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Determinants of Citation in Epidemiological Studies on Phthalates

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Abstract

Gillian Davidson for technical help.

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er smmsg nonuloser deidconcentention sbodteMis diluted less than five times Objective-To determine the quality of randomised controlled trials of excercise therapy for back pain.

Design-Computer aided search of published papers and blinded assessment of the methods of studies.

Subjects-23 randomised controlled trials, of which 16 studied exercise therapy given by physiotherapists to individual patients with back pain. Other conservative treatments could be included.

Main outcome measures-Score for quality of methods (based on four main categories: study population, interventions, measurement of effect, and data presentation and analysis) and main conclusion of author(s) with regard to exercise therapy.

Results - Only four studies scored more than 50 points (maximum 100), indicating that most were of poor quality. Six studies found that exercise was better than reference treatments and 10 reported it to be no better or worse than the reference treatment. Those reporting positive results tended to have higher methods scores (4/6 positive v 4/10 negative scored ≥ 42).

Conclusions - No conclusion can be drawn about whether exercise therapy is better than other conservative treatments for back pain or whether a specific type of exercise is more effective. Further trials are needed in which greater attention is paid to methods of study.

Introduction

Epidemiological studies indicate that about 80% of the population will suffer from back pain during their active lives.12 Fortunately, the complaints are usually self limiting, and in about 90% of patients the complaints disappear within a few months, often with the help of some rest, analgesics, and home exercises.23 For patients with chronic back pain there are many therapeutic interventions available, but none seems to be clearly better than the others.23

Although exact figures are lacking, physiotherapy is probably the treatment most widely used for back complaints.46 Physiotherapists usually give exercise therapy, alone or in combination with other treatments (for example, massage, heat, traction, ultrasound, or short wave diathermy). Despite their widespread use the efficacy of these treatments still remains questionable.2378 Rationales for exercise in the management of back pain include relieving compression of the nerve in the intervertebral foramen, shifting nuclear material away from the bulging annulus (in the case of a protruded disc), increasing endorphin concentrations, strengthening weak muscles, decreasing mechanical stress, stabilising hypermobile segments, and improving posture and mobility.910 Whether the presumed rationale is valid can only be evaluated in randomised clinical trials. The methods used in such trials of physiotherapy have been shown to vary substantially.8 Studies with serious flaws in their methods tend to report biased outcomes. We present a review of randomised controlled trials assessing the efficacy of exercises for back pain.

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We conducted a MEDLINE search of papers published during 1966-90 (keywords: backache, musculoskeletal diseases, joint diseases, spinal diseases, physical therapy, evaluation studies, outcome, and process assessment). In addition, a number of relevant journals that are not covered by MEDLINE were screened. Abstracts and unpublished studies were not included. To be included in this review studies had to meet three conditions. Firstly, the physiotherapy regimen should include exercise therapy provided by physiotherapists. Additional physical treatment modalities (for example, ultrasound or short wave diathermy) were allowed. Studies in which the exercise therapy was given in groups (for example, fitness training, back school programmes) were excluded. Secondly, the subjects in the study must have had back pain at the moment of inclusion. Initially, we were also interested in the efficacy of physiotherapy exercises for neck pain, but only one study was found.11 Thirdly, the study must be a randomised clinical trial. This design is generally considered to be the paradigm for intervention studies because of its potential to provide a valid assessment of the efficacy of an intervention. 12 13

Table I shows the criteria used for assessing the methodological quality of the trials. This list was adapted from Ter Riet et al,14 and the criteria are based on generally accepted principles of intervention research.12 13 Studies could earn points in four categories dealing with the study population, interventions, measurement of effect, and data presentation and analysis. The maximum score was 100 points. The papers to be reviewed were first blinded for author(s), journal, and outcome by one of us (BWK). Thereafter the quality of the studies' methods was assessed by two blinded reviewers (HB, GJMGH) independently. In a subsequent meeting the reviewers tried to reach consensus on each criterion they disagreed about. Where disagreement persisted, a third blinded

TABLE I — Criteria for assessing methods in randomised clinical trials of physiotherapy exercises for back complaints

