

EVIDENCE-BASED PRACTICE IN OCCUPATIONAL THERAPY

Eddie Ka Hang Leung

Evidence-based practice (EBP) was introduced to the occupational therapy (OT) profession to aid in the development of clinical services and to substantiate daily OT practices. It refers to the conscientious, explicit and judicious use of the current best evidence in making decisions about the care of individual clients.

In this article, a systematic and critical review of published randomized controlled trials in OT was performed in order to critically appraise the current level of evidence provided with respect to EBP and provide recommendations accordingly. Searches of MEDLINE EXPRESS and the Cochrane Collaboration Library databases of the English-language literature with keywords “randomized clinical trial”, “controlled clinical trial” and “clinical trial” for publication type, and “occupational therapy” in any field were made. Forty-six randomized, controlled trial publications of OT treatment were identified, and two independent reviewers assessed their quality according to a preset protocol.

Among the 46 trials, 29 were classified as average or above. The remaining 17 trials were graded as poor quality. About 50% of the trials studied geriatric, paediatric or stroke patients. These areas had higher evidence grades. In terms of the quality of design, most studies adequately described the measurement methods, duration of therapy and group assignment, but handling of blinding method and sample size calculation were poorly described.

In this systematic and critical review, I conclude that there were far too few randomized, controlled OT trials. The quality of one third of the trials was low and there were insufficiencies in their reporting as well. Therefore, more properly designed and conducted randomized controlled clinical trials of OT treatment with proper reporting based on reference to the CONSORT statement are necessary.

KEY WORDS: Evidence-based practice • Trial • Occupational therapy

Introduction

In the continuing development of Occupational Therapy (OT) clinical services, practitioners must locate the most current facts to substantiate daily practices. For this reason, evidence-based practice (EBP) was introduced to the OT profession. EBP refers to the conscientious, explicit and judicious use of the current best evidence in making decisions about the care of individual clients (Sackett et al., 1996).

EBP can be established in several ways including conducting research studies such as case control studies, cohort studies, and randomized, controlled clinical trials. Additionally,

systemic review of publications in an area of interest followed by meta-analysis provides another way to substantiate EBP. An overview of randomized, controlled OT trials was performed in order to identify and critically appraise the current body of published OT research.

Evidence-Based Practice

EBP is helpful for the development and implementation of disease management programmes and clinical practice guidelines because it embodies conscientious, explicit and judicious use of the most current, best available evidence in

Occupational Therapy Department, Rehabilitation Building, Kowloon, Hong Kong.

Reprint requests and correspondence to: Eddie Ka Hang Leung, Occupational Therapy Department, 1/F, Rehabilitation Building, Kowloon Hospital, 147A, Argyle Street, Kowloon, Hong Kong.

E-mail: eddleung@hutchcity.com

caring for patients. How can we practitioners ensure EBP? It can be assured by integrating individual clinical expertise with the best available external clinical evidence obtained by systemic research. By individual clinical expertise, we mean the proficiency and judgement that individual clinicians acquire through clinical experience and professional practices. On the other hand, to obtain the best available external clinical evidence, we can investigate the efficacy of present practice. Practically, the identification of external resources of evidence is followed by a systematic review of the identified publications, which forms the basis for a meta-analysis (Lauder & Kumana, 1998).

Alternatively, we can obtain evidence through a series of research studies, including retrospective cohort studies, case control studies and prospective confirmatory studies e.g. randomized, controlled trials (Chappell, 1998). Each type of clinical research is important under different situations. Nonetheless, it is commonly believed that prospective, randomized, controlled trials (with blinding when appropriate) can provide the most accurate evidence about the efficacy and safety of study treatments (Chappell, 1998).

Occupational Therapy and Evidence-Based Practice

Techniques and devices in OT are developing relatively faster than before in order to fulfil the increasing demand for quality services. Recently, Dubolouloz (1999) launched a survey on Occupational Therapists' perceptions of EBP. The OT practitioners were asking "Why should I use this kind of activity to treat my patients?" or "What is the rationale of doing this?" I believe these questions need to be answered appropriately. Moreover, there were conflicting conclusions on the effectiveness of an OT treatment or a specific OT treatment modality (Ottenbacher & Maas, 1999; Severens et al., 1999; Ballinger et al., 1999). Under this situation, EBP can help to address these questions by a systematic and critical review of the best available evidence.

In the process of EBP, the search for external evidence is of equal importance to actual clinical studies. Meta-analysis is a statistical technique to combine results from different studies of a similar type of intervention in order to produce a more reliable conclusion on the efficacy or safety of the intervention. Hence, to conduct meta-analysis of existing published studies is one way to consolidate existing evidence to produce more powerful conclusions (Sackett, 1997). Nonetheless, our observation of a sample of meta-analyses of OT studies indicates that their quality was often insufficient. For example, Meta-Analysis of Research on Sensory Integration Treatment by Vargus & Camilli (1999) considered studies other than

randomized, controlled trials, which is undesirable for the objective of evaluating the best evidence of the effect of OT on patients. We know that randomized controlled trials provide the best evidence for EBP over other study types. One of the main reasons for the lack of good meta-analyses is, perhaps, the diversity among OT treatments focusing on a wide variety of outcome measures and therapeutic areas that make the meta-analyses more difficult. It is, therefore, worthwhile to conduct a systematic and critical review of existing research on OT in order to thoroughly understand the existing quality of research on OT and the diversity of different areas of applications considered. This will help to standardize future research on OT and draw attention to situations in which meta-analyses can be performed in the future.

For assessing the quality of randomized controlled trials, the "Checklist for assessing randomised controlled trials" is useful and has been previously used for this purpose (Karlberg et al., 1999). It rates the quality of a randomized, controlled trial publication on a 4-point scale (0–3) according to subject selection, trial design, data collection, data analysis, treatment comparisons and reporting of results and conclusions. This checklist is, therefore, accepted as a comprehensive review tool for the evaluation of published studies on OT.

