Randomized Controlled Trials

Review of the Evidence of Effectiveness from Reality Orientation for Dementia: A Systematic

The effectiveness of classroom reality orientation (RO) in dementia was evaluated by conducting a systematic literature review. This yielded 43 studies, of which 6 were randomized controlled trials meeting the inclusion criteria (containing 125 subjects.) Results were subjected to meta-analysis. Effects on cognition and behavior were significant in favor of treatment (cognition standardized mean difference [SMD] = −0.59; 95% confidence interval [CI] = −0.95–−0.22; behavior SMD = −0.64, 95% CI = −1.20–−0.08). The evidence indicates that RO has benefits on both cognition and behavior for dementia sufferers. However, a continued program may be needed to sustain potential benefits. Future research should evaluate RO in well-designed multicenter trials.

Key Words: Memory impairment, Alzheimers, Cognition, Behavior, Therapy

Reality Orientation for Dementia: A Systematic Review of the Evidence of Effectiveness from Randomized Controlled Trials

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Reality orientation (RO) was first described (Taulbee & Folsom, 1966) as a technique to improve the quality of life of confused elderly people, although its origins lie in an attempt to rehabilitate severely disturbed war veterans. RO involves the presentation of orientation and memory information, relating, for example, to time, place, and person. This was thought to provide the person with a greater understanding of his or her surroundings, possibly resulting in an improved sense of control and self-esteem. Before this there had been little research on psychological therapies for dementia (Cosin, Mort, Post, Westropp, & Williams, 1958). The early RO work marked the advent of the use of psychological therapies in the care of dementia, which had previously been seen primarily as a medical problem with medical interventions.

RO can be of a continuous 24-hr type, whereby staff involve the patients in reality-based communication in every contact throughout the day, or “classroom RO,” where groups of people meet on a regular basis to engage in orientation-related activities. A prominent focus of classroom RO is often the “RO board,” which typically displays information such as the day, date, weather, name of next meal, and other details (Holden & Woods, 1995). There have been a number of studies on classroom RO since Taulbee and Folsom (1966), many reporting positive findings. For example, improvements were reported in “orientation to reality and in motivation toward selfcare, responsibility and social involvement” (Salter & Salter, 1975, p. 406). Controlled studies have shown varied results. Some authors have found that classroom RO can lead to some improvements in cognitive function, with no effect on behavior (e.g., Hanley, McGuire and Boyd, 1981), whereas others have found positive effects on behavior, with no significant changes in cognition (Baines, Saxby, & Ehert, 1987). There has been criticism of RO in clinical practice, with concern that it has sometimes been applied in a mechanical fashion and has been insensitive to the needs of the individual (e.g., Powell-Proctor & Miller, 1982). Moreover, it has been argued that constant relearning of material can actually contribute to problems in mood and self-esteem (Butler & Lewis, 1977). In recent years, RO has lost some of its popularity, but nevertheless a number of its principles have been incorporated into everyday clinical practice (e.g., RO boards). In many settings, it has been overtaken by more popular developments such as validation therapy (Feil, 1971), which is not primarily memory oriented. There has also been increasing interest in the use of cognitive rehabilitation for people with dementia (e.g., Quayhagen & Quayhagen, 1989). Thus, a reconsideration of the efficacy of RO is timely.

RO studies have often been small in size and of variable quality, making the effectiveness of RO open to debate, due to the lack of a sound evidence base. There has also been a lack of clear guidance for clinicians and practitioners, and little consistent application of psychological therapies like RO in dementia services. The aim of this study was to conduct a sys-
tematic review of RO trials in dementia. It was carried out under the auspices of the Cochrane Collaboration Cognitive Impairment and Dementia group, based in Oxford, United Kingdom.

