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COUNSELLING PATIENTS WITH EMOTIONAL  
PROBLEMS IN GENERAL PRACTICE: EFFECTS ON  
PSYCHOLOGICAL, SOCIAL AND ECONOMIC OUTCOMES

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in Medicine, Royal Free Hospital School of Medicine,  
University of London.

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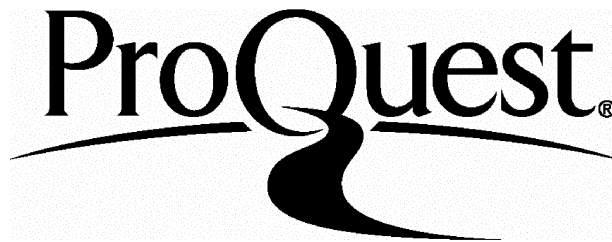
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ABSTRACT

Anxiety and depression are common mental disorders found in general practice. There has been an increasing number of counsellors attached to general practice over the past ten years, despite there being little evidence on effectiveness. Many studies have suffered from serious methodological weaknesses.

This prospective, randomised controlled trial compares non-directive counselling with routine general practitioner care in assisting people with emotional problems. Fourteen general practices were recruited. Counselling sessions ranged from 1 to 12 sessions over 12 weeks. Most patients suffered from depression due to relationship or family problems. Self-report questionnaires on psychological, social, economic and patient satisfaction outcomes were used at baseline interview and at the three and nine months follow-up interviews.

The sample consisted of 136 consenting general practice attenders, mean age 39 years old. Most of the sample were female (81%) and predominately Caucasian (92%). Seventy patients were randomised to the counsellor and 66 patients to the general practitioner.

Patients in both groups improved significantly over time, but there were no significant differences on the psychological and social outcome measures between a non-directive counselling intervention and routine general practitioner care. However patients who scored as cases on the Beck Depression Inventory, were younger and from manual classes improved to a greater extent by seeing a counsellor

compared to seeing the general practitioner. Patients were also more satisfied and felt less troubled after seeing a counsellor. In terms of cost, counselling was less cost-effective than routine general practitioner care immediately post-treatment, but became cost-effective on direct costs only after nine months.

This study indicates that non-directive counselling is as efficacious as routine general practice treatment. The findings on cost effectiveness were equivocal. Patients were more satisfied with seeing a counsellor compared to a doctor. Further research is needed to assess which particular patients could benefit from counselling and whether counselling becomes cost-effective long-term.

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## **1.0 INTRODUCTION**

Counselling in general practice has become very popular with patients and general practitioners over the past twenty years (Sheldon, 1992). As a profession, it has expanded greatly since the 1970s with a parallel increase in counselling training (Bond, 1995). In addition to the increase in counsellors generally, the Department of Health white paper "Promoting Better Health" (Department of Health, 1987) and the new general practitioner contract (Chisholm, 1990) encouraged general practitioners to employ more staff by firstly, reimbursing most of the staff costs, secondly, employing staff through health promotion clinics (even though there have been restrictions placed on the use of this money) and thirdly, increasing staff numbers through fundholding (Pringle and Laverty, 1993). Not only have general practitioners employed more counsellors but there has been a similar expansion with other professionals, such as practice nurses (Stilwell, 1991) or mental health professionals, such as community psychiatric nurses (Corney, 1994) and psychologists (Briscoe and Wilkinson, 1989), working in general practice. According to Sibbald et al (1993) one third of practices in England and Wales now employs a professional whose principal task in the practice is to provide counselling.

Despite this expansion, there has been a lack of convincing evidence of its efficacy (Corney, 1992) and responses to counsellors by general practitioners have varied. Some general practitioners work enthusiastically with counsellors and others know little or nothing about them (McLeod, 1992). General practitioners who have favoured counsellors have often done so on the basis of anecdotal



evidence or the belief it is a good thing (Fallowfield, 1993). However other general practitioners have cautioned against the widespread expansion of counselling (Lewis, 1995; Martin, 1988; Pringle and Laverty, 1993). The Social Affairs Unit produced a booklet "Magic in the Surgery" questioning the wisdom and rapid expansion of counselling and comparing counselling with a religious movement (Harris, 1994). Counselling is an emotive topic and some people are in favour of it (Hazard, 1995), whereas others are more sceptical and demand evidence (Lewis, 1995). Lambert et al (1991) believe that scientific research is necessary to explore relationships that exist between variables, such as treatment variables on client functioning. They also feel it is important for the welfare of patients. They state:

"Thus, counselling-outcome research is a necessary component of the highest ethical practice and a fundamental aspect of counselling services" (Lambert et al, 1991, p. 51).

### **1.1 PURPOSE**

The purpose of this thesis is to evaluate the efficacy and cost-effectiveness of counselling compared to routine general practitioner care. It will try to answer whether a counsellor in addition to the general practitioner is more helpful to patients with emotional problems than a general practitioner working alone.

## **1.2 NULL HYPOTHESIS**

For patients presenting in general practice with emotional problems, there is no difference in outcome between usual management by their general practitioner and referral to a counsellor.

## **1.3 AIMS**

The aims were to:

- i) compare the efficacy of counselling plus routine general practitioner care with routine general practitioner care alone;
- ii) evaluate the efficacy of counselling in terms of psychological and social outcomes;
- iii) explore the factors determining the effectiveness of counselling;
- iv) examine patient satisfaction with counselling;
- v) determine the cost-effectiveness of counselling.

## **1.4 DEFINITIONS**

Counselling has become a common word used in many different medical and general settings. The following definitions are to help the reader understand how the terms have been used in this thesis.

#### **1.4.1 COUNSELLING**

Counsellors, most doctors and other health care professionals use counselling skills in their daily work. However this thesis does not examine counselling in this broader sense, but tries to evaluate counselling used by qualified "generic" counsellors. In section 3.2, a clearer distinction is made between counselling skills and counselling used by a professional counsellor or equivalent.

#### **1.4.2 COUNSELLOR**

In this thesis I have evaluated professional counsellors with qualifications recognised and accreditable by the British Association for Counselling (1992a). These professional counsellors are trained in counselling skills and theory and have had to undertake supervised practice. They provide a talking therapy, which usually lasts for an hour in each of a set number of appointments.

However, there is some confusion between the term counsellor as any person providing counselling in primary care and the profession of counselling. The term counsellor will sometimes be used in its wider sense in this thesis and the definition by Sibbald et al (1993) has been adopted:

"Someone who offers (formal) sessions to patients in which patients are helped to define their problems and enabled to reach their own solutions. General practitioners and other provide counselling in the ordinary course of their work, but we need to know

about the provision of counselling as a *distinct* or *separate* activity within the practice." (Sibbald et al, 1993, p.30)

#### **1.4.3 PATIENT, CLIENT OR SUBJECT**

Patients are people seen by doctors, clients are seen by counsellors and subjects participate in a research study. These terms have been used interchangeably in the thesis and but may refer to the same person or people.

#### **1.4.4 RESEARCHERS**

The author of this thesis has been the principal researcher throughout the study. She is referred to in the first person throughout the thesis. Michael King and Margaret Lloyd acted as supervisors and assisted on a decision and advice level. In addition, there was a fourth academic, John Horder, who was involved primarily at the early stages of the proposal, but subsequently provided minimal support. I was involved in all stages of the research, including in the development of the study.

#### **1.5 LAYOUT OF THESIS**

The thesis has been divided into 9 chapters. Chapters 2 to 4 review the literature on common mental disorders, counselling and research methodologies to evaluate counselling. These are followed by the methods chapter (chapter 5) and three results chapters (chapters 6-8). Chapter 6 summarises the descriptive data, whilst chapter 7 and 8 report on the clinical efficacy and cost effectiveness of the trial, respectively. Finally, the

discussion and conclusions drawn are presented in chapter  
9.

## **2.0 MENTAL DISORDERS IN PRIMARY CARE**

According to Mann (1993) the importance of common mental health disorders in primary care is often overlooked for four reasons: psychiatric disorders are not considered a major health issue; they are not "real" mental illness; not much is known about these disorders; and a belief that people with a common mental illness recover spontaneously. However, as Goldberg and Huxley (1992) point out common mental disorders can cause enormous suffering, cause severe disability and may last for long periods of time. This chapter will present the background on common mental disorders in the primary care setting. It examines the prevalence of common mental illness and the consequent workload for general practitioners, the factors associated with common mental disorders, such as disability and number of days lost at work, and the current management of these disorders in the primary care setting.

### **2.1 PREVALENCE OF MENTAL DISORDERS IN PRIMARY CARE**

Since the pioneering work of Shepherd et al (1966), many researchers have studied the prevalence of psychiatric morbidity in general practice. However difficulties have arisen from the use of different classification systems of disorders and the lack of standardisation of how these disorders have been measured (Blacker and Clare, 1987; Higgins, 1994).

Two main classification systems for mental disorders have been used in research as well as clinical practice. These are: the World Health Organisation's (WHO) (1992) International Classification of Disease (now in its tenth

edition and known as ICD-10) and the American Psychiatric Association's (1994) Diagnostic and Statistical Manual (now in its fourth edition and known as DSM-IV). The most recent editions are quite similar and have become compatible (Gelder et al, 1996). The main differences are in structure and content. ICD-10 is categorised on a single axis (even though a multi-axial system is available) and does not include social consequences of the disorder, whereas DSM-IV is structured on a multi-axial framework and includes significant impairment in social, occupational or other areas of functioning. In addition, ICD-10 includes a simplified classification system for use in primary care.

There have been criticisms however of these classification systems and their clinical application to general practice (Jenkins et al, 1988; Goldberg, 1994). Jenkins et al (1988) proposed a model of classification for the primary care setting basing it on four dimensions: psychological illness, social stresses and supports, personality and physical illness. However as Goldberg (1994) pointed out, general practitioners are reluctant to use formal multi-axial systems. In response to the difficulties of using complicated classification systems in general practice, the International Classification of Primary Care (ICPC) produced by World Organisation of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONCA) produced a list of 41 mental conditions, but this system too has been criticised (Goldberg, 1994). Üstün et al (1995) describe the development of the new primary care version of the ICD-10 chapter five for mental and behavioural disorders. This provisional version focuses on 24 complaints, which are fairly common in primary care. These are presented on a set

of 24 cards, each detailing the complaint, the diagnostic features and the management of the condition. The advantage of this system is that it has been linked to clear advice on management. Field trials have been conducted in a number of centres and results have yet to be published (Üstün et al, 1995).

In addition to the difficulties in classification, there have been problems in the measurement of common mental disorders, deciding on a gold standard and defining caseness. Many epidemiological surveys in primary care have used a version of the General Health Questionnaire (Goldberg and Williams, 1988), or a standardised interview conducted by a psychiatrist, such as the Present State Examination (Wing et al, 1974), as the gold standard. In addition, Higgins (1994) pointed out that some researchers have used their own definitions of caseness or let the general practitioners decide when a person qualified as a case. These definitions have ranged from strict DSM or ICD classified disorders to loosely defined conditions, such as "mainly psychological presentation or consultation". These difficulties have led to different prevalence rates of mental disorders in general practice.

Prevalence rates have also been measured either using an annual point prevalence for the practice population or the prevalence in consecutive attenders at a general practice. The denominator of the two types of prevalence differ, with the former using the entire practice population as the denominator, whereas the prevalence of consecutive attenders uses the number of subjects who attended the general practice on the day(s) of the data collection. The prevalence rate of consecutive attenders usually is higher



since it only considers patients who attend the surgery and who tend to be more ill than the general practice population as a whole. In sum, the problems of classification, defining a case and sampling from the whole practice population over a year or consecutive attenders on several days has led to different prevalence rates of common mental disorders.

Shepherd et al (1966) were the first to make a systematic study of the prevalence of mental disorders in general practice. General practitioners recorded their consultations for a one year period and classified the presenting conditions in a standardised manner. From the 46 London general practices, they found a nine-fold difference between practices in reported rates of psychiatric disorders and speculated that the wide variance was due to differences between doctors in their attitudes towards psychiatric disorders rather than differences between practice populations. Nevertheless, they estimated that the prevalence of psychiatric morbidity was 139 per 1000 at risk, of which 102 were "formal psychiatric illnesses". Other categories were psychosomatic conditions, organic illness with psychiatric overlay and psychosocial problems.

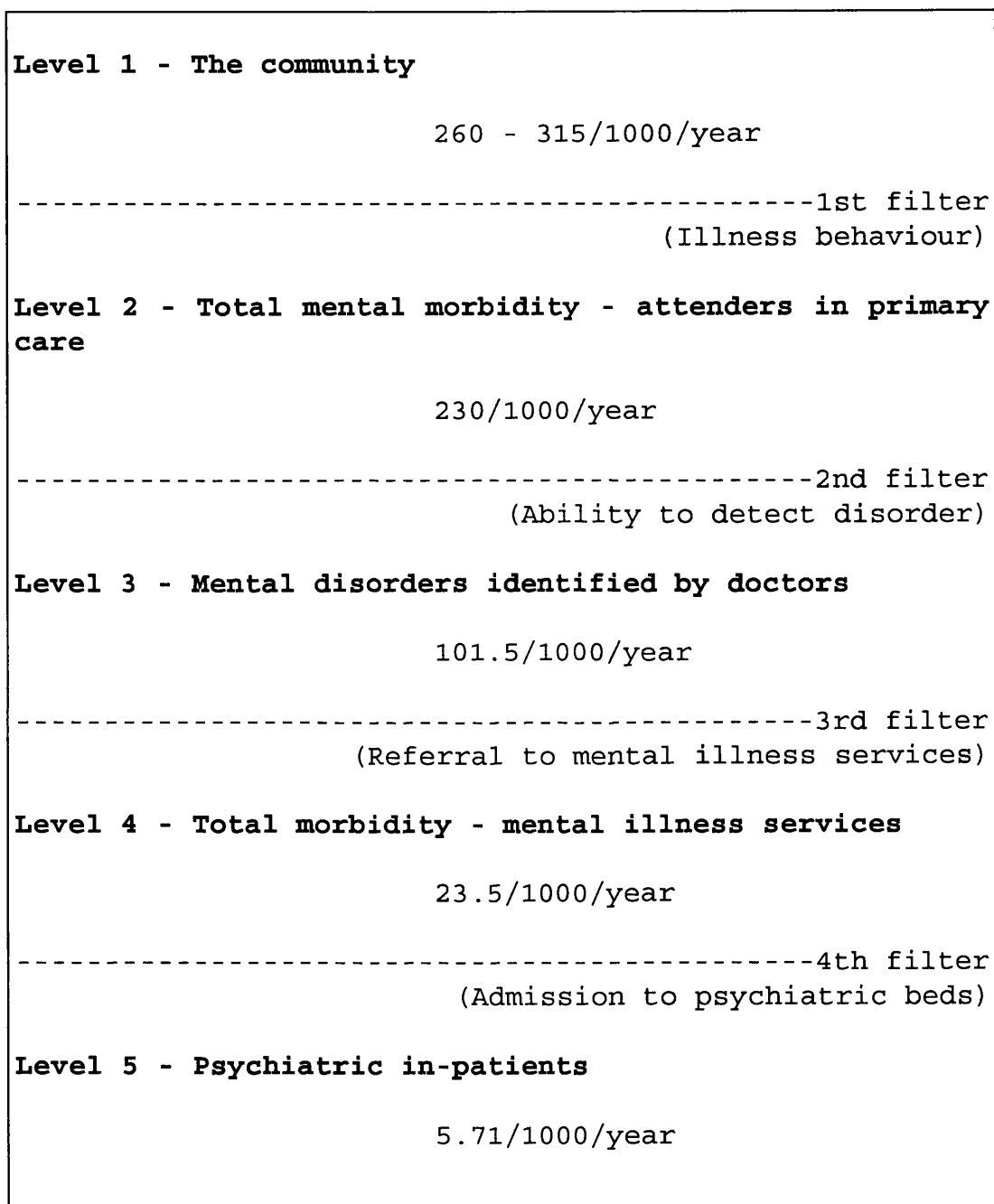
However, an additional difficulty in estimating prevalence was recognised. In 1980, Goldberg and Huxley first introduced a framework to understand pathways whereby some people with mental disorders, seek medical help from the general practitioner and eventually may gain access to specialist mental health services. The model identified two prevalence rates at the general practice level: the total morbidity and the conspicuous morbidity. It became clear that not all mental disorders were recognised by general

practitioners and general practitioners reporting these disorders would only reflect the conspicuous morbidity.

The Goldberg and Huxley (1992) framework includes five levels and four filters through which patients must pass in order to receive generalist and/or specialist help. Figure 2.1 shows the five levels with estimates of annual period prevalence rates at each level (number of people with a given disease in the population at any point in time). As can be seen from figure 2.1, only a proportion of patients in general practice will be recognised as suffering from psychiatric morbidity and pass through the second filter. It seems that most people with psychological problems or disorders visit their doctor at some time, but only approximately half of these problems get recognised and labelled as mental disorders (Marks et al, 1979; Tiemens et al, 1996).

The recent 1991-92 National Morbidity Statistics (RCGP et al, 1995) showed that over 7% of the general practice attenders consulted with a mental disorder (ICD 290-319), or a prevalence rate of 728 per 10,000 person years at risk. The data was collected over a one year period and used the ICD-9 classification system. Mental disorders was the only ICD chapter of specific diseases to decline since the previous survey of 1981-82, in which the number of consultations with the doctor was 1,761 per 10,000 person at years at risk. The decrease was mainly for patients with the intermediate category of severity, such as depressive disorders. There was less of a decrease in "trivial" conditions (minor self-limiting illnesses which require no specific treatment). The authors speculated that the decline in consultation rates for the "trivial" disorders

**Figure 2.1 Number of people suffering from a mental disorder (taken from Goldberg and Huxley, 1992).**



may have arisen from the increasing employment of counsellors in general practice (RCGP et al, 1995).

The above rates were based on annual point prevalence. In the recent international WHO Study, 15 studies were conducted around the world to estimate prevalence rates according to consecutive attenders. The study also aimed to define types of disorders that occur in primary care (Üstün and Sartorius, 1995). The advantage of this study was that it standardised data collection and instruments. They used a primary care version of the Composite International Diagnostic Interview (CIDI-PHC), as well as the 12 item General Health Questionnaire (von Korff and Üstün, 1995). They found that over the 15 centres and according to the CIDI-PHC, 24% of consecutive attenders had current mental disorders reaching ICD-10 criteria for well-defined disorders and another 9% had sub-threshold disorders (those who have clinically significant symptoms clustering in anxiety, depression or somatization groups but do not meet the full criteria for an ICD-10 mental disorder category) (Goldberg and Lecrubier, 1995).

Kisely et al (1995) conducted the WHO study in Manchester. They found prevalence rates similar to the overall world-wide prevalence: 26% of the sample had a well-defined ICD-10 diagnosis. General practitioners identified 46.5% of the sample as having psychological problems, of which just over half were mild. The agreement between the CIDI-PHC and the general practitioner was 46%, however general practitioners identified 62% of those found to have an ICD-10 diagnosis.

Many other studies of prevalence rates in general practice have been conducted in Britain (Goldberg and Blackwell,

1970; Marks et al, 1979; Skuse and Williams, 1984) as well as in America (Hoepfer et al, 1979; Schulberg et al, 1985; Barrett et al, 1988). It is difficult to estimate the exact prevalence of mental disorders in general practice, but Pereira Gray (1988) believes that the prevalence lies between 7% and 30%.

### **2.1.1 PREVALENCE OF DIFFERENT MENTAL DISORDERS IN PRIMARY CARE**

Goldberg and Huxley (1992) distinguished common mental disorders from severe mental disorders by classifying the former as depressive illnesses and anxiety-related disorders and the latter as the organic mental disorders, schizophrenia and bipolar affective disorders. The National Morbidity Statistics revealed that of patients consulting for mental disorders, 85% did so for neurotic, personality or other non-psychotic mental disorders or 649 per 10,000 person years at risk (RCGP et al, 1995). Organic psychotic conditions and other psychoses had prevalence rates of 31 and 77 per 10,000 person years at risk, respectively. From these figures, it is clear that the majority of patients with mental health problems consult for neurotic, personality and other non-psychotic mental disorders rather than the more severe psychotic conditions.

In further detail, the prevalence rate for neurotic disorders was 344 per 10,000 person years at risk (RCGP et al, 1995). Specific conditions reported under neurosis were anxiety states, neurotic depression and neurasthenia. The incidence of neurotic disorders was 271 per 10,000 person years at risk. Depression not elsewhere classified has a prevalence rate of 110 per 10,000 person years at risk and

special syndromes or syndromes not elsewhere classified a rate of 97 per 10,000 (RCGP et al, 1995). These were mainly disorders of sleep and pains of mental origin. In addition, 26 per 10,000 people consulted for acute reaction to stress and 36 for adjustment reaction (RCGP et al, 1995).

The most common diagnosis according to ICD-10 in the WHO international study and based on consecutive attenders were current depression (10.4%), generalised anxiety disorder (7.9%), neurasthenia (5.4%) and problems with alcohol and alcohol dependence (3.3% and 2.7%) (Goldberg and Lecrubier, 1995). The high rate of neurasthenia is because this syndrome was allowed to be present when co-morbid with depression and anxiety, otherwise if the strict ICD-10 exclusion rule had been applied, the prevalence of neurasthenia would have been 1.7%. Somatization disorder had a prevalence of 2.7% (Goldberg and Lecrubier, 1995).

Kisely et al (1995) in Manchester found that current depression had a prevalence of 17%, followed by neurasthenia (10%) and generalised anxiety (7%). Neurasthenia seems to have a higher prevalence in Manchester than across the total 15 centres and may be because chronic fatigue syndrome can still be recorded under neurasthenia using ICD-10 (Gelder et al, 1996).

In conclusion, common mental disorders found in the community and general practice include depressive disorders, anxiety-related disorders and somatisation disorders (Goldberg and Huxley, 1992). Many studies have found that depression is most common disorder in British general practices (Casey et al, 1984). Factors associated

with depression and other common mental disorders will be now discussed in further detail in the following sections.

## **2.2 FACTORS ASSOCIATED WITH COMMON MENTAL DISORDERS**

There are many factors that are associated with common mental disorders and some of these will be explored in this section. Biological and genetic factors as well as personality factors are clearly important in the aetiology of and vulnerability to mental disorders (Goldberg and Huxley, 1992) but will not be discussed in this thesis.

### **2.2.1 SOCIO-DEMOGRAPHIC FACTORS**

The National Morbidity Statistics (RCGP et al, 1995) found that more women consulted for neurotic disorders, depressive disorders not elsewhere classified, special symptoms or syndromes not elsewhere classified, acute reaction to stress and adjustment reaction. The male to female ratio is approximately 1:2 across all these disorders. Blacker and Clare (1987) reviewed studies on depression in general practice and found that women outnumbered men in the number of cases of depression. They found that the sex ratio was anything from 2:1 to 4:1. However, they pointed out that men may have a higher prevalence of alcohol problems and suicide and tend to seek medical help less often than women.

Most of the common disorders get worse over time, with people over 65 suffering from more adjustment reactions and depressive disorders, not elsewhere classified. The highest number of people suffering from neurotic disorders was in the 45 to 64 year old people (RCGP et al, 1995). It seems

that many mental disorders become more common with increase in age, however Blacker and Clare (1987) in their review found that major depressive disorder peaked in the age group 25 to 44.

Evidence for links to marital status, work status and social class are conflicting and no concrete conclusions can be drawn (Blacker and Clare, 1987). However, Goldberg and Huxley (1992) believe that most studies show greater rates for common mental disorders in people from lower social classes. Reviewing studies on work status, they found that unemployment was associated with an increase in mental disorders.

#### **2.2.2 LIFE EVENTS AND SOCIAL FACTORS**

Brown and Harris's (1978) well known study on a random sample of women in Camberwell, South London, stressed the importance of life events and social support in the onset of depression. They found that the loss of the mother before the age of 11, absence of an intimate, confiding relationship, unemployment and the presence of several children under the age of 14 living at home were related to the increased vulnerability of depression. However, as Goldberg and Huxley (1992) pointed out, the relationship between mental health, life events and social support is complex and it is still not clear why some people who experience adverse life events and do not have a supportive social network do not develop a mental health disorder. There is the chicken and egg situation of which comes first: the absence of social support led to a mental disorder or the mental disorder led to a reduced social support network (Markus et al, 1989).



It is difficult to conclude whether life events and social support play a role in the aetiology of common mental disorders. People who present with mental disorders usually present with recent life events and with a degree of social impairment (Klerman, 1989). Paykel et al (1971) and Weissman and Paykel (1974) found significant differences in social adjustment between 40 depressed female out-patients and 40 normal women from the general population. Depressed women were more impaired in their work roles, including their roles as housewives, and in intimate relationships such as marriage and parenthood. In a more recent study, Pini et al (1995) compared the number of social problems reported by general practice attenders and community subjects with emotional distress. They found that women attending general practice reported more social problems than women in the community, but did not find the same difference in men. In addition, they found that relationship problems with the spouse or partner were reported significantly more often in general practice attenders than in the community sample regardless of gender.

### **2.2.3 RATE OF RECOVERY OF PATIENTS IN GENERAL PRACTICE**

Mann et al (1981), in a follow-up study of a 100 general practice attenders with 'conspicuous' non-psychotic disorders, re-interviewed 93 patients at a one year follow-up and found that 24% of the patients had improved on psychiatric symptoms, 52% showed a variable course of morbidity, with evidence of remission and relapse of psychiatric symptoms over the year and 25% of patients were chronically ill with psychiatric symptoms present continuously. They found that patients who had higher

psychiatric symptoms scores, were on psychotropic medication and had a poorer social life scores, including poor family life score, were more likely still to be depressed at one year. In their recent 11 year follow-up, they managed to obtain data on 68 patients and found that 35 (52%) patients were classified as cases on the 12 item General Health Questionnaire (Lloyd et al, 1996). Twenty-two (32%) patients were well, 14 (21%) had experienced one acute episode of psychiatric illness lasting less than a year and 32 (47%) had a relapsing or chronic psychiatric disorder (Lloyd et al, 1996). In addition, they reported that a high initial General Health Questionnaire score was strongly associated with a high General Health Questionnaire score at 11 years, chronic course of psychiatric illness and high consultation rate. No association were found with initial personality and social problems assessment (Lloyd et al, 1996).

Studies on prognosis have yielded conflicting results (Dowrick and Buchan, 1995). Some research studies have shown better outcomes for patients suffering from common mental disorders (Wright and Anderson, 1995), but it seems that at least 12% of patients are likely to become chronic (Dunn and Skuse, 1981). Lloyd et al's (1996) recent findings support the view that common mental disorders can become chronic and are associated with raised mortality and high service use.

### **2.3 COST OF COMMON MENTAL DISORDERS IN PRIMARY CARE**

O'Donnell et al (1988a), in a review of economic evaluations of mental health care, pointed out that mental health resources are extremely scarce and choices between

alternative services need to be made. However most therapies have not been evaluated and decisions are made on the basis of received wisdom and customary practice.

Wilkinson et al (1990) adapted Quality Adjusted Life Years (QALY) in a psychiatric setting and tried to assess the costs of care per QALY in people with schizophrenia, affective disorders and neurosis. They found the costs were highest for people with neurosis and lowest for people with schizophrenia. However this study had some serious methodological flaws and its aim was mainly to assess whether QALYs were applicable to people with a psychiatric disorder. In a different study Croft-Jeffreys and Wilkinson (1989) estimated the costs of neurotic disorders in general practice. They compared the costs of neurotic disorders with uncomplicated hypertension by estimating both direct costs and indirect costs. Direct costs included number of consultations, medications prescribed and personal costs, such as prescription charges. Indirect costs included number of days off sick and sickness benefit due to days lost at work. They found that the costs of neurotic disorders and uncomplicated hypertension were similar, however neurotic disorders were more expensive in GP time and lost production, whereas hypertension had higher medication and personal costs. The authors were unable to evaluate some of the costs, such as people who dropped out of the labour force because of chronic illness, and therefore speculated that the £373 million for neurotic disorders in 1985 was an under-estimate of total costs. They concluded that most of the costs were due to lost production rather than expensive medical services.

A similar study estimated the cost of depression seen by general practitioners in England and Wales (Kind and Sorensen, 1993). They predicted the costs by using published data and making a number of assumptions about the prevalence of depression, the treatment of depression and days lost at work. Analysing the direct service costs, they found that acute hospital admissions for mental illness accounted for 40% of the direct costs and general practice consultations accounted for 27%. Drug costs only represented 11.3% of these total annual direct costs of £420 million. However, they speculated this may increase to 15% with the introduction of newer and more expensive drugs. The indirect costs were considerable and they estimated the costs to sufferers of depression and their carers in excess of £3.5 billion annually (Kind and Sorensen, 1993).

The above studies show that the greatest costs are due to lost production. In America, there is a similar picture. Wells et al (1989) in the Medical Outcomes Study found that patients with depressive disorders or symptoms tended to have worse physical, social and role functioning than patients who had chronic medical conditions. Particularly, the patients with depressive symptoms spent a significantly greater number of days in bed than patients with hypertension, diabetes and arthritis. Broadhead et al (1990) in the Epidemiologic Catchment Area Study in North Carolina found that subjects with major depression had a 4.8 times greater risk of disability than subjects who had had no symptoms of depression during the 6 months before entry to the study. They defined disability as when a person spent all or part of the day in bed or was kept from usual activities. In addition, people with minor depression

with mood disturbance had a 1.6 increased risk and because of its greater prevalence, may account for 51% more disability days than individuals with major depression. With these studies it begins to become clear that it is vital to include indirect costs in the economic evaluation of patients with common mental disorders.

#### **2.4 RECOGNITION AND MANAGEMENT OF MENTAL DISORDERS IN PRIMARY CARE**

From the epidemiological studies, it is clear that common mental disorders are a major health problem in general practice and these disorders cause great distress in terms of psychiatric symptoms and social functioning. Many patients will suffer from a relapse of symptoms or develop a chronic illness. In addition, there is a substantial economic burden to society, particularly in terms of lost production. Thus, it is vital that general practitioners and primary health care teams who deal with the majority of patients with common mental disorders relieve the psychological, social and economic suffering in an effective manner.

In January 1992 the Royal College of Psychiatrists in association with the Royal College of General Practitioners launched the Defeat Depression Campaign (Baldwin and Priest, 1995). The campaign has tried to highlight the need for appropriate detection and management of depression in primary care, by trying to improve public and professional awareness, publishing two consensus statements (Paykel and Priest, 1992; Katona et al, 1995) and a report on shared care of patients with mental health problems. In addition a mental health fellow was established and funded by the

Department of Health, Mental Health Foundation and Gatsby Charitable Foundation to take a national lead on general practice education.

#### **2.4.1 RECOGNITION OF MENTAL DISORDERS**

Numerous studies have shown that general practitioners have failed to recognise common mental disorders when their diagnosis is compared to psychiatric interviews (Marks et al, 1979; Ormel et al, 1990). Freeling et al (1985) found that general practitioners missed major depression more often in patients who had physical illness. This finding was confirmed by Tylee et al (1993) who found that women with unrecognised major depression experienced more physical illness and were more tired than women who had their depression recognised. More recently they found that the women were five times more likely to have their depression recognised if they mentioned their psychiatric symptoms early in the consultation compared to those who either mentioned it later or never mentioned them. After adjusting for physical illness the likelihood of recognising depression increased to 10 if the women mentioned their psychiatric symptoms at the beginning of the consultation (Tylee et al, 1995).

There is conflicting evidence on whether recognition and disclosure of mental disorders makes a difference to patient outcomes (Dowrick and Buchan, 1995). Nevertheless, there have been many attempts to improve recognition skills of mental disorders by group training for both general practice registrars (formerly known as trainees) and established general practitioners (Gask et al, 1987; 1988).

### 2.4.2 THE CONSULTATION

There are several things the doctor can do to manage a person with a common mental disorder. Markus et al (1989) mention the consultation in which the general practitioner can gain a trusting relationship with the patient and build on it. Neighbour (1987) reviews many of the different models of consultations available to general practitioners. Over the years the medical model has been heavily criticised for being too task orientated and doctor centred and concerned only with pathology and the physical aspects of illness. Many general practitioners have however been influenced by Balint (1957), a psychoanalyst, who wrote the influential book "The Doctor, His Patient and the Illness". He explored the doctor and patient relationship and made general practitioners aware of the psychoanalytic aspects of the consultation. Byrne and Long (1976) studied the behaviours of general practitioners when talking to their patients and found a range of styles used by the doctors, ranging from completely doctor centred, that is closed information gathering, to completely patient centred, using non-directive counselling skills. Neighbour (1987) provides a structure for a five stage consultation.

### 2.4.3 MEDICATION

Several types of medication are used to help patients with common mental illnesses in general practice. These are anti-depressants, anxiolytics and hypnotics, other psychotropic medication and other drugs such as beta-blockers for anxiety.

The Defeat Depression Campaign has emphasised the need for adequate prescribing of anti-depressants in general practice (Paykel and Priest, 1992). Kerr (1994) examined prescribing habits of general practitioners and psychiatrists through a postal questionnaire survey. Fifty two per cent of the 68 general practitioners and 17% of the 60 psychiatrists reported using lower than recommended dosages of anti-depressants and 40% of general practitioners and 7% of 62 psychiatrists used shorter than recommended periods of continuation therapy. Thakore and John (1996) reviewed the recommendations provided by Family Health Services Authorities (FHSAs) and health boards to general practitioners. They found that a few FHSAs were recommending anti-depressants at a sub-optimal dose. The older tricyclic anti-depressants were still recommended as the first line agents, despite evidence that the newer Selective Serotonin Reuptake Inhibitors (SSRIs) may have fewer side-effects and therefore may have better compliance (Cookson, 1993). However SSRIs are more expensive and if they were to substitute for the older tricyclics it could increase the NHS drug budget in England by over £100 million (Freemantle et al, 1993).

There has been a considerable decrease in benzodiazepine prescription over the past 15 years (Bashir et al, 1994). The Committee on the Review of Medicines (1980) published the risks of dependence of long-term benzodiazepine use and in 1988 the Committee on Safety of Medicines recommended that benzodiazepines should not be used for more than four weeks. Deans and Skinner (1992) conducted semi-structured interviews with 15 general practitioners and 15 general practitioner trainees. Most doctors admitted to prescribing benzodiazepines to patients suffering from anxiety. The



average estimated percentage of patients given medication was 44%, however medication was only prescribed short-term. Most doctors agreed that the use of counselling skills could be as effective as benzodiazepines, but felt that counselling was too time consuming and therefore it was quicker to prescribe medication. Two thirds of these doctors would have favoured employig a counsellor within the practice.

#### **2.4.4 REFERRAL TO SECONDARY SERVICES**

Goldberg and Huxley (1992) have demonstrated that only approximately 5% of general practice attenders with a mental health problem are referred to secondary services. However, in recent years psychiatrists and general practitioners have worked more closely together (Pullen et al, 1994) and established different working patterns, such as psychiatric liaison attachments to general practice (Dowrick, 1992). General practitioners can also refer to other mental health professionals such as members of a community mental health team, community psychiatric nurses, clinical psychologists and social workers. They can also recommend patients to contact local mental health organisations such as MIND or a counsellor known in the area.

#### **2.4.5 PSYCHOLOGICAL THERAPIES**

The general practitioner can also use a number of psychological therapies themselves or refer to a specialist trained in a psychological therapy. Markus et al (1989) talk about counselling, individual psychotherapy, family and couple therapy, group therapy, crisis intervention and

transition counselling. In the recent book published by the Royal Colleges of Psychiatrists and General Practitioners "Psychiatry and General Practice Today", two chapters have been written on counselling and psychotherapy and cognitive behaviour therapy (Pullen et al, 1994). Some of the health professionals trained in psychological therapies are counsellors, psychotherapists, clinical psychologists, community psychiatric nurses and psychiatrists. There are many more however who have experience of or have been trained in using a psychological therapy.

In conclusion, this chapter has highlighted common mental disorders, such as depression and anxiety, as a major public health concern in terms of psychological, social and economic suffering. General practitioners and the primary health care team are well placed to recognise and treat these common disorders in an effective manner. Both pharmacological and psychological therapies are used in general practice. The psychological therapies will now be discussed in greater detail in the next chapter.

### **3.0 COUNSELLING IN GENERAL PRACTICE**

This chapter will explore how counselling is defined, who counsellors are in general practice and examine in depth the evidence of efficacy and cost effectiveness of counselling in general practice.

