Treating depression in primary care in low-income women in Santiago, Chile: a randomised controlled trial

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Summary

Background Depression in women is one of the commonest problems encountered in primary care. We aimed to compare the effectiveness of a stepped-care programme with usual care in primary-care management of depression in low-income women in Santiago, Chile.

Methods In a randomised controlled trial, in three primary-care clinics in Chile, 240 adult female primary-care patients with major depression were allocated stepped care or usual care. Stepped care was a 3-month, multicomponent intervention led by a non-medical health worker, which included a psychoeducational group intervention, structured and systematic follow-up, and drug treatment for patients with severe depression. Data were analysed on an intention-to-treat basis. The primary outcome measure was the Hamilton depression rating scale (HDRS) administered at baseline and at 3 and 6 months after randomisation.

Findings About 90% of randomised patients completed outcome assessments. There was a substantial between-group difference in all outcome measures in favour of the stepped-care programme. The adjusted difference in mean HDRS score between the groups was –8·89 (95% CI –11·15 to –6·76; p<0·0001). At 6-months' follow-up, 70% (60–79) of the stepped-care compared with 30% (21–40) of the usual-care group had recovered (HDRS score <8).

Interpretation Despite few resources and marked deprivation, women with major depression responded well to a structured, stepped-care treatment programme, which is being introduced across Chile. Socially disadvantaged patients might gain the most from systematic improvements in treatment of depression.

Lancet 2003; **361:** 995–1000

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Introduction

Depression is a major public health problem in rich and poor countries, and is especially common in women, and in particular in women who are socially disadvantaged.[1–4] In primary care, depression is highly prevalent and almost twice as common in women as in men.[5] Access to mental-health specialists in developing countries is inadequate, especially for the poorest sectors of society, so most depression is treated in primary care. However, management of depression in primary care is disorganised and often ineffective in rich and in poor countries. Depression is often unrecognised, and initiation and adherence to effective treatment is usually poor.[5–9] Results of clinical trials and comparative studies have shown the potential effectiveness of drug treatment or brief structured psychotherapy.[10–13] Unfortunately, this potential is seldom realised. Treatment of depression often consists of more than one therapeutic component used as part of a complex sequence of management decisions with the ultimate goal of overall improvement. Thus, in sequential, multicomponent programmes (stepped-care model), patients without severe depression receive low-intensity treatment, which is followed-up with intensive management if they do not respond.[14] Some components, such as systematic monitoring and brief psychological interventions, can be effectively delivered by trained non-medical personnel, reducing costs and demands on family practitioners.[15,16]

Primary-care clinics are the main source of care for almost every poor person in Chile. These clinics are underfunded and insufficiently resourced, but most have nurses, social workers, auxiliary nurses, midwives, and doctors. Primary-care physicians are in short supply and most have little formal training in primary care. These doctors typically see six-to-ten patients per hour. Most clinics have established programmes, usually led by nurses, for chronic medical conditions, but not for depression. Most primary-care physicians spend less than 2 years in primary-care posts, whereas nurses and social workers stay much longer. Specialty mental health care is available on referral, but waiting times for an initial consultation typically exceed 2 months.

We designed a multicomponent, stepped-care programme to improve treatment practices for depression and the efficiency with which resources are used. In keeping with these goals, the programme was led by a trained non-medical health worker; a doctor was involved only if medication was needed for patients with severe depression. We aimed to compare the effectiveness of this stepped-care programme with usual care in primary-care management of depression in low-income women.

Methods

Participants

We enrolled participants in three primary-care clinics in deprived urban areas of Santiago, Chile, between March,

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2000, and November, 2001. The clinics were representative of Santiago primary-care clinics in terms of resources and of clinical and sociodemographic characteristics of patients.[17] We used a two-stage screening process to identify female primary-care patients aged 18–70 years with current major depressive illness. Consecutive female patients were approached while they were waiting for consultation. All eligible and consenting patients were asked to complete the general health questionnaire (GHQ-12). All women with a score of 5 or more were asked to return for another GHQ-12 assessment 2 weeks later. Those scoring 5 or more at the second screening were invited for a baseline assessment within 1 week. The double screening was part of the stepped-care strategy to direct resources toward patients with persistent depression.