Methods

Search Method

We conducted a systematic search for randomized controlled trials (RCTs) evaluating the effectiveness of classroom RO with dementia sufferers. A combination of the terms reality orientation, dementia, alzheimer’s, controlled study and trial were used to search Medline Express 1966–1997 (1988), PsycLIT (1967–1997) Journal Articles 1974–1997, PsycLIT (1967) Chapters and Books 1/87–12/97, Embase (1980), the Cochrane Database of Systematic Reviews (1998), OMNI (Organising Medical Networked Information), BIDS (Science Citation Index and Social Science Citation Index, 1994), Dissertation Abstracts International: 1861–1997, and SIGLE (System for Information on Grey Literature). We searched internet sites for relevant information: Healthweb, including Medweb (Mental Health Infosource, American Psychiatric Association, Internet Mental Health, Mental Health Net), and the National Health Service Confederation. The following journals were handsearched: Aging and Mental Health, The Gerontologist (1961–1994), Journals of Gerontology (1960–1978), Current Opinion in Psychiatry (1988–1997), and Current Research in Britain, Social Sciences (1991–1995). In addition, we searched in the Alzheimer’s Disease Society library, and letters were published in PSIGE magazine (Psychologists Special Interest Group in the Elderly) and The Psychologist, the journal of the British Psychological Society, requesting information on any RCTs which might otherwise be missed, such as unpublished papers. Bibliographies of all relevant articles were scanned, and an optimally sensitive search strategy was additionally performed by a coreviewer. Experts in dementia care were consulted.

Inclusion Criteria

Studies.—All RCTs examining the effect of RO for dementia were initially included. Authors were contacted for missing data, such as details of randomization, means, and standard deviations.

Participants.—Participants were elderly people (mean age >55) diagnosed with dementia (cognitive impairment, Alzheimer’s disease, organic brain syndrome, etc.) according to the Diagnostic and Statistical Manual of Mental Disorders (4th ed., American Psychiatric Association, 1994), International Classification of Mental and Behavioral Disorders (10: World Health Organization, 1992), or comparable. For inclusion, it was necessary for more than 60% of the participants to have completed the study.

Interventions.—Participants attended regular therapy groups (at least 10) for a minimum period of 3 weeks. These groups from 30–60 min, involving (among other cognitive activities) the presentation, repetition, and use of orientation information (time, place, and person related). There was a minimum of 4 participants in each group.

Outcome measures.—Cognitive and/or behavioral outcome measures were necessary for entry into the review.

Data Extraction

Descriptive characteristics (such as quality of randomization and blinding) and study results were extracted by means of a standard data extraction form. Additionally, letters and E-mails were sent to all authors of controlled trials asking for essential information (statistics and/or details of randomization). Data were extracted from psychometric tests measuring changes in cognition and behavior. Where possible, the data were independently pooled across studies. In some cases, trials used more than one scale to measure similar outcomes (Baines et al., 1987). For the purpose of meta-analysis, it was only possible to use one scale from each study. Cognitive tests were chosen by using the following criteria (in decreasing order of importance): (a) well-recognized published cognitive tests; (b) orientation tests; (c) short-term memory tests; (d) information tests; (e) any test of cognition using some of b–d. Behavioral tests were selected using the following criteria (in decreasing order of importance): (a) well-recognized, published behavioral tests and (b) primarily tests of activities of daily living/adaptive social behavior. Discussion between the two reviewers and the other authors were used to resolve any queries.

Analyses

RevMan 3.0 (Update Software, 1996) was used. Analyses were adjusted to the random effects model, due to the heterogeneity of trials. Because trials used different tests to measure the same outcomes, standardized mean differences (SMDs) were used. These were calculated by dividing the difference between the treatment and control means by the pooled standard deviation within each study, thus enabling them to be compared with the other trials in a standardized way.

Results

Selection of Trials

Forty-three publications were identified through the literature search. A reviewer and coreviewer independently assessed eligibility. Twenty-two publications were immediately excluded: four were not trials, 5 examined nondementia populations, 4 were case studies, 2 were observational studies, and 7 were uncontrolled. The remaining 21 trials were all controlled, but of these 6 were clearly not randomized (e.g., participants were selected or chosen), and 2 looked at 24-hr RO only. This left 13 trials, and of these 6 had no mention of randomization; authors
were contacted and asked if (and how) participants had been randomly assigned to groups. One of these trials was randomized (Ferrario, Cappa, Molaschi, Rocco, & Fabris, 1991). The other 7 controlled trials all included the term(s) randomized, randomly assigned, or similar. We decided that this was acceptable for inclusion into the review. Therefore, eight RCTs were included in the analysis.

Quality of Included Studies

The quality of each study was assessed according to the four criteria outlined in the Cochrane Collaboration Handbook (Mulrow & Oxman, 1996): selection bias, performance bias, attrition bias, and detection bias. Details of randomization concealment (detection bias) can be seen in Table 1. In view of the lack of detailed information on methods of randomization, we did not assign a formal quality score to the studies.