Cr	iterion* of 9330 benous from	Weighting
Sti	irea (table	
A	Homogeneity	is the 2 an
В	Comparability of relevant baseline	5
	characteristics	eater than
C	Adequate randomization procedure	For4xa
D	Drop outs described for each study group separately	main ³
E	<20% loss to follow up	ed 212 se
73	<10% loss to follow up	2
F	>50 subjects in the smallest group	8
	>100 subjects in the smallest group	15 01 9
Int	erventions (n=25):	
G	Interventions included in protocol and described	10
H	Pragmatic study	5
I	Co interventions avoided	e cx 05 m
J	Placebo controlled	please 5 of
Me	asurement of effect (n=30):	CIUMON (M
K	Patients blinded	s greater.
L	Relevant outcome measures	10 08
M	Blinded assessments of outcome	10
N	Adequate follow up period	5
Da	a presentation and analysis (n=10):	ess Tus o
0	Intention to treat analysis	5
P	Frequencies of most important outcomes	5
	presented for each treatment group	CHES CAP WAY

^{*}Further details given in appendix.

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L M Bouter, PHD, associate professor of epidemiology H Beckerman, MSC, research fellow losuneury [editorial]. Lancer

G J M G van der Heijden, MA, research fellow PG Knipschild, MD, professor of epidemiology

Correspondence to: Mr Koes.

BMJ 1991;302:1572-6

reviewer (LMB) made the final decision. The assessments resulted in a hierarchical list in which higher scores indicate studies that used better methods.

A study was labelled "positive" if its author(s) concluded that one of the exercise modalities was more effective than the reference treatment. Generally, this meant that the differences were significant. A study was considered "negative" when the author(s) reported no difference between the study treatments or showed better results with the reference treatment.

Results

on visual analogue scale for pain and

Results

5-0 (-8-4/31-4); (1) 2-0 (-11-7/

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rating (5 point scale) after 5 weeks:

11.8; (iii) 7.6. isometric

er 4 and 12 weeks: (exercises i and n

A total of 23 studies were considered for inclusion, seven of which were rejected. In three of these all study groups received the same exercises thus making it impossible to assess the effects of the exercise regimen separately,15-17 two publications described different aspects of the same trial in which the exercises were given in groups, 18 19 and in one trial only a few patients in both study groups performed exercises.20 Two publications turned out to deal with the same study. After assessing both publications the one with the lowest score was rejected.²¹ Sixteen randomised clinical trials met the conditions for inclusion. Table II presents all trials in a hierarchial order according to their methods score.

Only four trials scored 50 or more points, indicating that the methods of most studies were poor. The main shortcomings were: lack of description of drop outs, considerable loss to follow up, small samples sizes, use of cointerventions with exercise therapy, no placebo control group, lack of blinding of patients, and no intention to treat analysis.

or necessary -laberaries of terrorisas microscope coments Positive result (n=6)Negative result (n=10)100

Relation between methods score of trials and their results. (Positive result shows exercise is better than reference treatment, negative result shows exercise is no better or worse than reference treatment)

Methods score

The figure presents the relation between the methods score and the overall conclusion (positive or negative) of the studies. Included are six positive studies and 10 negative studies. Only four (40%) of the 10 negative studies scored 43 points or more, while four (67%) of the six positive studies scored 42 points or more. In general the positive studies seemed to have higher methods scores.

It is difficult to draw conclusions about the efficacy of exercise therapy, because some studies compare exercise therapy with another conservative treatment

of measurement sumus missing values (irrespective

TABLE II—Randomised trials of the efficacy of exercise therapy for back pain in order of methods score

