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ETHICAL CONSIDERATIONS FOR COGNITIVE-BEHAVIORAL THERAPISTS IN PSYCHOTHERAPY RESEARCH TRIALS

Kirsten L. Haman and **Steven D. Hollon**
Vanderbilt University Medical Center

Abstract

Psychotherapy research studies can place particular demands on clinicians, patients, and research staff due to the need to balance the pursuit of knowledge with the offer of treatment. However, the literature with regard to ethical considerations in psychotherapy trials is minimal. The current paper aims to depict CBT community standards of practice in the context of two NIMH-funded treatment trials of major depression, both involving CBT and medication. We describe issues that arose; discuss the ethical considerations involved; and describe our course of action, along with our rationale.

INTRODUCTION

Over 20 years ago, Imber and colleagues published an article related to their experiences with ethics issues during the NIMH Treatment of Depression Collaborative Research Program (Imber et al, 1986). They identified several areas, specific to psychotherapy research, where ethical dilemmas could arise. They concluded that, due to a lack of empirical data on issues related to clinical treatment trials,

> "…the importance of other investigators presenting the ethical problems encountered in their work and the decisions made about them cannot be too strongly emphasized" (p. 145, Imber et al, 1986).

Since the publication of their article, little has been added to the literature with regard to ethical considerations in psychotherapy treatment trials. However, controlled studies of psychotherapeutic treatments are being conducted with ever-increasing frequency. Newer therapies, such as Acceptance and Commitment Therapy (ACT: Hayes, Strosahl, & Wilson, 1999), Cognitive-Behavioral Analysis System of Psychotherapy (CBASP: McCullough, 2003) and Behavioral Activation (BA: Martell, Addis, & Jacobson, 2001), are being evaluated against other forms of therapy and in different disorders. Other trials are examining traditional Cognitive-Behavioral Therapy (CBT) for use in the community (Rush, Trivedi, Wisniewski, Nierenberg, et al., 2006), prevention of depression recurrence (e.g., Hollon , DeRubeis, Amsterdam, Shelton, et al., 2005), or applicability in other domains, such as insomnia (Edinger, Wohlgemuth, Radtke, Marsh, et al., 2001), or headache (e.g., Thorn, Pence, Ward, Kilgo, et al., 2007).

Research is distinguished from clinical practice by the intention to advance general knowledge and draw broad conclusions about a treatment's impact (Fulford & Howse, 1993).In order to gain knowledge, some degree of extra constraint or demand is often placed on patient and therapist. The benefits of the knowledge to be gathered are expected to balance these extra costs of study participation. In reality, maintaining a balance between costs associated with

Address correspondence to: Kirsten L. Haman, Adult Outpatient Psychiatry, Vanderbilt University Medical Center, 1500 21st Ave. South, Suite 2200, Nashville, TN 37212; Kirsten.haman@vanderbilt.edu.

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gathering knowledge and offering enough benefits to make participation worthwhile for clients can offer some ethical challenges.

For instance, a number of potential ethical concerns must be considered when designing a psychotherapy treatment study. Randomization to treatment, use of a wait-list or other control group, enrolling vulnerable populations (children or adolescents, people who may have impaired judgment as a result of illness), reimbursement for patient participation, methods of patient recruitment, and exclusion rules are all areas where researchers must consider the balance between scientific rigor and the general ethical principles, especially those of beneficence/nonmaleficience and respect for people's rights and dignity (American Psychological Association, 2002). Several thoughtful articles examine these study design issues in the context of mental health research (see, for example, Alvidrez & Arean, 2002; Borkovec 1990; Chalmers, 1990; DiMascio, Klerman, Weissman, Prusoff, et al., 1979; Garfield, 1987; Hall, 2001; Imber et al, 1986; Noble, Gelfand, & DeRubeis, 2005).

The focus of the current article, however, is on what happens after the study is designed and participants are enrolled – that is, on the delivery of psychotherapeutic services in a research framework. Our goals are twofold: to examine the impact of a research protocol on clinical practice, and to describe CBT community standards of practice in the context of psychotherapy research trials. In order to accomplish these goals, we will describe the protocols of two NIMH-funded treatment trials of major depression, both involving CBT and medication. Then we will discuss three types of challenges – to patients, to therapists, and to other research staff. We will present relevant ethical guidelines; describe challenges (specific to psychotherapy) to these guidelines that arose during the course of the studies, illustrated via (disguised) clinical experiences; and discuss the actions taken, along with the rationale for our decisions.

One final note: Although we refer to the ethical guidelines specific to the American Psychological Association, we do so primarily because of its degree of detail (and because we, as psychologists, are most familiar with them). The principles, however, are common to guidelines from psychiatry, nursing, and social work organizations.

STUDY DESCRIPTION

We conducted two NIMH-funded, multisite, treatment studies for patients with major depressive disorder. The first, Cognitive Therapy and Pharmacotherapy in the Treatment of Major Depressive Disorder (CPT2), compared the efficacy of CBT to paroxetine over 16 weeks of acute treatment (for more details, see DeRubeis, Hollon , Amsterdam, Shelton, et al., 2005). The second trial, Cognitive Therapy and Pharmacotherapy in the Prevention of Recurrence of Major Depression (CPT3), compares medication treatment alone to the effect of medications plus CBT. Follow-up for this trial is ongoing and results have not yet been published. The goal of CPT3 is to get as many people into a state of recovery from major depression as possible, so flexibility in terms of medications and therapy duration are key aspects of this study.

Across both studies, patients had a principal diagnosis of current major depressive disorder. The majority of patients had comorbid Axis I or Axis II disorders. All patients in CPT3 met criteria for recurrent and/or chronic major depression, while those in CPT2 had to meet additional severity criteria but could be in their first episode. Participants came from a wide range of socioeconomic levels.

