Mental Health and Learning Disabilities Research and Practice, 2007, 4, 83 -97

Formulating Research Questions that are Relevant to Psychotherapy Peter Stratton¹

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Abstract

This paper argues that the National Institute for Health and Clinical Excellence (NICE) has created misleading recommendations and that their interpretation by the Improving Access to Psychological Therapies (IAPT) initiative is likely to inflict lasting damage on the operation and development of psychotherapy. I propose that the root of the problem lies in persevering with an inappropriate research question. Both the research question 'which therapy works best' and the research methodology to which it leads, the Randomised Controlled Trial (RCT), were transferred from medical treatments for clearly defined illnesses. I explore the consequences of this process, and propose a research question that is an example of a better fit to the purposes of psychotherapy. The implications of the therapeutic alliance, and of working in relation to the relational contexts in which the client lives their life, demonstrate the limitations of the reliance on RCTs. The approach taken by the IAPT initiative is shown to be based on a selective reading of NICE guidelines. Suggestions are made of strategies for research to improve the usefulness of psychological therapies.

Keywords: RCT, depression, therapeutic alliance, systemic psychotherapy, IAPT, NICE.

Introduction

My starting point is to claim that no amount of smart methodology can salvage something from research that fails to ask the right question. The phenomenon I want to examine is the persisting dominance of the competitive outcome question despite its long history of relative failure in mental health.

A question posed by this formulation is whether we should continue the competitive process with increasing effort and methodological refinement, or should the research effort now be directed to ways of making psychotherapy even more effective? The position taken in this paper is that we have much to learn about how to do psychological therapies effectively and that we have plenty of indicators of the kinds of research that would be most fruitful. Therefore the effort and resources should be directed to different research questions: Those that will improve current provision, and those that will improve the effectiveness in everyday practice of psychotherapy.

While this paper makes an argument for developing psychotherapy, and proposes that this means maintaining or increasing the variety of forms of psychotherapy on offer, the current political context is working in the opposite direction. As will be evident from other papers in this issue, the way the argument for IAPT is being conducted will, if it succeeds, cause lasting damage to the range and quality of psychotherapy. The damage will be immediate as resources are drained away from the training and practice of most forms of therapy, but the most damaging effect will be in the future as research and practice into new directions for therapy become increasingly unlikely.

There are many reasons to be concerned about the exclusion by IAPT of anything except cognitive behavioural therapy (CBT). Here I concentrate on the lessons to be taken from applying concepts of good research governance to the issue. Almost as an aside, it is remarkable that the direction taken by IAPT is being defended by claims that it is essential to base the practice on the recommendations of "gold standard" research used by NICE. The ways the pilot studies are being conducted do not remotely approach the methodological standards that NICE would apply in deciding whether they produce reliable evidence.

Where Has The Outcome Question Taken Us?

In one sense the output of outcome research has been very positive. Psychotherapy has been shown to achieve remarkably consistent positive results whichever therapy is being considered. When therapy is compared with 'treatment as usual' it is almost always superior; when psychotherapy is compared with drug treatment it is generally at least as good and more acceptable; when two psychotherapies are compared they are as good as each other. This is a substantial achievement when methods of psychotherapy were developed primarily from theoretical positions with only limited refinement through empirical research into which aspects were responsible for therapeutic change. For example Salkovskis (2002) states that: "CBT ... is quite different now to CBT as practised ten or even five years ago. This process is evolutionary and interactive, and pragmatic outcome trials play a relatively minor part in this development" (p. 2)

Outcome research starting from the question of "which kind of psychotherapy is most effective" has not produced clear and consistent results. Wampold (2001) makes a strong case that research comparing realistic alternative therapies has failed to find substantial differences. This "equivalence phenomenon" had led many writers, along with Wampold, to posit the existence of 'common factors' that are shared by all therapies and account for their effectiveness. There is, in fact, a good discussion of this debate, and associated criticisms of reliance on RCT data in the current NICE guidelines on depression (NICE guideline 23, 2004). More recently, Norcross et al (2006) offer a balanced discussion of the arguments around this issue. Sprenkle and Blow (2007) point to the evidence that characteristics of the therapist play "an essential role in effective therapy. In fact, we find it shocking that relatively little attention is paid to therapist variables in psychotherapy research." (p.219). Norcross et al also suggest that the statistical procedures used in RCTs make it impossible for the data to indicate whether or not there were differences between the therapists.

