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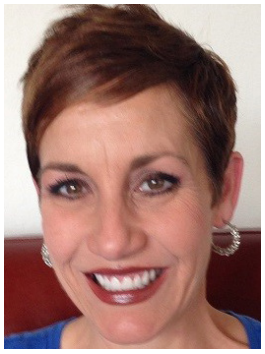

PRESIDENT'S COLUMN

Research with Diverse Groups is Critical for the Future of Clinical Psychology

Elizabeth A. Yeater, Ph.D.

I hope this moment finds you safe and healthy during this continued unprecedented and difficult time. I plan only to convey a few sentiments for my third entry into The Clinical Psychologist. In this edition of tCP, you will have the pleasure of reading the Diversity Spotlight, which highlights the work conducted by Dr. Tahirah Abdullah. Dr. Abdullah is a clinical psychologist and an Associate Professor in the Department of Psychology at the University of Massachusetts, Boston. As you will see, Dr. Abdullah's work focuses on the influence of racism on the mental health of Black Americans, broadly defined. She examines also mental health inequities, treatment barriers, and resilience within this population. I suspect this crowd does not need me to highlight how important these issues are or emphasize how much recent events have cast them under a sharp, harsh, and unpleasant light.

I have two colleagues in my department at the University of New Mexico who do work similar to Dr. Abdullah's but with American Indian populations. I unabashedly make this claim – this work is exceptionally difficult – I believe more onerous than your average research program (which is sufficiently hard!). Imagine, for instance, what it takes to get American Indian populations to trust the motivations of researchers! Think of our country's history, after all. Yet, despite the exceptionally long time that it takes to conduct this work, these researchers (who are often from marginalized populations themselves), are held to the same standards as others doing work that is, by all appearances, easier to execute. That is, the metrics we use in academia to judge "success" are applied without a contextual understanding or appreciation of the complexities of the work involved – What is the researcher's h-index? What is the impact factor of the journals they publish in? And so it continues, as do the inequities inherent in academia.

We need to stop this excessive focus on metrics alone. Clearly, our country is hurting. Long-standing pain and inequities stand out against the backdrop of America. We have not moved the needle much on human suffering. Psychology needs to value the type of work that Dr. Abdullah and others do and make room for it. As Skinner said long ago (okay, one of my psychology

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heroes!) we need a thorough going analysis of human behavior to change and understand behavior, which means that all levels of analysis in psychology – brain, behavior, environmental context, culture – are worthy of investigation and of importance.

Enjoy the article on Dr. Abdullah. I will now step out of the way.

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Personality and Treatments for Depression and Anxiety: Do Personality "Traits" Change?

Jay C. Fournier, Ph.D.
University of Pittsburgh
School of Medicine

Researchers and clinicians have long recognized links between personality and psychopathology (see, e.g., Clark, 2005a), and numerous studies have documented strong relationships between specific personality features and symptoms of the depressive and anxiety disorders (see, e.g., Bienvenu, Nestadt, & Samuels, 2001; Gershuny & Sher, 1998; Griffith et al., 2009; Kotov, Gamez, Schmidt, & Watson, 2010). Not only are scores on measures of personality and measures of psychopathology correlated, but a large and growing body of work suggests that the presence of particular personality features predict better, or worse, response to specific treatments for depression and anxiety (Bagby et al., 2008b; Fava et al., 1994; Fournier et al., 2008; Hollon et al., 2014; Joyce et al., 2003; Levenson, Wallace, Fournier, Rucci, & Frank, 2012; Maddux et al., 2009; Mulder, 2002; Tyrer, Seivewright, Ferguson, Murphy, & Johnson, 1993). Critically, personality not only appears to affect treatment outcomes, but treatments for depression and anxiety also seem to alter measures of personality itself in ways that cannot be explained by a reduction in symptoms (Quilty, Meusel, & Bagby, 2008; Roberts et al., 2017; Sauer-Zavala et al., 2020; Tang et al., 2009). Below, we review evidence suggesting that treatments for internalizing psychopathology have specific effects on measures of personality and we provide recommendations for ways in which researchers and clinicians can incorporate measures of personality into their work to add to our understanding of the nature of these changes.

Defining Personality

Personality can be difficult to define precisely, but most descriptions suggest that it represents a characteristic way of being that is relatively stable over time and across situations. Although theorists place their emphasis differently, four psychological components, cognition, emotion, motivation, and behavior, are commonly highlighted in models of personality and personality pathology (Beck & Freeman, 1990; Livesley & Jang, 2000; Millon & Davis, 1995; Mischel & Shoda, 1995; Westen, 1995). Mischel and Shoda (1995) and Beck and Freeman (1990), for example, independently developed theories of normal and abnormal personality, respectively, that fundamentally integrate these four components to explain the development, maintenance, and course of personality and personality pathology. Mischel and Shoda (1995) developed the cognitive-affective system theory of personality in order to reconcile the notion that personality should remain relatively stable over time with empirical evidence showing that behavior is heavily influenced by situational factors. The theory holds that personality is a relatively stable structure of cognition, affect, and motivation that selects, interprets, and guides behavioral and emotional responses to individually determined, salient features of the environment. Beck's (Beck, 2015; Beck & Freeman, 1990) cognitive theory of personality disorders, on which cognitive behavioral approaches to personality disorder are built, explains that genetic predispositions and environmental experiences combine to form schemas, or internal cognitive structures that interpret information and assign meaning to events in the world. In the case of personality pathology, negative schemas develop early in life and produce consistently biased judgments and cognitive errors. The combination of biased information processing and negative beliefs about the self, others, and interpersonal relationships generates affect, directs motivation, and leads to behavioral responses to the incoming information in the environment (Beck, 2015; Beck & Freeman, 1990).

Jay C. Fournier, Ph.D.

Clinicians, researchers, and theorists have developed a large number of systems with which to capture both normal range and pathological manifestations of personality (see Widiger & Simonsen, 2005 for a review). Since the 1980s, the most prominent of these models has been the Five-Factor Model of Personality (FFM; Digman, 1990; Livesley, 2001; O'Connor & Dyce, 2001; Wiggins & Pincus, 1992). Research on the FFM can be traced back to 1932, with the work of McDougall who hypothesized that personality was composed of five components, and Thurstone, in 1934, who factor analyzed sixty trait adjectives and found that they could be reduced to five broad dimensions (Digman, 2002). Although researchers do not always agree on the nature of the five factors extracted from this kind of approach (John, 1990), multiple researchers have recovered a version of the FFM even when using diverse sets of individual items and measures (see Digman, 1990). The version of the FFM offered by Costa & McCrae (1992) has perhaps become the most widely accepted. The five dimensions described in this model are neuroticism, which reflects emotional instability and vulnerability to psychological distress; extraversion,

which represents the degree to which one is prone to social interaction, activity, excitement, sensation seeking, and optimism; openness to experience, which is characterized by active imagination, intellectual curiosity, and independence of thought and judgment; agreeableness, which represents altruism, trust, and helpfulness; and finally, conscientiousness, which reflects reliability, achievement striving, and determination (Costa & McCrae, 1992).

The Relationship Between Personality and Psychopathology

There is little doubt that personality and psychopathology are connected, and converging evidence indicates that the relationship between them may be quite complex. There is now abundant evidence that personality traits, such as those described in the FFM, are strongly correlated with symptoms of depression (Rosellini & Brown, 2011) and anxiety (Bienvenu et al., 2004; Rosellini & Brown, 2011). The correlation between neuroticism and depression, for example, has been reported to be as high as r = 0.60 (Rosellini & Brown, 2011). When modelled collectively, the relationship between neuroticism and symptoms of the internalizing disorders (including major depression, dysthymia, and each of the anxiety disorders with the exception of post-traumatic stress disorder) was observed to be as high as r=0.98 (Griffith et al., 2009). Not only are personality and internalizing psychopathology related concurrently, but there is ample evidence that prior levels of neuroticism are prospectively related to the emergence of new depressive symptoms (Clayton, Ernst, & Angst, 1994; Hirschfeld et al., 1989; Kendler, Gatz, Gardner, & Pedersen, 2006). Moreover, substantial individual differences in neuroticism exist even among those diagnosed with major depressive disorder, and these differences have consequences for interpersonal functioning (Fournier et al., 2019) and treatment outcomes. Higher levels of neuroticism at baseline have been associated with better response to selective serotonin reuptake inhibitor (SSRI) medication compared to cognitive therapy (CT) in the treatment of depression (Bagby et al., 2008b). Similar results were obtained by Fournier and colleagues (2008), who observed that the presence of a comorbid personality disorder diagnosis likewise predicted superior response to SSRIs over CT. Other studies have also observed that the presence of personality pathology predicts response to treatments for depression across different treatment modalities (e.g., Hollon et al., 2014; Levenson et al., 2012; Maddux et al., 2009).

Several theoretical models of the nature of the relationship between personality and psychopathology have been proposed to capture elements of the complexity noted above. The six most prominent models (see, e.g., Bagby, Psych, Quilty, & Ryder, 2008a; Kotov et al., 2010; Krueger & Tackett, 2003 for reviews) cover each of the logical possibilities for the nature of the relationship. The Vulnerability model suggests that personality features come first in a causal chain leading to the development of psychopathology. The Scar model flips the direction of causality and suggests that life experiences, including the emergence of psychopathology, can permanently alter personality. The Pathoplasty model suggests that although personality and psychopathology may develop independently, the former can alter the clinical course of the latter. The Spectrum model contends that personality features and symptoms of psychopathology represent different points on a shared continuum of experience, and the Common Cause model posits that personality and psychopathology are correlated manifestations of a common underlying process that gives rise to each. Finally, the Complication model suggests that much of the apparent relationships among personality and psychopathology are merely epiphenomena of the reliance on self-report ratings of symptoms and personality during periods of acute distress. There is no clear winner among these possibilities, and there is evidence in support of each. This has led some (e.g., Ormel, Riese, & Rosmalen, 2012) to develop hybrid models that combine aspects of several of these possibilities.

Effect of Treatment on Personality

Although the precise nature of the relationship between personality and internalizing psychopathology remains an area of active research and debate, an emerging body of work is beginning to support the possibility that treatments that were developed to address symptoms of clinical psychiatric disorders, like depression and anxiety, may exert separate effects on personality itself. One challenge in this area is that relatively few studies have examined this issue or assessed personality more than once. This may be due to a general belief that personality ought to be stable, particularly over the short time intervals typically employed in clinical trials. But we now know that personality can change. A large number of studies have demonstrated that mean levels of personality scores change over the lifespan (Edmonds, Goldberg, & Hampson, 2013; Hampson & Goldberg, 2006; Terracciano, McCrae, Brant, & Costa, 2005) and that they can change in response to life events (Roberts & Mroczek, 2008; Specht, Egloff, & Schmukle, 2011; Sutin, Costa, Wethington, & Eaton, 2010). This suggests that it is possible for patients to respond differently on measures of personality over time, and there is now a growing number of studies suggesting that personality scores can and do change following relatively short-term treatments. In a recent meta-analysis of 35 studies, Roberts and colleagues (2017) observed moderate changes in personality variables across a wide variety of psychotherapeutic and pharmacological treatment modalities. Neuroticism and extraversion were the personality characteristics that changed the most, and personality change was

particularly notable for patients receiving treatment for anxiety disorders, with less change observed for treatments of eating and substance use disorders.