e extension significantly	Score for methods criteria*												fic	llow up >	10% analysis on intention to				
eeks): (i) 38%, (ii) 35% rodtu	A (2)	B (5)	C (4)	D (3)	E (4)	F (17)	G (10)	H (5)	I (5)	J (5)	K (5)	L (10)	M (10)	N (5)	O (5)	P (5)	Total score	Indication†	Conclusion‡
Deyo et al ²²	1	3	4	3	2	8	10	5		hine		10	2	3	5	5	61	Chronic low back pain	Positive
Manniche et al ²³	0 12 10	respire	4	3	2		10	5		religion so		10	2	5	10015	5	54	Chronic low back pain	Positive
Evans et al24	2	5				8	10	5				10	2	5		5	50	Acute low back pain	Negative
Coxhead et al25	1	2			4	17		5				6		5	ort.5 91	5	50	Sciatic symptoms	Negative
Lidström, Zachrisson 4	1	2		3	4		10	5				6	2	3	5	5	46	Chronic low back pain and sciatica	Positive
Zylbergold, Piper 5	1 .	2		3	4		10	5				6		3	5	, 5	44	Lumbar disc disease	Negative
Waterworth, Hunter 26	2	508		3	4	Imoa	5	5	5	as or	DEFE	6	mo	3	5	ni o	090B43 B	Acute low back pain	Negative
Stankovic, Johnell 27	blog	3	4	3	4		10	5		ISSIA	rige.	2	1570	5	5	TEN I	3 5 18 42 100	Acute low back pain	Positive
Nwuga 28	2	4	2				10	5			3	2	2	3		. 5	38	Prolapsed disc	Negative
Farrell, Twomey 29	2	5	up tun		2	I CAM	10	5				8	2	3	HOIË		37	Acute low back pain	Negative
Kendall, Jenkins 30	alam	trip	2		2	TAY B	10	5				6	2	3		5	36	Chronic back pain	Positive
Martin et al6	2		2		ation		10	5		5		6	2	3			35	Chronic low back pain	Negative
Davies et al ³¹	2	3	sere i	JaJ .	4		19191	5	1533	461711	3	6	2	3		5	33	Sub (acute) low back pain	Negative
Buswell ³²	2011	some			of y		10	5	14. USE	time	DIT	4	riser	5	5	ringe	30	Chronic low back pain	Negative
Nwuga, Nwuga ³³	2	2	2 .				alaide	5	TEAR		3	4	2	3	a tor	5	28	Prolapsed disc	Positive
White ³⁴	1 98	xerc	o diff	413		8		5	5	Philli	1166	2	58A 1	3	10 1	dires	24	Chronic low back pain	Negative

^{*}See appendix for details of criteria.

†The labels chronic and acute are according to the authors of the study. Classification might therefore vary between the studies.

‡Conclusion of the authors(s) of the study. Positive conclusion=exercise better than control treatment; negative conclusions=exercise worse than or equally effective as control treatment.

TABLE III—Details of trials comparing exercise therapy with other conservative treatments

Author		Exercise regimen (No of patients)	R	eference treatment (No of patients)	Method	s score	Results*
Lidström, Zachrisson	(i)	Isometric strengthening and pelvic traction (20)	(iii)	Hot packs and rest (21)	5V8V4	5 mod	No of patients with noticeable improvement after 4 weeks: (i) 17, (ii) 9, (iii) 12
an extension pro-	(ii)	Mobilising/strengthening hot packs and massage (21)		na cintrionarithm other pro cintomo ao amor iam	no esti		Patients in group (i) significantly better than those in other groups
Zylbergold, Piper ⁵	3-1	Flexion and heat (10) Home care instructions (10)	(iii)	Manual therapy and heat (8)	Polinte etails c	the break	Mean (SD) change in pain intensity on 5 point scale after 1 month: (i) $-1.0 (0.85)$, (ii) $-1.5 (0.10)$, (iii) $-0.6 (0.82)$. No significant difference in pain or mobility
Waterworth, Hunter,26	(i)	Flexion and extension, short wave diathermy and ultrasound (34)	277113	Non-steroidal anti-inflammatory drugs (36) Manipulation (38)	00 d	Bur ve	Mean change in pain intensity on 4 point scale after 4 and 12 days: (i) -0.9 , -1.6 ; (ii) -0.9 , -1.7 ; (iii) -1.1 , -1.7 . No significant difference in pain and mobility
Stankovic, Johnell ²⁷	(i)	McKenzie (extension) (50)	-	Mini back school (50)	ь 42	2 70 81	Less pain in exercise group with reference at 3 weeks and a year (no data)
Nwuga ²⁸ anizinal bru	(i)	Isometric flexion back and abdominal muscles and short wave diathermy (25)		Manipulation (26)	g the	S Steel 8	Improvement in spinal flexion and straight leg raising: (i) 13°, 4°; (ii) 4 34°, 39°. Manipulation significantly better than exercise
Farrell, Twomey29	(i)	Isometric flexion abdominal muscles and microwave diathermy (24)	(ii)	Manipulation and mobilisation (24)	chronn:	7	Manipulation group were symptom free in significantly less days (data in graphs)
Davies et al31		Extension and short wave diathermy (14) Isometric flexion and short wave diathermy (14)		Short wave diathermy (15)	ine ber		No of patients showing improvement after 2 and 4 weeks: (i) 11, 13; (ii) 7, 12; (iii) 8, 10. No significant difference

^{*}Results of the most important outcome measure according to the author(s) of the study. When not explicitly stated presentation of pain or a global measure of improvement. p Values < 0.05 were taken as significant.

