Psychological rehabilitation after myocardial infarction: multicentre randomised controlled trial

D A Jones, R R West

Abstract

***Objective*—To evaluate rehabilitation after myocardial infarction.**

***Design*—Randomised controlled trial of rehabilitation in unselected myocardial infarction patients in six centres, baseline data being collected on admission and by structured interview (of patients and spouses) shortly after discharge and outcome being assessed by structured interview at six months and clinical examination at 12 months.**

***Setting*—Six district general hospitals.**

***Subjects*—All 2328 eligible patients admitted over two years with confirmed myocardial infarction and discharged home within 28 days.**

***Interventions*—Rehabilitation programmes comprising psychological therapy, counselling, relaxation training, and stress management training over seven weekly group outpatient sessions for patients and spouses.**

***Main outcome measures*—Anxiety, depression, quality of life, morbidity, use of medication, and mortality.**

***Results*—At six months there were no significant differences between rehabilitation patients and controls in reported anxiety (prevalence 33%) or depression (19%). Rehabilitation patients reported a lower frequency of angina (median three versus four episodes a week), medication, and physical activity. At 12 months there were no differences in clinical complications, clinical sequelae, or mortality.**

***Conclusions*—Rehabilitation programmes based on psychological therapy, counselling, relaxation training, and stress management seem to offer little objective benefit to patients who have experienced myocardial infarction compared with previous reports of smaller trials.**

Introduction

A role for rehabilitation after acute myocardial infarction "to ensure the best possible physical, psychological and social conditions so that patients . . . may, by their own efforts, preserve their proper place in society" has been widely acknowledged.[1,2] Physical rehabilitation owes its origins to "armchair" treatment.[3] While post-discharge exercise based rehabilitation developed in some countries[4] Britain lagged behind[5]: until recently most survivors in Britain were discharged with no more than one page of written advice. Patients who have experienced myocardial infarction may also suffer anxiety or depression,[6-8] and some rehabilitation initiatives developed round psychological therapy.[9]

Several small trials attempted to evaluate group therapy, counselling, psychoeducation, and relaxation training.[10-15] A larger trial of type A behaviour modification among 849 men reported significant reduction in cardiological end points (fatal and non-fatal myocardial infarction combined).[16] Another, of 461 men, reported reduction in cardiac mortality after one year of supportive therapy for patients ascertained by monthly telephone interview to be in need.[17] The only multicentre collaboration with enough power to detect a mortality reduction of about 20% was of comprehensive rehabilitation[18] and therefore could not be cited as an evaluation of psychological therapy.

Published reports implied possible benefit in several different morbidity measures and in cardiac mortality, but even by pooling the findings of all trials the reduction in mortality failed to achieve significance at the 5% level. Furthermore, most trials included only men aged under 65, whereas nearly one third of patients with myocardial infarction are women and nearly half are aged over 65. It was therefore not possible to generalise trial findings to all potentially eligible patients.

Against this background a randomised controlled trial was designed to evaluate rehabilitation by psychological therapy and counselling independent of possible contamination by exercise training or risk factor modification. The rehabilitation programme was designed to be suitable for patients of all ages with few practical exclusions; to be considered appropriate and practicable by referring clinicians, rehabilitation therapists, and health service managers; and to be acceptable to patients. Sample size was based on an anticipated reduction in one year mortality from 15% to 12% (significance $P<0.05$ and 80% power) based on overviews of previous trials and a 20% reduction in the prevalence of clinically significant anxiety and depression. A multicentre design was chosen to accommodate interhospital variation in needs of patients for formal rehabilitation and in delivery of the common programme.

Methods

All patients discharged home from hospital within 28 days of confirmed myocardial infarction were entered into the trial irrespective of age, sex, or previous cardiac history. The only exclusions were for prolonged hospital stay (over 28 days) and discharge to long term institutional care. The rehabilitation programme was designed in collaboration with physicians, clinical psychologists, nurses, and managers to provide psychological therapy and opportunities for group and individual counselling. The programme comprised seven two hour outpatient sessions led by clinical psychologists and health visitors.