In randomized controlled trials examining differential change in personality dimensions from the FFM-model, evidence suggests that not all treatments may be equally effective at altering personality. Using data from a randomized controlled trial examining the efficacy of cognitive therapy, selective serotonin reuptake inhibitor (SSRI) medication, and placebo, Tang and colleagues (2009) observed strong and specific effects of the SSRI treatment on neuroticism scores after only 8 weeks of treatment. Specifically, they reported that whereas neuroticism was reduced, and extraversion was increased, in both the SSRI and cognitive therapy arms relative to placebo, in the SSRI arm those changes could not be explained away by concurrent changes in symptoms. In the cognitive therapy arm, once changes in symptoms were controlled, cognitive therapy no longer differed from placebo regarding personality change. Moreover, Tang and colleagues demonstrated a dissociation between change in depression scores and change in neuroticism scores in the trial. Whereas depression was reduced in the placebo condition, neuroticism was not. By contrast, both depression and neuroticism changed with SSRI treatment. Finally, they observed that greater reductions in neuroticism during treatment predicted lower depression relapse rates following treatment, even after controlling for residual depression symptoms. This long-term effect persisted regardless of whether patients remained on their medications or not (Tang et al., 2009). This pattern of findings suggests that the medications were having a specific effect on the personality variables themselves, irrespective of symptom change. Similar findings have been observed by others (see Roberts 2017 for a review), and Quilty and colleagues (2008) observed that neuroticism was not only reduced more by SSRI medications than by non-SSRI antidepressants, but that change in neuroticism scores mediated reductions in depressive symptoms, not the other way around. (Quilty et al., 2008).

SSRIs are not the only treatment modality to show a specific effect for reducing levels of neuroticism. Examining differences between psychotherapeutic treatments for anxiety disorders, Sauer-Zavala and colleagues (2020) observed that one particular treatment, the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (UP), reduced neuroticism scores to a greater degree than either a waitlist control condition or more standard, disorder specific exposure based cognitive behavioral therapy interventions. The UP was designed to be a transdiagnostic CBT-based treatment for internalizing disorders that focuses on helping patients reduce the distress associated with the experience of strong emotions. Although no differences were observed between the UP and standard exposure-based conditions for the reduction of anxiety specific symptoms, and both were superior to a wait-list control in reducing anxiety (Barlow et al., 2017), patients receiving the UP experienced greater reductions in neuroticism at the end of treatment compared to those receiving the disorder specific treatments, even after controlling for concurrent reductions in symptoms of anxiety and depression. The authors interpreted their findings as reflecting possible differences in mechanisms of change between the treatments. Indeed, the findings of both Tang and colleagues and Sauer-Zavala and colleagues cannot be explained away easily by reference to a concurrent reduction in symptoms. Rather, both sets of findings suggest that the active treatments changed something specific that led patients to change their answers on measures of personality. That is, these treatments led patients to change the way they saw themselves, at least as captured on standard measures of the FFM.

What Might be Changing?

We currently do not know precisely why these relationships between personality, symptoms of mood and anxiety disorders, and response to treatments exist. Likewise, we do not yet fully understand what it is that changes during the course of treatments that leads patients to report differently about their personalities. But findings from neuroscience may provide some clues. Individuals high in neuroticism, as well as individuals experiencing symptoms of depression or anxiety, show similar alterations in underlying neurobiological functioning associated with at least two psychological process, emotion regulation and fear learning. More work will clearly be needed to fully determine the mechanisms leading to the relationships described above, but treatment effects on one or both of these systems may help to explain how it is that treatments for internalizing disorders can independently effect personality.

Neural models of emotion perception and emotion regulation identify multiple limbic and prefrontal cortical brain regions that interact during both the generation of emotional experience and the deployment of automatic and effortful emotion regulation strategies (Morawetz et al., 2020; Phillips, Ladouceur, & Drevets, 2008). Depressed patients show deficits in the functioning of these systems such that emotion regulation processes that are typically accomplished by more automatic elements of the system can fail to downregulate regions associated with the generation of emotions, and higher-order regions that are typically involved in more effortful regulation are engaged to compensate (Anand et al., 2005; Etkin & Schatzberg, 2011; Siegle, Thompson, Carter, Steinhauer, & Thase, 2007). Higher levels of neuroticism are likewise associated with the functioning of the emotion regulation system, and among adults with depression, higher levels of neuroticism are associated with altered activity

in and connectivity among key nodes of this system (Fournier et al., 2017; Webb et al., 2015). Individual differences in the functioning of the emotion regulation system have consequences for treatment response (Mayberg et al., 1997; Mulert et al., 2007; Pizzagalli, 2010). Furthermore, there is mounting evidence that both psychotherapeutic (see Fournier & Price, 2014; Weingarten & Strauman, 2014) and antidepressant (Höflich, Baldinger, Savli, Lanzenberger, & Kasper, 2012; MacNamara et al., 2015) treatments alter the functioning of prefrontal cortical regions that are critical for emotion regulation. As such, by altering the individual's ability to cope with and manage negative emotional experience, it is possible that these treatments may be altering elements of personality that capture how vulnerable a patient feels to their emotional experiences. Again, more work will be needed to test this possibility and to determine which specific aspects of altered emotion regulation function are associated with symptom change and which with personality change.

Likewise, changes in neural response during fear-related learning may also play a role in helping to understand the relationships between personality, symptoms, and treatment response. Fear learning is a healthy and adaptive process that allows us to learn about impending danger from the environment (see Delgado, Olsson, & Phelps, 2006 for a review). Individuals with elevated anxiety (Lissek et al., 2005; Wong & Lovibond, 2018), however, show abnormally strong responses during fear learning, over-generalization of fear-related associations, and abnormally increased activity in the amygdala (Indovina, Robbins, Núñez-Elizalde, Dunn, & Bishop, 2011). Neuroticism has been linked to very similar processes of over-generalized fear learning (Lommen, Engelhard, & van den Hout, 2010) and increased amygdala response (Hooker, Verosky, Miyakawa, Knight, & D'Esposito, 2008). Critically, psychotherapeutic treatments for anxiety disorders appear to alter activity in key limbic regions associated with fear learning and may help to explain these relationships (Fournier & Price, 2014; Lange et al., 2016).

Future Research

Clearly, more work is needed to understand why different dimensions of personality affect outcomes for particular treatments and how it is that some treatments are able to alter personality more than others. Perhaps most critical at this stage is the collection of additional data regarding the extent to which personality changes across different settings, different populations, and different treatment modalities. The received view that personality does not change over short-term treatments appears to be inaccurate – at least for some patients and some treatments. But this belief may be the reason that relatively few clinical trials include the repeated measurement of personality. More data is needed to determine the extent to which personality changes with treatment and to characterize the conditions that foster or limit this change. We would expect this knowledge to carry enormous significance. High levels of neuroticism, for example, have substantial public health consequences, whether or not an officially recognized psychiatric disorder is also present. These consequences include: Increased medical treatment utilization, reduced longevity and quality of life, and higher economic costs than even the most common psychiatric disorders (Cuijpers et al., 2010; Lahey, 2009). Below we describe brief and more extensive personality assessment instruments that researchers and clinicians can use to examine the degree to which interventions lead to personality changes.

Assessing Personality

Although unstructured clinical interviews can represent an important part of the psychotherapeutic and assessment process, we urge caution in relying on such methods on their own for the evaluation of personality and personality change. These types of interviews tend to be less accurate when compared with well validated instruments (Miller, 2001; Miller, Dasher, Collins, Griffiths, & Brown, 2001; Steiner, Tebes, Sledge, & Walker, 1995; Zimmerman, 1994). Moreover, when relying on unstructured interviews alone, it can be quite difficult to overcome known cognitive biases that can interfere with accurate clinical assessment, including primacy effects, confirmation bias, and halo effects (see, e.g., Baron, 2000). When deciding between formal assessment tools, clinicians and researchers first need to decide whether to use self-report based or interview-based measures and whether they aim to assess normal range or more pathological manifestations of personality. A comprehensive review of personality assessment tools is beyond the scope of this article (see, e.g., Furnham, Milner, Akhtar, & Fruyt, 2014; Germans, Van Heck, & Hodiamont, 2012; Grucza & Goldberg, 2007 for more extensive reviews). Below we highlight a number of different measures from brief (8-item) to longer (300-item) instruments that could be used to assess the impact of treatment on personality.

Numerous self-report measures exist that can assess personality and personality pathology. Perhaps the most widely known are the NEO measures devised by Costa and McCrae (Costa & McCrae, 1992; McCrae & Costa, 2010) and used to assess the components of their version of the FFM described above. A shorter 60-item version measures the five higher-order domains and a longer 240-item version assesses the domains along with their sub-facets. Several alternative, open-source measures of the FFM are also available. These include the 44-item Big-Five Inventory (BFI, John & Srivastava, 1999) and a 300-item (Goldberg,

1992) and 120-item (Johnson, 2014) version of the International Personality Item Pool (IPIP; https://ipip.ori.org/) measure of the FFM. The IPIP is open source collection of items relevant to the assessment of personality. Researchers and clinicians can also use this resource to customize the measurement of additional personality dimensions as they see fit. Other self-report instruments assess different models of personality. For example, short (48-item) and long (100-item) versions of the Eysenck Personality Questionnaire-Revised (Eysenck & Eysenck, 1991) assess dimensions of Eysenck's Psychoticism (an externalizing dimension of personality), Extraversion, and Neuroticism (PEN) model of personality. The 226-item Temperament and Character Inventory assesses Cloninger's Temperament and Character model (TCI; Cloninger & Svrakic, 1994). In addition, several self-report measures have been developed to assess elements of the cognitive model of personality disorders, including the full (Beck & Beck, 1991) and short-form (Butler, Beck, & Cohen, 2007; Fournier, DeRubeis, & Beck, 2012) versions of the Personality Belief Questionnaire, the Personality Disorder Belief Questionnaire (Dreessen & Arntz, 1995), and the full and short-form versions of the Schema Questionnaire (Young, 1990; Young, 1998).

