R. S., Khatib, Z., & Mansell, W. (2013). Motor control as the control of perception. *Perceptual and Motor Skills, 117*, 236-247. doi:10.2466/24.23.PMS.117x15z2

Marken, R. S., & Carey, T. A. (2015). Understanding the change process involved in solving psychological problems: A model-based approach to understanding how psychotherapy works. *Clinical Psychology & Psychotherapy, 22,* 580-590. doi:10.1002/cpp.1919

Miller, N. E. (1944). Experimental studies of conflict. In J. McV. Hunt (Ed.), *Personality and the behavior disorders* (Vol. 1, pp. 431-465). New York: Ronald Press.

Morrison, A. P., Nothard, S., Bowe, S. E., & Wells, A. (2003). Interpretations of voices in patients with hallucinations and non-patient controls: A comparison and predictors of distress in patients. *Behaviour Research and Therapy, 42,* 1315–1323. http://dx.doi.org/10.1016/j.brat.2003.08.009

Mowrer, O. H. (1960). *Learning theory and behavior*. New York: Wiley.

Newman, D. L., Moffitt, T. E., Caspi, A., & Silva, P. A. (1998). Comorbid mental disorders: Implications for treatment and sample selection. *Journal of Abnormal Psychology, 107,* 305-11.

NICE. (2009). *Depression: The treatment and management of depression in adults*. London, UK: National Institute for Health and Clinical Excellence.

Pellis, S. M., & Bell, H. C. (2011). Closing the circle between perceptions and behavior: a cybernetic view of behavior and its consequences for studying motivation and development. *Developmental cognitive neuroscience, 1,* 404-13. http://dx.doi.org/10.1016/j.dcn.2011.07.010

Piantadosi, S. (2005). *Clinical trials: A methodologic perspective* (2nd ed.). Hoboken, NJ: Wiley.

Powers, W. T. (2005). *Behavior: The control of perception* (2nd ed.). New Canaan, CT: Benchmark.

Powers, W. T., Clark, R. K., & McFarland, R. L. (1960). A general feedback theory of human behaviour: Part I. *Perceptual and Motor Skills, 11,* 71-88.

Salter, A., & Louise, J. (2015). *Design of randomised controlled trials: Study guide.* Adelaide: School of Population Health, University of Adelaide.

Strosahl, K. D., Hayes, S. C., Wilson, K. G., & Gifford, E. V. (2004). An ACT primer: Core therapy processes, intervention strategies, and therapist competencies. In S. C. Hayes and K. D. Strosahl (Eds.), *A practical guide to Acceptance and Commitment Therapy* (pp. 31-58). New York: Springer. doi:10.1007/978-0-387-23369-7_2

Wells, A. (2005). The metacognitive model of GAD: Assessment of meta-worry and relationship with DSM-IV

      generalized anxiety disorder. *Cognitive Therapy and Research, 29*, 107-21. doi:10.1007/s10608-005-

      1652-0

Whiteford, H. A. et al. (2013). Global burden of disease attributable to mental and substance use disorders:

      findings from the Global Burden of Disease Study 2010. *Lancet, 382,* 1575-86.

      http://dx.doi.org/10.1016/S0140-6736(13)61611-6