Lebow (2006) points out that: "Psychotherapy researchers typically focus exclusively on different clinical interventions while ignoring the psychotherapists who make use of them. It's as if treatment methods were like pills, in no way affected by the person administering them. Too often researchers regard the skills, personality, and experience of the therapist as side issues, features to control to ensure that different groups receive comparable interventions." (pp. 131-132).

While, there is evidence that therapist allegiance is a crucial factor in effectiveness, researcher allegiance is a problematic variable in research. Interpretation of RCT data is made difficult by the fact that the results may be influenced by the motivations of the researcher. Since Luborsky et al (1999) pointed out the effect of the allegiance of the researcher on outcome this factor has regularly been included in research designs but it remains as a potential source of spurious differences between therapies. For example, Elliott et al (2003) conducted a meta-analysis of 79 controlled outcome studies which included an experiential therapy. Once effects due to the allegiance of the researcher were partialled out, the apparent difference between therapy models disappeared. Luborsky & Barrett (2006) review this and six other meta-analyses as well as directly reviewing 24 subsequent studies. They conclude that there is clear evidence that researcher allegiance affects the measured outcomes.

So the results of many years of outcome trials could be conceptualised as demonstrating that the research question on which they were based has taken them as far as they can go. Well-trained psychotherapists, regardless of the model they are using, produce good results but in fact the results are not good enough. A typical figure of improvement in 70-75% of clients justifies the provision of psychotherapy but does not indicate that further development of psychotherapy is unnecessary. Research to show which of the current forms of psychotherapy works best does not tell us how to increase effectiveness. The present situation should be a spur to radically different ways of formulating the research question. In particular to shifting from competitive comparisons of which therapy works best to the more productive direction of what makes therapy effective:

"Once we move away from simply asking what are the most important factors and what works best, to questions of *how* treatments work, how different factors interact to enhance or interfere with the process of change, we stop being driven towards focusing all our research on randomised trials, which although important are not the only way of moving our understanding forward.... they obscure what in the end is going to move us on the most, which is understanding how therapies work rather than knowing what works." (Eisler, 2007, p. 332).

If RCTs are so ineffective, why are they so dominant?

The dominance of RCT methodologies, and thereby of the therapies that fit that kind of research most closely, may benefit from some deconstruction. Approaches that are most easily researched using the medical paradigm of methodology fit the dominant epistemology and are therefore favoured.

There is a long-standing tendency to give higher status to explanations of psychological disorder that are physiological or medical. The RCT methodology comes, most recently, from medicine and perhaps has some of that assumption of superiority. Once the RCT became the favoured technique, a self-sustaining cycle has formed. Because RCTs were formulated to deal with consistent physical conditions (cf. Stratton, 2007) they apply best, as argued above, to methods of therapy that mimic medical treatments. The political basis of funding directs the available research. Then, because NICE will only accept one kind of research, funding is channelled to the forms of therapy and definitions of psychological problems that fit this paradigm. NICE then ends up in the comfortable position that the treatments that most closely fit its medically derived model are the ones with the most evidence. If you do not look too closely, this circular process seems to validate its initial stance. All of this is not to claim that RCTs are worthless, but that their conclusions have to be couched in terms like: research methods that make X assumptions about the nature of psychological problems and their treatment, demonstrate that certain therapies are slightly more effective than others. It turns out that the slightly more effective therapies are those whose formulation is most similar to X, and which are measured by instruments that are most compatible with the definition. Any therapy with processes or outcomes that do not lend themselves to RCT requirements can be dismissed as "ineffective".

There is also an apparent belief that the high level of untreated psychological disturbance is because there is too much psychotherapy that is not CBT. This is said to be wasteful even though there is no evidence that intensive psychotherapy is not necessary for entrenched psychological problems. It seems that it is partly that patients will only come for treatment that fits NICE guidelines: "Because evidence-based psychological services have not been universally available, many of these people do not come forward for treatment." (CSIP 2007, page 8).