Principal objectives were (*a*) to give information about the heart and circulation, heart disease, myocardial infarction, treatment and management, and the natural recovery process in order to allay fears and reduce anxiety; (*b*) to increase awareness of stress and stressful situations; (*c*) to teach relaxation skills; (*d*) to improve responses to stressful situations and develop coping skills; (*e*) to promote positive adjustment to illness; and (*f*) to rebuild confidence in patients and spouses. Sessions included teaching, practical exercises with patient participation, group discussion, and individual counselling. The importance of practice between sessions was emphasised and patients were asked to keep records of progress with diaries of activity, stress, and relaxation. Patients and spouses were given the opportunity to discuss problems, concerns, experiences, anxieties, fears, and coping strategies separately. Other components of comprehensive rehabilitation—smoking, diet, weight control, exercise—were not included in the programme.

Randomisation to intervention and control groups was undertaken at the coordinating centre with knowl-

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BMJ 1996;313:1517–21

Table 1—*Prevalence of angina, glyceryl trinitrate medication, disability, anxiety, and depression at baseline and frequencies or scores*

	Rehabilitation patients (n = 1159)		Controls (n = 1155)	
	No	(%)	No	(%)
Angina[21]	630	(55)	612	(54)
In past week	438	(38)	449	(39)
Frequency per week,median (5th, 95th centiles)	4 (1, 30)		4 (1, 24)	
Glyceryl trinitrate (patch, spray, tablets)	446	(39)	473	(41)
In past week (spray, tablets)	341	(30)	375	(33)
Frequency per week, median (5th, 95th centiles)	4 (1, 30)		4 (1, 25)	
Disability[23]:				
None	142	(12)	143	(13)
Mild	482	(42)	457	(40)
Moderate	295	(26)	298	(26)
Severe	221	(19)	244	(21)
Anxiety[26]:				
Clinically significant†	378	(33)	350	(31)
Score, median (5th, 95th centiles)	2 (0, 9)		2 (0, 9)	
Depression[26]:				
Clinically significant†	213	(19)	219	(19)
Score, median (5th, 95th centiles)	1 (0, 8)		1 (0, 9)	

†Scores of 4 or more.

edge only of date of admission and eligibility for discharge and not of patients' ages, severity of infarct, progress of recovery, or durations of stay. All patients in the intervention group were invited by letter from their consultant physician (posted from the coordinating centre) to attend a seven week course of rehabilitation to start two to six weeks after discharge. Spouses (or partners) were invited to attend the first two sessions. Patients in the control group were managed according to current discharge procedures with no formal rehabilitation. Cases and controls received the usual cardiological care by their general practitioner, at the district general hospital, or at a specialist referral centre, as considered appropriate clinically.

Baseline information was collected, firstly, as a one page clinical summary in the coronary care unit, with enough information to calculate a prognostic index[19 20] (the information including details of any previous myocardial infarction, hypertension, diabetes, site of infarct, electrocardiogram, enzyme values, and complications). Secondly, patients and spouses were interviewed separately at home by trained interviewers, blind to their randomisation status. The structured interview schedule included validated questionnaires for angina,[21] usage of glyceryl trinitrate, diet,[22] functional disability,[23] leisure time exercise,[24] smoking[25] and drinking,[26] social support, anxiety and depression,[27] state anxiety,[28] attitudes to myocardial infarction, and expectations of future life.

Outcome was assessed at six months by a second structured interview in the patients' homes, by clinical examination at 12 months in the hospital outpatient department, and by long term mortality follow up. The second interview covered further myocardial infarction, coronary artery surgery, angina, medication,[29] functional disability, psychological wellbeing, social support, sexual activity, and leisure activities and, as potential confounders, diet, smoking, drinking, and exercise. Having maintained case or control "blindness" through the standard questions, the interview concluded by seeking patients' assessment of the programme or reasons for non-attendance, as appropriate. Spouses were also reinterviewed.