#### **3.1 HISTORICAL BACKGROUND**

The beginnings of counselling can probably be dated back to the early 1900s and has its roots in vocational guidance in America (Feltham, 1995). It was Carl Rogers who introduced non-directive counselling, distinguishing it from psychotherapy, and suggested that counselling could be conducted by non-medical practitioners. The first counselling courses in Britain were set up in the 1960s, with the influence of Rogers and of student-orientated counselling. The Standing Conference for the Advancement of Counselling was founded in 1971, which became the British Association for Counselling in the mid 1970s (Feltham, 1995).

It is difficult to know when the first counsellor started to practice in British general practice. Interest in psychotherapy in general practice was certainly recorded as early as 1956 (Hopkins, 1956), but it was not until 1975 that Marsh and Barr published the first paper on counselling in general practice. Kincey (1974) and Broadhurst (1977) examined the interest of psychology to general practice.

### 3.2 DEFINITION OF COUNSELLING

Counselling has become a confusing word and society now expects counselling to be available for many reasons such as disasters, personal trauma or marriage guidance. Bond (1995) described how different people, including health professionals, hold different concepts of counselling. Some people see it as advice giving and some consider it a time set aside (usually an hour a week over several weeks) for discussing psychosocial issues with a trained professional. Stokes (1994) in a postal questionnaire survey found that 43% of general practitioners defined counselling as 'listening' or 'helping', 54% gave a more detailed definition of specific counselling skills being used in a non-directive exploration of the patient's problem and 3% equated counselling with psychotherapy.

The British Association for Counselling (1992b) has its own definition:

Counselling is the skilled and principled use of relationships which develop self-knowledge, emotional acceptance and growth, and personal resources. The overall aim is to live more fully and satisfyingly. Counselling may be concerned with addressing and resolving specific problems, making decisions, coping with crises, working through feelings and inner conflict, or improving relationships with others.

The counsellor's role is to facilitate the client's work in ways that respect the client's values, personal resources, and capacity for self-determination.

In the above definition, counselling is about developing and facilitating the strength of clients in order for them to determine their future lives. Counselling is seen to enhance, usually in a non-directive style, a person's capacity to find their own solutions to their problems. The counsellor refrains from giving advice and reassurance and discourages the development of long term dependence, so that patients are enabled to help themselves rather than use the directives of others (Rowland and Irving, 1984).

Rowland (1993) made a further distinction. She differentiated between counselling skills and counselling. Counselling skills, such as listening, reflecting and conveying empathy, are not exclusive to the counsellor. They are used by other people, for example doctors and nurses, and are applied to facilitate communication between people. In contrast, Rowland (1993) argued that counselling is essentially an ethical task underpinned by a code of ethics and practice. According to the British Association for Counselling (1991):

"people become engaged in counselling when a person, occupying regularly or temporarily the role of counsellor, offers or explicitly agrees to offer time, attention and respect to another person or persons temporarily in the role of client".

Rowland (1993) argued that the counsellor tries to develop a therapeutic relationship with the client and use empathy to understand the client's situation. It is a distinct period of time set aside when two or more people discuss psychosocial problems. There is a contract between the client(s) and counsellor to explore the client's feelings

and concerns. Bond (1995) suggested that this should not diminish the use of counselling skills by other professionals besides counsellors or that counselling skills are a lower order activity compared to counselling. He argued that with proper training, experience and supervision anybody can counsel, including doctors and nurses. However, who should do the counselling is open to debate (Rowland et al, 1989; Shepherd, 1989; Noon, 1992).

### **3.3 MODELS OF COUNSELLING**

Over 200 different models of counselling have been described (Bond, 1995). Often counsellors describe themselves as eclectic and use a variety of models. There are three common models: person-centred or humanistic counselling, psychodynamic counselling and cognitive behaviour counselling (Bond, 1995). Some counsellors may work with groups of people as well as one-to-one counselling (Irving and Heath, 1989). This section explores the difference between counselling and psychotherapy and examines the main models of counselling in some further detail.

#### **3.3.1 DIFFERENCE BETWEEN COUNSELLING AND PSYCHOTHERAPY**

It is difficult to be exact about the differences and similarities between counselling and psychotherapy, since as Feltham (1995) pointed out, there are two main views: "one that they are entirely or largely synonymous, and the other that they are largely or utterly distinct" (p.42). Some of the perceived difference seems to be that psychotherapy may be long term and more in depth, particularly dealing with the unconscious, whereas

counselling is briefer, non-judgmental and possibly more superficial (Feltham, 1995). However, some counsellors work with clients over a long period of time and usually study the same texts as their psychotherapy colleagues. Feltham (1995) believes that many of the differences between psychotherapy and counselling stem from historical, ideological and political factors and prejudices, rather than there being essential differences between the work of counsellors and psychotherapists. Rowland (1993) believes the differences between counselling and psychotherapy are usually of orientation and degree. She pointed out that counsellors concentrate less on the transference between counsellor and client and focus on current problems whereas psychotherapists deal with more deep-seated personal life problems.

### **3.3.2 THE HUMANISTIC MODEL**

Humanistic models include person-centred, Gestalt, psychodrama and feminist therapy to name but a few (Feltham, 1995). They have in common a belief in self-actualisation or fulfilment, where a person is seen as striving to create, achieve or become (McLeod, 1996). A person is seen as a whole not as body and mind in conflict (Feltham, 1995). Therapists are usually very non-directive relying on openness, empathy and unconditional positive regard (McLeod, 1996).

### **3.3.3 THE PSYCHODYNAMIC MODEL**

Psychodynamic models of counselling originate from Freudian theory (Feltham, 1995). They have in common the unconscious conflict and techniques such as transference and suggestion

are used to explore both conscious and unconscious thoughts and feelings (Roth and Fonagy, 1996). Clients are often in therapy or counselling for one to two years of once or twice weekly sessions.

#### **3.3.4 THE COGNITIVE-BEHAVIOURAL MODEL**

The cognitive-behavioural model is seen as a more directive model and which has its roots in classical learning theory and social learning theory (Roth and Fonagy, 1996). The therapist is concerned with maladaptive behaviours, thoughts and beliefs and challenges these in a problem solving manner. The therapist is not particularly concerned with the cause of the maladaptive beliefs and behaviours, but relies on self-monitoring, identifying and challenging negative thoughts, decatastrophising and scheduling activities (Roth and Fonagy, 1996).

#### **3.4 COUNSELLORS BACKGROUND, TRAINING AND EXPERIENCE**

As has already been mentioned in section 1.4.2, anybody can call themselves a counsellor, even though many have different backgrounds, qualifications and experiences. Here the term counsellor is used in the wider sense as per Sibbald et al's (1993) definition.

According to Sibbald et al (1993), there are three principal "counsellors" in general practice who offer counselling. In a survey of 1542 general practices in England and Wales, 484 (31%) had a "counsellor". They were mainly community psychiatric nurses (181 or 12%), clinical psychologists (95 or 6%) and "practice counsellors" (134 or 9%). They comprised 85% of all practices with a counsellor.



Other "counsellors" included general practitioners, practice nurses and health visitors.

Sibbald et al (1993) found that out of the three main groups of counsellors, 106 (26%) were accredited by the British Association for Counselling and a further 91 (22%) were trained by Relate (formerly Marriage Guidance Council) or had completed a counselling or psychotherapy course. The general practitioner did not know what qualifications, if any, were held by 85 (21%) of their counsellors. Other qualifications that counsellors held were registered general nurse, community psychiatric nurse diploma, social work training, health visitor training or psychology degree.

Some years earlier, McLeod (1988) had reported similar results in her smaller survey of counsellors in general practice. Most counsellors were nurses, several being psychiatric nurses, but there was also a social worker, a psychology graduate and several counsellors and psychotherapists. Their training varied enormously. Some were trained through Relate, some only had a year certificate course, others used their psychiatric nursing training and some were trained in psychotherapy.

At present counsellors do not require any specific training in order to set up in practice (Fallowfield, 1993). There is also little consistency between training courses and the level of competency varies from course to course (Cocksedge and Ball, 1995). However the British Association for Counselling in the mid 1980s developed an accreditation system in an attempt to standardise the training of counsellors (Rowland and Irving, 1984). This ensures that

counsellors have fulfilled a certain number of hours of training and supervised practice. It also includes a commitment to continuing personal and professional development. At present there are not many accredited counsellors, but there are guidelines to ensure that counsellors have sufficient training and experience (British Association for Counselling, 1992) and the British Association for Counselling (1993a) has produced a list of approved courses in counselling. In 1982 a division in the British Association for Counselling called the Counselling in Medical Settings was established (Rowland and Irving, 1984). They concern themselves with the working conditions of counsellors in general practice and what advice to give to general practitioners about counsellors. In 1993, the Counselling in Medical Settings published "Guidelines for the employment of counsellors in general practice" (British Association for Counselling, 1993b).

Psychologists also do not need to be specifically trained to set up as counsellors. However psychologists can register with the British Psychological Society (BPS) as chartered clinical psychologists or very recently as chartered counselling psychologists (Farrell, 1996). A new Division of Counselling Psychologists was set up in 1994 to reflect the growing interest and demand in this relatively new area of psychology, together with an approved diploma in counselling psychology (Farrell, 1996).

In summary, anybody can call themselves a counsellor and practice however they like. More recently, Family Health Services Authorities or health agencies have stipulated that counsellors should be British Association for Counselling accredited or have undertaken a recognised

training course in order to standardised the quality of counsellors (Salinsky and Curtis Jenkins, 1994). Many Family Health Services Authorities or Health Agencies have started to reimburse general practitioners for counsellors. Counsellors are employed on sessional basis, usually one session being equal to three hours counselling with three different clients. However, it is usually up to the general practitioner and the counsellor as to who the counsellor sees in the surgery and up to the counsellor as to what type of therapy she or he might use.

### **3.5 CLIENTS/PATIENTS CHARACTERISTICS**

Counsellors in general practice frequently work as generalists seeing a variety of different people with a range of problems and therefore use different methods to assist the patient to arrive at their own solutions (Rowland, 1993).

Almost any emotional or behavioural problem appears to be within the remit of counselling. Waydenfeld and Waydenfeld (1980) asked doctors to record the reason for referral to the counsellor. They found the common problems were anxiety, marital problems, relationship problems, sexual problems and psychosomatic problems. Other problems included violence, depression, alcoholism, childbattering, suicide attempt, mental illness in the family, compulsive overeating, abortion counselling and bereavement.

Despite this wide range of possible problems that may lead to a referral to a counsellor, there is some evidence of specialisation. A survey in the mid 1980's found that marriage guidance counsellors tended to be referred more

women than men or couples and of these married women aged between 30 and 50 years and single women between 20 and 29 years predominated (Corney, 1986a). Sibbald et al (1993) found that community psychiatric nurses were more likely to be referred patients with anxiety or depression, personality disorder or psychotic illness; practice counsellors were more likely to be referred bereaved patients; and clinical psychologists were more likely to be referred patients with psychosexual problems, eating disorders, phobias or obsessive-compulsive disorders. Bond (1995) lists 13 areas which are generally considered suitable for counselling: bereavement; recovery from trauma; terminal illness; anxiety associated with major transition in life; stress management; problems with use of alcohol or drugs; interpersonal and relationship problems; sexual problems; family planning; infertility; HIV/AIDS; psychological and less severe psychiatric problems; and decision making about the course of treatment when the patient has alternatives to choose between.

Unlike specialist HIV or bereavement counsellors, counsellors in general practice work in a generalist field and encounter people with a wide variety of problems. It is unclear whether all counsellors working in general practice are equipped to cope with this range and how they might seek the resources of other more specialised therapists.

### **3.6 EFFECTIVENESS OF COUNSELLING IN GENERAL PRACTICE**

There have been numerous studies describing and evaluating counselling in general practice. These can be broadly divided into 4 groups: descriptive studies; randomised controlled trials using stated hypotheses about

counselling; economic evaluations; and meta-analyses. Most studies include evaluations of counselling conducted by generic counsellors, psychologists, community psychiatric nurses, health visitors, social workers and general practitioners.

Tables 3.1 and 3.2 summarise the papers published on the subject of counselling in general practice. Table 3.1 outlines descriptive studies of counsellors in general practice. This table does not include studies on psychologists, nurses or other health professionals. Table 3.2 summarises trials comparing counsellors or other health professionals with usual general practitioner care. The tables represent most of the relevant published papers on counselling in general practice. Some of these studies will be discussed further.

### **3.6.1 DESCRIPTIVE STUDIES**

Descriptive studies outline the role of a counsellor attached to the practice, highlight the advantages to the doctor, the patient and the counsellor, examine outcomes like number of prescriptions, consultation rates and patient satisfaction and describe the process of referrals and who is referred.

The first papers published on counselling in general practice appeared in the 1970s. Marriage guidance counsellors started to offer their services to general practitioners on a voluntary basis as it became increasingly clear that many doctor consultations had a social and psychological element to them and that a "single

**Table 3.1 Descriptive studies of counsellors attached to general practice in chronological order of year and month of publication.**

<b>Authors</b>	<b>Number included</b>	<b>Type of study</b>	<b>Process and Outcome</b>
Marsh and Barr (1975)	160 consultations	Descriptive study of attached marriage guidance counsellor over 12 months	Type of problems described. Patient, GP and counsellor satisfaction.
Cohen (1977) Cohen and Halpern (1978)		Descriptive studies of the attached marriage guidance counsellor	4 examples where counselling could be helpful. Reduced prescribing.
Anderson and Hasler (1979)	80 patients recruited, 55 completed questionnaires	Questionnaires completed by patients and counsellors and survey of patient case notes	Patients preferred to see the counsellor, satisfaction with service. Less prescribing of psychotropics and fewer consultations.
Waydenfeld and Waydenfeld (1980)	103 recruited, 88 patients used in the study	Questionnaire survey and interviews with patients, 9 counsellors and 1 GP from 9 practices	Patient satisfaction. Reduced surgery consultations and reduced prescribing. Small number felt counselling had not helped.
Martin and Mitchell (1983)	87 patients 42 questionnaires completed	Descriptive study of attached marriage guidance counsellor and questionnaire survey	Process data on number of consultations, failed to attend and problems at presentation. Most found counselling useful.
Corney (1986a, 1987a)	28 out of 38 GPs and 10 counsellors	Postal questionnaire survey of GPs and the attached marriage guidance counsellors	GPs found counsellor attachments helpful. Types of referrals described.
McLeod (1988)	17 counsellors	Interviews with counsellors and GPs	Identified workload of counsellors. Types of referrals, training of counsellor and relationship with GPs discussed.
Sibbald et al (1993)	1542 (82%) GPs completed questionnaire	Postal questionnaires and telephone interview with a sample of GPs in England and Wales	586 counsellors were distributed among 484 practices. Type & training of counsellor and referrals described.
Thomas (1993)	100 out of 105 patient completed questionnaires	Questionnaire survey on perceptions of counselling in general practice. A sample of patients in GP surgery.	Over 50% would have liked to talk to a counsellor over the past 3 years and 85% would prefer to see a counsellor in the GP surgery.

**Table 3.1 Descriptive studies of counsellors attached to general practice in chronological order of year and month of publication (cont.).**

<b>Authors</b>	<b>Number included</b>	<b>Type of study</b>	<b>Process and Outcome</b>
Webber et al (1994)	95 patients referred	Retrospective analysis of counselling referrals over one year in one general practice	Description of referrals. Out of the 95, 12 never attended, 12 terminated their contract prematurely.
Speirs and Jewell (1995)	293 patients referred over 2 years	Evaluation of 1 counsellor attached to 2 practices over 2 years	Description of referrals. Reduction in psychotropic medication. Most patients felt counselling was useful.
Burton et al (1995)	210 patients (counsellor) 174 patients (psychologist)	Comparison of referrals to counsellor in 2 general practices and GP referrals to district clinical psychology department over 4 years	Counsellors see more patients with anxiety, depression, marital problem, child management and physical illness than psychologists.
Fletcher et al (1995)	82 general practices	Cross-sectional study comparing rate of psychotropic drug prescribing with counselling provision	Practices with an attached counsellor had a slightly higher rate of psychotropic drug prescribing.
Sibbald et al (1996)	214 (37.5%) general practices participated	Comparison of practices with or without a counsellor and the rate of psychotropic drug prescribing	Found no major differences between practices with or without a counsellor in terms of prescribing rates and costs.

**Table 3.2 Randomised controlled trials and trials with matched control groups.**

<b>Author(s)</b>	<b>Number included</b>	<b>Type of study and treatments</b>	<b>Outcome</b>
<b>Counsellor/ psychotherapist</b>			
Ashurst and Ward (1983)	726	Counselling vs routine GP care	No major differences in outcome.
Martin and Martin (1985)	174	Comparative trial with a matched sample, counselling vs routine GP care	No major differences in outcome.
Brodaty and Andrews (1983)	56	Psychotherapy vs counselling by GP vs routine GP care	No major differences in outcome.
Boot et al (1994)	192	Counselling vs routine GP care	Counselling group had significantly lower GHQ scores & fewer antidepressant prescriptions.
King et al (1994)	21	Pilot study, RCT by patient preference, counselling vs routine GP care	No major differences in outcome.
<b>Nursing staff</b>			
Ginsberg et al (1984)	50	Nurse therapist providing behavioural psychotherapy vs routine GP care	No major differences in outcome.
Marks (1985)	92	Nurse therapist providing behavioural psychotherapy vs routine GP care	Nurse group were significantly better than the GP group.
Holden et al (1989)	50	Counselling by health visitor vs routine GP care	Health visitor group had a higher rate of recovery than the GP group.
Wilkinson et al (1993)	61	Pilot study. Practice nurse support vs routine GP care	No major differences in terms of medication and compliance.
Gournay and Brooking (1992, 1994)	177	Counselling by CPNs vs routine GP care	No major differences in outcome.
<b>Psychologist</b>			
Robson et al (1984)	429	Behaviourally orientated psychologist vs routine GP care	Patients seeing the psychologist improved more quickly but no major differences at 12 months.
Teasdale et al (1984)	34	Cognitive therapy vs routine GP care	Cognitive therapy group was better at end of treatment but no major differences at 3 months.
Earll and Kincey (1982)	50	Psychologist providing behavioural psychotherapy vs routine GP care	No major differences in outcome, except psychologist group had fewer psychotropic prescriptions during treatment.



**Table 3.2 Randomised controlled trials and trials with matched control groups (cont.).**

<b>Author(s)</b>	<b>Number included</b>	<b>Type of study and treatments</b>	<b>Outcome</b>
<b>Social workers</b>			
Cooper et al (1975)	189	Matched comparison of general practices with and without an attached social worker	Social work group experienced some benefit in psychiatric and social outcomes.
Corney (1984, 1987c)	80	Attached social worker vs routine GP care	No major differences, except women with acute on chronic depression and had major marital difficulties and saw the social worker did better.
<b>Doctors</b>			
Catalan et al (1984)	91	Patients prescribed anxiolytics vs patients given brief counselling by GP without anxiolytic prescription	No major difference in outcome.
Catalan et al (1991)	113	Problem solving by psychiatrist vs routine GP care	Problem solving group had significantly greater reduction in psychiatric symptoms than the GP group.
Mynors-Wallis et al (1995)	91	Problem solving by GP or psychiatrist vs amitriptyline with routine GP care vs placebo with routine GP care	More patients receiving problem solving reduced their depression scores than drug or placebo group.
<b>More than one professional</b>			
Scott and Freeman (1992)	121	Psychiatrist vs social worker vs psychologist vs routine GP care	No major differences in outcome, except that specialist treatment costs more than GP care.

solution, diagnosis, or definitive treatment" may not be helpful (Cohen and Halpern, 1978).

In the first paper published, Marsh and Barr (1975) described a marriage guidance counsellor working in a group practice. The counsellor worked for 6 hours accepting referrals from all general practitioners and seeing patients. Common problems seen were infertility, desertion, sexual dysfunction, physical violence, alcoholism and depression. They felt there were advantages to the patient, doctor and counsellor, particularly that problems were identified at an earlier stage and that counselling took place in the safe and confidential atmosphere of the doctor's surgery. The counsellor also felt part of a team.

In June 1979 the Journal of the Royal College of General Practitioners published a series of articles on counsellors and psychologists attached to general practice. An anonymous editorial (1979) recognised that a large proportion of general practitioner consultations have a psychosocial component and that the pathological model of illness was no longer fully appropriate for people with behavioural problems in general practice. It described the increased prescribing of psychotropic medication such as Diazepam and suggested that counselling could be an alternative treatment for these problems. It also questioned whether people with behaviour problems are best treated by general practitioners or by counsellors, psychologists or social workers, and whether these problems should be treated within the primary health care team at all.

More surveys began to appear in the medical press. Counselling was increasingly welcomed by patients who felt it should be a service generally available in general practice (Anderson and Hasler, 1979). A number of studies showed a reduction in prescriptions for psychotropic medication, fewer consultations and doctors felt that their patients had improved their ability to cope (Waydenfeld and Waydenfeld, 1980; Anderson and Hasler, 1979). On the whole, counsellors, patients and general practitioners felt that counselling was beneficial and that patients had improved. Waydenfeld and Waydenfeld (1980) found similar results in their survey of 103 patients, but also found that some patients felt counselling was not helpful. The counsellor judged that 19 out of 101 patients had not improved and the doctor felt that 11 out of 100 had not improved and that one patient had deteriorated. Only two patients felt they had not been helped at all. This report was the first to suggest that counselling might have a detrimental effect and that side effects were an important outcome to measure in evaluations of counselling.

Martin and Martin (1985) investigated the effect of employing a counsellor over a period of 7 years on consultation rate and psychotropic drug prescribing, by examining a random sample of 300 patient case notes. The number of psychiatric diagnoses recorded in the notes fell by nearly 6%. The number of anti-depressants drug prescriptions fell by 17% and the number of prescriptions of minor tranquillisers and sedatives rose by 30%. They questioned whether the change in prescribing and diagnosis may have reflected the changes in medical structure of the practice or the presence of the counsellor making the general practitioners more sensitive to psychological

problems. In the same study, Martin and Martin (1985) compared the notes of 87 patients who attended the counsellor before the survey with an age and sex matched control group. The number of psychotropic drugs prescribed and the number of contacts with the doctor were recorded for the year before and after the date of the patient's first appointment with the counsellor. They found no significant changes in outcome and psychotropic drug prescriptions rose in the counselled group by 56%. They discovered that 88% of the increase in prescriptions was accounted for by a large number of prescriptions given to only four of the patients in the study. These studies suggest that reduced prescribing is not necessarily an indicator of whether counselling works, because it could mean that general practitioners have become more psychologically minded and therefore are prescribing more psychotropic medication.

Two recent studies (Fletcher et al, 1995; Sibbald et al, 1996) compared the rate of psychotropic drug prescribing and costs in general practices that had an attached counsellor compared with practices that had no counsellor on-site. Both studies found unexpected and surprising results. Fletcher et al (1995) found that practices with an attached counsellor had higher levels of prescribing of psychotropic drugs than practices that referred their patients to a counsellor not working on the practice premises. Sibbald et al (1996) found no significant differences between practices with and without an attached counsellor in terms of prescribing rates or costs. These studies question why psychotropic drug prescriptions do not decrease when a counsellor is attached to a practice, but speculate that counsellors only see a small proportion of

patients with emotional illness in general practice. It is also possible that general practitioners who employ counsellors in their practices are more psychologically minded and may recognise more emotional illness and therefore prescribe more psychotropic medication.

It is difficult to draw conclusions from the studies above and other similar studies (Cohen, 1977; Corney, 1987a; Ives, 1979; Kock, 1979; McLeod, 1988) about the effectiveness of counselling in general practice, because there are no control groups. In any case it is doubtful whether the utilisation of medical services can be used to argue the case for the cost effectiveness of counselling (Corney, 1992). Tolley and Rowland (1995) point out that these studies only include basic cost data and no attempt has been made to compare outcomes using randomisation.

### **3.6.2 RANDOMISED CONTROLLED TRIALS**

Randomised controlled trial designs are often considered the most powerful methods available to test hypotheses of cause and effect relationships between variables. In England and Wales, only two randomised controlled trials and one pilot study on counsellors and counselling in general practice could be found using Medline and Embase. An additional study from Australia was identified. Several other randomised controlled trials comparing other health professionals with usual general practitioner care are also described.

### **a) Counsellors or psychotherapists**

In the first published randomised controlled trial of counselling in Britain, patients were randomised to counselling or the routine general practitioner care (Ashurst and Ward, 1983). Patients were identified by the general practitioner in several ways: patients for whom a first or repeat prescription of psychotropic medication was given or considered, or patients for whom counselling without medication was considered necessary. All patients were approached to take part in the study and 37% of patients were randomly allocated to counsellors. Counsellors favoured using a Rogerian approach, but also used other approaches such as behavioural techniques, gestalt and dream work. They recruited 726 patients, of whom 273 were randomised to the counsellor. Of these only 157 (58%) actually made contact with the counsellor and received counselling help. Both doctors and patients found counselling acceptable and useful. There were no significant differences in outcome on consultation rates or scores on the General Health Questionnaire (Goldberg, 1974) at 1 year. Patients who received counselling were no less likely to reduce their use of psychotropic medication, in fact patients who had been randomised to the general practitioner were more likely to stop their use of psychotropic medication. Interestingly, patients who rejected counselling (42%) were less likely to feel better and twice as likely to continue using psychotropic medication than those that accepted counselling or the control group. As Corney (1992) points out, client motivation was not taken into consideration, since not all patients recruited into the study specifically wanted

counselling and this may have reduced the treatment effects.

During the same time another randomised controlled trial was evaluating brief psychotherapy in family practice in suburban family practice in Sydney, Australia (Brodaty and Andrews, 1983). Patients had persistent psychological problems for at least 6 months. They needed to score five or above on the 30 item General Health Questionnaire (Goldberg, 1972). They recruited 128 patients but 35 patients refused to take part at all and another 25 patients declined treatment, 12 dropped out of therapy and 4 patients were lost to follow-up. In the intervention group, 18 patients received 8 weekly half hour sessions of brief problem, orientated, dynamic psychotherapy from a qualified psychotherapist. Another group of 18 patients received 8 weekly half hour appointments with their family practitioners, who had no specific training and in the third group, 20 patients received no additional therapy. No differences between the three groups were found in the final outcome of symptom severity, social dysfunction, physical disability and medication. Psychotherapy was acceptable to both the patients and the doctors. However, these results are difficult to interpret because of the high refusal and drop-out rate.

In a more recent trial, Boot et al (1994) compared patients randomised to receive counselling from a trained counsellor accredited or accreditable by the British Association for Counselling or usual general practitioner support and advice. Most patients in the counselling group received a one hour session of individual counselling per week for a period of 6 weeks. Patients were assessed prior to

randomisation and 6 weeks later. They recruited 192 eligible patients into the study, but only 108 (56%) returned the follow-up questionnaires. Both groups reduced their General Health Questionnaire (Goldberg and Williams, 1988) scores but the counselled group did significantly better. The counselled group also received significantly fewer prescriptions for psychotropic medication. However these results need to be interpreted with caution, because of the short follow-up of only 6 weeks and the large drop-out rate at follow-up.

These trials have in common high drop-out rates, apparent lack of motivation on the part of patients, small sample sizes and short follow-ups. Although other randomised controlled trials have been conducted with other health care professionals, many too suffer from the same methodological short-comings.

#### **b) Health visitors**

In a study evaluating health visitors counselling women with post-natal depression (Holden et al, 1989), the authors found that the intervention group had a higher recovery rate on the Standardised Psychiatric Interview (Goldberg et al, 1970) and on the Edinburgh Post-Natal Depression Scale (Cox et al, 1987) than women randomised to usual care. The advantage to this study was that the patients and their treatment were homogenous. Health visitors used Rogerian counselling and all the women had post-natal depression. The difficulties of the study were the small sample size of 50 patients and the short follow-up of 13 weeks.



### **c) Community psychiatric nurses**

A study comparing counselling by community psychiatric nurses attached to general practice with standard doctor care, found no significant differences in mental health outcome and patient satisfaction (Gourney and Brooking, 1992; 1994). It is difficult to draw conclusions from this study, because of the complexity of the trial design. A third arm was added to the trial (waiting list control) after the start of the trial, because there seemed to be a delay in patients seeing community psychiatric nurses. In addition, 50% of the subjects dropped out of the community psychiatric nurse group (Friedli and King, 1995).

### **d) Clinical psychologists**

Clinical psychologists have used randomised controlled trials to evaluate their therapies but it is not always appropriate to regard their work as counselling (King, 1995). In several randomised studies comparing treatment from a clinical psychologist to usual general practitioner care, significantly greater reductions in medication and consultation rates were found in the patients seeing a psychologist, but these reductions were not maintained at the follow-ups of 3 to 7 months (Earll and Kinsey, 1982; Teasdale et al, 1984). In addition, these studies suffered from small sample sizes and their analyses were not conducted on an intention to treat analysis. Robson et al (1984) had a much larger sample size of 429 patients, but it is unclear how their analysis was conducted. They found that patients seeing the psychologist improved significantly over patients randomised to routine general practitioner care up to 34 weeks. At the 12 months follow-

up the difference was no longer significant. They did not use any standardised questionnaires thus making their results less comparable to other studies.

#### **e) Social workers**

One study evaluating social workers as "counsellors" (Corney, 1984) reported no significant differences with usual general practitioner care, except in one subgroup. Women who suffered from acute or chronic depression and had a poor relationship with their partner tended to benefit the most. The social workers rated these women as the most highly motivated to receive help.

#### **f) General practitioner**

Other studies have examined the general practitioner as the person providing the counselling. Catalan et al (1984) compared counselling by the general practitioner (without anxiolytics) to treatment with anxiolytic drugs in a study of 91 patients selected by the doctors with new episodes of minor affective disorders. No differences between groups were found. Surprisingly, the doctors spent less time with the patients randomised to receive counselling. Real differences may have been obscured because the same doctors managed patients in both groups. However, this study suggested that brief counselling by general practitioners was as least as effective as psychotropic medication. In a more recent study, three groups were compared: problem solving given by a psychiatrist or general practitioner; amitriptyline with standard general practitioner care; and drug placebo with standard general practitioner care (Mynors-Wallis et al, 1995). Ninety-one patients with major

depression were recruited after clinical assessment and completing the Hamilton Depression Scale (Hamilton, 1967). After 12 weeks they found that 60% of patients receiving the problem solving had recovered on the Hamilton scale compared to 52% patients given amitriptyline and 27% patients given placebo. Again the study contained only a very short follow-up period and no indication was given of how many patients had refused to enter the trial.

#### **g) Evaluating more than one health professional**

Scott and Freeman (1992) conducted a randomised controlled trial to compare three specialist treatments with routine general practitioner care. Patients were randomised to a psychiatrist who prescribed amitriptyline and described the nature of the depressive illness and how antidepressants work including side-effects; to a clinical psychologist who gave cognitive behaviour therapy; to a social worker for case work; or to routine care by the general practitioner. They recruited 121 patients suffering from depressive illness into the study. The main outcome was an observer rating of depression using the Hamilton Rating Scale (Hamilton, 1960) at outset and after 4 and 16 weeks and the number of patients recovered at 4 and 16 weeks. All treatment groups improved over the 16 weeks, but there were no major differences between the specialist groups and the usual general practitioner care group. This study has a number of methodological shortcomings. The patients in the various groups were not equal at baseline, the social work group had patients at baseline who were considered non-cases on the Hamilton Rating Scale (Hamilton, 1960) and the allocation to treatment was not strictly random. The follow-up period was only 16 weeks and the psychiatrist

treatment could be seen as atypical since normally they see patients for an assessment interview and often for psychological therapy.

Most studies have had problems with conducting randomised controlled trials of counselling. King et al (1994) concluded that most trials suffered from small sample sizes, ill defined therapies, inadequate evaluation and short follow-up periods. They highlighted common problems such as difficulty in recruitment of patients, maintaining motivation, training staff and data management. King (1995) lists 9 suggestions that could serve as a guide to conducting randomised controlled trials more effectively.

### **3.6.3 ECONOMIC EVALUATIONS OF COUNSELLING**

Economic evaluations are assuming greater importance in all outcome research. Most of these studies have relied on simple economic techniques and just considered direct service costs. Robson et al (1984) calculated that over a quarter of the salary of a senior psychologist working in general practice could be found from savings in the drugs bill alone.

Ginsberg et al (1984) randomly allocated patients with neurosis to behavioural psychotherapy by a nurse therapist or to routine general practitioner care. Clinical and economic outcomes at one year were significantly better for patients cared for by the nurse therapist. The practitioner group had increased its resource usage mainly because of increased absence from work and more hospital treatment and drugs. However their numbers were small, 22 patients in the nurse therapist group and 28 patients in the routine doctor

care group and some patients failed to complete the trial or did not complete the economic questionnaire. In another trial described above (Gourney and Brooking, 1992), the authors reported that there was a net economic benefit associated with community psychiatric nurse counselling. The only significant difference was attributable to one measure, taking time of work. These studies need to be interpreted with caution, because of the short-comings in their methodology.

Scott and Freeman (1992) also tried to evaluate the cost-effectiveness of the three specialist treatments compared with usual general practitioner care. They found that the specialist treatments were more expensive compared to routine general practitioner care, however with the methodological short-comings described above, the results need to be interpreted with caution.

#### **3.6.4 META-ANALYSIS**

Meta-analysis is a technique of integrating the results from a number of studies on a given topic. The advantage is that several primary papers will be reviewed in a scientific and rigorous way and that more general conclusions can be made. The main advantage is an increase in sample size and hence in power.

Balestrieri et al (1988) analysed 11 British studies comparing treatment by a specialist mental health professional in general practice with usual general practitioner treatment. They found that the specialist mental health professional had a 10% greater success rate than usual general practitioner treatment. However, some of

the studies reviewed had small sample sizes, three did not use randomised control groups and the mental health professionals ranged from psychologists to social workers to psychiatric clinics in general practice. Only two studies compared counsellors with usual general practitioner care. The results are difficult to interpret, because the mental health professionals probably used different therapies with their patients.

Despite the popularity of counselling with general practitioners and their patients, there is still no good evidence that counselling is clinically or cost effective. The next chapter explores in depth the methodological issues in running a randomised controlled trial to evaluate an intervention such as counselling in general practice.

#### **4.0 METHODS OF EVALUATION IN PSYCHOTHERAPY, COUNSELLING AND GENERAL PRACTICE**

In the present climate of seeking evidence on clinical as well as cost effective health care, researchers have become increasingly interested in developing more sophisticated research methodologies in order to evaluate different health care interventions (Parry, 1992; McPherson, 1994). In addition, there has been a movement towards gathering and sharing relevant and scientific information and practising evidence based health care (Sackett et al, 1991). Archie Cochrane's ideas expressed in his book "Effectiveness and Efficiency: Random Reflections on Health Service" (Cochrane, 1972) have stimulated clinicians and researchers alike in carrying out experimental trials and applying this scientific knowledge to the clinical setting. Recently two new centres have been developed to facilitate this process: the Cochrane Centre in Oxford (Chalmers et al, 1992) and NHS Centre for Reviews and Dissemination in York (Sheldon and Chalmers, 1994). This chapter explores the development of research methodologies in psychotherapy, counselling and general practice research. In particular, randomised controlled trial methodology in relation to counselling in general practice will be examined. Finally, relevant outcomes measures in psychotherapy, counselling and general practice are explored.

#### **4.1 OUTCOME RESEARCH**

There has been considerable debate on outcome research and what type of research is best suited to evaluating effectiveness of a treatment (McLeod, 1994; Black, 1996). McLeod (1994) discusses the tensions between quantitative

and qualitative methods used in psychotherapy research and concludes that the approach used is essentially based on "values, philosophical considerations, practical resource constraints and intended audience". He acknowledges that medicine and psychology have mainly been influenced by the ideas of Popper (1962) and Kuhn (1962) in gaining knowledge. It is dominated by a logical scientific and quantitative approach of cause and effect relationships between variables.

Within medicine the debate has recently intensified challenging the notion that randomised controlled trials are the "gold standard" for evaluation (Brewin and Bradley, 1989). Black (1996) criticises the belief that experimental methods are the only valid type of evaluation. He expresses some of the difficulties in conducting randomised controlled trials and suggests other methodologies could complement experimental studies and be more appropriate in gaining knowledge. These are non-randomised trials, cohort studies and case-control studies.