Researchers and clinicians have several self-report tools from which to choose to assess for the presence of personality pathology. The Standardized Assessment of Personality Abbreviated Scale (SAPAS) offers a very short, 8-item self-report screening tool that can be used to quickly evaluate for the presence of personality disorder (Moran et al., 2003). This could be used, for example, to indicate the need for more careful assessment. Longer self-report instruments, including the Schedule of Nonadaptive and Adaptive Personality (SNAP; Clark, 2005b) and the Dimensional Assessment of Pathological Personality (DAPP; Livesley, 1990), capture multiple dimensions of personality pathology. In addition, the Personality Inventory for DSM-5 (PID-5), a 220-item self-report measure, has been developed to assess the dimensions of personality recognized in the alternative dimensional model of personality pathology presented in DSM-5 (see Bagby, 2013). A 100-item short-form (PID-5-SF, Maples et al., 2015) and a 25-item brief screening version (PID-5-BF; see Anderson, Sellbom, & Salekin, 2016) have also been developed. Finally, several structured clinical interviews have been developed to assess for personality disorder as defined in DSM. These include the Structured Clinical Interview for DSM-5 Personality Disorders (SCID-5-PD; First, Williams, Benjamin, Spitzer, 2016), the International Personality Disorder Examination (IPDE; Loranger et al., 1994), and the Structured Interview for DSM-IV Personality (SID-P; Pfohl, Blum, & Zimmerman, 1997).

Conclusions

The relationship between personality, internalizing psychopathology, and treatment response is poorly understood. Markers of personality pre-treatment are associated with the likelihood of responding to specific treatments. Moreover, pharmacological and psychotherapeutic treatments that were designed to treat clinical psychiatric disorders appear to alter personality over the short term in ways that cannot be explained simply by concurrent symptom change. We strongly encourage researchers and clinicians to consider incorporating formal self-report or interview-measures of personality into their work, and critically, to assess personality at multiple points in time. Gathering more data about the conditions, treatments, and populations in which personality changes with treatment could have enormous impact, both for our understanding of the relationship between personality and psychopathology, but also for directing patients to the treatments that are the most likely to help them.

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SOCIETY OF
CLINICAL PSYCHOLOGY

Ethical Considerations in Integrated Care Settings

Adam Fried, Ph.D.

Kate Jensen, Ph.D.

Midwestern University

Psychologists have become value members of integrated care teams, providing a range of psychological assessments and interventions. The growth of psychology's role in integrated health has been significant in recent years, with benefits noted in patient care and for other health care professionals working alongside psychologists.

Work in integrated health settings may differ in important ways from more traditional forms of practice in terms of the types of services offered, the duration of services, and the focus on interdisciplinary collaborations with other health professionals. The legal and ethical guidelines of the various professions represented in the integrated health setting can inform organizational policies and general practices, and, thus, affect the work of psychologists. The setting of the care can also significantly impact psychologists' work and create unique ethical dilemmas, such as in military primary care settings (Dobmeyer, 2013) or academic health centers (Ashton & Sullivan, 2018).

A recent article by Chenneville and Gabbidon (2020) highlighted important ethical dilemmas in integrated health care, including those related to confidentiality and reporting requirements, professionals taking on multiple roles with a patient, competence to provide different types of care, and informed consent in therapy and assessment. In their article, the authors applied principles and standards from the APA Ethics Code (APA, 2017) to inform some of these ethical questions. In this column, we highlight some of these ethical issues and some additional ones that may be unique to psychologists' work in integrated health settings.

One question that psychologists may face in integrated settings is determining when professional work with a patient constitutes a formal therapeutic relationship (versus a consultation, for example). Psychologists who are members of integrated care teams regularly consult with medical providers on cases. These consultations take several forms. Some are "curbside consultations" wherein the medical provider describes the patient or concern and the psychologist offers advice or opinion without meeting the patients or accessing any specific information about them. Others are more formal consultations, similar to "warm handoffs" wherein the psychologist is introduced to the patient by the medical provider, and briefly meets with and learns more about the patient. These handoffs may conclude in scheduling an intake appointment with the psychologist or the psychologist providing referrals or recommendations for other services. There are times, however, when lack of clarity between providing consultation and accepting someone as a formal patient can unintentionally lead to patient confusion about the relationship. Below is an example of the type of dilemma that can occur:

A medical provider requests a consultation with the psychologist, and following a warm handoff, the psychologist provides the patient with some brief recommendations (including relaxation techniques) and a referral to an outside provider for follow up care. Over the next several months, the patient stops by regularly to see the psychologist to update her on her progress and to tell her more about her situation and seek the psychologist's advice. The psychologist is concerned that the patient may be confused about the nature of their relationship.

For some patients, consultations with psychologists in integrated health settings may be potentially confusing. As Ashton and Sullivan state (2018), "Patients may be referred on the spot, who were never intending to see a psychologist or address a mental health issue at the visit." (p. 241). In addition, as Hodgson, Mendenhall, and Lamson (2013) point out, patients in integrated care settings may not understand that a discussion with a treatment team that includes a psychologist could be part of a more formal mental health assessment. Warm handoffs provide many benefits in terms of continuity of care, but, depending on how the handoff is conducted, may create questions about the nature of a continuing professional relationship (if any) that would be clarified during an informed consent process or discussion.

Informed consent is a cornerstone of ethical care in therapy, assessment and research. The distinctions between consultation, independent evaluation, and therapy are often critical in terms of determining professional responsibilities. At times, working in an integrated setting can make otherwise clear delineations of responsibility somewhat muddled. The Standard 10.01 (Informed Consent to Treatment) of the APA Ethics Code (APA, 2017) requires psychologists to provide informed consent as early as is feasible in the therapeutic relationship. As in the case above, it's important to educate the patient to clarify the nature of the professional relationship as soon as possible (see Hudgins, Rose, Fifield, and Arnualt, 2013, for helpful recommendations about consent during the "warm hand off" and how to present behavioral health services to patients).

Another important issue in integrated care settings is multiple relationships. Chenneville and Gabbidon (2020) raise the issue of multiple relationships in their article, highlighting conflicts that arise when a psychologist serves as therapist and researcher with the same patient (a scenario that may be more

salient in academic health center settings). Another interesting dilemma in integrated health settings is when psychologists are called upon to provide services for an employee of the health organization (or their families; Ashton & Sullivan, 2018), as illustrated in the example below.

A new psychologist is working in a primary care clinic in a medium sized town. Within this practice, it is common for the medical providers to see both office staff and each other for basic primary care needs. The psychologist goes to the waiting room and calls back her scheduled patient and is surprised to see one of the front desk staff stand up and walk back. Upon sitting in the therapy room, the front desk staff explains that she was glad to see a therapist joined the practice, since she has been wanting to pursue psychotherapy.

There are cultural differences between medicine and psychology that can lead to misunderstandings and ethical conundrums for the psychologist in these settings. It is not uncommon for medical providers to provide care for colleagues and staff. In the example above the psychologist is balancing several different concerns. The first are the immediate psychological needs of the front desk staff who sought services; it is important for the psychologist to consider what is in the patient's best interest, especially if there is an acute psychological situation. The second concern is the psychologist's relationship within the primary care team. Should the psychologist decline to work with office staff and providers, they may then be working under different expectations than the rest of the team. This is not necessarily a bad thing, but often requires additional discussion with colleagues to clarify ethical and legal requirements, especially when these differ across disciplines. Finally, the psychologist must evaluate his or her actions in terms of relevant ethical standards. Standard 3.05 (Multiple Relationships) of the APA Ethics Code (APA, 2017) prohibits activities that could impair judgment or risk harm to the patient. Within psychological practice it is not uncommon for providers to decline working with individuals they know outside of therapy or relatives of friends or colleagues when they could reasonably be expected to be harmful (see also Standards 3.04, Avoiding Harm, 3.06 Conflict of Interest, and 10.07 Therapy with Former Sexual Partners).

Finally, there can be some tricky confidentiality questions that arise in integrated health settings. Working as a team may be helpful in terms of sharing information with other providers but can also result in some complex ethical dilemmas (Van Liew, 2012). When working within an integrated care team the psychologist may, and often does, regularly communicate with the patient's other care providers about their progress or new concerns. This regular communication, either via medical record review or direct with the provider, often benefits the patient, as medical providers are kept up to date with new psychosocial concerns, as well as physical symptoms, medication side effects, or other health concerns that they may not otherwise know about. Similarly, the psychologist is kept abreast of any medication changes or physical health concerns that may be impacting therapeutic progress.

Several authors (e.g., Ashton & Sullivan; Chenneville & Gabbidon, 2020; Kanzler et al., 2013; Knowles, 2009; Van Liew, 2012) have highlighted some confidentiality risks associated with records that are accessible by others within the organization, including level of medical record detail and access. Providers often struggle with questions about how much personal information about a patient should be entered, especially when that information can be accessed by other providers. Some of these questions are informed by the relevance of the information and the focus of the referral question. Additionally, access by others to confidential or sensitive information is often a concern of psychologists in integrated care settings. Some have recommended special procedures, such as restricted access to psychological records or mechanisms that provide a warning to users that they are about to access sensitive information, as in the case of electronic health records (Chenneville & Gabbidon, 2020; Reitz, Common, Fifield & Stiasny, 2012). These situations may be further complicated in hospital settings when the patient is also an employee; providers must consider who has access to the information, such as therapy notes or psychological assessments.

The nature of confidentiality and information access in integrated settings may also be unclear to patients. For example, depending on the setting, patients may not realize that their detailed information may be shared with others in the organization. Consider the following scenario:

An integrated care psychologist begins work with a new patient. This patient also regularly sees one of the primary care providers and pharmacists in the same clinic. During the intake session, the informed consent document mentions that all information from the therapy sessions is confidential within the treatment team. Several sessions later, when meeting with her primary care provider, the physician mentions some information that was included in one of the therapy notes. The patient was surprised that the physician knew this information, and expressed concern that information from therapy sessions was accessible to the rest of the team.

Many have recommended that patients be told what information may be recorded and who (such as other members of the care team) has access to the information (Ashton & Sullivan, 2018; Chenneville & Gabbidon, 2020; Nielson, Baum, & Soares, 2013; Van Liew, 2012). This is often a key part of the informed consent process in an integrated setting when

discussing confidentiality. Ensuring that the patient, other providers within the treatment team, and the psychologist share an understanding of the type of information that is expected to be shared, as well as the level of detail to be included in the shared medical record, can help avoid potential misunderstandings and ethical concerns.

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SCP Member Spotlight on Dr. Michelle Mlinac

Dr. Michelle Mlinac is a Staff Psychologist at VA Boston and an Assistant Professor of Psychology in Psychiatry at Harvard Medical School We had the opportunity to learn more about Dr. Mlinac through our Q&A correspondence. Read on to learn more!

Please provide an overview of your work

I am a geropsychologist doing primarily clinical work with older adults with complex chronic medical conditions. I go to Veterans' homes, complete assessments (capacity, cognitive, etc.) in addition to providing evidence-based practice (EBP), and provide interdisciplinary consultation to team members. I also engage in Geropsychology training of interns and fellows. I do a lot of QI work, and I am mainly interested in how we can be innovative in our work with older adults around mental health care, primary care, and late life issues. In response to the social isolation and worry in older adults due to COVID, we recently created a virtual therapy group manual which can be accessed for free at gerocentral.org.