The clinical examination at 12 months was undertaken primarily at outpatient clinics; in most hospitals these were dedicated trial clinics and in others they were part of normal clinics by consultants and their firms. Patients who did not attend after two invitations were asked to attend their local health centre by their general practitioner, who undertook the clinical review. The 12 month examination included blood pressure measurement and electrocardiography; questioning about further myocardial infarction, cerebrovascular accident, other cardiac complications, and interventional cardiology and cardiac surgery, verified if necessary in the clinical records; and an exercise stress test and serum cholesterol estimation when clinically indicated.

Mortality was reported at the six month follow up, at 12 months, by general practitioners, by local registrars of deaths, and, finally, by the NHS Central Registry. Copies of death certificates were sought of all patients believed dead.

All information was coded and stored in the university computer and analysed by SPSS X. Rehabilitation and control outcomes were compared for prevalence or "caseness" (χ^2 test), frequencies or scores (Wilcoxon rank sum test), and survival (Kaplan-Meier life table and Mantel-Haenszel log rank tests).

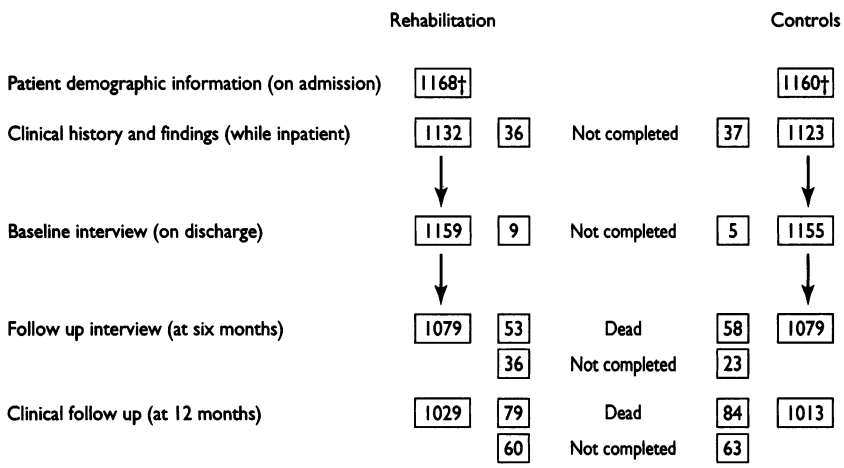

Fig 1—*Flow diagram of patients randomised to rehabilitation and control groups*
†Five other cases and four other controls who completed neither baseline nor follow up interview were excluded from analysis

Results

Twenty six physicians (all except one) in six district general hospitals referred patients for the trial. Of the 2328 patients included, 1168 were randomised to the rehabilitation group ("cases") and 1160 to the control group (fig 1). Patients with unconfirmed myocardial infarction and those still in hospital were excluded. Clinical histories and findings were completed for 2255 (97%) patients, initial patient interviews shortly after discharge for 2314 (99%), and the six month follow up interviews and 12 month clinical follow up for 2158 (97%) and 2042 (94%) surviving patients respectively.

Patients randomised to the rehabilitation and control groups were similar in age and sex distribution, medical history, site and size of infarct and complications, smoking, drinking, and physical exercise before myocardial infarction (tables A-C, available from DAJ). Baseline measures of the principal outcomes for psychological rehabilitation are listed in table 1. Over half the patients reported angina and 40% reported using glyceryl trinitrate (446 (39%) in the rehabilitation group, 473 (41%) controls). Prevalence rates of clinically significant anxiety and depression were 32% (378 (33%) rehabilitation patients, 350 (31%) controls) and 19% (213 (19%), 219 (19%)) respectively.