Therapy and evaluation sessions were videotaped. All therapists were licensed and experienced, and most were clinical psychologists (we had one psychiatric nurse practitioner). Therapists participated in ongoing weekly supervision of cases, during which taped sessions were viewed and discussed. Patients paid no fees for psychotherapeutic treatment provided in

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the study, and received payments upon completion of certain evaluation procedures. (Please see Alpert, Biggs, Davis, Shores-Wilson, et al., 2006, for a discussion of the ethics involved in serving the under-insured).

Due to the nature of research, the experience of therapy is artificial in some ways. First, in our studies, status is assessed via regular administration of structured clinical interviews and self-report questionnaires. This is a much more extensive and frequent battery than would typically be used in practice. Second, length of treatment, especially in CPT2, was predetermined. Third, therapists were not autonomous in terms of limits they could impose. Finally, therapists in both studies were rated on their adherence to CBT techniques, and in theory might be dissuaded from using certain tools inconsistent with the treatment under study. These constraints on both patients and therapists, combined with other external issues, led to some ethical challenges.

TREATMENT-RELATED ETHICAL CHALLENGES

I. CHALLENGES RELATED TO STUDY DEMANDS ON PATIENTS

As a function of research, there are aspects of study participation that may place additional demands on participants. These include: randomization to treatments; post-randomization changes in study status (i.e., re-randomization to a treatment after certain criteria have been met); required attendance at evaluations in addition to sessions; and constraints on length of treatment.

A. Initial randomization to treatment (CPT3)

1.Description of issue: Because of the need to prevent (as much as possible) selection bias in terms of who gets what treatment, volunteers are randomly assigned to a treatment arm. In CPT3, they could receive medication alone, or medication plus CBT.

2. Vignette: It was more common for volunteers to be unhappy about being in the pharmacotherapy-alone arm. However, Volunteer W was randomly assigned to receive both medication and CBT in CPT3. He had previously expressed to several staff his preference to NOT receive psychotherapy. At his first visit with his therapist, he refused to talk about any issues or situations, was very guarded in terms of revealing any personal information, and while he set some goals, he did not elaborate on these. This did not change in subsequent sessions.

3. Ethical guidelines: The relevant guidelines include 3.10a (Informed Consent), and 8.02 a and b (Informed Consent to Research).These are listed in more detail in Table 1.

4. Our course of action: Volunteers are told at the first phone contact, at the signing of the informed consent, and repeatedly throughout the intake process that treatment assignment is random, and they may not receive the treatment arm they most desire. A small number of participants drop out immediately after being randomized (10 out of 450 participants in CPT3 and 3 of 240 participants in CPT2, less than 2% of the patients randomized overall). Although this could be due to a mismatch between what they wanted and what they got, we don't always know. If a volunteer overtly refused their treatment after randomization, we would try to refer them to a community provider in line with their wishes.

However, other volunteers stay with the project despite not getting the treatment they want. Volunteers undergo a lengthy and elaborate intake process before they are randomized (diagnostic interviews with raters and also with a physician or nurse; a brief physical exam; completion of a large battery of questionnaires), and some volunteers may feel obligated to stay with the study no matter what treatment they receive. Also, other factors like prestige (associated with being in a treatment program at a well-respected institution) or the fact that

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the volunteer may not have many other options for low-cost treatment may lead participants to pursue a treatment they don't actually want. Interestingly, a recent paper using the data from CPT2 suggests that a match or mismatch to preferred treatment had minimal impact on treatment outcome, so that these factors may not have a significant negative effect on outcomes (Leykin, DeRubeis, Gallop, Amsterdam, et al., 2007).

In the vignette above, the assigned CBT therapist was also W's assigned medication provider. The therapist made it clear to W that if he wanted to talk about things in his life or work on solving problems, they could do that at any point; however, she would also be able to provide him with medication treatment even if he never changed his mind about therapy. They worked together for almost two years and W eventually improved enough to meet recovery criteria (6 months free from relapse following a month of minimal symptoms). He never did engage in psychotherapy. We handled W's data as we did that of other participants who were noncompliant with treatment.

If W had been assigned to a CBT therapist and a medication provider separately, we would have followed the same steps (he would have received medication, and could have started therapy at any point), but he would not have been required to participate in either.

B. Re-Randomization to treatment (CPT3)

1. Description of issue: One of the primary goals of CPT3 was to evaluate the long-term benefits of CBT in prevention of recurrence. In order to test this, the study was set up to treat people first to remission and then to the point of recovery, phase out psychotherapy, and re-assign volunteers to either medication or placebo. This would allow us to see whether prior CBT had an impact on recurrence in the presence or absence of medications.

This is a relatively complicated design, and although we explained it thoroughly at intake, re-randomization often occurred long after study entry. Volunteers occasionally forgot a) that therapy would end, and b) that they might not continue to receive medications. Although volunteers with resources could always choose to leave the study and get therapy or medicines on their own, many of our participants could not afford treatment outside of the study. Therefore, just as therapy was terminating (possibly before the client was subjectively ready for it), the potential to lose effective medications was also looming.

2. Vignette: A client (Q) who was self-employed (having both low income and no insurance) remitted from his depression. He maintained improvement for 6 continuous months, thus meeting criteria for recovery. It had taken Q over a year to get to that point, and he had forgotten the study design in that time. While he had consistently been doing well, his therapist (Dr. X) had not been keeping up to date with the time frame. Neither Q nor Dr. X realized the change to the next phase was due, so they had not specifically addressed it other than as a general part of relapse prevention. After his evaluation, the study coordinator reminded Q that he would be transitioned to the next stage, and there was a 50–50 chance he would be tapered off his antidepressant medication. The client became extremely anxious. He also became angry at the study in general and the coordinator in particular.

3. Ethical guidelines: The most relevant ethical guidelines involve 10.10 (Terminating therapy), especially section c (offering pre-termination counseling and alternative service providers), and 8.02 a and b. See Table 1 for the full guidelines.

4. Our course of action: Although psychotherapy was not ended forever by a change of phase (clients could receive a limited number of booster sessions), access to medication might effectively be eliminated. The therapist, being part of the study, needed to be aware of the study activities and to explicitly address conflicts between study goals and client goals in therapy.Dr.

