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INSIGHT IN SCHIZOPHRENIA AND THE EFFECT OF COGNITIVE BEHAVIOUR THERAPY

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ABSTRACT

FACULTY OF MEDICINE, HEALTH AND BIOLOGICAL SCIENCES

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Doctor of Medicine

INSIGHT IN SCHIZOPHRENIA AND THE EFFECT OF COGNITIVE BEHAVIOUR THERAPY

By Shanaya Rathod

Aims: To determine whether there is a difference in the degree of change in the three components of insight (adherence, recognition of illness and ability to re-label mental disturbances as pathological) in patients with schizophrenia with a brief, insight focussed Cognitive Behaviour Therapy (CBT) intervention.
To determine if any change in total insight with therapy is associated with the demographic characteristics of the participants.
To determine if the change in total insight and its components is associated with a change in symptoms of depression and psychosis in the participants.
To determine if there is a correlation between insight, its components and psychopathology.

Method: A randomised trial carried out at six sites in the United Kingdom, in which participants with schizophrenia and their carers received six sessions of insight focussed CBT (and three sessions for carers) from trained nurses in the community.

Results: At the end of therapy (three months), the intervention group demonstrated statistically significant improvement in insight into adherence with treatment ($p=0.003$) and insight into ability to re-label their psychotic symptoms as pathological ($p=0.02$) compared with the Treatment as usual group. Those participants who demonstrated improved insight into having a mental illness, schizophrenia, tended to become depressed ($p = 0.03$). At one-year follow-up assessment, the result of insight into adherence remained significant ($p = 0.01$).
The African-Caribbean group at three months and the Black African group at one year had a statistically significant higher dropout rate and poor improvement in insight compared with the white group following therapy.
Participants in part time employment at three months did significantly better than the other groups following therapy. There was no statistically significant improvement in psychotic psychopathology.
The correlations between components of insight and between insight and psychopathology improved with therapy.
Conclusions: A brief CBT programme delivered by nurses can improve insight into compliance with treatment in patients with schizophrenia in the community and the results are durable at one year. This may have a role in relapse prevention. Acceptance of the diagnosis of schizophrenia may have implications.
There are problems in engaging patients from ethnic minorities and the need for further development and research in this area is highlighted.

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PREFACE

Insight in schizophrenia is an evolving concept. Although poorly defined, it has widespread use in clinical practice as it may have bearing on issues such as compliance with treatment, dangerousness, suicide and prognosis of illness.

The traditional 'all or nothing' view of insight has been challenged in recent years by those who argue for a continuum. The ability of patients to track decomposition into psychosis through monitoring of early warning signs is consistent with this view.
Very few studies focus on the effects of improving insight in psychosis.

The Insight into schizophrenia study was set up in 1999 in six centres across the United Kingdom, which aimed to look at the effects of Cognitive behaviour therapy on insight in schizophrenia. In the same year, with my appointment as honorary lecturer at the Department of Psychiatry in Southampton, I was involved with the project with Professor David Kingdon.

This thesis presents a sub analysis from the main study and presents the effects of Cognitive behaviour therapy on the components of insight, demographics of patients who show a significant improvement in insight following therapy and the effects of therapy on psychotic symptoms and depression with change in insight and its components.

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CHAPTER 1: INTRODUCTION

Introduction is presented in three sections:

- The first section describes the concept of insight including historical background, proposed aetiology, measurement and the components of insight.

- The second section presents a brief review of the role of psycho-education and cognitive behaviour therapy in schizophrenia.

- In the conclusion, I have attempted to bring the above concepts together in order to justify the objectives of the thesis.

Literature review

The introduction is not a systematic review of the topic as the aim was to describe the rationale that led to this work. In order to arrive at the research question, a review of existing literature was carried out according to the guidelines of systematic reviews. Wherever appropriate, these are cited. Electronic searches of the following databases was undertaken:

The Cochrane Library (Issue 2, 2003),
The Cochrane Schizophrenia Groups' Register of Trials,
Embase – 1980 to Present
Medline – 1966 to Present
Psychinfo – 1872 to current

Papers were also selected from references and books were read.

Keywords used: Insight, schizophrenia, psychosis, patient compliance (treatment compliance: Psychinfo), acceptance of illness, acceptance of mental illness, belief systems, demographics (demographic characteristics: Psychinfo), ethnic groups. The search was updated before submission. A detailed search history is presented in Appendix 1.

Section 1.1: Concept of Insight in Schizophrenia

The World Health Organization reports lack of insight as the most frequent symptom in patients with schizophrenia, occurring in 97% of a sample group with acute illness (World Heath Organization, 1973). The *Oxford English Dictionary* defines insight as ' an inner sight, a discernment, wisdom, mental vision or a glimpse of you beneath the surface'.

In psychiatry, assessment of insight is part of the mental state examination and it helps in drawing inferences regarding severity of illness, suicidal risk, compliance and attitude to treatment depending on the responses. Lack of insight correlates with failure to obtain treatment early, leading to poor long-term prognosis (Loebel *et al*, 1992). Nevertheless, insight is not just a term - it is a multidimensional phenomenon. Aetiological theories span a broad spectrum from psychoanalytic theories describing it as due to psychological defence, to the other extreme where the theoretical position implicates cognitive deficit. A number of researchers have reviewed literature on the concept (Kemp and David, 1997; Beck-Sandler, 1998).

Historical background

Although the concept of insight has gained a lot of attention in the last 10 years (David, 1990; Amador *et al*, 1991; Markova and Berrios, 1992), the notion of 'self knowledge' dates to ancient Greek philosophy (Watts, 1987). Not much is documented on the subject before 1850. The concept of partial, emotional, and volitional insanity during the second half of the 19th century led to the questioning of patients' attitudes towards insanity (Berrios and Gili, 1995). Dagonet (1881) discussed the effects of mental illness on self-awareness. Seven years later, Parrant wrote in the context of self-awareness in insanity:

> "Concerns the state in which the patient is aware of his experiences, acts, of all internal changes and of their consequences...Thus understood, this awareness implies not only knowledge of illness but capacity by degrees to judge it" (Parrant, 1888).

Lewis (1934) defined insight as 'a correct attitude to morbid change in oneself', acknowledging the problems with interpreting each of those terms. He believed that during the earlier stage of schizophrenia patients often showed a considerable amount of insight that was associated with a struggle against the illness. Furthermore, changes in the level of insight had a prognostic value, as did the gaining of retrospective insight.

Karl Jaspers stated that patients were perplexed in the early stages of their psychotic illness, but tried to make sense of their experiences as their illness progressed, sometimes by elaborating their delusional systems. Furthermore, as the illness affected personality, a patient's attitude to illness became less understandable to others. He wrote,

> ' Patients' self observation is one of the most important sources of knowledge in regard to morbid psychic life; so is their attentiveness to their abnormal experience and the elaboration of their observation in the form of a psychological judgement so that they can communicate to us something of their inner life.' (Jaspers, 1959)

Jaspers based the concept of insight partly on clinical observation and according to him, it was the patients' ability to judge what was happening to them during the development of psychosis. These judgements, however, depend on the intelligence and education of the individual and Jasper was aware of the difficulties involved in theorising about patients' insight.