Ethics approval was granted by Comite Etica, Hospital Clinico, University of Chile. Patients gave written informed consent before being invited to participate.

Procedures

At baseline, a clinician administered three assessments: the mini international neuropsychiatric interview (MINI)[18] to ascertain a *Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition* (DSM-IV) diagnosis of major depression, manic or psychotic episode, or alcohol abuse; the Hamilton depression rating scale (HDRS);[19] and the short form 36 questionnaire (SF-36). HDRS, the primary outcome measure, has been shown to give reliable and valid results in primary-care patients,[20] as has the Spanish-language version.[21] SF-36 is used to assess functional impairment across a range of mental and physical domains.[22] Four aspects of SF-36 were selected as secondary outcomes: mental health, emotional role, social functioning, and vitality (selected because of responsiveness to change in depression). In primary-care populations similar to ours it has shown good reliability and sensitivity to change with severity of depression. A Spanish-language version has been used successfully in studies of depression in Spanish-speaking primary-care patients.[23]

All patients with current DSM-IV major depression were eligible. Patients with current psychotic symptoms, serious suicidal risk, history of mania, or current alcohol abuse were excluded and referred back to their primary-care physician. Patients who had had a psychiatric consultation or admission to hospital in the 3 months before the interview were also excluded.

Patients were randomly assigned the stepped-care improvement programme or usual care. Randomisation was stratified by clinic and done in blocks of 20 by use of computer-generated random numbers; individuals who recruited patients were neither involved in nor aware of the procedure used to generate allocations. Allocations were kept in numbered sealed envelopes in each clinic, and were opened by an individual who had not recruited patients. The method of randomisation was chosen to obtain groups of equal size.

The stepped-care improvement programme was a multicomponent programme consisting of a structured psychoeducational group, systematic monitoring of clinical progress, and a structured pharmacotherapy programme for patients with severe or persistent depression. Figure 1 shows an overview of the programme. The psychoeducational intervention group consisted of seven weekly sessions and two booster sessions at weeks 9 and 12; each session lasted 75 min. Each group included about 20 participants. Topics

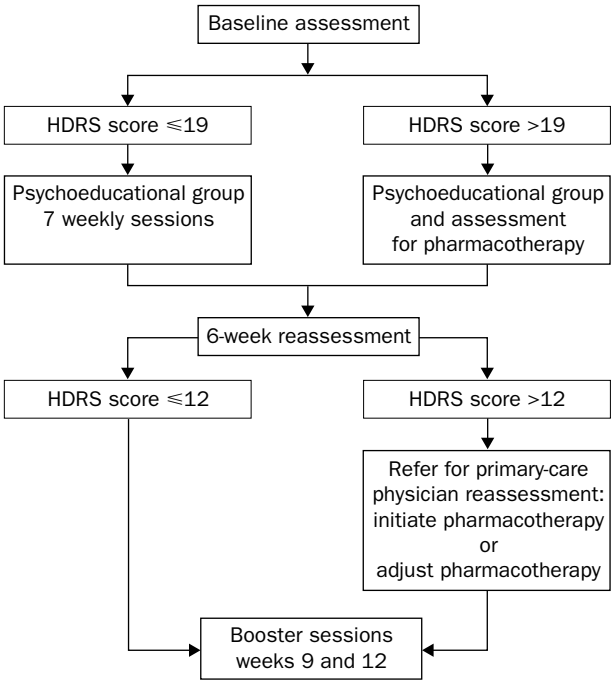

Figure 1: **The stepped-care intervention programme**

covered included information on symptoms and causes of depression, available treatment options, scheduling positive activities, problem-solving techniques, and basic cognitive and relapse-prevention techniques. Patients were given a manual with detailed information of the contents of each session accompanied by examples and exercises. Group leaders were social workers and nurses who received 12 h of training and 8 h of supervision from the principal investigators. Most group leaders were employed in local primary-care clinics. Patients were discouraged from contacting the group leader outside the sessions unless essential.

