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Frequency of reporting of adverse events in randomized controlled trials of psychotherapy vs. psychopharmacotherapy

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Abstract

Background: Psychopharmacology and psychotherapy are the two main therapies in mental health. It is common practice to consider adverse events (AEs) of medications, but it's not clear this occurs with psychotherapy.

Aim: This study investigates the frequency with which reports of AEs occur in clinical trials using either psychopharmacology alone, psychotherapy alone, or combined approaches.

Methods: Forty-five articles of randomized trials published in high-impact journals were chosen from a Medline search, and separated into three groups of 15 articles: pharmacotherapy alone (M), psychotherapy alone (T) and combined studies that looked at the effect of both a psychotherapeutic (CT) and psychopharmacologic (CM) intervention. Criteria for what defines an AE were established and the papers were rated for mentions of AEs in papers as a whole and by each section.

Results: The χ^2-analysis of AE mentions showed significant differences between the four study conditions in terms of each paper as a whole (χ^2: 10.1, $p < 0.018$), and by section. Medication (M + CM) and psychotherapy papers (T + CT) were then combined into two groups to compare the odds that one was more likely to mention AEs than the other. Bivariate logistic regression yielded statistically significant odds ratios ranging from 9.33 to 20.99, with medications being far more likely to mention AEs.

Conclusion: We believe the difference in reports of AEs mirrors the attitudes researchers and providers. It's critical to consider, and standardize the definition of, AEs in psychotherapy, and imperative to identify and address potential AEs in psychotherapy research.

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1. Introduction

Psychopharmacology and psychotherapy are the two main therapeutic modalities for the treatment of behavioral and emotional problems. Each approach may be used individually or the two may be practiced concurrently, as is often the case. As adverse events can occur in any form of treatment, it is important to be aware of the nature and frequency of adverse consequences of each modality. To this end, and as mandated by the Food and Drug Administration (FDA), medications are tested and screened carefully for side effects during their development and post-marketing period [1]. It is common practice to inform patients about possible side effects and risk–benefit ratios whenever psychotropic drugs are initially prescribed. On the other hand, it is unclear whether the frequency and nature of adverse events are so rigorously explored in regard to the application of psychotherapy. Barlow has recently noted the lack of attention to this issue within the psychotherapy community, concluding that "it is time to focus attention in a more systematic manner on those unfortunate cases where harm might occur or benefit is conspicuously absent [2]." One article emerging from the STAR*D report noted an increase in suicidality after the initiation of cognitive therapy [3]. The authors state in their discussion they "thought it noteworthy that although the U.S. Food and Drug Administration warns of the emergence of suicidal ideation as a hazard following initiation of antidepressant medication, several cases of suicidal ideation occurred as serious adverse events following the initiation of cognitive therapy in our study [3]." Thus as an initial step towards improving our understanding of the potential for adverse events in psychotherapy, we investigated the frequency with which adverse events were mentioned in randomized controlled