At six months rehabilitation patients and controls showed no difference in the principal outcomes for psychological rehabilitation, clinically significant anxiety and depression (table 2). Prevalence rates were unchanged from those at discharge and there were no

Table 2—*Prevalence of angina, glyceryl trinitrate medication, disability, anxiety, and depression at six month follow up and frequencies or scores*

	Rehabilitation patients (n = 1079)		Controls (n = 1079)	
	No	(%)	No	(%)
Angina[21]	778	(73)	812	(75)
In past week	438	(41)	440	(41)
Frequency per week, median (5th, 95th centiles)	3 (1, 36)		4 (1, 70)	
Glyceryl trinitrate (patch, spray, tablets)	614	(57)	646	(60)
In past week (spray, tablets)	393	(37)	417	(39)
Frequency per week, median (5th, 95th centiles)	4 (1, 28)		4 (1, 32)	
Disability[23]:				
None	256	(24)	223	(21)
Mild	458	(43)	443	(41)
Moderate	188	(17)	219	(20)
Severe	175	(16)	193	(18)
Anxiety[26]:				
Clinically significant†	365	(34)	339	(32)
Score, median (5th, 95th centiles)	2 (0, 9)		2 (0, 10)	
Depression[26]:				
Clinically significant†	201	(19)	208	(19)
Score, median (5th, 95th centiles)	0 (0, 9)		0 (0, 9)	

† Scores of 4 or more.

Table 3—*Contact with health services and use of medication at six months and clinical sequelae and findings at 12 months*

	Rehabilitation patients†		Controls†	
	No	(%)	No	(%)
Use of services and medication at six months				
General practitioner within past four weeks	591	(55)	579	(54)
Home visit	113	(11)	116	(11)
Surgery attendance	516	(48)	488	(45)
Hospital readmissions since index myocardial infarction:				
None	803	(74)	805	(75)
1	195	(18)	190	(18)
2	62	(6)	57	(5)
≥3	19	(2)	27	(3)
Use of prescribed medication in past 24 hours:				
None	52	(5)	28	(3)
1	124	(11)	114	(11)
2	214	(20)	199	(18)
3	218	(20)	225	(21)
4	175	(16)	175	(16)
5	106	(10)	142	(13)
≥6	190	(17)	195	(18)
Clinical sequelae and findings at 12 months				
Further myocardial infarction	43	(4)	48	(5)
Stroke (cerebrovascular accident)	16	(2)	21	(2)
Heart failure	67	(7)	59	(6)
Murmur	82	(8)	74	(8)
Lung embolus	12	(1)	6	(1)
Heart surgery or angioplasty	47	(5)	54	(6)
Hypertension:				
Severe (systolic blood pressure >180 mm Hg)	42	(4)	36	(4)
Moderate (systolic blood pressure 150-179 mm Hg)	276	(28)	291	(30)

† Numbers of patients in each group at six and 12 months are given in figure 1.

differences in changes of scores between discharge and follow up—anxiety 0 (5, 4) *v* 0 (5, 5), depression 0 (-5, 5) *v* 0 (4, 4) (median, 5th, and 95th centiles). State anxiety assessed with another scale[28] gave very similar results. Subgroup analysis by sex, age, hospital, or initial anxiety or depression showed no evidence of a subgroup benefit. Rehabilitation patients experienced little benefit in angina prevalence compared with controls (778 patients (73%) *v* 812 (75%); 95% confidence interval of difference 0.8% to 6.7%). Use of glyceryl trinitrate in the past week showed little difference (393 (37%) *v* 417 (39%); 95% confidence interval of difference 1.8% to 6.4%) but the frequency of reported anginal episodes in the past week was lower (median 3 *v* 4; 95% confidence interval of difference 0 to 2 (z = 2.03)).

