

FEATURE ARTICLE

Critique of Falloon and the Optimal Treatment Project

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ABSTRACT: *The Optimal Treatment Project advocated by Falloon has been demonstrated through the scientific research literature to be efficient and effective treatment strategies for people experiencing severe mental illness. For this reason, there is little critique of this approach. While the potential value of the project is acknowledged, it is important to identify the appropriateness of the model for specific services and to understand comprehensively the resources necessary for successful implementation. The aim of this paper is to review the literature in relation to the Optimal Treatment Project with a view to exploring the complexities associated with the model. It is concluded that the involvement of multiple stakeholders, including consumers of mental health services, should become an essential element of any implementation strategy.*

KEY WORDS: *consumers, Falloon, implementation, mental health services, Optimal Treatment Project.*

INTRODUCTION

Substantial evidence suggests that a core set of 'optimal treatment strategies' can assist individuals with serious mental illness to attain better outcomes in terms of symptoms, psychosocial functioning, and quality of life. For individuals with schizophrenia, these evidence-based practices include, at a minimum, optimal dose antipsychotics, psychoeducational training for consumers and carers, and assertive case management (Economou *et al.* 2005; Falloon & The Optimal Treatment Project Collaborators 1999; Falloon *et al.* 1998a; 2004; Fenton & Schooler 2000; Lehman *et al.* 1998; 2004; McCann 2001; McFarlane *et al.* 2003; Malm *et al.* 2003).

The Optimal Treatment Project was established by Falloon in 1994. The project comprised an international study of 51 sites over 23 countries to evaluate the effectiveness of a combination of biomedical and psychosocial for the treatment of psychotic disorders. From the findings of the evaluation, it was concluded that, if services adhere to specified programmatic standards and implementation procedures, this core set of interventions should improve client and service outcomes more than existing practices (Falloon & The Optimal Treatment Project Collaborators 1999; Falloon *et al.* 1998a,b). Moreover, it is claimed that these strategies can be implemented and evaluated in publicly funded services without the need for additional resources (Falloon *et al.* 2004). Unfortunately, however, this conclusion may represent an optimistic, oversimplified account of the results (Carpinello *et al.* 2002; Dixon *et al.* 2001; Torrey *et al.* 2001). It is the aim of this paper to provide a critique of the model particularly with respect to its implementation. It is not the intention of the authors to dispute the merit of the project but rather to contribute to a greater under-

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standing of the conditions and resources required for the effective introduction of the optimal treatment strategies within the practice realm.

First, it is important to note that the sites participating in the evaluation were specifically selected because they had highly motivated administrators and clinicians, as well as sufficient resources for training and supervision, ongoing internal and external monitoring and evaluation (Falloon & The Optimal Treatment Project Collaborators 1999). Indeed, Falloon indicated the best predictor of continued participation in the project was the ability to secure continued funding for evaluation. Ongoing monitoring and evaluation are important to ensure fidelity to the treatment model and successful outcomes. Second, the recommended optimal treatment strategies may be too cumbersome for use in regular clinical facilities (Young *et al.* 1998). Finally, in the Afterword by column editors, the reader is informed that sites where Falloon was unable to provide 'his consultation and technical assistance, programme failure and withdrawal from the project have been the unfortunate consequence' (Falloon & The Optimal Treatment Project Collaborators 1999). Thus, the success of the evidence-based practices trialled in the Optimal Treatment Project does appear to be at least partly reliant on well-resourced services with motivated staff, as well as ongoing expert consultation and assistance.

It is important to recognize that evidence-based practices 'do not provide the answers for all persons with mental illness, all outcomes, or all settings' (Drake *et al.* 2001; p. 180). Services need to assess the suitability of their clients and practice setting, and be fully aware of the often complex implementation procedures to determine whether the introduction of these practices will increase the likelihood of positive client and service outcomes in their service. They also need to consider the use of other innovative practices that are highly regarded by practitioners, consumers, and families (Anthony *et al.* 2003; Frese *et al.* 2001; Lehman *et al.* 1998; Liberman 2002; Liberman & Kopelowicz 2002; Torrey *et al.* 2005), but for which little evidence exists owing to more complex research requirements (Kane *et al.* 1998; p. 28).