Research Aims

The aims of this article are:

- To make a systematic and critical overview of published, randomized, controlled trials on OT treatments.
- To describe the common strengths and weaknesses of randomized, controlled trials on OT.
- To examine the strength of evidence provided by randomized, controlled trials on OT.
- To recommend areas of OT practice that require more support by EBP.

Occupational Therapy Search

Before the start of the OT search, sets of inclusion and exclusion criteria for the identification of OT publications were identified and accepted by a panel comprised of one occupational therapist (M.Med.Sc. degree candidate) and two members of the staff at the Clinical Trials Centre, The University of Hong Kong (one an M.D., Ph.D.; the other a Ph.D. in Statistics).

Inclusion Criteria

1. A clinical trial focused on evaluating an OT intervention
2. A randomized clinical trial

3. A controlled clinical trial

Exclusion Criteria

1. A non-randomized study
2. A study not evaluating an OT intervention
3. Publications written in a language other than English.

Identification of publications on OT was initiated by searching through two electronic databases: MEDLINE EXPRESS and the Cochrane Collaboration Library (Cochrane Library). The search covered databases from January 1966 to February 2000. The following keywords were used in searching the two electronic databases:

- RANDOMIZED-CLINICAL-TRIAL, CONTROLLED-CLINICAL-TRIAL, and CLINICAL-TRIAL in publication type.
- CLIN*, TRIAL*, and RANDOM* in any field where "*" is a wildcard character representing any string
- OCCUPATIONAL THERAPY in any field.

The publications identified in the two electronic databases were compared and combined. The search was extended by contacting academic staff specializing in OT at the Hong Kong Polytechnic University (PolyU), through internet and email.

The abstracts of all collected publications were studied and coded in accordance with the pre-defined selection criteria. Those abstracts not satisfying the inclusion criteria, or those that met one or more of the exclusion criteria, were excluded from the subsequent detailed critical review. The full papers on the selected studies were analysed, and their study design, sample size, results, conclusions and treatment modality were summarized into tables.

Review Process

All selected publications of OT clinical trials were reviewed for their strengths and weaknesses. Two persons reviewed the selected publications in a standardized manner. The two reviewers used the "Checklist for assessing clinical trials" (Karlberg et al., 1999) (Appendix) to assess the study design, statistical analysis and report of all identified published trials. After reviewing each item in the checklist, an overall quality score ranging between 0 and 3 was given for each trial:

- "3" for a high-quality study (methodologically strong without important weakness in design or results).
- "2" for a study of reasonable quality (some weakness in study design or results).
- "1" for a weak study (definite shortcomings in design or results).
- "0" for a poor study (serious weakness in design or results).

Each publication was graded by each of the two reviewers independently. After completing the review of all trial publications, the quality grades of the two reviewers were compared and any discrepancies were discussed and resolved.

Results

Search Results

The adopted search key words and the resulting summary of the MEDLINE search are shown in Table 1. A total of 209 publications of randomized controlled trials on OT dated from January 1966 to February 2000 were identified. The same set

Table 1. MEDLINE search steps for randomized controlled trials on occupational therapy

No.	Records	Request
1	128,757	RANDOMIZED-CONTROLLED-TRIAL in PT
2	53,207	CONTROLLED-CLINICAL-TRIAL in PT
3	13,345	RANDOMIZED-CONTROLLED-TRIALS
4	277,601	CLINICAL-TRIAL in PT
5	82,359	explode CLINICAL-TRIALS/ all subheadings
6	1,316,547	clin*
7	208,134	trial*
8	15,474	(clin* near trial*) in ti
9	1,316,547	clin*
10	208,134	trial*
11	44,855	(clin* near trial*) in ab
12	212,689	random*
13	432,522	#1 or #2 or #3 or #4 or #5 or #8 or #11 or #12
14	119,366	occupational
15	1,619,271	therapy
16	7,383	occupational therapy
17	432	#16 and #13
18	212,689	#13 and #12
19	209	#18 and #16

of key words was also used in searching the Cochrane Library database, and exactly the same number of publications was found. Titles and authors of the two sets of publications from MEDLINE and the Cochrane Library, respectively, were then printed and compared. No discrepancies were found. On the other hand, 15 academic staff specializing in OT at PolyU were contacted by letter for information on publications of OT trials, and eight of them (53.3%) replied. No additional complete OT publications were found, based on their responses.

Abstracts of the 209 identified publications were then studied and screened by the author, in accordance with the pre-defined selection criteria described in method section. Most publications reported non-randomized trials or were not primarily focused on an OT programme. A few publications were meta-analyses or were not written in English. As a result, a total of 163 publications were excluded.

The study designs, sample sizes, results, conclusions, and treatment modalities of the 46 full publications are summarized in Table 2.

Quality Grades of the Identified Publications

The two reviewers with different backgrounds reviewed the 46 OT trial publications independently, according to the standardised checklist (Appendix). A quality score from zero to three was given to each publication based on its design, statistical analysis, and conclusions. The two reviewers gave the same scores on 33 (70%) publications. The scores of the remaining 14 publications differed by only one grade unit. The Figure presents the graphical distribution of the quality scores. There were 29 publications graded with a score of two or three, which constituted 63% of the selected OT trial publications.

Of the 29 publications with a score of two or three, only 10 (34%) had proper sample size calculations before the studies were conducted. Blinding was also considered in 10 publications (34%), one of which even considered a triple blinded design, i.e. the patients, investigators and trial statisticians were all blinded to the types of treatment administered to the patients. Baseline comparisons were performed in 28 publications (97%), and none of them revealed any significant baseline difference between the comparison groups. Studies with a score of two or three also had proper handling of missing values. A total of 25 publications (86%) adopted the intention to treat approach for all statistical analyses. Regarding the types of treatments used for comparisons with OT treatments, there were 14 publications that compared an OT treatment with another OT treatment and 32 publications that compared an OT treatment with a non-OT treatment.