Many researchers agree that the clinical trial is not the only mechanism to yield information on health services. Corney (1995), when referring to research on counselling, points out both types of research are needed, that is, the research on the process (non-experimental) as well as the outcome of treatments or services (experimental). Despite the criticisms of the experimental design, the randomised controlled trial still remains an important tool to assess the efficacy of health care interventions. This is evident in the recent Department of Health review on "Research on the Efficacy and Effectiveness of the Psychotherapies" (Roth and Fonagy, 1996). It almost entirely based on



controlled studies, because uncontrolled studies "rarely yield unambiguous conclusions".

Lambert et al (1991) believe that randomised controlled trials are:

"a necessary component of highest ethical practice and fundamental aspect of counselling services" (p.51).

It is fundamental for patient care to ensure that the treatments they receive are of benefit to them and do not cause them any harm. Clinicians, health service managers and patients need to know whether psychotherapy or counselling is a clinical and cost effective treatment and the randomised controlled trial is still the most appropriate method of assessing this (Marks, 1994).

#### **4.2 RANDOMISED CONTROLLED TRIAL**

Randomised controlled trial methodology has become increasingly popular in psychotherapy (Parry, 1992; Lambert et al, 1991) and general practice research (Silagy, 1993; Silagy and Jewel, 1994; Pringle and Churchill, 1995). Randomised trial methodology in psychotherapy and general practice has essentially been adopted from evaluations used in drug trial (Shapiro, 1989; Black, 1996). However, researchers have experienced difficulties in conducting this type of research in these settings (Shapiro, 1989; Katon et al, 1994; Peto et al, 1993; Tognoni et al, 1991). Marks (1994) and Corney (1993) point out that clinical trials are time consuming, expensive and often difficult to undertake. However, the randomised controlled trial still remains the best method to evaluate the efficacy and

effectiveness of an intervention in the health service (Sackett et al, 1991). Some of these advantages and difficulties will be outlined below and related to evaluating counselling in general practice.

#### **4.2.1 INTERNAL VERSUS EXTERNAL VALIDITY**

Cook and Campbell (1979) highlight two important issues in outcome research: internal and external validity of studies. Internal validity refers to whether there is a causal relationship between the independent and dependent variables, whereas external validity allows conclusions to be drawn about the generalisability of the causal relationship. In addition, Roth and Fonagy (1996) clearly distinguish between the efficacy and the clinical effectiveness of a therapy. Efficacy refers to the research findings from a setting of a research trial whereas effectiveness is the outcome of a therapy in routine everyday practice.

Lambert et al (1991) explore the possible threats to internal and external validity. There will always be a natural tension between internal and external validity since there is conflict when a researcher tries to conform to both. Most studies in psychotherapy are focused on the actual therapy rather than a service in its naturalistic setting (Parry, 1992) and therefore try to achieve high internal validity. It is important to achieve good internal validity in order to make conclusions regarding the intervention (Shapiro, 1989). However, a study with high internal validity uses therapies, settings and clients or volunteers which are rarely found in everyday practice. It therefore becomes difficult to interpret clinical

effectiveness from studies on efficacy of therapies (Roth and Fonagy, 1996).

An analogy is the explanatory trial versus the pragmatic trial (Black, 1996). Black (1996) points out that pragmatic trials are rarely undertaken, whereas the explanatory trial provides evidence in the "most favourable circumstances". This includes highly trained therapists and often manualised therapies, homogenous sample of patients, strict randomisation, extensive monitoring of patients' progress and specialised clinical setting (Roth and Fonagy, 1996; Lambert et al, 1991). Katon et al (1994) recognise that randomised controlled trials in primary care are more suited to conducting pragmatic trials. They state four reasons: primary care patients are seen at earlier stages of illness and often have co-morbid physical illness, primary care interventions are provided at lower intensity than the same treatments provided by specialists and finally, primary patient care patients may be more ambivalent about the need for treatment and less motivated to carry out treatments than patients attending specialist based trials.

Shapiro (1989) believes the perfect study does not exist and that a "creative compromise" needs to be reached between achieving good internal and external validity. He states:

"In practice, the definitive evaluation of a given method requires complementary and convergent evidence from a body of methodologically diverse studies ranging from laboratory analogues with good internal and

statistical conclusion validity to field trials with good external validity." (Shapiro, 1989, p.183)

#### **4.2.2 RECRUITMENT TO TRIALS**

It has been shown in several studies that recruitment of patients to clinical trials in general practice is troublesome (Tognoni et al, 1991; Peto et al, 1993; Fairhurst and Dowrick, 1996). All studies found a large discrepancy between the number of general practitioners who agreed to take part and the number who actually participated. Peto et al (1993) found that time and forgetfulness were the main factors for low recruitment, but other reasons were reluctance on the part of doctor and patient to enter a research study.

Fairhurst and Dowrick (1996) discontinued a randomised controlled trial of counselling in general practice after five months when only one patient had been recruited. They followed up one general practitioner from each of the eight practices and asked them about their motivation, expectations and views on this type of study. They discovered that general practitioners had created an ethical dilemma for themselves wherein they felt that patients really needed counselling, yet they were aware there was no proof of effectiveness. They were reluctant to send a patient to a study where they only had a 50% chance of seeing a counsellor. In addition, general practitioners saw counselling as a last resort and therefore did not want patients being returned to them for treatment. Some patients specifically asked for counselling and declined to take part in the study where there was no guarantee of seeing a counsellor. It seems counselling is a particularly

emotive subject. Patients need to believe that both arms of the trial are of near equal effectiveness. It may be unethical if some patients potentially perceive an experimental treatment to be superior or inferior compared to the control group (Levine, 1993).

Many of the problems that occur in recruiting patients to trials centre on the discrepancy between the researchers', doctors' and counsellors' agendas. Murphy et al (1992) list a number of strategies in gaining access to primary care and recruiting subjects, such as involving general practitioners and other primary care staff, providing information and negotiation. Jonker and Sumajow (1992) found that sending a personal letter relating the actual to planned number of patients that has been referred and visiting general practices regularly increased their recruitment rate sharply. King et al (1994) in a controlled pilot study on counselling in general practice found that general practitioners needed reminders of the study protocol as well as regular updates on numbers of patients recruited.

#### **4.2.3 HOMOGENEITY OF TREATMENT, THERAPIST AND SAMPLE**

Stiles and Shapiro (1989) outline the inconsistency between psychological treatments and drug treatments in the context of the experimental design. They argue that psychological treatments cannot be controlled like a drug. Therapist, patient and therapist-patient interaction variables could influence the process and therefore confound the outcome to a greater extent than in drug trials. For this reason, and to achieve good internal validity, therapies have often been manualised and training has been provided to the

therapist prior to the start of the trial. In addition, therapists should be similar in age, orientation, training, commitment and experience (Lambert et al, 1991). King et al (1994) found that using existing counsellors attached to the general practice in a research study decreased the internal validity of the results. Counsellors came from diverse backgrounds with variable experience and training. This made conclusions about the therapy difficult.

Equally, patient samples should be homogenous and satisfy inclusion and exclusion criteria. These may include caseness according to ICD or DSM criteria. However, as Katon et al (1994) and Clarkin et al (1996) point out, patients in general practice often exhibit co-morbid physical or mental disorders. It would be very difficult to adhere to strict criteria expected in an explanatory trial. With the demand for effectiveness trials rather than efficacy trials, a greater number of patients in everyday practice should be asked to participate in trials (Clarkin et al, 1996).

#### **4.2.4 RANDOMISATION AND THE CONTROL GROUP**

According to Pocock (1983), randomisation:

“guarantees that there is no bias in the selection of patients for the different treatments and also helps considerably to reduce the risk of differences in experimental environment” (p.65).

However, Bradley (1993) questions whether randomisation is always feasible, particularly when treatments are not blind and the patient expresses a strong preference for the

treatment under investigation. The patient's preference could influence the patient's motivation to continue with a trial if randomisation to the unwanted treatment made them feel resentful. This in turn could affect recruitment and attrition (Bradley, 1993). Nevertheless, randomisation is still considered the only reliable method for allocating treatments and evaluating efficacy (Silverman and Altman, 1996).

McLeod (1994) lists seven different types of control groups used in psychotherapy and counselling research. These are illustrated in table 4.1. There are more types of control groups, but the best control groups are randomised and the client, doctor or therapist administering the treatment and the researcher making assessments are blind to the active and control treatments (Pocock, 1983). However, blinding is not feasible in psychotherapy trials and even with double blind drug trials there is uncertainty whether trials are truly blind (Oxtoby et al, 1989).

Shapiro (1989) outlines further outcome designs, including no treatment control groups (Table 4.2). Roth and Fonagy (1996) claim that ideally researchers would compare treatment with no treatment, however this is not ethically or practically possible. In addition, having a placebo or attention control group is also problematic because of the difficulty in blinding a treatment and the probable lack of credibility on behalf of the patient. It is therefore most common to find comparison of one treatment with another.

**Table 4.1 Types of control groups used in counselling and psychotherapy outcome research (taken from McLeod, 1994).**

Type of control group	Definition
Waiting list	Clients are randomly allocated to a waiting list and receive no treatment or contact while on the list.
Minimal contact	Clients are randomly allocated to a waiting list, are contacted regularly and given reassurance. Clients in need are removed from the study and given treatment if necessary.
Non-scheduled treatment	Clients randomly allocated to a waiting list are invited to begin treatment whenever they feel they need it. They are regularly re-assessed and are automatically removed from the list if in need of treatment.
Placebo controls	Clients randomly allocated to a control group are given an active placebo experience (e.g. reading instructional literature) that includes positive expectations for change.
Own controls comparison	All clients have to wait for a period of time. Change during counselling is compared with baseline measures obtained before counselling.
Non-client comparison group	Change over time is assessed in a group of people who report psychological problems but who are not seeking help.
Normative comparison	Change in clients is defined as movement from extreme symptomatic scores to "normal" range on a standardised measure with reliable norms.

**Table 4.2 Types of control groups and outcome designs (taken from Shapiro, 1994).**

Design	Features	Control for:
No-treatment control	Patients assigned to treatment or to no treatment control group	Spontaneous remission or passage of time
Placebo control	Patients assigned to treatment or placebo treatment control	1) As above 2) Expectations of benefit
Comparative outcome study	Patients assigned to one of several active treatments	1) As above 2) As above but more convincing and ethical



#### **4.2.5 HAWTHORNE AND RESEARCHER EFFECT**

Patients may be influenced by the fact they are participating in a study and therefore have an undesired effect on the dependent variables (Polit and Hungler, 1991). This is known as the Hawthorne effect. Particularly, researchers may have opinions about the treatment under investigation and subconsciously influence the patients in the study. In addition, they usually spend more time, ask more questions and take more interest in the patients than clinicians in ordinary, everyday settings (Polit and Hungler, 1991). Researchers therefore may have a biasing effect on the outcome measures (Shapiro, 1989).

#### **4.2.6 ATTRITION**

Every study will lose patients at various points in the study. This could disrupt the randomisation and restrict statistical conclusions drawn from the study (Roth and Fonagy, 1996). If attrition from treatment is not random, Hunt and Andrews (1992) propose the drop-out rate could be used as an outcome measure. Efforts need to be made to reduce the missing data. Myerson (1993) suggests methods of improving response rate with general practitioners, which could be applied to patients.

#### **4.2.7 FOLLOW-UP ASSESSMENT**

The length of follow-up assessments are very different between studies and can range from weeks to years (Roth and Fonagy, 1996). The researcher should be aware of the natural history of the disorder and plan the follow-up accordingly. However, Roth and Fonagy (1996) also caution

against using extended follow-up periods, because it becomes increasingly difficult to attribute change to the original experimental treatment.

#### **4.2.8 STATISTICAL ANALYSIS AND SAMPLE SIZE**

Statistical analysis can be flawed if researchers use too many outcome measures (Pocock et al, 1987), too many univariate tests (Frison and Pocock, 1992; Everitt, 1995) and too small sample size (Pocock, 1983).

#### **4.3 ECONOMIC EVALUATION**

Increasingly, health budgets are under pressure (Tillett, 1996) and researchers have been encouraged to carry out cost analyses alongside controlled trials (Robinson, 1993a). O'Donnell et al (1988b) recognise the problems of scarcity and opportunity costs within the health service in providing adequate care to people with a mental illness. They believe research should inform policy makers, clinicians and managers in making informed choices between competing treatments, personnel and locations. The Department of Health recently produced a guide by Professor Drummond from the Centre of Health Economics at the University of York. The guide introduces the basic principles of economic evaluation in trials and encourages economic data collection and analysis (Drummond, 1994). Drummond (1994) particularly recommends carrying out economic evaluation alongside pragmatic randomised controlled trials.

Economic evaluations try to draw up "a balance sheet of the advantages (benefits) and disadvantages (costs) associated

with each option" so that a decision can be made about which option should be implemented (Tolley & Rowland, 1995). Economic appraisals assist decision making and should allow clinicians or managers to make more rational choices (O'Donnell et al, 1988b). However, O'Donnell et al (1988b) point out the limitations to economic evaluations and claim they are not decision making tools. They mention two main reasons why economic evaluations may be limited: firstly, other criteria besides economic efficiency exist on which to base resource allocation and secondly, it is not always possible to account for or measure all the benefits or costs in one evaluation.

Four main approaches are currently used in health economic evaluations (table 4.3). Cost-minimisation analysis is the simplest type of analysis, but there must be no difference in outcome between two health care interventions (Robinson, 1993b). This allows for a simple comparison of costs alone. In cost-effectiveness analysis the outcome between the various interventions varies and therefore the differences in costs needs to be compared with the difference in consequences (Drummond, 1994). Hence, the difference in costs is related to the main difference in effects, expressed in natural units. For example, a general practitioner may evaluate counselling with routine general practitioner care in terms of reduction in depressive symptoms for a certain cost. Cost utility analysis expands the concepts of cost-effectiveness when comparing treatments where a single common measure does not exist. An overall index of health gain is used such as the quality adjusted life year (QALYs) gained (Robinson, 1993c). It is a subjective level of wellbeing that people experience in different states of health. Finally, cost benefit analysis

**Table 4.3 Types of economic evaluations (taken from Robinson, 1993a; Drummond, 1994).**

Type of economic evaluation	Measurement and valuation of consequences
Cost-minimisation analysis	Outcomes the same between options. No measurement necessary.
Cost-effectiveness analysis	Outcomes measured in natural units (for example, life years gained). Clinical outcome of options differ.
Cost-utility analysis	Utility measures or health state preference values (for example, quality adjusted life years gained (QALYs))
Cost-benefit analysis	Outcome valued in monetary terms.

attempts to define costs and outcomes in the same units (usually money) and is the most comprehensive form of analysis (Drummond, 1994). However it is very difficult to place a monetary term on health interventions, even though researchers have tried to ask people how much they would be willing to pay for certain treatments (Drummond, 1994).

This study will concentrate on using a cost-effectiveness analysis. Other economic considerations in a cost-effectiveness analysis are uncertainty, sensitivity analysis and discounting (Robinson, 1993d). In most studies there is uncertainty about the costs and effectiveness of different procedures. An approach to deal with this uncertainty is sensitivity analysis. Robinson (1993d) describes different types of sensitivity analyses, where the variables are assigned different values to see how they affect the results. This allows researchers to test the robustness of their results and whether the conclusions are meaningful. Discounting is based on a behavioural principle where people or agencies prefer to delay costs but wish to obtain immediate monetary benefits (Tolley and Rowland, 1995). In other words, future benefits and costs should have a lower value than current benefits and costs. There is however some disagreement whether discounting should be used in health services research (Robinson, 1993d).

Finally, a cost-effectiveness analysis can be analysed using average or incremental costs (Tolley and Rowland, 1995). In using an average cost analysis, the researcher simply compares the options and selects the lowest average cost per unit increase in quality of life (Tolley and Rowland, 1995). However, the more common analyses are the incremental or marginal cost analyses. With the incremental

cost analysis, the new intervention is compared with the alternative in terms of extra benefits obtained for the extra costs, whereas with the marginal cost analysis the costs and benefits are calculated in terms of an expanding or contracting existing service (Drummond, 1994, Tolley and Rowland, 1995).

#### **4.4. MEASUREMENT OF OUTCOME**

Measurement of health and disease outcomes is essential in order to draw conclusions about the effectiveness of health care interventions (Wilkin et al, 1992). An outcome measure has been defined as "the dependent variable in experimental research, i.e., the measure that captures the outcome of the experimental intervention" (Polit and Hungler, 1991). There are several types of outcome measures: self-report, observational and physiological measures (Peck and Shapiro, 1990). Many researchers advocate a multi-level approach to measurement (Hamilton and Shapiro, 1990), however it is not always possible to use all types of measures. This thesis relies on self-report measures because: observational and physiological measures require more training by the researcher; observational measures suffer from biases such as enhancement of contrast effects, central tendency and halo effects (Polit and Hungler, 1991), which can lead to low inter-rater reliability; the lack of sensitivity and specificity of physiological measures of depression (Hamilton and Shapiro, 1990); and finally self-report measures are often cheaper and less time consuming to administer than observational and physiological measures (Hamilton and Shapiro, 1990). However, it is important to remember that self-report measures are a subjective account of the patient, therapist or doctor involved in the

intervention. Bowling (1995) draws attention to social desirability bias, interviewer bias and the tendency of respondents to answer yes to items regardless of the content.

It is therefore important to choose an outcome measure carefully. An ideal outcome measure must both be reliable and valid. Reliability addresses the question of consistency (Peck and Shapiro, 1990) and is defined by Polit and Hungler (1991) as:

"the degree of consistency or dependability with which an instrument measures the attribute it is designed to measure". (p.653)

Reliability is usually measured as a reliability coefficient and one should aim for a reliability of at least 0.8 and treat with considerable caution any measure with a reliability of less than 0.7 (Peck and Shapiro, 1990). Validity is related to reliability, in that a measure that is unreliable cannot be valid. Polit and Hungler (1991) describe validity as:

"the degree to which an instrument measures what it is intended to measure". (p. 657)

Many different types of reliability and validity are used in psychometric testing. A researcher must carefully assess the reliability and validity of any potential measure, as well as a host of other criteria such as: relevance, sensitivity, comprehensibility, time to complete the measure, range of expected values, reactivity and

simplicity (Polit and Hungler, 1991). The next sections will explore the outcome measures chosen in the thesis.

#### **4.4.1 MEASUREMENT OF PSYCHOLOGICAL OUTCOMES**

There has been an explosion of self-report questionnaires and interviews in psychology, psychiatry and psychotherapy (Bowling, 1995; Freeman and Munro, 1990). Most measures are defined in terms of presence or absence of mental illness rather than psychological well-being (Wilkin et al, 1992). Three psychological outcome measures were chosen as it was considered an important area for potential change to occur after receiving counselling.

##### **4.4.1.1 BECK DEPRESSION INVENTORY**

The Beck Depression Inventory (BDI) is a self-report questionnaire originally designed by Beck et al (1961). The amended version has 21 items assessing the severity of depression in adults with psychiatric illness (Beck, 1979) (Appendix A). It includes questions on mood, pessimism, sense of failure, self-dissatisfaction, guilt, punishment, self-dislike,, self-accusations, suicidal ideas, crying, irritability, social withdrawal, indecisiveness, body image change, work difficulty, insomnia, fatigability, loss of appetite, weight loss, somatic preoccupations and loss of libido. Each item has a possibility of 4 responses, rated 0 to 3. Possible scores range from 0 to 63, with 0 representing no depression and 63 extremely severe depression. Different studies use different cut-off points, but Beck and Steer (1987) urge clinicians or researchers to used cut-offs appropriate to their situation. The Centre for Cognitive Therapy at the University of Pennsylvania



Medical School has distributed guidelines on cut-off scores: scores 0 to 9 represent normal or asymptomatic; 10 to 18 indicate mild-moderate depression; 19 to 29 indicate moderate-severe depression; and 30 to 63 indicate extremely severe depression (Beck and Steer, 1987).

**a) Reliability:**

In their original study, Beck et al (1961) calculated the split-half reliability using 97 patients. With a Pearson rho, they computed a coefficient of 0.86. They found it was difficult to measure test-retest reliability because a patient's clinical state was susceptible to change over time, particularly if a patient was receiving treatment. However they administered the Inventory to 38 patients at two different times (ranging from 2 to 5 weeks apart) and monitored parallel changes in their clinical state of depression. The percentage of agreement between the number of patients who improved or declined on the Inventory and the clinical assessment was 85%.

Beck et al (1988) in an meta-analysis reviewed several studies using psychiatric and non-psychiatric patients and found high internal consistency. They cited the range of test-retest reliabilities using Pearson product-moment correlations. For varying time intervals for psychiatric patients, the correlations ranged from 0.48 to 0.86, whereas the non-psychiatric samples ranged from 0.60 to 0.90 (Beck et al, 1988).

**b) Validity:**

Beck et al (1961) using a Pearson biserial rho found the concurrent validity between a psychiatrist's rating and the Inventory was 0.66. A similar study in England calculated a Kendall's rank correlation coefficient of 0.62 between the psychiatrist rating and the Inventory (Metcalfe and Goldman, 1965). The more recent meta-analysis showed that the concurrent validity of the Beck Depression Inventory was high, with mean correlations of over 0.70 when compared to the Hamilton Depression Scale (Hamilton, 1976) and clinical ratings for psychiatric patients (Beck et al, 1988).

Results from factor analysis depend on the samples studied, but have generally revealed three factors: negative attitudes or suicide (cognitive-affective), performance difficulty and somatic complaints (Beck and Steer, 1987; Bowling, 1995).

**c) Limitations:**

Even though the Beck Depression Inventory is one of the most widely used measures for depression (Wilkin et al, 1992), it lacks normative data for general practice populations. Only three studies could be found on general practice data. Salkind (1969) collected data from 73 out of 80 consecutive general practice attenders in rural Britain, whereas Williamson and Williamson (1989) calculated normative scores on 484 patients from an North American Family Medicine Care Centre.

Despite the lack of population norms, the Beck Depression Inventory seems to be a reliable and valid tool in measuring depression. It is particularly suited for general practice patients who often exhibit co-morbid physical illness because of the relatively small contribution of somatic symptoms to the total score (Wilkin et al, 1992).

#### **4.4.1.2 BRIEF SYMPTOM INVENTORY**

The Brief Symptom Inventory (BSI) (Derogatis & Melisaratos, 1983) is a shortened version of the revised Symptom Checklist 90 (SCL-90-R) (Derogatis et al, 1976) (Appendix B). It is a 53 item, self-report questionnaire designed to assess psychiatric and medical patients as well as subjects who are not patients. The 53 questions reflect 9 primary symptom dimensions: somatization, depression, anxiety, obsessive-compulsive, interpersonal sensitivity, hostility, phobic anxiety, paranoid ideation and psychoticism. In addition to the 9 primary symptom dimensions, there are three global indices of distress: the General Severity Index (GSI), the Positive Symptom Distress Index (PSDI), and the Positive Symptom Total (PST). The General Severity Index is the single best indicator of current distress level. It combines information on the numbers of symptoms and the intensity of perceived distress, whereas the Positive Symptom Distress Index is a pure intensity measure and Positive Symptom Total is a count of symptoms which the patient reports experiencing to any degree.

Published norms exist on three groups of people: heterogeneous out-patients; psychiatric in-patients; and a non-patient community sample. The data can be presented as

raw scores or as standardised T-scores when comparing the data to the norms (Derogatis, 1992).

Each item on the Brief Symptom Inventory is rated on a five point Likert scale (0 to 4) ranging from "not at all" to "extremely". The range of scores for the nine symptom dimensions, the General Severity Index and the Positive Symptom Distress Index are the same as each item, that is 0 to 4, when 0 is equal to "not at all" and 4 is equal to "extremely". For the Positive Symptom Total, the scores can range from 0 to 53, with 0 equal to scoring all a zero on each item and 53 scoring a non-zero on all the items.

**a) Reliability:**

Derogatis (1992) provides good reliability coefficients on internal consistency and test-retest reliability for all 9 primary symptom dimensions and the three global indices. The internal consistency coefficients were obtained from a sample of 719 psychiatric out-patients, using Cronbach's alpha. The coefficients ranged from 0.71 to 0.85 for the 9 dimensions (Derogatis, 1992).

For test-retest reliability, a sample of 60 non-patient subjects were tested across a two week interval. The coefficients ranged from 0.68 for somatization to 0.91 for phobic anxiety, with 0.90 for the General Severity Index, 0.87 for Positive Symptom Distress Index and 0.80 for Positive Symptom Total (Derogatis, 1992). This is strong evidence that the General Severity Index score represents a consistent measurement over time.

## **b) Validity:**

Construct validity was evaluated using principle component analysis and normal varimax rotation on scores of 1002 psychiatric outpatients (Derogatis, 1992). Seven symptom constructs were clearly reproduced and an eighth dimension, anxiety, was split into two well defined clinical manifestations, panic anxiety and general anxiety. The ninth dimension, interpersonal sensitivity, did not stay together as a linear dimension (Derogatis, 1992).

## **c) Limitations:**

Although this questionnaire has been used widely in all types of settings including psychotherapy trials (Derogatis, 1992), it has been less often used in general practice. No general practice norms were found, however the questionnaire has been completed by 376 subjects from households in Nottinghamshire (Francis et al, 1990).

### **4.4.1.3 COMPUTERISED REVISED CLINICAL INTERVIEW SCHEDULE**

The original Clinical Interview Schedule (CIS) was designed by Goldberg et al in 1970. Lewis et al (1990; 1992) adapted and standardised the interview for use by lay interviewers in assessing minor psychiatric disorder in the community and primary care. In addition, they developed a computerised version of the revised Clinical Interview Schedule (CIS-R) or PROQSY (**PRO**grammable **Q**uestionnaire **SY**stem) (Lewis et al, 1988; 1991). It measures psychiatric symptoms, particularly neurotic symptoms found in the community. The computerised version of revised Clinical Interview Schedule has effectively changed the interview

into a self-report measure, because the patient no longer needs to be assessed by a trained interviewer. There are 16 sections and each section is scored for symptoms experienced over the past 7 days. The sections are: somatic symptoms; fatigue; concentration and forgetfulness; sleep problems; irritability; worry about physical health; depression; depressive ideas; worry; anxiety; phobias; panic; compulsions; obsessions; elation; and ideas of reference. Each section is rated on a 0-4 scale, except 'depressive ideas' which can score up to 5. A score of 2 or more is approximately the point at which the symptom becomes clinically significant. A total score is the sum of all the above sections, except 'elation' and 'ideas of reference'. The recommended threshold for non-case to case is 11/12, that is, a subject scoring 12 or more is considered a case and corresponds to the point when a general practitioner would begin to be concerned about a person's mental health (Lewis & Pelosi, 1990).

**a) Reliability:**

The advantage of the PROQSY is that no rater is required as the computer calculates the individual scores. Hence inter-rater reliability becomes less important. No studies on test-retest reliability were found, however, Lewis et al (1988) used a statistical program LISREL to compute the relative reliabilities of the revised Clinical Interview Schedule, PROQSY and the General Health Questionnaire. This method assumes that the tools are measuring the same constructs represented by a single factor. The reliabilities calculated show the accuracy with which they measure this presumed construct. Using this method they found reliabilities of 0.88 for the revised Clinical

Interview Schedule, 0.84 for PROQSY and 0.82 for the General Health Questionnaire (Lewis et al, 1988).

**b) Validity:**

Assessing concurrent validity between the revised Clinical Interview Schedule and the PROQSY computer questionnaire, correlation coefficients of 0.86 and 0.77 were found in samples of dermatology out-patients and a sample of civil servants, respectively (Lewis et al, 1988). Individual scores were compared and found that the majority of kappa values were above 0.5 with the exception of anxiety and excessive bodily concern.

**c) Limitations:**

Some changes have been made to PROQSY with excessive bodily concern being removed from the questionnaire and anxiety split into anxiety or nervous tension and worry about a particular thought. However, no reliability or validity studies could be found on the revised PROQSY questionnaire.

Some of the questions and rigid predetermined responses on the PROQSY do not allow patients to explain their particular situation which may force a patient to answer a question incorrectly. However, patients found the computer assessment easy and acceptable to use in hospital and community settings, as well as in general practice (Lewis et al, 1988; Wilkinson and Markus, 1989). In addition, it save considerable time for the researcher with data entry and checking.

#### **4.4.2 MEASUREMENT OF SOCIAL ADJUSTMENT**

Social adjustment refers to ineffective performance in the everyday roles and tasks of an adult's life and dissatisfaction with that performance (Bowling, 1995). There have not been many self-report questionnaires suitable for general practice (Wilkin et al, 1992), however several have been used in psychiatry (Bowling, 1995). The modified Social Adjustment Scale has been used in a number of talking therapy trials in Britain (Mynors-Wallis et al, 1995; Hawton et al, 1987; Catalan et al, 1984a; 1984b) and America (Weissman et al, 1978).

##### **4.4.2.1 MODIFIED SOCIAL ADJUSTMENT SCALE**

The Social Adjustment Scale was first derived as an interview (Weissman and Paykel, 1974) and later developed as a self-report questionnaire (Weissman and Bothwell, 1976) in America. Cooper et al (1982) adapted it for the British population. It is a self-report questionnaire and is divided into 7 sections covering work, work in the home, social and leisure activities, relationships with extended family, relationships with partner, functioning as a parent and functioning in the family unit. It has 45 questions in total, with a varying number of questions in each section. The questionnaire ratings can be interpreted in three ways: six role areas (work and work in the home are considered as one role area), four descriptive categories (performance, interpersonal behaviour, friction and feelings) and a total score (Appendix C).

Patients were asked to think about the past two weeks and rate the 45 items themselves. All questions were scored on



a five point Likert scale. Most of the questions used the same scales consisting of: all the time; most of the time; about half the time; occasionally; not at all. All the scores, including the role areas, descriptive areas and total score, ranged from 1 to 5, with 1 indicating good social adjustment and 5 indicating poor social adjustment.

**a) Reliability:**

No test-retest reliability calculations could be found. However, Cooper et al (1982) found that the modified Social Adjustment Scale changed in the same direction as mental health assessments (Present State Examination and the Profile of Mood Sates) pre and post operatively and after 6 month follow-up.

**b) Validity:**

Concurrent validity was measured by the modified Social Adjustment Scale and the psychiatrist ratings on the interview Social Adjustment Scale. Pearson Rho correlations ranged from 0.63 to 0.80 between the overall mean scores (Cooper et al, 1982). Most of the role areas and descriptive categories had acceptable correlations, except performance. In addition, the modified Social Adjustment Scale was compared to the Present State Examination and the Profile of Mood Sates. Correlations ranged from 0.17 to 0.74. Only friction did not correlate significantly with the Present State Examination.

**c) Limitations:**

Despite the limited psychometric examination of this scale, it appears to have face validity. It lacks normative data, but a number of British studies have used the modified Social Adjustment Scale in evaluating talking therapies and in general practice.

**4.4.3 PATIENT SATISFACTION**

Patient satisfaction is difficult to measure, because of lack of variation and large ceiling effects (Fitzpatrick, 1993). No satisfactory questionnaire was found to evaluate counsellors and general practitioners views of the therapy. A questionnaire was adapted for the study from the Brief Structured Recall (Elliott and Shapiro, 1988). The Brief Structured Recall assesses significant therapy events, however it requires taping each therapy session and playing back the tapes to identify the significant change processes. Some of the items were used as a questionnaire for the present study. There are 14 items, each of which is rated on a 5 point Likert scale, where 1 equals 'not at all' and 5 equals 'very much' (Appendix D). Elliott and Wexler in 1994 published an article about a brief patient reported measure, the Session Impacts Scale. It was developed from the Brief Structured Recall and is similar to the questionnaire used in the present study. An additional question was added which asked patients directly how satisfied they had been with the care they had received from the counsellor or the general practitioner.

#### **4.4.4 EXPECTANCY AND CREDIBILITY**

It is important to establish whether two or more treatments being compared elicit similar levels of expectation for improvement and have similar credibility (Bradley, 1993). Any difference in expectancy and credibility could have an effect on the outcome measures and reduce statistical conclusions (Borkovec and Nau, 1972). A questionnaire was designed for the purpose of the study to assess these effects just after patients had been randomised (Appendix E).

#### **4.5 SUMMARY OF LITERATURE REVIEW**

The introduction outlined the purpose, null hypothesis and aims of the study. Chapter two showed that anxiety and depression are a considerable burden on the individual and society in terms of psychological, social and economic outcomes. It also identified general practice as an important provider to people suffering from common mental disorders. Chapter three explored counselling as a rapidly increasing treatment to people with psychological problems, despite the lack of scientific evidence of its clinical efficacy and cost effectiveness. This chapter has examined methodological issues which need to be considered when planning a randomised controlled trial of counselling in general practice.

## **5.0 METHODS**

This chapter describes the details of how the prospective randomised controlled trial to evaluate counselling was carried out.

### **5.1 PILOT STUDY**

The pilot study was conducted by King et al (1994). They used a patient preference randomised controlled trial design to evaluate counselling with routine general practitioner care. The practitioners carried out the randomisation procedure and recruited 24 patients to the study: 19 saw the counsellor and five patients saw their doctor. Patients suffering an acute episode of emotional disorder or suffering from a long term problem but with a recent increase in symptoms were eligible to enter the trial. Patients were interviewed by a research doctor within two weeks of recruitment and before treatment from a counsellor or the general practitioner. Outcomes were measured using the self-report measures: the original Clinical Interview Schedule (Goldberg et al, 1970), 28-item General Health Questionnaire (Goldberg and Williams, 1988), Beck Depression Inventory (Beck et al, 1961) and the Social Problems Questionnaire (Corney, 1988). The patients were followed up 12 weeks and six months after the initial interview.

#### **5.1.1 AMENDMENTS**

The pilot study revealed it was possible to conduct a randomised controlled trial of counselling in general practice (King et al, 1994). However, the following issues

needed amendment: the randomisation procedure; techniques to motivate the doctors to participate in the study; adequate and useful information for the general practitioners; employment of counsellors; self-report questionnaires and the length of follow-ups. These changes will be discussed in the main text.

## **5.2 SETTING OF THE MAIN STUDY**

General practices in North London were invited to participate in the study. Both single handed and group practices were approached and only doctors, that is general practice principals, assistants, locums or trainees, were asked to refer patients to the study. Referrals from other members of the primary care team, such as practice nurses, were not accepted, since they may have differed from doctor referrals.

## **5.3 SAMPLE OF THE MAIN STUDY**

The sample was derived from consenting patients attending the general practice. Patients were selected by the general practitioner for inclusion in the study if they fulfilled the following criteria:

- i) 18 years old or over;
- ii) suffering from an emotional problem that the general practitioner considered required a counselling intervention;
- iii) the onset of their problem(s) had been within the last six months;
- iv) been free of emotional illness for 12 months prior to the index episode.