Author		Exercise regimen (No of patients)	Reference treatment (No of patients)	Methods score	Results*
Deyo et al ²²	(i)	electrial nerve stimulation (34)	ii) Transcutaneous electrial nerve stimulation (31)	bell 61 al	Mean improvement on visual analogue scale for pain and activity (0-100%) after 4 and 12 weeks: (exercises i and ii)
	(ii)) Stretching exercises and sham (i transcutaneous electrical nerve stimulation (29)	v) Sham transcutaneous electrical nerve stimulation (31)	he reference	52%, 48%; (reference iii and iv), 37%, 41%. Exercise significantly better
Evans et al ²⁴	flugger (i)	(65) (i	ii) Bedrest (60) v) No intervention (65)	50	No of patient reporting no pain after 6 and 12 weeks: (i) 34, 47 (ii) 33, 46 (iii) 36, 44 (iv) 33, 43
	(ii)) Isometric flexion and education (62)	study treatments or showed		No significant difference in pain, mobility or daily activities
Coxhead et al ²⁵	(i)	Exercises using all ranges of motion and (i muscle groups given alone or with traction, manipulation, or corset (150)	i) No intervention, traction, manipulation, or corset (142)	ith the refer	No of patients reporting to feel better compared with baseline after 4 weeks and 4 months: exercise (i) 120, 85; reference (ii) 107, 96. No significant difference
Martin et al*	(i) (ii)	Mobilising abdominal and back muscles (i (12) Isometric abdominal and pelvic floor muscles (12)	ii) Detuned ultrasound and detuned short wave diathermy (12)	35 muhlisited	Change in pain intensity (5 point scale) after 5 weeks (i) decrease, (ii) increase (iii) decrease. No significant difference in this or other physiological and clinical measures

^{*}Results of the most important outcome measure according to the author(s) of the study. When not explicitly stated presentation of pain or a global measure of improvement. p Values < 0.05 were taken as significant.

TABLE V—Details of trials comparing different exercise regimens

ne low back pain

Positive

Positive

Negative

Vegative

Positive

Negative

Negative

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Positive.

NEGRATIVE

Negative

Negative

Negative

remods score	Author	Exercise regimen (No of patients)	Methods score	Results*
e than reference readment, negative result e than reference readment) e than reference readment) clasion between the methods	Manniche et al ²³	i) Intensive back extensor (27) ii) Mild isometric and massage and hot compress (32) iii) Mild back extensor (31)		Improvement (median and 10th/90th centile) in combined pain, disability, physical impairment index (0-100 points) after 3 and 9 months: (i) 14·7 (-3·2/29·4), 15·0 (-8·4/31·4); (ii) 2·0 (-11·7/19·5), 5·5 (-12·8/19·5); (iii) 5·7 (-4·4/23·7), 7·0 (-11·0/21·5). Intensive back extensor exercises (i) significantly better
re six positive studies and 10 ur. (40%) of the 10 negative		i) Isometric flexion and pelvic traction (20) ii) Mobilising/strengthening, hot packs and massage (21)	46	No of patients with noticeable improvement after 4 weeks: (i) 17, (ii) 9. Isometric flexion (i) significantly better than (ii), but not significant
er more, while four (67%) of cored 42 points or more. In	Kendall, Jenkins ³⁰	i) Isometric flexion (14) ii) Mobilising (14) iii) Extension (14)	36	No of patients symptoms free or improved after 1 and 3 months: (i) 13, 11; (ii) 11, 8; (iii) 7, 6. Isometric flexion significantly better
lies seemed to have higher		i) Isometric flexion abdominal and pelvic floor- muscles (12) ii) Mobilising abdominal and back muscles (12)	al or szol old	Change in pain rating (5 point scale) after 5 weeks: (no exact figures given) (i) deterioration (ii) improvement. No differences in physiological and clinical measures
ause some studies compare	AAND SEA CREAMBLANCE DISKS!	i) Isometric flexion and short wave diathermy (14)	33	No of patients improved after 2 and 4 weeks: (i) 7, 12 (ii) 11, 13. No significant difference
HIGHLIKEL SVERVIERIOE TEHNO	Buswell ³²	ii) Extension and short wave diathermy (14) i) Flexion programme (25) ii) Extension programme (25)	30	Similar improvement in pain and function after treatment for both groups (duration and exact figures not given)
		i) McKenzie (extension) (31) ii) Williams (flexion) (31)	28	Change in 10 points pain rating after 6 weeks: (i) -5.3, (ii) -2.7. McKenzie extension significantly better
Indication† Conclusion‡		i) Mild static trunk and short wave diathermy (76) ii) Vigorous flexion and extension (72)	24	Proportion of patients showing improvement after treatment (maximum 7 weeks): (i) 38%, (ii) 35%. No significant difference

