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Abstract
The widespread availability of the Internet offers opportunities for improving access to therapy for people with mental health problems. There is a seemingly infinite supply of Internet-based interventions available on the World Wide Web. The aim of the present study is to systematically assess the methodological quality of randomized controlled trials (RCTs) concerning e-therapy for mental health problems. Two reviewers independently assessed the methodological quality of the RCTs, based on a list of criteria for the methodological quality assessment as recommended by the Cochrane Back Review Group. The search yielded 14 papers that reported RCTs concerning e-therapy for mental-health problems. The methodological quality of studies included in this review was generally low. It is concluded that e-therapy may turn out to be an appropriate therapeutic entity, but the evidence needs to be more convincing. Recommendations are made concerning the method of reporting RCTs and the need to add some content items to an e-therapy study.

Key words: mental health, e-therapy, randomized controlled trials, Cochrane Back Review Group

Introduction
Today, the Internet offers a wide variety of online treatment programs for mental health problems. However, the question is: What is known about the effectiveness of these e-therapy programs? To answer this question, this review will first provide background information and then systematically assess the quality of e-therapy studies.
In our opinion, the best definition of e-therapy is given by Andersson et al.\textsuperscript{17} In e-therapy, there is active involvement of a therapist, and as a consequence the formation of an ongoing, helping relationship between therapists and patients can take place purely via Internet communication. This occurs although patient and therapist are in separate or remote locations. Communication is usually asynchronous (i.e., via e-mail the interaction occurs with a time gap between the patient’s and the therapist’s responses).\textsuperscript{11,12,18}

Many studies have been conducted in the field of e-therapy, with promising results.\textsuperscript{17,19–28} (Lange A et al., unpublished data) However, the quality of e-therapy studies has not been evaluated in a rigorous way. Reviews in the related field of computerized (fully automated or tailored) or Internet health interventions mention the tendency for poor methodological quality of studies. A review from Copeland and Martin\textsuperscript{8} on different types of programmed Internet interventions (with little or no direct therapist involvement) showed that many studies have high dropout rates, involve small sample sizes, or lack control groups. Bessell et al.\textsuperscript{29} concluded their review on consumer use of online health information as follows: “At present, there is almost no evidence regarding the effect of consumer Internet use on health outcomes. Well-designed controlled studies, instead of anecdotes and opinions, about the risks and benefits of using the Internet are urgently needed (p. 34).” The systematic review from Kaltenthaler et. al.\textsuperscript{10} on the efficacy of computerized cognitive behavior therapy (CCBT) for anxiety and depression showed that the quality of studies ranged from poor to moderate. Andersson et al.\textsuperscript{17} conducted a review on the use of the Internet in using different types of treatment for anxiety disorders (different types of treatment) and concluded that trials have been small and that studies in psychiatric settings mostly recruited patients via advertisement. Spek et al.\textsuperscript{30} conducted a meta-analysis of 12 randomized controlled trials of Internet-based CBT programs for symptoms of depression and anxiety. Overall, the authors concluded that their analysis indicated that Internet-based interventions are effective, especially those with therapist involvement. However, Spek et al.\textsuperscript{30} also emphasized the limitations: for example, the number of studies available, the small number of subjects in some studies, and the differing inclusion criteria. None of the reviews mentioned systematically assessed the methodological quality of studies based on a list of sound criteria. As a consequence, the major aims of the present study are to systematically assess the methodological quality of studies, to identify the weaknesses, and to address the difficulties. The quality of randomized controlled trials of stand-alone Internet interventions, with therapist involvement, for mental health problems will be assessed. Not assessed are Internet interventions without therapist involvement\textsuperscript{31–43} or Internet interventions with face-to-face or telephone contact as part of the treatment.\textsuperscript{44–46}

**Methods**

Details of the protocol for the selection and evaluation of the published studies are given below.

**TYPES OF STUDIES**

This study compared randomized controlled trials (RCTs) of e-therapy versus control interventions.

**TYPES OF INTERVENTIONS**

The Internet interventions comprised therapist involvement for problem drinking, drug abuse, and other mental health problems.