Conrad's (1958) conceptualisation of the awareness of change in self and the environment due to mental illness relates to what Jasper called 'insight'. He also stated that schizophrenia was an illness affecting the higher mental functions and it affected the whole self-concept, in particular, the ability of the individual to effect the normal transition from looking at oneself from within to looking at oneself from the outside. Therefore, over the century the concept of insight evolved.

Psychodynamic theory

The psychodynamic understanding of insight – mainly dealing with neurotic and personality difficulties – is broader and refers to the ability to link previous experiences to present problems. Most psychoanalytic explanations emphasise the role of unconscious defences in understanding mental phenomenon. Freud used the German term 'Einsicht/Einblick' or insight predominantly to denote knowledge of, or awareness of, being ill (Freud, 1981), but his own concept of insight changed in relation to therapy and cure. While initially he maintained the existence of a direct relationship between the attainment of insight and cure, he later acknowledged the equal importance of time, working through, and inner resistances (Fisher and Greenberg, 1977). However, Freud never saw patients with psychosis and his insight into this illness would be limited.

Empirical studies in the past have mainly compared outcomes of insight-oriented psychotherapy (Hartlage, 1970). Lack of a definition of insight makes interpretation of the results difficult. An example is the assumption that 'interpretation' equates to insight and when one can interpret, insight is attained (Roback, 1974). A decade later, the Boston Collaborative study (Stanton *et al*, 1984, Gunderson *et al*, 1984) demonstrated the benefits of reality-adaptive supportive therapy based on cognitive techniques over exploratory insight-oriented therapy based on psychoanalytic theory and psychodynamic practice.

Aetiology of poor insight in schizophrenia

The most important approaches, which explain the aetiology of poor insight in schizophrenia, are:

1. Poor insight as a psychological defence

Denial of illness has aroused much interest and extensive discussion. The defensive strategies of patients with schizophrenia might involve denial of the psychotic experience (Mayer-Gross, 1920). This includes unawareness of the signs and

symptoms of the illness. These patients may also be in denial of future implications, i.e. they deny the possibility of future events and have problems with attribution processes. This is a limited review of the topic as it is relevant to the study and its findings.

An elegant description of various styles of recovery from schizophrenia by McGlashan *et al,* (1975) includes 'integration' where patients are interested to learn about their symptoms and discuss their experiences and 'sealing over' where some patients prefer not to think about their psychotic experiences during recovery. On evaluation of personalities, the authors found that the patients who sealed over attributed their illness to external forces or were unaware of them. The integrators took responsibility for their symptoms. In a recent study by Tait *et al,* (2003) the researchers concluded that sealing/integration lie at the heart of service disengagement and treatment reluctance. Clinicians may therefore be able to tailor their interventions with patients according to their recovery style leading to effective engagement, coping strategies and successful psychological adjustment.

Based on the same concept, Fowler *et al,* (1995) discuss three patterns of psychological reactions to psychotic illness:

- Denial and lack of awareness of psychosis: Some people fail to recognise their psychotic symptoms and may refuse to cooperate with the health professionals.
- Resignation or Engulfment into the social role of chronic patient: Such individuals may wish to accept care from the services.
- Acceptance of psychotic illness: these patients adjust their lifestyle and behaviour and maximise their independence under care.

Denial is an adaptive coping mechanism and an explanation of the gross unawareness of illness observed in schizophrenia could be the disruption of normally adaptive cognitive biases. It could also be a form of self-deception, which is protective against distress (Sackeim, 1983). Loss of this protective mechanism may explain post psychotic depression (McGlashan and Carpenter, 1976).

2. Neurological abnormalities and neuropsychological deficit

Gerstman (1942) has reported a phenomenon in post stroke patients where they may behave as though their paralysed limb was normal. Early theories suggested that psychotic symptoms are intractable to confrontation and that at least some form of poor insight stemmed similarly from neuropsychological deficit (Amador *et al*, 1991). This view is supported by the fact that patients with schizophrenia are often unaware of their tardive dyskinesia (Caracci *et al*, 1990). The subjective nature of unawareness in neurological disorders and schizophrenia is similar as well, for example, patients with schizophrenia may be aware of one of their symptoms but not the other, similar to anosognosia, where the patient may be aware of memory problems but not paralysis.

3. Social and cultural influences

Personal and cultural background influences insight into psychiatric illness and societal views of mental illness and disability are important (Blackwell, 1976). It often seems that mentally ill patients have taken the place of lepers as targets of public disgust and rejection (Lewis, 1934). Patients are more likely to deny mental illness if they come from a social group in which it is highly stigmatised. Previous studies have suggested that patients' attitudes and degree of knowledge about mental illnesses tend to resemble those of their background rather than those of mental health professionals (Bentinck, 1967). There is substantial diversity in the representation of mental illness, which members of different social groups bring to their transactions with their doctors (Johnson and Orrell, 1995).

Townsend (1975) compared the perceptions of patients and non-patients in psychiatric hospitals in Germany and United states. The German view of mental illness was that it is inherited, enduring, and difficult to cure and not influenced by personal effort. Americans saw it as transient and a result of difficult circumstances. German patients were more likely than the American group to deny being mentally ill and were less optimistic about the prognosis.

Angermayer and Matschinger (1994) studied the lay beliefs about schizophrenia through a population survey in Germany. In the order of frequency, psychosocial stresses; biological factors like brain disease; intrapsychic factors like lack of will power, too much ambition; influence of socialisation like broken homes and finally state of society and supernatural powers were the attributed causes. There was no observed association with age, sex or level of education. There was also a major preference of the public for psychotherapy as opposed to treatment with psychotropic drugs.

Health beliefs shape the attitudes of patients and their relatives towards mental illness, help seeking behaviour and compliance with treatment. Despite the evidence, the influence of culture and background in the concept of insight remains ill researched.

Measurement of insight

Assessment of insight has always been part of a psychiatric assessment although usage of the term varies. Earlier attempts to measure insight were based on psychodynamic therapies. Tolor and Reznikoff (1960) developed a test using hypothetical situations based on common defence mechanisms and found a correlation with intelligence. This test was used by Roback and Abramowitz (1979) who found a correlation in patients with schizophrenia between more subjective distress and better behavioural adjustment. The validity of this test is debatable as the concept of insight is based on psychodynamic rather than clinical psychiatric principles.

Until recently there has been a lack of a standardised assessment tool for insight. Heinrichs and colleagues (1985) developed a scale for quantifying a patients awareness of relapse and found it to be related to the frequency and timing of subsequent hospital admissions in schizophrenia patients.

McEvoy and colleagues (1989) proposed an eleven-item insight scale called the Insight and Treatment Attitudes Questionnaire (ITAQ). It assessed insight on two dimensions namely awareness of possessing mental disorder/symptoms, and

awareness of need for treatment. ITAQ and BPRS (Brief Psychiatric rating scale) correlated poorly in schizophrenia (Sanz *et al*, 1998).

Greenfield and colleagues (1989) constructed a schedule for assessing insight that had questions on awareness of illness, treatment compliance and perceived ability to influence the illness and identify stressors. This scale might indirectly measure IQ rather than insight as it depends on a patient's ability to respond correctly to the questions asked.