^{*}Results of the most important outcome measure according to the author(s) of the study. When not explicitly stated presentation of pain or a global measure of improvement.

or with a placebo therapy, or both, whereas other studies compare different types of exercise. Tables III-V give more specific information on the interventions and the study results.

> Table III shows the seven trials that contrasted exercise therapy with other conservative treatments. Two studies found that exercise therapy was better than hot packs and rest, or mini back school (that is one session of 45 minutes with instructions and education).27 In the last study the difference between the two groups was still present one year after randomisation. The five other studies indicated that exercise therapy was not better than manual therapy or home care instructions, non-steroidal anti-inflammatory drugs,26 manipulation,28 manipulation and mobilisation,29 or short wave diathermy.31 These studies included patients with either acute or chronic back pain. However, three negative studies had a low methods score (<40 points).

> Table IV gives details of four trials that contrasted exercise therapy with no exercise therapy or placebo therapy. The studies that compared with no exercise therapy used factorial designs22 24 25; the other comparisons included in the factorial design will not be discussed. The study with the highest methodological score22 showed that exercise therapy was better than no exercise therapy for chronic low back pain. After three months follow up the benefit had disappeared. Two other studies with high methods scores found no positive effect for patients with acute low back pain²⁴ and patients with sciatic symptoms.25 The only

study comparing exercise therapy with placebo therapy (detuned ultrasound and detuned short wave diathermy) indicated no differences in effect.5

reperting to be reviewed were first blindedowned in the

Table V shows the eight trials which compared different types of exercise therapy. The comparisons were mainly between isometric flexion exercises and extension exercises. Four studies reported no differences between the exercise regimens, but these had major flaws in the design (≤35 points).6 31 32 34 In four other studies the results favoured one type of exercise therapy over other types. 4 23 30 33 In the study with the highest score23 the results favoured an exercise scheme of three months intensive dynamic back extensor exercises over a similar treatment at one fifth of the exercise intensity and mild isometric training, massage, and heat for patients with chronic low back pain. One other study found on an extension programme to be better than a flexion programme,33 but two studies suggested that a flexion programme was better. Lidstrom and Zachrisson reported that isometric flexion exercises in combination with pelvic traction were more effective than mobilising and isotonic strengthening exercises in combination with massage and heat,4 and Kendall and Jenkins showed that flexion was more effective than both mobilising exercises and extension exercises.30

Discussion

The 16 trials included in our review can be considered to be the best studies evaluating the efficacy of

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(iii) 8, 10. No significant difference

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p Values < 0.05 were taken as significant. throng low back pain and scianca

physiotherapy exercises for back pain. Because of their use of control treatments and random allocation of the patients their potential to supply valid answers on this topic is much larger than that of uncontrolled or nonrandomised studies. Nevertheless, we have found that most randomised clinical trials investigating the efficacy of physiotherapy exercises for back pain have major flaws in their methods. Our screening suggests that in the future more attention should be given to the size of the study populations, prevention of loss to follow up (including an adequate description of the patients lost to follow up), comparison with placebo therapy (to control for placebo effects and to avoid bias of effect measurements), and adequate data presentation and statistical analysis.

The reviewers who assessed the trials were blind to the outcome of the studies to prevent reviewer bias. This method has been described by Chalmers et al and used to assess the quality of trials on other topics.35 36 The criteria chosen for assessing the methods of the studies were not intended to be exhaustive. By using these criteria, however, we believed (before as well as after assessment of the trials) that we could distinguish good studies from bad ones. We chose not to pool the results of the available trials, mainly because we dislike pooling data from studies of high and low methodological quality. The trials that reported negative results of exercises more often had relatively low methods scores. We did not pool the results of the trials with higher methods scores because we thought that the patient characteristics and treatments used in these trials were not similar enough to permit pooling.