Table 1. Bias in Reality Orientation (RO) Studies

<table>
<thead>
<tr>
<th>Name of study</th>
<th>Amount of intervention</th>
<th>Content of RO</th>
<th>Alternative activity</th>
<th>Randomization concealment</th>
<th>Attrition bias (dropouts)</th>
<th>Detection bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baines et al. (1987)</td>
<td>30 min 5 times a week 4 weeks</td>
<td>RO board, multisensory stimulation</td>
<td>Reminiscence therapy/no treatment</td>
<td>No details</td>
<td>0/15 dropouts</td>
<td>Assessment by independent psychologist and staff not involved in therapy</td>
</tr>
<tr>
<td>Baldelli et al. (1993)</td>
<td>60 min 3 times a week 3 months</td>
<td>No details</td>
<td>No treatment</td>
<td>No details</td>
<td>0/23 dropouts</td>
<td>Assessment by psychologist unaware of group membership No details of assessors</td>
</tr>
<tr>
<td>Breuil et al. (1994)</td>
<td>60 min 2 times a week 5 weeks</td>
<td>Drawing, associated words, object naming/ categorizing</td>
<td>No treatment</td>
<td>No details</td>
<td>5/61 dropouts (3 experimental, 2 control)</td>
<td>Assessment by psychologist unaware of group membership No details of assessors</td>
</tr>
<tr>
<td>Ferrario et al. (1991)</td>
<td>60 min 5 times a week 21 weeks</td>
<td>No details</td>
<td>No treatment</td>
<td>No details</td>
<td>2/21 dropouts (1 in each group, due to illness)</td>
<td>Assessment by independent person blind to group membership</td>
</tr>
<tr>
<td>Gerber et al. (1991)</td>
<td>60 min 4 times a week 10 weeks</td>
<td>RO board, exercises, food preparation, discussions</td>
<td>Social interaction/no treatment</td>
<td>Random number tables</td>
<td>5/24 dropouts (1 in each of 3 groups died, 2 discharged in RO group)</td>
<td>Assessment by independent person blind to group membership</td>
</tr>
<tr>
<td>Hanley et al. (1981)</td>
<td>30 min 4 times a week 12 weeks</td>
<td>RO board, clocks, calendars, maps, posters</td>
<td>No treatment</td>
<td>No details</td>
<td>1/58 dropout (unclear which group, due to transfer)</td>
<td>Ratings for some tests were blind, others were not</td>
</tr>
<tr>
<td>Wallis et al. (1983)</td>
<td>30 min 5 times a week 3 months</td>
<td>RO board, general orientation</td>
<td>“Diversional occupational therapy” (group and individual activities)</td>
<td>Drawing from a hat, consecutive allocation</td>
<td>22/60 dropouts. No details of groups (death, 6; illness, 8; other, 8)</td>
<td>Assessments by senior nurse &amp; occupational therapists, unaware of group membership</td>
</tr>
<tr>
<td>Woods (1979)</td>
<td>30 min 5 times a week 20 weeks</td>
<td>RO board, orientation discussions/ demonstrations</td>
<td>“Social therapy” (various group activities)</td>
<td>Drawing from a hat</td>
<td>4/18 dropouts (1 in each group died,1 control refused assessment)</td>
<td>Mixture: some assessments blind, some not</td>
</tr>
</tbody>
</table>

Performance bias was difficult to evaluate. With psychological interventions, unlike drug trials, it is impossible to blind patients and staff totally to treatment. Patients may be aware that they are being treated preferentially, staff involved may have different expectations of treatment groups, and independent assessors may be given clues about group assignment from patients during the assessments. There may also be contamination between groups, in terms of groups not being held in separate rooms and staff bringing ideas from one group to another. The latter effect would be reduced with clear therapeutic protocols, the existence of which was not mentioned in any of the studies; although B. Woods (personal communication, 1998) stated that “checks were made to ensure compliance with the therapeutic protocol.” Most of the studies did not provide enough information to draw conclusions about contamination and blinding. The authors of two trials (Baines et al., 1987; Wallis, Baldwin, & Higgenbotham, 1983) both
stated that the staff were unaware of the allocation of patients to groups, as they were removed from the setting for treatment. There was no evidence of blinding in the other studies. How far patients were blind to treatment remains a controversial issue. This would depend on how much information was given to them and their level of comprehension. Most authors said that the RO groups were held in separate areas, reducing the chance of contamination (Baines et al., 1987; Ferrario et al., 1991; Hanley et al., 1981; Wallis et al., 1983; Woods, 1979). The groups may have been held in separate rooms in the other studies, although this information was not provided. The nature of the biases and differences between studies (such as length and content of RO sessions) were considered as variables affecting outcomes and are discussed subsequently.