**EXCLUSION CRITERIA**

- No therapist contact at all: studies with Web site access only or fully automated programs.
- Face-to-face therapy or telephone contact as an additional component of the treatment program.
- The Internet therapy program is not stand-alone.
- Age <18
- Exclusively group interventions

**INCLUSION CRITERIA**

- Primarily Internet-based interventions
- Therapist involvement
- Internet therapy is the exclusive treatment program (with the exception that an initial face-to-face meeting is permitted in order to explain the treatment in the beginning and/or for assessment purposes during treatment. Telephone contact is also permitted for assessment purposes).
- Age of target group at least 18.

**SEARCH STRATEGY**

Studies were identified using the computer-aided engines MEDLINE, EMBASE, and PsychINFO. The Cochrane Library, 2006, issue 2 was screened. Reference lists of relevant studies were checked for potential sources. The search was conducted between October 2006 and February 2007. The search terms were the following: randomized controlled trial, Internet, e-health, online, Web-based, e-therapy, treatment, counseling, cognitive behavioral therapy, alcohol, problem drinking, substance abuse, dependence, and addiction.

**QUALITY REVIEW**

The list of criteria for the methodological quality assessment recommended by the Cochrane Back Review Group\textsuperscript{47} was used (Table 1). An item was scored “positive (+)” if the criterion was fulfilled, “nega-
tive (-)" if not fulfilled, or registered as "unclear (?)." A total "quality score" (QS) was computed by counting the number of positive scores. Two reviewers (first and second authors) independently assessed the methodological quality of the RCTs. If the two reviewers did not agree, the topic was discussed and a third reviewer (third author) was consulted. Due to the diversity of interventions, definitions of e-therapy, study populations, and outcome measures, no attempt was made to perform a meta-analysis of the results of QS.

Results

Fourteen papers were identified that reported RCTs concerning e-therapy for mental-health problems (Table 2). These studies all met the inclusion criteria of therapist involvement and no face-to-face or telephone contact as part of the treatment program, except for the permitted telephone or face-to-face contact for assessment purposes or for explanation of treatment (participation). Most of the studies included describe e-mail or Internet-driven, asynchronous therapy (i.e., with a time lag in communication between therapist and patient).

METHODOLOGICAL QUALITY

The results of the methodological quality assessment are presented in Table 1.

Half of the studies gave a detailed description of randomization procedure. The other half just mentioned that participants had been randomly assigned, without any explanation concerning the method of randomization.

Treatment allocation was scored positive (+) in four studies. In these studies the person who performed treatment allocation was

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Table 1. Methodological Quality of Randomized Controlled Trials

<table>
<thead>
<tr>
<th>FIRST AUTHOR</th>
<th>PUBLICATION YEAR</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carlbring</td>
<td>2003</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>?</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>7</td>
</tr>
<tr>
<td>Carlbring</td>
<td>2005</td>
<td>+</td>
<td>?</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>?</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>7</td>
</tr>
<tr>
<td>Klein</td>
<td>2006</td>
<td>+</td>
<td>+</td>
<td>?</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>?</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>6</td>
</tr>
<tr>
<td>Lange</td>
<td>2003</td>
<td>?</td>
<td>?</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>4</td>
</tr>
<tr>
<td>Richards</td>
<td>2006</td>
<td>?</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>?</td>
<td>?</td>
<td>+</td>
<td>+</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Ström</td>
<td>2004</td>
<td>?</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>Wagner</td>
<td>2006</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>?</td>
<td>+</td>
<td>?</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>7</td>
</tr>
</tbody>
</table>

1 = Randomization, 2 = treatment allocation, 3 = similarity of baseline characteristics, 4 = blinding of patients, 5 = blinding of therapist, 6 = blinding of observer, 7 = co-intervention equal, 8 = compliance, 9 = dropout rate, 10 = timing of outcome assessment, 11 = intention-to-treat analysis.

a This item is scored negative if only self-report outcome measures were used.

b This item is scored positive when online self-report questionnaires were used.