Patients were excluded if they:

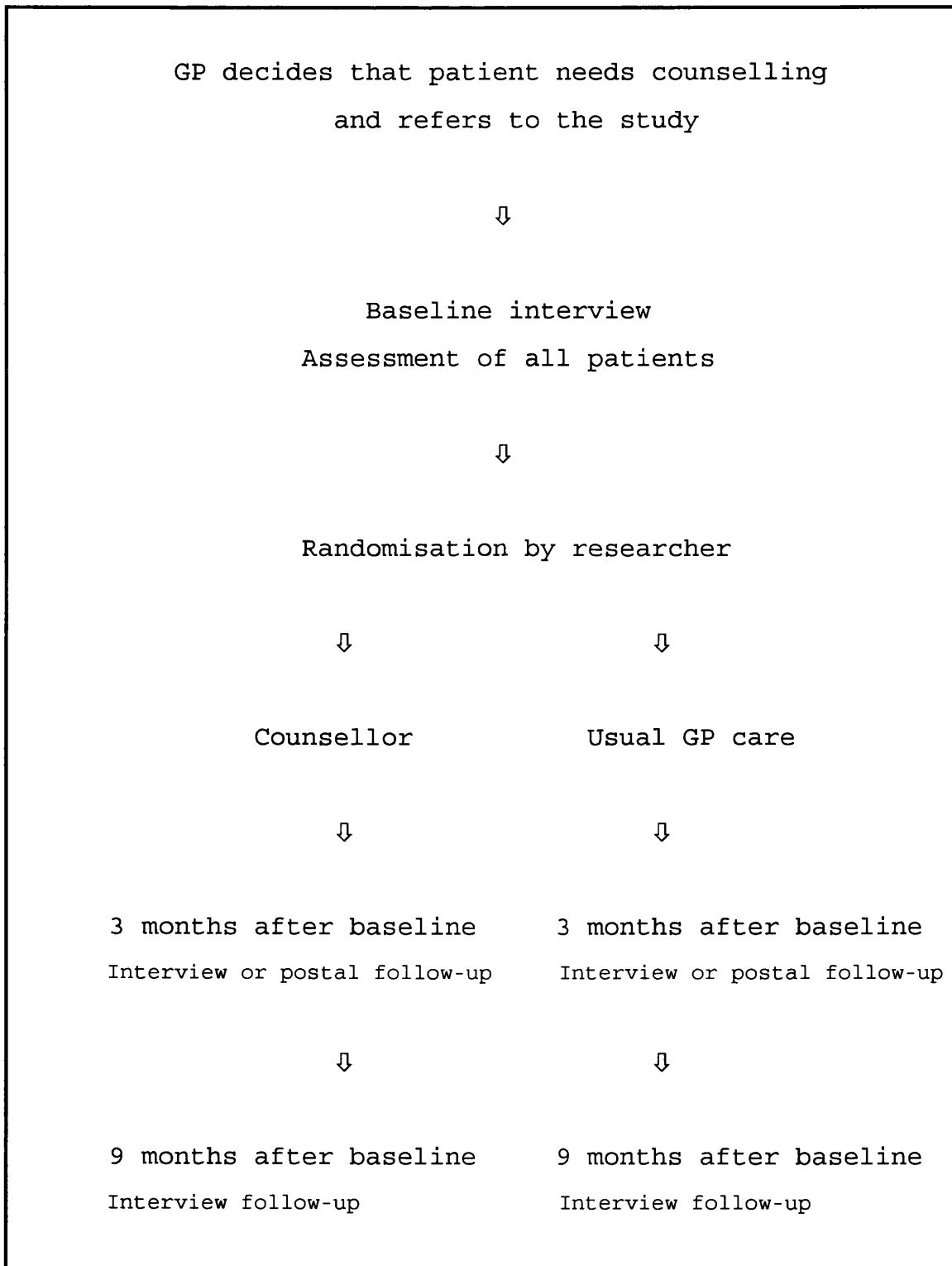
- i) were currently in counselling or any other form of psychological intervention;
- ii) were psychotic;
- iii) suffered from a chronic mental illness, including chronic depression;
- iv) were actively suicidal;
- v) had a severe drug or alcohol dependence;
- vi) were physically ill/ infirm such that they could not reach the surgery;
- vii) could not complete the questionnaires for any reason such as language problems, illiteracy or learning disability.

The general practitioners were asked to refer every patient that suited the above criteria to the study. Medication, including psychotropic medication, was not an exclusion criterion.

#### **5.4 DESIGN OF THE MAIN STUDY**

A prospective randomised controlled trial design was chosen as the most appropriate method to evaluate the effects of short term counselling. Patient preference was abandoned as not enough patients chose to be randomised in the pilot study (King et al, 1994). Patients were followed-up at three and nine months. Figure 5.1 presents a summary of the design of the study.

**Figure 5.1 Summary of the design of the study.**



## **5.5 EXPERIMENTAL AND CONTROL GROUPS**

The intervention was non-directive person-centred counselling provided by a trained counsellor. Usual general practitioner care was chosen as the control. However, patients randomised to the counsellor intervention were not excluded from seeing their general practitioner. These interventions will be explained further in the sections below.

### **5.5.1 COUNSELLING**

The counsellors used a humanistic non-directive person-centred counselling model advocated by Carl Rogers (Nelson-Jones, 1982). Counsellors did not give advice, but used empathy and advanced listening skills to help patients come to their own solutions of their problems. This type of counselling is the most common type of counselling carried out in general practice (Sheldon, 1994). The counsellors adhered to the British Association for Counselling's code of ethics and practice (British Association for Counselling, 1992b).

At the first counselling appointment, patients were given a counselling information sheet (Appendix F), which explained briefly what the counselling would entail. Patients were offered six sessions of counselling initially, which meant fifty minutes of counselling once a week over six weeks. If patients wanted and the counsellor felt it was appropriate, the number of counselling sessions could be extended to 12 sessions.



Counsellors told each patient that sessions were completely confidential and that only in extreme circumstances, such as the possibilities of self harm or violence to others, would the general practitioner be consulted.

Patients were asked for their consent to have a random session of counselling audio-taped. The tapes were assessed by an independent trained counsellor for adherence to the non-directive person-centred counselling style.

The counsellor offered patients sessions when there was available space at the surgery and when both the counsellor and the patient were able to attend. Patients were asked to telephone the surgery, if they could not attend the counselling session. If patients failed to attend for counselling on two consecutive appointments and had not left a message for the counsellor, the counsellor wrote a standard letter, asking the patient to contact them. If patients failed to respond to the counsellor, the counselling was stopped and the patient was not seen again by the counsellor.

#### **5.5.2 USUAL GENERAL PRACTITIONER CARE**

The instructions to all general practitioners were the same regardless of whether patients were randomised to the counsellor or back to the general practitioner. After the completion of the baseline interview, each doctor was informed by letter, whether the patient had been randomised to the counsellor or the general practitioner. General practitioners had requested some information from me about patients randomised back to them. A summary sheet of the PROQSY (computerised revised Clinical Interview Schedule)

described in section 5.6.1. was sent to the doctors who had patients randomised back to them.

Patients were told that they had been randomised back to their general practitioner and it was left to them to organise another appointment with their doctor. The general practitioners were asked not to refer patients to other counsellors, psychologists, community psychiatric nurses or other health professionals for counselling, particularly during the first three months after the baseline interview. In addition, between the three and nine months follow-ups, doctors were discouraged from referring patients taking part in the trial to these mental health professionals except where it was absolutely necessary. Otherwise they were asked by myself to manage patients in exactly the same way as they would during their routine clinical practice. This included prescribing antidepressants, benzodiazepines or other psychotropic medication and using counselling skills, if the general practitioner felt this to be appropriate.

## **5.6 MEASURES**

The main measures used in the study were psychological outcome measures, but many more measures were used. They were administered by myself at the three time points, namely at the baseline, three and nine months follow-up assessments. A small amount of data was obtained from medical case notes, the general practitioner and the counsellor.

Most of the measures were self-report measures completed by the patients. I was not blind to the allocation of

experimental or control group and therefore tried not to influence the patients' responses. However, I did provide assistance with the questionnaires if it was required.

A number of the self-report measures used in the pilot study were changed. The revised version of the Clinical Interview Schedule was used and administered in a computerised fashion (Lewis et al, 1988; 1991). The General Health Questionnaire (Goldberg and Williams, 1988) was replaced by the Brief Symptom Inventory (Derogatis and Melisaratos, 1983) and the Social Problems questionnaire (Corney, 1988) was replaced by the modified Social Adjustment Scale (Cooper et al, 1982). Both the Brief Symptom Inventory and the modified Social Adjustment Scale have been used more frequently in counselling and psychiatric research and were felt to be more appropriate for the sample being studied.

#### **5.6.1 PSYCHOLOGICAL OUTCOME MEASURES**

Psychological outcomes were assessed using the Beck Depression Inventory (Beck, 1979), Brief Symptom Inventory (Derogatis & Melisaratos, 1983) and the computerised version of the revised Clinical Interview Schedule or PROQSY (**PRO**grammable **Q**uestionnaire **S**ystem) (Lewis et al, 1988; 1991) (Appendices A and B).

For the Beck Depression Inventory and the Brief Symptom Inventory, patients first read the instructions at the top of the questionnaire. They were asked to think about how they had been feeling over the past week and score the questionnaire appropriately.

The PROQSY computer programme is set up on a portable computer and started up for each patient. Clear instructions tell the patient that the computerised questionnaire will assess their health and general well-being over the past week. There are also a few simple instructions on how to use the computer. I ensured that patients were able to use it with ease. PROQSY provides the user with a summary file on each patient at the end of the interview. The file can be printed on one sheet of A4 paper. It includes the total score, a score for each section and some extra information on, for example, suicidal ideas, biological symptoms of depression or the nature of a phobia. It also stresses that the summary file should not be used on its own for diagnosis or management of a patient. A clinical assessment is also needed and the summary report is intended only as a tool to help the doctor or other health professional on the diagnosis and management. General practitioners requested some information on patients only if they were randomised back to them. These summary reports were sent.

Cut-off points were used on the three standardised psychological outcome measures to define caseness. For the Beck Depression Inventory, a cut-off of 14/15 was used as this may detect possible depression in a normal population (Beck and Steer, 1987). For the Brief Symptom Inventory, all raw scores needed to be converted to standardised T-scores and a T-score greater than or equal to 63 indicates caseness (Derogatis, 1992). For a non-patient normal population, this represents a score of greater than or equal to 0.58 for men and 0.83 for women on the General Severity Index (Derogatis, 1992). For PROQSY, the recommended cut-off point is 11/12 and for the individual

symptoms, a score above 2 or more is approximately the point at which the symptom becomes clinically significant (Lewis and Pelosi, 1990; Lewis et al, 1991).

In addition to the standardised self-report measures above, a brief numerical rating scale was adapted from Gournay and Brooking (1992) which had been originally derived from Shapiro (1961). First patients had to clearly state their main problem(s) and then decide how upsetting or disturbing this problem(s) was/were at the present time. Patients could score between 0 and 8, with 0 indicating 'not at all' and 8 indicating 'very severely and continuous'.

#### **5.6.2 SOCIAL OUTCOME MEASURE**

Social outcomes were measured using the modified Social Adjustment Scale (Cooper et al, 1982) and asking people about their work and marital status on the economic questionnaire (Appendix C).

For the modified Social Adjustment Scale, patients were asked to think about the past two weeks and rate the 45 items themselves. For each item they were asked to tick the most appropriate box. There were separate instructions for each role area section. If the section applied to the subject, they were told to complete it. If the section was not relevant, for instance, if a subject did not have a job, they were told to go straight to the next section.

To define caseness on the modified Social Adjustment Scale, a cut-off point of greater than or equal to 2 was used (Paykel et al, 1971).

### **5.6.3. ECONOMIC OUTCOMES**

Data were collected on both direct and indirect costs. With advice from a health economist, a questionnaire was designed for the purpose of the study (Appendix G). A small amount of data was obtained from the counsellor process notes (see below in section 5.7.6) and from the general practitioner case notes.

#### **5.6.3.1 BASELINE DATA**

Baseline data were collected from the patients only, that is from the baseline economic questionnaire. These data were necessary to ensure equivalence in randomisation. For example, if one group had a significantly higher income at baseline, adjustments would need to be made in the main economic analysis.

A patient's income and household composition were needed to cost living expenses. Ideally family income would have been collected, but many did not know what their partners earned and there were a large proportion of the sample who were single. Therefore data on the patient's gross income was collected and if patients did not have a salary, data on social security benefits were gathered. Data on number of people living at the patient's home were collected.

Employment status was recorded to cost lost employment. Patients needed to record how many weeks they had been unemployed or off work because of long-term sickness.

Details on each patient's accommodation were collected to check that patients did not require specialist care accommodation, for example hostel accommodation.

#### **5.6.3.2 DIRECT COSTS**

Direct costs included service costs and are described below.

##### a) General practitioner consultations.

The number of general practitioner consultations were recorded by the patients on the economic questionnaire and from the case notes. Consultations were divided into surgery visits and home visits. The patients also estimated how much time they spent with each general practitioner.

##### b) Counsellor consultations.

As with the general practitioner consultations, details of number and length of sessions were collected from the economic questionnaire and the counsellor process notes.

##### c) Other consultations

From the economic questionnaire, patients reported whether they had contact with other health professionals, such as community psychiatric nurses, other nurses, social workers, psychologists, psychiatrists or other health professionals. The number and duration of visits was recorded.

d) In-patient and out-patient treatments

Patients were asked to report the number of days they had spent in hospitals, general or psychiatric, and the number of appointments in out-patient departments. Also they were asked about the reason for their visits.

e) Medication

Data on prescriptions were collected from the economic questionnaire and from the medical case notes. Details were taken for both antidepressant and other psychotropic medication, as well as medication for physical illnesses.

**5.6.3.3 INDIRECT COSTS**

a) Lost employment

Days off work were recorded according to periods off sick and unemployment. Sickness was categorised into number of days taken off because of any problem or days taken off sick because of the presenting psychological problem.

b) Travelling and childcare costs

Travelling and childcare costs were recorded on the economic questionnaire.

**5.6.3.4 UNIT COST ALLOCATION**

A compendium of unit costs produced and published by the Personal Social Services Research Unit (Netten and Dennett, 1996) was used to calculate the cost of the general



practitioner, nursing staff, in-patient stays and out-patient appointments. Unit costs for a psychiatrist, other specialist doctor, alternative health practitioner, housing, welfare officer, physiotherapy, occupational therapy and dentist were obtained from Professor Martin Knapp at the Personal Social Services Research Unit. A list of the unit costs is contained in the Appendix H.

Work absence was calculated using the person's actual gross income. Travelling costs were calculated using the actual fare of the bus or train and mileage was calculated using figures obtained from the Automobile Association (AA).

Childcare was costed using actual cost of the childcare.

#### **5.6.4 PERCEIVED CREDIBILITY AND EXPECTATIONS**

Each patient was asked about the credibility and expectancy of improvement from either counselling or general practitioner care. A questionnaire designed for the purpose of study was adapted from Borkovec and Nau (1972) (Appendix E).

#### **5.6.5 PATIENT SATISFACTION**

A self-report questionnaire was adapted from the Brief Structured Recall (Elliott and Shapiro, 1988) for the purpose of this study (Appendix D).

#### **5.6.6 COUNSELLOR PROCESS DATA**

Counsellors were given semi-structured forms to complete regarding the process of counselling. These forms were

designed for the purpose of the study and recorded the number of sessions attended, number of sessions missed and reasons for ending sessions. The counsellors were asked their opinions of whether or not the referrals had been appropriate.

#### **5.6.7 DEMOGRAPHIC VARIABLES**

Age and sex were collected on the PROQSY computer. Data on other demographic variables social class, religion, ethnic grouping and education were collected on the economic questionnaire (Appendix G). Social class was classified using the standard occupational classification (Office of Population Censuses and Surveys, 1990; 1991) and ethnic grouping according to the process used in the last national census carried out by the Office of Population Censuses and Surveys in 1991.

#### **5.6.8 OTHER INFORMATION**

Other information on the length of the research interview, the date of the research interview, the GP referral form and refusal form were collected. If patients refused to enter the study, the general practitioners were asked to complete a refusal form. Doctors were asked to supply basic demographic data, the nature of the patient's psychological problem and the patient's reason for refusal to enter the study (Appendix I).

#### **5.7 PROCEDURES**

The following sections described the procedures in detail.

### **5.7.1 ETHICAL APPROVAL**

Ethical approval was sought and received from the Ethical Practices Subcommittee of the Royal Free Hampstead National Health Service Trust. If a general practitioner participated in the study, she or he needed to agree to let myself have access to the patient and their medical records.

### **5.7.2 RECRUITMENT OF GENERAL PRACTITIONERS**

If a general practitioner expressed interest in taking part, I arranged a meeting to discuss the study in more detail. Information packs were made up to give to the general practitioners. These consisted of the patient information sheet, referral and refusal forms, a flow diagram outlining of the study, a step by step guide to the study, definitions of counselling and counsellors and the inclusion and exclusion criteria (Appendices J to O). General practitioners were encouraged to ask questions about the study. Once the general practitioner(s) agreed to take part, every effort was made to liaise with other practice staff and to keep the general practitioner and practice informed on the progress of the study. The pilot study revealed that doctors would have liked updates and reminders of the protocol. A progress report, reminders of the inclusion and exclusion criteria and the step by step guide were sent to each participating general practitioner at regular intervals (Appendices J to P).

### **5.7.3 RECRUITMENT OF COUNSELLORS**

The pilot study had used counsellors already employed at the participating surgeries. They found they had very different backgrounds, qualifications and experiences. In addition, some of the counsellors had long waiting lists. Therefore, counsellors were recruited specifically for the purpose of this study. They had to have relevant and similar qualifications and experience accreditable by the British Association for Counselling (1992a) and general practice experience was preferable. Counsellors worked peripatetically. Each counsellor was required to have regular counselling supervision. In addition, I held regular meetings with the counsellors to discuss the study or difficulties they encountered either with practices or patients, such as organising suitable appointments.

### **5.7.4 RECRUITMENT OF PATIENTS**

General practitioners were asked to approach every patient who consulted for a psychological problem and whom the general practitioner thought counselling would help. General practitioners were given patient information sheets to give to the patients (appendix J). If patients agreed to take part, the general practitioner referred the patient to me by either completing a referral form or telephoning me directly. If I was not in my office, it was possible for the general practitioner to leave a message on my answerphone. I contacted the patient usually within a week of referral and arranged to see the patient at the surgery or at their home.

### **5.7.5 RANDOMISATION**

A block randomisation as suggested by Pocock (1983) was chosen to allocate patients to the counsellor or routine general practitioner care. The pilot study had found a wide range of distress in patients at the baseline interview. To reduce chance differences between the random groups, stratification was used. Two sets of blocks of six (three counsellor and three general practitioner) random combinations were sealed in consecutive envelopes. The patients were stratified according to the Beck Depression Inventory. If patients scored 23 or above on the Beck Depression Inventory, patients were randomised from a separate set of envelopes compared to patients who scored 22 or below. The cut-off point on the Beck Depression Inventory was relatively high and was decided on the basis of the results of the pilot study (King et al, 1994) and Metcalfe and Goldman (1965). Patients in the pilot study had a mean Beck Depression Score of 21.9 at baseline interview. The stratification was used to ensure that the level of distress was equally distributed between the counsellor and general practitioner groups.

Patients were told immediately about the randomisation. If they were randomised to the counsellor, they were told that the counsellor would contact them over the next few days to arrange a suitable time. They were given the same counselling information sheet, which counsellors provided at the first counselling session (Appendix). If patients were randomised to the general practitioner, it was up to the patient to make contact with their general practitioner. If patients asked what they should do now, I

did not give any further information, except suggest they see their general practitioner again.

#### **5.7.6 BASELINE RESEARCH INTERVIEWS AND INFORMED CONSENT**

Patients were contacted by telephone or letter to arrange the first meeting. Patients were interviewed by me either at the referring surgery or at home. Each patient was given a choice. Some patients had relationship or family problems and could not be seen at home because they had not told their partner or family about the counselling.

At the start of the baseline interview, I spent 5 to 10 minutes explaining the study. The patient information leaflet was given to the patient again (Appendix J). The patients were encouraged to ask any questions regarding the study. Finally the patients were asked to sign a consent form to agree to participate in the study (Appendix Q).

At the end of the baseline interview patients were randomised to one of the two arms of the study using the sealed envelopes. After randomisation, each patient was given the credibility/expectancy questionnaire, which was not repeated at the follow-up interviews.

I arranged the interview, so that while the patients answered the self-report questionnaires, I remained silent. I only interacted with the patient if the patient had a question about the questionnaires. I remained neutral throughout the interview and did not express any personal opinions. Some rapport was necessary, particularly at the beginning and the end of the interview, but this mainly

consisted of showing empathy towards the patient. I did not give advice or counsel patients in any way.

#### **5.7.7 FOLLOW-UP INTERVIEWS**

Patients were followed up at three and nine months after the initial baseline interview. At the three months follow-up, half the patients were interviewed again and the other half of the patients were sent the questionnaires in the post. Patients were randomly selected, using a block of two sealed envelopes of interview or postal questionnaires. It was not feasible to re-interview every patient at three months because of the time constraints. At the nine months follow-up all patients were contacted again, for a face to face interview. As with the baseline interview, patients were given the choice of whether they wanted to be seen at the surgery or at home.

At the follow-up interviews, the patients started with the satisfaction questionnaire, which was not used at the baseline interview. Otherwise the order of all the questions and questionnaires were the same for each interview at all time points.

#### **5.7.8 DATA COLLECTION**

Data collection took place over 25 months with recruitment lasting 16 months. The first interviews were conducted in August 1993 and the last interview was completed in October 1995.

### **5.7.9 CODING**

Most data did not require coding and could be entered directly into the computer. Some of the data on the economic questionnaire, from the general practitioner case notes and the counsellor process notes required a coding framework. Coding sheets were prepared for the economic questionnaire and the counsellor process notes. For the general practitioner case notes a coding framework had already been devised by another member of staff in the University Department of Psychiatry (Dr Khaver Bashir).

### **5.7.10 DATA ENTRY AND COMPUTING**

The Statistical Programme for Social Sciences (SPSS/PC) for Windows version 6.0 was used to enter the data and analyse the results.

### **5.7.11 DATA CLEANING**

The data were entered twice and checked for errors. After the data had been entered twice, frequencies on each variable were computed and the value labels checked to see whether any undefined variables had been coded into SPSS/PC for Windows (Barhyte and Bacon, 1985).

### **5.7.12 SAMPLE SIZE AND POWER CALCULATION**

The number of patients required for the study was based on the Beck Depression Inventory as the main outcome variable. To detect a mean difference of 0.5 standard deviation at 0.05 significance level at a power of 80%, requires a sample size of 126, or 63 in each random group. With a 15%



drop-out rate anticipated, the sample size would need to be increased to 145 patients, or 72 or 73 in each random group.

### **5.7.13 ANALYSIS**

Univariate and bivariate parametric and non-parametric statistics were used to describe the data obtained in the study and infer relationships between the variables. This section explains why the particular statistical descriptions and tests were used.

Outcomes were measured in terms of scores on the questionnaires, considering in turn psychological, social and economic scores. To avoid multiple testing a summary score was used as suggested by Frison and Pocock (1992) and Everitt (1995). It consisted of the mean of the two follow-up scores. Analysis of covariance was used in testing the hypothesis. In addition, cut-off points were employed to assess the proportion of patients who had recovered.

To deal with drop-outs in the analysis, the procedure recommended by Altman (1991) was applied. It involves:

- a. Assigning the most optimistic outcome to all patients who drop out and analysing the data.
- b. Assigning the most pessimistic outcome to all patients who drop out and analysing the data.
- c. Analysing the data excluding all drop-outs.

If all three analysis yield similar results in the same direction we can be fairly confident of the findings.

For the sub-group analysis, two-way analysis of covariance was used. Demographic, symptom and service use variables were dichotomised. Together with the group variable of counselling or no counselling, the analysis enabled the interpretation of the change process, of which the mean Beck Depression Inventory was used. In addition, the main analysis was repeated on a sub-group of patients who scored as cases at the baseline interview.

A cost-effectiveness analysis was conducted taking account of direct costs of counsellor and/or GP time and prescribing, as well as indirect costs such as patients' absence from work due to either the emotional distress and/or the need to visit the practice; travel to the practice; and childcare arrangements. To account for some uncertainty in the unit estimates and outcome measures, a sensitivity analysis was performed.

## **6.0 RESULTS I - CHARACTERISTICS AND COMPARABILITY OF THE SAMPLE**

This chapter describes the characteristics and comparability of the subjects taking part. First the sample size and response rate will be presented, followed by the background details of the general practices and counsellors. The background and demographic details of the patients are described next. Then the preference, credibility and expectancy data will be explored. Finally, a summary of the total scores of the psychological and social as well as the sub-scores will be outlined.

### **6.1 RESPONSE RATE AND FINAL SAMPLE SIZE**

One hundred and seventy one patients were referred to the study. Thirty five patients did not enter the study. Nine did not meet the entry criteria, six refused to take part in the study, 14 changed their minds between being referred by the general practitioner and the first research interview and I was unable to contact six patients. The reasons for refusing to take part were several: lack of time, a wish not to be randomised, inability to face the current problems, no longer feeling the need for help from a counsellor, not wanting to be part of a study or a relative not wanting the patient to take part in a study or see a counsellor. Reasons for not being eligible were already seeing a counsellor or other mental health professional for the current psychological problems and not fulfilling the criterion for age. Patients dropping out of the study after randomisation will be discussed in chapter 7.0.

The mean age of patients who did not enter the study was 34.5 years (SD 16.7, range 16-77, n=17) and 80% of this sample were female (n=35). These patients were slightly younger than the patients who participated in the research. However this was not statistically significant.

One hundred and thirty six patients took part in the main study, 70 of whom were randomised to the counsellor and 66 randomised back to their general practitioner.

## **6.2 BACKGROUND AND DEMOGRAPHIC VARIABLES OF THE GENERAL PRACTICES, GENERAL PRACTITIONERS AND COUNSELLORS**

Background data on the general practitioners, general practices and counsellors participating in the study are presented in this section.

### **6.2.1 GENERAL PRACTICES**

General practices associated with the Royal Free Hospital in the North London area were sent an invitation to participate in the study. Initially 40 general practices expressed an interest in the study, but after introduction and reading the proposal, 19 practices agreed to refer patients. Fourteen general practices eventually took part in the study. The majority of the referring practices were group practices ranging from three to seven partners and only three were single handed practices.

Table 6.1 shows the referral rates for the individual practices according to the two random groups and the patients who did not enter the study. Referrals to the study took place between August 1993 and November 1994. The

Table 6.1 Number of referrals per practice according to the random groups and patients who did not enter the study.

No.	Number of referring doctors per general practice	Mental health professional on site	Patients in counsellor group	Patients in routine general practitioner group	Patients who did not enter the study
1	8	1 psychotherapist 1 psychologist	11	14	5
2	1	1 psychotherapist	0	1	0
3	3	1 clinical psychologist	3	1	0
4	2	1 counsellor	1	1	1
5	3	1 counsellor	8	5	5
6	1	1 clinical psychologist	2	3	1
7	6	2 counsellors	3	8	1
8	5	-	13	12	7
9	2	1 community psychiatric nurse	10	3	3
10	4	-	12	8	7
11	1	1 counsellor 1 psychologist	5	7	2
12	1	-	2	2	0
13	2	1 community psychiatric nurse	0	1	2
14	1	-	0	0	1

average referral rate for each practice was 12.2 patients (SD 10.9, median 9, range 1-32). Excluding the patients who did not enter the study, the referral rate was 9.7 patients per practice (SD 8.7, median 8, range 0-25).

Some general practices referred many more patients than did others, even though each practice received similar reminders and information on the study. As expected by using a block randomisation, approximately equal numbers of patients were randomised to the counsellor or routine general practitioner care. However in practice nine, more patients were randomised to the counsellor, whereas in practice seven more patients were randomised to the general practitioner. In practice 14, only one patient was referred who did not enter the study.

Four of the referring practices already had an attached counsellor, four practices had an attached psychologist, two practices had a psychotherapist and two practices had a community psychiatric nurse who saw patients with emotional problems. Only four of the 14 referring practices did not have a mental health professional on site (table 6.1).

### **6.2.2 GENERAL PRACTITIONERS**

Sixty-two general practitioners from the 19 practices agreed to refer patients to the study. Eventually only 40 doctors from 14 practices referred patients to the study. The mean number of referrals per general practitioner was 4.3 (SD 4.2, range 1-16) and 3.4 (SD 3.2, range 0-12) excluding the patients who did not enter the study.

There were 22 female and 18 male doctors who referred patients. Three were single handed practitioners and 37 worked in group general practices with more than two doctors. None of the general practitioners were fundholding general practitioners at the time of the study, even though some were considering becoming fundholding in the future. Thirty-three of the doctors were principals in general practice, two were assistants in general practice, one doctor was a long-term locum and four doctors were general practice trainees.

### **6.2.3 COUNSELLORS**

Four counsellors were employed for the study, all of whom were women (table 6.2). The counsellors were all accreditable by the British Association for Counselling. In other words they all had had at least 250 hours of theory, 200 hours of skills development and 450 hours of supervised counselling practice. Two of the counsellors had had general practice experience. In addition, the counsellors had other relevant experience such as speech therapy, youth work, social work, voluntary work for a women's group and children/family work.

The counsellors saw different numbers of patients in 11 different practices. In 4 of the practices, two or more counsellors saw patients. Some patients were unable to attend the counselling sessions at certain times of the day and having two or three counsellors gave patients more choice in appointments. Practices 2 and 13 had no patients randomised to see a counsellor. Some counsellors were more flexible and had more time available for the study. One counsellor saw 36 patients, whereas the other counsellors

Table 6.2 Age, qualifications and experience of counsellors in the study.

No.	Age	Qualifications and experience
1	33	Certificate and Masters of Science in Psychodynamic Counselling; 2 years experience with student counselling.
2	59	Diploma in Counselling; 12 years experience of counselling: 12 years with MIND, 6 years in private practice and 3 years in general practice.
3	39	Diploma and Masters of Science in Psychological Counselling; 4 years experience of general practice counselling.
4	53	Certificate and Diploma in Counselling; 8 years experience at a community counselling centre.



saw between 9 and 14 patients. They were attached to 3 to 5 practices each.

### **6.3 BACKGROUND AND DEMOGRAPHIC VARIABLES OF THE PATIENTS**

This section describes the background and demographic variables of the patients who entered the study.

#### **6.3.1 PATIENT INTERVIEWS**

Nearly 62% (84/136) of patients chose to have their baseline interview at home. The baseline interview took from 35 to 125 minutes, with an average of 73 minutes (1 hour 13 minutes).

#### **6.3.2 DEMOGRAPHIC DETAILS OF THE PATIENTS**

Demographic details of the sample are shown in tables 6.3 and 6.4.

Slightly more married, older patients and more men were randomised to see the counsellor than to the general practitioner.

Patients who only saw their doctor had a higher number of first degrees despite the counselling group holding a higher number of post-graduate qualifications. However, there was a slightly higher percentage of unemployed patients in the general practitioner group. All these differences were not statistically significant.

Table 6.3 Demographic details of the sample. Figures show numbers of patients in that category (column percentages).

	Counselling group	Routine practitioner group	General group	Total sample group
<b>Age</b>	(n=70)	(n=66)	(n=136)	
18 - 30	23 (33)	22 (33)	45 (33)	
31 - 40	13 (19)	18 (27)	31 (23)	
41 - 50	19 (27)	14 (21)	33 (24)	
51 - 60	11 (16)	9 (14)	20 (15)	
61 - 80	4 (6)	3 (5)	7 (5)	
<b>Gender</b>	(n=70)	(n=66)	(n=136)	
Female	54 (77)	56 (85)	110 (81)	
Male	16 (23)	10 (15)	26 (19)	
<b>Marital Status</b>	(n=70)	(n=66)	(n=136)	
Single	24 (34)	29 (44)	53 (39)	
Married/ cohabiting	26 (37)	20 (30)	46 (34)	
Widowed	3 (4)	3 (5)	6 (4)	
Separated	9 (13)	7 (11)	16 (12)	
Divorced	8 (12)	7 (11)	15 (11)	
<b>Ethnicity</b>	(n=70)	(n=66)	(n=136)	
White (European)	58 (83)	61 (92)	119 (88)	
White (other)	4 (6)	2 (3)	6 (4)	
Black (African, Caribbean or other)	3 (4)	2 (3)	5 (4)	
Indian	3 (4)	1 (2)	4 (3)	
Other	2 (3)	-	2 (2)	
<b>Religion</b>	(n=70)	(n=65)	(n=135)	
None or non-practising	22 (31)	22 (34)	44 (33)	
Church of England	17 (24)	22 (34)	39 (29)	
Roman Catholic	10 (14)	15 (23)	25 (19)	
Jewish	7 (10)	1 (2)	8 (6)	
Other	14 (20)	5 (8)	19 (14)	

Table 6.4 Socio-demographic details of the sample. Figures show numbers of patients in that category (column percentages).

	Counselling group	Routine practitioner group	General practitioner group	Total sample
<b>Education</b>	(n=70)	(n=66)	(n=136)	
Ordinary GCEs or equivalent	30 (43)	22 (33)	52 (38)	
Advanced GCEs or equivalent	10 (14)	9 (14)	19 (14)	
Degree or equivalent	9 (13)	18 (27)	27 (20)	
Post-graduate qualification	8 (11)	3 (5)	11 (8)	
Other	2 (3)	-	2 (2)	
None of the above	11 (16)	14 (21)	25 (18)	
<b>Employment Status</b>	(n=70)	(n=66)	(n=136)	
Full-time	27 (39)	26 (39)	53 (39)	
Part-time	9 (13)	5 (8)	14 (10)	
Houseperson	7 (10)	7 (11)	14 (10)	
Unemployed	13 (19)	18 (27)	31 (23)	
Retired	4 (6)	2 (3)	6 (4)	
Long-term sick	3 (4)	2 (3)	5 (4)	
Other	7 (10)	6 (9)	13 (10)	
<b>Social Class</b>	(n=66)	(n=60)	(n=126)	
Social Class 1	14 (21)	5 (8)	19 (15)	
Social Class 2	24 (36)	27 (45)	51 (40)	
Social Class 3a	17 (26)	17 (28)	34 (27)	
Social Class 3b	7 (11)	6 (10)	13 (10)	
Social Class 4	4 (6)	2 (3)	6 (5)	
Social Class 5	-	3 (5)	3 (2)	

### 6.3.3 PATIENTS PROBLEMS

Patients were referred to the study when the general practitioner felt they had psychological problems that could possibly benefit from counselling. The patient's problem was defined by the patient and the referring doctor on a baseline questionnaire and the general practitioner referral form, respectively. In addition, PROQSY classified the main psychological symptom after the completion of each computer questionnaire by the patient.

More than 50% of patients and their doctors mentioned depression as a problem. Anxiety, stress and difficulties with coping were also common problems (table 6.5), however the general practitioner mentioned difficulties with coping more often than the patients. With regards to causes of problems, both the patients and the doctors mentioned similar reasons. Relationship and family problems were the most frequently mentioned explanations (table 6.6). The general practitioner did however disclose relationship, family and work problems more often than the patient. Substance misuse (alcohol or drugs) was no different between the patient and the doctor.

On the PROQSY questionnaire, the symptom with the largest score is described as the main symptom. If there is a tie, the main symptom is determined by their order in the list of symptoms in Table 6.7. The highest symptom on the list becomes the main symptom. For example, if anxiety and depression had the same score, the main symptom would be classified as depression. Although depression was the most common main symptom patients could have equally been suffering from other symptoms (table 6.7).

Table 6.5 Number of problems mentioned by the patient and general practitioner. Figures are number of times (column percentage) a problem was stated. More than one problem could be mentioned by the patient or general practitioner.

Problem	Patient (n=136)	General practitioner (n=131)
Depression	70 (52)	67 (51)
Anxiety	30 (22)	29 (22)
Stress	18 (13)	19 (15)
Difficulties with coping	18 (13)	22 (17)
Sleep problems	10 (7)	12 (9)
Distressed and angry	8 (6)	14 (11)
Somatic symptoms	5 (4)	8 (6)
More than 2 problems	3 (2)	7 (5)

Table 6.6 Number of causes of the problems mentioned by the patient and general practitioner. Figures are number of times (column percentage) a cause was stated. More than one cause could be mentioned by the patient or general practitioner.

Cause of the problem	Patient (n=136)	General practitioner (n=131)
Relationship difficulties	23 (17)	47 (36)
Family difficulties	21 (15)	30 (23)
Bereavement	14 (10)	12 (9)
Physical health	14 (10)	15 (12)
Work difficulties	12 (9)	22 (17)
Physical and sexual abuse	7 (5)	9 (7)
Substance misuse	4 (3)	5 (4)
Housing	3 (2)	5 (4)
Eating problem	2 (2)	2 (2)
Money	2 (2)	1 (1)
Legal	1 (1)	0
More than 2 problems	15 (11)	11 (8)

Table 6.7 Number of main symptoms as mentioned by PROQSY according to the two random groups. Figures are number of patients (column percentage).

Problem	Counsellor (n=65)	General practitioner (n=63)
Depression	26 (40)	26 (41)
Anxiety	7 (11)	10 (16)
Worry	7 (11)	7 (11)
Irritability	3 (5)	7 (11)
Compulsions	1 (2)	1 (2)
Obsessions	4 (6)	2 (3)
Fatigue	10 (15)	8 (13)
Somatic symptoms	4 (6)	-
Poor concentration	1 (2)	-
Sleep problems	2 (3)	2 (3)

It is clear, from the different methods of data collection, that depression was the main problem affecting at least half the sample. Anxiety, stress or worry, difficulty with coping and fatigue were also common symptoms experienced by these patients.

#### **6.3.4 DURATION OF THE PROBLEM**

Duration of the main problem was assessed in two ways. Patients were asked directly in a baseline questionnaire and again on the computerised PROQSY questionnaire. The question concentrated on how long they had had their problem, rather than the date of onset of the recent episode of problems. Some patients had acute or chronic problems and therefore had been troubled by their problems for longer than six months. However, according to the general practitioner, these patients had experienced an increased intensity of their problems recently.