Patients with severe depression (HDRS score >19) at baseline or persistent depression (HDRS score >12) after 6 weeks of group treatment were referred back to their primary-care physician for a structured pharmacotherapy programme.[24] Primary-care physicians received 4 h of training to enable them to deliver a brief pharmacotherapy protocol that included structured assessment at initial and follow-up visits and the use of a standard medication algorithm to ensure adequate dose and duration of treatment (fluoxetine, amitriptyline, or imipramine). Group leaders monitored medication adherence and attendance at follow-up visits for patients receiving pharmacotherapy (figure 1).

Patients assigned usual care received all services normally available in the primary-care clinic, including antidepressant medication or referral for specialty treatment. Before the initiation of the study, primary-care physicians in the control group received guidelines on how to treat depression in primary care. No services normally available were restricted or withheld, and primary-care physicians received no information from study workers about patients in the usual-care group.

All participants were invited to attend the primary-care clinics for outcome assessments at 3 and 6 months after randomisation. Follow-up interviews were done by an independent clinician blinded to treatment assignment. Patients attending outcome assessments received a small payment to cover travel expenses.

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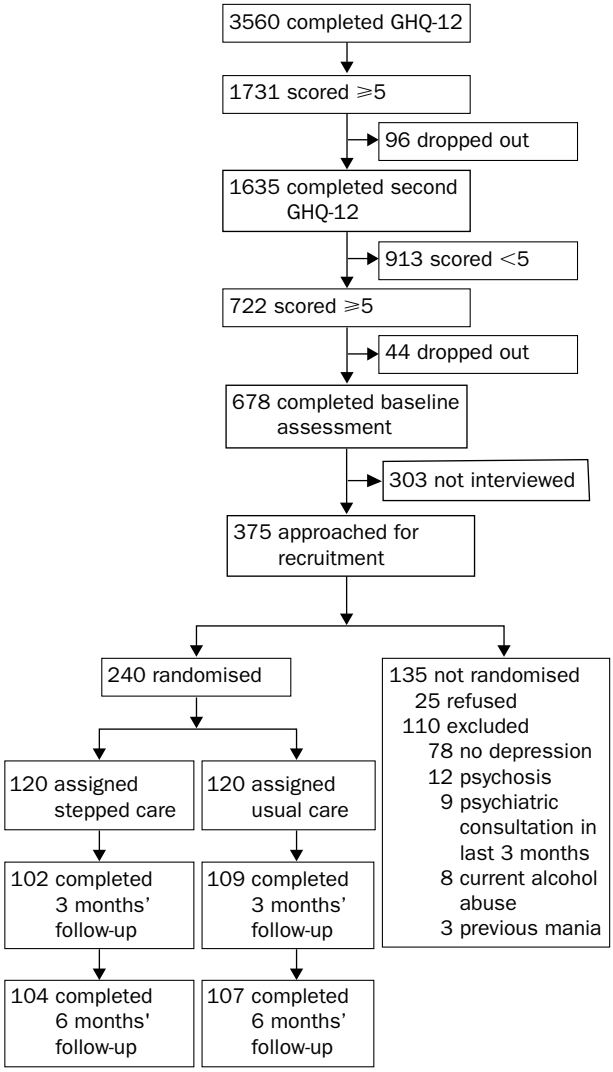

Figure 2: **Trial profile**

Statistical analysis

On the basis of data from other primary-care studies, we anticipated that follow-up HDRS scores would have an SD of about 7 points. Thus, a sample size of 120 patients per group would have 80% power for detection of a difference of 2·5 points in mean HDRS score between groups with two-sided significance of 5%.

Data were analysed in accordance with CONSORT guidelines; between-group comparisons were by intention-to-treat. We obtained descriptive statistics for the primary outcome measure (HDRS score) as a continuous and categorical (proportion of patients improved [defined as a 50% score reduction] and recovered [score <8]) variable. Primary comparison between groups was by repeated measures analysis of covariance[25] with adjustment for baseline and clinic in a random effects model. Interaction between time and group were assessed (for changes in group effects with time) and, in the absence of such an interaction, the overall difference between groups across the two follow-up assessments was calculated (95% CIs and p values). To investigate the effect of loss to follow-up on the intention-to-treat analysis, we did a sensitivity analysis using the last-observation-carried-forward approach. Secondary analyses included adjustment for baseline characteristics. Secondary outcomes were analysed with the same procedures. All analysis was done with Stata (version 7.0).