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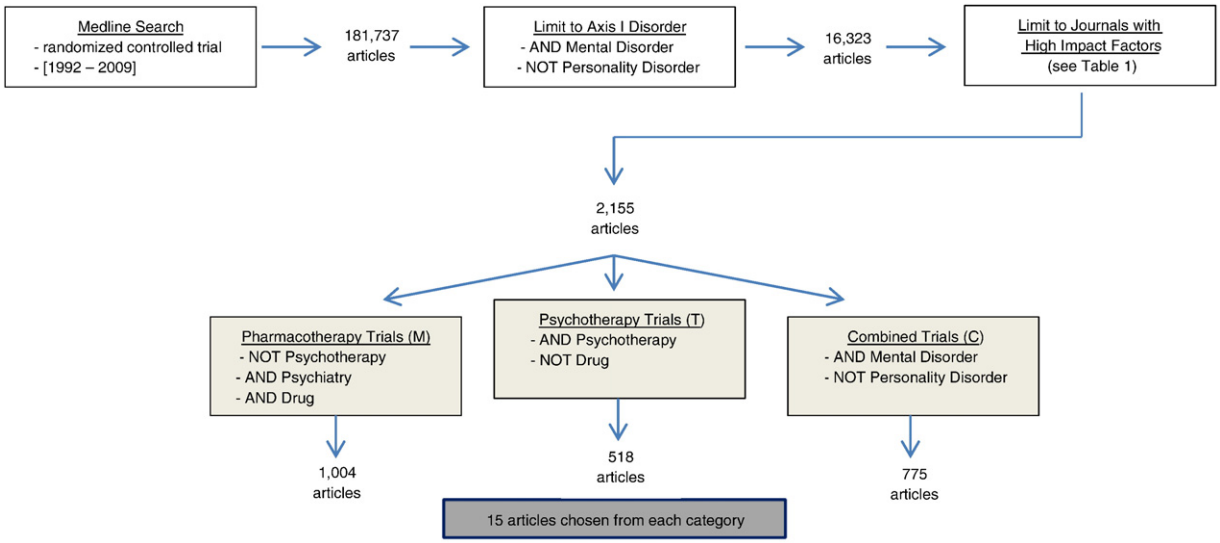

Fig. 1. Outline of Journal Publication Search.

trials of both psychotherapy and pharmacotherapy. More specifically, the study outlined below investigates the frequency with which reports of clinical trials using either psychopharmacology alone, psychotherapy alone, or combined approaches, consider the incidence of adverse events in their outcome data. It is not the purpose of this paper to document the frequency with which adverse events actually occur; rather it is our intention to document the relative frequency of their consideration by the study authors. Our hypothesis is that researchers are more apt to consider and report the possibility of adverse events when addressing the use of medications. We believe this study provides a necessary first step towards better assessment of AEs in psychotherapy research.

2. Methods

2.1. Article selection

A Medline search in journals of psychiatry and psychology of randomized controlled trials limited to Axis I disorders was performed which yielded over 10,000 hits (see Fig. 1). To narrow down the selection of articles, the following inclusion/exclusion criteria were used: 1) publication in a journal with high impact factor (i.e., > 5); 2) Phase II, III & IV clinical psychopharmacology trials; 3) psychotherapy trials that studied commonly used therapeutic modalities (e.g., cognitive therapy, supportive therapy, group therapy, etc.); 4) reviews, editorials, meta-analyses, practice guidelines and brief reports were excluded. Out of the remaining pool of articles, 15 articles (see Table 1) were chosen at random for each of three groups: pharmacology trials alone (M), psychotherapy trials alone (T), and combined trials (C), in which the effects of both psychotherapy and psychopharmacology were under investigation. Of note, in some of the psychotherapy alone (T) articles, study participants may have been taking medication as well. However, the effects of medication were not the focus of those studies and were not measured for outcomes.

2.2. Rating process

Two study investigators (BV and MA) reviewed the articles and rated them for *mentions* of *possible* (denoting that the authors were considering the possibility) or *actual* adverse events (AEs). The articles were rated for the presence or absence of AE mentions in the paper as a whole and also in each of the four article sections: Introduction, Methods, Results and Conclusion/Discussion. The 15 combined trials (C) were rated for AE mentions attributed to medications (CM) and also for AE mentions attributed to psychotherapy (CT). In sum, there were four study conditions (M, T, CM and CT) that were assessed over a total of 180 paper sections.

2.3. Identification of adverse events

An AE was defined as a deleterious result attributed directly to a treatment intervention. Sometimes, it was not clear whether a negative outcome was considered an AE of the study intervention. A system for identifying mentions of AEs was developed and is detailed below.

The coding system for rating AE mentions delineated specific linguistic terms and clinical constructs deemed to be related to AEs.

1. Linguistic terms considered to explicitly denote AEs included: “adverse event(s),” “side effect(s),” “risks and benefits” (only when the risks of the intervention were stated explicitly), “safety,” “negative effect(s),” “acceptability/suitability” (only when this referred to the intervention being potentially harmful to patients, thus making it unacceptable/unsuitable), and “tolerability.”

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