David (1990) argued on theoretical and empirical grounds that insight is composed of three different but overlapping components. These are (Appendix 2)

- A patient's treatment adherence, both expressed and observed
- Their self-recognition of suffering a mental illness
- Their ability to re-label mental disturbances (for example, hallucinations and delusions) as pathological

The Schedule for the Assessment of Insight (SAI) comprises probe questions to assess the above three dimensions. There is the expanded version of this scale which includes items on awareness of change, difficulties resulting from mental condition and key symptoms, with a maximum score of 24 plus the score for hypothetical contradiction added to evaluate the subject's capacity to take into account another person's perspective (Kemp and David, 1997).

Markova and Berrios (1992) broadened the concept and suggested that individuals hold views not only about the disorder affecting them but also about how the disorder affects their interaction with the world. Their insight scale consists of 32 items.

Amador and colleagues (1993) included awareness of social consequences in their scale for assessment of insight. This Scale to Assess Unawareness of Mental Disorder (SUMD) consists of six general items and four sub-scales from which 10 summary scores can be calculated. The SUMD requires training to administer and the reliability among raters is variable on some items.

Birchwood and colleagues (1994) proposed a self-report Insight Scale for Psychosis based on the three dimensions defined in the Schedule for assessment of Insight. It is aimed to measure change in insight.

Other approaches have been to use 'the lack of insight and judgement' item of the Positive and Negative Syndrome Scale (PANSS) as a single global measure of insight. This measure consists of seven levels from no impairment to extreme lack of insight.

McEvoy and colleagues (1993) used vignettes, which cast specific psychopathological features in every day language to judge whether patients demonstrated these features and the degree to which they attributed them to mental illness. They found that patients failed to acknowledge negative symptoms and failed to view positive symptoms as evidence of mental illness.

It is evident that the trend has been from earlier impressionistic psychodynamic based assessments of a global nature to the use of operationalised definitions and standardised instruments. Although the different instruments may measure different aspects of a complex phenomenon there is an agreement that the concept of insight embraces more than one construct.

Criticisms

The above instruments for measurement of insight attract their share of criticism as the concept of insight in itself has poor construct validity. Medical anthropologists have criticised the concept of insight for failing to recognise that people can have various culturally shaped frameworks to explain their illnesses, all possibly valid. From this point of view, the concept of insight is "eurocentric and essentially arrogant" (Perkins and Moodley 1993). This is reflected in the various scales used to assess insight, which categorically exclude the socio demographic axis.

The various definitions and measurement of insight give the impression that apart from agreeing that they are mentally ill and requiring treatment, patients need to agree to re-construct their experiences within the terms and concepts of Western psychiatry. Social and cultural backgrounds influence perceptions of stigma from mental illness. For example, the ability to relabel mental phenomena as abnormal beliefs are

embedded in beliefs about the causation of mental illness. Though there are very few studies in this area, evidence seems to be emerging that socio-cultural and demographic factors are important in insight and the diagnosis and outcome of psychopathology.

Insight and symptoms of psychosis

There are conflicting views on the relationship between insight and psychopathology. Various American studies have demonstrated that certain aspects of psychopathology are associated with non-compliance. These include higher rates of paranoid symptoms, hostility, perplexity, frank delusions and hallucinations about medication (Hoge *et al*, 1990; Marder *et al*, 1983). Depressive feelings and demoralisation are also associated with poor compliance (Pan and Tantam, 1989). Cognitive impairment resulting from severe psychosis may impair a patient's understanding of a need for treatment (Young *et al*, 1993).

Rossell *et al*, (2003) found an inverse correlation between insight, delusions and thought disorder. On the other hand, McEvoy *et al*, (1989) compared insight and psychopathology in 52 patients diagnosed as schizophrenia according to the DSM-111 criteria (American Psychiatric association, 1980) and found no consistent relationship between the level of psychopathology and insight over time. In a metaanalysis of the topic, it was concluded that there might be a small negative relationship between insight and positive and negative symptoms (Mintz *et al*, 2003).

If there is a relationship between insight and the severity of psychosis, it is rather weak and possibly non linear. Alternatively, it is possible that certain aspects of insight - as compliance with medication- are associated with the severity of psychosis rather than the whole concept. There is little knowledge about the relationship of the components of insight and psychopathology.

Insight and outcome

The validity of the concept of insight in schizophrenia is widely questioned amongst experts, as no consensus exists with regard to aetiology, prognosis and treatment of

the illness. Insight entails patients' views on the value of compliance with medication, the implications of their illness and its effect on self and others and understandably there is no consensus on the impact of improved insight on the prognosis of psychosis. Several questions must be answered before any conclusions can be drawn from existing literature with regard to the question of whether there is any association between increased insight and better outcome. These include validity of methodology, definition of insight used and definition of outcome.

Some studies have shown measures of insight to be correlated with the course of the illness (Amador *et al*,1993); rates of rehospitalisation and compliance with treatment post discharge (McEvoy *et al*,1989b). Other studies have related improved insight in psychosis to increased suicidal risk in schizophrenia (Amador *et al*, 1996) while, conversely, schizophrenic patients with poor insight have been found to have better outcomes and quality of life rating scores in spite of poorer treatment compliance (Dickerson *et al*, 1997).

The importance of neuroleptic treatment in schizophrenia is now widely accepted and prognosis of illness is associated with compliance (Vaughn and Leff 1976). Non-adherence is a major contributor to relapse and rehospitalisation (Green, 1998; Hayward *et al*, 1995), resulting in high costs for the National Health Service (NHS). The incidence of non-compliance in psychosis varies between 10 and 80 per cent (Babiker, 1986; Young *et al*, 1986). It has been reported that between 24 and 63% of schizophrenia out patients fail to take the correct drug in the correct dosage (Van Putten 1974; Renton *et al*, 1963).

Compliance within itself is a much more complex phenomenon affected by social, cultural and demographic factors and beliefs about health and sickness. The relationship between compliance and other aspects of insight may also be different and it may be possible that outcome in schizophrenia may not be associated with insight as a whole but may vary with its different constructs. It is important to discuss each individually.

Insight and compliance

Non-compliance consists of a wide variety of behaviours, including failure to enter a treatment programme, premature termination of therapy and incomplete implementation of instruction (Blackwell, 1976). A number of reviews (Fenton *et al*, 1997; Kampman and Lehtinen, 1999; Lacro *et al*, 2002) have identified factors linked to poor compliance. These include demographic factors, socio-economic status, lifestyle and attitudes towards illness and medication, side effects from medication, style of service delivery and psychopathology. Models generated through compliance research explain some of these variables. These include (Blackwell, 1992):

- *Biomedical model*: Focuses on aspects of treatment regimens. This model ignores social and interpersonal factors.
- *Operant behavioural model*: Emphasises environmental reward systems and teaches specific skills to model behaviour. Ignores less conscious motivations and is a less individualised approach.
- *Educational model*: Focuses on communication between provider and patient. This model may ignore attitudinal and interpersonal factors.
- *Health belief model*: Considers attitudinal factors as subject to rational appraisal by patient. This may ignore unconscious or socially determined behaviours.
- *Self-regulatory systems model*: Examines congruence between patient and practitioner with respect to illness representation, coping behaviour and appraisal of action. It is multivariate and difficult to apply.

Compliance and demographic factors

There have been conflicting reports on the association of age and compliance with treatment. While some studies have shown no association (Turner *et al*, 1970; Buchanan, 2000), others have found a significant association between increasing age and better compliance (Myers, 1975). Sellwood and Tarrier, (1994)) concluded that although age bore a significant relationship to compliance in certain sub groups, overall this factor did not have a major impact on compliance.