THE OPTIMAL TREATMENT PROJECT

The Optimal Treatment Project is an international multi-site study established in 1994 to 'evaluate the benefits and costs of applying evidence-based, optimal biomedical and psychosocial strategies for treatment of schizophrenia and other non-affective psychotic disorders over a five-year

period' (Falloon & The Optimal Treatment Project Collaborators 1999; p. 615). Fifty-three sites in 21 countries initially entered the project (Falloon & The Optimal Treatment Project Collaborators 1999); however, a more recent report from June 2004 indicated over 80 participating centres (Falloon *et al.* 2004). In each centre, multidisciplinary teams were provided extensive training (60–100 hours) in the optimal treatment strategies. After team members were certified as competent, they began assessing and treating individuals with schizophrenia according to the project guidelines. Preliminary results after 2 years of optimal treatment indicated that, if applied in a systematic way, the evidence-based treatment strategies used in the Optimal Treatment Project are more effective than more traditional case management programmes for individuals with schizophrenia (Falloon *et al.* 2004).

As stated previously, sites were chosen to participate in the project based on specific characteristics (Falloon & The Optimal Treatment Project Collaborators 1999). Namely, administrators and clinicians had to be committed to developing practice according to an evidence-based model. Services also needed to have sufficient resources to support the sound implementation, and ongoing monitoring and evaluation of this complex treatment model. Additionally, sites chosen to participate had a demonstrated history of partnerships with local consumer organizations. While not stated explicitly, it can be assumed that these characteristics were deemed necessary to maximize the likelihood of sound programme implementation and positive client outcomes. Difficulties with programme implementation and a failure to achieve optimal outcomes may be more likely in services that do not share the characteristics of those chosen to participate in the Optimal Treatment Project (i.e. with less motivated staff and/or insufficient resources).

Optimal treatment strategies

The Falloon model comprises a set of core practices for the optimal treatment and clinical management of individuals with schizophrenia. These practices include: minimally effective doses of antipsychotic medication, as well as education and training to maximize compliance; education for the consumer and their caregivers to cope more effectively with environmental stresses; assertive case management to help prevent and resolve major social needs and crises, including exacerbations of symptoms; social living skills training; and targeted strategies for persistent and/or emerging symptoms (Falloon & The Optimal Treatment Project Collaborators 1999). Extensive evidence exists to support the efficacy and effectiveness of each of these practices (Drake *et al.* 2001; Falloon &

The Optimal Treatment Project Collaborators 1999; Falloon *et al.* 2004; Fenton & Schooler 2000; Lehman *et al.* 1998; 2004). Only one article was found that provided a critical assessment of aspects of the Falloon model (Bellack *et al.* 2000) and one letter was found that provided a critique of assertive community treatment – the broader model encompassing assertive case management (Gomory 2001).

Using data from the Treatment Strategies in Schizophrenia (TSS) study, Bellack *et al.* (2000) provided a critical assessment of Falloon's Behavioural Family Therapy model. They found no difference in outcome between an applied family management intervention based on Falloon's model and a less intensive supportive family management intervention. Both interventions had a demonstrable clinical benefit. Thus, the higher costs associated with the Falloon model were not associated with greater benefits to consumers and their families. Although the TSS study was not purposefully designed to assess the effectiveness and efficacy of Falloon's family therapy model, findings from this study clearly indicate that, at this stage, evidence does not provide unequivocal support for the preferential use of the Falloon model (Falloon *et al.* 2001).

Implementation, evaluation, and monitoring strategies

The implementation of optimal treatment practices is complex, difficult, and resource intensive. Research indicates that the quality of implementation of evidence-based practices in routine mental health services strongly influences outcomes (Torrey *et al.* 2001). As stated by Drake *et al.* (2001):

[O]ffering a service that resembles an evidence-based practice is not sufficient; adherence to specific programmatic standards, often referred to as fidelity of implementation, is necessary to produce expected outcomes. (p. 180)

Consequently, it is recommended that standard guidelines and training materials be used to aid the implementation of such practices and improve client outcomes (Drake *et al.* 2001; Falloon & The Optimal Treatment Project Collaborators 1999; Torrey *et al.* 2001). Additionally, the inclusion of 'fidelity measures and self-correcting feedback mechanisms' is suggested (Torrey *et al.* 2001). These measures and mechanisms can be used to titrate levels of fidelity to produce better clinical results.

Torrey *et al.* (2001) outline six core steps required to effectively establish and maintain a desired practice, including:

... clearly voiced administrative support for change before training; initial clinical training using didactic methods; observation of practice, and written materials; ongoing weekly supervision by an expert, based on written principles and practices; follow-up visits by a program expert with feedback on implementation; and feedback on services and outcomes. (p. 48)

All of the above steps were carried out in the Optimal Treatment Project. Organizations were only included in the project if they had motivated administrators and staff. Following initial consultation, multidisciplinary teams from sites participating in the project received formal training. Falloon developed standard methods to assist the faithful implementation and delivery of the optimal treatment strategies, such as workbooks for therapists and guidebooks for consumers. Falloon and the Optimal Treatment Project collaborators also used continuous audits to assess levels of fidelity, annual independent reviews at each site, and extra training to maintain and improve the quality of the project (Falloon & The Optimal Treatment Project Collaborators 1999; p. 616).

