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## **Recent Randomized Controlled Trials of Psychological Interventions in Healthcare: A Review of Their Quantity, Scope, and Characteristics**

Filip K. Arnberg, Ph.D.<sup>1\*</sup>; Iman Alaie, M.Sc.<sup>2</sup>; Thomas Parling, Ph.D.<sup>2</sup>; Ulf Jonsson, Ph.D.<sup>3,4</sup>

### **Affiliations**

<sup>1</sup> Department of Neuroscience, psychiatry, Uppsala University, Uppsala, Sweden

<sup>2</sup> Department of Psychology, Uppsala University, Uppsala, Sweden

<sup>3</sup> Swedish Council on Health Technology Assessment, Stockholm, Sweden

<sup>4</sup> Division of Insurance Medicine, Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

\*Corresponding author: Filip K. Arnberg, Department of Neuroscience, Akademiska sjukhuset ing 10 fl 3, 751 85 Uppsala, Sweden. Phone: +46-18 611 88 98.

Fax: +46-18 611 21 53. E-mail: [filip.arnberg@neuro.uu.se](mailto:filip.arnberg@neuro.uu.se)

### **Running Head**

Recent Trials of Psychological Interventions

## Abstract

**Objective:** This study aimed to describe the quantity, scope, and fundamental characteristics of recently published randomized controlled trials (RCTs) of psychological interventions.

**Methods:** We queried two major databases (PsycINFO and PubMed) for primary reports published in 2010 of RCTs of psychological interventions for participants with a medical condition. We collected data on the characteristics of the trials, participants, interventions, outcomes, and reports.

**Results:** Of 3,696 retrieved reports 295 primary publications were included. About half (53%) of trials included participants with a mental disorder and more than half evaluated interventions based on a cognitive behavioral therapy (CBT) framework. A majority of trials recruited participants in North America and Europe (79%). A minority of the trials focused on children and adolescents (17%) or the elderly (8%). The median sample size of the intervention arm was  $n = 41$ . Thirty-nine percent of trials reported solely patient-reported outcomes. Only 5% of reports indicated funding from for-profit organizations. The median 2010 impact factor of the journals in which reports were published was 2.96.

**Conclusion:** This snapshot of the research on psychological interventions suggests that the evidence base for psychological interventions is expanding mainly for CBT interventions for adults in high-income countries. Although the restrictive inclusion criteria limit the generalizability of these results, researchers and funding agencies might be advised to strive for greater diversity regarding interventions, geographical/cultural settings and age groups. Regularly updated reviews of this research field, with gradually refined methodology and increased scope, may further inform funders and researchers.

**Keywords:** behavioral interventions; psychotherapy; randomized controlled trials; systematic review; healthcare policy; evidence base

## Introduction

The role for psychological interventions in healthcare is increasingly being recognized. An increasing number of randomized controlled trials (RCTs) suggest that these interventions can be successfully applied to a range of mental disorders with effects comparable or superior to pharmacological interventions [1, 2]. In addition, a majority of patients seem to prefer psychological treatment to pharmacotherapy for mental disorders [3, 4]. Importantly, psychological interventions can be applied also to diseases and disorders that are common in healthcare but often difficult to medically manage [5-7].

There is much to be gained by expanding the evidence base for psychological interventions for patients in all age groups worldwide. Thirteen percent of all disability-adjusted life years (DALYs) pertain to neurological and psychiatric disorders and depression is one of the leading causes of DALYs globally [8]. Neuropsychiatric disorders are the main cause of years lost because of disability for 10-24 year old individuals [9] and dementias are projected to be the fourth leading cause of DALY in high-income countries in 2030 [10]. Mental disorders also increase the risk for communicable and non-communicable diseases and are a common corollary of physical disorders [11-14]. For example, the risk of self-harm is elevated for patients with various physical illnesses [16]. However, although patients referred to specialist medical services often have clear symptoms of depression only a minority receive minimally adequate treatment for this condition [15].

RCTs of psychological interventions have been published only since the late 1970s and very few were published until the 1990s. The output has increased rapidly, however, and at present it is nearly impossible to keep pace with the total output of RCTs. Yet, there are to date no available data on the number of trials published annually and the characteristics of these trials. While several reviews are available for individual disorders and for individual types of treatment, we are not aware of any review of the full spectrum of psychological interventions in healthcare.

Comprehensive reviews of the field could provide an overview of recent trials with regard to how, where, why, and for whom they are conducted. Regular updates of these reviews could provide valuable information about changes over time in these characteristics. Policy makers, clinicians, researchers, and other stakeholders in healthcare rely on peer-reviewed reports of clinical trials to make decisions about, for example, the funding and planning of trials. Adequate information about current research is needed to avoid waste of resources and potential harms to participants. The recently initiated work with reporting guidelines specifically for RCTs of social and psychological interventions is an important step [17, 18]. However, it is difficult to monitor a multi-faceted research field such as that of psychological interventions. There is a risk that abundant trials are conducted and that research efforts and resources are not allocated to the most urgent trials. Hence, regular monitoring of this research field could guide both researchers and funding agencies by identifying gaps in current research.