Reported use of general practitioner services, hospital admissions, and use of medication showed no differences between the rehabilitation patients and controls (table 3). Over half the patients had contacted their general practitioner in the preceding four weeks and one quarter had been admitted to hospital since their index admission. Almost all patients were receiving regular prescribed medication but the numbers of medicines taken in the preceding 24 hours were slightly lower among cases (z = 1.54; NS).

There were no differences in smoking (260 (24%) rehabilitation patients *v* 252 (23%) controls) or drinking (208 (19%) *v* 216 (20%) moderate or heavy) between the groups, and a small difference in physical activity (230 (22%) *v* 262 (24%) patients reported no activity) was not significant (z = 1.69). At six months 363 patients (17%) had returned to paid employment, 237 (11%) were on sick leave, 231 (11%) were unemployed, and 1327 (62%) were retired or not in paid employment (including housewives); there were no significant differences between the rehabilitation patients and controls. Of patients who returned to work, 48 (13%) changed jobs, 138 (39%) reduced their hours, and one fifth (36 (19%) *v* 39 (23%); NS) described their jobs as extremely or moderately stressful.

Clinical examination at 12 months found no difference between the groups in the incidence of further myocardial infarction (91 patients; 5%), cerebrovascular accident (37; 2%), heart failure (126; 7%), heart surgery or angioplasty (101; 5%), or other complications or sequelae of the index myocardial infarction (table 3). Usage of medication was also very similar: 425 (31%) patients were taking β blockers, 465 (34%) diuretics, and 1022 (75%) aspirin.

Seven hundred and ninety two patients (73%) attended a rehabilitation programme, of whom 72-80% described the relaxation training, cardiac education, group discussion, and individual counselling as helpful or very helpful and rated programmes 8 or more out of 10.

Mortality from 28 days to 12 months estimated by life table methods was low (151 deaths; 7%) (fig 2). At six months the number of deaths among rehabilitation patients was slightly lower than among controls (34 *v* 47) but by 12 months this small benefit had been lost (76 v 75). Though rehabilitation in months 2 and 3 may have been associated with very modest postponement of death, log rank analysis showed this to be not significant (1-6 months $\chi^2 = 2.3$; 1-12 months $\chi^2 = 0.0$).

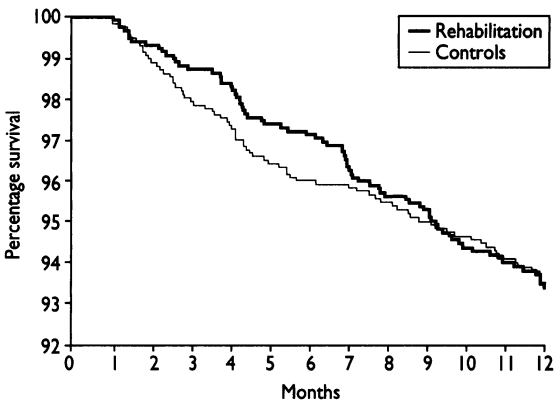

Fig 2—*Percentage survival after 28 days in rehabilitation and control groups*

Discussion

This trial, with more patients than the pooled experience of all previous trials of psychological rehabilitation,[29] found very little benefit. There were no differences between patients offered rehabilitation and controls in anxiety and depression—two variables most expected to show effects of a psychologically oriented rehabilitation programme—clinical sequelae, health service use, return to work, or mortality. Only modest and mostly not statistically significant benefits were observed in angina frequency, usage of medication, physical disability, and leisure time activity. Several possible explanations for differences between these findings and those in previous trials deserve consideration.

Most previous trials were selective and included mostly men aged under 65, selected patients, or volunteers (six months or more after myocardial infarction, "who knew the investigators' prior publications relating to behaviour and heart disease" and "were probably highly motivated to change behaviour").[16] This trial kept exclusions to a minimum and included most myocardial infarction patients in the six participating hospitals irrespective of age, previous history, coexistent disease, or disability. If a "true" effect were present only in a subgroup of patients and not observed, some dilution might be expected but some effect should still be observed in a trial of this size.