The majority of patients had had their problems for less than 1 year (table 6.8). Up to 76% (102/134) had experienced their problem for 2 years or less and 87% (116/134) had experienced their problem for 5 years or less. The median was nine months with a range of 1 to 264 months. Two patients said they had had their problems for some months but were unable to be more specific. They were coded as missing data. Patients seeing the counsellor tended to have had their problems for slightly less time than patients randomised to the general practitioner (table 6.8).

With the PROQSY questionnaire, 55% (70/128) of patients had experienced their main psychological symptom for 12 months

Table 6.8 The number of months or years a patient experienced their problem. Figures are number of patients (column percentage).

Number of months or years	Counsellor (n=69)	General practitioner (n=65)
1 to 3 months	17 (25)	9 (14)
3 to 6 months	8 (12)	13 (20)
6 to 9 months	11 (16)	6 (9)
9 to 12 months	6 (9)	10 (15)
1 to 2 years	11 (16)	11 (17)
2 to 5 years	11 (16)	3 (5)
Over 5 years	5 (7)	13 (20)

Table 6.9 The duration of the patient's main symptom according to PROQSY. Figures show number of patients (column percentage).

Duration of symptoms	Counsellor (n=65)	General practitioner (n=63)
Less than 3 months	14 (22)	7 (11)
3-12 months	24 (37)	25 (40)
1-5 years	13 (20)	14 (22)
More than 5 years	8 (12)	6 (10)
All the subject's life	6 (9)	11 (18)



or less compared to 60% with the above questioning. Up to 76% (97/128) of patients considered that they had had their main symptom for 5 years or less (table 6.9). Again patients seeing the doctor tended to have had their problems for a longer time, particularly the category "All the subject's life", compared to the counselling group.

There are slight discrepancies between the two methods of data collection. The questions, however, did address slightly different problems and used different categorisation. Asking patients an open question on how long they had had their problem or asking patients about their main symptom and giving them 5 choices as to duration (PROQSY questionnaire) produces slightly different results. Patients' views of the duration of their problem are generally shorter than PROQSY's estimate of main symptom duration. In summary, most patients had problems and symptoms which had occurred within the year prior to referral to the study.

#### **6.3.5 SOCIAL IMPAIRMENT**

The PROQSY questionnaire asked patients whether they felt that their psychological symptoms had interfered with or stopped their everyday activities. Only 9% of the patients (12/128) felt they were not affected by their symptoms, whereas 48% (62/128) felt that things were more difficult but everything got done. Up to 42% (54/128) reported that one or more activity had been stopped. This was true for both the counsellor and general practitioner groups.

## **6.4 PREFERENCE AND CREDIBILITY/EXPECTANCY**

This section describes the potential preference of patients to see either the counsellor or general practitioner and the credibility and expectancy of seeing either one of these professionals for their problem.

### **6.4.1 PREFERENCE**

Seventy one patients (52%) would have liked to see the counsellor if they had been given a choice, 58 (43%) did not mind who they saw and only 7 (5%) would have preferred to see their doctor for their problem. Of the patients who would have preferred to see a counsellor, 37 (52%) were randomised to see a counsellor and 34 (48%) were randomised to the doctor. This was similar for patients with a preference to see their doctor (4 randomised to the counsellor and 3 randomised to the general practitioner). Patients who had no preference were randomised equally between the two groups, with 29 patients in each group.

### **6.4.2 CREDIBILITY AND EXPECTANCY**

With regard to credibility, patients who were randomised to the counsellors felt their treatment was more logical or sensible than patients who were randomised back to their doctor. Using a Student t-test for independent samples the two groups were highly significantly different ( $t=6.32$ ,  $p<0.001$ ). Table 6.10 shows the credibility and expectancy scores.

The expectancy scores or confidence in treatment were also significantly different between the two random groups.

Table 6.10 Credibility and expectancy scores for the two random groups.

Measure	Counsellor (n=68)		General practitioner (n=62)	
	Mean (SD)	Range	Mean (SD)	Range
How logical does the treatment seem to you?	8.2 (1.9)	5-10	5.8 (3.2)	0-10
How confident are you that the treatment will relieve your problem?	6.8 (1.9)	1-10	4.9 (2.5)	0-10
How confident are you in recommending this treatment to a friend?	7.7 (2.3)	0-10	4.7 (2.7)	0-10
How successful do you feel the treatment will be in helping your problem?	7.2 (1.8)	1-10	5.1 (2.9)	0-10

Key 0 indicates not at all logical, confident or successful  
 10 indicates completely logical, confident or successful

These figures indicate that patients felt counselling was the more appropriate treatment for their problems and therefore had more confidence in counselling.

## **6.5 DESCRIPTION OF MAIN PSYCHOLOGICAL AND SOCIAL OUTCOME VARIABLES**

In this section, the main psychological and social outcome variables at baseline are assessed. The total scores as well as the separate dimension or role area scores are described for the Beck Depression Inventory, Brief Symptom Inventory, PROQSY, modified Social Adjustment Scale and the distress scale. To examine whether the randomisation produced two equal groups, the scores have been separated into the counselling and general practitioner groups.

### **6.5.1 TOTAL SCORES AND CASENESS ON THE PSYCHOLOGICAL AND SOCIAL OUTCOME MEASURES**

Table 6.11 summarises the baseline data for the four main outcome variables and the numerical rating scale of distress.

Most patients in the study experienced a significant amount of psychological distress (table 6.11). The mean score on the Beck Depression Inventory suggests that patients were suffering from moderate to severe depression (Beck and Steer, 1987). When comparing the Brief Symptom Inventory scores with normative scores, the sample in this study corresponds to a psychiatric outpatient sample (Derogatis, 1992). On the PROQSY questionnaire, the mean was well above the cut-off point of 12 indicating when a general practitioner recognises psychiatric problems as clinically important (Lewis et al, 1991). On the modified Social

Table 6.11 Baseline total scores on the main clinical outcome measures for the two random groups.

Measure	Counsellor			General practitioner		
	Mean (SD)	Range	n	Mean (SD)	Range	n
<b>Beck Depression Inventory</b>						
	19.3 (8.9)	0-39	70	21.8 (9.3)	3-46	66
<b>Brief Symptom Inventory - GSI</b>						
	1.2 (0.7)	0.04-2.9	70	1.5 (0.7)	0.3-3.6	66
<b>PROQSY</b>						
	24.0 (12.3)	0-49	70	26.7 (9.8)	1-53	66
<b>Modified Social Adjustment Scale</b>						
	2.4 (0.5)	1.5-3.9	69	2.5 (0.5)	1.8-4.1	66
<b>Distress scale</b>						
	5.9 (1.5)	2-8	70	5.7 (1.5)	2-8	66

Key Distress Scale  
 0 indicates not at all  
 8 indicates very seriously, continuously

Adjustment Scale patients scoring above 2 is an indication of impaired social function (Paykel et al, 1971).

The randomisation of patients was evenly balanced. The counsellor group did however score slightly lower on all main outcome measures, except the distress scale. The Beck Depression Inventory and PROQSY scores in particular showed that patients seeing counsellors were slightly less depressed and suffered from less psychiatric symptoms than patients who were randomised back to the doctor.

When cut-off were used to define caseness on the four standardised outcome measures, the differences between the groups were more noticeable. Fewer patients randomised to the counsellor scored as cases on the psychological and social outcome measures than patients who were randomised back to their doctor (table 6.12). These differences will have occurred by chance and will be taken into account in the main analysis in chapter 7.0. Table 6.13 shows how many patients scored as cases on none to all four outcome measures. The majority of patients (64%) scored as cases on all four measures.

#### **6.5.2 SUB-SCORES ON THE PSYCHOLOGICAL AND SOCIAL OUTCOME MEASURES**

In the following section the sub-scores for the Brief Symptom Inventory, PROQSY and the modified Social Adjustment Scale are presented.

Table 6.12 Caseness on baseline scores on the main clinical outcome measures for the two random groups. Figures show number of patients (column percentage).

Measure	Counsellor		General practitioner	
	n	%	n	%
<b>Beck Depression Inventory</b>				
Cases	48	69	53	80
Non-cases	22	31	13	20
<b>Brief Symptom Inventory - GSI</b>				
Cases	49	70	57	86
Non-cases	21	30	9	14
<b>PROQSY</b>				
Cases	57	81	62	94
Non-cases	13	19	4	6
<b>Modified Social Adjustment Scale</b>				
Cases	52	75	57	86
Non-cases	17	25	9	14

Table 6.13 Caseness on different number of questionnaires. Figures show number of patients (column percentage).

	Counsellor group (n=69)	General practitioner group (n=66)	Total sample group (n=135)
None	9 (13)	3 (5)	12 (9)
Case on 1 questionnaire	4 (6)	1 (2)	5 (4)
Case on 2 questionnaires	8 (12)	6 (9)	14 (10)
Case on 3 questionnaires	9 (13)	8 (12)	17 (13)
Case on 4 questionnaires	39 (57)	48 (73)	87 (64)

### **a) Brief Symptom Inventory**

The Brief Symptom Inventory consists of three global scores and nine symptom dimension scores. The General Severity Score (GSI) has already been described as the total Brief Symptom Inventory score. The scores on the PST (Positive Symptom Total), PSDI (Positive Symptom Distress Index) and the nine symptom dimensions are described in Table 6.14. The PST gives an indication of the number of "positive" (non-zero) items symptom responses and PSDI is the mean score of all the "positive" (non-zero) scores.

As can be seen patients in the general practitioner group scored higher on all the dimensions than those in the counsellor group, however both groups had a similar scoring profile. Patients scored the highest on depression, anxiety, interpersonal sensitivity and obsessive-compulsive dimensions.

### **b) PROQSY**

A score of 2 or more is approximately the point at which the symptom becomes clinically significant (Lewis et al, 1991). On most sub-scores the general practitioner group scored higher than the counsellor group (table 6.15). Patients in both groups were symptomatic with regard to fatigue, depression, depressive ideas and worry. Eighty-two patients felt hopeless and life wasn't worth living and 30 patients had had suicidal thoughts or plans. There was no major difference between the groups except a slightly higher number of patients felt hopeless in the general practitioner group. Most patients were worried and depressed about family problems, including their partner.



Table 6.14 Brief Symptom Inventory sub-scores according to the two random groups.

Sub-scores	Counsellor (n=70)		General practitioner (n=66)	
	Mean	SD	Mean	SD
PST	30.3	12.0	34.2	10.0
PSDI	1.98	0.55	2.20	0.59
Somatization	0.91	0.79	1.05	0.89
Obsessive- compulsive	1.54	0.94	1.84	0.93
Interpersonal sensitivity	1.44	1.05	1.75	1.04
Depression	1.53	0.98	1.88	0.94
Anxiety	1.47	0.91	1.78	0.99
Hostility	1.02	0.92	1.39	1.02
Phobic Anxiety	0.75	0.90	0.96	0.94
Paranoid ideation	1.18	0.99	1.33	0.91
Psychoticism	1.07	0.81	1.27	0.93

Table 6.15 PROQSY sub-scores according to the two random groups.

Sub-scores	Counsellor		General practitioner	
	Mean (SD)	n	Mean (SD)	n
Somatic symptoms	1.8 (1.6)	70	1.8 (1.5)	66
Worry over physical health	0.9 (1.3)	70	1.2 (1.4)	66
Fatigue	2.5 (1.4)	70	2.7 (1.4)	66
Sleep problems	1.8 (1.4)	70	2.2 (1.5)	66
Irritability	1.9 (1.4)	70	2.2 (1.4)	66
Poor concentration	1.9 (1.4)	70	2.3 (1.2)	66
Depression	2.2 (1.6)	70	2.5 (1.4)	66
Depressive Ideas	2.8 (1.3)	64	3.1 (1.1)	62
Phobias	0.8 (1.0)	69	0.6 (0.9)	65
Worry	2.5 (1.4)	70	2.8 (1.2)	66
Anxiety	1.8 (1.7)	69	2.5 (1.5)	65
Panic	1.7 (1.6)	47	1.3 (1.6)	54
Compulsions	0.5 (1.0)	69	0.5 (1.1)	65
Obsessions	1.7 (1.6)	69	1.7 (1.6)	65
Elation	0.2 (0.5)	69	0.2 (0.5)	65
Ideas of Reference	0.3 (0.7)	69	0.5 (0.9)	65

After family problems, patients in the counsellor group worried mainly about work and money, whereas the patients in the doctor group worried more about their mental health, work and housing. Both groups were depressed about their mental health and 60% of the sample felt stress was the cause of their fatigue.

Patients in the general practitioner group scored above 2 on sleep problems, irritability, poor concentration and anxiety. Sixty percent of patients in the doctor group complained of sleep problems compared to 42% in the counsellor group. However, 79% of patients in the counsellor group felt worry was the cause of their sleep problems compared to 67% in the general practitioner group. Patients in the doctor group did not know the reason for their sleep problems in 24% of cases. Seventy-five percent of patients in the general practitioner group scored 2 or above on anxiety compared to 51% in the counsellor group.

### **c) Modified Social Adjustment Scale**

The counsellor group scored lower on all sub-scores compared to the general practitioner group (table 6.16). However, the scoring profiles were similar in both groups and nearly all the mean scores were above two in the role areas as well as the four descriptive areas. Only friction or having overt arguments did not score above two for both groups.

Table 6.16 Modified Social Adjustment Scale sub-scores according to the two random groups.

Sub-scores	Counsellor		General practitioner	
	Mean (SD)	n	Mean (SD)	n
Work or housework	2.2 (0.6)	69	2.3 (0.7)	66
Social and leisure	2.5 (0.7)	69	2.6 (0.6)	66
Extended family	2.4 (0.7)	69	2.4 (0.5)	65
Partner	2.7 (0.6)	34	2.9 (0.7)	33
Parental	2.0 (0.9)	34	2.3 (1.1)	23
Family unit	2.4 (1.0)	36	2.3 (0.9)	26
Performance	2.9 (0.7)	69	2.9 (0.7)	66
Interpersonal behaviour	2.7 (0.6)	69	2.8 (0.6)	66
Friction	1.6 (0.5)	69	1.6 (0.6)	66
Feelings and satisfaction	2.2 (0.7)	69	2.4 (0.6)	66

## **7.0 RESULTS II - COMPARISON OF THE INTERVENTION AND CONTROL GROUPS**

The effects of counselling on the major psychological and social outcome variables are described in this chapter. Sub-group analyses will examine in further depth effects on individual patients. The counsellor treatment will be described in detail and patients' satisfaction and view of the impact of counselling will be explored towards the end of the chapter.

### **7.1 BACKGROUND INFORMATION TO THE MAIN ANALYSIS**

This section considers the number of drop-outs from the research study and compares baseline scores of patients who completed the research interviews at the three and nine months follow-up. In addition, the length of each interview and the time interval between interviews are summarised.

#### **7.1.1 DROP-OUT OF PATIENTS FROM THE RESEARCH**

The number and percentage of drop-outs from the research at the three and nine months follow-ups and across the two random groups are shown in table 7.1. There was a slightly higher percentage of drop-outs in the control group, however there were no significant differences in number of drop-outs between the two random groups ( $\chi^2=1.1$ ,  $p=0.30$  for three months follow-up and  $\chi^2=0.8$ ,  $p=0.39$  for the nine months-follow-up).

The number of patients who dropped out matched the number of completed questionnaires. However, the number of completed PROQSY questionnaires was different to the number

Table 7.1 Number of patients who dropped-out and failed to complete the PROQSY questionnaire across two random groups. Figures show number of patients who dropped out of the study or who did not complete the PROQSY questionnaire (percentage).

Number of drop-outs	Counsellor (n=70)	General practitioner (n=66)	Total sample (n=136)
3 months follow-up	11 (16)	15 (23)	26 (19)
9 months follow-up	8 (11)	11 (17)	19 (14)
<b>Number of uncompleted PROQSY questionnaires</b>			
3 months follow-up	42 (60)	39 (59)	81 (60)
9 months follow-up	14 (20)	16 (24)	30 (22)

Key At the 3 months follow-up, only half the patients were seen for a face to face interview and re-interviewed with the PROQSY questionnaire. The other half were sent the questionnaires by post, who were unable to complete the computerised PROQSY questionnaire.

of patients who dropped out of the research, particularly at the three months follow-up. Half of the sample were randomly selected to be interviewed at the three months follow-up and the other half were contacted by post. This meant that it was only possible to administer the PROQSY computer questionnaire to half the sample at the three months follow-up. Table 7.1 shows the number of patients who failed to complete the PROQSY questionnaire. There were no significant differences in the number of drop-outs between the two groups using a  $P^2$  test.

#### 7.1.2 COMPARISON OF PATIENTS WHO DROPPED OUT OF THE RESEARCH STUDY WITH PATIENTS WHO COMPLETED THE RESEARCH INTERVIEWS

There were no significant differences on baseline figures between patients who completed the research interviews at the three and nine months follow-up periods compared to patients who dropped out of the research (table 7.2 and table 7.3). Patients who dropped out were slightly younger, more likely to be divorced or separated and better educated than patients who completed the research interviews. If a patient was catholic or belonged to social class 3a, they were also more likely to drop out. These differences were not statistically significant. There was a trend for patients suffering from a more recent rather than a long-term problem to drop out at the nine months follow-up interview using a Mann-Whitney U-test ( $U=791.5$ ,  $p=0.09$ ).

With regard to the main psychological and social outcome measures, there were no significant differences between patients who completed the follow-up interviews and patients who dropped out (table 7.4). However, the mean scores of all baseline measures were slightly higher for

Table 7.2 Comparison of baseline demographic variables of patients who completed and who dropped out at 3 and 9 months follow-up questionnaires. Figures show number of patients (column percentage).

Socio-demographic variable	3 months follow-up		9 months follow-up	
	Patients who completed the questionnaires	Patients who dropped out	Patients who completed the questionnaires	Patients who dropped out
<b>Age</b>	(n=110)	(n=26)	(n=117)	(n=19)
Mean (SD)	39 (13)	38 (13)	39 (13)	37 (13)
<b>Gender</b>	(n=110)	(n=26)	(n=117)	(n=19)
Female	89 (19)	5 (19)	22 (19)	4 (21)
Male	21 (81)	21 (81)	95 (81)	15 (79)
<b>Marital Status</b>	(n=110)	(n=26)	(n=117)	(n=19)
Single	44 (40)	9 (35)	45 (39)	8 (42)
Married/cohabiting	40 (36)	6 (23)	43 (37)	3 (16)
Other	26 (24)	11 (42)	29 (25)	8 (42)
<b>Ethnicity</b>	(n=110)	(n=26)	(n=117)	(n=19)
White (European & other)	101 (92)	24 (92)	106 (91)	19 (100)
Other	9 (8)	2 (8)	11 (9)	-
<b>Religion</b>	(n=110)	(n=25)	(n=117)	(n=18)
None or non-practising	36 (33)	8 (32)	37 (32)	7 (39)
Church of England	32 (29)	7 (28)	34 (29)	5 (29)
Roman Catholic	19 (17)	6 (24)	19 (16)	6 (33)
Jewish	6 (6)	2 (8)	8 (7)	-
Other	17 (16)	2 (8)	19 (16)	-

Key Some patients who dropped out at the three months follow-up were traced and followed-up at the nine months follow-up.

Table 7.3 Comparison of baseline socio-demographic variables of patients who completed and who dropped out at 3 and 9 months follow-up questionnaires. Figures show number of patients (column percentage).

Socio-demographic variable	3 months follow-up		9 months follow-up	
	Patients who completed the questionnaires	Patients who dropped out	Patients who completed the questionnaires	Patients who dropped out
<b>Education</b>	(n=110)	(n=26)	(n=117)	(n=19)
Ordinary GCE's or equivalent	39 (36)	9 (35)	43 (37)	5 (26)
Advanced GCE's or equivalent	11 (10)	3 (12)	11 (9)	3 (16)
Degree or equivalent	22 (20)	7 (27)	21 (18)	8 (42)
Post-graduate qualification	10 (9)	1 (4)	10 (9)	1 (5)
Other	8 (7)	1 (4)	8 (7)	1 (5)
None of the above	20 (18)	5 (19)	24 (21)	1 (5)
<b>Employment Status</b>	(n=110)	(n=26)	(n=117)	(n=19)
Employed	54 (49)	13 (50)	59 (50)	8 (42)
Unemployed	24 (22)	7 (27)	26 (22)	5 (26)
Other	32 (29)	6 (23)	32 (27)	6 (32)
<b>Social Class</b>	(n=99)	(n=23)	(n=107)	(n=15)
Social Class 1	15 (15)	2 (9)	16 (15)	1 (7)
Social Class 2	43 (43)	6 (26)	41 (38)	8 (53)
Social Class 3a	24 (24)	10 (44)	29 (27)	5 (33)
Social Class 3b	13 (13)	-	12 (11)	1 (7)
Social Class 4	3 (3)	3 (13)	6 (6)	-
Social Class 5	1 (1)	2 (9)	3 (3)	-
<b>Length of problem</b>	(n=103)	(n=26)	(n=110)	(n=19)
Median (Range)	36 (0-288)	25 (2-240)	36 (0-288)	24 (2-120)

Key Some patients who dropped out at the three months follow-up were traced and followed-up at the nine months follow-up.



Table 7.4 Comparison of baseline outcome measures of patients who completed and who dropped out at 3 and 9 months follow-up interviews. Figures show the mean (standard deviation).

Main outcome variables	3 months follow-up		9 months follow-up	
	Patients who completed the interview	Patients who dropped out	Patients who completed the interview	Patients who dropped out
Beck Depression Inventory	20 (9)	22 (11)	20 (9)	24 (11)
Brief Symptom Inventory - GSI	1.3 (0.7)	1.5 (0.9)	1.3 (0.7)	1.5 (0.7)
PROQSY	25 (10)	26 (12)	25 (11)	27 (12)
Modified Social Adjustment Scale	2.4 (0.5)	2.5 (0.6)	2.4 (0.5)	2.6 (0.4)
Distress scale	5.9 (1.5)	6.0 (1.5)	5.8 (1.5)	6.3 (1.2)

Key Distress Scale

0 indicates not at all

8 indicates very seriously, continuously

patients who dropped out at the follow-up interviews. This was particularly the case on the BDI mean score at the nine months follow-up, possibly indicating that patients who dropped out were more depressed at the start of the study than patients who completed the study interviews.

### **7.1.3 DURATION AND TIME BETWEEN INTERVIEWS**

Follow-up interviews took place between November 1993 and October 1995. The average time between the baseline and the three months follow-up interview was 103 days (SD 12, range 80-128 days) or approximately three months and 13 days. The average time between the baseline and nine months follow-up interview was 288 days (SD 20, range 260-368 days) or approximately nine months and 18 days.

The average length of interviews for the three and nine months follow-ups were 46 minutes (SD 16, range 25-100 minutes) and 44 minutes (SD 14, range 20-90 minutes), respectively.

For the three months follow-up, 38% of patients chose to be seen at home, 14% of patients were seen at the surgery and 48% of patients received the questionnaires by post. For the nine months follow-up interview, 70% of patients were seen at home and 25% at the surgery. At the nine months follow-up, a small percentage of patients (5%) did not have the time for an interview, but agreed to answer the questionnaires if sent to them by post.

## **7.2 COMPARISON OF MAIN OUTCOME VARIABLES**

The following analyses are performed with the use of summary scores and analysis of covariance as suggested by Frison and Pocock (1992). The summary score represents the mean score of the three and nine months follow-up interviews. All analyses have been conducted on an intention to treat analysis, that is all randomised patients have been kept in the analysis. This includes all non-compliers with counselling and patients who sought psychological help outside the study.

The total scores of all four major outcome measures were the main focus of the analysis. In addition, the distress scale was also considered important in the hypothesis testing. The sub-scores of the Brief Symptom Inventory, PROQSY and modified Social Adjustment Scale were considered of lesser importance. No calculations on the sub-scores were conducted as this would have only increased the chance of a type 1 error and make the interpretations less meaningful. The significance level was chosen at 0.05.

### **7.2.1 EFFECTS OF COUNSELLING ON THE MAIN OUTCOME MEASURES**

Table 7.5 shows the total mean scores of the various outcome measures. All measures decreased in severity over time regardless of whether patients saw the counsellor or the doctor. The counsellor group had lower scores on all the validated outcome measures compared to the general practitioner group.

The results of the analyses of covariance are shown in table 7.6. Time had a highly significant effect, that is

Table 7.5 Mean and standard deviations of the total scores on the main outcome measures across time and groups.

	Counsellor		General practitioner		Total sample
	Mean (SD)	n	Mean (SD)	n	Mean (SD)
<b>Beck Depression Score</b>					
Baseline	19.3 (8.9)	70	21.8 (9.3)	66	20.5 (9.1)
3 months	11.7 (7.7)	59	15.6 (10.5)	51	13.6 (9.3)
9 months	9.7 (8.5)	62	13.5 (10.7)	55	11.5 (9.7)
<b>General Severity Index</b>					
<b>Brief Symptom Inventory</b>					
Baseline	1.2 (0.7)	70	1.5 (0.7)	66	1.3 (0.7)
3 months	0.8 (0.6)	59	1.1 (0.9)	51	1.0 (0.8)
9 months	0.7 (0.6)	62	0.9 (0.7)	55	0.8 (0.7)
<b>PROQSY</b>					
Baseline	24.0 (12.3)	70	26.7 (9.8)	66	25.3 (11.2)
3 months	13.8 (11.8)	28	14.9 (13.5)	27	14.3 (12.5)
9 months	12.2 (12.7)	56	13.5 (12.7)	50	12.9 (12.7)
<b>Modified Social Adjustment Scale</b>					
Baseline	2.4 (0.5)	69	2.5 (0.5)	66	2.5 (0.5)
3 months	2.2 (0.5)	59	2.3 (0.6)	51	2.2 (0.5)
9 months	2.0 (0.5)	62	2.2 (0.5)	55	2.1 (0.5)
<b>Distress Scale</b>					
Baseline	5.9 (1.5)	70	5.9 (1.5)	66	5.9 (1.5)
3 months	4.3 (2.0)	56	3.8 (2.2)	50	4.1 (2.1)
9 months	3.6 (2.3)	62	3.3 (2.0)	54	3.5 (2.2)

Key Distress Scale  
 0 indicates not at all  
 8 indicates very seriously, continuously

Table 7.6 Analysis of covariance showing baseline and main group effects for the main psychological and social outcome measures.

Source of variation	Sum of squares	Degree of freedom	Mean square	F	Significance of F
Beck Depression Inventory Baseline effect	3600.9	1	3600.9	65.6	0.000
Main effects	153.5	1	153.5	2.8	0.097
Brief Symptom Inventory Baseline effect	23.4	1	23.4	76.9	0.000
Main effect	0.3	1	0.3	1.0	0.314
PROQSY Baseline effect	4247.4	1	4247.4	37.2	0.000
Main effect	22.0	1	22.0	0.2	0.662
Modified-Social Adjustment Scale Baseline effect	10.0	1	10.0	59.0	0.000
Main effect	0.4	1	0.4	2.2	0.139
Distress Scale Baseline effect	33.1	1	33.1	8.9	0.004
Main effect	1.0	1	1.0	0.3	0.613

Key The baseline effects (time from baseline and using the baseline score as the covariate) were all statistically significant. The main effect (difference between the two treatments and using the baseline score as the covariate) were not statistically significant.

patients in both random groups improved significantly from the baseline scores across all outcome measures. There were no significant differences between the two random groups of patients at follow-up. However, with the Beck Depression Inventory Score there was a trend towards the counselling group having lower scores at the mean follow-up period ( $F=2.8$ ,  $df=1$ ,  $p=0.097$ ).

Analyses of co-variance were conducted separately for each follow-up period and compared to the analyses using the mean value of the two follow-up periods. They produced similar results and in the same direction, therefore justifying using the mean score in the main analysis. This was particularly important as the low number of completed PROQSY questionnaires at the three months follow-up.

#### **7.2.2 EFFECTS OF COUNSELLING ON CASENESS ON THE OUTCOME MEASURES**

Table 7.7 shows the number of cases on each outcome measure across time and by group. Using Pearson's  $P^2$  tests, no differences were found to be significant, when including the whole sample or when excluding patients who were not cases at baseline.

It can be seen from tables 7.8 and 7.9 that patients in the counsellor group scored more often as non-cases on all outcome measures and over time than the general practitioner group. With regard to change in caseness from the baseline measurement, there were no major differences between the groups, except at the three months follow-up. A greater number and percentage of the general practitioner group became non-case on the Brief Symptom Inventory and the PROQSY questionnaire compared to the counsellor group.

Table 7.7 Number of cases (percentage) on the three main psychological outcome measures across time and by group.

	Counsellor		General practitioner		Total sample	
	n	(%)	n	(%)	n	(%)
<b>Beck Depression Score</b>						
Baseline	48/70	(69)	53/66	(80)	101/136	(74)
3 months	20/59	(34)	25/51	(49)	45/110	(41)
9 months	18/62	(29)	21/55	(38)	39/117	(33)
<b>General Severity Index</b>						
<b>Brief Symptom Inventory</b>						
Baseline	49/70	(70)	57/66	(86)	106/136	(80)
3 months	31/59	(53)	27/51	(53)	58/110	(53)
9 months	19/62	(31)	25/55	(46)	44/117	(38)
<b>PROQSY</b>						
Baseline	57/70	(81)	62/66	(94)	119/136	(88)
3 months	15/28	(54)	12/27	(44)	27/55	(49)
9 months	24/56	(43)	22/50	(44)	46/106	(43)
<b>Modified Social Adjustment Scale</b>						
Baseline	52/69	(75)	57/66	(86)	109/135	(81)
3 months	35/59	(59)	34/51	(67)	69/110	(63)
9 months	31/62	(50)	33/55	(60)	64/117	(55)

Table 7.8 Change (in terms of number of patients and column percentage) in patients' status of caseness or non-caseness from the baseline interview to 3 month follow-up assessment.

	Counsellor		General practitioner		Total sample	
	n	(%)	n	(%)	n	(%)
<b>Beck Depression Score</b>						
Non-case → non-case	17	(29)	10	(20)	27	(25)
Non-case → case	2	(3)	-	-	2	(2)
Case → non-case	22	(37)	16	(31)	38	(35)
Case → case	18	(31)	25	(49)	43	(39)
<b>General Severity Index</b>						
<b>Brief Symptom Inventory</b>						
Non-case → non-case	16	(27)	5	(10)	21	(19)
Non-case → case	3	(5)	2	(4)	5	(5)
Case → non-case	12	(20)	19	(37)	31	(28)
Case → case	28	(48)	25	(49)	53	(48)
<b>PROQSY</b>						
Non-case → non-case	4	(14)	1	(4)	5	(9)
Non-case → case	1	(4)	1	(4)	2	(4)
Case → non-case	9	(32)	14	(52)	23	(42)
Case → case	14	(50)	11	(41)	25	(45)
<b>Modified Social Adjustment Scale</b>						
Non-case → non-case	11	(19)	4	(8)	15	(14)
Non-case → case	4	(7)	3	(6)	7	(6)
Case → non-case	13	(22)	13	(25)	26	(24)
Case → case	30	(52)	31	(61)	61	(56)



Table 7.9 Change (in terms of number of patients and column percentage) in patients' status of caseness or non-caseness from the baseline interview to 9 month follow-up assessment.

	Counsellor		General practitioner		Total sample	
	n	(%)	n	(%)	n	(%)
<b>Beck Depression Score</b>						
Non-case → non-case	19	(31)	11	(20)	30	(26)
Non-case → case	1	(2)	1	(2)	2	(2)
Case → non-case	25	(40)	23	(42)	48	(41)
Case → case	17	(27)	20	(36)	37	(32)
<b>General Severity Index</b>						
<b>Brief Symptom Inventory</b>						
Non-case → non-case	18	(29)	8	(15)	26	(22)
Non-case → case	1	(2)	1	(2)	2	(2)
Case → non-case	25	(40)	22	(40)	47	(40)
Case → case	18	(29)	24	(44)	42	(36)
<b>PROQSY</b>						
Non-case → non-case	9	(16)	4	(8)	13	(12)
Non-case → case	1	(2)	-	-	1	(1)
Case → non-case	23	(41)	24	(48)	47	(44)
Case → case	23	(41)	22	(44)	45	(43)
<b>Modified Social Adjustment Scale</b>						
Non-case → non-case	12	(20)	6	(11)	18	(16)
Non-case → case	4	(7)	2	(4)	6	(5)
Case → non-case	19	(31)	16	(29)	35	(30)
Case → case	26	(43)	31	(56)	57	(49)

However, the PROQSY results need to be interpreted with caution because of the small numbers at the three months follow-up. The counsellor group did better on the Beck Depression Inventory with patients in this group changing to non-caseness more often than the general practitioner group. These tables also highlight that some patients who were non-cases at the baseline interview became cases during the intervention period. This occurred to a greater extent at the three months follow-up.

Another interesting observation was the change amongst the different outcome measures. Fewer patients remained cases at follow-up on the psychological scales than the modified Social Adjustment Scale. On the psychological scales the percentage of patients who changed from a case to non-case at the follow-up interviews was 28 up to 44% for the whole sample, whereas for the modified Social Adjustment Scale was 24 up to 30%.

### **7.2.3 ANALYSIS TAKING INTO CONSIDERATION DROP-OUTS**

To take into consideration the drop-outs and have confidence in the above analyses, Altman (1991) suggests repeating the analysis, assigning the most optimistic and pessimistic outcome to all patients who dropped-out and comparing it with the analysis where patients were simply excluded. Tables 7.10 and 7.11 show that the number of cases and percentages of cases if taking the most positive or negative outcome for dropouts. Using Pearson's  $\chi^2$  tests, no differences were found at the 0.05 significance level.

Table 7.10 Number of cases (percentage) on the three main psychological outcome measures across time and by group and assuming the most positive outcomes for dropouts.

	Counsellor		General practitioner		Total sample	
	n	(%)	n	(%)	n	(%)
<b>Beck Depression Score</b>						
Baseline	48/70	(69)	53/66	(80)	101/136	(74)
3 months	20/70	(27)	25/66	(38)	45/136	(33)
9 months	18/70	(26)	21/66	(32)	39/136	(29)
<b>General Severity Index</b>						
<b>Brief Symptom Inventory</b>						
Baseline	49/70	(70)	57/66	(86)	106/136	(80)
3 months	31/70	(44)	27/66	(41)	58/136	(43)
9 months	19/70	(27)	25/66	(38)	44/136	(32)
<b>PROQSY</b>						
Baseline	57/70	(81)	62/66	(94)	119/136	(88)
3 months	15/70	(21)	12/66	(18)	27/136	(20)
9 months	24/70	(34)	22/66	(33)	46/136	(34)
<b>Modified Social Adjustment Scale</b>						
Baseline	52/69	(75)	57/66	(86)	109/135	(81)
3 months	35/70	(50)	34/66	(52)	69/136	(51)
9 months	31/70	(44)	33/66	(50)	64/136	(47)

Table 7.11 Number of cases (percentage) on the three main psychological outcome measures across time and by group and assuming the most negative outcomes for dropouts.

	Counsellor		General practitioner		Total sample	
	n	(%)	n	(%)	n	(%)
<b>Beck Depression Score</b>						
Baseline	48/70	(69)	53/66	(80)	101/136	(74)
3 months	31/70	(44)	40/66	(61)	71/136	(52)
9 months	26/70	(37)	32/66	(49)	58/136	(43)
<b>General Severity Index</b>						
<b>Brief Symptom Inventory</b>						
Baseline	49/70	(70)	57/66	(86)	106/136	(80)
3 months	42/70	(60)	42/66	(64)	84/136	(62)
9 months	27/70	(39)	36/66	(55)	63/136	(46)
<b>PROQSY</b>						
Baseline	57/70	(81)	62/66	(94)	119/136	(88)
3 months	57/70	(81)	51/66	(77)	108/136	(79)
9 months	38/70	(54)	38/66	(58)	76/136	(56)
<b>Modified Social Adjustment Scale</b>						
Baseline	52/69	(75)	57/66	(86)	109/135	(81)
3 months	46/70	(66)	49/66	(74)	95/136	(70)
9 months	39/70	(56)	44/66	(67)	83/136	(61)

### **7.3 SUB-GROUP ANALYSIS**

There were no statistically significant differences in the main analysis. This section explores the data in greater depth in order to discover whether certain subgroups of patients had a greater improvement in the counsellor group compared to the general practitioner group. Several types of analyses were conducted. This included dichotomising the variables and subjecting them to a two-way analysis of covariance. The mean Beck Depression Inventory score was used in the two-way analysis of covariance as the main outcome measure of change in psychological symptoms. All analysis adjusted for baseline differences by including the baseline Beck Depression Inventory score.