Gender of the patient does not consistently affect the likelihood of compliance with treatment (Buchanan, 2000), although Tunnicliffe and colleagues (1992) found in their study that men were less likely to comply with medication than women were. Often the differences found are trivial or in specialised groups. Cultural factors certainly come into play, especially for the African Caribbean group (Tunnicliffe *et al,* 1992). Sellwood and Tarrier (1994) reported that gender and ethnicity were significant predictors of non-compliance in schizophrenia and there was a 31% chance that male African Caribbean would refuse prophylactic medication. African Caribbean were also less likely to accept psychiatric help. The authors attributed these results to two possible causes. One was that the subjective experience of medication was different in different ethnic groups and secondly, it was possible that African Caribbean patients received larger doses of neuroleptic medication than other groups.

There is an association between low socio-economic status and poor compliance (Winkleman, 1964; Young *et al*, 1986). This effect may be associated with social stability through areas of residence, occupation, marriage and support networks (Mwaba and Molamu, 1998). Lack of family support is an important predictor (Piatowska and Farnill 1992), although this finding has been challenged (Tunnicliffe *et al*, 1992).

Insight into acceptance of illness and compliance

Patients with schizophrenia often deny or are unaware of their mental illness (Amador *et al*, 1994). Illness symptoms may be attributed to life stresses, outside forces or other predicaments and the need for compliance may not be recognised. The attitudes and belief systems of patients related to illness, specifically mental illness contributes towards help seeking behaviour (Sullivan *et al*, 2000), their compliance with treatment (Amador and Strauss, 1993) and hence decreased rates of rehospitalisation (McEvoy *et al*, 1989b). Acceptance of illness leads to development of better coping strategies by patients (Solano and Whitbourne, 2001) and a better quality of life.

Socio demographic variables may be associated with non-acceptance of illness. In a study of 60 consecutive acute admissions to wards serving an inner city area in London (Perkins and Moodley, 1993), the results indicated that 55.8% of the sample did not consider themselves to have psychiatric problems; 15.4% said they had no problems at all and 40.4% thought they had physical or social problems rather than psychiatric ones. Significantly, more of those who denied problems had compulsory admissions. African Caribbean were more likely to consider that they had no problems at all and to be admitted compulsorily. The authors have attributed this difference to the stigma of mental illness added to the burden of oppression in this group, making acknowledgement of illness more difficult.

Pyne and colleagues (2001) used a simple self-report measure to identify patients who did not believe they were mentally ill and analysed the relationship between illness belief and sociodemographic, clinical and attitudinal factors. Of the 177 inpatients and outpatients studied, 37% did not believe they were mentally ill. Younger age (less than 30 years), fewer depressive symptoms, perceived medication efficacy, greater satisfaction with current mental health and less concern with stigma were some of the associations with illness non belief. An explanation used by them to explain this finding was that patients less than 30 years old were very early into their illness history implying that insight into presence of an illness appeared at a later age. They have emphasised the role of educational interventions among this group. However, their measure of illness belief was based on a single question.

Insight into awareness of illness and depression

Although awareness of illness is important, it can lead to development of depression in psychotic patients. Birchwood and Iqbal (1998), following their study of post psychotic depression, found that patients reported greater insight into their illness supporting the belief that psychosis is what patients are depressed about. For the same reasons, insight has also been defined as 'a global capacity for realistic thinking or capacity for accurate perceptions of self, the environment and future. Distortions in self-awareness in the form of overly positive judgements and perceptions are

associated with positive mood states. On the other hand, more accurate and realistic views of the self can cause depressive states (Kiersky, 1998).

In conclusion, although awareness of illness is important for better compliance with treatment and indirectly better prognosis, depression is a potential side effect of the same. The relationship may be non linear.

Insight into relabelling psychotic symptoms

It may be appropriate to view normal experience and psychosis as two ends of a continuum. Focussing on individual symptoms of psychosis helps to understand the origin of the delusion or the hallucination and the pathways that lead to systematisation of the delusion and their maintenance. This can help the patient and therapist to understand the personal significance of the symptom, which may be a source of distress depending on the content. Understanding and developing control over symptoms can reduce distress and may improve compliance.

The concept -that normal belief formation processes may be involved in formation of bizarre beliefs and symptoms of psychosis-may be difficult to understand but a study into history leaves little doubt about the importance of beliefs in the lives of humans. Among others, the accounts of the holy crusades, witch trials, strange concoctions that were said to cure cancer, reading of horoscopes, search for love – make us realise that much of the cultural evolution over the past thousands of years may aptly be described as behaviour organised around beliefs.

Maher (1988) suggests that the mechanisms that produce delusions are no different from the cognitive psychology of a normal believer, a view emphasised by cognitive behaviour therapist that delusions are on a continuum from normal experiences. Different cultures have different ideas of normality. Indeed, at any one time, several different explanations of the same events may circulate together among social groupings. For instance in the middle ages, Bubonic plague amongst other explanations was considered to be due to a number of culturally accepted natural and supernatural causes including conspiracy of certain ethnic groups, divine interventions

and bad smell. Small pox, draught and famines were again the curse of Gods in ancient India. Epilepsy was considered to have a divine origin for years although medical opinion challenged this view. Similarly syphilis, was considered to be a symbol of punishment and the fear of the same fed by guilt of promiscuity, could lead to hypochondria cal delusions of suffering from the disease. It would also give rise to delusions of guilt; ' I have done something wrong to deserve it'. This can further lead to passivity phenomenon and reference to supernatural being in the religious sense or internalisation of guilt.

The same view is emphasised by Sacks and colleagues (1974) who elegantly demonstrated that recovery from delusions involves three phases, i.e.

- The delusional phase
- Double awareness, where a patient establishes distance from the delusion and questions its reality
- The non-delusional phase

Similarly, Brier and Strauss (1983) describe three phases of self-control in psychotic disorders as:

- Self-monitoring and awareness of the existence of psychotic and prepsychotic behaviour
- Self-evaluation of these behaviours
- Employment of mechanisms of self-control

The above arguments suggest that it is possible to help the patient to understand their psychotic symptoms and weaken the strength of the delusion. Kingdon and Turkington (1994), have discussed that strength of the belief may depend upon:

- The time period over which the belief has been present
- The psychological and social consequences of relinquishing the belief – more so if an individual has acted on his delusion for a long time and faced repeated confrontation leading to entrenchment

- The opportunity to discover alternative explanations, and the manner in which these explanations are presented i.e. the degree of collaborative information gathering as opposed to didactic statements of fact
- The quality of the relationship with the therapist including such parameters as trust, empathy, honesty and personal disclosure

In summary, contrary to earlier thinking, it may be possible to weaken the strength of a delusion and help psychotic patients to understand their symptoms as pathological, which in turn would increase insight and compliance and help reduce distress.

