

A randomized controlled trial and economic evaluation of counselling in primary care

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SUMMARY

Background. *Counselling in primary care settings remains largely unevaluated. Such evaluation has been strongly recommended.*

Aim. *To determine the relative effectiveness and cost-effectiveness of generic counselling and usual general practitioner (GP) care for patients with minor mental health problems.*

Method. *A randomized controlled trial and health economic evaluation were carried out in nine general practices. Access to generic counselling (brief counselling, generally involving up to six 50-minute sessions) was compared with usual GP care. A total of 162 patients aged 16 years and over with diverse mental health problems (excluding phobic conditions and psychoses) were randomized. The Hospital Anxiety and Depression (HAD) scale, COOP/WONCA (World Organization of Family Doctors) functional health assessment charts, and the delighted-terrible faces scale were used to assess outcome four months after randomization.*

Results. *The two groups were similar at baseline. There were significant improvements in both groups between randomization and follow-up for most outcome measures, but no significant differences between the study arms. The 95% confidence limits were narrow and excluded clinically significant effects. Under various assumptions concerning the cost of secondary care referrals and of counselling time, no clear cost advantage was associated with either intervention.*

Conclusions. *This pragmatic trial demonstrates no difference in functional or mental health outcome at four months between subjects offered access to counselling and those given usual care by their GP. There is no clear difference in the cost-effectiveness of the two interventions. Purchasers should take account of these findings in allocating resources within primary care.*

Keywords: randomized controlled trials; economics; counselling.

Introduction

THE provision of counselling within general practices has become widespread in recent years.^{1,2} Several factors have contributed to this trend, including the increasing workload of general practitioners (GPs), increased consumer demand for counselling, the growth of GP fundholding, and the extension of the reimbursement of ancillary staff salaries to a wider range of professionals.

Evidence for the effectiveness of counselling is sparse and often of poor quality. Flaws include the absence of concurrent controls or non-random allocation of subjects, use of ecological study designs, inadequate sample sizes, high drop-out rates, and failure to assess outcomes objectively.³⁻¹⁴ Some studies have involved only patients with a specific diagnosis, precluding extrapolation of findings to the wide range of psychological problems presenting in general practice.¹⁵⁻¹⁹ Others have evaluated specific psychotherapies as opposed to the practice of generic counsellors.²⁰⁻²³ None have undertaken a comprehensive assessment of the costs associated with counselling. Some have even suggested that the ethical and practical difficulties associated with randomization of patients with mental health problems in the primary care setting may be insurmountable.^{24,25}

The need for rigorous evaluation of generic counselling in primary care has been identified as a research and development priority.^{26,27} The pragmatic, randomized, controlled trial reported here aims to evaluate the effectiveness and cost-effectiveness of qualified counsellors in primary care, using a range of validated outcome measures.

Methods

The interventions compared were access to counselling and usual care by the GP. A short course of counselling was used (generally up to six 50-minute sessions at weekly intervals), broadly involving a person-centred approach, in which the emphasis is on listening rather than giving advice.²⁸ Counsellors were either British Association of Counselling (BAC) accredited or trained to diploma level. None were health professionals. Within this framework, the exact counselling method used (for example solution focused, cognitive behavioural) was not standardized. Subjects offered counselling were also allowed normal access to their GP. Counsellors were able to recommend that GPs should refer clients to secondary care. All counsellors worked part-time and had been in post for at least four months before the trial commenced.

Nine general practices participated (five in Cardiff and four in Swansea), ranging in size from small two-partner practices to larger health centre practices. The practice populations showed a wide spread of social class. Any adult patient with any emotional or relationship problem was eligible for inclusion in the trial, irrespective of previous mental health history. Only patients under the age of 16 or with well-defined phobic conditions or frank psychoses were excluded.