The weights that are given to the criteria listed in table 1 have been chosen arbitrarily. For example, we gave sample size a large weight (17 points). The first argument for this was our concern for prognostic comparability at baseline. Because there is only limited knowledge of the aetiology in most cases of back pain and neck pain a major problem is to obtain a homogeneous study population. With increasing numbers of participants one can be more confident that the randomisation procedure will succeed in dividing the known and unknown prognostic factors equally over the study groups. We also thought that publication bias would be less likely with large sample sizes. The effort and costs entailed increase the probability that the trial will be submitted and accepted for publication.37 The description of an adequate randomisation procedure was given low weight (four points) as all the studies included were randomised clinical trials and thus satisfied our demand of random allocation of the participants. Studies could, however, earn points with a proper description of an adequate randomisation procedure. Generally the weights were based on our assessment of the relative importance of each criterion. Readers may wish to choose different weights for specific criterion and calculate their own scores.

We conclude that the quality of intervention research on physiotherapy exercises is disappointingly low. Despite its frequent application exercise therapy has not been shown to be more efficacious than other conservative treatment modalities, nor has it been shown to be ineffective. There is little evidence in favour of a specific exercise regimen. Further trials are clearly needed in which much more attention is given to the methods of the studies.

Appendix

Scoring for criteria listed in table I. Each criterion must be applied independently of the other criteria.

A Description of inclusion and exclusion criteria (1 point).

Restriction to a homogeneous study population (1 point).

B Comparability for duration of complaints, value of

outcome measures, age, recurrences, and radiating complaints (1 point each).

C Randomisation procedure described (2 points).

Randomisation procedure which excludes bias (2 points).

D Information about which group subjects dropped out from with reason for withdrawal (3 points).

- E Loss to follow up: all randomised patients minus the number of patients still in study at main point of assessing the main outcome measure (according to the author(s)), divided by all randomised patients multiplied by 100.
- F Size of smallest group immediately after randomisation.
- G Physiotherapy treatment explicitly described (5 points).
 All reference treatments explicitly described (5 points).
- H Comparison with other treatments.
- Other medical interventions avoided in the design of the study (except analgesics or use at home of heat, rest, or a routine exercise scheme).
- Comparion with placebo therapy.
- K Placebo controlled study: attempted blinding (3 points), blinding evaluated and fully successful (2 points).

 Pragmatic study: patients fully naive (3 points), or time restriction (no physiotherapy exercises in at least one year) (2 points), naiveness evaluated and fully successful
- (2 points).
 L Outcome measures assessed and reported: pain, global measure of improvement, functional status (activities of daily living), spinal mobility, use of medication and medical services (2 points each).
- M Each blinded measurement mentioned under criterion L earns 2 points.
- Outcome measures assessed during or just after treatment (3 points). Outcome measures assessed after six months or longer (2 points).
- O Intention to treat analysis. When loss to follow up is less than 10% analysis of data is on all randomised patients for main outcome measures and at the most important times of measurement minus missing values (irrespective of non-compliance and cointerventions). When loss to follow up >10% analysis on intention to treat basis as well as a worst case analysis that accounts for missing values.
- P Frequency of main outcome measures at the most important times of measurement. In the case of (semi) continuous variables presentation of the mean or median with a standard error or centiles.
- 1 Kelsey JL, White AA. Epidemiology and impact of low back pain. Spine 1980;5:133-42.
- 2 Frymoyer JW. Back pain and sciatica. N Engl J Med 1988;318:291-300.
- 3 Spitzer WO, Leblanc FE, Dupuis M, eds. Scientific approach to the assessment and management of activity-related spinal disorders. Spine 1987;12 (suppl 7):1-59.
- 4 Lidström A, Zachrisson M. Physical therapy on low back pain and sciatica. Scand J Rehabil Med 1970;2:37-42.
- 5 Zylbergold RS, Piper MC. Lumbar disc disease: comparative analysis of physical therapy treatments. Arch Phys Med Rehabil 1981;62:176-9.
- 6 Martin PR, Rose MJ, Nichols PJR, Russell PL, Hughes JG. Physiotherapy exercises for low back pain: process and clinical outcome. Int Rehabil Med 1980;8:34-8.
- 7 Nachemson A. A critical look at the treatment for low back pain. Scand J. Rehabil Med 1979;11:143-7.
- 8 Deyo RA. Conservative therapy for low back pain. JAMA 1983;250:1057-62.
 9 Jackson CP, Brown MD. Is there a role for exercise in the treatment of patients with low back pain? Clin Orthop 1983;179:39-45.
- 10 Jackson CP, Brown MD. Analysis of current approaches and a practical guide to prescription of exercise. Clin Orthop 1983;179:46-54.
- 11 Goldie I, Landquist A. Evaluation of the effects of different forms of physiotherapy in cervical pain. Scand J Rehabil Med 1970;2:117-21.
- 12 Meinert CL. Clinical trials: design, conduct and analysis. New York: Oxford University Press, 1986.
- 13 Feinstein AR. Clinical epidemiology: the architecture of clinical research.
 Philadelphia: WB Saunders, 1985.