The objective of the present study was to provide a first attempt to review the quantity, scope, and characteristics of recently published RCTs of psychological interventions,

focusing on characteristics that are desirable for generating reliable evidence from clinical trials, with regard to the trials themselves (their sample size, type of comparison condition, and the length of any follow-up assessments), the participants (which diagnoses and participants, with regard to age and location, are commonly included), the interventions (type, length, and setting of intervention, type and training of therapists), the type of outcomes that the interventions were aiming to affect, and, finally, who funds and performs these trials.

## **Methods**

### **Protocol and registration**

This review was initiated and registered internally at the Swedish Council on Health Technology Assessment, which is a public authority that has the mandate of the Swedish Government to comprehensively assess healthcare technology from medical, economic, ethical, and social standpoints. No international database of prospectively registered protocols for this specific kind of systematic reviews was found at the time when this review was planned. The present study was conducted in line with the Declaration of Helsinki and adheres to the ethical principles of the American Psychological Association.

### **Eligibility criteria**

*Type of reports and study design:* Primary reports of RCTs in peer-reviewed journals in English and published in print or online in the calendar year of 2010. We decided to limit our review to the year of 2010 in order to retrieve the most recent trials, thus describing current practice. We selected the most recent year for which the database indexing was complete, in order to minimize the risk that relevant trials would not yet

be indexed in the databases at the time of the search. In order to be able to present findings pertaining to individual full-scale trials, we excluded secondary publications or follow-ups of previously published trials and RCTs identified as a pilot or exploratory study by the authors. In the following, the term *trial* refers to the study itself and the term *report* to the publication.

*Participants:* Participants of any age that were diagnosed according to the International Classification of Diseases and Related Health Problems version 10 (ICD-10) [19] or the Diagnostic and Statistical Manual of Mental Disorders, 4<sup>th</sup> edition, text revised (DSM-IV-TR) [20].

*Intervention:* Any psychological intervention. To the best of our knowledge, there is no universally accepted definition of what constitutes a psychological intervention. We defined psychological intervention as a method to improve health by means of strategies that induce changes in a patient's cognitions, emotions, and behaviors according to an explicit psychological theory. For example, if the intervention was thought to affect weight status through a positive effect on self-concept [21]. Or, in the case of diabetes, that the patient's glycemic control would improve through bolstered autonomous motivation and self-efficacy [22]. If there were no explicit explanations in the report of the mechanisms of change, we judged the intervention as psychological or not based on its similarity with other established psychological treatments (e.g., cognitive behavioral therapy [CBT]). Further, the effects of the psychological intervention must have been evaluated for the report to be eligible for inclusion. Accordingly, reports were excluded if the intervention included a psychological component only as part of a treatment package and the effects of the

psychological component were not evaluated specifically. For example, we would exclude a trial that reported the effect of an intervention that included free-of-charge pre-packaged prepared foods together with one or more psychological treatment components (e.g., motivational interviewing). Reports were included if the active intervention included only behavior modification (e.g., aimed at changing the diet, increasing exercise, or both, by means of a purported psychological intervention).

*Comparison:* Any.

*Outcome measure:* Any health-related outcome measure.

### **Search strategy**

Reports were identified by searching the electronic databases PubMed (NLM) and PsycINFO (EBSCO) for RCTs of psychological interventions that were published in print or online ahead of print in a peer-reviewed journal in 2010. The search strategy for PubMed was: psychotherapy [MeSH] OR nursing [MeSH] OR psychology, applied [MeSH] OR rehabilitation [MeSH] OR preventive health services [MeSH] OR behavioral medicine [MeSH] OR psychosomatic medicine [MeSH]. The search was filtered by publication date 2010-01-01 to 2010-12-31 and by publication type (RCT). The search in PsycINFO used the following subject headings (including subheadings): healthcare psychology, behavioral medicine, rehabilitation, psychosomatic health, habilitation, prevention, psychotherapy, health education, clinical psychology, health behavior, lifestyle changes, skills learning and early intervention. The search was conducted on 15 November 2011 and was limited to reports published between 2010-01-01 to 2010-12-31 and treatment outcome/clinical trials.



## **Study selection**

Two independent reviewers screened the titles and abstracts of all identified reports (UJ screened all abstracts; FKA, IA and TP screened one third each). Disagreements between reviewers were resolved by consensus. The main reasons for exclusion in the screening stage were that the abstract made clear that the study was not an RCT, did not evaluate a psychological intervention (e.g., orthopedic interventions), or did not recruit participants with medical conditions (e.g., workplace interventions). The included reports were retrieved in full-text and allocated to one of the four reviewers who assessed the reports in detail for inclusion. Suggestions for exclusion at this stage were discussed by all four reviewers and resolved by consensus. Figure 1 illustrates the selection process. The Appendix lists all included reports and those that were excluded after full-text reading.