It is likely that the positive clinical outcomes observed in the Optimal Treatment Project were influenced by the rigour and consistency with which the evidence-based practices were implemented. Consequently, other services that wish to implement evidence-based strategies (or the comprehensive treatment model developed by Falloon) to improve outcomes need to ensure fidelity of implementation. This requires adherence to programmatic standards, as well as continuous monitoring and evaluation. In turn, this requires adequate resources and suitably trained staff to undertake continuous audits of fidelity and internal reviews. Indeed, adequate finding is of utmost importance to both implement and sustain evidence-based practices over time.

Falloon and The Optimal Treatment Project Collaborators (1999) reported that the ability to secure ongoing funding for evaluation was the key predictor of continued participation in the project. Over time, it became evident that few publicly funded services are adequately resourced to deliver the optimal treatment programme advocated by Falloon (Falloon *et al.* 2004). Indeed, an inability to ensure the continued provision of optimal treatment strategies was the reason why a substantial number of participating centres were forced to withdraw from the project. Administrators should be mindful that funding is required to cover a range of costs not associated with existing care including initial training and ongoing supervision and feedback, as well as the cost of collecting clinical outcome data and measuring fidelity

(Torrey *et al.* 2001). Moreover, all of these costs include both direct costs and opportunity costs (i.e. time away from direct clinical practice).

Inadequate funding is not likely to be the only challenge faced by administrators. A number of authors suggest that one of the first challenges faced by those wishing to introduce new practices is communicating the need and garnering support for change (Carpinello *et al.* 2002; Torrey *et al.* 2001). There are many potential barriers to change. These barriers may be attitudinal, knowledge-based, practical, or systemic (Dixon *et al.* 2001; p. 903). They may derive from various stakeholders including mental health authorities, administrators, clinicians, consumers and their families. These barriers must be identified and overcome before the process of implementing evidence-based practices is attempted. Many factors influence whether practice implementation is successful. Aligning the support of multiple stakeholders may increase the probability of success, provided adequate training and resources are also available. In contrast, poor support from relevant stakeholders may cause the implementation of an otherwise efficacious practice to fail.

Organizations are responsible for predisposing stakeholders, including clinicians, to the introduction of evidence-based practices via sensitive, well-conceived strategies that bring the practices to life. Many administrators and researchers back the introduction of these practices, as evidenced by the proliferation of practice guidelines and toolkits to support their implementation. Nevertheless, a great deal more than the publication and distribution of guidelines and toolkits is required to change the practice of clinicians. According to Torrey *et al.* (2001), clinicians are 'generally not eager to change and must be convinced to adopt a new practice' (p. 47); however, they are more amenable to adopting a new practice if they can clearly see how the new practice will benefit themselves and their clients.

Clinicians should be given the time and opportunity to evaluate the rationale and theory behind the introduction of a new practice, as well as discuss their concerns. Torrey *et al.* (2001) consider that the following may assist clinicians in this process: research support, compelling vignettes, impressions of those who have already adopted the practice, and provision of a practice ideology or theory that is aligned with their own values and experiences. Services should endeavour to use as many of these methods as possible because the support of clinicians, their willingness to adopt a new practice, can substantially influence outcomes. Ongoing training and support for clinicians are also indicated to ensure the consolidation

and reinforcement of new practices. The maintenance of practices over time can also influence client outcomes.

Limitations associated with the evidence supporting optimal treatment strategies

There are at least three major limitations relevant to the scientific evidence currently available to support optimal treatment strategies. First, research is conducted on specific samples, in specific contexts, and examines specific outcomes. Consequently, the results from these investigations may be limited by the population, outcome, and context (Drake *et al.* 2001; p. 181). Positive outcomes may be specific to the particular population and context within which the research took place. Therefore, it is of utmost importance that organizations assess the comparability of their clients and context; otherwise, different outcomes may be expected. In those instances where extensions of the evidence are made, services need to ensure sound reasoning underpins their decisions, the implementation of practices are carefully planned and documented, and, most importantly, practice implementation and outcomes can be evaluated (Drake *et al.* 2001; p. 182).