#### **7.3.1 CASENESS AT BASELINE**

Not all patients were cases at the baseline interview. One hundred and one patients scored as cases on the Beck Depression Inventory ( $BDI > 14$ ) at the baseline interview. The data from these patients were subjected to an analysis of covariance using the mean follow-up score. A significant difference was found ( $F=4.6$ ,  $df=1$ ,  $p=0.035$ ). In other words, patients seeing the counsellor showed a greater improvement than the general practitioner group. When the analyses were conducted separately for the two follow-up points, there was a larger trend at the three months follow-up interview ( $F=3.5$ ,  $df=1$ ,  $p=0.066$ ) than at the nine months follow-up interview ( $F=2.8$ ,  $df=1$ ,  $p=0.10$ ).

These analyses were not significant when cases were selected on the Brief Symptom Inventory, the PROQSY and the modified Social Adjustment Scale questionnaire.

### **7.3.2 DURATION OF PROBLEM**

There were no associations with the length of time a person suffered from their emotional problem, decrease in mean Beck Depression Inventory score and group allocation. Two questions were asked about the duration of the problem, one on the PROQSY questionnaire and another on the baseline economic questionnaire. Length of time was dichotomised to 12 months or less and 12 months or more for both questions and at six months or less and six months or more just for the question on the economic form. Using a two-way analysis of variance no significant associations were found for either question using 12 months cut-off or the six months cut-off with the question from the baseline economic questionnaire.

### **7.3.3 SOCIO-DEMOGRAPHIC VARIABLES**

There was a significant association with age, that is younger patients who saw a counsellor had a higher chance of reducing their mean symptom score ( $F=4.0$ ,  $df=1$ ,  $p=0.05$ ). Age was dichotomised at 35 years.

There was a trend and a significant change for patients who were unemployed and from social classes 3b to 5, respectively. They reduced their psychological symptoms to a greater extent in the counsellor group compared to the general practitioner group (Employment status:  $F=3.6$ ,  $df=1$ ,  $p=0.06$ ; Social class:  $F=10.1$ ,  $df=1$ ,  $p=0.002$ ).

There no associations with gender, marital status, ethnicity, religion and education.

#### **7.3.4 PREFERENCE**

Most patients either had a preference to see a counsellor (52%) or did not mind who they saw (43%). Thirty seven out of the 71 patients (52%) who would have preferred to see a counsellor were randomised to the counsellor. A two-way analysis of covariance showed that preference for a particular treatment and randomisation did not influence the change in symptom score ( $F=0.4$ ,  $df=1$ ,  $p=0.5$ ).

#### **7.3.5 MEDICATION**

There were no significant differences between patients taking anti-depressants or not, group allocation and mean Beck Depression Inventory score ( $F=3.1$ ,  $df=1$ ,  $p=0.08$ ). However examining the variables more closely, patients who were on anti-depressants and seeing the general practitioner made a slightly better recovery than patients seeing the doctor and not taking any anti-depressant medication. This was the opposite for the counselling group. Patients did better with the counsellor if there were not taking any anti-depressants. None of these differences were statistically significant.

The above analyses demonstrate that caseness on the Beck Depression Inventory (BDI >14) and younger age (<35 years old) are associated with a better outcome in the mean Beck Depression Inventory score when seeing a counsellor rather than the general practitioner alone.

## **7.4 COUNSELLOR TREATMENT**

Seventy patients were randomised to see the counsellor. The following section describes data relating to the process of counselling.

### **7.4.1 TYPE OF COUNSELLING APPROACH**

The counsellors were instructed to use a non-directive, brief, person-centred approach to counselling, based on the theories of Carl Rogers. The counsellors audiotaped a random number of sessions with their clients. An independent and qualified counsellor reviewed one tape chosen randomly for each study counsellor. The independent counsellor had no other involvement in the study besides evaluating the tapes and did not know the study counsellors personally.

The independent counsellor quoted "broadly all the counsellors, followed the instructions given". None of the counsellors used directive methods, however some were better at showing empathy and using advanced listening skills. One of the counsellors was particularly good at staying with the client and reflecting back what they had said. On the other hand, one counsellor "failed to explore the feelings that were underneath what this young woman was speaking about". The independent counsellor felt that the differences were in counselling style rather than the counselling model used.



#### **7.4.2 DIFFERENCES IN OUTCOME BETWEEN COUNSELLORS**

Table 7.12 shows the mean total scores on the main outcome variables across time and by counsellor. Using analysis of covariance, there were no significant differences between the counsellors, despite possible differences in counselling style. In other words, no counsellor was more effective than another. There were missing data on one patient.

#### **7.4.3 PATIENTS WHO REFUSED TO SEE THE COUNSELLOR**

Of the seventy patients who were randomised to counselling, four patients never saw the counsellor. Two of them decided they no longer needed to see a counsellor. The husband of one of these patients did not approve of his wife seeing a counsellor. One patient fell out with the counsellor while trying to arrange the first appointment and decided not to continue. She withdrew from the study altogether. The fourth patient did not attend the first two counselling appointments even with reminders and letters from the counsellor.

#### **7.4.4 NUMBER OF CONTACTS**

The number of counselling sessions attended varied from 1 appointment to 12 appointments. The mean number of sessions was 7.7 (SD 3.8, mode 12). Just under 22% attended 12 sessions. There were missing data on 2 patients.

The mean number of booked appointments was 9.3 (SD 3.6, range 1-15, mode 12). Just over 42% of patients wanted to use as many sessions as were available, that is 12

Table 7.12 The mean (standard deviation) of the main outcome variables across time and by different counsellors.

	Counsellor 1	Counsellor 2	Counsellor 3	Counsellor 4
<b>Number of patients seen</b>	12	36	9	8
<b>Beck Depression Inventory</b>				
Baseline	18.5 (9.3)	19.5 (8.5)	19.1 (11.6)	19.3 (8.8)
Follow-up mean score	9.4 (6.2)	11.0 (8.1)	13.3 (10.1)	8.7 (6.9)
<b>General Severity Score Brief Symptom Inventory</b>				
Baseline	1.1 (0.6)	1.2 (0.8)	1.4 (0.7)	1.1 (0.7)
Follow-up mean score	0.7 (0.4)	0.8 (0.7)	0.9 (0.9)	0.6 (0.5)
<b>PROQSY</b>				
Baseline	22.5 (12.4)	24.3 (12.3)	26.2 (15.4)	21.7 (10.7)
Follow-up mean score	12.7 (12.8)	12.0 (12.0)	12.3 (14.2)	12.0 (9.2)
<b>Modified Social Adjustment Scale</b>				
Baseline	2.3 (0.4)	2.4 (0.5)	2.6 (0.7)	2.3 (0.5)
Follow-up mean score	2.1 (0.4)	2.1 (0.5)	2.2 (0.7)	1.9 (0.4)

sessions. Four patients had booked more than 12 sessions. This only happened when they had missed an appointment and they had to rearrange another to be able to have the full 12 sessions. There were missing data on 2 patients.

The 66 patients who saw the counsellor missed on average 1.5 sessions (SD 1.6, range 0-6 sessions). About a third of the sample (32.4%) did not miss any appointments. Just over 26% missed one session and 20.6% missed 2 sessions.

#### **7.4.5 WHY COUNSELLING ENDED**

There were several reasons why the counselling sessions ended. In 46.2% of the sample, patients had completed the specified number of counselling sessions arranged. Ten patients (15.4%) eventually failed to attend counselling and therefore did not complete their counselling. In the other 25 cases (38.5%) there was an agreement between the counsellor and the patient to end the counselling. There were missing data on one case (Table 7.13).

The conclusion from table 7.13 is that counselling usually went the full 12 sessions (or near enough) unless the patient requested that it stop, or dropped out.

#### **7.4.6 THE APPROPRIATENESS OF COUNSELLING REFERRALS**

Most of the referrals for short-term counselling were regarded as appropriate by the counsellor. However, in 14% of cases the counsellor considered that the referrals were inappropriate. They felt that these patients required long term therapy or a psychiatric intervention.

Table 7.13 The reasons for ending the counselling sessions.

Reason for session ending	Number (%)	Mean (SD) (range) of sessions attended	Mean (SD) (range) of sessions booked	Mean (SD) (range) of sessions missed
End of specified time	30 (46.2)	10.5 (2.3) (4-12)	11.4 (2.4) (4-15)	1.0 (1.3) (0-5)
Patient's request	14 (21.5)	4.0 (2.3) (1-9)	5.7 (2.8) (1-10)	1.7 (1.1) (0-4)
Patient failed to turn up	10 (15.4)	4.0 (3.5) (0-11)	7.9 (3.9) (3-12)	3.0 (1.8) (1-6)
Agreement between counsellor and patient	5 (7.7)	6.6 (2.7) (4-11)	8.6 (3.1) (5-12)	2.0 (2.5) (0-6)
Suggested further referral	5 (7.7)	9.2 (1.8) (7-11)	11.6 (0.6) (11-12)	2.4 (2.1) (0-5)
Counsellor's decision	1 (1.5)	5	5	0

## 7.5 PATIENT SATISFACTION AND SESSION IMPACTS

The satisfaction and modified session impact scale contained 15 items. Tables 7.14 and 7.15 report the mean scores and standard deviations for all 15 items at the three and nine months follow-up. Patients were clearly more satisfied with counselling than routine care from a general practitioner at the three and nine months follow-up. Patients felt better understood, less troubled and less criticised by the counsellor compared to the doctor. In addition, patients became more aware of their feelings and experiences and understood something new about themselves and their partner more often after seeing the counsellor than the general practitioner. There were no significant differences between the counsellor and the general practitioner group on ways of coping with problems and knowing what needed to be changed in the patient's life.

Table 7.14 Patient satisfaction and session impacts questionnaire at the 3 months follow-up and according to the two random groups.

	Counsellor		General practitioner		Mann-Whitney U-tests	
	Mean	(SD)	Mean	(SD)	U	p
I understood something new about myself	3.1	1.1	2.5	1.4	961	0.005
I understood something new about my partner or somebody else	2.8	1.2	2.2	1.4	892	0.009
I understood something new about the relationship with my partner	2.4	1.2	2.2	1.6	843	0.13
I became more aware of my feelings and experiences	3.4	1.2	2.9	1.4	1042	0.03
I know what needs to be changed in my life	3.3	1.3	3.1	1.4	1246	0.56
I found out ways of coping with problems	3.0	1.3	2.6	1.3	1109	0.17
I felt understood	3.9	1.0	3.0	1.3	782	0.0003
I felt supported	3.9	1.1	3.1	1.4	871	0.004
I felt less troubled	3.3	1.2	2.5	1.2	826	0.001
I felt more bothered by unpleasant thoughts	2.2	1.3	2.0	1.3	1122	0.32
I felt pressure on me to do something	1.7	1.1	2.4	1.5	1052	0.04
I felt criticised	1.2	0.6	1.7	1.1	916	0.0003
I felt confused	1.8	1.1	2.4	1.4	991	0.04
I felt bored	1.3	0.9	1.9	1.4	970	0.02
Generally, how satisfied were you with the help you received	4.1	1.0	2.9	1.5	682	<0.0001

Key 0 indicates not at all  
5 indicates very much

Table 7.15 Patient satisfaction and session impacts questionnaire at the 9 months follow-up and according to the two random groups.

	Counsellor		General practitioner		Mann-Whitney U-tests	
	Mean	(SD)	Mean	(SD)	U	p
I understood something new about myself	3.1	1.3	2.2	1.1	981	0.0002
I understood something new about my partner or somebody else	2.8	1.3	2.0	1.2	881	0.001
I understood something new about the relationship with my partner	2.6	1.3	2.0	1.4	803	0.02
I became more aware of my feelings and experiences	3.4	1.2	2.3	1.3	836	<0.0001
I know what needs to be changed in my life	3.2	1.5	2.7	1.5	1233	0.051
I found out ways of coping with problems	2.9	1.3	2.4	1.6	1273	0.06
I felt understood	3.8	1.2	2.9	1.5	1078	0.003
I felt supported	3.7	1.3	3.2	1.5	1328	0.13
I felt less troubled	3.1	1.3	2.4	1.3	1123	0.006
I felt more bothered by unpleasant thoughts	1.8	1.2	2.2	1.4	1386	0.21
I felt pressure on me to do something	1.8	1.1	2.2	1.5	1410	0.27
I felt criticised	1.2	0.7	1.9	1.2	986	<0.0001
I felt confused	1.7	1.0	2.2	1.4	1281	0.06
I felt bored	1.3	0.7	1.7	1.3	1386	0.12
Generally, how satisfied were you with the help you received	4.0	1.2	3.0	1.5	1013	0.0004

Key 0 indicates not at all  
5 indicates very much

## **8.0 RESULTS III - SERVICE UTILIZATION AND COST-EFFECTIVENESS ANALYSIS**

This section describes the service utilization and economic analysis. Firstly, the data collection and type of data used for the economic evaluation will be explained. Secondly, the background variables, such as accommodation, number of people in the household and personal income are described. Next each direct and indirect economic outcome variable is examined in turn. Finally, the cost-effectiveness analysis and a sensitivity analysis will be presented.

### **8.1 TYPE OF DATA USED**

Data were collected from patients, patients' case notes in general practice and from counsellors. Most of the data used in this chapter comes from the patient economic questionnaire.

Data was obtained from 92 (68%) of the patient records. Missing data were mainly accounted for by patients having left the surgery by the time I was able to carry out the note search later on in the study. In addition, I was unable to complete all the note searching in two group practices, because of lack of time. Some difficulties were experienced with note searching. It was sometimes difficult to distinguish between doctor and practice nurse consultations and no information on length of consultations was given. In addition, medication was not always recorded in the case notes, particularly repeat prescriptions. All surgeries were computerised and held some of the drug information on the computer. I tried to match information



obtained from the case notes with computer print-outs of a patient's medication. On the other hand, the economic questionnaire completed by the patient gave an indication of how long a patient spent with each doctor. I encouraged patients to look at diaries and count the number of consultations they had attended.

The data obtained from the different methods were compared using a Spearman correlation coefficient. For the number of general practice consultations from the patient questionnaire and the general practice notes, the correlation coefficient ranged from 0.52 to 0.77. For Tricyclic and Selective Serotonin Reuptake Inhibitor antidepressants, the patient questionnaire and general practice case notes correlated between 0.49 to 0.85. For counsellor appointments, the patient questionnaire and the counsellor process notes correlated at 0.82.

After discussion with the health economist, it was decided to use the data obtained from patient questionnaire except for the number of appointments with a study counsellor which was taken from the counsellor process notes. Medication was not considered in the cost-effectiveness analysis, because the unit costs for general practitioners included the costs of drugs and dispensing. All costs were based on 1995-96 prices.

## **8.2 BACKGROUND ECONOMIC VARIABLES**

Certain background variables were examined at the baseline interview. The counselling group had a higher percentage of home owners/occupiers, lived more often as two adults with children and had a slightly higher proportion of two

bedroom accommodation (table 8.1). The general practitioner group on the other hand lived more often in local authority rented accommodation and as a single person in a one bedroomed residence.

There was a trend for patients in the counsellor group to be higher earners than the general practitioner group ( $t=1.87$ ,  $df=125$ ,  $p=0.064$ ). This difference was significant at the three months follow-up with patients in the counsellor group having higher weekly gross incomes than patients in the general practitioner group ( $t=2.70$ ,  $df=83$ ,  $p=0.008$ ). With regard to social security benefits, the counselling sample tended to claim for shorter period of time and claimed for less money than patients randomised to the general practitioner group (table 8.2).

Besides the significant difference in income, there were no significant differences between the groups on household composition, employment and accommodation either at baseline or at the two follow-up points. None of patients lived in specialised accommodation. It was therefore not necessary to include these data in any further analysis. However, patients' income was accounted for in the sensitivity analysis.

### **8.3 EFFECTS OF COUNSELLING ON ECONOMIC VARIABLES**

The following section describes the direct and indirect cost variables. Each variable is discussed in turn and can be seen as outcomes in their own right, this is particularly true for the service utilization outcomes.

Table 8.1 Accommodation. Figures show numbers of patients (column percentages).

	<b>Counselling group</b>	<b>General practitioner group</b>	<b>Total sample</b>
<b>Accommodation</b>	<b>(n=69)</b>	<b>(n=66)</b>	<b>(n=135)</b>
Rented from local authority	11 (16)	16 (24)	27 (20)
Privately rented	14 (20)	13 (20)	27 (20)
Owner/occupier	34 (49)	24 (36)	58 (43)
Other	10 (15)	13 (20)	23 (17)
<b>Number in household</b>	<b>(n=65)</b>	<b>(n=59)</b>	<b>(n=124)</b>
1 adult, no children	12 (19)	15 (25)	27 (22)
2 adults, no children	14 (22)	15 (25)	29 (23)
3 or more adults, no children	7 (11)	8 (14)	15 (12)
1 adult with child or children	12 (19)	9 (15)	21 (17)
2 adults with child or children	18 (28)	10 (17)	28 (23)
3 or more adults with child or children	2 (3)	2 (3)	4 (3)
<b>Number of bedrooms</b>	<b>(n=70)</b>	<b>(n=66)</b>	<b>(n=136)</b>
1 bedroom	7 (10)	13 (20)	20 (15)
2 bedrooms	25 (36)	16 (24)	41 (30)
3 bedrooms	19 (27)	19 (29)	38 (28)
4 or more bedrooms	19 (27)	18 (27)	37 (27)

Table 8.2 Gross income and social security benefit. Figures show numbers of patients (column percentages).

	<b>Counselling group</b>	<b>General practitioner group</b>	<b>Total sample group</b>
<b>Income per week</b>	<b>(n=64)</b>	<b>(n=63)</b>	<b>(n=127)</b>
Under £100	18 (28)	21 (33)	39 (31)
Between £101 - £225	16 (25)	21 (33)	37 (29)
Between £226 - £375	16 (25)	14 (22)	30 (24)
More than £376	14 (22)	7 (11)	21 (17)
<b>Social security benefit</b>	<b>(n=25)</b>	<b>(n=29)</b>	<b>(n=54)</b>
Income support	12 (52)	11 (38)	23 (44)
Unemployment benefit	2 (9)	2 (7)	4 (8)
Income support and rent, housing or mortgage relief	2 (9)	12 (41)	14 (27)
Disability, invalidity or sickness benefit	3 (13)	3 (10)	6 (12)
Other	4 (17)	1 (3)	5 (10)
<b>Number of weeks on benefit</b>	<b>(n=23)</b>	<b>(n=28)</b>	<b>(n=51)</b>
Less than 3 months	9 (39)	5 (18)	14 (28)
Between 3 and 6 months	2 (9)	4 (14)	6 (12)
Between 6 and 12 months	4 (17)	5 (18)	9 (18)
More than 1 year	8 (35)	14 (50)	22 (43)
<b>Amount of benefit per week</b>	<b>(n=24)</b>	<b>(n=29)</b>	<b>(n=53)</b>
Under £45	8 (33)	8 (28)	16 (30)
Between £46 - £70	5 (21)	8 (28)	13 (25)
Between £71 - £100	6 (25)	5 (17)	11 (21)
More than £101	5 (21)	8 (28)	13 (25)

### 8.3.1 DIRECT COST VARIABLES

#### a) General practitioner consultations

Table 8.3 shows the average number of consultations, the average number of home visits and the total average time spent with each patient six months before the baseline interview and three and nine months after the baseline interview.

Patients randomised to see a counsellor visited their general practitioner slightly less often in the six months before the baseline assessment than patients randomised to see their doctor. There were significant changes from baseline in the number of appointments or total time per month spent with the general practitioner three months after the baseline interview. The patients seeing a counsellor reduced their actual number of appointments and total time per month spent with the doctor from the baseline measurement ( $F=6.1$ ,  $df=1$ ,  $p=0.02$ ), whereas patients in the general practitioner group increased their number of consultations and total time per month spent with the doctor ( $F=5.1$ ,  $df=1$ ,  $p=0.03$ ). Patients in the counsellor continued to reduce their number of consultations and total time per month spent with the doctor at the nine months follow-up ( $F=17.5$ ,  $df=1$ ,  $p<0.001$ ). After the three months follow-up, patients in the general practitioner group reduced their consultations and total time per month with the doctor by the nine months follow-up ( $F=10.4$ ,  $df=1$ ,  $p=0.002$ ).

In addition, there was a significant trend at the three months follow-up with regard to number of visits to the

Table 8.3 Mean number (SD) of general practitioner consultations and home visits and total time spent with the general practitioner.

	Counsellor		General practitioner		Total sample
	Mean (SD)	n	Mean (SD)	n	Mean (SD)
<b>Number of GP consultations</b>					
Baseline	3.7 (3.4)	69	4.6 (4.7)	65	4.0 (3.8)
3 months	1.6 (1.9)	59	2.9 (3.3)	51	2.2 (2.7)
9 months	2.1 (2.2)	61	3.4 (4.1)	55	2.7 (3.3)
<b>Number of home visits</b>					
Baseline	0.1 (0.5)	69	0.1 (0.4)	64	0.1 (0.5)
3 months	0.0 (0.2)	31	0.1 (0.2)	38	0.0 (0.2)
9 months	0.2 (0.4)	43	0.1 (0.4)	39	0.1 (0.4)
<b>Total time spent with the GP (minutes)</b>					
Baseline	48.7 (49.6)	69	65.2 (65.1)	65	54.4 (52.9)
3 months	22.6 (35.7)	53	55.2 (90.7)	49	38.3 (69.5)
9 months	28.4 (40.7)	61	41.9 (53.7)	55	34.8 (47.6)

general practitioner and the total time spent with the general practitioner between the two groups. The counselling group saw the general practitioner less often than the general practitioner group at three months ( $F=3.8$ ,  $df=1$ ,  $p=0.053$ ) and for less time ( $F=3.6$ ,  $df=1$ ,  $p=0.062$ ).

#### b) Counsellor

Table 8.4 shows the average number of consultations and total time spent with a counsellor. No patients entering the study were currently seeing a counsellor or equivalent. However, five patients in each group had seen a counsellor or taken part in a self-help group in the six months previous to the baseline interview.

There were no significant differences at baseline and at the nine months follow-up assessment. In addition to the study counsellor, one patient in the counsellor group and nine patients in the GP group saw a counsellor or equivalent during the intervention period (baseline to the three month follow-up) and eight patients in the counsellor group and 11 patients in the GP group saw a counsellor or equivalent between the three and nine months follow-up.

#### c) Other health professionals

With regard to other consultations, patients in both groups did not see many other health professionals (tables 8.5 and 8.6). Table 8.5 shows the mean number of consultations across the entire sample which were used for costing purposes, whereas table 8.6 shows the actual number of patients seeing the particular professional. There was a significant difference regarding contact with a

Table 8.4 Mean number (SD) of counsellor consultations and total time spent with the counsellor.

	Counsellor		General practitioner		Total sample
	Mean (SD)	n	Mean (SD)	n	Mean (SD)
<b>Number of counsellor consultations</b>					
Baseline	0.2 (1.1)	69	0.4 (1.8)	66	0.3 (1.4)
3 months	7.2 (4.3)	61	0.9 (2.3)	51	4.3 (4.7)
9 months	1.4 (5.1)	62	1.7 (4.4)	55	1.5 (4.7)
<b>Total time spent with the counsellor (minutes)</b>					
Baseline	21.9 (94.8)		24.6 (105.8)		22.7 (99.9)
3 months	396.6 (242.4)		50.0 (133.7)		238.8 (264.3)
9 months	78.9 (301.9)		92.0 (258.8)		85.0 (281.3)



Table 8.5 Mean number (SD) of other professional consultations for the whole sample.

	Counsellor		General practitioner	
	Mean (SD)	n	Mean (SD)	n
<b>Psychiatrist</b>				
Baseline	0.44 (3.6)	70	0.05 (0.3)	66
3 months	0.20 (1.2)	59	0.02 (0.1)	51
9 months	0.07 (0.4)	62	0.36 (1.7)	55
<b>Specialist</b>				
Baseline	0.49 (1.4)	68	0.45 (1.4)	65
3 months	0.15 (0.4)	59	0.12 (0.4)	51
9 months	0.29 (1.0)	62	0.42 (1.2)	55
<b>Occupational health doctor</b>				
Baseline	0.07 (0.4)	70	0.02 (0.1)	66
3 months	0.05 (0.4)	59	0	51
9 months	0.02 (0.1)	62	0.02 (0.1)	55
<b>Clinical psychologist</b>				
Baseline	0	70	0	70
3 months	0	59	0	51
9 months	0.10 (0.8)	62	0.06 (0.3)	55
<b>Social worker</b>				
Baseline	0.17 (0.9)	70	0.02 (0.1)	66
3 months	0.02 (0.1)	59	0	51
9 months	0	62	0	55
<b>Community psychiatric nurse</b>				
Baseline	0	70	0	66
3 months	0	59	0.18 (1.3)	51
9 months	0	62	0.06 (0.4)	55
<b>Practice nurse</b>				
Baseline	0.20 (0.7)	70	0.17 (0.5)	66
3 months	0.03 (0.2)	59	0.14 (0.5)	51
9 months	0.05 (0.2)	62	0.18 (0.8)	55
<b>District nurse</b>				
Baseline	0	70	0	66
3 months	0	59	0	51
9 months	0	62	0.02 (0.1)	55
<b>Health visitor</b>				
Baseline	0.03 (0.2)	70	0.05 (0.3)	66
3 months	0.03 (0.3)	59	0	51
9 months	0	62	0	55
<b>Other professional</b>				
Baseline	1.00 (3.5)	70	0.39 (1.4)	66
3 months	0.05 (0.4)	59	0.33 (1.8)	51
9 months	0.24 (1.0)	62	0.66 (2.2)	55

Table 8.6 Mean number (SD) of other professional consultations for the sample who actually had contact.

	Counsellor		General practitioner	
	Mean (SD)	n	Mean (SD)	n
<b>Psychiatrist</b>				
Baseline	15.5 (20.5)	2	1.5 (0.7)	2
3 months	6.0 (2.8)	2	1.0	1
9 months	2.0 (1.4)	2	5.0 (4.8)	4
<b>Specialist</b>				
Baseline	3.3 (2.0)	10	2.6 (2.5)	11
3 months	1.1 (0.4)	8	1.5 (0.6)	4
9 months	2.6 (1.5)	7	2.6 (2.0)	9
<b>Occupational health doctor</b>				
Baseline	1.7 (0.6)	3	1.0	1
3 months	3.0	1	-	-
9 months	1.0	1	1.0	1
<b>Clinical psychologist</b>				
Baseline	-	-	-	-
3 months	-	-	-	-
9 months	6.0	1	1.5 (0.7)	2
<b>Social worker</b>				
Baseline	3.0 (2.8)	4	1.0	1
3 months	1.0	1	-	-
9 months	-	-	-	-
<b>Community psychiatric nurse</b>				
Baseline	-	-	-	-
3 months	-	-	9.0	1
9 months	-	-	3.0	1
<b>Practice nurse</b>				
Baseline	2.0 (0.8)	7	1.4 (0.7)	8
3 months	1.0 (0)	2	1.8 (0.5)	4
9 months	1.0 (0)	3	2.5 (1.7)	4
<b>District nurse</b>				
Baseline	-	-	-	-
3 months	-	-	-	-
9 months	-	-	1.0	1
<b>Health visitor</b>				
Baseline	2.0	1	1.5 (0.7)	2
3 months	2.0	1	-	-
9 months	-	-	-	-
<b>Other professional</b>				
Baseline	7.7 (6.8)	9	5.0 (2.1)	5
3 months	3.0	1	4.8 (5.0)	4
9 months	3.0 (1.9)	5	6.0 (3.4)	6

psychiatrist at baseline, but this was due to one person in the counsellor group having seen a psychiatrist 30 times.

#### d) Medication

Table 8.7 show the number and type of medications taken by the patients. There were no significant differences between the two random groups in type of medication prescribed even in the intervention period between baseline and the three months follow-up. Six months before the baseline interview, 32% of the sample were prescribed psychotropic medication, whereas at the three and nine months follow-ups 22% and 24% of patients were prescribed some form of psychotropic medication, respectively. With regard to anti-depressants, 24% of the sample were prescribed anti-depressants six months before the baseline assessment, and 20% and 15% at the three and nine months follow-up assessments.

#### e) Out-patient appointments and in-patient stays

All out-patient appointments and in-patients stays were examined, including psychiatric hospital contacts. There were no admissions to any psychiatric hospitals six months before the study and during the study. Four patients attended a psychiatric out-patient department six months before the baseline interview and three and six patients attended a clinic three and nine months after the baseline interview. These appointments were included in the total number of out-patient appointments.

Seeing a counsellor led to a slight decrease in the number of out-patient appointments from baseline, whereas patients seeing only the general practitioner led to an increase in

Table 8.7 Number and type of medication prescribed at baseline, three and nine months follow-up.

<b>Baseline</b>	<b>Counsellor n=70</b>	<b>General practitioner n=66</b>
Tricyclic antidepressants	13 (19)	9 (14)
Selective serotonin reuptake inhibitors	6 (9)	4 (6)
Anxiolytics and hypnotics	4 (6)	9 (14)
Other psychotropic medication	2 (3)	1 (2)
Other medication	44 (63)	49 (74)
<b>3 months follow-up</b>	<b>Counsellor n=58</b>	<b>General practitioner n=50</b>
Tricyclic antidepressants	6 (10)	5 (10)
Selective serotonin reuptake inhibitors	4 (7)	7 (14)
Anxiolytics and hypnotics	2 (3)	3 (6)
Other psychotropic medication	1 (2)	-
Other medication	33 (57)	31 (62)
<b>9 months follow-up</b>	<b>Counsellor n=62</b>	<b>General practitioner n=55</b>
Tricyclic antidepressants	5 (8)	2 (4)
Selective serotonin reuptake inhibitors	5 (8)	5 (9)
Anxiolytics and hypnotics	4 (6)	4 (7)
Other psychotropic medication	-	5 (9)
Other medication	35 (57)	36 (66)

the number of appointments (Table 8.8 and 8.9). This was also true for hospital admissions however the numbers were very small. There were no admissions to any psychiatric hospitals six months before the study and during the study. Despite these slight changes in opposite direction, there were no significant differences in the number of appointments or the number of nights in hospital between the two groups at all three time points. There were also no significant differences when calculating the proportion of patients attending for an appointment or stay in hospital.

### **8.3.2 INDIRECT COSTS**

#### a) Days off work/lost production

There were no significant differences between the mean number of days taken off sick because of any problems or the present emotional problems between the two groups (table 8.10). At baseline, patients in the counsellor group took a greater mean number of days off sick but a greater proportion of patients in the general practitioner group took at least one day off sick for any reason.

During the intervention period (baseline to the three months follow-up) a greater proportion of patients in the counsellor group took time off sick as well as taking a higher mean number of days off sick than patients in the general practitioner group. However by the 9 months follow-up, patients in the general practitioner group were taking a higher number of days off. Nevertheless, the percentage of patients taking at least one day off work reduced in both groups. The reduction was greater in general

Table 8.8 Mean number (SD) of out-patient, in-patient and day hospital appointments for the whole sample.

	Counsellor		General practitioner	
	Mean (SD)	n	Mean (SD)	n
<b>Number of out-patient appointments</b>				
Baseline	1.46 (4.3)	70	0.73 (1.6)	66
3 months	0.40 (0.9)	58	0.76 (3.1)	50
9 months	0.50 (1.2)	62	1.40 (2.7)	55
<b>Number of in-patient stays</b>				
Baseline	0.20 (1.0)	70	0.08 (0.4)	66
3 months	0.10 (0.7)	59	0.14 (0.9)	51
9 months	0.11 (0.7)	62	0.33 (1.2)	55
<b>Number of day hospital</b>				
Baseline	-	-	-	-
3 months	-	-	-	-
9 months	0.03 (1.2)	62	0.22 (1.6)	55

Table 8.9 Mean number (SD) of out-patient, in-patient and day hospital appointments for the sample who actually had an appointment or in-patient stay.

	Counsellor		General practitioner	
	Mean (SD)	n	Mean (SD)	n
<b>Number of out-patient appointments</b>				
Baseline	4.25 (6.5)	24	2.67 (1.9)	18
3 months	1.80 (1.2)	13	3.17 (6.0)	12
9 months	2.21 (1.5)	14	3.67 (3.3)	21
<b>Number of in-patient stays</b>				
Baseline	4.67 (2.5)	3	1.67 (0.6)	3
3 months	3.0 (2.8)	2	3.5 (3.5)	2
9 months	3.5 (2.2)	2	3.6 (2.1)	5
<b>Number of day hospital</b>				
Baseline	-	-	-	-
3 months	-	-	-	-
9 months	1	2	12	1

Table 8.10 Mean number (SD) of days taken off sick.

	Counsellor		General practitioner	
	Mean (SD)	n	Mean (SD)	n
<b>Time taken off sick for any reason</b>				
Baseline	11.8 (24.3)	44	9.7 (11.6)	38
3 months follow-up	6.7 (14.2)	35	5.0 (13.8)	25
9 months follow-up	7.8 (18.3)	36	12.0 (27.4)	33
<b>Time taken off sick for present emotional problems</b>				
Baseline	8.6 (22.0)	44	6.5 (11.0)	38
3 months follow-up	5.7 (13.9)	35	4.0 (13.9)	25
9 months follow-up	5.7 (18.3)	36	8.1 (26.6)	33

Table 8.11 Number (percentage) of patients taking at least one days off work.

	Counsellor		General practitioner	
	n	%	n	%
<b>Time taken off sick for any reason</b>				
Baseline	30/44	68	29/38	76
3 months follow-up	19/35	54	11/25	44
9 months follow-up	22/36	61	18/33	55
<b>Time taken off sick for present emotional problems</b>				
Baseline	22/44	50	19/38	50
3 months follow-up	11/35	31	5/25	20
9 months follow-up	12/36	33	9/33	27

practitioner group than in the counsellor group (table 8.11).

b) Travelling costs

The counsellor group had slightly higher travel costs, in terms of mileage whereas the general practitioner group had spent more money on public transport between the baseline and nine months follow-up. There were no significant differences between the groups, except for a trend at the three months follow-up. Patients in the counsellor group drove greater distances by car to general practices or hospitals than patients in the general practitioner group ( $t=1.81$ ,  $df=110$ ,  $p=0.074$ ) (tables 8.12 and 8.13).

c) Childcare

Most of childcare arrangements consisted of family, friends or school looking after the child(ren) or the patient actually taking the child(ren) with them to the appointment. Only one patient in the general practitioner group used a crèche or a baby-sitter for their child at each assessment point (table 8.14). Because of the small number of patients making formal child care arrangements, it was considered not important to incorporate child care costs into the cost-effectiveness analysis.

#### **8.4 COST-EFFECTIVENESS ANALYSIS**

Unit costs used in the cost-effectiveness analysis were based on marginal opportunity costs. A list of the unit costs is contained in the Appendix H.



Table 8.12 Travel costs (£) according to the counsellor or general practitioner group.

	Counsellor		General practitioner	
	Mean (SD)	n	Mean (SD)	n
<b>Travel costs (bus and train fares)</b>				
Baseline	1.31 (5.4)	70	1.04 (2.8)	66
3 months	0.71 (3.2)	61	1.40 (4.4)	51
9 months	1.82 (6.8)	62	4.12 (13.2)	55
<b>Travel costs (pence per mile)</b>				
Baseline	3.39 (9.0)	70	1.60 (5.3)	66
3 months	3.68 (10.3)	61	0.98 (3.1)	51
9 months	1.33 (4.0)	62	1.09 (4.0)	55

Table 8.13 Travel costs (£) according to the counsellor or general practitioner group who had non-zero costs.

	Counsellor		General practitioner	
	Mean (SD)	n	Mean (SD)	n
<b>Travel costs (bus and train fares)</b>				
Baseline	6.43 (5.3)	8	5.29 (4.2)	13
3 months	8.64 (8.1)	5	8.93 (7.7)	8
9 months	11.28 (13.8)	10	18.90 (23.8)	12
<b>Travel costs (pence per mile) mileage)</b>				
Baseline	7.91 (12.4)	30	7.03 (9.4)	15
3 months	11.8 (15.8)	19	5.58 (5.5)	9
9 months	5.49 (6.7)	15	7.48 (8.5)	8

Table 8.14 Childcare arrangements at the baseline interview and three and nine months follow-up.