## **Data collection process**

We developed a data extraction sheet in Microsoft Excel. Each reviewer extracted data from their allotted reports. Two reviewers (FKA and UJ) inspected the completed extraction sheet for inconsistencies. In case of uncertainty a second reviewer audited the report. Throughout the process, we excluded reports on secondary analyses and double publications. The final extraction sheet was therefore examined for similarities in the extracted data with particular attention to multiple publications by the same author.

## **Data items**

We extracted data from the reports on a number of pre-specified variables relevant for the generalizability, reliability, and validity of the trials.

1. Geography: The country in which the trial participants were residing. If it was not stated explicitly we assumed that the trial was conducted in the country of the ethical review board or the authors' university. The countries were categorized in accordance with the continents (Africa, Asia, Europe including Russia, North America, Oceania, and South/Central America).
2. The age of the trial participants were categorized as follows: *children* if only participants in ages 0-19 were included, *adolescents* if only ages 13-19 were included, *elderly* if participants were more than 60 years of age, or else as *adults*.
3. Diagnosis: The primary diagnosis for which the study sample had been selected was categorized according to the chapters and diagnostic categories of the ICD-10. Some results are presented separately for mental disorders, which refer to mental and behavioral disorders in the ICD-10, and physical disorders, which refer to all other chapters in the ICD-10.
4. Sample size: The number of participants before and after the intervention in all trial arms. If there was more than one number reported before or after treatment we chose the number that was closest in time to the intervention so that the calculated dropout rate would reflect treatment dropout rather than study dropout.
5. Comparison characteristics: We extracted the number of control conditions and whether any control condition was an active control. We defined as active controls those conditions that were described by the authors as plausible to have an effect on the main outcomes. Hence, treatment as usual could be either an active or a passive control condition.
6. The psychological interventions were grouped in general categories. The categorization was done ad hoc because we did not know beforehand what interventions we would find. The guiding principle was to categorize in

accordance with how the authors identified the intervention. If no identifier was found (e.g., motivational interviewing) we categorized the intervention according to the authors' description or references used in the description. We use established treatment paradigms where possible whereas interventions that did not match a specific paradigm were categorized according to their main components, if they clearly pertained to a paradigm (e.g., cognitive restructuring). Interventions that neither fit an established paradigm nor included such components were categorized according to how the expected change was described to occur by the authors (e.g., by means of change in cognitions, social relations, motivation, or behaviors).

7. Duration of intervention: We extracted the number of sessions and the length of each session using the actual mean or median values if reported, or else we used the authors' prediction of the number and length of each session.
8. The delivery of intervention was coded as face-to-face individually or in group-sessions, or as delivered through other means such as the Internet, telephone, audio or video recording. We also coded whether or not a therapist was involved in the actual delivery of therapeutic content.
9. Therapists: We coded if any of the therapists in each trial was a psychologist/psychotherapist or not, or otherwise as not reported. We also extracted all relevant statements on the method-specific training of the therapists.
10. Symptom description: The type of symptoms targeted by each primary outcome measure was extracted. If no primary outcome was defined, all types of targeted symptoms were extracted. To simplify the presentation, the outcomes were then categorized according to functional similarity and are presented with one or more descriptive labels.

11. Outcome assessment: The outcome assessment was also coded with respect to objectivity in the following hierarchical order: any outcome measured by an apparatus, a biological measure, or retrieved from a registry; assessed by clinical/researcher; retrieved from significant others; or patient-reported. We also extracted information about whether and when a follow-up assessment was undertaken.
12. Conflict of interest was coded as yes/no if a relevant paragraph was found in the report, otherwise as not reported.
13. Financial disclosure was coded as either government/non-profit/none or for-profit if a relevant paragraph was found in the report, otherwise as not reported.
14. The journals' impact factors were retrieved from the 2010 Journal Citation Reports® (Thomson Reuters, 2012).

### **Data analysis**

The present study provides descriptive statistics for the reports. For ordinal and interval variables the median is reported for central tendency, supplemented by the interquartile range (IQR) and total range. For nominal variables the proportions are reported. The data were coded in a Microsoft Excel spreadsheet and descriptive statistics were calculated using SPSS v. 20 (IBM, Chicago, IL). The data are available on request.

