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Consensus statement on defining and measuring negative effects of Internet interventions

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ABSTRACT

Internet interventions have great potential for alleviating emotional distress, promoting mental health, and enhancing well-being. Numerous clinical trials have demonstrated their efficacy for a number of psychiatric conditions, and interventions delivered via the Internet will likely become a common alternative to face-to-face treatment. Meanwhile, research has paid little attention to the negative effects associated with treatment, warranting further investigation of the possibility that some patients might deteriorate or encounter adverse events despite receiving best available care. Evidence from research of face-to-face treatment suggests that negative effects afflict 5–10% of all patients undergoing treatment in terms of deterioration. However, there is currently a lack of consensus on how to define and measure negative effects in psychotherapy research in general, leaving researchers without practical guidelines for monitoring and reporting negative effects in clinical trials. The current paper therefore seeks to provide recommendations that could promote the study of negative effects in Internet interventions with the aim of increasing the knowledge of its occurrence and characteristics. Ten leading experts in the field of Internet interventions were invited to participate and share their perspective on how to explore negative effects, using the Delphi technique to facilitate a dialog and reach an agreement. The authors discuss the importance of conducting research on negative effects in order to further the understanding of its incidence and different features. Suggestions on how to classify and measure negative effects in Internet interventions are proposed, involving methods from both quantitative and qualitative research. Potential mechanisms underlying negative effects are also discussed, differentiating common factors shared with face-to-face treatments from those unique to treatments delivered via the Internet. The authors conclude that negative effects are to be expected and need to be acknowledged to a greater extent, advising researchers to systematically probe for negative effects whenever conducting clinical trials involving Internet interventions, as well as to share their findings in scientific journals.

1. Introduction

During the last two decades research has provided increasing evidence for the use of Internet interventions (Andersson et al., 2013). Numerous clinical trials have demonstrated the efficacy of treatments delivered via the Internet for a wide range of psychiatric conditions, e.g., depression (Wagner et al., 2014), social phobia (Andrews et al., 2011), panic disorder (Carlbring et al., 2006), generalized anxiety disorder (Titov et al., 2009), insomnia (van Straten et al., 2013), tinnitus (Nyenhuis et al., 2013), pathological gambling (Carlbring and Andersson, 2006), comorbid anxiety disorders (Johnston et al., 2013), irritable bowel syndrome (Ljótsson et al., 2011), among others. Until recently, Internet interventions have mainly involved the use of cognitive behavior therapy. However, current research also indicates that psychodynamic psychotherapy can be delivered as guided self-help with

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promising results for both depression (Johansson et al., 2013c) and anxiety disorders (Andersson et al., 2012a; Johansson et al., 2013a), as well as guided physical activity (Ström et al., 2013), and problem-solving therapy (Warmerdam et al., 2008). Internet interventions are assumed to have several advantages over face-to-face treatment, e.g., higher cost-effectiveness, increased access to evidence-based treatments, and greater opportunity to reach patients on remote locations (Carlbring and Andersson, 2006). Hence, it is reasonable to assume that Internet interventions will become a common alternative to face-to-face treatments in order to meet an increasing demand of mental health services (Johansson et al., 2013b; Kohn et al., 2004).

Because research on Internet interventions has primarily focused on examining its effectiveness little is known about the occurrence or characteristics of negative effects (Boettcher et al., 2014). However, this is far from unique in its field and reflects a major shortcoming of psychotherapy research in general (Nutt and Sharpe, 2008). Investigations on negative effects have primarily dealt with so called fringe psychotherapies or potentially harmful therapies, e.g., rebirthing, scared straight interventions, critical incidence stress debriefing, and recovered-memory techniques, whilst paying less attention to the potential negative effects of evidence-based treatments (Berk and Parker, 2009; Beyerstein, 2001). In recent years, the importance of exploring negative effects of established treatments has also been proposed in order to avoid the possibility of some patients getting worse despite receiving best available care (Barlow, 2010). Similarly, Foulkes (Foulkes, 2010) pointed out that any treatment with the potential of alleviating distress also carries with it the risk of evoking negative effects. In other words, therapists should be aware of the probability of inadvertently inducing negative effects during the course of treatment (Castonguay et al., 2010).