This item is scored positive if control group becomes treatment group immediately after post measure.

e Treatment credibility was evaluated in this study.

f Compliance is mentioned sometimes, but no single study described a cutoff point about satisfied compliance.

g Participants were not asked about use of other treatment programs.

h Detailed description of the time spent on the assignments, log-in frequencies, or number of sessions attended, but no cutoff point mentioned.
unaware of the group to which the patient was allocated, or alloca-
tion was done by computer with notification of the randomization
being done by an independent third party. The remaining studies
mostly did not mention the methods of treatment allocation.

In 11 studies, groups were similar at baseline with regard to the
most important prognostic factors such as duration and severity of
complaints, age, and demography.

Due to the nature of the interventions, patients mostly cannot
be blind with regard to their treatment allocation. Just one study
included an evaluation of treatment credibility.20

Blinding of care providers to treatment is not possible in the inter-
ventions studied, because the type of communication between patient
and care provider is part of the therapeutic program and what distin-
guishes the experimental condition from control condition.

Blinding of outcome assessor is possible and was done in nine of
the studies that were scored positively, in the main, because of the
use of online self-report questionnaires.

In 10 studies, co-interventions were mentioned as avoided in the
design, or the numbers of co-interventions were equally divided
among the study groups (+). In most of the studies participants were

| Table 2. Study Characteristics: Randomized Controlled Trials |
|-----------------|-----------------|-----------------|-----------------|
| STUDY           | COUNTRY OF ORIGIN | DESIGN | N | SUBJECTS | INTERVENTION | CONTROL | FACE-TO-FACE CONTACT? CONTACT WITH THERAPIST? |
| Andersson et al. (2005) | Sweden          | RCT | 117 | Individuals with depression | Internet-based CBT with minimal therapist contact + participation in online discussion group (n=57) | Online discussion group only (n=60) | No |
| Carlbright et al. (2001) | Sweden          | RCT | 26 | Individuals suffering from panic disorder | Internet-delivered self-help program plus minimal therapist contact via e-mail (n=13) | Waiting-list control group (n=3) | No |
| Carlbright et al. (2003) | Sweden          | RCT | 22 | Individuals suffering from panic disorder | Internet-delivered CBT self-help program plus minimal therapist contact via e-mail (n=11) | Applied Relaxation (a CD with instructions) plus minimal therapist feedback (n=11) | No (participants were just selected in an in-person interview) |
| Carlbright et al. (2005) | Sweden          | RCT | 49 | Individuals with panic disorder | A 10-module self-help program, plus minimal therapist contact, on the Internet (n=25) | 10 face-to-face weekly sessions of CBT (TAU) (n=24) | No (1 month and 1 year after treatment in an in-person interview) |
| Devinini & Blanchard (2005) | USA           | RCT | 139 | Individuals with chronic tension and/or migraine headache | 1. Tension-type headache treatment 2. Migraine-only or mixed headache treatment Both are online self-help with minimal e-mail assistance | Delayed treatment (online symptom monitoring) | No |
| Klein et al. (2008) | Australia       | RCT | 55 | Individuals with panic disorder | 1. Internet-based CBT with e-mail contact (n=19) 2. Therapist-assisted CBT manual with telephone contact (n=18) | Internet-based information-only with telephone contact (n=18) | No (clinical interview by telephone; by 2 students) |
| Lange et al. (2003) | The Netherlands | RCT | 184 | Individuals with mild to relatively severe trauma symptoms | Internet-driven treatment of posttraumatic stress (n=122) | Waiting-list control group (n=62) | No |
| Lange et al. (2005) | The Netherlands | RCT | 57 | Individuals with depression | Internet-driven treatment for depression (n=40) | Internet psycho-education control group (n=17) | No |
asked about any co-interventions and treatment received elsewhere was an exclusion criterion, however, regulation of medication use differed greatly between studies. Although in the majority of studies the dosage of any medications used had to be consistent for 3 months before starting the Internet treatment on occasions, a period of 4 weeks was approved. Furthermore, if participants were on a co-prescribed drug, most studies asked them to agree on keeping the dosage constant throughout the study. Some studies, however, did not do this, or failed to give any information on co-prescriptions. Sometimes it also was not clear whether study participants were asked about their actual behavior concerning co-interventions: At post-treatment, for example, did participants really not change medication or visit any other therapist?