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X, then, had to a) help Q use CBT tools to avoid relapse in the face of elevated stress; b) address Q's thoughts about the study treating him unfairly while being part of that same study; and c) prepare Q to possibly come off medicines which, in Q's mind, had "saved his life" by helping reduce depression. The therapist accomplished a) and b), and worked to address c).As it happened, Q was re-randomized to stay on medication. Additionally, the therapist had to do some condensed termination work, as therapy also was tapered at this phase. Dr. X learned the importance of staying aware of clients' status, and began to incorporate more frequent and pointed discussions about the likelihood and implications of going off medications into therapy with other study clients. Finally, study personnel were reminded of the need to check the participants' understanding of the study design more often throughout the study, which is consistent with the recommendations of Appelbaum (1985). Although we did not implement a formal change to procedures in order to remind therapists and personnel to check in with participants, such a change might be recommended, especially given the potential for change in staff over multi-year trials.

C. Impact of evaluations (Both CPT2 and CPT3)

1. Description of issue: In order to test study hypotheses and evaluate progress, a number of clinician-administered and self-report inventories were administered regularly in both studies by raters who were not told of treatment assignment. The clinical interviews took roughly an hour, and the self-reports required between 15 minutes and two hours, depending on the evaluation. Some volunteers would skip evaluations, while still coming to therapy or staying in contact with the therapist, despite the fact that they would not receive pre-set monetary incentives if they did not complete the assessments.

2. Vignette: Several months into the study, volunteer U began to leave the clinic right after her therapy visit but before her evaluation session. She did not respond to calls from the study coordinator or other staff, although she would sporadically return calls from her therapist, with whom she was still working. Her therapist noted that U's depression had improved. However, because U had not done an evaluation in several months, it was unclear whether she was improved sufficiently to meet criteria for remission and thus move into the next phase of the study. Her therapist was enlisted to try to improve U's compliance with evaluations.

3. Ethical guidelines: The most relevant ethical guidelines involve 8.06 (Offering inducements for research participation), particularly section b (offering professional services to encourage research participation). See Table 1 for the full guidelines.

4. Our course of action: When U's missing evaluations were noticed, the investigators, coordinator, and therapists discussed options. One possibility involved withholding therapy until evaluations were completed. However, this would have been coercive and therefore inappropriate, and so was not implemented. Evaluations were attempted by phone (U did not answer and did not return calls).Finally, the therapist ended up administering the missing evaluation during the next therapy session (which interfered with therapy time), and discussed the pros and cons of completing vs avoiding evaluations with U. U continued to skip many evaluations, with no further consequences other than missing the incentive payments for completion.

D. Limited time of treatment (CPT2)

1. Description of issue: In our first study (CPT2), the length of treatment was set at 16 weeks. One of the study's goals was to see if the 16-week course of CBT had an enduring effect over a two-year follow-up period. Clients whose depressive symptoms improved sufficiently to meet recovery criteria at the end of 16 weeks were not offered regular psychotherapy during the 2 years of follow-up, even if they had other issues to work on. Clients could receive up to

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three booster sessions over the ensuing year, but no more than one in any given month. If clients asked for more psychotherapy, the rationale for limiting it was explained to them.

2. Vignette: Participant J had a significant remission of depressive symptoms at the end of 16 weeks of CBT. However, she had come in with a comorbid diagnosis of social phobia, which J believed predated and had contributed to the development of the depression. She stated that although she knew the trial was only to last 16 weeks, she really wanted more time in psychotherapy in order to work on the social fears and avoidance behaviors, and thought such work could prevent depression later on.

3. Ethical guidelines: Guideline, 3.12 (Interruption of Psychological Services) is relevant: "Unless otherwise covered by contract, psychologists make reasonable efforts to plan for facilitating services in the event that psychological services are interrupted…" (see Table 1 for the full guideline).

4. Our course of action: In this case, the pre-set length of treatment was covered by the informed consent contract. J and her therapist had talked about future treatment options while working on relapse prevention, but the client had not realized she wanted more therapy until after she and the therapist had terminated. The client then contacted the study coordinator, who told the client (in accordance with the study protocol) that it was more helpful for the study if the client did not seek further treatment until the study follow-up was finished. On the other hand, the coordinator made it clear that the client could do what she thought was necessary. The client, who had consistently been very compliant with study demands, ended up not pursuing other therapy during the follow-up period, and did have a short recurrence of depression during the second year of follow-up.

This is an issue that is less of a problem in our ongoing CPT3 project, due to the longer time possible for acute and continuation therapy (up to 36 months), but is an example of where the limits needed to draw conclusions about treatment effectiveness may come into conflict with what may be best for the client. There may be no optimal solution for time-limited treatment trials, but if the clients are a) aware that they can take whatever actions they think are in their best interests, including dropping out of the study, and b) if the clients have sufficient resources to take those actions, ethical dilemmas are minimized. Study therapists will want to explore their own thoughts about adherence to protocol, and will benefit from developing a policy they are comfortable with. For instance, if not forbidden a priori by protocol (as was the case in the NIMH TDCRP (Elkin, Shea, Watkins, Imber, et al., 1989) and the Behavioral Activation project (Dimidjian, Hollon, Dobson, Schmaling, et al., 2006)), a set number of booster sessions or a certain amount of phone contact post-termination may be acceptable to the study investigators, and may allow some continuity of care over whatever follow-up period is required.

II. CHALLENGES RELATED TO STUDY DEMANDS ON THERAPISTS

Study therapists occasionally found themselves treating volunteers differently than they might private clients. Areas where differences were noted included: constraints on length of treatment (in this case, keeping therapy going *longer* than therapists might prefer); constraints on follow-up; and constraints on techniques or resources that might otherwise have been used.