All of the publications with a score of one lacked predetermined sample calculations and had no discussion of

the adequacy of sample size. Only six of the publications (31%) performed baseline comparisons. None of the publications considered blinding when it was appropriate, and none had properly handled missing values.

Table 3 summarizes the key randomized clinical trial characteristics of all 46 identified OT trial publications. Of these, 44 had a prospective parallel design. The other two had a cross-over design. Sample size varied moderately among the trials. Specifically, 8 (17%) had more than 100 study subjects, 12 (28%) had between 50 and 100 study subjects and the remaining 25 (55%) publications had fewer than 50 study subjects. A total of 21 publications (45%) reported a positive conclusion on the OT treatment efficacy, while 15 publications (34%) reported a negative OT treatment effect. The remaining 10 publications (21%) did not arrive at a conclusion on whether OT was better than the comparison treatment, or vice versa.

There appeared to be a chronological order to the quality of the OT trials. In the 1980s and 1990s, there were more reported trials with a score of two or three, which constituted 4/12 (33%) and 24/32 (75%), respectively. From the sample size perspective, score 3 trials averaged 182 subjects, while score 2 trials averaged 55 subjects. Score 1 trials averaged only 32 subjects. When the scores were compared for results and conclusions, 8/11 (72%) of score 3 trials, 9/18 (50%) of score 2 trials and 4/13 (30%) of score 1 trials concluded with positive efficacy for OT treatments. A further observation was that all score 3 trials had significant conclusions.

Therapeutic Areas

Table 4 presents a summary of the quality of the 46 OT publications classified by therapeutic area and the domain of concerns such as OT core values. The therapeutic areas, in descending order of the number of studies, were geriatric, 10 (22%), stroke 8 (17%), core values 7 (15%), paediatrics 6 (13%), brain injuries 4 (8%), rheumatoid arthritis 4 (8%), psychiatry 3 (6%), others 3 (48%), parkinsonism 1 (2%), and work rehabilitation 1 (2%). The treatment modalities that varied the most among the publications were activity therapy, group intervention, preventive measures and assistive devices/technology. The other treatment modalities usually referred to a specific treatment technique, such as sensory integration, neurodevelopmental treatment and memory training.

Discussion

Search for Occupational Therapy Randomized, Controlled Trials

I identified a total of 209 publications on OT randomized controlled trials. After screening by predefined selection criteria,

Table 2: Summary of 46 publications of randomized controlled trials on occupational therapy classified by therapeutic area

Trial no./ Category	Author	Year	Title	Quality score	Subjects	Results	Sample size	Treatment modality
1 Stroke rehab	Greenberg et al.	1980	Kinesthetic biofeedback: a treatment modality for elbow range of motion in hemiplegia	1	VP	-	20	Exercise therapy
2 Stroke rehab	Logan et al.	1997	A randomized controlled trial of enhanced social occupational therapy for stroke patients	3	P	+	111	Assistive devices
3 Stroke rehab	Drummond et al.	1995	A randomized controlled trial of leisure rehabilitation after stroke	2	2P	+	65	Leisure activities
4 Stroke rehab	Jongbloed et al.	1990	An investigation of involvement in leisure activities after a stroke	2	P	-	40	Leisure therapy
5 Stroke rehab	Carter et al.	1983	Effectiveness of cognitive skill remediation in acute stroke patients	2	P	+	33	Cognitive therapy
6 Stroke rehab	Jongbloed et al.	1988	Stroke rehabilitation: sensorimotor integrative treatment versus functional treatment	3	P	-	90	Sensory integration therapy
7 Stroke rehab	Walker et al.	1999	Occupational therapy for stroke patients not admitted to a hospital: a randomised controlled trial	3	P	+	185	Home therapy
8 Stroke rehab	Corr et al.	1995	Occupational therapy for stroke patients after hospital discharge – a randomised controlled trial	2	P	+	110	Home therapy
9 Geriatrics	Ratchford	1993	The effectiveness of life review reminiscence activities on depression and self-esteem in older adults	1	VH	-	24	Reminiscence therapy
10 Geriatrics	Wallis et al.	1983	Reality orientation therapy – a controlled trial	1	P	-	38	R.O. program
11 Geriatrics	Nelson	1988	Effects of project versus parallel groups on social interaction and affective responses in senior citizens	1	VH	-	41	Social group
12 Geriatrics	Liddle et al.	1996	Can occupational therapy intervention play a part in maintaining independence and quality of life in older people? A randomised controlled trial	2	H	NS	105	Assistive devices
13 Geriatrics	Robichaud et al.	1993	Efficacy of sensory integration programme on behaviours of inpatients with dementia	3	P	-	40	Sensory integration therapy
14 Geriatrics	Clark et al.	1997	Occupational therapy for independent-living older adults. A randomized controlled trial	3	VH	+	361	Community preventive therapy
15 Geriatrics	Thralow et al.	1974	Remotivation for geriatric patients. Using elementary school students	2	P	NS	72	Remotivation group therapy
16 Geriatrics	Cumming et al.	1999	Home visits by an occupational therapist for assessment and modification of environmental hazards: a randomized trial of falls prevention	3	P	+	530	Fall prevention
17 Geriatrics	Close et al.	1999	Prevention of falls in the elderly trial (PROFET): a randomised controlled trial	3	P	+	397	Fall prevention
18 Geriatrics	Zisselman et al.	1996	A pet therapy intervention with geriatric psychiatry inpatients	2	P	-	58	Pet therapy
19 *Core value	Morton et al.	1992	A comparison of performance measures of an added-purpose task versus a single purpose task for upper extremities	1	VH	-	30	Activity therapy
20 *Core value	LaMore et al.	1993	The effects of options on performance of an art project in adults with mental disabilities	1	P	+	22	Activity therapy
21 *Core value	Steinbeck	1986	Purposeful activity and performance	1	VH	+	30	Activity program
22 *Core value	Zimmerer et al.	1995	Occupationally-embedded exercise versus rote exercise: a choice between occupational forms by elderly nursing home residents	1	H	-	52	Activity therapy
23 *Core value	Nelson et al.	1996	The effects of occupationally embedded exercise on bilaterally assisted supination in persons with hemiplegia	2	P	+	26	Activity therapy
24 *Core value	Kremer et al.	1984	Effects of selected activities on affective meaning in psychiatric patients	2	P	-	22	Activity therapy