	Group	
	Stepped-care	Usual-care
Age, years (mean, SD)	43·0 (12·8)	42·1 (14·3)
Marital status		
Single	19 (16%)	13 (11%)
Married	67 (56%)	61 (51%)
Cohabiting	6 (5%)	10 (8%)
Previously married*	28 (23%)	36 (30%)
Occupation		
Housewife	102 (85%)	98 (82%)
Student	2 (2%)	2 (2%)
Employed	16 (13%)	20 (17%)
Number of children (mean [SD])	3·0 (1·7)	2·7 (1·9)
GHQ-12 score (mean, SD)	10·0 (2·3)	10·0 (2·2)
HDRS score (mean, SD)	19·8 (3·4)	19·7 (4·0)
SF-36 mental health score (mean, SD)	14·7 (12·7)	15·6 (14·8)
SF-36 emotional role score (mean, SD)	8·6 (19·1)	8·9 (20·6)
SF-36 social functioning score (mean, SD)	33·9 (25·2)	36·4 (24·9)
SF-36 vitality score (mean, SD)	14·2 (13·5)	16·1 (16·7)
Disability		
None	4 (3%)	6 (5%)
Mild	20 (17%)	24 (20%)
Moderate	7 (6%)	3 (3%)
Severe	89 (74%)	87 (73%)
Chronic illness	26 (22%)	36 (30%)
Previous depression	65 (54%)	71 (59%)

Data are number (%) unless otherwise indicated. *Separated and widowed.

Table 1: **Baseline characteristics**

Role of the funding source

The sponsors of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Figure 2 shows the trial profile. 3560 consecutive female patients completed initial screening. 1731 (49%) scored at least 5 in the GHQ-12. 1635 (94%) returned for the second GHQ-12, but only 722 (44%) were still above the threshold. All patients received an appointment for a baseline assessment within 48 h, but only 375 were interviewed before a sufficient number of women had been recruited. Recruited and non-recruited patients had similar GHQ-12 scores. Of those interviewed, 240 (64%) were eligible and agreed to be randomised (figure 2). Among patients excluded, most were women who did not meet DSM-IV criteria for major depression. For practical

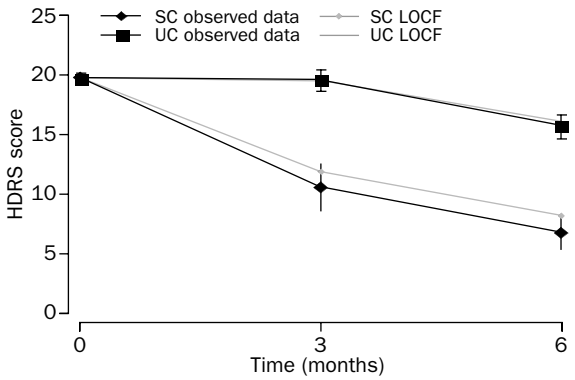

Figure 3: **HDRS score over time**

SC=stepped care. UC=usual care. LOCF=last observation carried forward. Bars are 95% CIs.

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	Difference in mean scores (95% CI)	p
HDRS score	–8·89 (–11·15 to –6·76)	<0·0001
SF-36 mental health score	22·78 (16·80 to 28·77)	<0·0001
SF-36 emotional role score	20·72 (12·31 to 29·13)	<0·0001
SF-36 social functioning score	19·32 (13·11 to 25·53)	<0·0001
SF-36 vitality score	21·23 (15·10 to 27·37)	<0·0001

Analysis based on observed data only. *From repeated measures analysis of covariance, adjusting for baseline and clinic in a random effects model.

Table 2: **Adjusted difference in mean scores for stepped-care minus usual-care programmes***

reasons the number of patients recruited varied: 40, 80, and 120 were recruited in each clinic, respectively. The number not completing blinded outcome assessments were similar in the stepped-care and usual-care groups at 3 months (18 *vs* 11, respectively) and 6 months (16 *vs* 13, respectively).