Eligible patients were identified by GPs, who, after obtaining informed consent, recorded baseline data for each subject. This

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© *British Journal of General Practice*, 1998, 48, 1043-1048.

included demographic details and mental health history. Subjects then completed the Hospital Anxiety and Depression (HAD) scale,²⁹ the Dartmouth COOP/WONCA Functional Health Assessment Charts (a quality-of-life measure with six subscales for use in community settings),³⁰ the delighted–terrible faces scale for overall quality of life,³¹ and the Duke Functional Social Support Questionnaire.²⁹ The Short Form (SF) 36 was included by the study coordinators overseeing the Swansea practices only. Subjects were randomly allocated using opaque sealed envelopes prepared outside the practices by the research team. Regular checks were carried out to ensure that envelopes were being opened in strict number order. Block randomization (block size six) was used, with a two-to-one ratio in favour of counselling.

Subjects allocated to usual GP management were offered a further appointment with the GP. Those allocated to counselling were contacted by the counsellor and offered an appointment. During the four-month follow up, resource utilization data were collected on the number and duration of all consultations with the GP and the counsellor, on referrals to other agencies, and on all prescriptions.

The same questionnaires that were administered at the start (excluding the Duke Social Support Questionnaire) were posted to each subject four months after randomization. Non-responders were sent a further questionnaire, and GPs made individual contact with persistent non-responders. South and West Glamorgan research ethics committee approvals were obtained.

Sample size and statistical analysis

The sample size calculation was based on a difference between study arms in any continuous outcome measure of 0.6 standard deviations, similar to the effect sizes reported in previous studies. To give 90% power to detect such a difference (two-tailed alpha of 0.05), using a two-to-one randomization ratio, 100 subjects were required in the counselling arm and 50 in the usual care arm. Samples of these sizes confer 80% power to detect a difference of 0.5 standard deviations.

Analysis was conducted on an intention-to-treat basis using STATA software (Stata Corporation, College Station, Texas, USA). The principal analysis considered the differences between baseline and follow-up scores on the outcome measures. These difference scores were compared in the two study arms using unpaired *t*-tests for data that were acceptably close to a normal distribution and Mann–Whitney tests for other data. Absolute scores at follow up were also compared cross-sectionally in the two study arms (using Mann–Whitney tests).

Multiple linear regression was used to determine whether there were significant centre effects between Swansea and Cardiff upon the difference scores after controlling for potential confounding variables. Predictor variables were entered as continuous variables in some cases, and in other cases as categorical (dummy) variables.

An economic analysis was carried out to compare the mean resource utilization of subjects in the two groups. The costs included were those of prescribed medication, practice staff and counsellor time, and referrals to other agencies. The cost of GP time was calculated at £25 per hour (based on £43 000 annual remuneration, 20% on-costs [e.g. pension and national insurance costs], and a notional 40-hour week). Counsellor time was calculated both at the actual employment cost (including employer on-costs) in this study of £11 per hour and also at the mean cost of £15 per hour found in a recent survey.³² Costs were those prevailing in the period 1992–94. Data were collected using specific proformas inserted into the clinical notes of each subject. For ease of data collection, referral costs were based on the current

mean prices set by National Health Service (NHS) trusts in Avon.

The health economic analysis incorporated a sensitivity analysis using three different approaches to calculating referral costs. The first approach considered only NHS costs and assumed that the number of outpatient appointments attended was consistent with specialty-specific follow-up patterns observed among NHS trusts in Avon. The second approach included private referral costs within the above assumptions. The third approach assumed that each outpatient referral resulted in only one appointment and included the cost of private referrals. Mental health referral costs were also examined separately within each of these three approaches.

Results

Of the 162 subjects entered into the trial during 1993 and 1994, 111 were randomly allocated to the group offered counselling and 51 to the group given usual GP care.

As shown in Table 1, the study arms were broadly similar in terms of a wide range of potential confounding variables. The median ages differed by only three years, although the interquar-

Table 1. Baseline characteristics: demographic characteristics and medical history.