Trial no./ Category	Author	Year	Title	Quality score	Subjects	Results	Sample size	Treatment modality
25 *Core value	Ferguson & Trombly	1997	The effect of added-purpose and meaningful occupation on motor learning	2	VH	+	28	Activity therapy
26 Paediatrics	Polatajko et al.	1995	A clinical trial of the process-oriented treatment approach for children with developmental co-ordination disorder	3	P	-	79	Process oriented treatment
27 Paediatrics	Parush et al.	1997	The efficacy of early prevention programme facilitated by occupational therapist: a follow-up study	1	H	+	55	Prevention program
28 Paediatrics	Gaebler et al.	1996	The effects of prefeeding stimulation program on preterm infants	1	P	-	18	Prefeeding program
29 Paediatrics	Edelson et al.	1999	Behavioural and physiological effects of deep pressure on children with autism: a pilot evaluating the efficacy of Grandin's hug machine	1	P	NS	12	Autism treatment technique
30 Paediatrics	Law et al.	1997	A comparison of intensive neurodevelopmental therapy plus casting and a regular occupational therapy programme for children with cerebral palsy	3	P	-	50	Neurodevelopmental therapy
31 Paediatrics	Exner	1990	The zone of proximal development in in-hand manipulation skills of non dysfunctional 3- and 4-year-old children	2	H	NS	28	Cues variety
32 Rheumatoidology	Gerber et al.	1987	Patient education program to teach energy conservation behaviors to patients with rheumatoid arthritis	1	P	NS	25	Education program
33 Rheumatoidology	Van Deusen & Harlow	1987	The efficacy of the ROM dance program for adults with rheumatoid arthritis	1	P	+	46	ROM program
34 Rheumatoidology	Helewa et al.	1991	Effects of occupational therapy home service on patients with rheumatoid arthritis	3	P	+	105	R.A. management
35 Rheumatoidology	Pagnotta et al.	1998	The effect of a static wrist orthosis on hand function in individuals with rheumatoid arthritis	2	P	+	40	Splintage
36 Brain injury	Soderback	1988	The effectiveness of training intellectual functions in adults with acquired brain damage	1	P	NS	67	Cognitive therapy
37 Brain injury	Neistadt	1992	Occupational therapy treatments for constructional deficits	2	P	NS	45	Cognitive group
38 Brain injury	Neistadt	1994	The effects of different treatment activities on functional fine motor coordination in adults with brain injury	2	P	NS	45	Functional task
39 Brain injury	Dirette et al.	1999	Comparison of remedial and compensatory interventions for adults with acquired brain injuries	2	P	-	30	Remedial intervention
40 Psychiatry	Liberman et al.	1998	Skills training versus psychosocial occupational therapy for persons with persistent schizophrenia	2	P	+	80	Skills training group
41 Psychiatry	Kopelowicz et al.	1998	Teaching psychiatric inpatients to re-enter the community: a brief method of improving the continuity of care	3	P	+	59	Skills training group
42 Psychiatry	DeCarlo et al.	1985	The effectiveness of verbal versus activity groups in improving self perceptions of interpersonal communication skills	1	P	-	19	Skills training program
43 Work rehab	Dortch III et al.	1990	The effects of education on hand use with industrial workers in repetitive jobs	1	VH	NS	18	Preventive group
44 Parkinsonism	Gauthier et al.	1987	The benefits of group occupational therapy of patients with Parkinson's disease	2	VP	+	64	Group therapy
45 Others	Glickman et al.	1996	The effect of switch control site on computer skills of infants and toddlers	2	H	+	72	Computer therapy
46 Others	Cooper et al.	1993	Elbow joint restriction: effect on functional upper limb motion during performance of three feeding activities	1	VH	-	19	Joint ROM

Subjects: VH: voluntary healthy, VP: voluntary patient, H: healthy, P: patient. Results: +: positive, -: negative, NS: Not significant. *Core value: OT domain of concerns. It is the area of activity of daily living, productivity and leisure activities.

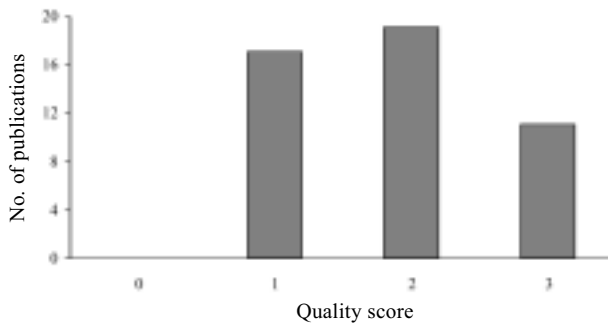


Figure: Distribution of the quality scores of the 46 publications of randomized-controlled trials.

only 46 publications remained. These publications were then evaluated for their quality of design, analysis and reporting in a systematic manner.

I used both the MEDLINE and the Cochrane Library databases in my search and also contacted staff specializing in OT at the Hong Kong Polytechnic University to identify published, randomized, controlled OT trials. Due to restricted time available for this research study, I did not use other sources, such as abstracts from recent scientific meetings or a reference list of published progress. Nonetheless, I strongly feel that I was able to give a realistic and clear picture of the strength of OT research up to the year 2000.