Where did you complete your training?

I graduated from Xavier University in Cincinnati. Xavier is a Jesuit University and its doctoral psychology program focuses on underserved populations. I chose geropsychology and was hooked! I completed my internship at Temple University, with a training mix of behavior medicine and rehabilitation psychology that allowed a more direct interaction with medical residents and staff. I also completed a Postdoctoral Fellowship at VA Boston in geropsychology.

What is your current position/occupation?

I am a Staff Psychologist in Home Based Primary Care (HBPC) at VA Boston. I am also Assistant Professor of Psychology in Psychiatry at Harvard Medical School. Finally, I am a national training consultant for Problem Solving Therapy in HBPC.

Can you describe the ways that your career has taken shape over time? How did you get to where you are today?

I knew my path was to be a geropsychologist from day one of graduate school. I have been shaped by mentors and peers along the way, and I continue to learn a lot from people I am mentoring now. I have the luxury of having the perfect job for me--being able to see older adult patients in their homes. This job was brand new when I started in 2008, so I was able to craft it to meet the needs of our patient community. It's fun and I enjoy having an interdisciplinary team as partners in this work.

Michelle Mlinac, Ph.D.

How long have you been a member of SCP?

I have been a member for the past 5 years, but I have been a Section 2 member since I was in graduate school. As I built more skill delivering EBPs, Division12 seemed like a good place to be involved. More recently I have joined APAHC (Section 8) which is doing important work for psychologists in academic health centers.

Please describe any roles you have with APA or other national, state, or local organizations.

In addition to Division 12, I am a member of APA Divisions 18 and 20 and the Gerontological Society of America. I have served on Division 12's Program Committee. In terms of leadership roles, I am a board member of American Board of Geropsychology, working as an examiner and I coordinate their mentoring program. I am Chair-Elect to the Council of Professional Geropsychology Training Programs (CoPGTP).

What do you see as an important direction for the field of Psychology?

We need to develop more people who have expertise in working with older adults, and ensure most clinicians have some understanding of how to do this work. We also need to support caregivers, including underpaid and undervalued direct care workers. Psychology can bring a lot to the table related to geriatric healthcare. As we do that, we need to recognize health disparities among older adults and how anti-racism work within psychology and healthcare can help address those. Treating older people where they are at, in their homes, assisted livings, or long-term care settings, can help to redistribute some of the power differential between psychologists and those with whom they work. We also need to continue to innovate around telehealth and part of doing that is working to address the limited access many people have to basic internet services.

I have a book coming out: Providing Home Care for Older Adults: A professional guide for mental health practitioners, from Routledge, due out in September.

It is really the first to describe the model of integrated mental healthcare with this population and features many contributions from psychologists who do this work every day. https://www.routledge.com/Providing-Home-Care-for-Older-Adults-A-Professional-Guide-for-Mental-Health/Terry-Mlinac-Steadman-Wood/p/book/9780367345273

What's something nobody would know about you?

I am a massive fan of English Football and follow Tottenham Hotspur very closely. If I wasn't a psychologist I think I would want to work in museums. Prior to COVID I took my family to the National Museum of Psychology in Akron and we all really enjoyed it.

What are your hobbies?

I am a big movie fan. I have been to the Sundance Festival for the past 2 years. I like thinking how psychology fits in with film, and it is exciting to see emerging filmmakers share stories from all over the world. I am learning Welsh and Navajo on Duolingo, and trying to keep my Spanish strong as well. Since I'm in the car a lot, I listen to many podcasts. For interested Division 12 members I would recommend "Short Takes on Suicide Prevention" by the Rocky Mountain MIRECC, and "The Well Helper" by a former VA Boston fellow and current Div 12 member, Dr. Kate King from William James College. I was also recently a guest on a geropsychology podcast by my colleague, Dr. Lindsey Jacobs which can be heard at TheGeropsychologyPodcast.com.

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Diversity Spotlight:

Dr. Tahirah Abdullah

The current spotlight is on Dr. Tahirah Abdullah for her work in promoting the health and wellness of Black Americans. Dr. Abdullah received her B.A. from the University of Miami, double majoring in Psychology and Africana Studies. She then went on to complete her doctoral degree in Clinical Psychology at the University of Kentucky, earning her Ph.D. in 2013. Dr. Abdullah is recognized for her excellent research, teaching and service at the University of Massachusetts Boston, where she is a faculty member. She is currently on sabbatical, with a post-doctoral fellowship appointment at Spalding University Counseling and Psychological Services. Dr. Abdullah also recently co-founded Black Advocacy, Resistance, and Empowerment (BARE) Mental Health & Wellness with the mission of providing services to promote mental health and wellness within Black communities through community-based conversations, workshops, and presentations, and through consultation and training for systemic change within mental health, healthcare and educational institutions, businesses, agencies, and firms. Her work is so impressive, so important, and so impactful that we have chosen to highlight it here in the Clinical Psychologist's Diversity Spotlight.

Dr. Abdullah has been interested in the impact of racism and discrimination on the mental health of Black Americans. Her work has already influenced many areas, including the relationship between ethnocultural factors and mental health outcomes, barriers to help-seeking for mental health problems, mental illness and its treatment, and understanding the mental health treatment experiences of Black Americans. Dr. Abdullah has aimed to use the knowledge gained from her research to improve the quality and accessibility of mental health services and reduce the stigma associated with mental illness and mental health treatment in the Black community. She is also looking at issues of Black American empowerment. There are so many critical aspects to Dr. Abdullah's work. Here, we highlight three.

Treatment of mental illness is difficult even when there are few barriers. Black Americans often experience barriers to engagement and continuation in treatment. Dr. Abdullah and her collaborator, Dr. Jessica Graham-LoPresti of Suffolk University, have initiated a research study to examine how Black Americans experience therapy. This is a critical investigation given many Black Americans drop out of treatment before they can reap its benefits. This novel study has two research arms and is aimed at understanding those individuals who engage in treatment all the way through, and those individuals that desist, or drop out of treatment early after only one or two sessions. This is a crucial study, with a qualitative flair, that will uniquely inform Dr. Abdullah's research team about the reasons behind issues like disengagement and early termination among Black Americans. The study will also shed light on the factors that help Black Americans stay committed to treatment, and will have implications for training therapists to be more culturally responsive in their work with Black clients. Knowledge of these factors will help her team determine important considerations for clinical training and mental health centers to improve efforts to more effectively engage Black Americans in therapy early in the process. Dr. Abdullah's work in this area is path breaking in its attention to the specific experiences of Black Americans and its emphasis on systemic change.

Tahirah Abdullah, Ph.D.

Despite the detrimental impact of racism on mental health, many people of color who experience racism engage in efforts to resist racism. Dr. Abdullah is focused on better understanding Black Americans' experiences with racial discrimination and also how leading or participating in direct actions may both support wellbeing and support collective efforts to dismantle systemic racism. Dr. Abdullah's research team in collaboration with Dr. Karen L. Suyemoto's research team (also at UMass Boston) have recently developed the Resistance and Empowerment Against Racism scale, a measure intended to better index the specific experiences of resistance and empowerment against racism. Specifically, there are a number of ways in which people of color resist racism, including through actions that advance personal and interpersonal awareness and support motivation for resistance; direct, interpersonal opposition; participation in organizations and/or activities with the aim of resisting racism; and leading or organizing efforts to resist racism. Dr. Abdullah's research in this important area is measuring these resistance efforts and is exploring the extent to which people of color are coping with, and showing resistance to racism, as well as endorsing empowerment. The development and validation of this new scale are described in a recent article that is in press in the journal, Cultural Diversity and Ethnic Minority Psychology (Suyemoto et al., in press).

Third, and related to the projects above, Dr. Abdullah is committed to public scholarship and values reaching not only academic audiences, but also the broader

public in disseminating her work. This is reflected in the outreach and advocacy work her lab does, as well as the applied work she does with BARE Mental Health & Wellness. Dr. Abdullah has promoted work abroad and also continued to publish her work in scientific journals and other relevant outlets. She has co-authored papers such as "The Link between Experiences of Racism and Stress and Anxiety for Black Americans: A Mindfulness and Acceptance Coping Approach," "Potential Barriers to Mental Health Care for Black Americans: How to Get Help," and "Understanding Racism and Its Related Stress Can Help People of Color Cope with Negative Effects," published on anxiety.org.

Fortunately, Dr. Abdullah's shares what she knows with her graduate and undergraduate students. Impressively, Dr. Abdullah has now taught close to a thousand undergraduate students. She teaches standard psychology courses like Introduction to Psychology and Abnormal Psychology, but importantly she also teaches courses that bring much more awareness to the important topic of race and culture in the United States. Her undergraduate course titled "Race, Culture and Relationships" has been incredibly well-received. She also offers a Culture and Mental Health course where she includes discussions centered on relevant race, power, and privilege issues. Dr. Abdullah's mentorship and teaching style inspires students. She was the UMass Boston recipient of the 2019 Manning Prize for Excellence in Teaching, highlighting her exemplary teaching. Her undergraduate students remark on her impactful and encouraging style and her high level of commitment and involvement on campus. For instance, Dr. Abdullah has lived on campus as Faculty in Residence, has participated in and helped organize social justice teach-ins on campus, and has been involved in promoting leadership and professional development for undergraduate and graduate students alike. Dr. Abdullah also devotes time to important groups off campus like the Muslim Justice League, where she currently serves as President of the Board of Directors and a member of the Health Justice Team.

At the graduate student level, Dr. Abdullah inspires her students to maximize their potential. Aside from helping with research ideas, Dr. Abdullah is actively building bridges for her students to excel in the field of clinical psychology and to be observing more widely around the world to help society. One graduate student, Shannon Hughley, was working as a post-baccalaureate conducting biomedically related animal research at Yale University when she came across one of Dr. Abdullah's articles in the Journal of Black Psychology and was inspired to apply to work with her. Shannon is currently entering her 5th year of graduate research and working on her dissertation. Shannon shared that she could tell after reading Dr. Abdullah's articles that she wanted to work with her. She noted that Dr. Abdullah is "very grounded as a person" and she also is "always thinking about the broader societal issues, and this inspired me." Shannon stated that Dr. Abdullah helped her obtain internships abroad in Italy and Cape Town, South Africa so that she could gain experience, as well as helped her to work through costs and how to pay for her education. She stated that Dr. Abdullah allows students to explore and grow into themselves while at the same time providing professional guidance and opportunities. Finally, Shannon discussed how Dr. Abdullah helped her shape an important dissertation developing an intervention for coping with racism-related stress for Black Americans, adding that Dr. Abdullah really gets to know her students, which helps her guide them.