	Counsellor	Usual care	Both groups combined
Age (years) (<i>n</i> = 160)			
Median	36.0	39.0	37.0
Interquartile range	14.3	22.8	16.1
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
Sex (<i>n</i> = 162)			
Male	26 (23)	16 (31)	42 (26)
Female	85 (77)	35 (69)	120 (74)
Social class (<i>n</i> = 152)			
Non-manual	40 (39)	14 (29)	54 (36)
Manual	12 (12)	6 (12)	18 (12)
Economically inactive	51 (50)	29 (59)	80 (53)
Marital status (<i>n</i> = 157)			
Single	27 (25)	11 (22)	38 (24)
Married	52 (49)	26 (52)	78 (50)
Divorced	20 (19)	8 (16)	28 (18)
Widowed	8 (8)	5 (10)	13 (8)
Previous mental health referral (<i>n</i> = 145)			
No	76 (78)	40 (83)	116 (80)
Yes	21 (22)	8 (17)	29 (20)
Presenting problem^a (<i>n</i> = 154)			
Relationship problem	25 (21)	12 (21)	37 (21)
Anxiety	47 (40)	17 (30)	64 (37)
Bereavement	12 (10)	6 (11)	18 (10)
Depression	23 (20)	18 (32)	41 (24)
Other	10 (9)	4 (7)	14 (8)
Current use of psychotropic drugs (<i>n</i> = 152)			
No	72 (70)	31 (63)	103 (68)
Yes	31 (30)	18 (37)	49 (32)

^aIn 12 cases, two presenting problems were specified and, in four cases, three problems.

tile range was greater in the usual care group (22.8 years versus 14.3 years). Also shown is the case mix of eligible subjects, categorized into relationship problems, bereavement, anxiety, and depression.

Table 2 shows the median scores for social support and psychological health of each group at entry into the trial. The two groups had similar scores on the Duke Functional Social Support scale, the delighted–terrible faces scale, and on all dimensions of the COOP/WONCA scale. The baseline median scores on the HAD scales were slightly higher in the usual care group.

Outcome data were obtained from 122 subjects (75%) at the four-month follow-up assessment. There was no difference between the study arms in the proportion lost to follow-up (26% and 24%). Non-responders did not differ significantly from responders with regard to any of the baseline measures of mental health status or social function. The only significant difference was that non-responders were younger than responders (mean difference in age 5.8 years; 95% CI = 9.8 – 1.9). The median number of counselling sessions attended by subjects in the counselling arm was three (mean 4.2), with an interquartile range of 5.3. Three (3.6%) subjects successfully followed up, who were

randomized to counselling, did not attend any sessions. Two (5.3%) subjects randomized to usual care did see the practice-based counsellor (in one case for one session and in the other case for seven sessions).

The mean difference between baseline and follow-up scores in each study arm is shown in Table 3, together with 95% confidence intervals. In both groups, there was a statistically significant improvement in mean scores for the delighted–terrible faces scale, anxiety and depression on the HAD scale, and feelings, daily activities, social activities, and overall health on the COOP/WONCA scale.

The last two columns in Table 3 give 95% CIs for the difference between the study arms in the mean improvement on each outcome measure, and *P* values. All the CIs include zero. There was no significant difference between the improvement observed in the counsellor and control groups for any of the measures used, and the 95% CIs were all narrow. Additionally, Mann–Whitney tests performed cross-sectionally on the follow-up outcome scores, rather than using difference scores, were all clearly non-significant (not shown in Table 3).

Table 4 shows improvement scores for Swansea subjects only

Table 2. Baseline characteristics: psychological and social support measures.

	Counsellor			Usual care			Both groups combined		
	<i>n</i>	Median	Range	<i>n</i>	Median	Range	<i>n</i>	Median	Range
COOP/WONCA subscales									
Feelings	102	4.0	1–5	47	5.0	2–5	149	4.0	1–5
Daily activities	102	4.0	1–5	47	4.0	1–5	149	3.0	1–5
Social activities	94	4.0	1–5	45	4.0	1–5	139	4.0	1–5
Pain	94	3.0	1–5	44	4.0	1–5	138	3.0	1–5
Physical fitness	97	3.0	1–5	48	3.0	1–5	145	3.0	1–5
Overall health	98	4.0	1–5	48	4.0	1.5–5	146	4.0	1–5
Delighted–terrible faces	98	4.0	1–5	47	4.0	2–5	145	4.0	1–5
Hospital Anxiety and Depression scale									
Subscales									
Anxiety	100	15.0	2–21	47	16.0	7–21	147	15.0	2–21
Depression	99	10.5	1–21	47	12.0	2–19	146	11.0	1–21
DUKE Functional Social Support scale									
Subscales									
Confidant support	93	15.0	5–25	44	15.0	5–25	137	15.0	5–25
Affective support	94	9.0	1–15	46	8.0	3–15	140	8.0	1–15

Table 3. Improvement scores (baseline minus four-month score).