The intention to treat analysis might also dilute any true therapeutic effect, as one in four invited patients did not attend. Two main reasons for non-attendance were difficulty with transport and an ambulance strike, and several patients expressed considerable frustration over these. Dilution by attrition through mortality would be very modest: the mortality difference at six months (non-significant) was too small to mask a clinically important difference in anxiety or depression "caseness."

A possible true effect might have been diluted by shortness of the programme, as the suggestion for improvement most frequently proffered by patients was for more. However, though some trials that reported benefit evaluated very intensive programmes with weekly or even biweekly sessions for up to a year,[16] this was not true of all.[17] The seven week programme evaluated in this trial was chosen on the basis of professional wisdom at the time and practical and resource considerations. This may not be long or intensive enough to benefit the average patient who has experienced myocardial infarction.

A Hawthorne effect or contamination of controls is another possible explanation. The climate regarding rehabilitation changed substantially over the period of the trial locally and nationally. Though there were no rehabilitation programmes within the health districts of participating hospitals, nor in any neighbouring districts at the time the trial was started, this was not true when the trial ended. Both the establishment of these six centres and initiatives nationally raised awareness. However, despite local interest doctors, nurses, and therapists postponed development of potential alternatives until completion of the trial, so contamination was minimal.

WAS FOLLOW UP TOO EARLY?

A further possible explanation is that follow up was too early. Though several small trials suggested benefit in anxiety and depression within six months,[12-15 31] there is growing clinical opinion that both are slow to improve (fifth world congress of cardiac rehabilitation, Bordeaux, 1992). Another possibility is that the psychometric measures were not sensitive enough in this cardiological context. Some loss of sensitivity is possible when anxiety or depression is assessed in the presence of physical disease, as most scales include several physical symptoms. However, two measures of anxiety yielded similar results, and prevalence rates in previous small trials cannot be distinguished statistically from those reported here. The small reductions in reported angina, use of medication, physical disability, and leisure time activity might imply that these measures are more sensitive to small changes in post-myocardial infarction patients. As patients reported subjective benefit it is possible that measures sensitive enough to identify improved wellbeing after myocardial infarction have yet to be developed.

One year mortality among 2328 patients showed no benefit as might be inferred in the pooled findings of previous trials of psychologically based rehabilitation (1987 patients; relative risk 0.72 (95% confidence interval 0.51 to 1.03)).[30] In part this might be due to low overall mortality consequent on the successive introduction of aspirin, β blockers, and thrombolysis.[32] Alternatively, publication bias may have contributed to an unrealistic estimate of the true effect on mortality.[33 34]

The overall effect on mortality, morbidity, and quality of life of seven week psychologically based rehabilitation evaluated in this trial was weak. Possible explanations include patient selection, programme duration, treatment targeting, treatment dilution, psychometric measures, and timing of outcome measurement. Programme duration and resource commitment were chosen to be economical for this new service. With the recent increase in interest in cardiac rehabilitation[2 5 35] programmes are attracting more resources. Though objective benefits were equivocal, rehabilitation may nevertheless have a role in "quality of care." Patients and spouses were appreciative and thought that the programmes had helped. As modern practice strives for shorter hospital stay and early discharge to the community some rehabilitation provision may be necessary for good management of patients through that transfer.

Key messages

- Psychological rehabilitation on its own after myocardial infarction has little effect on mortality, morbidity, anxiety, depression, medication, or disability
- In this series there were no important differences by age, sex, hospital, or baseline anxiety or depression
- At six months the prevalence rates of clinical anxiety and depression remained high (33% and 19% respectively)
- Patients and spouses rated programmes highly, which suggests a "quality of care" role for rehabilitation

Tables A-C may be obtained by writing direct to DAJ.