A. Constraints on terminating early

1. Description of issue: We had a small number of participants in each trial who were either inconsistently involved in therapy, or were markedly interpersonally difficult. Because the emphasis was on keeping participants in the study so that we might have the most interpretable outcomes possible, fewer limits were placed on participants than would be typical in private

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practice. Without the study, the therapists would have referred these clients out, suggested a break from treatment until clients were ready to engage, or required that they treat study staff appropriately (or face termination from the practice).

2. Vignettes: Volunteer T consistently used remarkably demeaning and condescending language and behavior toward staff. The staffer who first interviewed him over the phone ended the interview in tears; personnel interacting with him at his weekly visits routinely experienced strong negative responses to T's behavior. Therapist supervision time became increasingly focused on T's therapist's cognitions about working with him.

Another example involved client G, who, in addition to depression, had a varied array of physical complaints. G had a strong belief that her depression was biological in nature and that her thoughts or behavior would have no impact on moods. She was skeptical of the CBT model throughout her time in treatment. However, she did enjoy talking about past experiences and she thought her therapist was pleasant. She attended sessions sporadically (roughly once per month, although she would schedule a session every week), did not complete any homework, and was reluctant to do much other than vent in sessions.

3. Ethical guidelines: The relevant ethical guidelines involve 3.04 (Avoiding Harm), and 10.10 (Terminating Therapy), particularly sections a (terminating when it seems clear that the client/patient no longer needs the service or is not likely to benefit) and b (terminating therapy when threatened or otherwise endangered by the client/patient).

4. Our course of action: The study's emphasis was on keeping clients involved, both in order to obtain the most complete dataset possible, and in hopes that something positive could be achieved therapeutically. Therefore, the therapists did not terminate therapy, and study personnel continued to schedule appointments for these clients. Ultimately, both clients ended their participation themselves. In the first case, T's therapist tried to work effectively with him and for the most part managed to ignore his provocations. Eventually T took offense to something she said and quit the study with a flurry of threatening phone calls to staff. In the second case, G's therapist attempted a number of techniques, including motivational interviewing, focusing on pain coping skills, and mindfulness strategies, with no discernable results. G continued to miss appointments. Her time in the study ran out after 78 weeks, which was a limit set by the project's Data Safety Monitoring Board. She was transitioned to the local mental health center, which closed her case after three missed appointments.

Neither client was clearly being harmed by continued care, but it did seem to the therapists after a certain time that the clients were not particularly benefiting from sessions. Additionally, the therapists and study personnel were put in uncomfortable positions. With each no-show, G's therapist lost an hour a week that could have gone to another client, and the study lost money by paying the therapist for that time. Volunteer T was verbally abusive (although never physically threatening) toward staff. Outside of the study, the therapists for these two clients would not have continued to schedule appointments into the future and would have suggested alternative options, such as taking a break from treatment. Additionally, T's therapist would have requested a change in his behavior toward staff, which if not observed would have been followed by termination from the therapist's practice.

It can be difficult to maintain a balance between serving the participants and collecting as much solid data as possible. Sometimes staff, especially if invested in the study, can be overly willing to tolerate maladaptive behavior in an attempt to maintain this balance. It is important for investigators to realize that they have an ethical obligation to anticipate and prevent problems for staff as well as participants. Although finding a middle ground is not easy, encouraging therapists to set certain limits may be in the best interests of participants and those around them.

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B. Constraints on follow-up (CPT3)

1. Description of issue: The CPT3 protocol was designed to limit psychotherapy contacts once volunteers had reached the final stage (the "maintenance" phase, when clients had at least 6 continuous months where they had not been depressed). If people in the prior CBT arm continued to have regular psychotherapeutic contacts, and did better than the people in the medication-alone arm, it would be difficult to determine whether it was the prior course of CBT that had an enduring effect, or whether it was the ongoing contact that made a difference. Therefore, therapists were allowed only six booster sessions total (no more than four in year one and no more than two in each subsequent year) over the three year follow-up.

2. Vignette: Client Z improved with medication and CBT to the point where she was entered the maintenance phase of the study. Throughout her study participation, Z had demonstrated mood lability, strong reactivity to external events, and a tendency toward relationship instability, coupled with a tendency to put off seeking help until things were quite serious. Volunteer Z and her therapist worked on her reactions to events, her beliefs about help-seeking, and her relationship skills in therapy, with some progress made. However, when Z got upset, she tended to forget the skills she had learned. During active therapy, in vivo phone coaching and scheduled sessions were useful for improving her reactions to events. After the transition to maintenance, these contacts were no longer as available.

3. Ethical guidelines: The relevant ethical guideline here is 10.09 (Interruption of Therapy), particularly the balance between the contractual nature of the relationship and the welfare of the client (see Table 1 for full listing of the guideline).

4. Our course of action: The therapist was concerned about Z's ability to maintain her gains with the limited number of booster sessions allowed. The therapist would have preferred more consistent (perhaps monthly) contacts until both Z and therapist were sure she could remember and utilize more adaptive behaviors. The Principal Investigators of the study were also concerned about the effects of limiting follow-up contacts on the client's welfare, and were willing to be flexible. Unfortunately, Z moved out of state, and took a job which interfered with regular therapeutic contacts; the evaluations indicated a recurrence of depression had occurred shortly after she moved. Had she been more available, the optimal course of action (which the PIs had agreed to) would have been scheduled phone contacts, plus brief contacts when Z was in the clinic for evaluations, and full use of the booster sessions.

C. Constraints on techniques that might be used (CPT2 and CPT3)

1. Description of issue: Occasionally, individuals were enrolled into the study with issues that might have profited from the addition of other techniques or treatment options. This was primarily a problem for people randomized to medication alone, but also was an issue for some CBT clients. The most common examples involved volunteers with chronic pain, symptoms of Post-Traumatic Stress Disorder (PTSD), and/or behaviors typical of Borderline Personality Disorder. (Note: while we excluded people with full BPD, a number of volunteers with sub-threshold levels of borderline traits were included.)