## **Results**

### **Trial characteristics**

We identified 295 primary reports of RCTs of psychological interventions published in 2010 (Figure 1). The trials had a median sample size of 86 at baseline (IQR = 55–

149, range = 11–1483) and a median sample size of 41 for the primary intervention group (IQR = 25–68, range = 6–633). Most trials (n = 226, 77%) were two-group trials, 55 (19%) had three groups, 12 (4%) had four groups, and one each had five or six groups. Seventy-seven (26%) trials did not use an active comparison group whereas the majority (n = 178, 60%) included one active control intervention, 35 (12%) trials included two, 4 (1.4%) trials included three, and 1 (0.3%) trial included five active comparisons. The median sample size of the intervention group in trials that included one vs. no active comparison was 42 vs. 36 participants (IQR = 25–71 vs. 23–55). Most reports included a follow-up assessment (n = 191, 65%) with a median time to follow-up of 6 months (IQR = 3–12 mo.). The time to follow up is uncertain because several reports did not indicate if the starting point of the duration was at the baseline or the post-assessment.

### **Participants**

The majority of the trials (79%) had recruited participants in North America, mainly the United States, or Europe (Figure 2). Three of four trials included mainly or only adult participants (n = 221, 75%), whereas approximately one in six trials focused on children (n = 39, 13%) and adolescents (n = 11, 3.7%). Finally, 24 (8.1%) trials focused on elderly participants. In all, two of three trials (n = 191, 65%) included adults from Europe, North America and Oceania whereas 4 (1.4%) trials, none concerning mental and behavioral disorders, focused on children or adolescents from other geographical regions. A slight majority of the reports concerned participants with mental and behavioral disorders although diagnoses from all chapters in the ICD-10 were represented in the sample (Table 1).

## Outcomes

The most prevalent outcomes related to mental and behavioral functions, particularly anxiety, stress, and mood (Figure 3). The majority of reports ( $n = 210$ , 71%) included patient-reported outcomes, followed by outcomes assessed by clinicians or researchers ( $n = 113$ , 38%), by an apparatus or registry data ( $n = 73$ , 25%), and outcomes reported by the participants' significant others ( $n = 10$ , 3%). Only 114 reports (39%) relied solely on patient-reported outcomes whereas 98 (33%) included an outcome that was assessed by clinicians/researchers and 73 (25%) included an outcome measured by an apparatus or registry data. The reliance on patient-reported outcomes was somewhat higher in trials that included participants with physical disorders than with mental disorders (Table 2). One half of the reports ( $n = 146$ , 50%) did not specify a primary outcome measure or specified more than two primary outcome measures.

## Interventions

As seen in Table 2, the majority of the interventions were identified as within a cognitive behavioral framework, accounting for approximately two thirds of the interventions. No other theoretical or methodological framework accounted for more than 7% of the trials.

The interventions were mainly delivered face-to-face ( $n = 219$ , 74%). The remaining trials included interventions that were provided by other means (e.g., an audio/video-player or the Internet). We could not identify or compute the effective intervention length (i.e., session length  $\times$  number of sessions) for 89 trials (30%). For the remaining trials, the median effective intervention length was 10h (IQR = 3–17h) and the range was 0.07–155h after excluding one outlier with an intervention length of

2080h [23]. The duration of the interventions was longer in trials for mental disorders than for physical disorders (Table 2). The median treatment dropout was 14% (IQR = 3–21%, range = 0–73%) whereas the median dropout for all the 105 TAU comparison groups was 8% (IQR = 0–15%, range = 0–48%).

In the 257 trials that evaluated a therapist-led intervention, 118 (46%) reports stated that the therapists included at least one psychologist or psychotherapist. No statement on therapist profession was found in 75 reports (29%; e.g., only stated “interventionist”, “therapist”). We could find a valid statement on the extent of the method-specific therapist training in 114 (44%) of the reports with a therapist-lead intervention, although the quality of the information was highly variable in detail and relevance.

### **Conflicts of interest, funding and impact factors**

There was no declaration of potential conflicts of interest in nearly half of the reports (n = 140, 47%) whereas 126 reports (43%) declared no conflict of interest and 29 reports (10%) declared a conflict of interest. A statement on financial disclosure was absent in 70 reports (24%) whereas 14 reports (5%) reported funding from for-profit organizations and 211 trials (72%) reported governmental, non-profit, or no external funding. Finally, the median impact factor for the journals in which the present reports were published was 2.96 (IQR = 1.95–5.17, range = 0.26–33.63).

## **Discussion**

This review provides a first snapshot of the quantity, scope and characteristics of efficacy trials of psychological interventions intended for people with a medical

condition. The sheer amount of trials in one single year, nearly 300, is notable, as is the diversity of medical conditions for which the interventions were assessed. The true number of published trial in this single year is almost certainly higher: not all journals are indexed in the databases that we searched and the sensitivity of our search strategy was probably imperfect. In addition, publication bias would suggest that a significant proportion of trials are not even published [24]. Perhaps even more striking than the number of trials, however, is the relative lack of variation in terms of geographical location, age span of the participants, and treatment paradigms. There were very few trials that focused on children/adolescents and the elderly. Although a range of different treatment paradigms was evaluated, a clear dominance was observed for CBT.