The dominance of RCTs also seems to have arisen because the decision to use the methodology preceded any exploration of what research paradigm would be most appropriate for psychological distress. A common error when planning research is to start from the methodology and then look for a way to apply it. Every research supervisor must have had the experience of asking a student what they plan to research and being told 'I plan to use such-and-such methodology but I haven't yet decided on the topic'. One, of many, problems with this starting point is that the research question gets formed to fit the methodology. If your scientific method is a hammer, only nails are suitable subjects for research. If the only acceptable research method is the randomised controlled outcome trial, then comparing the outcomes of different treatments is the only legitimate scientific objective. But what if massive investment in the research fails to deliver clear-cut and useful findings? An old systemic saying is that if a solution is not working the tendency is to apply the same solution more intensively: "more of the same".

Applying a research paradigm that was developed for different purposes can be problematic.

To carry out an RCT rigorously in the complex world of psychotherapeutic practice, what Schön characterised as the "swampy lowlands" (Rycroft, 2004), is extremely difficult. In the attempt to make the methods work, the specifications are being made more and more rigorous. More of the same. I offer two examples. First, a claim has been made (Clarke, 2007) that outcome measures must always be applied at every session, the reason being that if clients drop out, it is essential to have data on the effects of therapy at that point. But this amounts to setting up a rule that would only be practicable and ethical with a narrow range of therapies. The most useful measures may cease to be meaningful if used repeatedly, and repeated use may have an adverse effect on the therapy. Clients are not passive recipients of what the therapist does (Bohart, 2006) and they will actively process outcome measures as indicators of the changes that their therapists want. The rule makes most sense when applied to physical measurement during ongoing administration of a standard dose of medical treatment. So we can expect it to be most appropriate for psychological therapies that most closely resemble the medical model. The rule is also only necessary when there is a significant level of dropout from the treatment. If, as in the family therapy arm of the Leff et al (2000) trial the number of dropouts is so small that they can safely be included in the count of treatment failures, then the rule is unnecessary. But clearly, when, as in that study, 72% of the participants in the CBT arm opt to discontinue treatment, data at the time of dropout are essential.

My second example of what can happen as RCTs become ever more rigorously prescribed comes from the effect of an EU directive. Even in what looks from here like the less problematic world of trials of medical products the European Parliament and Council Directive (2001) seems to have made it very difficult for RCTs to be carried out except with funding from industry. Hemminki and Kellokumpu-Lehtinen (2006) point to a substantial reduction in RCTs since the directive and their Editorial produced a stream of similar complaints from researchers in many different areas of medicine. The main complaint is that this ruling gives the pharmaceutical industry the power to choose which research will be done.

When a research question ceases to produce clear results it is time to go back to the phenomena around which the research question was formulated and ask whether there is something that has not been captured in that question. The research question that NICE depends on is something like: if you conceptualise anxiety and depression as if they were illnesses that people have got, then which talking therapy is most effective? Other papers in this issue will have pointed out that a research question formulated in this way is familiar and acceptable to bodies that fund outcome trials and so therapies that lend themselves to this formulation get more research funded and so have more positive data published. The current NICE recommendations are not so much that cognitive behavioural therapy (CBT) has been shown to be consistently more effective than other psychotherapies, as that other therapies have not been adequately researched. There is a suggestion that NICE will require all psychotherapists except when offering CBT to state that the treatment they are providing cannot claim to be effective (NICE press release, 2005). The warning would be more honestly phrased as 'the treatment has not yet been provided with adequate research funding to assess its effectiveness'. One could add "... within the narrow and inappropriate definition of research transferred by NICE from accurately diagnosable medical conditions treated with precisely measured standardised treatments". But by then your client will have lost interest and be wanting to get on with something useful.

While the "common factors" approach has attempted to broaden the focus of outcome research and has produced some interesting conclusions, I want to step further back to a claim that would be seen by most people as not just plausible but blatantly obvious, and then work through to define the research that would follow from such a claim.