Darrick Scott, a rising 4th year graduate student working with Dr Abdullah, similarly describes being inspired by her work. Specifically, Darrick articulated Dr. Abdullah's great balance between general support, accountability and being able to navigate with the factors that are most relevant to the student. He also noted liking "that self-care goals are a part of the process of working in Dr. Abdullah's lab." When discussing his experience working with Dr. Abdullah, Darrick reflected, "when I experienced challenges, she has been able to provide resources across various domains, including when I was have difficulties securing housing in Boston." Darrick received APA's Minority Fellowship Program award and attributes receiving this award in part to Dr. Abdullah's excellent mentorship. "She helps with professional development from every level," Darrick stated. He further stated, "As a first-generation African American student, she modeled how to be successful and how to navigate all the demands of working in graduate school and also generally in the professional world. She has integrity." Darrick is very interested in collective self-esteem and how it impacts mental health symptoms and experiences, a topic he began researching under the mentorship of Dr. Abdullah. More recently, he has also been interested in culturally centered interventions. Notably, Darrick spent two weeks in Ghana learning about culture and the current mental health resources there. Darrick is actively looking to return to Ghana to get further experiences and to learn from the community in Ghana.

The overarching goals of Dr. Abdullah's research are inspiring when considering the breadth of her work and the degree of societal issues she is addressing. Her program to improve the recovery for Black Americans with mental health problems is rooted in the recognition that Black Americans are not a monolithic group but that cultural factors may bear on mental health outcomes and the effectiveness of standard interventions. Her current approach is to generate research conducive to improving the recovery of African Americans with mental health problems. This emphasis of Dr. Abdullah's work involves a focus on better understanding the extent to which racism effects mental health, the relationship

stigma. Her research in this area is already having a significant influence and her mentorship to students is incredibly thoughtful and generous. It is so important to have people like Dr. Abdullah advancing knowledge on Black Americans and their experiences with racism, mental health treatment, and empowerment. Dr. Abdullah provides an effective model for how to conduct research on these critical topics, but also how to extend Clinical Psychology outside of the walls of academia in order to address real world problems that exist for Black Americans and other people of color. Ultimately, these efforts will help propel our understanding of racism-related mental health issues, and importantly, propel our ability to effectively address important racism-related issues within the field of Clinical Psychology.

Learn more about BARE Mental Health and Wellness by visiting www.baremhw.com and following on Twitter/Instagram @baremhw. Learn more about Dr. Abdullah's research by visiting her lab website: www.blackmhadvocacyandresearch.com or following her on Twitter @DrTahirah

SOCIETY OF
CLINICAL PSYCHOLOGY

Committee Updates: Science & Practice

In 1993, Division 12 led pioneering efforts to establish a list of efficacious psychological treatments based on their level of empirical support that could be widely shared with Division 12 members and consumers. What followed was a set of criteria colloquially referred to as the "Chambless Criteria," which classify treatments as "well established" and "probably efficacious." (Chambless et al., 1998).

For many years, the Division 12 Committee on Science and Practice has been directly connected to these ratings of empirically supported treatments (ESTs). In the years since the Chambless Criteria were implemented, more than 80 psychological treatments have been evaluated, and the corresponding list of ESTs is available to the public on the Division 12 website (www.div12.org/treatments/).

In 2015, Division 12 adopted the "Tolin Criteria" (Tolin et al., 2015) as a way to update the seminal work of Chambless and colleagues. Specifically, the Tolin Criteria are intended to address the concern that thresholds for well-established and probably efficacious are too low. Moreover, the Tolin Criteria are designed to better account for the improved quality and quantity of clinical research and the adoption of more sophisticated research synthesis and evaluation methods in the time since the Chambless Criteria were adopted (Tolin et al., 2015).

By 2018, Exposure and Response Prevention was the only treatment that had been evaluated using the Tolin Criteria, and this evaluation was done in conjunction with the publication of the Tolin Criteria (i.e., it was conducted by Tolin and others, though it was not published). The Committee on Science and Practice knew it was time to put the Tolin Criteria to work, but it seemed a daunting task. How could a voluntary committee evaluate the evidence base for 80 treatments that had been classified using the Chambless criteria in addition to newer treatments being submitted to the committee for consideration? The Committee on Science and Practice Co-Chairs (SR, RH) did not have the answer, but identified that pilot testing the Tolin Criteria would be the best way to start the brainstorming process. We believed that working (as a committee without previous experience with the Tolin Criteria) to evaluate a second treatment would be the best opportunity to learn first-hand what applying it would entail.

We began with member recruitment. We solicited interest in committee membership through an email to Division 12 members requesting candidates who had expertise in Cognitive Behavioral Therapy for Insomnia (CBT-I), or expertise in meta-analysis.

We were fortunate to recruit an advanced doctoral candidate with meta-analytic expertise (CB) to take the lead. Along the way, we were also fortunate to recruit a statistician (MM) who aided in effect size calculations to determine the overall strength of the evidence. Among the committee members, none had allegiance to CBT-I.

We chose CBT-I because insomnia occurs in approximately one-third of adults in the general population, with approximately 6-10% of the population meeting criteria (APA, 2013; Ohayon, 2002), and CBT-I is its most widely used psychotherapeutic intervention. In addition to the wide public health implications for understanding the strength of evidence for such a widely used treatment, there are numerous meta-analyses examining the efficacy of CBT-I. Thus, from a process perspective, we thought the challenge of identifying and extracting information from multiple quantitative reviews would prove to be a good test of the feasibility of the Tolin Criteria.

Our literature search took place on August 1, 2018, which culminated in an accepted manuscript on April 30, 2020 (Boness et al., in press). Over the course of nearly two years, our voluntary committee engaged in the various stages of review, including selecting studies for inclusion and exclusion, data extraction and coding, rating review quality using AMSTAR 2, calculating combined effect sizes, and considering additional contextual factors that could impact the rating.

Our work led us to conclude that there is high-quality evidence that CBT-I produces a clinically meaningful and statistically significant effect on symptoms of insomnia andother sleep-related outcomes, as evidenced by multiple meta-analytic reviews with acceptablequality. We found additional evidence that CBT-I can be delivered in a variety of modalities (with initial support for online treatment) and that it can produce meaningful relief in patients with medical and psychiatric comorbidities, such as symptoms of depression, anxiety, and pain.

Our “strong” recommendation was further supported by several contextual factors,including the cost-effectiveness of the treatment, evaluation of the treatment by a range of researchers without known allegiance to the treatment, and evidence of efficacy in treatinginsomnia across various psychiatric and medical populations.

Based on this experience, as a committee we believe that moving forward with applying the Tolin Criteria to specific treatments for specific disorders has merit. Now that the CBT-I evaluation is complete, our work of developing a strategy for implementing the Tolin Criteria to evaluate more than 80 treatments has only just begun. We are working to determine how best to speed up the process and involve the field at a national (or even international) level to participate in these reviews while maintaining quality control and transparency. To this end, we are delineating the role of the Committee on Science and Practice as an organizer of, but not the sole producer of, establishing ratings using the Tolin Criteria. It is our hope that participation in these evaluations will be broad and inclusive. To aid others, our committee has also begun preparing guidelines and shareable documents to streamline the process and minimize the learning curve.

Overall, from a process-perspective, at this stage, we still have more questions than answers. We look forward to continued, thoughtful discussions of ways to increase the speed and breadth of this work while maintaining its integrity.Ψ

Digital Therapeutics and the Medical Approval Paradigm

Jenna R. Carl, PhD
Big Health Inc., San Francisco, USA & London, UK

Deborah J. Jones, PhD
Department of Psychology & Neuroscience
University of North Carolina at Chapel Hill

Oliver J. Lindhiem, PhD
Department of Psychiatry
University of Pittsburgh

Brian D. Doss, PhD
Department of Psychology
University of Miami

Kenneth R. Weingardt, PhD
Woebot Health, San Francisco, USA

Adela C. Timmons, PhD
Department of Psychology
Florida International University

Jonathan S. Comer, PhD
Department of Psychology
Florida International University

Note: The authors collectively represent the Society of Clinical Psychology (American Psychological Association Division 12), Presidential Task Force, Technology & Mental Health, mHealth Subcommittee. This article was written on behalf of the Subcommittee[1].

In recent months, the United States' Food and Drug Administration (FDA) approved two digital mental health treatments as 'prescription-only' medical devices. One is a game-based intervention developed to target attention in children with attention-deficit/hyperactivity disorder (ADHD) and the other is a cognitive behavioral treatment (CBT) for insomnia. In addition to these two landmark approvals, many other digital mental health treatments based on psychological science are in various active stages of the design, development, and evaluation process. These activities are part of a growing industry of 'digital therapeutics,' defined as evidence-based therapeutic interventions driven by high quality software programs to prevent, manage, or treat a medical disorder or disease (Digital Therapeutics Alliance, 2020). By definition, digital therapeutics meet classification for Software as a Medical Device (SaMD) and, therefore, fall under FDA oversight[2].

With the recent approvals, it is clear that we have entered a new era in mental health care, one in which industry and the FDA play a more prominent and formative role in the dissemination and application of psychological and behavioral science than has traditionally been the case. While the downstream consequences associated with such changes are not yet at the forefront of our collective research and practice awareness, FDA's evolving regulations have considerable implications for how digital therapeutics are developed, evaluated, reimbursed, and delivered. As with many changes, there are both tremendous opportunities and challenges.

We see three significant opportunities. First, FDA and industry involvement has the potential to facilitate integration of evidence-based, non-pharmacological mental health interventions into mainstream medicine. This stands to benefit the broader mental health care system and patients by improving efficiencies and patient options across different points of care. Second, FDA oversight aims to ensure that marketed products have acceptable efficacy and safety profiles, as well as meet standards for quality software development and security (U. S. Food and Drug Administration, 2020). This process can, in turn, help to address concerns among mental health providers and potential consumers that digital programs are largely ineffective, or even iatrogenic (Baumel, Torous, Edan, & Kane, 2020; Weisel et al., 2019). Third, FDA and industry involvement can help reduce the well-documented accessibility gaps and barriers to evidence-based behavioral and mental health treatments that leave nearly 70% of individuals with mental health needs without care (Kessler et al., 2005). The traditional model of evidence-based treatment delivery, which hinges on regular in-person access to trained and licensed speciality mental health providers simply does not scale, highlighting one of the biggest challenges in the mental health care system today (Comer & Barlow, 2014; Kazdin & Blase, 2011). The inadequate reach of evidence-based mental health care already disproportionately affects marginalized groups, including ethnic and racial minorities, as well as lower income and/or geographically remote individuals, families, and communities (see Jones et al., 2013; 2016; Nelson & Bui, 2010 for reviews). Consistent with the financial capital the National Institutes of Health puts into its Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, it is increasingly clear that commercialization is one key pathway to successful dissemination and implementation of evidence-based mental health services. The recent FDA developments therefore provide a timely opportunity to oversee such commercialization and safely extend the reach of evidence-based mental health treatments to a broader population of individuals and communities in need.