### **Trial characteristics**

Given that pilot and exploratory trials were excluded from the present study, the included trials were relatively small: approximately one quarter of trials had 25 or fewer participants at baseline in the intervention group. An analysis of adequate power was beyond the scope of this review and the adequate sample size of a trial depends on many factors. Together with an average dropout rate of 14 percent, however, many trials probably suffer from nontrivial bias and low precision in their effect size estimates. Particularly trials with active comparisons may have suffered from low statistical power to detect true effects of the interventions. These trials normally result in smaller effect sizes yet they had sample sizes roughly similar to trials without active comparisons. Researchers need sufficient financial and human resources to conduct large enough trials with adequate control of potential sources of bias, and often over relatively long periods of time. More multi-center trials may be



needed in this field to recruit larger samples. The large amount of trials suggests that it might be advisable to conduct fewer but larger trials.

### **Participants**

The geographical imbalance highlights that for a significant portion of the global population there is meager scientific output of clinical trials. Although publications during only one year were reviewed herein, the findings are similar to results from a review that included several years' of trials registered at ClinicalTrials.gov [25]. Compared with all types of interventions in medicine, psychological interventions seem to be even less represented in Latin America and Africa [25]. The imbalance in this field reflects the challenges presented to the medical discipline in general [26]. However, psychological interventions are likely to be more bound by culture than are many medical treatments and often need to be cross-culturally adapted and tested before implementation in another cultural context, which increases the need even more for research in a variety of countries.

Further, the findings herein underscore the halting progress in the field of medicine on furthering the evidence base for interventions for children, adolescents, and elderly [25]. Importantly, many psychological interventions developed for adults cannot be applied to children or elderly without careful adaptation. It has been estimated that roughly half of all lifetime mental disorders start by the mid-teens and three quarters by the mid-20s, while later onsets mostly are secondary conditions [27]. The need for evaluation of psychological interventions for children and adolescents [28], particularly in low-income countries [29], has recently been highlighted. Yet, only four trials concerned children or adolescents outside Europe, North America and Oceania, and none of these concerned mental and behavioral disorders. As for the

elderly it seems that the projected large increase of elderly in developed countries [30] has not prompted researchers to conduct clinical trials aiming to improve mental health in this group. Finally, it is worth mentioning that there were almost as many trials with patients with a physical disorder, illustrating the propagation of psychological interventions into all areas of healthcare.

### **Outcomes**

The majority of outcomes were related to cognitions, emotions, and behaviors. Interestingly, clinician-reported outcomes were included nearly as often as participant-reported outcomes, with objective outcome measures (e.g., cell counts) being included in a somewhat less number of reports. Although clinical trials of behavioral interventions include participant-reported outcomes more often than do trials of other interventions [31], the proportion of trials that rely solely on participant-reported outcomes seem to be less than what one would expect and is encouraging.

### **Interventions**

A prototypical CBT includes education, strategies to reinterpret and evaluate cognitions, and systematic exposure to avoided or feared stimuli [32]. Variations of and derivations from the standard setup are common, however, and it can thus be challenging to categorize interventions. Indeed, there is no standard for how to group psychological interventions. The results herein should therefore be seen as an approximate comparison rather than an exact estimate of the presence of different theoretical paradigms in efficacy trials. Nevertheless, the dominance of the CBT paradigm is apparent.

The dominance of CBT might be seen as positive because the principles of social learning theory [33], cognitive theory [34], and behaviorism [35, 36] have been extensively studied in basic as well as clinical research. Yet the one-sidedness might also be a reason for concern. CBT has been shown to be effective for a range of medical conditions; yet, we know that a sizeable proportion of patients do not benefit to any large degree from CBT [1, 2]. Because of this, and with respect to patient autonomy, one may argue that other interventions need to be available.

Of note, the aim of most trials is to assess the efficacy of a treatment package that includes several components. Tests of purported theories of change in order to validate in what ways cognition, emotion, and behavior can be effectively changed is an undeveloped area of research [37]. Little is known about whether the components of these interventions actually produce change according to the underlying principles and it may thus be premature to establish intervention packages before mechanisms of change have been established. Finally, the difference in treatment duration deserves mention, with much shorter durations for interventions with participants who have a physical disorder as compared with mental disorders. We believe that to a large extent the brief durations of interventions reflect that only momentary or short-term effects were expected in the former condition (e.g., reduce distress during surgery) whereas long-lasting effects are sought after in the latter.

### **Reporting quality**

Existing guidelines for reporting RCTs in the field of psychology have yet to be fully implemented by investigators despite the fact that the first guidelines appeared more than 15 years ago [17, 38, 39]. Similarly to the findings from a recent review of reporting quality in this research field [17], a number of reports failed to provide basic,

yet important, information. More than half of the reports did not state their primary outcome measure, or indicated more than two primary outcomes. Also, we were not able to determine the proportion of dropouts for several trials due to lack of information about the allocation of subjects or about the frequency of dropouts. Other examples of basic information that was sometimes missing include time to follow-up and the lengths of the treatment sessions. We also note that several reports lacked a description of the randomization procedure. .