 14 Ter Riet G, Kleijnen J, Knipschild P. Acupuncture and chronic pain: a
- criteria-based meta-analysis. J Clin Epidemiol 1990;43:1191-9.

 15 Macdonald RS, Bell CMJ. An open controlled assessment of osteopathic
- manipulation in non-specific low-back pain. Spine 1990;15:364-70.

 16 Klaber-Moffett JA, Chase SM, Portek I, Ennis JR. A controlled prospective study to evaluate the effectiveness of a back school in the relief of chronic low back pain. Spine 1986;11:120-2.
- 17 Landen BR. Heat or cold in the relief of low back pain. Phys Ther 1987;47:1126-8.
- 18 Harkaapa K, Jarvikoski A, Mellin G, Hurri H. A controlled study on the outcome of inpatient and outpatient treatment of low back pain. 1. Pain, disability, compliance, and reported treatment benefit. Scand J Rehabil Med 1989;21:81-9.
- 19 Mellin G, Hurri H, Harkaapa K, Jarvikoski A. A controlled study on the outcome of inpatient and outpatient treatment of low back pain. 2. Effects on physical measurements three months after treatment. Scand J Rehabil Med 1989;21:91-5.

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20 Meade TW, Dyer S, Browne W, Townsend J, Frank OA. Low back pain of mechanical origin: randomised comparison of chiropractic and hospital outpatient treatment. BMJ 1990;300:1431-6.

21 Gilbert JR, Taylor DW, Hildebrand A, Evans C. Clinical trial of common treatments for low back pain in family practice. BMJ 1985;291:791-4.

22 Deyo RA, Walsh NE, Martin DC, Schoenfeld LS, Ramamurthy S. A controlled trial of transcutaneous electrical nerve stimulation (TENS) and exercise for chronic low back pain. N Engl J Med 1990;322:1627-34.

23 Manniche C, Hesselsoe G, Bentzen L, Christensen I, Lundberg E. Clinical trial of intensive muscle training for chronic low back pain. Lancet 1988;ii:1473-6.

24 Evans C, Gilbert JR, Taylor DW, Hildebrand A. A randomized controlled trial of flexion exercises, education, and bed rest for patients with acute low back pain. *Physiotherapy Canada* 1987;39:96-101.

Coxhead CE, Inskip H, Meade TW, North WRS, Troup JDG. Multicentre trial of physiotherapy in the management of sciatic symptoms. Lancet 1981;i:1065-8.
 Waterworth RF, Hunter IA. An open study of diflunisal, conservative and

manipulative therapy in the management of acute mechanical low back pain.

NZ Med J 1985;95:372-5.

27 Stankovic R, Johnell O. Conservative treatment of acute low back pain: a prospective randomized trial. Spine 1990;15:120-3.

28 Nwuga VCB. Relative therapeutic efficacy of vertebral manipulation and

conventional treatment in back pain management. Am J Phys Med 1982;61:273-8.

29 Farrell JP, Twomey LT. Acute low back pain: comparison of two conservative treatment approaches. Med J Aust 1982;1:160-4.

30 Kendall PH, Jenkins JM. Exercises for backache: a double-blind controlled trial. Physiotherapy 1968;54:154-7.

31 Davies JR, Gibson T, Tester L. The value of exercises in the treatment of low back pain. Rheumatology and Rehabilitation 1979;18:243-7.

32 Buswell J. Low back pain: a comparison of two treatment programmes. New Zealand Journal of Physiotherapy 1982;10:13-7.

Zealand Journal of Physiotherapy 1982;10:13-7.

33 Nwuga G, Nwuga V. Relative therapeutic efficacy of the Williams and McKenzie protocols in back pain management. Physiotherapy Practice.