2. Vignette: Volunteer A had an extensive history of physical, emotional, and sexual abuse. She had significant trouble with emotional regulation, had strong negative core beliefs related to worth and lovability, and repeatedly made problematic choices in relationships and interpersonal behaviors. A and her therapist worked on many of these factors, and A improved significantly, but her therapist thought A might have gotten additional benefit from ongoing participation in a DBT skills-training group.

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Volunteer R entered the study with a diagnosis of fibromyalgia. During her time in the study she focused heavily on somatic complaints. Although her therapist was able to use R's feelings and beliefs about pain and physical symptoms to illustrate the cognitive model, the therapist would have liked to refer R to a local CBT-based chronic pain group for additional support and skills training.

3. Ethical guidelines: The most directly applicable guideline is 3.09 (Cooperation with other professionals), which suggests that "When indicated… psychologists cooperate with other professionals in order to serve their clients/patients effectively and appropriately" (see Table 1 for the full guideline).An additional, more general guideline is 3.06 (Conflict of interest), specifically considering the conflict between the psychologist's role as study staff vs. that of treatment provider.

4. Our course of action: The PI's of the study were quite willing to allow extensions of CBT in the individual therapeutic milieu. Therapists freely used mindfulness exercises with volunteers, drew concepts and exercises from DBT and ACT, and engaged in exposure work with anxious clients. The PIs did not consider these tools to be inconsistent with the essential constructs of CBT (although debate about this is ongoing in the therapeutic community at large). When appropriate to the client's problems, attendance at lay-led or support groups such as AA was encouraged in all treatment conditions. Additionally, volunteers who had been in a therapeutic group for some time prior to intake were allowed to enroll in the study as long as they met the entry criteria.

On the other hand, the instances described above involved starting formal psychotherapeutic group work post-entry into the study. Unfortunately, enrollment in a therapist-led treatment group after randomization would have confounded the evaluation of treatment effects (by adding an additional therapeutic person or session which other participants wouldn't have). Additionally, it would potentially be difficult (and unethical) to ask a volunteer to taper attendance at these groups in the event that they recovered, the same way individual psychotherapy was tapered. For these reasons, study therapists were not able to take advantage of community resources in the same way as they might in clinical practice. However, therapists did discuss these outside options with clients as potential resources for post-study treatment.

III. CHALLENGES RELATED TO OTHER ISSUE

Study therapists dealt with complications related to the research milieu and patient population. These circumstances primarily concerned client characteristics and study personnel-client relations.

A. Client characteristics: Working with impoverished patients

1. Description of issue: Because our treatment trials did not charge for therapy, we enrolled a large number of people who were in significant financial straits. Therapists found themselves in much more overtly caretaking roles than would typically be the case in private practice. Additionally, therapists – who knew the toll circumstances were taking on their clients – occasionally were tempted to give these clients financial or material assistance.

2. Vignette: Participant H lived with his adolescent granddaughter. He was unable to work due to severe depression and degenerative physical ailments, and had no income other than sporadic help from his dysfunctional adult children. He had applied for disability once and been turned down, probably due to presenting his case ineffectively, and had been too demoralized and disorganized to pursue it. Additionally, his depression and anxiety interfered with the effective pursuit of other options, like food stamps or charitable aid. Throughout therapy, he had times where he could not afford food, had utilities cut off due to nonpayment,

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and could not afford such things as a winter coat. Because he could not afford transportation, many sessions were conducted via phone. He could not afford medical care, and was often in pain without any possibility of treatment. H had so many concrete needs that he was often unable to engage in therapy. Treatment became exclusively focused on problem-solving and social work issues, for which H's therapist had minimal training. H's therapist and other study staff also felt a strong pull to help H with financial or material donations.

3. Ethical guidelines: Two guidelines were involved for this situation. The primary guideline, 3.05 (Multiple Relationships), is relevant in terms of staff desire to help H with financial or other assistance, which could introduce another role to the relationship. Additionally, 2.01 (Boundaries of Competence) is relevant to the therapist's concerns about providing services which might be better done by a trained social worker. Please see Table 1 for a more complete listing of the guidelines.

4. Our course of action: First, we tried numerous paths to connect H with the practical assistance that he clearly (to us) needed, such as a case manager. However, due to a number of factors primarily related to the absence of assistance in the county where H lived, this did not happen. Therefore, H's therapist considered the situation to be consistent with 2.01(d), which specifies that when appropriate mental health services (social work, in this case) are not available, psychologists may provide such services if they make a reasonable effort to obtain the necessary knowledge.

Subsequent to this, H's therapist and other study staff encouraged H to re-apply for disability. Despite a great deal of effort on all parts H was turned down again. His financial situation became dire, and staff and his therapist wished to contribute aid so that he could make it through the winter. This, however, raised concerns about the issue of multiple relationships. After consultation with other community providers, the study PIs, and Ebert (2006), it was decided that concerns about dual relationships should not obstruct needed concrete help with food, clothing or money, and so the study staff paid a major utility bill for H, gave him winter clothing, and sent a basket of food. These gifts were made anonymously in order to minimize any risk of blurring boundaries, distorting the therapeutic alliance, or causing any emotional harm to H.

B. Other staff-client issues (CPT2 and CPT3)

1. Description of issue: Study coordinators and evaluators generally had experience in working with psychiatric outpatients. However, support personnel at our site were not licensed health care providers. They typically had varying levels of education and experience with ethical challenges and boundary setting. Additionally, our staff were very caring people who had a lot of contact with clients. Because staff and clients occasionally became emotionally attached to each other, some difficult situations arose.

2. Vignette: Client G was a depressed, socially anxious man who had minimal social contacts. He had been divorced for some time and reported feeling quite lonely. He typically met with an attractive, young, female evaluator for assessments and developed an attraction to her, of which she was unaware. In therapy, G was working on initiating relationships, and mentioned to his therapist that he had a specific person he would like to date (but did not mention who this person was). G and his therapist worked specifically to come up with a plan for him to approach and ask the object of his affection for a date. G successfully carried out his part of the plan, but the interaction did not go well. The evaluator was caught by surprise and responded with an emphatic "No, I don't think so." G interpreted this, unsurprisingly, as personally rejecting, and the evaluator had self-critical thoughts related to her reaction.