Compliance is scored positive if it was measured and was satisfactory in all study groups based on reported intensity, duration, and number and frequency of sessions. Besides Carlbring et al., there is no study that describes a cutoff point for “satisfactory” compliance. Although it was scored negative, Carlbring determined an intended time frame and described the percentage of participants who finished all modules within that time frame. Four other studies gave a detailed

<table>
<thead>
<tr>
<th>Study</th>
<th>Country of Origin</th>
<th>Design</th>
<th>N</th>
<th>Subjects</th>
<th>Intervention</th>
<th>Control</th>
<th>Face-to-Face Contact?</th>
<th>Contact with Therapist?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richards et al. (2006)</td>
<td>Australia</td>
<td>RCT</td>
<td>32</td>
<td>Individuals with panic disorder</td>
<td>1. Internet-based CBT (n=12)</td>
<td>Internet-based information-only (n=9)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>2. Internet-based CBT plus stress management (n=11)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ström et al. (2004)</td>
<td>Sweden</td>
<td>RCT</td>
<td>108</td>
<td>People with insomnia</td>
<td>Cognitive behavioral self-help treatment (n=54)</td>
<td>Waiting list control group (n=55)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Tate et al. (2003)</td>
<td>USA</td>
<td>RCT</td>
<td>92</td>
<td>Overweight or obese adults, and 1 or more other risk factors for type 2 diabetes</td>
<td>Internet weight loss program plus behavioral e-counseling (n=46)</td>
<td>Basic Internet weight loss program (n=46)</td>
<td>No</td>
<td>Yes</td>
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</tr>
<tr>
<td>Tate et al. (2008)</td>
<td>USA</td>
<td>RCT</td>
<td>192</td>
<td>Overweight or obese adults</td>
<td>1. HC = human e-counseling group (n=61)</td>
<td>3. NC = No counseling (n=67)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>2. AF = computer automated feedback group (n=64)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wagner et al. (2006)</td>
<td>Germany, Switzerland</td>
<td>RCT</td>
<td>55</td>
<td>Individuals diagnosed with complicated grief</td>
<td>Internet-based treatment program (n=29)</td>
<td>Waiting group (n=26)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Zabinski et al. (2004)</td>
<td>USA</td>
<td>RCT</td>
<td>60</td>
<td>College-age women at risk for developing an eating disorder</td>
<td>Chat-room group intervention (n=30)</td>
<td>Wait-list control group (n=30)</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

TAU, treatment as usual; CBT, cognitive behavior therapy; RCT, randomized controlled trial.
description of the time spent on the assignments, log-in frequencies, or the number of sessions attended, but gave no clear criterion to assess compliance (scored as ?).

Dropout rate is acceptable if the withdrawal/dropout rate is less than 20% for short-term follow-up and 30% for long-term follow-up. However, in six studies the dropout rates were higher.

In 11 studies, timing of outcome assessment is identical for all intervention groups (+). This item is also scored positive if patients in the control group stepped over to the treatment group immediately after post measure.

Ten studies included an intention-to-treat analysis (+).

In conclusion, it transpires that the methodological quality of studies included in this review was generally low (Table 1). Only 5 of the 14 studies had six (>50%) or more positive quality scores on the validity criteria, which is the predetermined threshold for high quality.

Discussion

In this review, we identified 14 randomized controlled trials of e-therapy. Of these, only five studies show high methodological quality; all other studies showed some degree of methodological limitations. Compared to other systematic reviews, the quality of studies about e-therapy is low. For example, in a systematic review about the community reinforcement approach, Roozen, et al. found 10 of 11 studies of high quality using the same criteria list.