The Alternatives

So what could be an alternative to "conceptualising anxiety and depression as if they were illnesses that people have got"? One, of several, alternatives is to recognise that a person's psychological condition is a function of their context and their relationships. I would suggest that this statement is uncontentious and taken to be obvious across a wide range of cultures. Psychotherapists, especially if they have a broad range of approaches that they can adapt for each individual client, usually work to help the client relate productively to their family, relational, and work contexts.

The proposed focus on context and relationship is known to be viable because many different kinds of systemic therapy, which is based on the assumption, have been shown to be effective (Stratton, 2005). As a straightforward example, Shadish & Baldwin (2003) undertook an analysis of 20 meta-analyses of couple and family therapy. They conclude that "marriage and family therapy is now an empirically supported therapy in the plain English sense of the phrase - it clearly works, both in general and for a variety of specific problems."

More specifically, they conclude:

- Marriage and family interventions are clearly efficacious compared to no treatment.
- Those interventions are at least as efficacious as other modalities such as individual therapy, and may be more effective in at least some cases.
- There is little evidence for differential efficacy among the various approaches within marriage and family interventions, particularly if mediating and moderating variables are controlled.

A focus on context and relationships would protect researchers from too narrow a definition of therapy objectives. Symptom reduction is not the goal of every patient who comes for psychotherapy: "relationship conflicts, patterns of relating and quality of life also bring patients to treatment, and the value of that treatment is not captured by a research study that does not evaluate change on these dimensions" (Stricker 2006, p. 276)

Such a formulation directs the research question away from 'which cure works best?' towards something like "can we help our clients resolve their psychological distress by working with them on their contexts and relationships?". This is still a question about outcome but it would direct the research to the therapeutic processes responsible.

Once the focus is shifted to how therapy works, much evidence points to the significance of the therapeutic alliance. The therapist-client relationship is claimed to predict improvement more strongly than any other factor (Orlinsky et al, 2004). The alliance is usually measured as agreement on therapeutic goals, on treatment tasks, and a relationship bond. A metaanalysis by Shirk & Karver (2003) of 23 studies in child and adolescent therapy gave a weighted mean correlation of 0.2, equivalent to a treatment effect d = 0.45, which is in the range of a medium level effect.

Once the idea of an alliance is accepted, attention turns to how different therapies handle it. Systemic family therapy has found that working with clients in a context that includes the people that provide their most significant relationships, and working with all of them together to redefine the contexts of their lives in more productive ways, leads directly to the therapeutic alliance. Training and practice place great emphasis on the way the therapists present themselves, the direct negotiation of shared therapeutic goals, and engagement of all members of the family. It works directly in terms of the life and relationships of the client outside the therapy.

The alliance message has been accepted by NICE. For adults with depression (Guideline 23, 2004): 4.4.2 ... "For all treatments the strength of the therapeutic alliance is important in ensuring a good outcome." For children (Guideline 28, 2005) Section1.1.5.6 states that "Therapists should develop a treatment alliance with the family." As discussed below, this concern with alliance does not follow through to recommending treatments that are likely to foster the necessary alliance. Rather, the alliance is assumed to depend on personal qualities of the therapist (guideline 23, 2004, 6.1.3): "The quality of the alliance/relationship may account for a significant percentage of variance in outcome (Norcross, 2002; Roth & Fonagy, 1996). Despite this, few research trials offer data on therapist characteristics or capacity to create a good therapeutic relationship". So even when something as interpersonal as the alliance between the therapist and client(s) is concerned, the overarching assumptions drive the research question into formulations about qualities of the individual.

Let us consider two examples of research within the systemic paradigm. Selef, Diamond, Diamond & Liddle (2005) report from a sample of 74

substance-abusing adolescents, finding that the alliance observed between the adolescent and the therapist predicted the extent of reduction in substance abuse and dependency post-treatment. The parent alliance but not that of the adolescent was associated with completing treatment. Further analyses indicated that adolescent alliance only predicted future substance use when there was at least a medium level of parental alliance. The authors suggest that the process may have been one in which parents who formed a good alliance with the therapist were more likely to support the necessary changes in their relationship with the adolescent and in daily activities. This suggestion, that lasting therapeutic gain depends on a good therapeutic alliance, was indicated by a further study from this group in which individual CBT was compared with family therapy. Both therapies were effective but the quality of alliance did not impact on results in the CBT. Alliance in the multi-dimensional family therapy was higher than in CBT but it was the (higher) alliances with parents that most consistently predicted improved outcome.