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3. Ethical guidelines: Although this is a gray area, some relevant guidelines are found in 2.05 (Delegation of Work to Others). In particular, section (3) notes that psychologists are to see that subordinates perform services competently, which includes adherence to the ethics code (and to its limits on multiple relationships, as per 3.05). Please see Table 1 for more details.

4. Our course of action: The outcome of G's approach to the evaluator was grist for the mill in therapy. G's therapist spoke with the evaluator, the PI, and other treatment team therapists at the weekly therapy supervision, where they discussed the evaluator's perspective and addressed any maladaptive thoughts the evaluator had. G and his therapist then explored the various possible explanations for the evaluator's reaction. G then was able to follow up and obtain evidence for his alternative explanations from the evaluator, which was extremely valuable. The evaluator very much wanted to make clear to G that her refusal was a matter of her internal ethical rules (no dating the participants), and that her reaction was not related to disgust or horror but was instead a function of being flustered. The episode ended up being very beneficial for G.

It is important to note that there is no overt prohibition against non-professional staff dating participants, or even against psychologists having relationships with research study participants who are not their clients. However, these situations are unprofessional and can easily cross the line into either impairing the caregiver's objectivity, or exploiting the client (3.05, Multiple Relationships), and thus will be avoided. Because established guidelines do not clearly delineate these boundaries, prudent PIs will want to set uniform guidelines prior to study implementation, and inform personnel of the rules and rationale, to ensure the highest and most consistent levels of professionalism.

CONCLUSION – What We Have Learned

Perplexing issues are bound to come up in any psychotherapeutic context. However, besides the standard ethical problems that arise in psychotherapy (reporting of child or elder abuse, for instance), research protocols may run into additional challenges as a function of study design and other variables.

Psychologists working in research situations balance both the interests of the client and the interests of science. The multiple roles of clinician and researcher will occasionally conflict. Sometimes a compromise can be reached between meeting the needs of the client and those of the study. On the other hand, situations may arise where the best course of action serves the client at the expense of the study, or vice versa. In these instances, the following may be helpful strategies:

1. Fall back on the General Principles

Principle A, Beneficence and Nonmaleficence, encourage mental health providers to do no harm. However, since conflicts between competing obligations may be inevitable, the basic goal is to "attempt to resolve these conflicts in a responsible fashion that avoids or minimizes harm." (APA, 2002) The expectation here is not that all will be free of inconvenience, or that neither side will have to compromise, but that providers will consider all the angles and work with study and client to develop the best outcome. Principle B, Fidelity and Responsibility, encourages clarification of roles and obligations. Although initial discussion of roles and obligations is a necessary part of informed consent, checking in and revisiting throughout the course of therapy will minimize later confusion. Additionally, maintaining trust in both directions – provider to study, provider to client – is of paramount importance, but when breaches occur, providers accept responsibility for their behavior and work to address the issues. Finally, Principle E, Respect for People's Rights and Dignity, notes that when working with vulnerable individuals who might have impaired decision making, providers may need to

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implement special procedures. In the case of studies, this may include explicit discussions with both clients and PIs about beneficial alternative treatments (even if study participation is affected), or with staff, clients, and PIs about proper behaviors, in order to protect all parties.

2. Problem-Solve in Advance

Expecting mental health professionals, study staff, and clients to reason through these complex ethical conflicts in the moment is a recipe for trouble. Therefore, careful advance planning is recommended to clearly establish within-study guidelines. For instance, if we had set up study-wide guidelines for client-staff interactions, with consequences for violations, we might have avoided several of the vignettes above. Similarly, clear procedures for checking client understanding of the study design would have helped us avoid some of the vignettes described above. One additional step we could have taken would have involved a patient advocate (Fisher, 2003).This person - outside of the study, as neutral as possible -- would monitor client understanding of study design, study requirements, and non-study options on an ongoing basis. Building such an advocate into our study designs (and budgets) early on would have been useful.

3.Use Consultation

Advance problem-solving is ideal. However, our experience is also that some challenges are unavoidable. Therefore, a treatment study might first plan for regular discussion of therapist concerns in a group supervision format. Second, outside consultation with peer therapists in the community can give an alternative perspective to help balance the research- vs. client-obligations the study therapists may be feeling. Third, we encourage regular consultation between providers and the study PI(s), who will ultimately have responsibility for the integrity of the science. However, be aware that the PI may not be wholly objective, since he or she will have a vested interest in protecting the integrity of the design in a manner that may not always be in the best interest of the clients or the study personnel. Fourth, contact state and national provider associations as needed for additional support.

4.Document

Document your decision, your actions, and your rationale in the study record. This will offer protection in the event of disastrous outcomes, and will provide consistency over the course of trials, which often last many years and undergo many staff changes. We must remember that the CBT concepts of recording situations, automatic responses, and alternative responses, and developing concrete action plans, are just as good for the therapists – and the studies -- as they are for the clients.

5.Remember Why We Do Research

Research does impose restrictions on therapy. Research does have an impact on both clients and therapists. However, the benefits of research are many. It can lead to increased quality of care, to provision of services to populations who might never have access otherwise, and to a more thorough understanding of ethical complexities and principles. Ultimately, research leads to the delivery of more efficient and effective care to those who will most benefit. Reminding ourselves of the benefits of the knowledge we gather can help us balance the conflicting needs of study participation.

REFERENCES

American Psychological Association. Ethical principles of psychologists and code of conduct. Washington, DC: Author; 2002.