I was surprised to learn of the relatively small number of randomized, controlled OT trials identified, i.e., only 46. 14 of them compared one OT treatment with another OT treatment while the rest compared one OT treatment with a non-OT treatment. Indeed, most of the excluded publications, which focused on the comparison of efficacy among OT or non-OT treatments, could have used randomization, but unfortunately, they did not. Moreover, there were studies that reported the efficacy of certain specific OT treatments as still uncertain (Severens et al., 1999; Ballinger et al., 1999), when a more definitive answer could have certainly been determined through

conducting randomized clinical trials (Chappell, 1998). It was also clear that with increasing demands by health authorities to provide evidence for clinical practice to garner future funding, OT research must be improved and follow modern concepts of clinical research methodology.

Quality of Occupational Therapy Trials

The quantity of OT clinical research, more specifically randomized, controlled trials, is essential for the development of the profession. However, quantity is not the only element. More important is the quality of the research conducted. In my review, I found that 65% (30/46) of the identified OT research published could be regarded as average or above average in terms of study quality. None of the 46 randomized, controlled trials reviewed were seen as excellent. Even the top-quality trials missed essential components of randomized clinical trials such as blinding. For example, for the trials by Close et al. (1999) in fall prevention and by Robichaud (1998) in geriatric dementia care, blinding was feasible. However, it was not applied. This can be regarded as lack of awareness of the concept of EBP. The concept of forming appropriate randomized clinical trials and its relation to EBP is relatively weak.

The overall impression of the quality of the 46 trials reviewed was fair or good. I was pleased that most articles described the patient populations studied in a clear way so that researchers knew to whom to apply the results. On the negative side, we emphasize three important study quality or design issues. The first issue is lack of calculations for a predetermined sample size, which was the most common deficit among OT trials. This was especially evident when the sample size was too small to be able to demonstrate a statistical difference of clinical significance. Secondly, there were issues with missing values in several studies. The authors realized the problem, but there were difficulties with the statistical analyses, given too many missing values. Thirdly, there was frequent lack of applying a blinding evaluation procedure. Non-blinded studies are known to run the risk of

Table 3. Number of publications with adequate quality characteristics classified by quality score

Quality characteristics	Score 1 (n = 17)		Score 2 (n = 18)		Score 3 (n = 11)	
	n	%	n	%	n	%
Patient type	16	94.0	18	100.0	10	90.9
Sample size rationale	0	0	1	5.5	9	81.8
Inclusion/exclusion criteria	12	70.5	14	77.7	11	100.0
Baseline comparison	6	35.3	17	94.4	11	100.0
Measurement used to access goal	14	82.4	18	100.0	11	100.0
Blinding	0	0	4	22.2	6	54.5
Missing data	2	11.8	14	77.8	11	100.0
Duration of therapy	16	94.1	16	88.9	11	100.0
Randomization	15	88.2	17	94.4	11	100.0

Table 4. Distribution of occupational therapy randomized, controlled trials by therapeutic area

No	Therapeutic areas	n (%)	Outcome measures	n (%)	Quality score		
					1	2	3
1	Geriatrics	10 (22)	Memory training	2 (20)	2		
			Preventive measures	3 (30)		1	2
			Social group	2 (20)	1		1
			Assistive device	1 (10)		1	
			Others	2 (20)		1	1
			Total		3	3	4
2	Paediatrics	6 (13)	Preventive program	1 (16)	1		
			Specific technique	5 (84)		3	2
			Total		1	3	2
3	Stroke	8 (17)	Home activity	2 (25)		1	1
			Leisure activity	2 (25)		2	
			Specific technique	2 (25)		1	1
			Assistive device	1 (12.5)			3
			Exercise	1 (12.5)	1		
			Total		1	4	5
4	Brain injury	4 (8)	Activity therapy	2 (50)		2	
			Cognitive therapy	1 (25)	1		
			Assistive device	1 (25)		1	
			Total		1	3	0
5	Rheumatoid arthritis	4 (8)	Education program	2 (50)	1		1
			Exercise	1 (25)	1		
			Preventive measures	1 (25)		1	
			Total		2	1	1
6	Parkinsonism	1 (2)	Group therapy	1 (100)		1	
			Total		0	1	0
7	Psychiatry	3 (6)	Group therapy	3 (100)	1	1	1
			Total		1	1	1
8	Core values	7 (15)	Activity therapy	7 (100)	4	3	
			Total		4	3	0
9	Work rehabilitation	1 (2)	Preventive measures	1 (100)	1		
			Total		1	0	0
10	Others	2 (6)	Assistive device	1 (50)		1	
			exercise	1 (50)	1		
			Total		1	1	0

introducing bias, so the treatment effect between groups appears larger than when a blinded study design is used.

Based on the above findings, I can be sure that the authors of the respective trials did not have an adequate knowledge of the Consolidated Standards of Reporting Trials (CONSORT) (Begg et al., 1996). The CONSORT statement is a checklist for reporting publications and is composed of 21 items pertaining to the content of Title, Abstract, Introduction, Methods, Results and Discussion. The statement provides the guidelines for reporting trials. Authors should follow the CONSORT statement so that readers understand the trial design, conduct, analysis and interpretation. Moher et al. (2000) also reported that the CONSORT statement improves the quality of randomized clinical trial reports.

Therapeutic Area of Occupational Therapy Randomized, Controlled Trials

The reviewed OT randomized, controlled trials studies comprised a wide spectrum of daily OT practices. These areas

were classified into geriatric, paediatric, cardiovascular accident (CVA) pathology, brain injury, rheumatoid arthritis, parkinsonism, specialities of psychiatry and vocational rehabilitation, and the professional philosophical core values of OT.

In the geriatric area, the scope of investigation was geared to the interaction between hospital care and the community or home care. Community geriatric programmes were extensively evaluated in the trials reviewed. Research included the enhanced function and fall prevention programmes. It not only covered the physical aspect of geriatric care, but also the psychosocial aspect of leisure rehabilitation. From the point of view of diversity and specificity, geriatric research was clearly the most impressive among the fields included in OT randomized, controlled trials.