Baseline	Counsellor (n=29)	General practitioner (n=14)
Crèche	-	1
Family	6	1
School	11	3
With patient	11	6
Friend	1	3
3 months follow-up	Counsellor (n=22)	General practitioner (n=10)
Baby sitter	-	1
Family	11	1
School	8	6
With patient	2	-
Friend	1	2
9 months follow-up	Counsellor (n=11)	General practitioner (n=9)
Baby sitter	-	1
Family	2	1
School	8	5
With patient	1	1
Friend	-	1

The total costs for the counsellor and general practitioner group are shown in tables 8.15 and 8.16. The counsellor group had slightly higher direct and indirect costs in the previous 6 months before the baseline interview. For direct costs after three and nine months, the average costs for the counsellor group were £223.57 and £353.04, and £187.84 and £474.08 for the general practitioner group (table 8.17). Therefore at three months the counsellor was £35.73 more expensive per patient than routine general practitioner care, but by nine months routine care was £121.04 more expensive (table 8.17). The general practitioner group had increased their costs with a higher average number of general practitioner consultations, out-patient appointments and in-patients stays.

If indirect costs were included in the cost analysis, the counsellor group became more expensive. The average costs per patient for seeing a counsellor at the three and nine months follow-up were £707.23 and £1361.20, whereas the costs for the general practitioner group were £334.26 and £1081.06 (table 8.17). The counsellor was more expensive after three months by £373.07 and after nine months by £280.14 compared to the general practitioner group (table 8.17).

In order to evaluate a cost-effectiveness ratio, the mean Beck Depression Inventory score was used to calculate the cost per unit of outcome. Table 8.18 presents the average cost-effectiveness analysis. In terms of average costs per unit Beck Depression Inventory reduction, the cost-effectiveness rate for the counsellor was £93.06 compared to the £53.90 per patient for the general practitioner group after three months and £141.79 compared to the

Table 8.15 Average costs (£) per patient of direct and indirect variables associated with the counsellor group.

Counsellor	6 months before baseline	3 months after baseline	6 months after 3 months follow-up
Counsellor costs	6.02 (n=70)	118.65 (n=69)	9.59 (n=61)
General practitioner costs	83.78 (n=69)	38.78 (n=53)	48.87 (n=61)
Other health professional costs	25.59 (n=70)	24.52 (n=59)	21.40 (n=62)
In-patient costs	37.94 (n=69)	19.02 (n=59)	21.11 (n=62)
Out-patient costs	84.26 (n=69)	22.60 (n=58)	28.50 (n=62)
Work absence	617.98 (n=44)	479.27 (n=35)	521.35 (n=36)
Travel costs	4.70 (n=70)	4.39 (n=61)	3.15 (n=62)

Table 8.16 Average costs (£) per patient of direct and indirect variables associated with the general practitioner group.

General practitioner	6 months before baseline	3 months after baseline	6 months after 3 months follow-up
Counsellor costs	2.50 (n=66)	5.80 (n=50)	19.27 (n=55)
General practitioner costs	112.07 (n=65)	94.99 (n=49)	72.12 (n=55)
Other health professional costs	13.58 (n=66)	18.06 (n=51)	53.85 (n=55)
In-patient costs	14.17 (n=66)	25.67 (n=51)	61.20 (n=55)
Out-patient costs	41.46 (n=66)	43.32 (n=50)	79.80 (n=55)
Work absence	580.22 (n=38)	143.93 (n=25)	455.45 (n=33)
Travel costs	2.64 (n=66)	2.39 (n=51)	5.21 (n=55)

Table 8.17 Total average costs (£) per patient at the three and nine months follow-ups and the difference in costs between the counsellor and general practitioner.

Counsellor costs	6 months before baseline	3 months after baseline	6 months after 3 months follow-up	9 months after baseline
Direct costs	237.59	223.57	129.47	353.04
Indirect costs	622.68	483.66	524.50	1008.16
Total costs	860.27	707.23	653.97	1361.20
General practitioner costs	6 months before baseline	3 months after baseline	6 months after 3 months follow-up	9 months after baseline
Direct costs	183.78	187.84	286.24	474.08
Indirect costs	582.86	146.32	460.66	606.98
Total costs	766.64	334.16	746.90	1081.06
Difference in costs	6 months before baseline	3 months after baseline	6 months after 3 months follow-up	9 months after baseline
Direct costs	53.81	35.73	-156.77	-121.04
Indirect costs	39.82	337.34	63.84	401.18
Total costs	93.63	373.07	-92.93	280.14

Table 8.18 Average cost-effectiveness of counsellor versus general practitioner at the three and nine months follow-up (costs and outcomes per patient £s).

Cost/ outcome variables	3 months Counsellor costs	3 months GP costs	9 months Counsellor costs	9 months GP costs
Cost per patient	£707.23	£334.16	£1361.20	£1081.06
Mean pre counselling BDI score	19.3	21.8	19.3	21.8
Mean post counselling score	11.7	15.6	9.7	13.5
Reduction in BDI score	-7.6	-6.2	-9.6	-8.3
Cost per unit reduction in BDI score	£93.06	£53.90	£141.79	£130.25

Key GP General practitioner  
BDI Beck Depression Inventory

£130.25 per patient for the general practitioner group. Seeing a counsellor was more costly both after three and nine months. However, by nine months the difference in average costs between the counsellor and general practitioner options had decreased to £11.54.

### **8.5 SENSITIVITY ANALYSIS**

To have confidence in the cost-effectiveness results, a sensitivity analysis should be performed. Assumptions about the outcome measures and estimates of unit costs are made in economic evaluations and uncertainty arises from the inaccuracy of these assumptions and estimates (Tolley and Rowland, 1995). It is important to identify these areas of uncertainty and apply them to a sensitivity analysis. This will test the reliability of the cost-effectiveness results (Tolley and Rowland, 1995).

There was some uncertainty in the outcome measures as data collection relied on self-report. However, any inaccuracies in the data should have been equally distributed between the two random groups. In addition, I encouraged patients to look in their diaries or calendars for the number of appointments they had attended in the past months to reduce errors in the data set.

Another area of uncertainty are cost estimates. Some unit costs are based on net salaries, exclude sickness payment or overhead costs. The unit costs used in this were based on best available gross salaries, overhead and associated capital costs study (Netten and Dennett, 1996). Only the cost of the counsellor was not available in the compendium

(Netten and Dennett, 1996). Therefore, the counsellor unit costs were subjected to a sensitivity analysis.

After examination of each variable for uncertainty and its potential impact on the cost-effectiveness analysis, only work absence costs were considered to be unreliable. At baseline and at the three months follow-up, patients seeing the counsellor were higher earners than patients seeing the doctor, but the number of days taken off sick was only slightly more in the counsellor group at the three months follow-up. An average salary unit cost, rather than patient's individual gross salaries, was used in the sensitivity analysis to test the reliability of the cost-effectiveness results.

The counsellor unit costs were based on the payment counsellors received (£15 per hour) at the start of the study in 1993. It is possible that a more realistic payment would have been £65 per 3.5 hours of client contact and administration or £65 per 3 hours of client contact only. This is what many counsellors have been earning in 1995/96 in general practices in North London. This results in unit costs of £18.57 and £21.67 per hour and would increase the direct costs of the counsellor group during the intervention period by £15.61 or £37.80, respectively.

If an average salary was used of £200 or £250 per week instead of each patients' personal income, the difference in work absence costs diminished. On a salary of £200 or £250 per week, the difference in indirect costs would decrease to £69.29 or £84.86 at the 3 month follow-up with the general practitioner group remaining cost-effective. However, after 9 months the difference would be -£103.87 or



-£129.83 with the counsellor group becoming more cost-effective.

Inserting the above figures into the cost effectiveness analysis in section 8.4, would still make the counsellor group more expensive during the first three months but considerably less expensive after nine months. Using this sensitivity analysis, the direct costs have remained robust, whereas the indirect cost calculations were not reliable. However, even with the unreliable indirect costs, the counsellor is more expensive than the general practitioner after three months in both direct and indirect costs. After nine months, the counsellor is less expensive in direct costs, but it is unclear whether they are more or less expensive in terms of indirect costs compared to the general practitioner.

## **9.0 DISCUSSION**

The current study has highlighted several important factors in comparing counselling with routine general practitioner care. This final chapter will firstly, summarise the results; secondly outline the limitations of the study, thirdly discuss the findings in more detail in relations to the aims and current literature on counselling; fourthly, explore their relevance and implications for policy, resource allocation, practice and research and finally present the conclusions of the study.

### **9.1 SUMMARY OF FINDINGS**

There were 136 patients in the study, aged 18-80, mean age 39 years old. Most of the sample were female (81%) and predominately Caucasian (92%). Most patients suffered from symptoms of depression according to themselves, the general practitioner and the PROQSY questionnaire. The main reasons for these symptoms were relationship and family problems. Over 50% of the patients had experienced their problems for less than one year.

Seventy patients were randomised to see the counsellor and 66 patients were randomised back to the general practitioner. At the baseline interview, patients in the general practitioner group had slightly higher scores on the psychological and social outcome measures than patients randomised to see the counsellor. On all the clinical outcomes, patients suffered from a significant amount of psychological and social distress. Between 74 and 88% of patients scored as cases on the self-report outcome measures at the baseline interview.

Due to slight differences on outcome measures at the baseline interview, an analysis of covariance was used to adjust for these differences. In addition, the mean of the two follow-up scores was used to reduce the number of statistical tests. Patients in both groups improved significantly between baseline and the mean follow-up on all the psychological and social outcome measures. However, there were no significant differences between the two groups on any of the mean follow-up total scores. Patients seeing a counsellor did not show significantly greater improvement over patients seeing their general practitioner only.

Subgroup analysis showed that patients who scored as cases on the Beck Depression Inventory at the baseline interview and saw a counsellor improved significantly more than patients randomised to the general practitioner. In addition, patients who were younger and came from manual class (Class IIIM, IV and V) did better by seeing the counsellor and there was a trend for patients who were unemployed to benefit more from a counsellor.

Patients were significantly more satisfied with counselling compared to usual general practitioner care. Counsellors were regarded as more understanding and less critical than doctors.

The economic evaluation showed that counselling was more expensive at the three months follow-up both in direct and indirect costs. However, by nine months, the direct costs had reduced and the general practitioner option was more expensive in terms of direct costs. Patients were seeing the general practitioner more and for longer appointments

and needed more out-patient and in-patient care than patients seeing the counsellor. When indirect costs were included, counselling became less cost-effective. Patients seeing the counsellor had higher work absence costs during the intervention period. Sensitivity analysis showed that the direct cost analysis were robust, but that the lost production costs were not. It was possible that in terms of work absence costs the general practitioner was less cost effective than the counsellor option after nine months.

## **9.2 LIMITATIONS TO THE STUDY**

The study needs to be seen in context of its shortcomings. This study particularly highlights the difficulties in carrying out randomised controlled trials in general practice and achieving good internal and external validity in the same study.

Patients recruited to the study were a heterogeneous group of people with a variety of emotional problems and causes. In addition, 9% of the patients did not score as cases on any of the outcome measures at the baseline interview. This may have reduced the internal validity of the study and may have compromised the statistical conclusions (Shapiro, 1989). It is possible that a more homogeneous group, for example patients with depression only, may have benefited from non-directive counselling more than patients with different problems. However, the heterogeneity of the current sample does make the study more generalisable to a general practice setting (Katon et al, 1994).

Patients suffering from acute or acute-on-chronic problems were recruited to the study. Even though all patients had

had recent crises when questioned at the baseline interview, it was suspected that some patients may have suffered from a chronic mental disorder. However, a two-way analysis of covariance did not show any significant differences in the duration of the problem in the two random groups. Stricter entry criteria on severity and chronicity of the disorder may have been warranted to improve internal validity and statistical power.

The sample was not necessarily a representative sample of patients seeing a counsellor in general practice, because only a small number of patients were referred from each general practitioner. I relied on doctors to refer patients to the study. With frequent reminders, doctors were encouraged to refer every patient that was suitable for counselling, however it was difficult to guarantee referral of all cases. It was suspected that general practitioners decided when patients were appropriate for the study, rather than for counselling and did not refer all suitable patients. How this may have affected the results is unknown. General practitioners may have chosen only to send heart-sink patients, or patients who actually asked to see a counsellor. Some general practitioners seemed to dislike the randomisation aspect of the study. Fairhurst and Dowrick (1996) found that general practitioners were reluctant to refer patients to a study where they only had a 50% chance of seeing a counsellor.

I asked each general practitioner to complete a refusal form every time a patient refused to take part in the study. Only six refusal forms were returned, despite frequent reminders. No studies have tried to assess the actual number of potential patients who could enter a

study. Boot et al (1994) found that 204 patients were identified by 28 general practitioners and 12 patients refused to take part. Mynors-Wallis et al (1995) reported that 173 patients were referred by the general practitioners, 107 met the entry criteria of whom 91 agreed to take part. However, these studies assessed patients who were referred to the study and subsequently refused and not those who the general practitioner was unable or unwilling to recruit into the study.

Patients often expressed a wish to see a counsellor and were disappointed to be randomised back to their doctor. This may have biased the results since 52% of patients expressed a preference for counselling and only 5% wanted to see the doctor. It suggests that the patients who had a preference for and were randomised to a counsellor should have improved to a greater extent than patients who were randomised to the doctor. This may be further evidence that there was no effect between counselling and routine general practitioner care.

Fairhurst and Dowrick (1996) discovered that general practitioners had created an ethical dilemma whereby they felt that a patient really needed counselling, but at the same time they were aware of the lack of evidence on counselling. This was detected in the present study and the tension led to slightly less insistence on general practitioners not to refer patients onto other counsellors or equivalent. However, I still discouraged all doctors from referring patients unless they felt there was a clinical necessity. Still nine patients in the general practitioner group and two patients in the counselling group sought additional counselling help between the

baseline and the three months follow-up interview. This may have affected outcome, in that patients in the general practitioner group may have benefited from other help not controlled for in the study. In addition patients in both groups may have sought additional support from friends or family. It is assumed that the effects of these other events are equally distributed with randomisation, so that conclusions can be drawn about the active treatment counselling. However, it is possible that the difference between the two groups has been diminished as more patients in the doctor group sought counselling help from outside the study.

Counsellors worked peripetatically for the research study and felt they were unable to develop good working relationships with the general practitioners. In addition, the counsellors felt a little restricted by only using a non-directive Rogerian model. From the pilot study (King et al, 1994), it was felt important to standardise the training, experience and model of counselling used by the counsellors. However, this standardisation may have been too rigid, even though it improved the internal validity of the study. The counsellors in Ashurst and Ward's study (1983) used a variety of techniques and approaches. Boot et al (1994) did not specify the model used by the five counsellors employed for their study, except that they were accredited or accreditable by the British Association for Counselling. It is possible that the strict standardisation of counselling and the peripatetic working pattern of the counsellors in the present study may have reduced their effectiveness.

I did not collect any data from the general practitioners on what they did with each patient. Therefore no data exist on whether doctors used counselling skills in their consultation or whether they involved the patient's family. Only data from the economic questionnaire and the case-notes exist on the number of consultations, medication and amount of time spent with each general practitioner. I decided not to burden the general practitioner with forms and to interfere as little as possible with their busy surgeries. The only form doctors were asked to complete was the referral form for patients entering the study or refusal forms for patients who did not want to take part in the research. It is probable that some general practitioners used counselling skills and provided empathy and may have had a therapeutic effect on the patients.

A fine balance needed to be found between keeping general practitioners informed about the progress of the study, reminding them about the protocol and referring patients to the study and interfering with all their other commitments and interests. It was difficult to find the right balance in liaising with doctors as some felt I was well organised, while others felt annoyed or guilty when I reminded them about referring patients. In addition, some general practitioners could not understand the importance of randomisation and felt that I could make exceptions for some patients who were in great need to let them see the counsellor. Also, there was often a misconception between the number of patients a practitioner had actually referred and the number they thought they had referred. This was particularly true with the number of patients who had been randomised back to them. All the above reasons may have led to a reluctance to refer more patients.



It was not possible for patients, doctors, counsellors and myself to be blind to the intervention or control group. Self-report measures were used to reduce the amount of researcher bias. I was very aware of trying to remain neutral and not express any opinion of counselling or routine general practitioner care. However, it was difficult to prevent some patient bias. Patients often felt disappointed when they were randomised to the general practitioner. It was unclear whether doctors or counsellors may have biased the results. It is probable that both doctors and counsellors were in favour of the counselling and may have influenced patients to think positively about counselling. However, this should have favoured counselling and led to a greater difference in outcome between the groups.

There may have been a Hawthorne effect, in that patients in the study were influenced by participation in a research study. By asking patients about their problems and administering questionnaires, I took an interest in them, which would otherwise not have been there. However, the Hawthorne effect should have been equivalent across the two random groups.

This study relied in large part on self-report and most of questionnaires measured psychological well-being. It is possible that the outcome measures chosen were not appropriate to detect a difference between the counsellor and general practitioner. Lambert et al (1991) describe the complex nature of counselling outcome as reflected in the divergence of patients and their problems, counselling models and their underlying assumptions and techniques, as well as the multidimensional aspect of the change process

itself. They suggest three broad ways to classify outcome measures: content, technology and source (Lambert et al, 1991). This study did use different contents in the chosen questionnaires, however it did not attempt to use any observational or physiological data.

The follow-up interviews were at three and nine months. The three months follow-up interview was supposed to coincide with the end of treatment. However, not all counselling sessions had been completed by the three months follow-up. It is possible that the patients still seeing a counsellor may have been in the middle of tackling difficult issues which were causing emotional distress. This may have resulted in worse outcomes for the counselling group at this point. Ideally, there would have been a longer follow-up period than nine months, however resources did not allow this. Boot et al (1994) only followed-up patients after six weeks, whereas Ashurst and Ward (1983) carried out the follow-up after 12 months.

There was a 15% attrition rate from the counselling intervention. This is a lower rate than many other counselling studies have reported. Ashurst and Ward (1983) found that 101 of 258 patients refused counselling. However, in this study patients did not necessarily want to see a counsellor at the start of the trial and this probably affected patient motivation. Boot et al (1994) did not cite the drop-out rate from counselling, whereas Gournay and Brooking (1994) found a 49% drop-out from community psychiatric nurse counselling. Nevertheless, an intention to treat analysis was performed on my sample, which included patients who dropped out of counselling.

Attrition of the sample size during a longitudinal study like this can be problematic. Every effort was made to contact patients for the follow-up appointments. Nineteen percent of patients dropped out at the three months follow-up and 14% at the later follow-up of nine months. For resource reasons it was not possible to see every patient in person at the three months follow-up and a random half of the sample were sent the questionnaires by post. The number of drop-outs was not significantly different between the two groups. This study had a much lower drop-out rate from the research compared to other counselling studies, such as Boot et al (1994) who had a drop-out rate of 44%.

A power analysis suggested 145 patients would be necessary in the total sample to show a clinically significant change on the Beck Depression Inventory. Using the attrition rate at the 9 months follow-up of 14%, the sample size should have been 165. Even with constant reminders to general practitioners, it was not possible to recruit the desired number of patients.

Unfortunately, there were some small differences at the baseline interview. An analysis of covariance was used to adjust for these baseline difference. No analyses were performed on the sub-scores of the Brief Symptom Inventory, PROQSY and the modified Social Adjustment Scale. Pocock et al (1987) suggest using a smaller number of tests to reduce the possibility of type I errors or exaggerated treatment effects.

Data used in the economic evaluation were collected from patients. It is possible that there are inaccuracies in the economic data, despite asking patients to look in their

diaries and check the number of appointments or the name of their medication. Only a comparison of average costs and a cost-effectiveness ratio were calculated. It is possible that a more complex behavioural cost function analysis (a type of multiple regression analysis) could have been performed (Knapp, personal communication). However all the patients improved on all outcome measures and there were no differences on any of these measures between the groups, therefore a simple comparison of the costs and summary outcomes for each group was considered adequate.

There are a number of limitations with the present study. The main shortcomings are the heterogeneous group of patients, the interference of patient preference, the sample size and the loss of data due to attrition. This study also emphasises the logistical difficulties of conducting a controlled trial in general practice.

### **9.3 DISCUSSION OF FINDINGS IN RELATION TO THE AIMS AND EXISTING RESEARCH**

Initially the demographic variables and patients' problems are assessed against other studies.

Patients seen by a counsellor were young or middle-aged adults. This was similar to several recent studies. Boot et al (1994) reported a mean age of 39 years for their sample, whereas Burton et al (1995) found mean ages of 39 and 47 years in patients seen by counsellors in two different surgeries. Webber et al (1994) found the most common age groups to be referred for counselling were 20-29 and 40-49 years. It seems that counsellors do not see many elderly patients. This study did not recruit teenagers, but from

the literature this does not appear to be a group being referred to a counsellor in general practice. It is possible that younger adults are more accustomed to seeing a counsellor and there is less stigma attached to seeing a counsellor. Elderly patients may feel that seeing a counsellor is admitting to failure and are perhaps more stoical about coping with their emotional problems. On the other hand, doctors may not necessarily refer elderly patients to counsellors because they feel depression may be part of growing older and therefore would not benefit from counselling (MacDonald, 1986).

Counsellors saw mainly women. A slightly higher proportion of women was found in the present study. Burton et al (1995) and Speirs and Jewel (1995) found between 74 and 75% of patients were female in their respective samples, whereas Boot et al (1994) found 68% of their sample were women. It is obvious that many more women than men see a counsellor. More women, particularly younger women, than men attend general practice and therefore will know their doctor (RCGP et al, 1995). They will have greater opportunities to talk about emotional problems, even if they are consulting for a physical problem or taking their child to the surgery. In addition, anxiety and depression are more prevalent in women than in men (Jenkins, 1985). It may be because women are better in talking about emotional problems and sharing these problems with others and therefore may accept the offer of counselling help more readily than men. Also general practitioners may ask women more frequently about family life which may lead to the disclosure an emotional problem, whereas with men the doctor may concentrate on the physical problem presented in the consultation.

Unlike other studies a higher proportion of people in social class I and II and single people was found. This study had particularly low number of patients in social class IV and V (7%), whereas Boot et al (1994) found 35% of their sample came from these social classes. Burton et al (1995) found that 47 and 51% of patients were married and 17 to 14% were single in two surgeries, whereas the present study found that only 34% of the sample were married and 39% were single. There were geographical differences in these studies, with the present study situated in mainly middle class areas of London. In addition, patients were younger and therefore more single people than in the Burton et al (1995) study.

In terms of presenting problems, the majority of patients suffered from depression and/or anxiety due to relationship or family problems in this study. Many other studies have classified problems and causes differently to this study as there is no consensus on classification of disorders in primary care (Goldberg, 1994). Despite these difficulties, Boot et al (1994) also found that depression, anxiety, relationship and family problems were most commonly mentioned by patients. Burton et al (1995) found anxiety was more often mentioned as a problem than depression amongst the patients in their audit project. Webber et al (1994) found the largest number of referrals were for relationship problems, followed by general stress, whereas Speirs and Jewell (1995) found the most common problems were anxiety/stress and interpersonal problems.

### 9.3.1 THE EFFICACY OF COUNSELLING PLUS ROUTINE GENERAL PRACTITIONER CARE COMPARED TO USUAL GENERAL PRACTITIONER CARE ALONE

The main analysis showed that all patients improved significantly over time on all the outcome measures. Although there was a lower percentage of patients in the counsellor group who scored as cases and had lower mean symptom scores at all time points compared to patients in the general practitioner group, there were no significant differences between the groups. There are a number of possible reasons for these findings, some of which may have been due to the limitations mentioned above.

General practitioners may have had a therapeutic effect and therefore no differences between the counsellor and doctor were found. Some doctors had a good relationship with their patients and after many years of knowing a patient and their family had a clear understanding of their personal circumstances. The doctors may have been psychologically minded with an interest in common mental disorders and thus participated in the study.

Both counselling and routine general practitioner care may have been ineffective with time causing patients to improve spontaneously. Patients may have come to see their doctor at a crisis point when they needed help desperately. Time would have decreased the acute nature of their problem(s) and therefore improved some of the symptoms.

On the other hand, it is possible that the counselling treatment was inadequate and the non-directive model of counselling did not have an effect. Possibly, short-term

counselling is ineffective, whereas the offer of a greater number of sessions may have revealed a difference between counselling and routine general practitioner care. In addition, the model of counselling used may have been inappropriate with some of the patients. Anecdotal evidence suggested some patients disliked the non-directive approach and felt they could just as well have talked to a friend who was good at listening. It is possible that a non-directive approach is not suitable for general practice and a more directive therapy such as cognitive behavioural therapy may be more useful. Alternatively, a certain type of patient may benefit more from a non-directive counselling, while others would improve more from a directive model of counselling. It may be that the type of counselling used needs to be shaped to the patient and their problem(s) (Roth and Fonagy, 1996).

It is possible that the sample size was too small to show a difference, although the differences between the counsellor and general practitioner would be small. In addition, the sample size calculations may have been inaccurate because of the heterogeneous nature of the patients and therefore any treatment effect would not have been found.

As already mentioned in the limitations, the outcome measures may have been inappropriate to detect a difference between the groups. The effects of counselling may be much more subtle than the "crude" changes that can be picked up on self-report questionnaires. In addition, these internal changes in "conscious" mental processes may have only shown up in a longer follow-up (Lambert et al, 1991).



There were no differences between the number of patients prescribed anti-depressants in the two groups. However, no data on compliance or drug dosage were collected. It is difficult to know in which direction this would have affected the results, however the number of patients actually prescribed antidepressants was small.

### **9.3.2 THE RELATIONSHIP BETWEEN THE EFFICACY OF COUNSELLING AND THE PSYCHOLOGICAL AND SOCIAL OUTCOMES**

The majority of patients in the study scored as cases on all the psychological and social outcome measures at the baseline interview. It highlights the considerable psychological morbidity encountered in general practice outlined in chapter 2.

Other counselling or equivalent studies (Mynors-Wallis et al, 1995; Gournay and Brooking, 1994) suggest that patients in the present study had slightly lower scores on the psychological and social measures than would have been expected. It is possible that doctors sent patients with more severe symptoms to other known counsellors or psychologists available in the local area and patients with less severe problems were recruited to the study. Nevertheless it was patients who scored as a case on the Beck Depression Inventory who benefited most from the counsellor. It is possible that only these patients who scored as cases on the Beck Depression Inventory should have been recruited for the study.

After three and nine months, half to a third of patients still scored as cases on the psychological outcomes, respectively. On the modified Social Adjustment Scale just

over half the patients still scored as cases. Mann et al (1981) found that about a quarter of patients with emotional problems in general practice improve on psychiatric symptoms, half show a variable course of morbidity and another quarter are chronically ill with psychiatric symptoms over a one year period. In the present study, the percentage of patients who changed from a case to non-case on the Beck Depression Inventory was 40% for the counsellor group and 42% for the general practitioner group, whereas 27% and 36% remained cases throughout the study for the counsellor and doctor group, respectively. It seems that patients had a better outcome in the present study than might be suggested by Mann et al (1981) and Lloyd et al (1996). It is possible that both the counsellor and the general practitioner had a therapeutic effect in this study and therefore an improvement was found in both groups. However, it may be that the follow-up was too short in the present study, since Mann et al (1981) followed them up after one year.

The case analysis also highlighted that some patients who were non-cases at the baseline interview became cases during the intervention period in both groups. Seven patients became cases after three months on the psychological and social measures in the counsellor group, whereas only four patients in the general practitioner group changed caseness on one or a combination of the measures. By nine months four and two patients became cases in the counsellor and general practitioner groups respectively. Counselling may do harm to some patients in terms of the patient's perception of their psychological and social well-being. Anecdotal evidence suggests that patients wanted more sessions of counselling. One patient

in particular felt she had been abandoned by the counsellor after 7 sessions of counselling.

Patients improved to a greater extent on the psychological outcome measures compared to the social outcome. It is possible that counselling may have a greater effect on mood state, whereas work or relationship problems take a longer time to resolve.

### 9.3.3 THE FACTORS DETERMINING THE EFFECTIVENESS OF COUNSELLING

The sub-group analyses revealed that patients who scored as cases on the Beck Depression Inventory at the baseline interview improved to a greater extent when seeing a counsellor rather than the general practitioner. Patients significantly reduced their mean follow-up score only on the Beck Depression Inventory. It seems that only patients who were depressed reduced their depressive symptoms significantly more when seeing the counsellor compared to the doctor. It is possible that the main effect of non-directive counselling is in alleviating depressive symptoms. It is difficult to know whether the actual counselling or the time given to each patient by the counsellor produced this effect. It may be that the presence of a person offering an hour per week of undivided attention reduces symptoms of depression, rather than the therapy itself.

Younger patients seemed to reduce their Beck Depression Scores to a greater extent when seeing a counsellor. It is possible that these patients may be more prepared and motivated to see a counsellor than older patients.

Patients who were in social classes IIIM to V seemed to improve to a greater extent than patients in social classes I to IIINM. It is possible that patients in the higher social classes sought out other types of help besides a counsellor in general practice compared to people in the lower classes. This challenges the belief that counselling is for middle class people. Perhaps counselling offered in general practice is more beneficial to lower class people than higher class people. In addition, there was a trend towards counselling being more helpful to patients who were unemployed.

Surprisingly, there were no associations with duration of problem. This contrasts with previous research that shows that patients with problems of acute-on chronic symptoms improved to a greater extent compared to patients with acute disorders (Corney, 1984; 1987c).

#### **9.3.4 PATIENT SATISFACTION OF COUNSELLING**

Patients seeing the counsellor were more satisfied with the intervention than those seeing the general practitioner. Patients liked the ample time allocated for counselling and complained that general practitioners never had enough time to listen to them. They felt they understood something new about themselves or somebody else more often than when seeing the general practitioner. It is possible that this new understanding may have been of greater importance to the patient than improving on the psychological outcome measures.

It is possible that the increased time and undivided attention made patients feel more understood and less

troubled when seeing a counsellor rather than the general practitioner. These feelings may not necessarily have had an effect on psychological and social outcomes, but nevertheless were important outcomes in their own right. After nine months there was a much larger difference between the two groups in terms of awareness of feelings and experiences than at the three months follow-up. It is possible that the awareness of feelings and experiences only changed after a longer period of time and that psychological outcomes will start to improve consequently.

#### **9.3.5 THE COST-EFFECTIVENESS OF COUNSELLING**

The results found that counselling is less cost-effective after three months compared to routine general practitioner care but that it was unclear after nine months. Counsellors were more expensive in direct costs during the intervention period despite patients in the general practitioner group seeing their doctor more often and for longer periods of time. In addition, patients in the counsellor group had a higher work absence cost than patients in the doctor group. It is possible that patients had to take time off work to see a counsellor because the counsellors normally worked between the hours of 9 a.m. to 5 p.m. Patients in the general practitioner group on the other hand were able to see doctors at the end of the day in an evening surgery.

Anecdotal evidence suggested that another reason for higher work absence costs is that counsellors may have encouraged patients to take time off work to deal with their problems more directly, whereas doctors may have suggested carrying on with work as a distraction to the current problems.

After nine months, the direct costs of the general practitioner option became more expensive compared to the counsellor option, because of increased general practitioner consultations, out-patient appointments and in-patient stays. It is possible that patients seeing only their general practitioner were examined for all types of illnesses besides just psychological problems and hence the general practitioner would order more tests or arrange out-patient appointments. It is also possible that the doctor and patient relationship would have developed further in the general practitioner group and the patient was able to reveal other symptoms, unlike patients in the counsellor group where discussions may have remained more exclusively psychologically orientated.

The sensitivity analysis tried to incorporate some of the limitations already mentioned earlier. The economic data were based on self-report as well as patients needing to think retrospectively over the last three or six months. This may have biased the data, even though I encouraged patients to look in their diaries to count the number of appointments or days off sick.

In addition, the number of days taken off sick was not significantly different between the two groups at all time points, whereas income was. Patients seeing a counsellor had higher salaries than patients seeing a general practitioner. The higher income may have accounted for higher work absence costs rather than patients seeing a counsellor taking more time off work.

#### 9.4 RELEVANCE OF STUDY FINDINGS: IMPLICATIONS FOR POLICY, RESOURCE ALLOCATION AND PRACTICE

There is an increasing emphasis on the importance of assessing methods used by health professionals to promote health, prevent and treat disease and to foster improved rehabilitation and long term care (Department of Health, 1992). One reason for this is to enable sound decisions about the deployment of resources. In addition, the advent of evidence based health care (Sackett et al, 1996) has stressed the importance of evidence in making decisions about patient care.

Counselling has become very popular in the last ten years or more, despite the lack of evidence for its efficacy (Harris, 1994). However, since the new general practitioner contract (Chisholm, 1990) when general practitioners were encouraged to employ more staff, such as counsellors, many Health Agencies (formerly Family Health Services Authorities) have become more aware of setting standards for counsellors in general practice. Some have even questioned the efficacy of counselling, but many practising counsellors or Health Agencies have not had the means to conduct a randomised controlled trial. Instead counsellors have started to audit their work (Webber et al, 1994) and tried to set standards in terms of education and experience of counsellors and referrals to counsellors.

More recently the Department of Health published a review on psychotherapies (Roth and Fonagy, 1996) and it has become an important area of consideration both nationally and locally for individual Health Agencies and general practitioners. However, Harris (1994) criticises the

increase in number of counsellors in both hospitals and general practice because of the lack of evidence, particularly in terms of cost. He maintains counsellors have become very popular and are replacing priests. People no longer believe in God but still need support for their problems (Harris, 1994). In addition, he criticises the stance taken by some counsellors who assert that counselling defies objective testing and even if conclusive evidence was produced, it would make very little difference.

It seems the intuitive appeal of counselling has made this study particularly difficult to manage. Many patients were disappointed to learn they were randomised back to the general practitioner and could not understand why an evaluation of counselling needed to be carried out. Nevertheless this study has managed to assess the efficacy and cost-effectiveness of counsellors in general practice.

In terms of policy, not all general practice patients should be sent to a counsellor. Only patients who score as a case on the Beck Depression Inventory have a significantly better chance of improvement when seeing a counsellor. In addition, it is possible that patients who are younger and of lower social class would also benefit more from a counsellor.

In terms of satisfaction, patients were much more satisfied with seeing a counsellor than general practitioner. The questionnaire also revealed that patients felt understood and less troubled. Counselling is efficacious in terms of patient satisfaction and it may be that counsellors are a positive addition to general practice.



In terms of resources, counselling is less cost-effective immediately after treatment compared to routine general practitioner care. In terms of direct costs, counselling becomes cost-effective after nine months, because patients in the general practitioner group increased their consultation rate, out-patient appointments and in-patient stays. However, if indirect costs are included the difference between the groups disappears and counselling may be also cost-effective.

### **9.5 IMPLICATIONS FOR FURTHER RESEARCH**

This study highlighted the need for several additional areas of research. Although there have been other trials of counselling, the present results need to be replicated across more general practices and with different counsellors.

Further randomised controlled trials of counselling in general practice have been funded and are currently being carried out. King et al (1994) are carrying out a patient preference trial evaluating non-directive counselling, cognitive behavioural therapy and routine general practitioner care in patients who suffer from depression and Corney et al (1994) are conducting a randomised controlled trial evaluating the efficacy and cost-effectiveness of counselling versus routine general practitioner care with patients with chronic depression and anxiety. These studies are still under way and there are no results at present.

It was possible that the instruments used in this study to evaluate counselling were not ideal. A further study or

systematic review could examine outcome measures used in psychotherapy research and come to a consensus which measures are most appropriate to use in counselling and primary care.

It is still unclear which patient suits which type of therapy. Lambert et al (1991) categorises counselling questions into three groups: is counselling effective?; what aspects of counselling are helpful?; and how can the effects of counselling be enhanced? King et al (1994) by incorporating another treatment, cognitive behavioural therapy, into a controlled study will be able to assess what aspect of different therapies are helpful. It is also important to evaluate other therapies in general practice, for example cognitive analytical therapy, which has become very popular with many counsellors. Or more simple treatments such as bibliotherapy given to patients by nurses in general practice. There has also been recent interest in using practice nurses to provide a brief counselling intervention for patients with depression (Wilkinson et al, 1993).

An additional interest would be to assess whether one counselling session is as effective as six or twelve sessions. However this may be difficult in general practice as this study showed only 46% of patients completed the arranged number of counselling sessions agreed at the first assessment. The number of sessions used is also a very individual factor decided between the patient and counsellor. Many patients change their minds about how many sessions they require while in treatment and agree with the counsellor on stopping counselling sooner or increasing the number of sessions.

In addition to the randomised trial, this study discovered that patients and doctors usually favoured counselling. It is very popular and many patients see it as an appropriate treatment. Using a more qualitative approach it may be possible to tease out why general practitioners and patients favour counselling, how they think the counsellor makes a difference to the patient and how it may change the working environment in primary care.