**Meta-Analysis**

Out of the eight studies, only six could be entered into "Metaview" (the Cochrane term for meta-analysis). The other two studies (Baldelli et al., 1993; Hanley et al., 1981) did not include the means and standard deviations on tests before and after the intervention, which were needed for the analysis. The authors were contacted with no response. From these six RCTs there was a total of 125 participants (67 in experimental groups, 58 in control groups).

The overall results in the cognition section were significantly in favor of treatment (Figure 1). The standardized mean difference was $-0.59$, with a 95% confidence interval (CI) of $-0.95$ to $-0.22$. Comparing the standardized mean difference with a normal distribution indicated that the average score for patients in the treatment groups was better than 72% of the control patients' scores. All studies contained cognitive measures, with a total of 125 participants.

The results were highly influenced by the largest study (Breuil et al., 1994). These results (on the Mini Mental State Exam) were significant in favor of treatment (SMD $= -0.71$, 95% CI $= -1.26$ to $-0.17$). For the other studies, statistics were as follows: Using the Weschler Memory Scale, SMD $= -0.66$, 95% CI $= -2.04$ to $0.71$ (Woods, 1979); using the Information/Orientation subscale of the Clifton Assessment Procedures for the Elderly (CAPE; Pattie & Gillean, 1979), SMD $= -0.81$, 95% CI $= -1.43$ to $-1.06$ (Baines et al., 1987); using the Information/Orientation subscale of the Clifton Assessment Schedule (CAS; Pattie & Gillean, 1976), SMD $= -0.96$, 95% CI $= -1.99$ to $-0.06$ (Ferrario et al., 1991); using the Orientation subscale of the Kingston Dementia Rating Scale (KDRS), SMD $= -0.76$, 95% CI $= -1.96$ to $0.45$ (Gerber et al., 1991); and using the cognitive subscale of the Royal College of Physicians (RCP; Hodkinson, 1973), SMD $= -0.03$, 95% CI $= -0.93$ to $0.88$ (Wallis et al., 1983). These results were not individually significant (confidence intervals overlapping zero); in all, the trend favored treatment (implying a negative value for the SMDs).

![Figure 1: Meta-analysis: Cognitive outcomes. The length of the lines represents the size of the confidence intervals and the gray boxes, the weight attributed to the trial. Results are significant if they do not cross the center line. The pooled total lies left of the center line, without touching it, indicating a significant result. SMD = standardized mean difference, CI = confidence interval, MMS = Mini Mental State Exam, CERAD = Consortium to Establish a Registry for Alzheimer's Disease, RCP = Royal College of Physicians, KDRS = Kingston Dementia Rating Scale.](https://academic.oup.com/gerontologist/article-abstract/40/2/206/554982)
The total result for behavior was again significantly in favor of treatment (see Figure 2). The SMD was \(-0.64\), with a 95% CI of \(-1.20\)–0.08, with a total of 57 subjects (33 experimental, 24 control). Comparing the SMD with a normal distribution indicates that the average score for patients in the treatment groups was better than 74% of the control patients’ scores. All individual studies had insignificant results, but the trends were again in favor of treatment. Statistics were as follows: using the Crichton, SMD = \(-0.45\), 95% CI = \(-1.58\)–0.40 (Wallis et al., 1983); using the Self-Care Functioning subscale of the M.O.S.E.S (Helmes, Csapo, & Short, 1987), SMD = \(-0.59\), 95% CI = \(-1.90\)–0.82 (Woods, 1979); and using the Behavioural subscale of the CAPE, SMD = \(-1.32\), 95% CI = \(-2.77\)–0.12 (Baines et al., 1987).

Discussion

This has been the first systematic review of RO in dementia. Six RCTs with a total of 125 participants met the inclusion criteria for the metaview (Spector, Orrell, Davies, & Woods, 1998). Trials varied greatly in factors such as length of intervention, methodological quality, and outcome measures. However, the results showed that RO had significant positive effects on both cognition and behavior. Results for cognition were more precise, due to a sample size of 125, compared with 57 for behavior.