Mean age of participants was 42·6 years (SD 13·6), 128 (53%) were married, and 200 (83%) were housewives. A previous depressive episode was reported by 136 (57%), five women had a previous psychiatric admission, and 62 (26%) had been diagnosed with a chronic medical illness. Mean GHQ-12 and HDRS scores were 10·0 (2·2) and 19·7 (3·7), respectively. Groups were similar with respect to demographic and baseline clinical characteristics (table 1). These characteristics were also similar across clinics—for example, mean HDRS scores at baseline in the three clinics were 19·5 (3·6), 19·3 (4·2), and 20·0 (3·7), respectively.

104 (87%) women in the stepped-care group attended at least one group session: ten attended one-to-two sessions; five attended three-to-four; 11, five-to-six; 34, seven-to-eight; and 44 attended nine sessions. Mean number of sessions attended was 6·26 (3·28). Non-attendance at group sessions was not always accompanied by loss to follow-up; of 16 women who never attended a group session, six underwent both outcome assessments and seven had at least one assessment. In the stepped-care group, 95 (79%) women were on antidepressant medication at some time during the study, compared with 41 (34%) in the usual-care group.

Mean HDRS score of the stepped-care group was about 10 points lower than that of the usual-care group at 3 and 6 months, with either missing values replaced by the last observation carried forward or exclusion of missing values and use of observed data only (figure 3). With observed data, in a repeated measures analysis of covariance adjusting for baseline HDRS score and clinic, there was no significant interaction between time and treatment allocation (–0·12; 95% CI –2·52 to 2·76; p=0·93), but the main effect of treatment allocation across both follow-up points was large and significant, in favour of the intervention (table 2). We repeated the analysis after adjusting for the large differences in the proportions prescribed antidepressants in the two groups. The estimate, 95% CIs, and p value for HDRS score was not much changed by either this adjustment or by controlling for the small baseline imbalance in chronic medical conditions. Likewise, a sensitivity analysis had almost no effect on the results, which was as expected on the basis of the data presented in figure 3. To aid interpretation of the primary analyses in table 2, descriptive statistics for the binary versions of HDRS scores are presented in table 3. For example, the proportion of women who recovered (HDRS <8) by 6-months' follow-up was 73 (70%) of 104 in the stepped-care group compared with 32 (30%) of 107 in the usual-care group (table 3).

We did similar analyses for secondary outcome measures (tables 2 and 4); between-group differences were large and significant in favour of the stepped-care group (table 2). Adjustment for antidepressants and baseline imbalance in chronic medical conditions did not alter the results for any of the SF-36 sub-scales that we analysed.

	Group	
	Usual-care (n=109)	Stepped-care (n=104)
SF-36 scores, mean (SD)		
Mental health		
3 months	35·0 (25·5)	57·4 (25·2)*
6 months	42·8 (25·4)*	66·2 (26·7)
Emotional role		
3 months	28·4 (35·1)	47·4 (41·0)*
6 months	34·6 (40·9)*	57·1 (41·2)
Social functioning		
3 months	44·0 (26·9)	63·8 (30·2)*
6 months	51·2 (28·9)*	70·1 (26·7)
Vitality		
3 months	34·8 (26·1)	53·7 (28·5)*
6 months	38·8 (27·0)*	62·8 (25·7)

Analysis comparing treatment groups as allocated with observed data only. *Data missing for two women.

Table 4: **SF-36 outcomes according to treatment group and follow-up assessments**

Discussion

Our results show a large and significant difference in favour of the stepped-care programme compared with usual care, consistent across all assessed outcomes, and stable during 6 months of follow-up. Rates of participation in the intervention programme were high, and participation in blinded outcome assessments exceeded 85% in both groups. The programme widened the role and responsibilities of non-medical workers and increased the participation of patients in their own treatment. These features are all important to modern service development in developing and developed countries.