Nearly one quarter of the reports did not include a statement on financial disclosure and nearly half did not include any statement on potential conflicts of interest. We note that none of the trials that were funded by for-profit organizations reported any conflict of interest. Several clinical psychology journals do not include declarations of potential conflicts of interest and financial disclosure in their published papers although such information may be solicited from the authors. However, the increasing acceptance for, and subsequent rising demand of psychological interventions, as well as the increasing use of technology to assist psychological interventions, may increase the financial stakes for researchers in the field and point to an increasing importance of transparency with regard to conflicts of interest.

### **Limitations**

The findings should be viewed in the light of the limitations of this review. First, it is important to note that the results pertain to work published in 2010 only and thus describe the accumulation of evidence during one year. Although it may be reasonable to expect that the findings reflect the RCTs conducted in the last few years, they cannot be extrapolated to the total evidence base for psychological interventions. Second, schools of psychotherapy have adopted to a varying degree the biomedical

research paradigm. It is possible that our search criteria excluded trials from schools that do not use medical diagnoses as the reason for inclusion or rely on other research designs than RCTs. Further, although PubMed and PsycINFO are the leading databases in the field of psychological and psychosomatic research we assume that our search failed to include all published trials despite tailoring the searches to each database. The indexing provided by the databases is imperfect [40]; however, the indexing allowed for the use of generic search terms for psychological interventions while keeping the number of results low enough to be feasible to scan. In addition, only reports written in English were included.

We safeguarded the selection of trials and the data extraction process by having two reviewers examine each abstract and double-checking the accuracy of the extracted data. However, the difficulties in defining and classifying psychological interventions suggest that some amount of misclassification is plausible, as the definition of a psychological intervention vary across and within disciplines [41]. If a different definition would have been applied, the results might have been somewhat different. Within the medical nomenclature the term behavioral intervention or psychosocial intervention is often used. This term was not used here because these definitions include not only interventions within a psychological framework but also, for example, occupational therapy and physiotherapy. Also, although the terms intervention, treatment, and therapy have been used interchangeably [42] we recognize treatment and psychotherapy as a class of interventions in the context of a professional relationship. The present findings thus include but are not limited to trials of psychotherapy.

These caveats notwithstanding, we find it unlikely that the reports we failed to include would have made substantial changes to the overall pattern of results. Nevertheless, the findings herein represent trials that have passed the peer-review process and may thus reflect higher quality trials [43]. Although a full qualitative assessment of the trial quality was beyond the scope of this review the overall quality can be gleaned from several of the variables included herein.

## **Conclusions**

The present study provides a first attempt to review the characteristics of recently published RCTs of psychological interventions in healthcare. Psychological interventions are being applied to a wide range of patient groups. Nonetheless, the evidence base, as reflected in RCTs, seems to be accumulating at a slow rate regarding psychological interventions in several parts of the world and for certain age groups. Regular monitoring of the development of this research field, with gradually refined methodology and increased scope, have the potential to inform both funding agencies and researchers. Future reviews could, for instance, include assessments of risk of bias and descriptions of the extent to which the reports conform to the current guidelines for reporting of RCTs.

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technology from medical, economic, ethical, and social standpoints. The views herein represent those of the authors and not of the funding agency or the authors' affiliated institutions.

### **Competing Interests**

The authors have no competing interests to report.

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## Tables

Table 1. Primary diagnosis category for participants in randomized controlled trials of psychological interventions in 2010

ICD-10 chapter and category	N	%	ICD-10 chapter and category <i>cont'd</i>	N	%
<i>Mental and behavioural disorders</i>	155	52.5	<i>Diseases of the respiratory system</i>	13	4.4
Anxiety disorders <sup>a</sup>	36	12.2	Asthma	9	3.1
Unipolar affective disorders	21	7.1	Chronic obstructive pulmonary disease	4	1.4
Schizophrenia, schizotypal and delusional disorders	16	5.4	<i>Neoplasms</i>	12	4.1
Mental and behavioural disorders due to psychoactive substance use	15	5.1	<i>Invasive surgical interventions</i>	11	3.7
Dementias	11	3.7	<i>Diseases of the circulatory system</i>	11	3.7
Reaction to severe stress, adjustment disorders	10	3.4	Cardiovascular diseases	11	3.7
Eating disorders	9	3.1	<i>Injuries</i>	9	3.1
Pervasive developmental disorders	8	2.7	Injuries to the head	4	1.4
Specific personality disorders	5	1.7	<i>Certain infectious and parasitic diseases</i>	8	2.7
Bipolar affective disorder	4	1.4	Human immunodeficiency virus disease	7	2.4
Hyperkinetic disorders	4	1.4	<i>Diseases of the digestive system</i>	7	2.4
Habit and impulse disorders	3	1.0	Irritable bowel syndrome	5	1.7
Nonorganic sleep disorders	3	1.0	<i>Other symptoms, signs and abnormal clinical and laboratory findings</i>	6	2.0
<i>Endocrine, nutritional and metabolic diseases</i>	20	6.8	Pain, mixed	5	1.7
Obesity	10	3.4	<i>Pregnancy, childbirth and the puerperium</i>	4	1.4
Diabetes mellitus	9	3.0	<i>Diseases of the genitourinary system</i>	4	1.4
<i>Diseases of the musculoskeletal system and connective tissue</i>	16	5.4	<i>Diseases of the ear and mastoid process</i>	2	0.7
Dorsalgia	8	2.7	<i>Certain conditions originating in the perinatal period</i>	2	0.7
Fibromyalgia	4	1.4	<i>Diseases of the blood and blood-forming organs</i>	1	0.3
<i>Diseases of the nervous system</i>	13	4.4	<i>Congenital malformations, deformations and chromosomal abnormalities</i>	1	0.3
Episodic and paroxysmal disorders	4	1.4			
Fatigue, mixed	4	1.4			