In CVA pathology, the research areas were broad and included impairment, disability and handicap. The studies included the specific handling techniques for CVA impairment such as sensory integration. It also encompassed exercise

activity in dealing with disabilities such as upper limb facilitation training. Furthermore, it investigated the efficacy of assistive device application for handling the issue of handicap level.

In addition to the above-mentioned two areas, there were several other areas that the identified OT randomized, controlled trials covered. However, coverage and strength was weaker than in the geriatric and CVA areas. In these other areas, there is clearly a need for further randomized, controlled trials to provide better evidence for improvement of patient care.

In psychiatry, I only found a small number of OT trial publications, and they were solely conducted in the area of group skills training. Nonetheless, the most important and the most time-consuming OT practices in psychiatry are industrial rehabilitation and independent-living skills training. I did not identify any randomized, controlled trials of such important clinical practices, which is both a remarkable and a critical finding.

Among studies of brain injured patients, there was also a notable lack of randomized controlled trials. The basis of OT brain injury rehabilitation is cognitive therapy, yet only one OT randomized, controlled trial was identified on this group of patients. Other important OT activities for brain injury rehabilitation are activity therapy and assistive therapy, and these two therapy areas are also in need of randomized controlled trials.

The number of OT randomized, controlled trials that addressed vocational rehabilitation of patients was also far from satisfactory. Only one trial was identified between 1966 and early 2000. This is alarming for the OT profession because the low level of activity in work rehabilitation is one of occupational therapists' biggest concerns.

The quantity of good-quality OT core value studies was also limited. At the traditional core of OT, the activity of human occupation is most essential. Proof of the efficacy of activity is necessary in daily practice. The concern is not only for treatment effectiveness, but also the usefulness of the activity in the treatment. It is, therefore, essential to build a strong base to prepare for further growth, and it merits more attention.

Evidence in the Clinical Practice of Occupational Therapy

In Hong Kong, as in the rest of the world, the concept of EBP is gaining ground. The concept is also becoming increasingly better understood among occupational therapists. Nonetheless, the main concerns of OT in clinical practice are still in the hands of expert opinion. The evidence is commonly provided by the experts' own experiences, and is not based on evidence

from research. A first step to entering the area of EBP is through a critical review of the current evidence.

From my review, I found good evidence for clinical benefits of OT practice in the following areas:

- Fall prevention in geriatric care
- Community geriatric function enhancement
- Ambulatory home rehabilitation for CVA patients
- Sensory integration in paediatric care

However, there is still a lack of evidence in most areas of OT practice. The most important of these are:

- Vocational rehabilitation
- Independent-living skills training in psychiatry
- Cognitive therapy in brain injury rehabilitation

Future Research

My review clearly shows a lack of solid clinical research in OT using the modern concepts of clinical research methodology. While we are not in a position to dictate the type of OT research that should be conducted, I found two areas, geriatric and CVA pathology, in which high-quality OT research on clinical practice has been published. On the other hand, other areas such as vocational rehabilitation and cognitive therapy have little research evidence on the efficacy of intervention. It would be natural and justifiable to direct research resources to these areas in the future.

The most critical point for improvement of OT clinical practice and research is the overall quality improvement of research designs. Out of a large number of OT publications, only a few (46) used the key research design for a proper evaluation of medical practice, i.e., the randomized controlled trial design.

The future of OT research design should shift emphasis from observational studies or uncontrolled experimental studies to randomized controlled trials to enhance EBP.

Weaknesses and Strengths of the Study

One could argue that this review is a restricted one, since only randomized controlled trials were reviewed. All other OT research reports, which may represent as much as 95% of all output, were not taken into consideration. We know that observational studies are important, for example, to produce clinical reference values, diagnostic test evaluations and to identify risk factors by means of case control studies. Nonetheless, the main theme of this study was to identify solid evidence of OT clinical practice in line with the recommendation provided by the Cochrane Library. In this respect, there are three levels of evidence. The weakest evidence is provided by

clinical experience, the moderate quality evidence grading is provided by non-randomized, controlled clinical studies and the strongest evidence only comes from randomized, controlled, blinded trials of adequate sample size.

I believe that I have produced a critical review of OT randomized, controlled trials, and we accept that this is only a partial picture of OT clinical research.