## **9.6 CONCLUSIONS**

In conclusion, the pragmatic approach of this randomised controlled trial found that patients with emotional problems visiting general practice suffered mainly from depression and anxiety due to relationship and family problems. There were no significant differences on psychological and social outcome measures between a non-directive counselling intervention and routine general practitioner care. However patients who scored as cases on the Beck Depression Inventory, were younger and from manual classes improved to a greater extent by seeing a counsellor compared to seeing the general practitioner. Patients were also more satisfied and felt less troubled after seeing a counsellor. Counselling is less cost-effective than routine general practitioner care immediately post-treatment, but becomes cost-effective on direct costs after nine months. It is unclear whether counselling becomes cost-effective on both direct and indirect costs after nine months.

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## Appendix A

### Beck Depression Inventory

Patient Codenumber :

Group:

Date : .....

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This questionnaire consists of 21 groups of statements. After reading each group of statements carefully, circle the number (0,1,2 or 3) next to the one statement in each group which best describes the way you have been feeling in the past week, including today. If several statements within a group seem to apply equally well, circle each one. Be sure to read all the statements in each group before making your choice.

---

- |    |   |  |     |   |  |
|----|---|--|-----|---|--|
| 1. | 0 | I do not feel sad.   | 7.  | 0 | I don't feel disappointed in myself.                                 |
|    | 1 | I feel sad.  |     | 1 | I am disappointed in myself.   |
|    | 2 | I am sad all the time and I can't snap out of it.                  |     | 2 | I am disgusted with myself.  |
|    | 3 | I am so sad or unhappy that I can't stand it.                      |     | 3 | I hate myself.   |
| 2. | 0 | I am not particularly discouraged about the future.                | 8.  | 0 | I don't feel I am any worse than anybody else.                       |
|    | 1 | I feel discouraged about the future.                               |     | 1 | I am critical of myself for my weaknesses or mistakes.               |
|    | 2 | I feel I have nothing to look forward to.                          |     | 2 | I blame myself all the time for my faults.                           |
|    | 3 | I feel that the future is hopeless and that things cannot improve. |     | 3 | I blame myself for everything bad that happens.                      |
| 3. | 0 | I do not feel like a failure.                                      | 9.  | 0 | I don't have any thoughts of killing myself.                         |
|    | 1 | I feel I have failed more than the average person.                 |     | 1 | I have thoughts of killing myself, but I would not carry them out.   |
|    | 2 | As I look back on my life, all I can see is a lot of failures.     |     | 2 | I would like to kill myself.   |
|    | 3 | I feel I am a complete failure as a person.                        |     | 3 | I would kill myself if I had the chance.                             |
| 4. | 0 | I get as much satisfaction out of things as I used to.             | 10. | 0 | I don't cry any more than usual.                                     |
|    | 1 | I don't enjoy things the way I used to.                            |     | 1 | I cry more now than I used to.                                       |
|    | 2 | I don't get real satisfaction out of anything anymore.             |     | 2 | I cry all the time now.  |
|    | 3 | I am dissatisfied or bored with everything.                        |     | 3 | I used to be able to cry, but now I can't cry even though I want to. |
| 5. | 0 | I don't feel particularly guilty.                                  | 11. | 0 | I am no more irritated now than I ever am.                           |
|    | 1 | I feel guilty a good part of the time.                             |     | 1 | I get annoyed or irritated more easily than I used to.               |
|    | 2 | I feel quite guilty most of the time.                              |     | 2 | I feel irritated all the time now.                                   |
|    | 3 | I feel guilty all the time.  |     | 3 | I don't get irritated at all by the things that used to irritate me. |
| 6. | 0 | I don't feel I am being punished.                                  | 12. | 0 | I have not lost interest in other people.                            |
|    | 1 | I feel I may be punished.  |     | 1 | I am less interested in other people than I used to be.              |
|    | 2 | I expect to be punished.   |     | 2 | I have lost most of my interest in other people.                     |
|    | 3 | I feel I am being punished.  |     | 3 | I have lost all of my interest in other people.                      |

## Appendix A

### Beck Depression Inventory (cont.)

13.	0	I make decisions about as well as I ever could.	18.	0	My appetite is no worse than usual.
	1	I put off making decisions more than I used to.		1	My appetite is not as good as it used to be.
	2	I have greater difficulty in making decisions than before.		2	My appetite is much worse now.
	3	I can't make decisions at all anymore.		3	I have no appetite at all anymore.
			19.	0	I haven't lost much weight, if any, lately.
				1	I have lost more than 5 pounds.
14.	0	I don't feel I look any worse than I used to.		2	I have lost more than 10 pounds.
	1	I am worried that I am looking old or unattractive.		3	I have lost more than 15 pounds.
	2	I feel that there are permanent changes in my appearance that make me look unattractive.			I am purposely trying to lose weight by eating less. Yes _____ No _____
	3	I believe that I look ugly.	20.	0	I am no more worried about my health than usual.
				1	I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
15.	0	I can work about as well as before.		2	I am very worried about physical problems and it's hard to think of much else.
	1	It takes an extra effort to get started at doing something.		3	I am so worried about my physical problems that I cannot think about anything else.
	2	I have to push myself very hard to do anything.			
	3	I can't do any work at all.			
			21.	0	I have not noticed any recent change in my interest in sex.
16.	0	I can sleep as well as usual.		1	I am less interested in sex than I used to be.
	1	I don't sleep as well as I used to.		2	I am much less interested in sex now.
	2	I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.		3	I have lost interest in sex completely.
	3	I wake up several hours earlier than I used to and cannot get back to sleep.			
17.	0	I don't get more tired than usual.			
	1	I get tired more easily than I used to.			
	2	I get tired from doing almost anything.			
	3	I am too tired to do anything.			

## Appendix B

### Brief Symptom Inventory

Patient Codenumber :       Group:

Date : .....

---

Instructions:

Below is a list of problems people sometimes have. Please read each one carefully, and circle the number to the right that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST 7 DAYS INCLUDING TODAY. Circle only one number for each problem and do not skip any items. If you change your mind, erase your first mark carefully. Read the example below before beginning, and if you have any questions please ask about them.

---

Example

How much were you distressed by:	Not at all	A little bit	Moderately	Quite a bit	Extremely
1.      Bodyaches	1	2	3	4	5

---

HOW MUCH WERE YOU DISTRESSED BY :

	Not at all	A little bit	Moderately	Quite a bit	Extremely
1.      Nervousness or shakiness inside	1	2	3	4	5
2.      Faintness or dizziness	1	2	3	4	5
3.      The idea that someone else can control your thoughts	1	2	3	4	5
4.      Feeling others are to blame for most of your troubles	1	2	3	4	5
5.      Trouble remembering things	1	2	3	4	5
6.      Feeling easily annoyed or irritated	1	2	3	4	5
7.      Pains in heart or chest	1	2	3	4	5
8.      Feeling afraid in open spaces	1	2	3	4	5
9.      Thoughts of ending your life	1	2	3	4	5
10.    Feeling that most people cannot be trusted	1	2	3	4	5

## Appendix B

### Brief Symptom Inventory (cont.)

HOW MUCH WERE YOU DISTRESSED BY :		Not at all	A little bit	Moderately	Quite a bit	Extremely
11.	Poor appetite	1	2	3	4	5
12.	Suddenly scared for no reason	1	2	3	4	5
13.	Temper outbursts that you could not control	1	2	3	4	5
14.	Feeling lonely even when you are with people	1	2	3	4	5
15.	Feeling blocked in getting things done	1	2	3	4	5
16.	Feeling lonely	1	2	3	4	5
17.	Feeling blue	1	2	3	4	5
18.	Feeling no interest in things	1	2	3	4	5
19.	Feeling fearful	1	2	3	4	5
20.	Your feelings being easily hurt	1	2	3	4	5
21.	Feeling that people are unfriendly or dislike you	1	2	3	4	5
22.	Feeling inferior to others	1	2	3	4	5
23.	Nausea or upset stomach	1	2	3	4	5
24.	Feeling that you are watched or talked about by others	1	2	3	4	5
25.	Trouble falling asleep	1	2	3	4	5
26.	Having to check and double check what you do	1	2	3	4	5
27.	Difficulty making decisions	1	2	3	4	5
28.	Feeling afraid to travel buses, subways, or trains	1	2	3	4	5
29.	Trouble getting your breath	1	2	3	4	5
30.	Hot or cold spells	1	2	3	4	5
31.	Having to avoid certain things, places, or activities because they frighten you	1	2	3	4	5
32.	Your mind going blank	1	2	3	4	5
33.	Numbness or tingling in parts of your body	1	2	3	4	5

## Appendix B

### Brief Symptom Inventory (cont.)

HOW MUCH WERE YOU DISTRESSED BY :

		Not at all	A little bit	Moderately	Quite a bit	Extremely
34.	The idea that you should be punished for your sins	1	2	3	4	5
35.	Feeling hopeless about the future	1	2	3	4	5
36.	Trouble concentrating	1	2	3	4	5
37.	Feeling weak in parts of your body	1	2	3	4	5
38.	Feeling tense or keyed up	1	2	3	4	5
39.	Thoughts of death or dying	1	2	3	4	5
40.	Having urges to beat, injure, or harm someone	1	2	3	4	5
41.	Having urges to break or smash things	1	2	3	4	5
42.	Feeling very self-conscious with others	1	2	3	4	5
43.	Feeling uneasy in crowds	1	2	3	4	5
44.	Never feeling close to another person	1	2	3	4	5
45.	Spells of terror or panic	1	2	3	4	5
46.	Getting into frequent arguments	1	2	3	4	5
47.	Feeling nervous when you are left alone	1	2	3	4	5
48.	Others not giving you proper credit for your achievements	1	2	3	4	5
49.	Feeling so restless you couldn't sit still	1	2	3	4	5
50.	Feelings of worthlessness	1	2	3	4	5
51.	Feeling that people will take advantage of you if you let them	1	2	3	4	5
52.	Feelings of guilt	1	2	3	4	5
53.	The idea that something is wrong with your mind	1	2	3	4	5

## Appendix C

### Modified Social Adjustment Scale

Patient Codenumber :

Group:

Date : .....

---

Instructions:

We are interested in how you have been in the past two weeks. We would like you to answer some questions about your work, spare time activities and your family life. Please answer the questions on the following pages by ticking the box of the answer which you think most nearly applies to you.

---

Work outside the home:

The following questions are about how things have been in your job (full-time or half-time). If you do not have a job go straight on to the next section.

Over the past two weeks have you:

- |    |  |              |                  |                     |                  |              |
|----|--|--------------|------------------|---------------------|------------------|--------------|
| 1. | missed any time from work?                         | Not at all   | Occasionally     | About half the time | Most of the time | All the time |
| 2. | been doing your job well?                          | All the time | Most of the time | About half the time | Occasionally     | Not at all   |
| 3. | felt ashamed of how you have been doing your work? | Not at all   | Occasionally     | About half the time | Most of the time | Constantly   |
| 4. | got angry with or argued with people at work?      | Not at all   | Occasionally     | About half the time | Most of the time | Constantly   |
| 5. | felt upset, worried or uncomfortable at work?      | Not at all   | Occasionally     | About half the time | Most of the time | Constantly   |
| 6. | been finding your work interesting?                | All the time | Most of the time | About half the time | Occasionally     | Not at all   |

Work inside the home:

The following questions are about how you have been doing your household tasks.

Over the past two weeks have you:

- |    |  |              |                  |                     |              |            |
|----|--|--------------|------------------|---------------------|--------------|------------|
| 7. | done the necessary household tasks each day? | All the time | Most of the time | About half the time | Occasionally | Not at all |
| 8. | been doing the household tasks well?         | All the time | Most of the time | About half the time | Occasionally | Not at all |

## Appendix C

### Modified Social Adjustment Scale (cont.)

9.	felt ashamed of how you have been doing the household tasks?	Not at all	Occasionally	About half the time	Most of the time	Constantly
10.	got angry with or argued with salespeople, tradesmen or neighbours?	Not at all	Occasionally	About half the time	Most of the time	Constantly
11.	felt upset, worried or uncomfortable while doing the household tasks?	Not at all	Occasionally	About half the time	Most of the time	Constantly
12.	found the household tasks boring, unpleasant or a drudge?	Not at all	Occasionally	About half the time	Most of the time	Constantly

Social and leisure activities:

The following questions are about your friends and what you have been doing in your spare time.

Over the past two weeks have you:

13.	been in touch with any of your friends?	Very often	Often	A few times	Very rarely	Not at all
14.	been able to talk about your feelings openly with your friends?	All the time	Most of the time	About half the time	Occasionally	Not at all
15.	done things socially with your friends (e.g. visiting, entertaining, going out together)?	Very often	Often	A few times	Very rarely	Not at all
16.	spent your available time on hobbies or spare time interests?	All the time	Most of the time	About half the time	Occasionally	Not at all
17.	got angry with or argued with your friends?	Not at all	Occasionally	About half the time	Most of the time	Constantly
18.	been offended or had your feelings hurt by your friends?	Not at all	Occasionally	About half the time	Most of the time	Constantly
19.	felt ill at ease, tense or shy when with people?	Not at all	Occasionally	About half the time	Most of the time	Constantly
20.	felt lonely and wished for companionship?	Not at all	Occasionally	About half the time	Most of the time	Constantly
21.	felt bored in your free time?	Not at all	Occasionally	About half the time	Most of the time	Constantly

## Appendix C

### Modified Social Adjustment Scale (cont.)

Extended family:

The following questions are about your extended family, i.e. your parents, brothers, sisters, in-laws, and children not living at home. Please do not include your partner or children living at home.

Over the past two weeks have you:

22.	got angry with or argued with any of your relatives?	Not at all	Occasionally	About half the time	Most of the time	All the time
23.	made an effort to keep in touch with your relatives?	Very often	Often	A few times	Very rarely	Not at all
24.	been able to talk about your feelings openly with your relatives?	All the time	Most of the time	About half the time	Occasionally	Not at all
25.	depended on your relatives for help, advice or friendship?	Not at all	Occasionally	About half the time	Most of the time	All the time
26.	worried more than necessary about things happening to your relatives?	Not at all	Occasionally	About half the time	Most of the time	All the time
27.	been feeling that you have let your relatives down at any time?	Not at all	Occasionally	About half the time	Most of the time	All the time
28.	been feeling that your relatives have let you down at any time?	Not at all	Occasionally	About half the time	Most of the time	All the time

Relationships:

The following questions are about how things have been between you and your partner. If you are NOT living with your partner or living with a person in a steady relationship, go straight on to the next section.

Over the past two weeks have you:

29.	got angry with each other or argued with one another?	Not at all	Occasionally	About half the time	Most of the time	All the time
30.	been able to talk about your feelings and problems with your partner?	All the time	Most of the time	About half the time	Occasionally	Not at all
31.	been making most of the decisions at home yourself?	Not at all	Occasionally	About half the time	Most of the time	All the time
32.	tended to give in to your partner and let him/her have his/her own way when there was a disagreement?	Not at all	Occasionally	About half the time	Most of the time	All the time
33.	and your partner shared the responsibility for particular matters that have arisen?	All the time	Most of the time	About half the time	Occasionally	Not at all
34.	had to depend on your partner to help you?	Not at all	Occasionally	About half the time	Most of the time	All the time
35.	been feeling affectionate towards your partner?	All the time <input type="checkbox"/>	Most of the time <input type="checkbox"/>	About half the time <input type="checkbox"/>	Occasionally	Not at all



## Appendix C

### Modified Social Adjustment Scale (cont.)

36.	and your partner had sexual relations? About how many times?	Four or more times	Three times	Twice	Once	Not at all
37.	had any problems during sexual intercourse (e.g. pain or difficulty reaching climax)?	Not at all	Occasionally	About half the time	Most of the time	Every time
38.	enjoyed your sexual relations with your partner?	Every time	Most of the time	About half the time	Occasionally	Not at all

Parental:

The following questions are about how things have been with your children. If you do not have any children living at home go straight on to the next section.

Over the past two weeks have you:

39.	been interested in your children's activities, e.g. school, friends, etc.?	All the time	Most of the time	About half the time	Occasionally	Not at all
40.	been able to talk to and listen to your children?	All the time	Most of the time	About half the time	Occasionally	Not at all
41.	been shouting at or arguing with your children?	Not at all	Occasionally	About half the time	Most of the time	Constantly
42.	been feeling affectionate towards your children?	All the time	Most of the time	About half the time	Occasionally	Not at all

Family unit:

The following questions are about how things have been with your immediate family, that is your partner and children at home. If you do not have an immediate family, please ignore this section.

Over the past two weeks have you:

43.	been worrying more than necessary about things happening to your family?	Not at all	Occasionally	About half the time	Most of the time	All the time
44.	been feeling that you have let your immediate family down at any time?	Not at all	Occasionally	About half the time	Most of the time	All the time
45.	been feeling that your immediate family has let you down at any time?	Not at all	Occasionally	About half the time	Most of the time	All the time

PLEASE CHECK TO SEE THAT YOU HAVE ANSWERED ALL THE QUESTIONS. THANK YOU

## Appendix D

### Patient satisfaction and session impact questionnaire

Thinking of the help you received from the counsellor, please answer the following questions by circling the point on the scale which most clearly reflects your opinion.

		Not at all	Slightly	Some- what	Pretty much	Very much
1.	I understood something new about myself	1	2	3	4	5
2.	I understood something new about my partner or somebody else	1	2	3	4	5
3.	I understood something new about the relationship with my partner	1	2	3	4	5
4.	I became more aware of my feelings and experiences	1	2	3	4	5
5.	I know what needs to be changed in my life	1	2	3	4	5
6.	I found out ways of coping with problems	1	2	3	4	5
7.	I felt understood	1	2	3	4	5
8.	I felt supported	1	2	3	4	5
9.	I felt less troubled	1	2	3	4	5
10.	I felt more bothered by unpleasant thoughts	1	2	3	4	5
11.	I felt pressure on me to do something	1	2	3	4	5
12.	I felt criticized	1	2	3	4	5
13.	I felt confused	1	2	3	4	5
14.	I felt bored	1	2	3	4	5
15.	Generally, how satisfied were you with the help you received?	1	2	3	4	5



## Appendix F

### Counselling - Information for Patients

The counsellor's task is to give you the opportunity to talk about what is troubling you, so that you can explore your thoughts and feelings about it, in a way which is not always possible with family and friends. Being listened to by someone who is respectful of you, nonjudgemental and accepting, can help you to see things in a fresh light. The counsellor will help you to decide what you want to do and to consider what possible steps you might take to reach a solution to your difficulties or, if the situation cannot be changed, to come to terms with it. The counsellor's job is not to give you advice or to tell you what to do.

Whatever you choose to say will be kept in strictest confidence by the counsellor and she will only disclose any information you give after seeking your permission. The only exceptions would be if there was a question of serious harm caused either to yourself or someone else.

For the purpose of the study, some taped material will be randomly selected and checked by a research assistant, to make sure that the counsellors are working the same way. This is done anonymously.

When the counselling has finished, the counsellor will write a short report about the process, not the content of the work, that is, how it went, not what you said. In the same way as you will be asked to assess if it has been helpful to you.

Each session last for fifty minutes. You may find that one session with the counsellor is enough. The average number of sessions might be 6, but we could extend that to a maximum of 12 sessions.

Please notify the GP surgery, if you are unable to keep an appointment, so that the session can be used by someone else. Thank you.

## Appendix G

### Baseline economic questionnaire

Please complete the following questions. Either tick the appropriate box or write your answer in the space provided.

- A 1 Marital Status                      Single                        
   Married/cohabiting                        
   Widowed                        
   Separated                        
   Divorced
- A 2 Religion                      .....
- A 3 Education                      CSE, RSA or equivalent                        
   Ordinary GCE's                        
   Advanced GCE'S                        
   Degree                        
   Higher degree                        
   Other                        
   please specify .....  
   None of the above
- A 4 Ethnic Origin                      .....
- A 5 Accommodation                      Rented from local authority                        
   Privately rented                        
   Board and lodging                        
   Housing association agreement                        
   Owner/occupier                        
   Other                        
   please specify .....
- A 6 Have you received any social security benefits or rent rebates  
over the last 6 months? (exclude child benefit)
- Yes                        
   No
- A 7 If yes, for how many weeks did you receive these benefits  
and approximately how much did you receive on each occasion:
- a) ..... weeks of ..... at £ .....
- b) ..... weeks of ..... at £ .....
- c) ..... weeks of ..... at £ .....
- d) ..... weeks of ..... at £ .....

## Appendix G

### Baseline economic questionnaire (cont.)

- A 8    Work Status                      Full-time                        
    Part-time                        
    Housewife/man                  
    Unemployed                      
    Retired                          
    Long term sick/disabled        
    Other

please specify .....

A 8A    Type of work                      .....

- A 9    Work Status of                      Full-time                        
    Partner                        Part-time                        
    Housewife/man                  
    Unemployed                      
    Retired                          
    Long term sick/disabled        
    Other

please specify .....

A 9    Type of work                      .....

A 10    How long have you been in the current employment/unemployment?

.....

A 11    Work History. Please complete the table below for the last 6 months, noting all job changes in that time and starting with your current status. Please also include periods of unemployment. Please state gross wage per week (that is, before national insurance, superannuation and other deductions).

Job change since last interview		Employed/ Unemployed	Average number of hours worked per week		Please state weekly income (ie. total before tax or other benefits during unemployment)	Did you change jobs because of your present problems? (Please circle)	
			Less than 30	More than 30		YES	NO
FROM month/year	TO month/year						
						YES	NO
						YES	NO
						YES	NO

A 12    How many days have you had "off sick" from work in the last 6 months?

.....

A 13    How many of these days off were due to your present problems?

.....

## Appendix G

### Baseline economic questionnaire (cont.)

A 14 What is your problem(s)?.....  
 .....  
 .....  
 .....

A 15 For how long have you had this problem?  
 .....

A 16 On a scale of 0 to 8, how disturbing/ upsetting is your main problem? Please circle one number.

0	1	2	3	4	5	6	7	8
Does not		Slightly/ sometimes		Definitely/ often		Markedly/ very often		Very severely/ continuously

A 17 Have you seen the following people for help in the last 6 months?

Agency	Number of contacts	Duration of contact	Home visit Yes or no	Cost of travel One way (£) or number of car miles	Child care arrangements
GP					
Psychiatrist					
Social worker					
Doctor/nurse at workplace					
Specialist doctor					
Practice nurse					
District nurse					
Community psychiatric nurse					
Health visitor					
Psychologist					
Other					

A 18 In the last 6 months have you seen a counsellor?

Yes   
 No

**Appendix G**

Baseline economic questionnaire (cont.)

A 19 Where was the counsellor employed/ who was the counsellor?

.....

A 20 How many times did you see the counsellor and for how long each time?

.....

A 21 Why did the counselling end?

.....

.....

A 22 Did the counsellor charge you for their service? If yes, how much?

.....

A 23 How much were the travelling costs to go and see the counsellor? (One way (£) or number of car miles)

.....

A 24 Did you need to make child care arrangements while seeing the counsellor? If yes, what?

.....

A 25 In the last 6 months, have you been:

a) an inpatient in a general hospital?

Yes

No

If yes, please specify (where, reason, number of days)

.....

.....

b) an inpatient in a psychiatric hospital?

Yes

No



**Appendix G**

Baseline economic questionnaire (cont.)

If yes, please specify (where, reason, number of days)

.....  
.....

c) an outpatient for any reason?

Yes              
No            

If yes, please specify (where, reason, number of appointments)

.....  
.....

A 26 Are you taking any medicines at present which have been prescribed by your doctor?

1 .....  
2 .....  
3 .....  
4 .....  
5 .....

A 27 Are you taking any other tablets or medicines?

1 .....  
2 .....  
3 .....  
4 .....  
5 .....

A 28 Would you prefer to see your GP or a counsellor?

GP                                      
Counsellor                             
Don't mind who I see              

A 29 Why would rather see the above?

.....  
.....

Thank you.

## Appendix H

Unit costs for 1995/96  
(taken from Netten and Dennett, 1996)

General practitioner	£1.72 per minute
Counsellor	£16.39 per hour
Psychiatrist	£67.72 per hour
Social worker	£21 per hour
Occupational health doctor	£67.72 per hour
Specialist doctor	£67.72 per hour
Practice nurse	£16 per hour
District nurse	£32 per hour
Community psychiatric nurse	£47 per hour
Health visitor	£47 per hour
Psychologist	£55 per hour
In-patient stay	£187 per night
Out-patient appointment	£57 per appointment
Day hospital attendance	£55 per day

**Appendix I**

Refusal form

PATIENT'S NAME: .....

DATE OF BIRTH: .....

PLEASE TICK

GENDER:                   MALE:                   

FEMALE:                   

PATIENT'S PROBLEM: .....

.....

.....

.....

.....

.....

.....

REASON FOR REFUSING TO ENTER STUDY:

.....

.....

.....

.....

.....

.....

.....

GP'S NAME: .....

DATE: .....

Please send the refusal form to Karin Friedli at: Royal Free Hospital School of Medicine, Academic Department of Psychiatry, Rowland Hill Street, London NW3 2PF. Thank you.

## Appendix J

### Patient information sheet

General practitioners have recently starting employing counsellors into their practices. Some studies show that counsellors are very helpful. Other studies show that general practitioners can provide an equally good service. We need to understand more about the similarities and differences between the care that counsellors and general practitioners provide to people. That is why a team of researchers at the Royal Free Hospital School of Medicine are doing a study to find out more about this. They invite you to take part in the study which has been funded by charity money.

Taking part in the study will initially involve a meeting with a researcher either at the surgery or at your home. This will give you an opportunity to learn more about the study and answer some initial questions. You will then either see your GP or the counsellor. Whom you see will be decided by random allocation. This means you cannot choose whom you see, but have an equal chance of seeing either your GP or the counsellor.

The researcher will contact you again three and nine months later to see how you have been getting on and ask you some questions about the treatment.

All information will be treated in the strictest confidence and only used for this research.

I do hope you will decide to take part in this important study. However, if you would rather not take part, you do not have to give a reason and it will not affect you future care. If you decide to take part and later change your mind, you can withdraw without giving a reason and without affecting your future care. You are welcome to ask any questions about the study at any time.

**Appendix K**

Patient referral form

PATIENT'S NAME: .....

PATIENT'S ADDRESS: .....

.....

PATIENT'S TELEPHONE NO: .....

REASON FOR REFERRAL: .....

.....

.....

.....

GP'S NAME: .....

DATE: .....

Please tick

PATIENT INFORMATION SHEET EXPLAINED

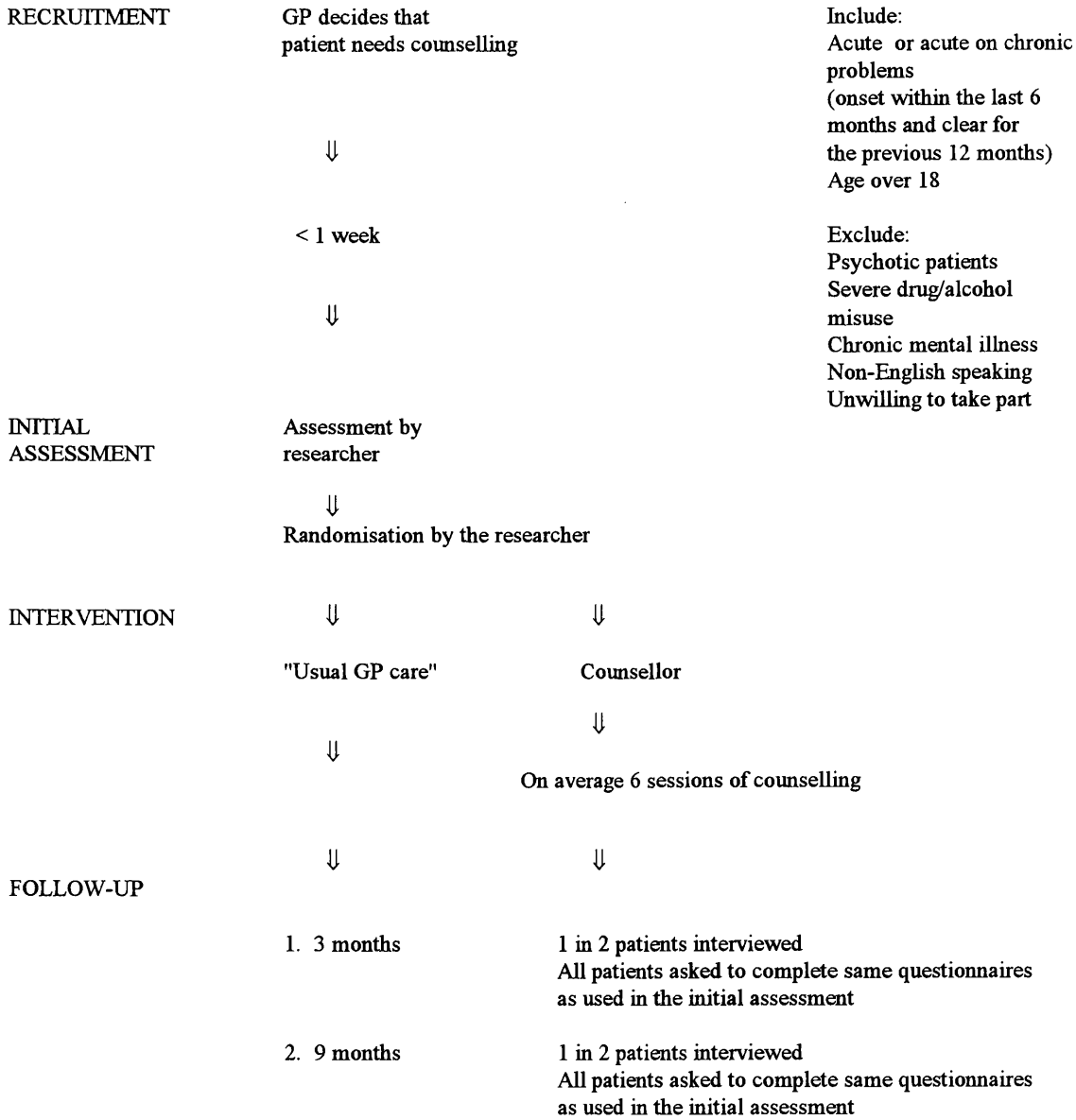
EXPLAIN RESEARCHER WILL CONTACT THE PATIENT

Please telephone Karin Friedli on 071-794-0500 extension 3712 to inform her about the referral and send a copy of the referral to her at: Royal Free Hospital School of Medicine, Academic Department of Psychiatry, Rowland Hill Street, London NW3 2PF. Thank you.

## Appendix L

### Flow diagram of the study

#### EVALUATION OF COUNSELLING IN GENERAL PRACTICE



GP's and counsellors asked to describe treatment/therapy given

Review of practice notes for consulting and prescribing patterns before and after entry

## Appendix M

### Step by step guide of the study

- 1) **Decide if the patient needs counselling.**
- 2) **If yes, discuss the study with each patient and give them the patient information sheet.**
- 3) **Check the inclusion and exclusion criteria to determine whether the patient is eligible for the study.**
- 4) **If the patient agrees to take part, fill in the referral form provided for the study. ( Karin Friedli, the researcher, will get written consent from the patient at the initial interview)**
- 5) **If the patient does not agree to take part, fill in the refusal form provided for the study.**
- 6) **You, your practice manager or the receptionist contact Karin by telephone and inform her about the referral.**
- 7) **Karin will contact the patient. She will interview the patient and randomise them into the GP care group or the counsellors group.**
- 8) **Karin will inform you into which group the patient has entered.**
- 9) **If the patient enters the GP care group, carry on your usual care.**
- 10) **If the patient enters the counsellors group, the counsellor will be in touch with the patient and your practice and will negotiate a suitable time and place for counselling. The counsellors will liaise with you about the patients.**
- 11) **Please do not refer patients onto another counsellor, CPN or other person for counselling, for the initial three months after referral and ideally not for nine months.**
- 12) **Karin will keep you up to date on referrals on all practices taking part in the study.**

**Any queries or problems, please phone Karin Friedli, the researcher, on 071-794-0500 extension 3712 (Answerphone).**

## **Appendix N**

### Definition of counselling and counsellors

#### **Definition of counselling:**

The task of counselling is to give the client an opportunity to explore, discover and clarify ways of living more resourcefully and towards greater well-being.

(British Association of Counselling, 1991)

#### **Role of the counsellor in the study**

All counsellors in the study have a diploma or master degree in counselling and have considerable practical experience in counselling.

They are all members of the professional organisation, the British Association of Counselling (BAC) and are all eligible for BAC accreditation. They all hold to the BAC code of ethics and practice.

The counsellors will have contact with your practice on a regular basis, seeing patients on a one-to-one basis, ideally in the practice. The counsellors will see patients on an average of 6 sessions.

All counsellors will have team meetings and their regular supervision.

The counsellors are fully funded by the study.



## Appendix O

### Inclusion and exclusion criteria

Is the patient over 18 years old?

↓  
Yes

↓  
No → EXCLUDE

↓

Has the onset of the patients problem been within the last 6 months?

↓  
Yes

↓  
No → EXCLUDE

↓

Has the patient been free of emotional illness for 12 months prior to the recent problems?

↓  
Yes

↓  
No → EXCLUDE

↓

Is the patient suffering from a psychotic illness, chronic mental illness or severe drug/alcohol dependency?

↓  
No

↓  
Yes → EXCLUDE

↓

Does the patient speak proficient English to answer questionnaires?

↓  
Yes

↓  
No → EXCLUDE

↓

Has the patient agreed to take part in the study?

↓  
Yes

↓  
No → EXCLUDE

↓

INCLUDE

## Appendix P

### Progress report

#### UPDATE

10/9/93

Recruitment has improved a little in the second three weeks of the study, with on average of 3.3 newly referred patients per week. We still need to aim for 5 or 6 newly referred patients per week.

So far, in total there are

12 women  
5 men

9 GPs & 3 GP trainees have referred patients  
6 practices have referred patients

The main problem amongst the sample is depression.

Other problems are:

- relationship problems
- anxiety
- stress
- sleep problems/ insomnia
- family problems
- unable to cope
- eating disorder
- housing/ neighbour problems
- work problems/ redundancy
- pain
- phobias

Please when referring patients to the study, ask all patients needing counselling. If the patient does not consent to take part, fill in the refusal form and send it to Karin Friedli at the Royal Free Hospital School of Medicine.

## Appendix P

Progress report (cont.)

### UPDATE 6

28/2/94

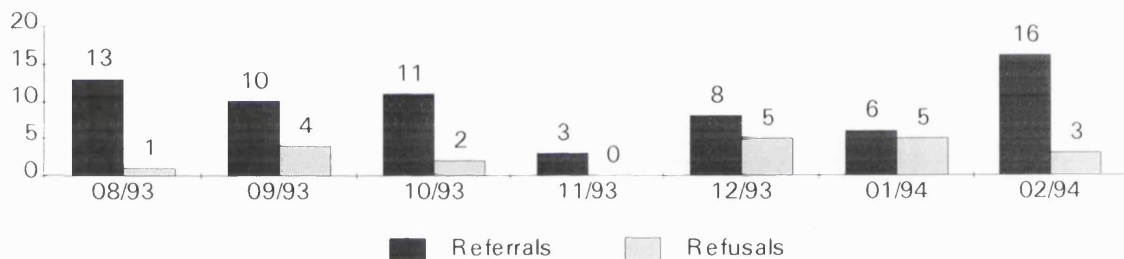
#### **The Sample**

We now have 67 patients in the study. So far, in total there are

54 women  
13 men.

Thirty GPs & 4 GP trainees in 14 different practices have referred patients.

There have been 20 refusals, that is, patients not consenting to take part in the study.



The above diagram shows the number of referrals and refusals over the last seven months. As you can see, February was an excellent month with 16 referrals. Thank you very much! We greatly appreciate all your hard work in inviting people into the study.

#### **Guideline Reminders**

Please remember to approach **all** patients that need counselling and advise them on the counselling study. Give each patient who is interested in participating in the study a copy of the **patient information sheet** to read. If the patient does not want to take part fill in the **refusal form**.

#### **Problems that patients present with**

Depression remains the main problem that patients complain of. The predisposing factors are relationship problems and work and financial problems. A number of patients present with anxiety and stress related problems.

For **more referral or refusal forms**, please contact Karin Friedli, at Royal Free Hospital School of Medicine, Rowland Hill Street, London NW3 2PF, or telephone 071-794-0500 extension 3712 (answering machine).

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