For obvious reasons, participants could not be blinded to treatment, and we cannot rule out the possibility that

	Group		
	Usual-care (n=109), n (% [95% CI])	Stepped-care (n=104), n (% [95% CI])	Odds ratios (95% CIs)
Outcome			
Improved (≤50% HDRS baseline score)			
3 months	19 (17% [11–26])	55 (54% [44–64])*	ND
6 months	34 (32% [23–42])*	81 (78% [69–85])	7·56 (4·08–14·01)
Recovered (HDRS<8)			
3 months	16 (15% [9–23])	50 (49% [39–59])*	ND
6 months	32 (30% [21–40])*	73 (70% [60–79])	5·52 (3·06–9·95)

Analysis comparing groups as allocated with observed data only. ND=not done. *Data missing for two women.

Table 3: **Outcome according to HDRS score**

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the clinicians who did outcome assessments learned of treatment allocation. However, we obtained similar results using a self-reported measure, the SF-36 mental health dimension. It is therefore unlikely that an assessment bias had much effect on our results.

Patients in the stepped-care programme received several treatment components (patients' education, behavioural activation, problem-solving techniques, systematic and structured follow-up, and/or pharmacotherapy). We did not aim to establish the effectiveness of isolated components of treatment, but rather to assess a programme that included components shown to be effective, available locally, and that could be used in an efficient stepped-care programme. In other words, our programme was intended to be as close as possible to what should be an adequate, efficient, and more importantly, feasible treatment programme in our particular setting. Even though there were large differences in the proportion of people in each group who were prescribed antidepressants, we think it is unlikely this could account for the significant differences in outcomes between the groups since adjusting our results for medication did not alter our main findings.

We did not design the programme to introduce radical changes to established practices. We aimed to improve existing care with structured protocols and rationalise the use of available resources. Often, innovative programmes are introduced that involve changes impossible to assimilate in the day-to-day delivery of care. The main innovative element was role enhancement for the non-medical group leaders, most of whom were available in the clinics and were often closely connected to local neighbourhoods. These workers were given the time and training to deliver the group psychological intervention effectively, monitor treatment progress, and act as advocates or care managers. They also acted as brokers between patients and doctors without interfering with doctors' work. On the contrary, doctors appreciated the help and information. We decided to concentrate our intervention in a high-risk group, poor women, so that the psychoeducational group intervention could focus on topics relevant for that group. This strategy seems to have worked because attendance rates and overall satisfaction with the programme were reasonably good.

Our results have some limitations. First, research has shown that benefits gained early during treatment tend to decline after 1 year or longer.[11,26,27] Unfortunately, we were unable to do a 1-year assessment, but our 6-month results compare favourably with those of other programmes.[11–13,26] Second, the usual-care group did worse than in other studies from developed countries, an unsurprising finding in view of the deficiencies in primary health care and the characteristics of patients in the Chilean sample. Third, our intervention was designed for ease of implementation in other primary-care settings, but we cannot be certain that our results are generally applicable. Finally, our psychological intervention included nine group sessions, which could be thought unrealistically intense in some settings. However, psychological interventions of similar intensity had already been tried with success in primary-care settings in Chile and the costs were acceptable to services and patients. Our main aim was to show that organised, improved treatment, as a first step, could effectively make a difference in a setting of socioeconomic disadvantage. Future interventions should test the effectiveness of less-intensive and costly psychological interventions.

Clinics and patients were representative of primary care in Santiago, Chile,[5,17] with high rates of morbidity, severe resource limitations, and socioeconomically deprived populations. These factors are common barriers to effective care in most public-sector clinics in developing countries. Thus, we think our results could be applicable in similar settings to ours, but also that similar strategies can be equally cost effective to manage depression or other chronic illnesses in more advantaged or organised practice settings. Contrary to some expectations, developed countries can learn much from developing countries in how best to rationalise resources when working with deprived populations under tight budgetary conditions.

The combination of high rates of depressive illness, poverty, and scarce resources can easily induce nihilism in physicians and policy-makers. Our findings should offer hope that modest interventions can have a substantial effect on depressive symptoms and functional impairment. The benefits of our programme exceed those seen with similar interventions in settings with less-deprived patients and more treatment resources. Unlike results from many other successful treatment studies, our results were well received by local policy-makers who have now launched a national pilot programme for the treatment of depression in primary care based on this intervention. Socially disadvantaged patients, especially in the developing world, might have the most to gain from modest investments in organised treatment of depression.