References

- American Occupational Therapy Association. <http://www.aota.org>
- Ballinger, C., Ashburn, A. & Low, J. (1999). Unpacking the black box of therapy: a pilot study to describe occupational therapy and physiology interventions for people with stroke. *Clinical Rehabilitation*, 13(4), 301–309.
- Begg, C., Cho, M., Eastwood, S., et al. (1996). Improving the quality of reporting of randomised controlled trials – The CONSORT statement. *Journal of American Medical Association*, 276, 637–639.
- Carter, L., Howard, B. & O’Neil, W. (1983). Effectiveness of cognitive skill remediation in acute stroke patients. *American Journal of Occupational Therapy*, 37(5), 320–326.
- Chappell, R. (1998). Confirmatory and exploratory research. In: J. Karlberg & K. Tsang (Eds.), *Introduction of Clinical Trials* (pp. 227–232). Hong Kong: Clinical Trials Centre, Faculty of Medicine, University of Hong Kong.
- Clark, F. (1997). Occupational therapy for independent living older adults – A randomized controlled trial. *Journal of American Medical Association*; 278(16), 1321–1326.
- Close, J. (1999). Prevention of falls in the elderly trial (PROFET) – A randomised controlled trial. *Lancet*, 353(9147), 93–97.
- Cooper, J., Shwedyk, E., Quanbury, A., Miller, J. (1993). Elbow joint restriction: effect on functional upper limb motion during performance of three feeding activities. *Archives of Physical Medicine and Rehabilitation*, 74(8), 805–809.
- Corr, S. & Bayer, A. (1995). Occupational therapy for stroke patients after hospital discharge – A randomised controlled trial. *Clinical Rehabilitation*, 9(4), 291–296.
- Cumming, G. (1999). Home visit is by an occupational therapist for assessment and modification of environmental hazards – A randomized trial of falls prevention. *Journal of American Geriatric Society*, 47, 1397–1402.
- DeCarlo, J. & Mann, W. (1985). The effectiveness of verbal versus activity groups in improving self perceptions of interpersonal communication. *American Journal of Occupational Therapy*, 39(1), 20–27.
- Dirette, D., Hinojosa, J. & Carnevale, G. (1999). Comparison of remedial and compensatory interventions for adults with acquired brain injuries. *Journal of Head Trauma Rehabilitation*, 14(6), 595–601.
- Dortch, H. & Trombly, C. (1990). The effects of education on hand use with industrial workers in repetitive jobs. *American Journal of Occupational Therapy*, 44(9), 777–782.
- Drummond, A. & Walker, M. (1995). A randomized controlled trial of leisure rehabilitation after stroke. *Clinical Rehabilitation*, 9, 283–290.
- Dubouloz, C., Egan, M. & Vallerand, J. (1999). Occupational therapists’ perceptions of evidence-based practice. *American Journal of Occupational Therapy*, 53(5), 445–453.
- Edelson, S., Edelson, M., Kerr, D., Granin, T. (1999). Behavioral and physiological effects of deep pressure on children with autism – A pilot study evaluating the efficacy of Grandin’s hug machine. *American Journal of Occupational Therapy*, 53(1), 145–152.
- Exner, E. (1990). The zone of proximal development in hand manipulation skills of nondysfunctional 3-and 4-old children. *American Journal of Occupational Therapy*, 44(10), 884–891.
- Ferguson, J. & Trombly, C. (1997). The effect of added-purpose and meaningful occupation on motor learning. *American Journal of Occupational Therapy*, 51(7), 508–515.
- Gaebler, C. & Hanzlik, J. (1996). The effects of prefeeding stimulation program on preterm infants. *American Journal of Occupational Therapy*, 50(3), 184–192.
- Gauthier, L., Dalziel, S. & Gauthier, S. (1987). The benefits of group occupational therapy for patients with Parkinson’s disease. *American Journal of Occupational Therapy*; 41(6), 360–365.
- Gerber, L., Furst, G., Shulman, B., Smith, C., Thornton, B., Liang, M., et al. (1987). Patient education program to teach energy conservation behaviors to patients with rheumatoid arthritis – A pilot study. *Archives Journal of Physical Medicine and Rehabilitation*, 68, 442–445.
- Glickman, L., Deitz, J., Anson, D., Stewart, K. (1996). The effect of switch control site on computer skills of infants and toddlers. *American Journal Occupational Therapy*, 50(7), 545–553.
- Greenberg, S. & Fowler, J. R. (1980). Kinesthetic biofeedback – A treatment modality for elbow range of motion in hemiplegia. *American Journal of Occupational Therapy*, 34(11), 738–743.
- Helewa, A. (1991). Effects of occupational therapy home service on patients with rheumatoid arthritis. *Lancet*, 337, 1453–1456.
- Jongbloed, L. & Morgan, D. (1991). An investigation in leisure activities after a stroke. *American Journal of Occupational Therapy*, 45(3), 420–427.
- Jongbloed, L. (1989). Stroke rehabilitation – Sensorimotor integrative treatment versus functional treatment. *American Journal of Occupational Therapy*, 46(6), 391–397.
- Karlberg, J., Fong, D., Wong, S., Au, P. (1999). How to read scientific publications on clinical trials. *Hong Kong Paediatric Society Education Bulletin*, 6(6), 1–4.
- Kremer, E., Nelson, D., & Duncombe, L. (1984). Effects of selected activities on affective meaning in psychiatric patients. *American Journal of Occupational Therapy*, 38(8), 522–528.
- Kopelowicz, A. (1998). Teaching psychiatric inpatients to re-enter the community: a brief method of improving the continuity of care. *Psychiatric Services*, 10, 1313–1316.
- Laliberte, R., Yu, B. A., Scott, E., Pajouhandeh, P. (2000). Exploration of the perspectives of persons with schizophrenia regarding quality of life. *American Journal of Occupational Therapy*, 54(2), 137–147.
- LaMore, K. & Nelson, D. (1993). The effects of options on performance of an art project in adults with mental disabilities. *American Journal of Occupational Therapy*, 47(5), 397–401.
- Lauder, I. & Kumana, C. (1998). Systemic reviews and meta-analysis of drug trials. In: J. Karlberg & K. Tsang (Eds.), *Introduction of Clinical Trials* (pp.158–174). Hong Kong: Clinical Trials Centre, Faculty of Medicine, University of Hong Kong.
- Law, M. (1997). A comparison of intensive neurodevelopmental therapy