The studies by Liddle and associates were not designed according to the research question that I posed earlier, but as RCTs. Major studies by Liddle's group (e.g. Liddle et al, 2004) compared multi-dimensional family therapy with standard intensive 6 month residential treatment and found that family therapy was both more effective and much more cost effective. But in the process they provide a clear specification of how to work with the various difficult contexts and the problematic relationships that constitute the lives of these very disturbed adolescents.

Leff et al (2000) has also been viewed as an RCT of outcome. They had to abandon the comparison with CBT because of the high dropout rate, but did compare family therapy with standard drug treatment. Again family therapy had better long-term outcome at comparable cost to medication. Interestingly this study investigated the hypothesis that improvement in depression would be associated with therapeutically induced changes in Expressed Emotion as it had been for schizophrenia (Leff et al, 1985). In this sense it was a much closer fit to my research question, though the attempt to understand therapeutic change through a change in the aspects of relational processes captured by the measures of Expressed Emotion was not fulfilled. Improvement in depression did not correlate with change in Expressed Emotion. This negative outcome makes the research a good example of an empirical test of a plausible assumption that might have misdirected therapeutic effort. As NICE (guideline 28, 2005) puts it: 6.1.3 ... "Treatments may work for reasons other than those for which their proponents think they do."

The Future

The IAPT programme insists on using NICE guidelines:

"If we want the government to provide psychological therapy on the NHS, they are only going to provide it for therapy for which there is a strong evidence base. Other therapies may well prove to be highly effective but, until they do, we should be pushing for implementation of the existing NICE guidelines." (Lord Richard Layard, Guardian, Feb 19th, 2007).

Anyone who does not know the facts would conclude from this that no other therapy than CBT has been shown to be highly effective. This is simply not true, and in many areas, NICE recognises the effectiveness of other therapies. However, for a practitioner the guidelines contain inconsistencies that seem confusing. The "acceptable" evidence does not show a clear superiority of CBT and yet the recommendations are consistent in recommending CBT as the first choice, and only offering the alternatives when CBT has failed.

For adult depression the NICE (guideline 23, 2005) states from its review of the evidence that: 6.8.4 "There is insufficient evidence to determine whether there is a clinically significant difference between couple-focused therapies and individual therapy (CBT or IPT) on reducing depression symptoms at the end of treatment as measured by the BDI' nor 'on reducing the likelihood of leaving treatment early". Note that the BDI (Beck Depression Inventory) is a measure of depression closely tied in to the methods and objectives of CBT so it would be expected to be more sensitive to effects of CBT than of other therapies.

6.8.5 Clinical summary: "There is some evidence for couple-focused therapies as effective treatments for depression when compared with wait list control, and they appear to be more acceptable than antidepressants. They appear to be as acceptable as individual therapy"

Despite the absence of direct comparisons that show a clear superiority of CBT the NICE guidelines for depression state: 4.5.3.1 "When considering individual psychological treatments for moderate, severe and treatment-resistant depression, the treatment of choice is CBT. IPT (inter-personal therapy) should be considered if the patient expresses a preference for it or if, in the view of the healthcare professional, the patient may benefit from it."

And: 4.5.3.9 "Couple-focused therapy should be considered for patients with depression who have a regular partner and who have not benefited from a brief individual intervention. An adequate course of couple-focused therapy should be 15 to 20 sessions over five to six months".

1.5.3.10 "Psychodynamic psychotherapy may be considered for the treatment of the complex co-morbidities that may be present along with depression".

A potential disadvantage of the stepped care model is that clients have to fail at one level before they are offered the next level of treatment. If therapists have no choice but to offer individual CBT first, regardless of the relational context of the client's difficulties, this disadvantage is compounded.