Contributors

R Araya and G Simon wrote the grant proposal. R Araya and T J Peters analysed data and wrote the final manuscript. G Rojas was the study coordinator and obtained data, assessed patients, and edited manuscripts. R Fritsch obtained data, assessed patients, entered and analysed data, and edited early versions of the manuscript. J Gaete was an independent outcome assessor and revised manuscripts. M Rojas was the site coordinator and collected data and edited manuscripts. G Simon provided advice on fieldwork and edited all versions of the manuscript.

Conflict of interest statement

R Araya received payment from Wyeth for a workshop. G Rojas received payment from Wyeth and Servier and R Fritsch received payment from Wyeth for participation in clinical trials. G Simon has received research grants from Eli Lilly and Solvay Pharmaceuticals. None of the other authors has declared any conflict of interest.

Acknowledgments

We thank the staff from the participating primary-care clinics. We also thank all the members of our team, in particular, C Valera, N Parra, M E Romero, E Lebrini, P Gonzalez, and J Espinola. Our thanks to Prof Glyn Lewis who read the manuscript and made useful comments. We thank the US National Institute of Mental Health for funding this project.

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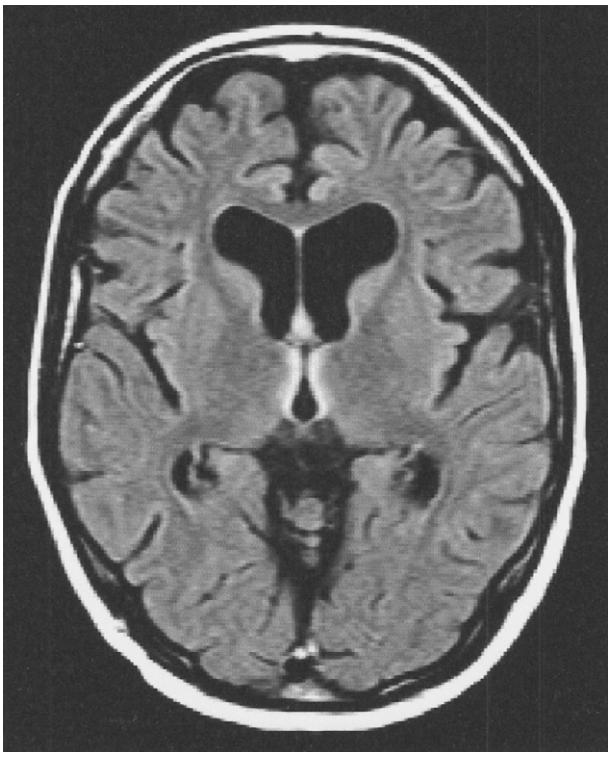
Clinical picture

Wernicke's encephalopathy

Markus Ploner, Alfons Schnitzler

A 36-year-old man was admitted to the emergency ward in a global confusional state. Apart from the patient's name and age no further information on the history was obtainable. Neurological examination revealed intermittent upbeat nystagmus, convergent strabismus, horizontal gaze palsy, and a severe ataxia of stance and gait. Laboratory findings showed an elevation of gamma-glutamyl transpeptidase, serum amylase and serum lipase, and a macrocytic anaemia. Drug and alcohol testing was negative. Based on the classical triad of clinical features—ophthalmoplegia, ataxia, and confusion—Wernicke's encephalopathy was diagnosed and thiamine was administered immediately. A fluid-attenuated inversion recovery (FLAIR) magnetic resonance-scan showed hyperintense signals around the third ventricle, in the fornix, and around the fourth ventricle, the hypothalamus, and the mamillary bodies (figure): findings characteristic of Wernicke's encephalopathy. Cerebrospinal fluid showed a small elevation of protein content. Within the first days ocular palsies nearly completely recovered while ataxia and confusion remained unchanged. A history of chronic alcohol abuse was confirmed.



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