Section 1.2: Psycho-educational Therapies and Insight in Schizophrenia

The updated Cochrane review on psycho-educational therapies in schizophrenia suggests that psycho-educational approaches are useful as a part of the treatment programme for people with schizophrenia and related illness. It reviewed all relevant randomised controlled trials focusing on psycho-education for schizophrenia and/or related serious mental illnesses involving individuals or groups. Outcome measures like compliance and relapse rates showed improvement and secondary outcome measures like insight and medication related attitudes on overall satisfaction with services of patients or relatives did not, but these findings rested on very few studies. Health economic outcome was only measured in one study and data were skewed. It was not possible to analyse whether different duration or formats of psycho-education influenced effectiveness. The review concluded that the fact that the interventions are brief and inexpensive should make them attractive to managers and policy makers. It recommends that better designed, randomised studies investigating the efficacy of psycho-education are conducted and reported (Pekkala and Merinder, 2002).

The problem of non-compliance in many medical conditions like diabetes, heart disease etc was recognised relatively early and compliance improving measures have been part of the treatment plan. Historically in psychiatry, literature has focussed on the biological model of the illness and treatments for severe mental illness such as schizophrenia have focussed on medication.

Recently there has been more acceptance of the stress vulnerability model, which suggests that, the interaction between biological, psychological and social factors for an individual are important in the formation of psychotic symptoms. This, with increased awareness of the fact that medication cannot completely eradicate psychotic symptoms and prevent relapse and the role of expressed emotion with a general rise in user involvement, has led to more awareness into the need for psychosocial treatments (Tarrier *et al*, 1999).

Psychosocial treatments for schizophrenia can be divided into three general categories:

- Family interventions
- Cognitive behaviour therapy for psychotic symptoms
- Early signs monitoring and early intervention

Each of these areas uses the following strategies:

- Support and educate individuals and families
- Provide specific skills training, e.g. social skills
- Problem or symptom focussed, e.g. CBT

In the past, most educational packages aimed towards the family and there are very few well designed empirically tested studies involving patients. The starting point for psycho-educational programmes for patients with schizophrenia was the result of studies showing a high informational deficit among them. Following this, a number of studies have evaluated the outcome of psycho-educational programmes carried out in different settings with different outcome measures.

In two meta-analytical studies of patient education used in chronic medical and psychiatric conditions, Mullen and colleagues (1985) concluded that educational interventions influence both knowledge and drug use errors; Mazzuca (1982) concluded that it improved compliance. There is no agreement as to which ingredients of these programmes effectively improve outcomes in psychotic illness.

In a review paper on patient education in schizophrenia, Merinder (2000) has deducted that seven out of nine short educational programmes (<10 sessions) had an impact on knowledge and compliance whereas four out of four studies with long interventions (>= 10) had an impact on knowledge and three out of four on compliance. Information on efficacy concerning insight and satisfaction is limited, although there may be an interaction between the individuals illness model and the professional disease model and would affect outcome of the intervention. He also

concluded that interventions using a behavioural component are more efficacious in improving compliance, thus suggesting that an education programme addressing compliance, in order to be efficacious should be multidimensional.

Some studies describe patient characteristics that determine outcome with particular models of psycho-educational intervention. Munetz and Roth (1985) established that younger patients (< 50 years) despite starting with higher baseline knowledge, retained acquired knowledge at follow up as opposed to older patients (> 50 years) who did not. Merinder and colleagues (1999) found no prediction of education gains by gender. Macpherson and colleagues (1996) found in a multivariate analysis that negative symptoms (measured by PANSS) and the dose of the antipsychotic medication were both significantly related to educatibility.

In summary, educational packages for patients with schizophrenia may influence certain aspects like knowledge and compliance with treatment. The effect on other aspects remain ill researched.

Cognitive Behaviour Therapy in Schizophrenia

The updated Cochrane review for cognitive behaviour therapy in schizophrenia (Cormac *et al*, 2003) reviewed twenty-two relevant papers describing thirteen trials. They found that cognitive behavioural therapy in addition to standard care did not significantly reduce the rate of relapse and readmission to hospital when compared with standard care alone. A significant difference was observed however favouring cognitive behavioural therapy over standard care alone, in terms of being able to be discharged from hospital. They also found that a cognitive behavioural therapy approach focusing on compliance may have some effects on insight and attitudes to medication, but the clinical meaning of these data was found to be unclear. When compared with supportive psychotherapy, cognitive behavioural therapy had no effects on relapse rate and clinically meaningful improvements in mental state.

The review concludes that Cognitive behavioural therapy is a promising but under evaluated intervention. Currently, trial-based data supporting the wide use of cognitive behavioural therapy for people with schizophrenia or other psychotic illnesses are far from conclusive. There is justification for more trials, especially in comparison with a lower grade supportive approach. They recommend that the design of these trials should be both clinically meaningful and widely applicable.

Recent studies have shown cognitive behavioural therapy (CBT) to be of benefit in the treatment of the positive symptoms (hallucinations or delusions) (Tarrier *et al*, 1998) and negative symptoms (Sensky *et al*, 2000) of schizophrenia.

Cognitive behaviour therapy is acceptable to the patient as it uses a collaborative approach, but involves investment of time of highly skilled health care practitioners and hence is not widely available in the United Kingdom. The National service framework (1999) has highlighted evidence of its effectiveness. The NICE guidelines for schizophrenia (2003) recommend the availability of CBT for patients with schizophrenia and their families.

Cognitive behaviour therapy Research

Cognitive behaviour techniques in psychosis were first used in 1952 by Beck in a patient who believed he was being followed and watched by the FBI. The patient was encouraged to trace the antecedents of the delusion and reality testing was used. Beck and colleagues followed this earlier work with a description of eight patients of who half appeared to improve using cognitive techniques (Hole *et al*, 1979).

This has been followed by a number of studies some of which are highlighted in the following table.

Table 1.1: Cognitive Behaviour Therapy Research

Author	No	Target symptom	Design	Outcome
Chadwick & Lowe, 1990	6	Delusions	Belief modification Individual, 1hr weekly	Five/ Six showed considerable drop in conviction of delusional belief
Kingdon & Turkington, 1991, 1994	64	Psychotic symptoms in outpatients	Normalising rationale, individual variable length and frequency of sessions	35/64 patients improved in acute psychotic symptoms
Haddock *et al*, 1996, 1998b	34	Hallucinations	Random assignment to Focussing/Reattribution group. Individual, I hr weekly	Treatment group showed reduction in voices and disruption caused by them; not maintained at follow-up.
Drury *et al*, 1996	40	Positive psychotic symptoms	RCT; CBT vs. structured activities over 12 week period	Reduction in delusional conviction; 9 month: CBT fewer positive symptoms. Recovery time reduced by 25% to 30%.

Author	No	Target symptom	Design	Outcome
Lecompte & Pelc, 1996	64	Positive symptoms	RCT; CBT and treatment as usual	Length of hospitalisation dropped in 1st year- 53.3 days to 30.2 days in CBT, & 48.9 to 43.4 days in control.
Garety et al & Kuipers et al, 1997, 1998	60	Medication resistant positive symptoms	RCT: 9-month treatment period. Individual, 1 hr or less, weekly then biweekly.	BPRS fell by 25%. No change in control at 9 and 18 months.
Jackson et al, 1998	80	Secondary symptoms after first episode	Group comparison: CBT vs. refusers vs. outside catchment area. Individual 40 min every week or 2 weeks	CBT group better than refusers on integration sealing over measure; difference in relapse rates as well

Cont:				
Tarrier *et al*, 1998, 1999	87	Outpatients stable on meds	Coping strategy enhancement; RCT; CBT vs. problem solving	CBT group eight times more likely to have 50% improvement in psychotic symptoms than other group; at 1yr CBT group had lower score on positive symptoms.
Sensky *et al,* 2000	90	Psychotic symptoms	RCT; CBT vs. befriending	Significant differences in positive and negative symptoms at 18 months

Cognitive behavioural therapists have long argued that insight, and indeed many other symptoms, are best explained through a continuum model. This allows the patient not to feel totally cut off from 'the normal world'. Secondly, if symptoms are indeed on a continuum, patients may feel less inclined to despair (Kingdon and Turkington, 1994). Thirdly, it has a deep impact on the stigmatisation process reminding the patient that everybody fluctuates - obviously more or less - up and down on his or her personal continuum. The patient should ideally discover that s/he himself has a certain degree of control of his present position on the continuum.