1985;1:99-105.

34 White AWM. Low back pain in men receiving workmen's compensation. Can Med Assoc J 1966;95:50-6.

35 Chalmers TC, Smith H, Blackburn B, et al. A method for assessing the quality of a randomized control trial. Controlled Clin Trials 1981;2:31-49.

Tysen J, Furzan J, Reisch J, et al. An evaluation of the quality of therapeutic trials in perinatal medicine. J Pediatr 1983;102:10-3.
 Kleiinen J, Knipschild B, Tee Birt G. Olivin in the control of the quality of therapeutic

37 Kleijnen J, Knipschild P, Ter Riet G. Clinical trials of homoeopathy. BMJ 1991;302:316-23.

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Complications of pregnancy and delivery in relation to psychosis in adult life: data from the British perinatal mortality survey sample

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Abstract

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Objective—To evaluate whether events occurring at or around the time of birth contribute to the onset of psychotic illness in adult life.

Design—Pregnancy and birth complications as possible causes of adult mental illness were studied in the population sample of the British perinatal mortality survey. Subsequent psychiatric admissions were independently identified through the Mental Health Enquiry and records of regional and special health authorities. Logistic regression was used to compare data on perinatal deaths with those on survivors to determine factors independently associated with perinatal death, and this equation was then used to calculate the risk of perinatal death for each survivor.

Subjects—16 980 people born in a single week in 1958 (the British perinatal mortality survey sample), including 252 patients admitted to psychiatric care; case notes of 235 patients were supplied.

Main outcome measures and results—Patients with a schizophrenic illness (whether defined by "broad" (n=57) or "narrow" (n=35) diagnostic criteria) did not have a greater mean risk of perinatal death than the population in general, but there was some evidence of increased liability (relative risk 2.43; 95% confidence interval 1.17 to 5.05) for those with affective psychosis (n=32). Specific high risk variables for affective psychosis were decreased gestation time (273.9 v 281.2 days; mean difference 7.3 days, 95% confidence interval 3.1 to 11.5; p<0.002) and prescription of vitamin K to the child in the first week of life (19% of patients v 5% of controls, p=0.016).

Conclusions—The findings give no support to theories that factors predicting perinatal mortality contribute significantly to causation of schizophrenic illness. Further investigation of decreased gestation length in relation to affective disorder is required.

Introduction

Schizophrenia and manic-depressive psychosis (the "functional" psychoses), the major causes of severe psychiatric morbidity in adult life, have a worldwide distribution with lifetime prevalences, where these

have been assessed, of 2-3%. The role of genetic factors has been established by twin⁴⁻⁶ and adoption studies. It is often assumed there are also environmental contributions, but their nature is obscure.

One suggestion is that brain damage occurring at or around the time of birth in some way contributes to the later onset of psychosis. The time interval (on average over 20 years) means that there are substantial practical difficulties in examining an association between perinatal trauma and the later development of psychosis. There have been two types of study: the first (retrospective) has identified a sample of schizophrenic patients and obtained information about their birth histories; the second (high risk) studied the confinements of mothers with schizophrenia, whose children are at high risk of going on to develop schizophrenia.

Retrospective studies (reviewed in table I)9-20 may include carefully selected and documented schizophrenic patients, but it is often difficult to obtain birth histories of good quality. Table I shows that in seven of 13 studies data were collected in whole or in part by asking the mother to recollect quite specific details after the patient had become ill (that is, after the passage of 20 or more years). Clearly neither she nor the person recording the history would have been blind to the fact that the patient had become mentally ill, and it cannot be assumed that this knowledge did not affect the information given or recorded. A more appropriate method is to make use of birth histories recorded before the onset of illness—that is, obtained through reference to obstetric records. Such records are often unsystematic, and they have been shown to be prone to error.21 The weakness of retrospective studies has been discussed by Lewis, who stated that the link between schizophrenia and a history of presumed obstetric complications "hides a wide discrepancy in methodology between studies. Paradoxically, the main similarity between the studies is their collective weakness: the use of retrospective assessment of obstetric histories even if assessed blindly."22

High risk studies²³⁻²⁸ may acquire birth histories of a high quality, but accounts of the mental states of the offspring in the period of maximum risk for schizophrenia in adult life are usually not available.

The separate limitations of retrospective and high risk studies can be overcome only by a systematic collection of birth histories of a large cohort in which a

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