For the ICD-10 chapters (in italics) the percentages add to 100%. Specific diagnostic categories that account for < 1% of the total number of categories are omitted.

<sup>a</sup>Includes obsessive-compulsive disorder/hoarding (10), panic disorder (8), mixed anxiety disorders (7), social (4) and specific phobias (3), and generalized anxiety disorder (3).

Table 2. Characteristics of randomized controlled trials of psychological interventions published in 2010

Intervention	No of trials				Developed regions <sup>a</sup>		For children/ adolescents		Treatment group size <sup>b</sup>		Treatment duration, hrs <sup>c</sup>		Reliance only on PROs	
	N		%		%		%		Mdn		Mdn		%	
	Total	Psy	Gen	N	N	Psy	Gen	Psy	Gen	Psy	Gen	Psy	Gen	Psy
<i>Total</i>	295	100	155	140	90	84	17	17	38	48	15.0	6.0	23	56
Cognitive behavior therapy	152	52	80	72	98	93	19	21	33	52	14.7	9.0	31	65
Motivational interviewing	22	7	10	12	70	83	10	0	56	113	10.5	3.0	10	42
Cognitive training	16	5	15	1	80	100	13	0	35	7	14.6	24.0	13	0
Expressive therapies	11	4	3	8	33	38	0	25	41	38	6.0	1.4	33	50
Relaxation	10	3	0	10		80		10		29		4.3		50
Biofeedback	10	3	1	9	100	44	0	11	8	21		6.0	100	44
Psychosocial skills training	9	3	6	3	83	100	67	33	60	99	30.0	6.0	0	33
Mindfulness	8	3	5	3	100	100	0	0	30	55	11.3	0.3	0	100
Psychoeducation	6	2	4	2	100	100	0	50	182	112	15.0	0.3	0	50
Problem solving training	6	2	3	3	67	100	0	33	60	37	26.7	6.0	33	33
Structured counseling	5	2	2	3	50	100	0	0	166	67	2.6	0.3	0	100
Psychodynamic therapy	5	2	5	0	100		0		52		30.0		20	
Family-focused therapy	5	2	4	1	75	0	25	0	25	33	24.0	5.5	0	0
Coping skills training	5	2	2	3	100	67	0	33	42	34	14.3		0	33
Interpersonal	4	1	4	0	100		0		45		17.4		0	
Environmental	3	1	0	3		67		33		44		0.5		33
Hypnosis	2	1	0	2		100		0		46		0.7		50
Dialectical behavior therapy	2	1	2	0	100		0		44		40.0		0	
Others (each n=1)	14	5	9	5	89	80	33	0	37	43	2.2	7.0	33	40