Cognitive behaviour therapy uses a collaborative approach between the patient and therapist in the form of guided discovery (re the origin and meaning of the symptom to the patient) and seeks to change errors like misinterpretations or biases in cognition. It involves exploring and rediscovering assumptions about self, the world and future and focuses on problem solving and development of better coping mechanisms.

Once the therapist has insight into the origin and meaning of the symptom, various options can be used to modify them.

- Belief modification: This involves challenging the belief and pointing out the irrationalities in the belief; reality testing of the belief, which is an actual test of the belief. Through the above studies, these techniques have shown to reduce the delusional conviction. Nevertheless, in most cases, outcome measures are based on self-report of the patients at the end of therapy sessions.
- Normalising rationale: Stressful events contributing to the illness are elicited and are used to explain the illness in a nonstigmatised way. This technique assumes that health and illness lie on a continuum.
- Reattribution: This is used for patients with persistent auditory hallucinations. The characteristics of the voices are assessed, explained and then the therapist aims to reformulate the voices as self generated by the patient.

- Education and coping strategies enhancement: The aim is to work with positive and negative symptoms and develop the patient's skills to cope with the illness better. It may also be useful in relapse prevention.

In a review of studies of cognitive behaviour therapy in schizophrenia, Dickerson (2000) has concluded that CBT is most beneficial in reducing conviction about and distress related to delusional beliefs. None of the studies she reviewed has focussed on patient characteristics that predict response. Not many studies have focussed on insight of the patient.

There are proposals of normalising rationales as well as other explanations – both psychosocial (vulnerability/stress) and biological – to improve understanding in schizophrenia (Kingdon and Turkington, 1994). In addition, adherence has been effectively improved by a brief Cognitive behaviour therapy (CBT) intervention in patients with schizophrenia (Kemp *et al*, 1996). The effect has been shown to be durable at short-term follow-up (Kemp *et al*, 1998) and the intervention (compliance therapy) to be cost-effective (Knapp and Healey, 1998).

Section 1.3: Conclusion

Schizophrenia is a chronic debilitating illness and lack of insight in patients with this illness has implications. There is a consensus that insight is a multi-faceted phenomenon although there are differences in opinion regarding the number of dimensions. Social and cultural aspects have not received sufficient attention although they have a role in determining a person's insight. Again, demographics of patients have a role in the outcome of the illness and hence would have a bearing in the outcome of an intervention study.

The various dimensions of the concept of insight studied are probably overlapping but their inter-relationship is not clear. There is some evidence that moderate correlations exist between different aspects of insight. It is also possible, as common clinical experience would show, for patients to manifest some aspects of insight and not others, such as having an awareness of mental illness but being unable to relabel their experiences as pathological.

Most studies have concentrated on improving either insight as a whole or any one dimension for e.g. compliance, using various techniques such as psycho education, motivational interviewing, or other models based on cognitive behaviour therapy or behaviour therapy. Few studies have looked at the differential effects of improving components of insight or explored the concept of partial insight, its implications and the relationship of the components between themselves and with psychopathology in schizophrenia. Another area less frequently researched is if any particular symptoms of psychosis are closely associated with differential levels of insight. As discussed above, increase in insight may lead to symptoms of depression. However little is known as to change in which components of insight leads to depression.

Studies have shown cognitive behavioural therapy (CBT) to be of benefit with psychotic symptoms but there is not much research on the effects of CBT on insight and its various constructs in schizophrenia.

CHAPTER 2: HYPOTHESIS AND OBJECTIVES OF THE STUDY

The hypothesis and objectives of this thesis form a sub analysis from the insight into schizophrenia study, which involves the use of a short insight-focussed cognitive behaviour therapy programme for patients with schizophrenia in the community. The proposition is that this form of therapy is an acceptable, effective and safe adjunct to neuroleptics and other psychosocial interventions. It may improve compliance with treatment, patient's understanding of their symptoms and acceptance of illness that may again lead to better coping, reduced disability and a better quality of life. The main insight study has analysed the change in total insight and psychopathology following therapy (Turkington *et al*, 2002).

Hypotheses

With a short insight focussed Cognitive behaviour therapy programme delivered by trained nurses to patients with schizophrenia in the community:

1. There is a difference in change from baseline to follow-up (three months and one year) in each of the three components of insight between the two treatment groups (intervention and treatment as usual); the components being:

    - Insight into compliance with treatment
    - Acceptance of illness
    - Relabelling psychotic phenomenon as pathological

2. There is a correlation between the components of insight and this may change with therapy

3. After controlling for treatment effect there is a differential change in total insight scores with the demographics of participants at three months and one year follow up.

4. There is a correlation between baseline scores of psychotic symptoms and baseline insight scores (total and components). The psychotic symptoms being (CPRS, appendix 3): Feeling controlled, disrupted thoughts, ideas of persecution, ideas of grandeur, other delusions, commenting voices and other auditory hallucinations.

5. There is an association between baseline scores of individual psychotic symptoms and change in total insight after controlling for therapy.

6. There is an association between change in individual psychotic symptoms and change in insight and its components after controlling for therapy.

7. There is a correlation between components of insight and total psychopathology measured by the Comprehensive psychopathological rating scale and this may change with therapy.

8. There is an association between change in total insight and its components and change in symptoms of depression after controlling for treatment (Depression assessed by the Montgomery Asberg Depression scale, Appendix 4)

Objectives

Based on the above hypothesis, this sub analysis has the following objectives:

With a short insight focussed Cognitive behaviour therapy programme delivered by trained nurses to patients with schizophrenia in the community:

1. To analyse a difference in change from baseline to follow-up values of each of the three components of insight between the two treatment groups (intervention and treatment as usual) at three months and one year follow up.

2. To determine if there is a correlation between the components of insight and whether this changes with therapy.

3. After controlling for treatment effect to determine if there is a differential change in total insight scores with the demographics of participants at three months and one year, follow up.

4. To determine if there is a correlation between baseline scores of psychotic symptoms and baseline insight scores (total and components). The psychotic symptoms being (CPRS, Appendix 3): feeling controlled, disrupted thoughts, ideas of persecution, ideas of grandeur, other delusions, commenting voices and other auditory hallucinations.

5. To determine if there is an association between baseline scores of individual psychotic symptoms and change in total insight after controlling for therapy at three months and one year.

6. To determine if there is an association between changes in individual psychotic symptoms and change in insight and its components after controlling for therapy at three months and one year follow up.

7. To determine if there is a correlation between components of insight and total psychopathology measured by the Comprehensive psychopathological rating scale and whether this changes with therapy.