The study (Ferrario et al., 1991) in which participants received much more RO than any of the other trials (105 hr in total) had the highest cognitive SMD (\(-0.96\)) in favor of treatment; however, our results did not show a clear relationship between amount of intervention and cognitive outcome. Additionally, the trial (Breuil et al., 1994) in which participants were given the least amount of RO (10 hr) was the only one to yield significant positive findings favoring RO. Many of the smaller RO trials are vulnerable to Type II statistical error due to insufficient numbers. Similarly, the results did not show a relationship between amount of intervention and behavioral outcome, or a pattern between length of sessions and outcomes.

The overall SMD (\(-0.59\)) was of a similar size to the SMD (\(-0.71\)) of the Breuil et al. (1994) study, which found a 2.1-point benefit on the Mini Mental State Exam for the stimulated group compared with the control group. Because Mini Mental State Exam scores are thought to decline by on average 4 points per year for dementia, the benefits of RO might equate to a 6-month delay in the usual cognitive deterioration. How far such a delay is of functional benefit to an individual patient would necessarily vary. The orientation process used by Breuil et al.’s (1994) study slightly differed from the other studies (see Table 1), being more advanced theoretically than the 1970s concepts, as much more was known about the neuropsychology of dementia. Their techniques were more akin to the sophisticated cognitive rehabilitation programs used in brain injury.

There was variation in the alternative activities offered to control groups, with some trials giving them no treatment (Baines et al., 1987; Breuil et al., 1994; Ferrario et al., 1991) and others providing control groups with some alternative social therapy (Gerber et al., 1991; Wallis et al., 1983; Woods, 1979). Our results showed no effects of these differences on out-
come, suggesting that the actual qualities of RO, rather than merely the therapeutic effect of social contact and attention, may affect individual outcomes. However, staff may have had greater expectations from the RO group, which may have affected participants’ performance.

There were 38 dropouts in the six studies with available data. In one study (Wallis et al., 1983), there were 22 dropouts, but no details were provided as to which groups they were in. Of the remaining 16, there were details of 8 RO participants and 6 controls. From these, it was clear that 3 experimental participants and 3 controls died; others, for example, went to the hospital or were discharged. Hence, there was no evidence in this study that RO had serious side effects. However, cases of adverse psychological and emotional effects in patients have been reported (Dietch, Hewett, & Jones, 1989). It has even been stated that “challenging their fantasies or attempting to educate and continually re-educate people with dementia is probably of no value” (Reisberg, 1981, p. 149).

There has been some evidence that RO patients actually performed worse at a 10-week follow-up than before treatment (Gerber et al., 1991), suggesting that benefits gained from RO were lost. Conversely, another study found that participants gained higher scores in both cognitive and behavioral tests 1 month postintervention (Wallis et al., 1983). The present analysis has provided no clear evidence of the long-term benefits of RO primarily because of a lack of follow-up data. It has been suggested that for RO to have more lasting effects, there should be a detailed schedule of reinforcement and follow-up, with a continuous, ongoing program. For example, low-key interventions like RO boards and signs could be used when a person is disoriented and distressed. The introduction of a 24-hr RO program might be a good way to retain what has been learned if the continuation of classroom RO is not feasible (Williams, Reeve, Ivison, & Kavanaugh, 1987).

With psychological interventions, unlike drug trials, double blinding is not possible and contamination between groups is more likely. Hence RCTs may be especially valuable if used in conjunction with more qualitative studies, such as case studies, or quasi-experimental studies in which different treatments are carried out in different centers. These may offer a greater insight into the most effective features of RO, the most effective ways in which it may be applied, and the types of people most suited. As with all psychological interventions, the success of RO may be dependent on it being used at the appropriate time, by sensitive and experienced practitioners, to receptive patients.

Future research should investigate the relationship between classroom and 24-hr RO; other outcomes, such as quality of life; more individualized psychological treatment approaches for people with dementia, with more detailed assessments of everyday memory skills and their remediation in individual programs; and how long the benefits of RO remain after treatment and whether continuation therapy is effective. In summary, this review found that classroom RO had clear benefits to patients with dementia in both cognitive and behavioral domains, suggesting that RO techniques should be considered as an important component of dementia care. The benefits of short-term RO may only be short lived, but a more long-term program may help sustain improvements. This review has shown that RCTs are possible in this field but that there is a need for multicenter trials of better quality and design methodology that include a clear rationale for the interventions used. We have recently been awarded grants to conduct a multicenter trial.

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