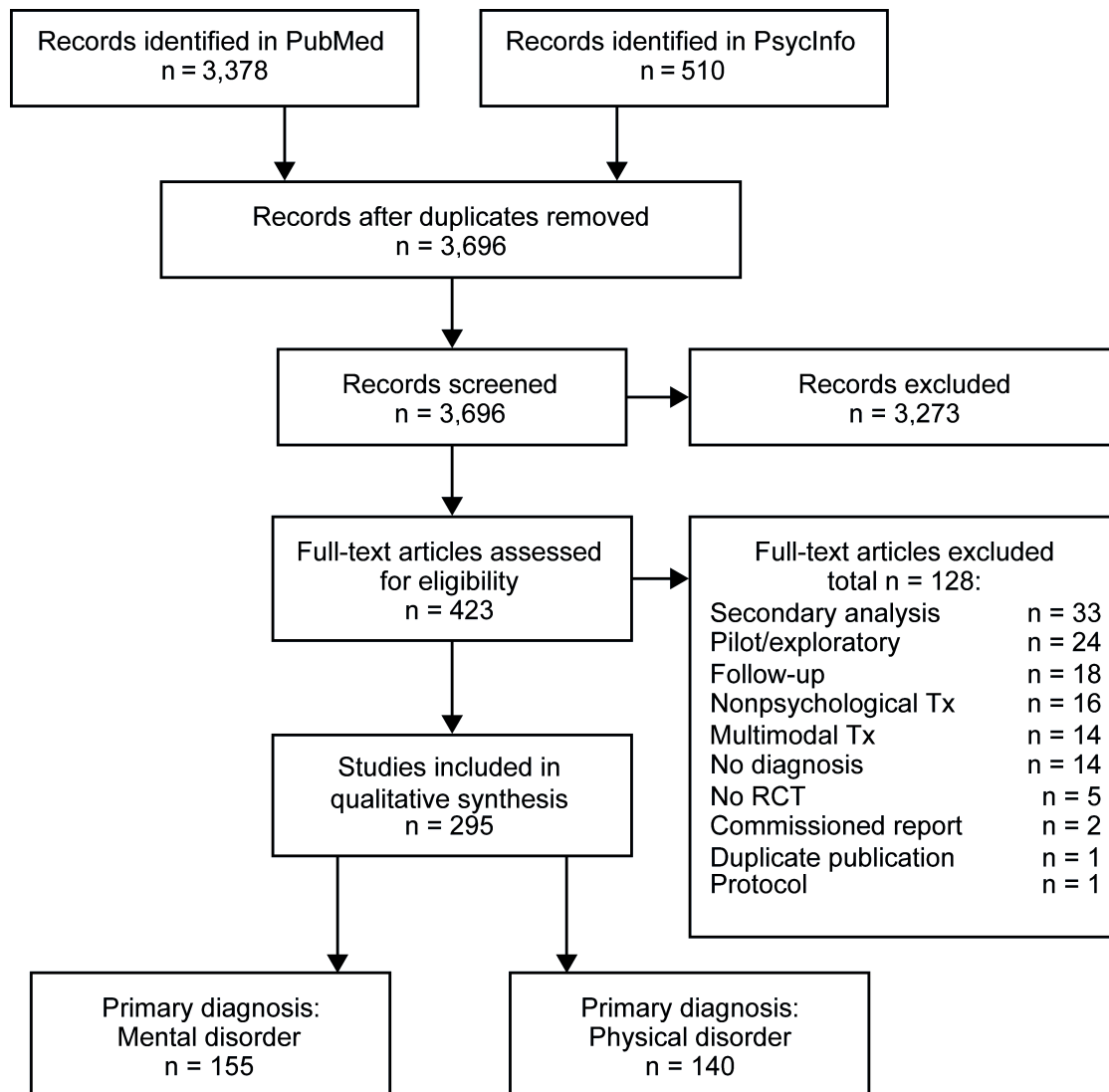
The data include only the primary psychological intervention in each trial. Interventions that could be defined as cognitive behavior therapy (e.g., dialectical behavior therapy) are tabulated separately for transparency. Psy = Trials for people with a primary mental or behavioral disorder. Gen = Trials for people with a primary physical disorder (i.e., all but those included in Psy according to ICD-10). PROs = patient-reported outcomes.

<sup>a</sup>North America, Europe, Oceania <sup>b</sup>At baseline. Missing data for Psy (n = 2) and Gen (n = 9). <sup>c</sup>Missing data for Psy (n = 54) and Gen (n = 35).

## Figure Captions

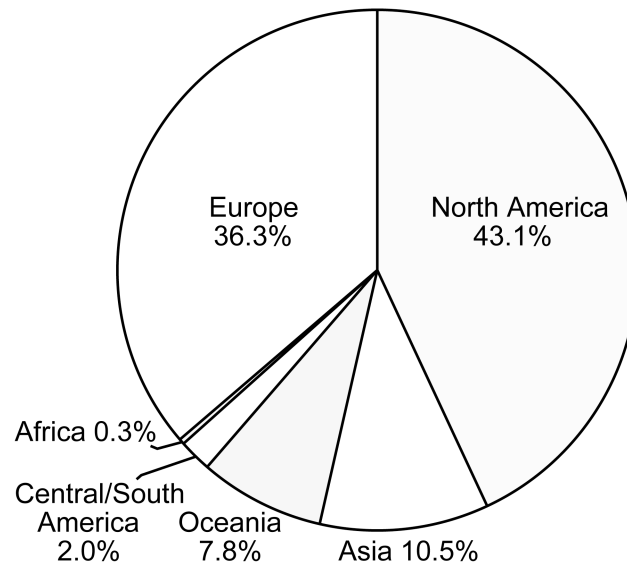
Figure 1

PRISMA flowchart.



**Figure 2**

Geography of randomized controlled trials for psychological interventions in healthcare published in 2010.





**Figure 3**

Categories of outcomes in randomized controlled trials of psychological interventions published in 2010. *Note:* The labels serve as representative categories and include other similar outcomes.