8. To determine if there is an association between change in total insight and its components and change in symptoms of depression after controlling for treatment (Depression assessed by the Montgomery Asberg Depression scale, Appendix 4).

CHAPTER 3: METHODOLOGY

Insight in schizophrenia is a randomised controlled multi-centre research project. An advisory board ensured that the concept of the programme was valid and monitored the progress of the project. The presentation of this thesis is based on CONSORT statement (Moher *et al*, 2001).

Unit Selection and Participant Enrolment

Six community mental health units in six locations around the UK took part in the study:

- Belfast
- Glasgow
- Hackney
- Swansea
- Newcastle
- Southampton

These units represent the spread of mental health services across inner city and metropolitan health authorities and the mix of services in the UK.

Centre Inclusion criteria

Each centre:

- Covers a minimum population of 100,000 people
- Had established community mental health teams
- Had effective shared leadership between consultant and local manager
- Had a local co-ordinator to drive the programme locally
- Was able to ensure minimum recruitment of 60 patients in order to enable comparator groups (intervention vs. control) to be run within the unit

Participant Recruitment

A list of patients with schizophrenia was constructed at each of the six sites according to the International Classification of Diseases tenth revision (ICD-10) research criteria. Compilation of lists used sources such as:

- Inpatient and outpatient case lists
- Depot clinics
- Clozapine clinics
- Community mental health team key workers lists
- Care programme approach registers
- Practice nurses lists

Patients were drawn randomly from the list to form a representative sample and to achieve robust external validity. In this way, a broad sample of stable patients with schizophrenia was selected for the study.

Responsible medical officers and key workers were approached to seek permission for the inclusion of their patients in the study. Where permission was given, the case notes were fully perused and the patients were approached by the Insight into Schizophrenia nurse employed at each site; where possible in the presence of the key workers.

Participant Eligibility Criteria

Patients were recruited to the study if they:

- Were aged 18-65 years
- Had schizophrenia diagnosed according to ICD-10 criteria

Patients were not recruited to the study if they:

- Had a coexisting brain disease

- Had a primary diagnosis of drug or alcohol dependence
- Had a learning disability severe enough to interfere with rating

Any patient who was deteriorating to such a degree as to be under consideration for a period of inpatient care or intensive home treatment was excluded from the study.

Intervention

Schizophrenia specialist nurses

Each centre was allocated a schizophrenia specialist nurse who worked as a member of the community mental health team and had a background of community psychiatric nursing. Recruitment of the Schizophrenia specialist nurses (SSN) were specific for the purpose and the following criteria were essential:

- Good communication and interpersonal skills
- Training in psychosocial interventions and cognitive behaviour therapy
- Experience of working with schizophrenia

The SSN received extra intensive training for 10 days by experts (Kingdon, Turkington) in cognitive behaviour therapy specific to the programme. They were tested on their skills through role-play and a written exam. A period of two weeks of settling into the community mental health team and getting used to local practice was allowed before referrals were accepted. Supervision consisted of a variety of methods during the study, including individual, group and telephone.

Intervention group - Therapy Sessions

The SSN saw the participants allocated to the intervention group individually for a total of six times over a period of two to three months. Carers received three sessions. Support material was provided to participants in the intervention group. Participants in the control group did not see the SSN except for enrolment. The assessor at the beginning and for follow-up assessments saw all the participants.

A therapist manual specially designed for the Insight in schizophrenia study was used by the SSN (Turkington *et al*) for the sessions. A semi-structured approach was used for therapy and treatment plans were individualised. Although the therapy was not designed specifically for the components of insight, the general design encompassed the components. A general overview of the sessions included:

- Engagement and development of an explanation
- Formulation
- Symptom management
- Adherence
- Schema change
- Relapse prevention

In all participants, the priority was to do a risk assessment at the outset and report any life threatening thoughts/behaviours to the consultant in charge of the participant. The next priority would be identification of therapy inhibiting factors such as paranoia involving the therapist or misinterpretations about the purpose of therapy. A brief description of CBT techniques used in the sessions and a case summary are presented in Appendix 5.

Carer Sessions

If the participant's carer agreed to take part in the programme, the SSN would see them for three sessions. The sessions were structured as follows:

First session:

- Explaining the programme with carer information sheet
- Obtaining consent and enrolment of the carer
- Identification of suitable carer module
- Discussion of illness and effect on their life; benefits of medication

Second session:

- Building on first session
- Use of additional modules if appropriate
- Exploring the carers attitude towards participants illness

Third session:

- Review of earlier sessions
- Assessment of changes in attitudes and progress of participants
- Review of education modules

Support materials

Five educational booklets developed specially for the study to help people with schizophrenia understand more about their illness and improve their insight formed support materials. This modular system of education aimed to act as a basis for CBT.

- About your treatment:
- Self care and lifestyle
- Leisure time and relationships
- Drug and alcohol advice
- Managing your symptoms

A further description of these booklets is presented in Appendix 5.

Treatment as usual group (TAU)

The participants randomized to this arm of the study were left to the care of their community mental health teams. The treatment as usual received by each participant depended on the individual study centre. The participants allocated to this group saw the SSN for enrolment and the assessors for ratings.

There was no face-to-face therapist time for participants in the TAU group. This can have advantages and disadvantages. The advantage is that it measures the actual effect of the therapy but on the other hand does not account for placebo effect and Hawthorne effect due to therapist.

Treatment as usual could vary in each centre depending on resources and practice followed at different centres. There was no consideration of the availability and use of psychology time for participants in this group, which may have been part of routine care.

Outcome Measures

Schedule for assessment of Insight (SAI, Appendix 2)

Devised by Anthony David, this scale rates insight on three dimensions:

- Compliance with treatment
- Acceptance of illness
- Relabelling of psychotic symptoms as pathological

Each dimension has two or three questions scored from 0 (no insight) to 2 (good insight) with a maximum score of 14.

The SAI is relatively brief, sensitive and reliable. It allows subscale analysis. The extended version was not used because the number of participants was large and the number and length of scales needed to be kept to within the limits likely to ensure patient agreement to remain in the study. Interscale reliability and concurrent validity (with SAI-expanded, ITAQ and PANSS insight item) have been demonstrated by Sanz *et al* (1998).

Comprehensive Psychopathological Rating Scale (CPRS, Appendix 3):

A well-established and sensitive tool for measuring a patient's mental state that takes the form of a flexible interview and observation. Patients are encouraged to describe

their symptoms. If necessary, specific questions are asked. There are sixty seven items in the scale, of which the first forty are interview based and the rest observed with global and reliability rating. It is an established tool for measuring change in psychopathology.

Montgomery Asberg Depression rating scale (part of the CPRS, Appendix 4):

This is a subscale of the CPRS and measures symptoms of depression on ten points.

Assessments

Participants were assessed at three months post therapy and at one-year follow up.

Assessors

Each centre had an assessor who assessed the participants at the beginning and end of the study. The assessors trained together at the start of the study for a week, at the end of which they were examined to ensure inter-rater reliability across the sites. They were examined on the outcome measures for the main insight study i.e. CPRS, SAI and HONOS. The initial correlation calculated using CPRS was acceptable at 0.71. CPRS was used, as it was the primary outcome measure for the main study.