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Alpert JE, Biggs MM, Davis L, Shores-Wilson K, et al. Enrolling research subjects from clinical practice: Ethical and procedural issues in the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial. Psychiatry Research 2006;141:193–200. [PubMed: 16457894]

Alvidrez J, Arean PA. Psychosocial treatment research with ethnic minority populations: Ethical considerations in conducting clinical trials. Ethics & Behavior 2002;12(1):103–116. [PubMed: 12171080]

Appelbaum PS. Missing the Boat: Competence and Consent in Psychiatric Research. American Journal of Psychiatry 1998;155:1486–1488. [PubMed: 9812106]

Borkovec TD. Control groups and comparison groups in psychotherapy outcome research. NIDA Research Monograph 1990;104:50–65. [PubMed: 2092225]

Chalmers TC. Ethical implications of rejecting patients for clinical trials. JAMA 1990;263(6):865. [PubMed: 2296150]

DeRubeis RJ, Hollon SD, Amsterdam JD, Shelton RC, et al. Cognitive therapy vs medications in the treatment of moderate to severe depression. Archives of General Psychiatry 2005;62(4):409–416. [PubMed: 15809408]

DiMascio A, Klerman GL, Weissman MM, Prusoff BA, Neu C, Moore P. A control group for psychotherapy research in acute depression: One solution to ethical and methodologic issues. Journal of Psychiatric Research 1979;15(3):189–197. [PubMed: 541784]

Dimidjian S, Hollon SD, Dobson KS, Schmaling KB, et al. Randomized trial of behavioral activation, cognitive therapy, and antidepressant medication in the acute treatment of adults with major depression. Journal of Consulting and Clinical Psychology 2006;74(4):658–670. [PubMed: 16881773]

Ebert, BW. Multiple relationships and conflict of interest for mental health professionals: A conservative psycholegal approach. New York: Professional Resource Press; 2006.

Edinger JD, Wohlgemuth WK, Radtke RA, Marsh GR, Quillian RE. Cognitive behavioral therapy for treatment of chronic primary insomnia: A randomized controlled trial. JAMA 2001;285(14):1856–1864. [PubMed: 11308399]

Elkin I, Shea MT, Watkins JT, Imber SD, et al. National Institute of Mental Health Treatment of Depression Collaborative Research Program. General effectiveness of treatments. Archives of General Psychiatry 1989;46(11):971–982. [PubMed: 2684085]

Fisher, CB. Decoding the Ethics Code: A Practical Guide for Psychologists. Thousand Oaks, CA: Sage Publications, Inc.; 2003.

Fulford KW, Howse K. Ethics of research with psychiatric patients: Principles, problems and the primary responsibilities of researchers. Journal of Medical Ethics 1993;19(2):85–91. [PubMed: 8331643]

Garfield SL. Ethical issues in research on psychotherapy. Counseling and Values 1987;31(2):115–125. [PubMed: 11659089]

Hall GC. Psychotherapy research with ethnic minorities: empirical, ethical, and conceptual issues. Journal of Consulting and Clinical Psychology 2001;69(3):502–510. [PubMed: 11495179]

Hayes, SC.; Strosahl, KD.; Wilson, KG. Acceptance and Commitment Therapy: An Experiential Approach to Behavior Change. New York: The Guilford Press; 1999.

Hollon SD, DeRubeis RJ, Shelton RC, Amsterdam JD, et al. Prevention of relapse following cognitive therapy vs medications in moderate to severe depression. Archives of General Psychiatry 2005;62(4):417–422. [PubMed: 15809409]

Imber S, Glanz L, Elkin I, Sotsky SM, Boyer JL, Leber WR. Ethical issues in psychotherapy research. American Psychologist 1986;41(2):137–146. [PubMed: 3516035]

Leykin Y, DeRubeis RJ, Gallop R, Amsterdam JD, Shelton RC, Hollon SD. The relation of patients' treatment preferences to outcome in a randomized clinical trial. Behavior Therapy 2007;38:209–217. [PubMed: 17697846]

Martell, CR.; Addis, ME.; Jacobson, NS. Depression in Context: Strategies for Guided Action. New York: W.W. Norton & Company, Inc.; 2001.

McCullough JP. Treatment for chronic depression using Cognitive Behavioral Analysis System of Psychotherapy (CBASP). Journal of Clinical Psychology 2003;59(8):833–846. [PubMed: 12858425]

Noble RE, Gelfand LA, DeRubeis RJ. Reducing exposure of clinical research subjects to placebo treatments. Journal of Clinical Psychology 2005;61(7):881–892. [PubMed: 15827998]

Rush AJ, Trivedi MH, Wisniewski SR, Nierenberg A, et al. Acute and longer-term outcomes in depressed outpatients who required one or several treatment steps: A STAR*D report. American Journal of Psychiatry 2006;163(11):1905–1917. [PubMed: 17074942]

Thorn BE, Pence LB, Ward LC, Kilgo G, et al. A randomized clinical trial of targeted cognitive behavioral treatment to reduce catastrophizing in chronic headache sufferers. The Journal of Pain. 2007 [Epub ahead of print: doi:10.1016/j.jpain.2007.06.010].