Outcome measure	Counsellor			Usual care			Difference between mean improvement scores (counsellor minus usual care) Point estimate and (95% CI)	<i>P</i> value (unpaired <i>t</i> -test)
	<i>n</i>	Mean	95% CI	<i>n</i>	Mean	95% CI		
COOP/WONCA								
Feelings	84	1.0	0.7, 1.3	37	1.2	0.7, 1.6	–0.2 (–0.7, 0.4)	0.50
Daily activities	84	0.9	0.6, 1.1	37	0.8	0.3, 1.1	0.1 (–0.4, 0.6)	0.56
Social activities	68	0.8	0.4, 1.2	33	1.0	0.5, 1.4	–0.2 (–0.7, 0.4)	0.60
Pain	67	0.2	–0.1, 0.5	32	0.2	–0.3, 0.7	–0.1 (–0.7, 0.6)	0.86
Physical fitness	77	0.3	0.07, 0.6	37	0.4	–0.04, 0.7	–0.0 (–0.5, 0.4)	0.91
Overall health	80	0.8	0.5, 1.0	37	0.6	0.2, 0.9	0.2 (–0.2, 0.6)	0.38
Delighted–terrible faces	81	0.9	0.6, 1.1	36	1.0	0.5, 1.3	–0.1 (–0.5, 0.4)	0.81
Hospital Anxiety and Depression scale								
Subscales								
Anxiety	79	3.0	1.9, 3.9	37	3.5	2.1, 4.9	–0.6 (–2.2, 1.1)	0.49
Depression	77	2.7	1.6, 3.7	38	3.4	1.8, 4.9	–0.7 (–2.6, 1.1)	0.43

in each of the eight domains of the SF 36 quality-of-life measure. The last column gives Mann–Whitney *P* values for the difference between the study arms. None was statistically significant, although it is acknowledged that the power to detect differences is relatively low for these outcome measures.

The absence of a differential outcome between the study arms was consistent across the two centres, with no evidence of an interaction between centre and intervention effect. However, there was a significantly greater mean improvement among all subjects recruited to the study in Cardiff than in Swansea for several outcomes. After controlling for age, sex, study arm, psychotropic medication, social support, social class, and history of previous mental health referral, this centre difference remained significant for the measures of social activity, overall health, and anxiety. The regression coefficients are given in Table 5, together with 95% CIs.

The economic analysis is summarized in Table 6. The sensitivity analysis produced a range of mean total costs per subject for each study arm. The range for the counsellor group (£71.21–81.23) fell below that for the usual care group (£89.67–109.51) when all referrals were considered. When non-mental health referrals were excluded from the model, the ranges overlapped, although the range for the usual care group (£67.32–83.91) extended beyond that for the counsellor group (£68.15–74.43).

When the cost of counsellor time was calculated at £15 per hour (not shown in Table 6), the range including all referrals was £85.89–95.91 for the counsellor group and £91.03–110.87 for the usual care group. The ranges including only mental health referrals were £82.83–89.11 and £68.68–85.51 respectively.

Discussion

This study was carried out in recognition of the fact that considerable NHS resources are being invested in an intervention that remains largely unevaluated.¹ An Effective Health Care bulletin reviewing the management of depression in primary care specifically recommended further research into the effectiveness of counselling in primary care.²⁶

The majority of existing trials evaluated therapies delivered by health care professionals. There have been only two previous randomized controlled trials of generic counselling in general practice settings in this country. One³³ has never been published in a peer-reviewed journal. The outcomes assessed were GP consultation time, prescriptions for psychotropic medication, patient satisfaction, and psychological disturbance, using the General Health Questionnaire (GHQ). No significant differences in outcome between the two groups were reported after a one-year follow-up period. This study was affected by methodological problems, including incomplete data collection, under-recording of prescription and consultation data, failure to measure GHQ scores at baseline, and high post-randomization attrition, making interpretation of the findings difficult.