To what extent negative effects occur in psychotherapy is a topic of great debate (Boisvert, 2010). Bergin (Bergin, 1966) is often acknowledged as the first person to describe the possibility of a treatment producing negative effects, although earlier examples are mentioned in the literature, e.g., Mohr (Mohr, 1995) presents a complete review. Bergin (Bergin, 1966) examined several psychotherapy outcome studies and found that some patients consistently seem to deteriorate during treatment. Lambert (Lambert, 2007) has suggested that between 5 and 10% of all patients undergoing psychotherapy deteriorate, a number that also appears in clinical trials at different outpatient care settings (Hannan et al., 2005; Hatfield et al., 2010; Heins et al., 2010; Lambert et al., 2002). However, determining whether the negative effects are a consequence of treatment requires a comparison group to control for the natural course of the target problem (Dimidjian and Hollon, 2010). Also, deterioration may not be the only negative effect associated with treatment (Boisvert and Faust, 2002). Hadley and Strupp (1976) conducted a survey among researchers and therapists on the prevalence and definition of negative effects, resulting in a summary of possible detrimental effects of psychotherapy ranging from low self-esteem to becoming dependent on the therapist. They proposed a tripartite model in which negative effects are assessed from the perspective of the patient, the therapist, and society (Strupp and Hadley, 1977; Strupp et al., 1977). Lilienfeld (2007) made a similar distinction, stating that any intervention might be experienced as negative by the patient, e.g., assertiveness training or exposure in vivo, even though it is believed by the therapist to be beneficial in the long run. Likewise, the outcome of psychotherapy in terms of symptom reduction, increased well-being, and greater independence does not necessarily represent a positive result for a partner or relative, who may have been enjoying secondary benefits from the patient's disorder (Crown, 1983; Kottler and Carlson, 2003; Stuart, 1970). Furthermore, Dimidjian and Hollon (2010) suggested that treatment nonresponse should also be considered negative, as it could have prevented the patient from receiving more adequate care, or experiencing spontaneous remission, prolonging or even increasing the distress. In sum, determining what constitute negative effects of treatment depends on both the perspective from which the treatment is evaluated (e.g., patient, therapist, significant other, or society) and what is regarded as a favorable outcome (Foa and Emmelkamp, 1983; Mays and Franks, 1980).

In comparison to psychotherapy research, monitoring negative effects is required when evaluating the benefits and risks of pharmacological medication (Wysowski and Swartz, 2005). In order to introduce a new drug, as well as to surveil possible adverse events of an existing drug, investigating negative effects is essential and regulated by the pharmaceutical industry, government agencies, as well as international committees, e.g., World Health Organization (Curtin and Schulz, 2011). Assessment is often based on benefit–risk ratios, quantifying the numbers of favorable outcomes achieved for each additional unfavorable outcome (Willan et al., 1997). However, the usefulness of this framework is limited to clinical trials using a single outcome measure and can only distinguish one type of adverse event at a time (Willan et al., 1997). Methods for exploring other possible negative effects have therefore been suggested (Curtin and Schulz, 2011). Kalachnik (1999) provides a review of the most common monitoring procedures of negative effects of pharmacological medication: measurements can be administered on an organizational level, e.g., retrospective data collected from patient journals or the use of laboratory methods, rating scales and checklists for specific negative effects or negative effects in general, and applied individual methods adapted from behavioral psychology, e.g., examining the frequency, intensity, and duration of a target behavior. Negative effects can also be classified as either predictable reactions or unexpected or idiosyncratic reactions (Edwards and Biriell, 1994). Kalachnik (1999) points out that no method will detect all negative effects and that it is advised to use a combination of measures when conducting clinical trials or examining negative effects in clinical practice. Similar to psychotherapy research, the medical literature is not uniform in terms of its terminology, resulting in the use of different definitions to describe the same phenomenon (Edwards and Biriell, 1994). The recommendation is therefore to report all negative effects of a drug even though it might not be related to the medication in use (Goldmann et al., 1995). This is deemed important as it could facilitate hypothesis generation, further investigation, and possibly the need for precautionary measures (Kalachnik, 1999).

Recently, the need for expanded monitoring of negative effects in clinical trials of psychotherapy has been discussed, resulting in different suggestions on how to define and measure negative effects (Peterson et al., 2013). Linden (2013) presented a comprehensive checklist dividing negative effects into different categories. This involves events and reactions unrelated to treatment, nonresponse, deterioration of illness, therapeutic risks and contraindications, and negative effects attributable to the treatment per se. Negative effects are however consistently defined as side effects, a concept primarily used in research of pharmacological medication (Kalachnik, 1999), but has previously been advised by Mays and Franks (1985) not to be used in psychotherapy research as it does not reveal whether the side effects are positive or negative. Furthermore, malpractice reactions are also included, although some argue that they should be distinct from negative effects of evidence-based treatments (Berk and Parker, 2009). On the one hand, Linden's (2013) checklist has a number of advantages in terms of detecting negative effects of treatment as it incorporates the perspectives of both the patient and the therapist, as well as deterioration on validated outcome measures. Parker et al. (2013) on the other hand, have proposed a questionnaire intended to survey the experiences of patients undergoing or having completed psychotherapy. In their research, negative effects were evaluated in relation to premature treatment termination, and then quantified and categorized according to recurrent themes. Results indicated that ineffective treatment, external factors (e.g., lack of money or time, and current work situation), and a dislike of the therapist or the therapeutic orientation were common reasons to terminate treatment prematurely. In particular, negative therapeutic alliance was deemed an important mechanism related to negative effects, but also non-specific therapeutic factors, e.g., relocation of therapist and interfering