The promising developments in this area, however, also raise concerns. Notably, although the rising wave

1 Disclosures: JRC is a salaried employee and shareholder at Big Health Inc. BDD is co-owner of OurRelationship LLC. ACT is an owner of Colliga Apps. KRW is a salaried employee and shareholder of Woebot Health. JSC reports personal fees from Macmillan Learning. All other authors report no declarations of interest.

2 A digital therapeutic may require explicit FDA review and clearance or be subject to 'enforcement discretion' depending on its claims and existing regulatory code.

of digital therapeutics headed toward FDA oversight are predominantly based on behavioral sciences and developed by psychological and behavioral scientists, to our knowledge, psychologists have been largely if not entirely absent from the review and approval process for digital therapeutics at FDA. Some of the early unintended consequences of this missing cross-disciplinary input are already apparent. For example, with few exceptions, the vast majority of mental health providers--which include psychologists, counselors, social workers, and credentialed practitioners from other allied disciplines--do not have 'prescription privileges' (a term originally rooted in pharmacologic practices). As a result, under current regulations, only traditional "prescribers" (which represents a very small proportion of mental health providers) can make FDA cleared digital therapeutics available to their patients. The U.S. Health Resources and Services Administration projects that by 2025, psychiatrists and behavioral health nurse practitioners will account for only 7% of practitioners in the mental health workforce (HRSA, 2016). Simply put, applying the model of "prescribers" that was developed to meet the needs of pharmacologic practices to digital therapeutics is clinically inappropriate and restricts the accessibility of these evidence-based treatments. Under this model, digital therapeutics are only accessible to patients receiving their mental health care from physicians and nurse practitioners, while the majority of credentialed practitioners of psychological and behavioral science are precluded from incorporating these interventions (that are explicitly based on psychological and behavioral science) into their clinical care. If this prescription-based model persists, it will ultimately undermine and limit the broad accessibility of these software-based interventions that have been explicitly designed to expand the accessibility of care

In addition, the FDA has required that all of the approved digital therapeutics be delivered as adjuncts to clinical (i.e., medical) care, rather than as standalone treatments, which may actually contradict the indications for the specific therapeutics that are clinically validated as standalone treatments. For example, CBT for Insomnia is a first line standalone treatment -- not clinically recommended as an adjunct to other therapy. Furthermore, recent meta-analytic findings provide evidence that digital therapeutics can be effective both as adjunctive devices and as standalone treatments (Lindhiem, Bennet, Rosen, & Silk, 2015), depending on the nature of the presenting issues and the level of risk in the patient population.

Moreover, there have been significant concerns about the efficacy of some of the recently FDA approved digital therapeutics (Ellison, 2020), which call into question the criteria and process used to evaluate these programs. For example, the FDA approval for the aforementioned game-based digital therapeutic for ADHD used improvement on video game performance as the primary outcome (Kollins et al., 2020), but the game did not actually improve domains of life functioning in children with ADHD, including attention or behavior. If such trends continue unchecked, the loss of trust among the patient populations we aim to serve could be significant.

Given the present picture, the field is at a critical juncture. It is time to consider our vision for a clinically and scientifically appropriate model for the validation, regulation, and delivery of digital therapeutics for mental health. The current needs for oversight of digital mental health therapeutics require a new model, rather than forcing them into a pre-existing process developed for other health care practices -- the proverbial square peg in a round hole. Indeed, FDA regulation has always been an evolving system, adapting to the latest innovations and therapeutic advances. For example, when President Gerald Ford signed the "The Medical Device Amendments of 1976", which adapted existing FDA procedures for bringing medical devices to market, he said that the law eliminated the deficiencies that accorded FDA 'horse and buggy' authority to deal with 'laser age' problems (Rados, 2006). He added, "I welcome this legislation and commend the FDA, who identified the need, cooperated in its development, and finally, will be entrusted with its enforcement." As the Society of Clinical Psychology (APA Division 12), Presidential Task Force, Technology & Mental Health, mHealth Subcommittee, we assert it is again time to reconsider the current deficiencies for regulating modern innovations in mental health care -- in this case related to digital therapeutics. In turn, we call on the FDA and the mental health community at large to cooperate in cross-disciplinary development of further advances in the system that will unlock the promise of increased reach and access to safe and efficacious psychological science for those in need.

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The History of the Early Controlled Trial: Lessons for Contemporary Clinical Psychologists and Students

Candice Basterfield, M.A.

Emory University
Department of Rehabilitation Medicine

Scott O. Lilienfeld, Ph.D.

Emory University
University of Melbourne

For today's clinical scientists, the ideal research design for ascertaining the effects of psychotherapy and other interventions is the randomized controlled trial (RCT). The RCT is now considered the optimal, albeit not perfect, standard with which to assess therapeutic efficacy, largely because it affords the best control over a host of sources of causes of spurious therapeutic effectiveness, such as regression to the mean, multiple treatment interference, history, and maturation (Lilienfeld, Ritschel, Lynn, Cautin, & Latzman, 2014).

The controlled trial and later, the RCT, dramatically altered the therapeutic toolbox of clinical psychologists and psychiatrists alike. It is all too easy to forget that in past centuries, such ineffective and barbaric "treatments" as prefrontal lobotomy, hydrotherapy, surgical removal of organs (e.g., gallbladders, uteruses), insula coma therapy, tranquilizing chairs, the Cox spinning chair, and the Utica crib, were justified largely on the basis of uncontrolled observations and clinical experiences (Lilienfeld, 2015; Lilienfeld & Basterfield, 2020). Many of these psychiatric treatments were justifiably albeit belatedly abandoned because the evidence supporting them no longer aligned with the new scientific standards, especially controlled trials and eventually, RCTs. As a consequence, they were rightly deemed useless and often iatrogenic (harmful; Grove & Meehl, 1996).

Many contemporary practitioners, researchers, and students understandably take the notion of the RCT, with its implementation of comparative experimentation with randomly assigned experimental and control groups, for granted. Nevertheless, the concept of the control group more broadly did not fully take hold in the scientific community until about a century ago (Dehue, 2000), suggesting that it may have been counterintuitive.

Indeed, the early history of the clinical trial teaches us that there has often been resistance to the early discoveries underpinning its development and to techniques borne out of its implementation, such as those comprising evidence-based practice (EBP). Even today, a number of influential scholars continue to argue that RCTs should not be prioritized above other sources of evidence, such as observational data and quasi-experimental data. For example, in 2018 the New Jersey State Psychological Association objected to the newly minted American Psychological Association practice guidelines for posttraumatic disorder on the grounds that RCTs were unduly prioritized above other evidentiary data (see Lilienfeld, McKay, & Hollon, 2018 for other examples). More broadly, a survey of licensed social workers found that many believed that their clinical experience and compatibility with one's theoretical orientation should be prioritized over controlled research evidence when selecting treatment interventions (Pignotti & Thyer, 2012). Similarly, Stewart, Chambless, and Stirman (2020) found that only six out of 25 independent practice psychologists used research evidence to make treatment decisions.

Candice Basterfield, M.A.

In this review, we traverse the long and fascinating journey of the clinical trial, which started with a variety of attempts to examine the effectiveness of psychological and medical interventions, and only later incorporated randomization, blinding, and use of placebos. We also briefly explore why many of these early discoveries were resisted or outright ignored, and how the counterintuitive nature of the clinical trial may help to explain the ongoing criticism and resistance to RCTs in contemporary clinical psychology (Lilienfeld, Ritschel, Lynn, Cautin, & Latzman, 2013). We hope that today's clinical psychologists, clinical psychology students, and clinical psychology instructors will find much of this material not merely interesting in its own right but informative in affording a broader historical perspective on modern views of EBP and resistances to it.

Development of the Clinical Trial: Early Precursors

Historians of medicine disagree regarding the date of the earliest recorded clinical trial. Some scholars bestow this distinction to a "study" described in the Bible, which probably occurred in about 600 B.C.E. (Grimes, 1995; Lewis, 2003). In the Old Testament Book of Daniel, Daniel proposed a method to test the effectiveness of a meat and wine diet recommended by the Babylonian leader, King Nebuchadnezzar. To do so, Daniel compared the outcomes of individuals who received this diet with the outcomes of those who received a vegetarian diet, the latter better construed as a comparison group than a strict control group:

Daniel said to the steward…Test your servants for ten days; let us be given vegetables to eat and water to drink. Then let our appearance and the appearance of the youths who eat the king's rich food be observed by you, and according to what you see deal with your servants." So he hearkened to them in this matter, and tested them for ten days. At the end of ten days it was seen that they were better in appearance and fatter in flesh than all the youths who ate the king's rich food. So the steward took away their rich food and the wine they were to drink and gave them vegetables.

Scott Lilienfeld, Ph.D.

Daniel's insights lay fallow for many centuries. In the mid-1600s, Jan Baptiste van Helmont (1580-1644), the Flemish chemist and physician who coined the term "bias" (including "bias humanum," meaning "human bias"), proposed a systematic method for evaluating the effectiveness of bloodletting, then a standard intervention for fever. Specifically, he put forward the idea of comparing a group of patients who received bloodletting with a group of patients who did not, rather morbidly using the number of funerals as an outcome measure. Further, he suggested that the two groups be allocated via a "casting of lots," a foreshadowing of the later concept of randomization. Still, historical records suggest that van Helmont's thought experiment never came to fruition (Donaldson, 2016).

Many historians date the first formal clinical trial to 1747, when Scottish physician James Lind (1716-1794) conducted an investigation to cure scurvy, then an often-fatal disease characterized by such signs and symptoms as jaundice, pain, tenderness, bodily swelling, and fatigue, among sailors in the British Royal Navy (according to some estimates, more British sailors of that time died of scurvy than of war-related injuries). Back then, scurvy was widely assumed to be attributable to infection. Boldly challenging prevailing clinical wisdom, Lind carried out an experiment on two groups of 12 sailors who displayed the cardinal features of scurvy. These sailors were divided into two pairs, and each pair was provided with a different diet, one of them consisting of citrus fruit. Lind's extremely small-scale but pioneering study suggested that citrus fruits enhance scurvy recovery (Doherty, 2005; A.M. Lilienfeld, 1982; Meldrum, 2000), but the fact that only two participants received the active treatment renders his study massively underpowered.

Although Lind published the results of his investigation in 1753, his promising but admittedly provisional findings were all but ignored, and the erroneous infection theory of scurvy prevailed. It was not until several decades later that physician Gilbert Blane (1749-1834), a British surgeon, came upon Lind's writings and ensured that they were put into routine practice during the Revolutionary War with America. Specifically, Blane ensured that British sailors' grog was spiked with lemon juice and later, lime juice, a life-saving procedure that gave rise to the nickname of "limey" for a British person. Blane couldn't save the British from losing the war, but he surely saved many British lives nonetheless (Dunn, 1997).