We are grateful to many doctors and nurses, in particular the centre coordinators Drs A G Chappell, R F Dowdle, B E Griffiths, M Heber, and M E Simmons and Professor P A Routledge for entering patients and undertaking painstaking follow up; the rehabilitation teams Ms L Speck, L Arwel, L France, L James, J Rees, M Rhodes, A Roberts, M Thomas, P Towl, and J Williams; the interviewers Mrs S Cranton, C Cobon, K Elias, J Hughes, J Jones, D Mainwaring, J Roberts, J Seabury, and S Ward; the office staff Miss P Harvey, Mrs G Mordecai, A Kingdon, and Y Routledge; and the patients and spouses.

Other consultants who referred patients to the trial were Drs D J Beale, J S Morris, W E Wilkins, and D Webb (Bridgend); P S Davies and J O Williams (Pontypridd); P Beck, J H Lazarus, and P M Smith (Llandough); W V Evans, A H El-Shaboury, C D Mistry, and T J Morris (Merthyr Tydfil); and P L Boardman, P Brown, L S Hill, P R Hunter, G D Kerr, W H Perks, and T G West (Shrewsbury and Telford).

Funding: British Heart Foundation and Welsh Office.

Conflict of interest: None.

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(Accepted 26 September 1996)

Prevalence of mental disorder in remand prisoners: consecutive case study

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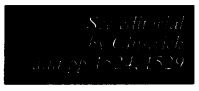

Abstract

***Objective*—To define the prevalence of mental disorder and need for psychiatric treatment in new remand prisoners and to determine to what extent these are recognised and addressed in prison.**

***Design*—Study of consecutive male remand prisoners at reception using a semistructured psychiatric interview.**

***Setting*—Large remand prison for men (HMP Durham).**

***Subjects*—569 men aged 21 years and over on remand, awaiting trial. *Main outcome measures*—Prevalence of mental disorder at reception, prisoners need for psychiatric treatment, identification of mental disorder by prison reception screening, and numbers placed appropriately in the prison hospital.**

***Results*—148 (26%) men had one or more current mental disorders (excluding substance misuse) including 24 who were acutely psychotic. The prison reception screening identified 34 of the men with mental disorder and six of those with acute psychosis. 168 men required psychiatric treatment, 50 of whom required urgent intervention; 16 required immediate transfer to psychiatric hospital. Of these 50, 17 were placed on the hospital wing because of mental disorder recognised at prison screening.**

***Conclusion*—Not only is the prevalence of mental disorder, in particular severe mental illness, high in this population, but the numbers identified at reception are low and subsequent management in prison is poor.**

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BMJ 1996;**313**:1521–4

Introduction

The problems of mentally disordered people in prisons were highlighted in a series of articles in 1984.[1 2] Bluglass subsequently drew attention to the lack of improvement despite numerous inquiries into the management of mentally disordered people in prison.[3] He pointed out the inadequacy of Home Office and Department of Health and Social Security reports, which relied heavily on the limited information available from censuses of mentally disturbed prisoners carried out by prison medical officers.

The effectiveness of health screening by prison medical staff has also been questioned.[4 5] The conditions and time constraints militate against the detection of clinically important information and the screening questionnaires used are of doubtful validity. In addition, some prisoners are difficult to deal with and allegations have been made of poor standards and lack of training in prison medical staff.

A recent national study of convicted prisoners using data collected by psychiatrists reported that 37% of sentenced prisoners have mental disorders.[6] The rates in remand prisoners are probably higher (S Dell, personal communication), partly because mentally disordered people are often remanded in custody for psychiatric reports. Evidence from North America suggests that mentally disordered people are more likely to be arrested than those who are not mentally disordered in similar circumstances.[7] Factors such as homelessness[8] and petty offences that are associated with mental disorder make remand more likely.

British research in the 1980s reported high rates of psychiatric morbidity in remand prisons,[9 10] but these studies may have underestimated the problem as they