- plus casting and a regular occupational therapy program for children with cerebral palsy. *Developmental Medicine and Child Neurology*, 39, 664–670.
- Lieberman, R., Wallace, C., Blackwell, G., Kopelowicz, A., Vaccaro, J., Mintz, J. (1998). Skills training versus psychological occupational therapy for persons with persistent schizophrenia. *American Journal of Psychiatry*, 155, 1087–1091.
- Liddle, J., March, L., Carfrae, B., Druce, J., Schwarz, J., Brooks, P. (1996). Can occupational therapy intervention play a part in maintaining independence and quality of life in older people? A randomised controlled trial. *Australian and New Zealand Journal of Public Health*, 20, 574–578.
- Logan, P. (1997). Randomized controlled trial of enhanced social service occupational therapy for stroke patients. *Clinical Rehabilitation*, 11, 107–113.
- Moher, D., Schulz, K. & Douglas, G. (2000) The CONSORT statement – Revised recommendations for improving the quality of reports of parallel group randomized trials. <http://www.consort-statement.org>
- Morton, G., Barnett, D. & Hale, L. (1992). A comparison of performance measures of an added purpose task versus a single purpose task for upper extremities. *American Journal of Occupational Therapy*, 46(2), 128–133.
- Neistadt, M. (1992). Occupational therapy treatments for constructional deficits. *American Journal of Occupational Therapy*, 46(3), 141–148.
- Neistadt, M. (1994). The effects of different treatment activities on functional fine motor coordination in adults with brain injury. *American Journal of Occupational Therapy*, 48(10), 877–882.
- Nelson, N., Konosky, K., Fleharty, K., Webb, R., Newer, K., Hazboun, V., et al. (1996). The effects of an occupationally embedded exercise on bilaterally assisted supination in persons with hemiplegia. *American Journal of Occupational Therapy*, 50(8), 639–646.
- Nelson, N., Peterson, C., Smith, D., Boughton, J., Whalen, G. (1988). Effects of project versus parallel groups on social interaction and affective responses in senior citizens. *American Journal of Occupational Therapy*, 42(1), 23–29.
- Ottenbacher, K. & Maas, F. (1999). How to detect effects: statistical power and evidence-based practice in occupational therapy research. *American Journal of Occupational Therapy*, 53(2), 181–188.
- Pagnotta, A., Baron, M. & Bitensky, N. (1998). The effect of a static wrist orthosis on hand function in individuals with rheumatoid arthritis. *Journal of Rheumatology*, 25(5), 879–885.
- Parush, S. & Markowitz, J. (1997). The efficacy of an early prevention program facilitated by occupational therapists – A follow-up study. *American Journal of Occupational Therapy*, 51(4), 247–251.
- Polatajko, H. (1995). A clinical trial of the process oriented treatment approach for children with developmental co-ordination disorder. *Developmental Medicine and Child Neurology*, 37, 310–319.
- Ratchford, R. (1993). The effect of life reminiscence activities on depression and self-esteem in older adults. *American Journal of Occupational Therapy*, 47(3), 413–420.
- Robichaud, L. (1998). Efficacy of a sensory integration program on behaviors of inpatients with dementia. *American Journal of Occupational Therapy*, 48(4), 355–360.
- Sackett, D., Richardson, W., Gray, J. W., Haynes, R. (1996). Evidence-based medicine: what it is and what it isn't. *British Medical Journal*, 312, 71–72.
- Sackett, D., Richardson, W., Rosenberg, W., Haynes, R. (1997). *Evidence-based medicine – How to practice and teach EBM*. London: Churchill Livingstone.
- Severens, J., Oerlemans, H. & Weegels, A. (1999). Cost-effectiveness analysis of adjuvant physical or occupational therapy for patients with reflex sympathetic dystrophy. *Archives Journal of Physical Medicine and Rehabilitation*, 80(9), 1038–1043.
- Soderback, I. (1998). The effectiveness of training intellectual functions in adults with acquired brain damage. *Scandinavian Journal of Rehabilitation Medicine*, 20, 47–56.
- Steinbeck, T. (1986). Purposeful activity and performance. *American Journal of Occupational-Therapy*, 40(8), 529–534.
- Thralow, J. & Watson, C. (1974). Remotivation for geriatric patients using elementary school students. *American Journal of Occupational Therapy*, 28(8), 469–473.
- Van Deusen, J. & Harlowe, D. (1987). The efficacy of the ROM dance for adults with rheumatoid arthritis. *American Journal of Occupational Therapy*, 41(2), 90–95.
- Walker, M. (1999). Occupational therapy for stroke patients not admitted to hospital – A randomised controlled trial. *Lancet*, 354, 278–280.
- Wallis, G., Baldwin, M. & Higginbotham, P. (1983). Reality orientation therapy – A controlled trial. *British Journal of Medical Psychology*, 56, 271–277.
- World Federation of Occupational Therapists. <http://www.wfot.org.au>.
- Zimmerer, S. & Nelson, D. (1995). Occupationally embedded exercise versus rote exercise: a choice between occupational forms by elderly nursing home residents. *American Journal of Occupational Therapy*, 49(5), 397–402.
- Zisselman, M., Rovner, B., Shmueli, Y., Ferrie, P. (1996). A pet therapy intervention with geriatric psychiatry inpatients. *American Journal of Occupational Therapy*, 50(1), 47–51.

Appendix

Checklist for assessing clinical trials

Title : _____

General characteristics

Objective: Major _____
 Subsidiary _____

Population	Discussed?	Problems?
1. Type (patients/healthy) 2. Rationale for size (n) 3. Expected difference 4. How recruited? 5. Inclusion criteria 6. Exclusion criteria 7. Comparability of groups Demographic Prognostic criteria Stage of disease Response to therapy Associated disease Similarity to usual patients		
Treatment Compared	Discussed?	Problems?
1. Dose rationale and details (amount/time) 2. Dosage form, route 3. Duration of therapy		
Experimental Design	Discussed?	Problems?
1. Control 2. Assignment of treatments: Randomised? (balanced?) Stratification? Other 3. Timing (schedule of visits, laboratory tests)		
Data Collection	Discussed?	Problems?
1. Measurements used to access goal 2. Method of collection 3. Adverse effects Subjective (volunteered, elicited) Objective		
Results	Discussed?	Problems?
1. Clinical efficacy 2. Bacteriological efficacy 3. Safety 4. Drop-outs Reasons Effect on results		
Data Analysis	Discussed?	Problems?
1. Missing data 2. Statistical tests Differences No difference due to limited power?		

Overall quality score

Note:

"3" for a high quality study (methodologically strong without important weakness)

"2" for one of reasonable quality (some weaknesses in study design or results)

"1" for a weak study (definite shortcomings in design or results)

"0" for a poor study (serious weaknesses)