Another significant milestone transpired in 1768, when British botanist and physician Sir William Watson (1717-1787) undertook a clinical trial of smallpox, then a major cause of death among children (Boylston, 2014). He divided 31 children into three groups who were roughly equated in their diet, living conditions, play habits, and the like; one of the groups received mercury with a laxative, another received a laxative, and still another received no medication. Watson's pioneering insight was to measure outcomes quantitatively rather than subjectively, as was routine at the time. Specifically, he asked hospital attendants to count the number of pustules on each child following treatment. Disappointingly, he found no apparent impact of mercury on smallpox outcome.

Later Advances in the Clinical Trial: Benjamin Franklin and Beyond

As important as the initial efforts of Lind, Blane, and Watson were, they were limited to the study of the effects of physical substances. Arguably the first controlled trial of a psychological intervention was conducted by a commission headed by Benjamin Franklin (1706-1790), then U.S. Ambassador to France, and Antonie Lavoisier (1743-1794), often regarded as the father of modern chemistry (Herr, 2005; Lynn & Lilienfeld, 2002). Also serving on the committee was Joseph-Ignace Guillotin, whose infamous killing machine would later prove to be Lavosier's undoing. The Franklin Commission, as it is often called, was tasked in 1784 by French King Louis XVI to investigate the claims of the flamboyant Austrian physician Franz Anton Mesmer (1734-1815). Mesmer, who maintained that he could harness the power of "animal magnetism," a purported universal life force generated by fluid that could cure all manner of physical and mental ailments, was then attracting enormous public attention in Paris. At the peak of his popularity, Mesmer held group sessions in which patients sat adjoining a wooden bathtub (baquet) filled with iron filings and magnetized water

supposedly imbued with the magical life force. Dressed in a flowing cape, Mesmer strolled around the baquet, touching patients with an iron wand. By doing so, he induced dramatic trance states and convulsions (and, according to some accounts, orgasms in some of his female patients), followed by ostensible cures. What was later called "mesmerism" was almost certainly a forerunner of modern hypnosis.

To test Mesmer's remarkable assertions, the commission cleverly asked D'eslon, Mesmer's assistant, to magnetize one of five apricot trees using a wand. According to D'eslon, only the magnetized tree should produce powerful psychological effects; yet, when a suggestible man who was blindfolded was asked to touch each tree in turn, he fainted in response to one of the non-magnetized trees (Herr, 2005). In other cases, the Franklin Commission found that patients instructed to touch glasses of magnetized water experienced convulsions when they believed they had been magnetized, even when they had not. In contrast, patients did not experience convulsions after touching glasses of water that had been magnetized if they believed them to be inert. The Franklin Commission had almost certainly stumbled upon what later became known as the placebo effect, the phenomenon whereby improvement results from the mere expectation of improvement (Lynn & Lilienfeld, 2002; Wampold & Bhati, 2004).

Other important advances in clinical trials originated in the mid-1800s. French physician Pierre Louis (1787-1872) conducted a comparative study in the 1820s to examine the effectiveness of bloodletting in treating pneumonia (Morabia, 2006). Using what he termed the "numerical method" of counting treatment results, Louis tabulated the treatment outcomes of 77 patients who initially exhibited extremely similar clinical presentations of pneumonia, demonstrating that patients who received early bloodletting (1 to 4 days following illness onset) improved more quickly, but died at higher rates, than did patients who received late (5 to 9 days following illness onset) bloodletting. This study, although not randomized, called into question the benefits of bloodletting for pneumonia. Echoing the collective reactions to James Lind's findings on scurvy, however, Louis' results were largely ignored, and his admonitions against bloodletting were not adopted (A.M. Lilienfeld, 1982; Meldrum, 2000).

In 1846, Hungarian physician Ignaz Semmelweis (1818-1865) noticed that units in a university hospital with a policy of instructing personnel to engage in regular handwashing exhibited much lower rates of post-childbirth maternal mortality owing to puerperal fever compared with other units. Semmelweis boldly decided to put these informal clinical observations to a systematic test: He asked some physicians to wash their hands with a chloride solution after treating patients and compared their outcomes with those yielded by standard medical care. The rates of death dropped by a factor of ten. Despite these dramatic reductions in maternal mortality, Semmelweis' conclusions were roundly rejected by the medical society of Vienna, largely because the germ theory of disease on which they were premised struck physicians of the time as grossly implausible (Doherty, 2005). In a tragic postscript, Semmelweis died in a mental institution before being vindicated by the scientific community

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An unsung hero in psychology, Charles Sanders Peirce (1839-1914), was a polymath who pioneered a variety of methods in mathematics and statistics. Although Pierce is widely acknowledged as the founder of the American Pragmatist movement in philosophy and recognized for his work in probability and statistics, he was also a brilliant psychological scientist whose most influential statistical work came in experimental psychology. According to some reports, Peirce and his influential student, Joseph Jastrow (inventor of the famous duck-rabbit bistable illusion), conducted the first strictly experimental psychology research published in the United States in 1884 (Hacking, 1998; Peirce & Jastrow, 1884). Most impressively, this study was probably the first blinded controlled randomized experiment in psychology (Hacking, 1998; Stigler, 1978), and it occurred about 50 years before these controlled studies became popular in the 20th century. In 1860, in an important book on psychophysics, Gustav Fechner argued that a specific threshold exists below which the human mind cannot discern small differences in sensation. In response to this assertion, Peirce and Jastrow (1884) performed a large-scale experiment to test it, and instead posited a probabilistic continuum of decreasing accuracy. They set up a study whereby one person was the experimenter and the other was the participant, with a screen between them to prevent unintentional experimenter cueing. A balance scale was modified, allowing the experimenter to place varying weights on his end while the other end exerted pressure on the participant's finger. Two slightly different known weights were presented sequentially to participants, and they would state in which of two possible orders they had been presented. The order of different weights was randomized using multiple deck of red and black playing cards: the operator either increased or decreased the weight according to the color of the next card. In addition, participants estimated their confidence in their judgments on a 3-point scale (with 0 indicating no confidence, 3 high confidence). Their findings supported their hypothesis of a continuum of decreasing accuracy. Although Peirce and Jastrow included a detailed description of the use of cards for randomization, they seemed not to not have recognized that their use of randomization was unique in experimental research, because they did not deem a discussion of this concept to be worthy of mention in the concluding section of their paper (or

perhaps they were just modest!).

Another important early controlled trial was undertaken by Coover and Angell (1907), who wished to ascertain whether training in one academic subject, such as card sorting, generalizes to another, such as reacting times using a typewriter. To do so, they examined the impact of such training in two groups, one that received the manipulation and one that did not, and reported promising results for the generalization hypothesis (Dehue, 2005).

The Introduction of Randomization and Blinding

Although Peirce, along with Jastrow, conducted the first blinded, controlled randomized experiment in psychology, it was not until 1925 that the idea of randomization to experimental conditions was readily taken up in research practices. The requirement of randomization in experimental design was first stipulated by the pioneering British statistician and geneticist Ronald A. Fisher (1890-1962) in 1925 in his book Statistical Methods, in which he developed the technique of analysis of variance (ANOVA) to evaluate the impact of differing agricultural practices on crop growth (as most readers know, the term "F test" in ANOVA was christened in Fisher's honor) (Armitage, 2003; A.M. Lilienfeld, 1982; see also Lilienfeld & Basterfield, 2020).

Fisher's requirement of randomization changed how experiments are carried out, and his principles of experimental design have revolutionized scientific methodology in psychology and other fields.

The Advent of the RCT

Among the earliest randomized controlled trials was conducted to examine the efficacy of sanocrysin (a gold-based compound) in the treatment of pulmonary tuberculosis. It became clear that the treatment for tuberculosis was proving difficult to assess using observational data. Hence, Amberson, McMahon, and Pinner (1931) conducted a controlled trial whereby they matched patients with tuberculosis by dividing them into two clusters, by tossing a coin, to decide which of the groups would receive sanocrysin. The control group received intravenous injections of distilled water (Bryder, 2014; A.M. Lilienfeld, 1982). Treatment outcomes were judged by observers who were kept unaware of the group to which patients had been assigned. No beneficial effects of sanocrysin were detected, and it was clear from the trial that the drug had severe adverse side effects (Lilienfeld & Basterfield, 2020).

Also contributing to the emergence of the RCT was G.W. Theobald (1896-1977), an obstetrician in London, who studied the effects of calcium and vitamin A and D on the incidence of pregnancy toxemia in 100 pregnant women. According to his report, "an equal number of blue and white beads" (presumably 50 and 50, respectively) were placed in a box (Theobald, 1937, p. 1397). Each woman was asked to draw a bead from the box, and those who drew blue beads were placed in Group A (the experimental group) and those who drew white beads were placed in Group B (the controls) (Olsen, 1999). Moreover, Theobald provided evidence that the groups exhibited similar age and parity distributions, and he even used blinding of the primary outcome assessors. In addition, Theobald asked a statistician, the famed Egon Pearson, to ascertain the extent to which his results (namely, that symptoms of toxaemia were less common in the treatment group) might have been due to chance. According to Pearson, "the difference in incidence of complications between the two groups is very unlikely to have arisen by chance" (Theobald, 1937, p. 1398). Theobald concluded that "it therefore seems logical to assume that the difference between the two groups must, if not due to chance, be attributed to the substances given" (Theobald, 1937, p. 1398). Theobald's study was published in 1937, and despite his careful methodology and use of randomization there is scant mention of his study in the literature (according to Google Scholar, it has been cited only 46 times as of this writing).

Another impressive clinical trial at the time was conducted by the People's League of Health in London between 1938 and 1939. The People's League of Health assigned over 5000 pregnant women from 10 hospitals to receive either no supplement or a supplement containing calcium, vitamin A, vitamin C, and halibut oil (Olsen & Secher, 1990; People's League of Health, 1942). The trial used alternate allocation rather than true randomization, producing two groups that were closely balanced for age and parity. The results revealed that the supplemented group resulted in fewer women experiencing early deliveries and toxaemia.

The first fully double-blind controlled trial that attracted the most notoriety was conducted by the Medical Research Council to investigate the efficacy of patulin (an extract of Penicillium patulinum) for the common cold (MRC, 1944). The treatment allocation was again conducted using an alternation procedure, in which patients were sequentially assigned to experimental and control conditions (Hart, 1999; see also Lilienfeld & Basterfield, 2020).