The second major limitation relates to the definition of what constitutes 'good research-based evidence' when developing recommendations for how best to help individuals with schizophrenia. This definition is problematic because it inadvertently obscures other sources of knowledge and secures the centrality of pharmacotherapies at the expense of other approaches preferred by consumers and other stakeholders (Kane *et al.* 1998; Lelliott & Quirk 2004). Eligible studies are generally required to meet specific inclusion criteria. Namely, the study sample must be limited to, or primarily composed of, individuals with schizophrenia spectrum diagnoses (according to the Diagnostic and Statistical Manual for Mental Disorders) and the study design is limited to comparative clinical trials (Lehman *et al.* 2004; p. 194). Although the number of studies assessing alternative, or adjunct, therapies that meet these criteria has increased (Hemsley & Murray 2000), the majority of acceptable scientific evidence available pertains to pharmacotherapies 'because medication trials are simpler to evaluate' (Kane *et al.* 1998; p. 28).

Consequently, we know much less about non-pharmacological interventions and evidence-based models appear to understate their importance (Lehman *et al.* 1998; pp. 1–2). This is an unfortunate situation. Science can offer little in the way of evidence about interventions that have attained support from clinicians, consumers and their families. Indeed, the absence of consumer perspectives on what constitutes a preferred intervention and a desirable outcome is resounding. At present, research

and service delivery are determined based on the wishes of other stakeholders (Noble & Douglas 2004). Although many theorists and clinicians agree that 'medications alone cannot maximize recovery' (Lauriello *et al.* 2000; p. 143) and psychosocial treatments are an important adjunct to antipsychotic medication (Hemsley & Murray 2000), research regarding psychosocial and consumer-preferred interventions is lacking.

The third and final limitation relates to the composition of study samples that form the basis of evidence-based treatment recommendations. Study samples are typically composed of individuals with schizophrenia spectrum diagnoses. This is problematic given the diversity of clinical symptoms that characterize schizophrenia (Kane *et al.* 1998) and the possibility of multiple pathways towards the development of this spectrum of disorders (Hill *et al.* 2001). Although some treatments may be beneficial for heterogeneous groups of individuals with schizophrenia, research and recommended treatments need to be sensitive to the likelihood that a 'one-size-fits-all' approach is likely inadequate. Stated another way, it may be necessary to design research that can investigate the possibility of differential outcomes based on theoretically or clinically derived subtypes and tailor interventions accordingly.

CONCLUSION

The impetus behind the implementation of evidence-based practices in publicly funded mental health services is the desire to provide individuals who experience mental illness with proven, effective services that improve the quality of their lives (Torrey *et al.* 2001; 2005). As the authors of this paper share this desire, the issues highlighted in the current paper are less criticisms of the Falloon model than a cautionary note to administrators to ensure they adequately assess the capacity for sound implementation and ongoing evaluation.

The implementation of evidence-based practices is complex, difficult, and resource intensive. 'Issues of organizational structure and commitment, resource development and clarity of roles and responsibilities must be addressed before training can be effective' (Drake *et al.* 2001; p. 182). The introduction of optimal treatment practices requires support from multiple stakeholders including mental health authorities, administrators, clinical staff, consumers and their families. Many of these stakeholders require extensive education and training to support and carry out the implementation of new practices, which may or may not differ substantially from existing practices. Where new practices are substantially

different, services and administrators require the support and commitment of clinicians to ensure the fidelity of implementation and expected outcomes. Administrators need to be mindful of the additional costs associated with implementing evidence-based practices; this includes substantial amounts of time away from direct treatment delivery. Initial start-up and continuous funding are required for monitoring and evaluation to sustain expected outcomes.

Administrators also need to be mindful of the limitations of research evidence. First, suggested practices may not be appropriate for their service, context, or clients. Second, as stated by Kane *et al.* (1998), it is often the case that evidence-based models:

[Do] not consider potentially relevant findings in other fields and cannot adequately consider exciting new concepts (e.g. very early intervention) or other perspectives that have not been studied adequately (e.g. the phenomenon or perspective of recovery). As a result . . . [they provide] only limited advice to those struggling to improve patterns of care. (Kane *et al.* 1998; p. 28)

At present, evidence-based models are biased towards incorporating those practices that achieve positive outcomes as defined by researchers (e.g. a reduction in hospitalization). Although these outcomes are often viewed favourably by hospital administrators, they do not represent the full range of outcome variables that could be included in evidence-based research (Frese *et al.* 2001). Multiple stakeholders, including consumers, should be invited to participate in the selection of outcome variables so that agreement can be reached regarding what constitutes a positive outcome. That way, evidence-based models can incorporate practices that achieve positive outcomes from the perspective of all stakeholders.

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