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TABLE 1

Relevant APA Guidelines

VIGNETTE	GUIDELINE	DESCRIPTION
Ia: W, didn't want therapy but was assigned to it	3.10 Informed Consent	(a) When psychologists conduct research or provide assessment, therapy, counseling, or consulting services in person or via electronic transmission or other forms of communication, they obtain the informed consent of the individual or individuals using language that is reasonably understandable to that person or persons except when conducting such activities without consent is mandated by law or governmental regulation or as otherwise provided in this Ethics Code
	8.02a and 8.02b, Informed Consent to Research	(a) When obtaining informed consent as required in Standard 3.10, Informed Consent, psychologists inform participants about (1) the purpose of the research, expected duration, and procedures; (2) *their right to decline to participate and to withdraw from the research once participation has begun*; (3) *the foreseeable consequences of declining or withdrawing*; (4) *reasonably foreseeable factors that may be expected to influence their willingness to participate such as potential risks, discomfort, or adverse effects*; (5) any prospective research benefits; (6) limits of confidentiality; (7) incentives for participation; and (8) whom to contact for questions about the research and research participants' rights. They provide opportunity for the prospective participants to ask questions and receive answers
		(b) Psychologists conducting intervention research involving the use of experimental treatments clarify to participants at the outset of the research (1) the experimental nature of the treatment; (2) *the services that will or will not be available to the control group(s) if appropriate*; (3) *the means by which assignment to treatment and control groups will be made*; (4) *available treatment alternatives if an individual does not wish to participate in the research or wishes to withdraw once a study has begun*; and (5) compensation for or monetary costs of participating including, if appropriate, whether reimbursement from the participant or a third-party payor will be sought
Ib: Q, moving into next stage, unhappy about being rerandomized	10.10 (Terminating Therapy), a and c	(a) Psychologists terminate therapy when it becomes reasonably clear that the client/patient no longer needs the service, is not likely to benefit, or is being harmed by continued service. (c) Except where precluded by the actions of clients/patients or third-party payors, prior to termination psychologists provide pretermination counseling and suggest alternative service providers as appropriate.
Ic: U, not completing evaluations	8.06 (Offering Inducements for Research Participation)	(a)Psychologists make reasonable efforts to avoid offering *excessive or inappropriate financial or other inducements for research participation when such inducements are likely to coerce participation.* (b) When offering professional services as an inducement for research participation, psychologists clarify the nature of the services, as well as the risks, obligations, and limitations.
Id: J, wanted more time in therapy than study allowed	3.12 (Interruption of Psychological Services)	Unless otherwise covered by contract, psychologists make reasonable efforts to plan for facilitating services in the event that psychological services are interrupted by factors such as the psychologist's illness, death, unavailability, relocation, or retirement or by the client's/patient's relocation or financial limitations.

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VIGNETTE	GUIDELINE	DESCRIPTION
IIa: T, who was unpleasant to staff, and	3.04 (Avoiding Harm)	Psychologists take reasonable steps to avoid harming their clients/patients, students, supervisees, research participants, organizational clients, and others with whom they work, and to minimize harm where it is foreseeable and unavoidable.
G, who didn't show up but got rescheduled anyway	10.10 (Terminating Therapy), a and b	(a) Psychologists terminate therapy when it becomes reasonably clear that the client/patient no longer needs the service, is not likely to benefit, or is being harmed by continued service (b) Psychologists may terminate therapy when threatened or otherwise endangered by the client/patient or another person with whom the client/patient has a relationship.
IIb: Z, who would lose her access to therapy as per study protocol	10.09 (Interruption of Therapy)	When entering into employment or contractual relationships, psychologists make reasonable efforts to provide for orderly and appropriate resolution of responsibility for client/patient care in the event that the employment or contractual relationship ends, with paramount consideration given to the welfare of the client/patient.
IIc: A and R, who could have used referrals	3.09 (Cooperation with other professionals)	When indicated and professionally appropriate, psychologists cooperate with other professionals in order to serve their clients/patients effectively and appropriately.
to other treatments	3.06 (Conflict of Interest)	Psychologists refrain from taking on a professional role when personal, scientific, professional, legal, financial, or other interests or relationships could reasonably be expected to (1) impair their objectivity, competence, or effectiveness in performing their functions as psychologists or (2) expose the person or organization with whom the professional relationship exists to harm or exploitation.
IIIa: H, where therapy had to include social work	2.01 (Boundaries of Competence)	(a) Psychologists provide services, teach, and conduct research with populations and in areas only within the boundaries of their competence, based on their education, training, supervised experience, consultation, study, or professional experience. (b) Where scientific or professional knowledge in the discipline of psychology establishes that an understanding of factors associated with age, gender, gender identity, race, ethnicity, culture, national origin, religion, sexual orientation, disability, language, or socioeconomic status is essential for effective implementation of their services or research, psychologists have or obtain the training, experience, consultation, or supervision necessary to ensure the competence of their services, or they make appropriate referrals, except as provided in Standard 2.02, Providing Services in Emergencies. (c) Psychologists planning to provide services, teach, or conduct research involving populations, areas, techniques, or technologies new to them undertake relevant education, training, supervised experience, consultation, or study. (d) When psychologists are asked to provide services to individuals for whom appropriate mental health services are not available and for which psychologists have not obtained the competence necessary, psychologists with closely related prior training or experience may provide such services in order to ensure that services are not denied if they make a reasonable effort to obtain the competence required by using relevant research, training, consultation, or study. (e) In those emerging areas in which generally recognized standards for preparatory training do not yet exist, psychologists

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VIGNETTE	GUIDELINE	DESCRIPTION
		nevertheless take reasonable steps to ensure the competence of their work and to protect clients/patients, students, supervisees, research participants, organizational clients, and others from harm.
	3.05 (Multiple Relationships)	(a) A multiple relationship occurs when a psychologist is in a professional role with a person and (1) at the same time is in another role with the same person, (2) at the same time is in a relationship with a person closely associated with or related to the person with whom the psychologist has the professional relationship, or (3) promises to enter into another relationship in the future with the person or a person closely associated with or related to the person. A psychologist refrains from entering into a multiple relationship if the multiple relationship could reasonably be expected to impair the psychologist's objectivity, competence, or effectiveness in performing his or her functions as a psychologist, or otherwise risks exploitation or harm to the person with whom the professional relationship exists. Multiple relationships that would not reasonably be expected to cause impairment or risk exploitation or harm are not unethical.
IIIb: G, who wanted to date the evaluator	2.05 (Delegation of Work to Others)	Psychologists who delegate work to employees, supervisees, or research or teaching assistants or who use the services of others, such as interpreters, take reasonable steps to (1) avoid delegating such work to persons who have a multiple relationship with those being served that would likely lead to exploitation or loss of objectivity; (2) authorize only those responsibilities that such persons can be expected to perform competently on the basis of their education, training, or experience, either independently or with the level of supervision being provided; and (3) see that such persons perform these services competently.