Another randomized blinded controlled trial was carried out by the MRC to evaluate streptomycin for treating pulmonary tuberculosis. The famed British statistician and epidemiologist Austin Bradford Hill (1897-1991) is credited with designing the trial. He

replaced alternation with randomization because he believed – correctly - that random assignment was the only means of avoiding systematic bias between the characteristics of patients assigned to different treatments. Random sampling numbers and sealed envelopes were used to assign pulmonary tuberculosis patients to the streptomycin treatment group and a no-treatment control group. Blindness of assessment was carried out by having two radiologists read the x-ray films independently without knowing to which group they belonged (Claridge & Fabian, 2005; Collier, 2009; Yoshioka, 1998; see also Lilienfeld & Basterfield, 2020). It was not until the 1950s that the first controlled study of outcomes in psychotherapy, in which controls were used, was undertaken by Carl Rogers (1902-1987) and Rosalind Dymond (1922-), later Rosalind Dymond Cartwright. Using the then-recently developed Q-sort methodology of self-concept congruence/incongruence, which measures discrepancies in ratings of actual and ideal-self, and allows for an ipsative (within-individual) measure of personality before and after treatment, Rogers and Dymond (1954) compared outcomes of individuals who received client-centered therapy with (a) individuals in a wait-list control condition, who received treatment two months following the active intervention group and (b) individuals who received no treatment at all, a condition that would probably arouse ethical concerns today. Consistent with Rogers' theory of therapy and personality change, they found that client-centered therapy resulted in a greater congruence between "real self" (what a person reports being like now) and "ideal self" (what a person reports desiring to be like one day) relative to control conditions (see Lilienfeld & Basterfield, 2020). Rogers and Dymond's study later received criticism for failing to randomize clients to treatment conditions; nevertheless, it was a major step forward in psychotherapy research that paved the way for RCTs in psychotherapy. Although they were pleased to have undertaken the first controlled trial in psychotherapy research, they stated modestly that "it isn't good research in psychotherapy, it's just the best that there is" (Rogers & Dymond, 1954, p .5). The rest, as they say, is history.

Resistance to the RCT

In the years since Rogers and Dymond's pioneering controlled study, the methodological rigor and sophistication of psychological research has improved substantially, including the use of methodologically superior RCTs that have provided strong evidence for the efficacy and effectiveness of psychotherapy outcomes. Nevertheless, in many quarters of clinical psychology, there continues to be resistance towards RCTs, and as well as to the concept of EBP more broadly (see Lilienfeld et al., 2018).

There are many reasons why high-quality evidence is not readily adopted into clinical practice. One likely reason is that the nature of scientific thinking is often counterintuitive (McCauley, 2011; Wolpert, 2013). For example, even though the RCT is now so well- established that most of us take its logic for granted in our research standards and practices, it is a relatively new accomplishment. The emergence of the control group appeared only as recently as the 18th century, when James Lind divided sailors with scurvy onboard a British ship into two groups. One potential reason why the control group took such a long time to develop is that the notion of a control group requires disconfirmatory thinking ("Could my observations of apparent improvement in my client be mistaken?"), a skill that does not come naturally to the human mind (Gilbert, 1991).

The concept of the RCT took even longer to develop, emerging only in the 19th century when Peirce and Jastrow conducted the first blinded, controlled randomized experiment in psychology (Jastrow & Peirce, 1884). Still, it took quite some time for this technique to catch on, perhaps in part because randomization necessitates an understanding of the law of large numbers (Tversky & Kahneman, 1971). This law tells us that a large random sample from a population will eventually yield a distribution that closely resembles that of the overall population. Nevertheless, psychological research has identified systematic biases in people's beliefs (held by scientists and lay people alike) regarding the relation between sample proportions and the population from which they are drawn. In particular, many people may have a difficult time grasping intuitively that with increasingly large samples, differences between groups gradually cancel out following randomization. It is perhaps not surprising then that it was not until the 1950s when prominent clinical psychologists began to heed the call for RCTs in psychotherapy (Meehl, 1955).

There may also be intuitive ethical objections to the concept of RCTs. Research on RCTs, otherwise known as A/B tests, suggests that people often approve of treatments (A or B) being given to all subjects. Ironically, however, they tend to object to randomized controlled experiments in which people are assigned to treatment versus placebo or alternative treatment conditions to determine which intervention is more beneficial (Meyer et al., 2019). That is, most people would prefer a scenario in which all individuals are given an entirely untested treatment A to one in which half of these individuals are assigned to this untested treatment and the other half are assigned to a placebo or another untested treatment B, even though such an arrangement is needed to determine whether treatment A works. Moreover, this effect is still pronounced even when there is no inherent reason to prefer one

condition over another (e.g., A to B or B to A). The A/B effect suggests that many people may possess an irrational aversion to RCTs, which may be a significant and largely unappreciated barrier to EBP more broadly. The use of RCTs and evidence-based practice has slowly become integrated into psychological science. Nevertheless, as we have seen, there has also been a consistent pattern of resistance to these concepts. The history of scientific thought is replete with examples of scientific advances that endured decades of rejection before being taken up into clinical practice. For example, Lind, Semmelweis, and Louis all provided at least provisional evidence for an effective therapy; however, their evidence was ignored or dismissed for decades, almost surely resulting in patients being denied effective treatments. In fairness, some of the evidence, such as Lind's, was preliminary and based on small sample sizes, but this limitation does not adequately explain why it took decades before their promising observations were followed up by more rigorous investigations. The term "Semmelweis reflex", named in honor of Ignaz Semmelewis, whose insights into handwashing went ignored, is sometimes used today to describe the knee-jerk tendency to dismiss scientific findings that run counter to prevailing wisdom (York & Brown, 2015).

Concluding Thoughts

In considering the history of the early clinical trial, we should we be wary of what historians of psychology term "presentism," the tendency to view the past exclusively through the lens of the present (Hilgard, Leary, & McGuire, 1991). In particular, with the benefit of hindsight, it is tempting to see the development of RCTs as the pinnacle of a steady progression from preliminary and flawed attempts at controlled trials to the more sophisticated methodologies of today. Such a straight line of progress would indeed be misleading. That said, it undeniable that we have come a long way since the incipient scientific insights of Daniel in the Bible.

In sum, the early history of the clinical trial imparts useful lessons for us today. The concepts of the controlled trial and the RCT took a surprisingly long time to gain a solid foothold in the scientific community (Dehue, 2000), and many promising early findings based on these methods were ignored. So it should perhaps not surprise us that many individuals continue to find these concepts counterintuitive and perhaps even objectionable today, and why some practitioners would prefer to prioritize informal clinical observations above controlled research evidence in their selection of treatments (Pignotti & Thyer, 2009). As a consequence, we may have our work cut out for us as clinical scientists and educators of future clinical scientists. The early history of the clinical trial reminds us that we should not take the concepts of the control group and RCT for granted merely because they are routinely integrated into our education and training. To the contrary, they are counterintuitive and relatively novel ideas that need to be explained anew to every generation of psychology students. A bit of historical perspective may help in this regard.

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The Clinical Psychologist is a quarterly publication of the Society of Clinical Psychology (Div 12 of the APA). Its purpose is to communicate timely and thought provoking information in the domain of clinical psychology to the Division members. Also included is material related to particular populations of interest to clinical psychologists. Manuscripts may be either solicited or submitted. In addition, The Clinical Psychologist includes archival material and official notices from the Divisions and its Sections to the members.

Inquiries and submissions should be sent
to the Editor, Shannon Sauer-Zavala Ph.D. at: ssz@uky.edu

To subscribe, contact Tara Craighead
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Danny Wedding, PhD, MPH
Distinguished Consulting Faculty Member, Saybrook University, Oakland, CA. Danny trained as a clinical psychologist at the University of Hawaii, and then completed a postdoctoral year of training at the University of Mississippi Medical Center. He retired from the University of Missouri School of Medicine and then taught at Alliant International University and the American University of the Caribbean. Dr. Wedding continues to write, lecture, and consult from his home in Berkeley, California.

Linda Carter Sobell, PhD, ABPP
Professor in the Center for Psychological Studies, Nova Southeastern University, Ft. Lauderdale, FL

Jonathan S. Comer, PhD
Professor of Psychology and Psychiatry Director, Mental Health Interventions and Technology (MINT) Program Center for Children and Families Florida International University Miami, FL

Kenneth E. Freedland, PhD
Professor of Psychiatry and Clinical Health Psychology, Washington University School of Medicine, St. Louis, MO

J. Kim Penberthy, PhD, ABPP
the Chester F. Carlson Professor of Psychiatry & Neurobehavioral Sciences at the University of Virginia School of Medicine in Charlottesville, VA

Hogrefe Publishing
30 Amberwood Parkway
Ashland, OH 44805
Tel. 800 228 3749 / Fax 419 281 6883
customerservice@hogrefe.com
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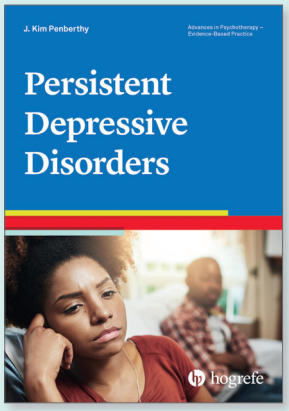

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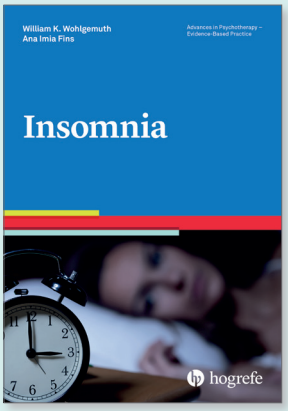

William K. Wohlgemuth / Ana Imia Fins

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Vol. 42, 2019, viii + 94 pp.
ISBN 978-0-88937-415-7
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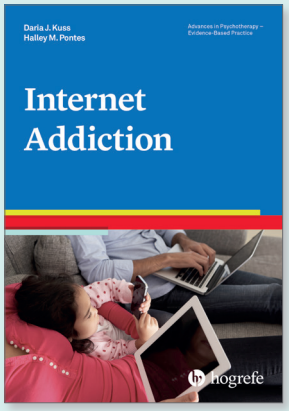
This concise reference written by leading experts for busy clinicians provides practical and up-to-date advice on current approaches to diagnosis and treatment of insomnia. Professionals and students learn to correctly identify and diagnose insomnia and gain hands-on information on how to carry out treatment with the best evidence base: cognitive behavioral therapy for insomnia (CBT-I). Copyable appendices provide useful resources for clinical practice.



Daria J. Kuss / Halley M. Pontes

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Vol. 41, 2019, iv + 86 pp.
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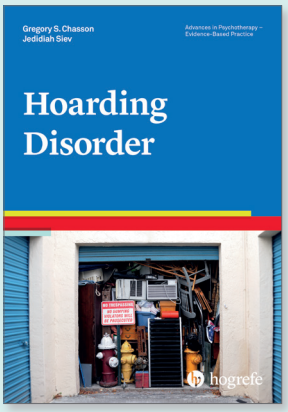

Gregory S. Chasson / Jedidiah Siev

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Vol. 40, 2019, viii + 76 pp.
ISBN 978-0-88937-407-2
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Hoarding disorder presents particular challenges in therapeutic work, including poor treatment adoption. This evidence-based guide written by leading experts presents the busy practitioner with the latest knowledge on assessment and treatment of hoarding disorder. The reader gains a thorough grounding in the treatment of choice for hoarding – a specific form of CBT interweaved psychosocial approaches to ensure successful treatment. Printable tools help practitioners carry out therapy.

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