REVIEWS

Manualized Treatment Programs for FSD: Research Challenges and Recommendations

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ABSTRACT

Introduction. The use of manualized treatment programs offers a useful research framework for assessing psychotherapeutic interventions for female sexual dysfunctions (FSDs), but it does not address all issues related to methodological rigor and replication, and raises new research issues in need of discussion.

Aims. The goals of this manuscript are to review the literature on treatment trials utilizing manualized psychotherapy treatments for FSD and to explore the benefits and research issues associated with the flexible use of treatment manuals.

Methods. The method used was the review of the relevant literature.

Results. While the use of manualized treatments for FSDs can address certain methodological issues inherent in psychotherapy research, flexibility in manual administration is necessary in order to allow tailoring for individual needs that can be beneficial to both the participant and the research. The flexible use of manuals, as opposed to strict manual adherence, may also be more relevant for clinical utility.

Conclusions. In order to administer manualized treatments for FSDs with appropriate flexibility, while also maximizing internal validity and replicability, the authors recommend that predetermined decision rules be utilized to guide individual tailoring, that potential gaps in the manual be identified and addressed, and that differing levels of motivation and readiness for treatment be taken into consideration in the treatment protocol. **Hucker A and McCabe MP. Manualized treatment programs for FSD: Research challenges and recommendations. J Sex Med 2012;9:350–360.**

Key Words. FSD; Psychological Treatments; Manualized Treatment Programs; Research Methodology

Introduction

Past research has demonstrated the effectiveness of medical interventions alone [1,2] and combined medical and psychological strategies [3,4] in the treatment of male sexual dysfunctions. However, the use of medical interventions for female sexual dysfunctions (FSDs) is not as well established [5,6], and currently there are no Food and Drug Administration approved medications for the treatment of FSDs. A limited amount of research has focused on the use of combined medical and psychological treatments for FSDs.

Given the nature of FSDs and the clear role of the relationship and other psychosocial factors involved in female sexual functioning [4,7], it has been suggested that psychological treatments alone or a combination of medical and psychological treatments may be the most effective interventions for FSDs [4,8]. For this reason, psychological researchers have been urged to continue research into the effectiveness of psychological treatments for FSDs [9,10].

Research into psychological interventions for FSDs has been criticized for a range of methodological problems, such as a lack of controlled studies, unclear definitions of outcomes, and the use of small samples [8]. While many of these concerns are valid, there has been a lack of recognition of the innovations of recent sex therapy research and more rigorous research standards have been put in place [8].

As part of the evidence-based practice (EBP) movement, manualized psychotherapy treatments have become an integral part of most efficacy research [11]. The use of manualized treatments in research is advocated in order to provide an operationalized description of treatment methods, to improve research rigor through the use of standardized procedures, and to aid the objective comparison of treatments [12–15]. The use of the phrase "manualized treatment" in this article will refer to psychotherapy treatments only.

While the use of manualized treatments in FSD research has the benefit of providing solutions for some of the methodological problems documented in much of the FSD research, it also raises new challenges for researchers. Designing a manualized treatment requires researchers to provide a clear description of their treatment protocol and method of delivery [11], usually with a specified timeline. While this may be relatively straightforward in medical research, psychological research is more difficult to describe and administer in such a standardized fashion. For example, while a daily 8 AM dose of a certain medication may be easy to describe and replicate, it may be more difficult to write a protocol regarding the amount and type of erotica that a woman should use in a homework task. For this reason, treatment manuals may end up being written in vague descriptions or, alternatively, written in a way that is too prescriptive and overly rigid. In response to this issue, the use of manualized treatments has at times been referred to as taking the "art" out of psychotherapy [11].

One of the major issues that is raised regarding the use of manualized treatments is the acceptable level of manual adherence and flexibilty [13]. While there is no clear cutoff for the degree of flexibility that is appropriate, current literature on the transfer of efficacy research to effectiveness research and clinical dissemination do suggest that an overly rigid manual may not transition well into clinical practice [14]. This article reviews the relevant literature on FSD manualized treatment trials and discusses the variability in treatment design and manual flexibility. Research challenges that arise from the use of flexible treatment manuals are then discussed. Lastly, research recommendations are provided, with a focus on specific strategies for incorporating appropriate flexibility into manualized treatments for FSDs.

Manualized Treatments for FSDs

Research studies into the use of manualized treatments for women with sexual dysfunctions are outlined in Table 1 [16–51]. The studies show variability in many characteristics, and these will be discussed in more detail after a brief discussion of the history of manualized treatment for FSDs.

Manualized Treatments

Masters and Johnson [30] were the first to describe a comprehensive sex therapy program for couples, which included psychoeducation, sensate focus, and communication exercises to address a range of sexual difficulties within a relationship. Although their treatment program initially showed very positive results, further applications demonstrated a need for a broader etiological approach [52–54].

Since Masters and Johnson's [30] behavioral sex therapy, the majority of manualized treatments developed and tested for FSDs have utilized cognitive-behavioral therapy (CBT) approaches. For example, Trudel et al. [46] compared a CBT group program for female hypoactive sexual desire disorder (HSDD) with a wait-list control condition, with outcome measures showing 74% of the treatment group no longer met HSDD criteria at posttreatment.

While most of the manualized treatments in Table 1 have targeted a specific FSD (e.g., HSDD and orgasmic dysfunction), a number of research studies have reported positive results for sexual symptoms other than those specifically targeted. The therapeutic techniques used in manualized treatments for FSDs also tend to overlap considerably [55]. For these reasons, the use of manualized treatments aimed at mixed FSDs is supported, and studies investigating manualized treatments for mixed FSDs have found positive results [24,27,30–32,36,39,41,47].

A recent and promising addition to the CBT approach for FSDs involves the inclusion of mindfulness meditation into manualized treatments [8,19,20]. Two studies have evaluated the incorporation of mindfulness training into a brief psychoeducational group manual for women with sexual desire and arousal problems [19,20]. Although lacking control groups, both studies reported significant increases in sexual desire and reductions in sexual distress.

The use of bibliotherapy and video-therapy manuals for FSDs has also been reported in the literature, and a review of outcome studies suggests that bibliotherapy and video-therapy manuals offer a viable alternate to face-to-face treatment programs [56]. Internet-based interventions are the most recent manualized treatment approach for FSDs and have been applied to mixed FSDs, with preliminary