A more recent trial³⁴ reported more favourable outcomes in the counsellor group, as measured by the GHQ, number of prescriptions for psychotropic medication, referrals to outside agencies, and patient satisfaction. There was no difference between the groups in GP consultation rates. The validity of these findings is compromised by a number of factors, most seriously by the unintended large imbalance in the number of subjects in the study arms. It is not clear how this occurred, but the possibility of non-random allocation cannot be excluded. There was also an exceptionally high rate of referral of subjects from the usual care group

Table 4. SF 36 improvement scores (baseline minus four-month score: Swansea subjects only).

Domain	Counsellor				Usual care				<i>P</i> value (Mann–Whitney test)
	<i>n</i>	Median	25th centile	75th centile	<i>n</i>	Median	25th centile	75th centile	
Physical functioning	34	0	-5.56	5.56	19	0	-10.00	10.00	0.93
Role: physical health	32	0	-25.00	25.00	18	0	-25.00	0	0.25
Bodily pain	35	0	-11.11	0.00	19	0	-11.11	11.11	0.72
General health	33	3.33	-10.00	10.00	19	-5.00	-20.00	7.00	0.14
Vitality	35	-10.00	-25.00	5.00	19	-10.00	-20.00	5.00	1.00
Social functioning	36	-7.50	-21.25	1.25	19	-2.50	-22.50	10.00	0.82
Role: Emotional health	32	0	0	0	17	0	0	0	0.63
Mental health	35	-4.00	-16.00	4.00	19	-8.00	-24.00	16.00	0.86

Table 5. Multiple regression coefficients for centre effects on change scores (baseline minus follow-up) for various outcome measures (controlling for age, sex, social support, social class, psychotropic medication, study arm, and mental health referral).

Outcome measure	<i>n</i>	Coefficient ^a	<i>P</i> value	95% CI for coefficient
COOP/WONCA				
Feelings	92	0.65	0.04	0.0, 1.3
Daily activities	92	0.59	0.05	0.0, 1.2
Social activities	77	0.82	0.03	0.1, 1.5
Pain	76	0.31	0.46	-0.5, 1.1
Physical fitness	86	0.44	0.13	-0.1, 1.0
Overall health	88	0.76	0.00	0.3, 1.3
Delighted–terrible faces	91	0.26	0.38	-0.3, 0.9
Hospital Anxiety and Depression scale				
Anxiety	91	2.56	0.01	0.5, 4.6
Depression	91	1.93	0.08	-0.2, 4.1

^aTo be interpreted as Cardiff change score minus Swansea change score.

Table 6. Mean resource utilization per patient.

Resource	Counsellor	Usual care
GP time ^a	0.63 hours = £15.75	1.50 hours = £28.75
Counsellor time ^b	3.67 hours = £40.37	0.34 hours = £3.74
Drugs prescribed	£10.97	£25.38
Mean no. of referrals	0.07	0.22
Cost (excluding referral costs)	£67.09	£57.87
Referral assumption 1 ^c		
All referrals	£9.89	£38.95
Mental health referrals	£3.72	£13.76
Referral assumption 2 ^d		
All referrals	£14.14	£51.64
Mental health referrals	£7.34	£26.04
Referral assumption 3 ^e		
All referrals	£4.12	£31.80
Mental health referrals	£1.06	£9.45
Total cost range (including referrals)		
All referrals	£71.21–81.23	£89.67–109.51
Mental health	£68.15–74.43	£67.32–83.91

^aGP time costed at £25 per hour (based on £43 000 gross salary, 20% on-costs, and a 40-hour week). ^bCounsellor time costed at £11 per hour (based on £18 000 gross salary, 20% on-costs, and a 37.5-hour week). ^cAssumption 1: costs to NHS assuming referrals involved follow-up appointments; private referral costs excluded. ^dAssumption 2: referrals involved follow-up appointments; private referral costs included.

^eAssumption 3: all referrals attended one appointment only; private referral costs included.

to outside agencies (63%). Despite the short period of follow up (six weeks), only 56% follow up was achieved.