With respect to the promising results of individual studies of e-therapy, we need to take into account their methodological quality. Given the increasing number of e-therapy interventions for mental health problems, substance abuse, and problem drinking, it is unfortunate that high-quality research in the field of e-therapy can be difficult. Surfing the World Wide Web, one finds an overwhelming supply of Internet interventions for health problems. However, just a small number of research groups are studying e-therapy interventions, often using small sample sizes. Thus, the authors believe there is a need for more well-conducted studies in the field of e-therapy, using larger numbers of participants and conducted by a variety of study groups. Although e-therapy interventions face a promising future, we have to be careful with interpretation of the current results. E-therapy may turn out to be an appropriate kind of treatment that can broaden the possibilities of healthcare, but the evidence needs to be more convincing. As in regular face-to-face therapy, the quality of the e-therapy can only be as good as the therapist is doing it. An important factor in the efficacy of a given treatment is the skill and good sense of the therapist. Therefore, we emphasize the importance of working with professional therapists in online treatment programs.

Recommendations can be made about the method of reporting a study and some content items need attention. For example, research reports have to be complete in describing study details: It is striking that the description of randomization procedures and treatment allocation is frequently incomplete. The recommendation sounds simple: Take care to report the complete study procedure and conduct. However, evidence indicates that in many research areas the quality of reporting RCTs is less than optimal. In response to the need for improvement in the conduct and reporting of RCTs, the CONSORT group developed a revised CONSORT statement with the intention of improving the procedures for the reporting of RCTs, enabling readers to understand a trial’s design, conduct, analysis, and interpretation, and to assess the validity of its results. It emphasizes that this can only be achieved through complete transparency from the authors.

Besides the reporting requirements, actual performance of RCTs in general practice also poses methodological and practical difficulties. Some clinicians might consider RCTs unethical; for instance, they may feel uncomfortable about offering an intervention to some patients while withholding it from others. Blinding of subjects and therapists to the allocated treatment can be complex, especially when the RCT protocol for evaluating the experimental therapy does not always mirror the routine care.

We would like to focus on the three most important weaknesses observed in the quality of the e-therapy studies evaluated.

First, we have seen that treatment compliance was never scored positively. With the online treatment interventions it was hard to decide whether compliance was satisfactory or not. We therefore recommend that before the study starts, the cutoff points for compliance should be defined in measurable terms in the protocol. Compliance can be expressed in quantity of time that patients have to spend on the e-therapy program or the minimum number of sessions that have to be finished. Such a cutoff point has to be formulated in advance, the main criteria being that it can be plausibly demonstrated that the patient could profit from the online treatment in the time frame specified. It would also be sensible to program the intervention in such a way that it is impossible to start a next treatment session if the preceding session is not fully completed.

A second aspect of studying e-therapy that needs attention is treatment credibility. Since it is nearly impossible to blind patients to treatment allocation, treatment credibility should always be evaluated as the next best option. This recommendation echoes that of the methodological quality assessment of the Cochrane Back Review Group, which also states that the credibility of treatment should
be evaluated when it is difficult to blind the patients to therapy. Moreover, treatment conditions should also be judged credible and acceptable by patients; although this necessitates extra investment, this client feedback will provide extra information and as a consequence, increases the quality of the study.

Thirdly, it appears that information about co-interventions is not always complete. Consequently, this can lead to clinically significant differences between treatment and control groups, especially in studies with small sample sizes. It is important to get information about co-medication use and at the end of the study, to check whether the patient participated in other treatment programs. Even if patients have indicated, in advance, a willingness to keep medication levels stable and not contact any other therapist, their situation can change during the study period. Patients should always be asked, post-treatment, whether their medication was taken properly during the study period and whether they have been in treatment elsewhere.

In the case of current medications, we strongly recommend keeping medication dosages constant for a period of at least 3 months because it is doubtful whether medication will be stabilized after 4 weeks.

The results of this review point to a serious need to improve the quality of future RCTs of e-therapy. Improvement in the evidence that underpins e-therapy interventions requires sufficiently more large, high-quality RCTs that use the most appropriate methodology for the specific intervention and outcome measures. There is also a need for better and more accurate reporting of trials. The revised CONSORT statement aims to increase the quality of reporting RCTs, thus facilitating improvement in the interpretation and the use of the results of such trials.

Drawing an analogy with the introduction of new medications, where strict procedures have to be followed before a new medicine is allowed on the market, we recommend introducing a quality standard for Internet interventions. Above all, an intervention should only be given a “seal of approval” if adequately documented evidence is supplied.

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