For childhood depression, the NICE guidelines (Number 28, 2005) are an interesting mixture. They recognise the significance of parents and the need to involve them, but do not integrate this recognition when recommending how to proceed. For example it is recognised that when a child is depressed there may well be psychiatric problems of the parents. The guideline suggests ensuring that the parents (separately) receive Section1.1.5.6 states that "Therapists should develop a treatment. treatment alliance with the family. If this proves difficult, consideration should be given to providing the family with an alternative therapist." So it is a characteristic of the therapist that determines whether there is a good alliance, not anything to do with whether the form of therapy is designed to create an alliance. But then they proceed to include family therapy: "1.6.1.2 Children and young people with moderate to severe depression should be offered, as a first-line treatment, a specific psychological therapy (individual cognitive behavioural therapy [CBT], interpersonal therapy or shorter-term family therapy); it is suggested that this should be of at least 3 months' duration."

Then, if psychological treatment combined with fluoxetine (which does not have evidence of effectiveness below 11 years of age) is ineffective: "1.6.3.2.

- An alternative psychological therapy which has not been tried previously (individual CBT, interpersonal therapy or shorter-term family therapy, of at least 3 months' duration), or
- Systemic family therapy (at least 15 fortnightly sessions), or
- Individual child psychotherapy (approximately 30 weekly sessions)."

Conclusions

I have proposed the research question "can we help our clients resolve their psychological distress by working with them on their contexts and relationships?" as an example of one that is likely to be more productive than "which cure works best". Alternative questions could readily have been generated from understandings created within other therapies, but systemic therapy had the advantage of putting the assumptions of NICE and IAPT into clear perspective. I would suggest that the proposed question is much more likely to generate findings that will help the practicing psychotherapists and the development of more effective therapies. Psychotherapists are not generally in a position analogous to choosing whether to prescribe the blue pills or the red pills. But most experienced therapists draw on a variety of forms of therapy in order to adapt them to the needs of their clients (Stratton, 2007).

The research reviewed puts family therapists in a somewhat anomalous position. Many studies that have a bearing on the proposed research question were formulated with a straightforward RCT model and generated data that demonstrate the effectiveness, or at least the efficacy, of systemic

therapy (Stratton, 2005). We could say that the RCT question is misdirected and there is much more productive research to be done, but that if the dominant system insists on RCT data, then we can play that game too. But is that really a legitimate and post-modern position?

So one option is to work with the IAPT programme to implement the detail of NICE evidence and conclusions. It would be necessary to abandon the stance that political support will only come if the Treasury is presented with a very simple consensus that the whole problem of psychological disability can be tackled by universal application of CBT. It may even transpire that the Treasury has some rather sophisticated awareness of the complexity of psychotherapy and will be antagonised by a simplistic and unrealistic message.

In a sense, the IAPT piloting could be a recognition that the existing RCT corpus is not a good enough basis for a major public investment. One suspects that there is a perception that the conditions of refined methodologies of research do not necessarily translate into everyday practice. So at the time of writing the Department of Health is offering to fund 10 "pathfinder projects". Offering just £200,000 to enhance the services and carry out the trial over a year in each of the 10 locations could be a carefully calculated move. It will ensure that the research stays very close to practice and that the outcomes must be substantial in the real world. The programme will also ensure that only CBT is trialled but this self-imposed and unnecessary restriction is another matter (or "more of the same", see above).

A broader objective would be to become involved with NICE to help them find ways of implementing their intention to consider a wide range of evidence. Part of this effort would be directed to a move away from a model of psychological disturbance as being a malfunctioning of the individual. If the data from systemic therapies and the common factors research are taken seriously it will be necessary to redefine what count as appropriate research methodologies. Therapeutic effectiveness will not be seen as an outcome of the treatment method combined with the skills and personality of the therapist. However, this shift would make the task of NICE much more complex. Perhaps the only way to make the job possible would be to formulate their research questions so that they start from the needs of effective psychotherapy rather than of forcing psychotherapy research into a mould derived from agriculture and illness.

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