The study reported here was carried out in nine typical group practices in two cities and involved nine counsellors. We believe that the findings may be extrapolated to other general practice settings. The patient eligibility criteria incorporated the broad spectrum of mental health problems found in primary care. The patients were similar to the subjects of previous studies in terms of the types of mental health problem reported. Anxiety was the most common main complaint, as has been reported previously.^{4,10,12,20,22,35,36} Subgroup analyses relating to specific mental health problems were deliberately not performed, as statistical power would have been substantially reduced.

The intervention evaluated was a brief course of counselling, which has been widely adopted in primary care. It was intended that patients should receive up to six sessions of counselling. The median of three sessions received is consistent with the high non-attendance rate seen in such patients.

The outcome measures were selected on the basis that they are short and simple to complete, while providing an objective assessment of mental health status and social function. The Hospital Anxiety and Depression (HAD) scale has been shown to perform at least as well as the longer GHQ for the detection of psychiatric morbidity in general practice.³⁷ The COOP/WONCA charts and the Duke Functional Social Support scale were both developed for use in primary care settings. The latter was used at the start of the study only, the intention being to establish comparability between the two groups.

Although the mean cost of staff time (counsellor and GP combined) was higher in the counselling arm, the cost of prescribed medication was lower than in the usual GP care group. We did not differentiate between psychotropic and other medication, on the basis that somatic and psychogenic complaints are not always distinguished reliably. Previous ecological studies have found either no difference in prescribing costs between practices with and without counsellors¹¹ or higher costs in those with counsellors.¹³ The design of such studies is relatively weak, as they use entire practices as the unit of analysis. Referral costs were lower in the subjects who were allocated to the counsellors. Longer follow up would be required to determine whether these costs were

merely deferred.

The comparison of resource consumption is particularly sensitive to the hourly rate for counsellor time. At the rate of £11 per hour used in this study, total resource use is generally lower in the counselling group, although the difference is not so apparent when only mental health referrals are considered. Increasing the hourly rate to £15 reduces the difference when all referrals are included in the model and throws the balance in favour of usual GP care when only mental health referrals are included.

Despite efforts to obtain these data, the proportion of potentially eligible patients entered into the trial is unknown. If a large proportion of those eligible were not included, the generalizability of the results to the wider population could be compromised.

Long-term outcomes were not assessed. The follow-up period of four months was chosen to minimize the proportion of subjects lost to follow-up. Although it would have been preferable to carry out another assessment after a further interval, bias caused by drop-out would have become a greater problem. Follow-up periods in similar studies have ranged from six weeks³⁴ to one year^{18,21–23,33} after entry. We think it unlikely that a difference that was not apparent at four months would emerge thereafter.

The results of this study provide no evidence that counselling is more effective than usual GP care in treating a wide range of mental health problems. There may be non-health benefits of counselling that we have failed to identify, or the main potential benefit may lie in reducing GP stress levels, which this study was not able to detect. The balance of advantage of cost between the two interventions varies with the assumptions made. There is no clear cost advantage associated with either intervention. These findings provide important evidence to inform future purchasing policy.

A potential conflict of interest arises from the fact that one of the nine counsellors in the study is the partner of the first author of this paper. This counsellor was not, however, involved in the design or analysis of the study.

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Acknowledgements

We would like to acknowledge the invaluable assistance given by Dr Lise Llewellyn and thank the staff of the general practices involved in this project. We also thank Ms Jo Coast for health economic advice and Mrs Marilyn Parker for administrative support. This study was funded by the South Glamorgan Family Health Services Authority and West Glamorgan Health Authority.

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This is a one day conference for GPs to examine and discuss claims and complaints. There will be speakers to illustrate the basic principles. There will be active participation in the discussion of cases histories involving claims for negligence and complaints. The aim of the conference is to be interactive and discussive. PGEA applied for. £75.00 + VAT.

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The RCGP is organising a one day conference to discuss the complex issues relating to increasing pressure on managing emergency care within the NHS. A range of speakers across a number of disciplines have been asked to particularly concentrate on the interface between general practice and other service providers. The meeting will be of interest to GPs, other team members and NHS Executive staff with particular responsibility for emergency care. The delegate fee to be confirmed. PGEA has been applied for. £80.00 + VAT

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