Data recorded at study entry relevant for this sub analysis included:

- Age
- Gender
- Ethnic group
- Marital status
- Employment status
- Housing status

Sample size

Calculation of power for the study was based on pilot work carried out in Nottingham and Sheffield (Turkington and Kingdon, 2000; tables in Appendix 6). The study predicted that with 90 patients at each site (60 receiving intervention and 30 receiving treatment as usual) and assuming a 20% drop out rate there was a 90% chance of detecting a 25% difference in overall symptomatology (measured by Comprehensive psychopathological rating scale) at the 0.01 level of significance should such a difference exist. The study would therefore have adequate power to detect symptomatic change. Pilot work also suggested that this number of patients would be adequate to detect a 20% improvement in insight with an 80% chance at the lower level of 0.05 significance.

For the insight study, a clinically significant improvement in the overall CPRS score was taken as being five from the pilot study. The calculation follows:

CBT Mean Baseline score = 33	Standard deviation = 8.8
CBT Mean score at 1 month = 18	Standard deviation = 10.4
CBT Mean score at 2 months = 14.3	Standard deviation = 8.7

Befriending Mean Baseline score = 36	Standard deviation = 12.1
Befriending Mean score at 1 month = 25.7	Standard deviation = 12.6
Befriending Mean score at 2 months = 21.5	Standard deviation = 11.4

$$N = \frac{A \times \text{Standard deviation squared}}{\text{Clinically significant difference squared}}$$

$N = 10.51 \times 100/25$

$N = 42$

Assuming a drop out, N = 44.5 i.e. 45 Patients in each group. Ninety participants therefore had to be recruited into the study to have a 90% chance of detecting a mean clinically significant difference of 5 CPRS points between the two groups should such a difference exist.

Although ninety patients were required per site, a 2:1 randomisation was performed in order to allow inter-site comparisons and improve recruitment. This should not materially have affected the power of the study although it would have been better to power the study from a position of clinical equipoise.

The sample size for the insight study was determined using CPRS as the primary outcome measure. This sub analysis was not specifically powered for. Therefore, confidence intervals have been reported wherever appropriate.

Randomisation and Blinding

Participants were randomised only after full written informed consent was given. This helped to reduce selection bias by the SSN. Enrolling included:

- Ensuring the participant understood the Insight study and the reasons for the study
- An information sheet was given and explained
- Completing a consent form
- Verifying that the participant was willing to have the therapy sessions recorded on audiotape. This was optional and did not affect the programme.

Randomisation was achieved within each centre based on a 2:1 ratio to deliver six sessions of therapy to the participant in intervention group and three sessions for their carers or treatment as usual with the rating scales measured over a similar time period as the intervention itself would take. Randomisation was conducted by computer-generated blocks of six random numbers and stratified by site. The results were placed in sealed envelopes and only opened at the time of treatment allocation.

An independent research worker geographically remote from the SSN broke the code for the randomisation of that participant and informed the SSN as to whether the participant was to receive cognitive behaviour therapy or treatment as usual. The allocation list was stored remote from the SSN.

Stratifying the randomisation was by centre owing to the large numbers of participants enrolled in the study. Separate randomisation schedules for each centre ensured that each centre contributed equally to intervention and TAU groups in order to reduce bias that may arise from differing effectiveness of treatment in different centres.

Assessors were, but participants and SSNs could not be blinded to the allocation group. Assessors were informed that some study material was to be left with some treatment as usual participants to help to preserve the blindness of the ratings and to avoid assessment bias. Each participant met the SSN at the point of recruitment to the study so that mention that they had met the nurse did not necessarily mean they were in the intervention arm of the study.

All assessors noted any perceived breaches of blindness as the study proceeded and attempts to guess the participant's study group. The blindness of the assessors appeared to be satisfactory as in the three circumstances where this happened, identification of allocated group was no more than expected by chance. The statisticians were separate from assessors and an analytic strategy (described later) was devised before the data was received. Data was not coded.

All treatment as usual (TAU) participants were told that they would receive therapy (if they wished for it) at the end of the follow-up rating period so that they did not feel discriminated against and this occurred.

Patient Confidentiality

The SSN assigned each participant a special code reference. The code ensured that all the information on each participant transmitted to the database was confidential and

could not be decoded by anyone outside the programme. All information, tapes and notes were stored securely.

Treatment fidelity

All sessions were audio taped when participants agreed to this. An independent psychologist using the cognitive therapy scale (Vallis, 1986) carried out an assessment of treatment fidelity on a stratified selection of tapes (early, middle or late therapy) and confirmed this.

Action plan in the event of deterioration

In the event of symptomatic deterioration the responsible treatment agency was notified.

Participant Withdrawal

In the event that a participant wished to withdraw from the project at any time, it had no effect on their ongoing management.

Ethical Approval and Consideration

The Multicentre Research Ethics Committee (MREC) and each Local Research Ethics Committee (LREC) approved the protocol for the study. Participants were enrolled in the study only where consent was unambiguously given. Identification of participants through any analysis was not possible due to codes. All information was strictly confidential.

Statistical Analytic Strategy

All data analysis was carried out according to a pre-established analysis plan using SPSS version 9 and 10. Following advice from the statistician, it was decided that an Intention to treat analysis would not be performed although dropouts were expected. It

was felt that the results could be biased through mean imputations leading to an artificial reduction in standard error. The insight study was a pragmatic trial and the primary aim of this sub analysis was to analyse difference in change in components of insight following therapy. In an intention to treat analysis all the participants randomised into the trial are analysed irrespective of whether they stayed in the trial or not. The main advantage is that this method prevents disturbances to the prognostic balance achieved by randomisation and prevents possible bias from allowing compliance, a factor related to outcome to determine the groups for comparison. However, for this particular analysis, insight into compliance was one of the outcome measures and it was important to analyse the drop out data separately in order to determine the generalisability of the intervention.

Except for the first objective, where statistical significance was decided at $P<0.05$, for all the other objectives statistical significance was decided at $P<0.01$ level as the number of tests performed were large.

The analytic strategy agreed before receipt of the data is as follows:

1. To analyse if there is a difference in change from baseline to follow-up (three months and one year) for each of the three components of insight between the two treatment groups (intervention and TAU), Independent sample T test was decided on for normal data. A T Test is a parametric test and is used to assess the statistical significance of differences between two groups. Normality was assessed by histograms and box plots. Measure of change was constructed by subtracting baseline scores from three month and one-year scores for each of the components of insight. For non-normal data, transformation using log or a Mann Whitney non-parametric test would have been used. Wherever appropriate, repeated measure ANOVA was used to analyse data at three time points.

2. To analyse a differential change in total insight scores with the demographics of participants at three months and one year follow up Linear Regression was performed. Regression is a statistical technique, which is used when it is believed that one variable is a direct cause of the other, that is, where the values of one variable

change are a direct consequence of the other. The dependent variable would be change in insight and the independent variable the demographic. The demographic variables found statistically significant were used for Multiple Regression.

3. To analyse a correlation between baseline scores of psychotic symptoms and baseline total insight scores and components, Pearson or Spearman correlation coefficients were used depending on whether the data was normal or not respectively.

4. To analyse an association between baseline scores of individual psychotic symptoms and change in total insight, an association between change in insight and its components and change in individual psychotic symptoms and an association between change in symptoms of depression and change in total insight and its components after controlling for treatment, linear regressions were performed.

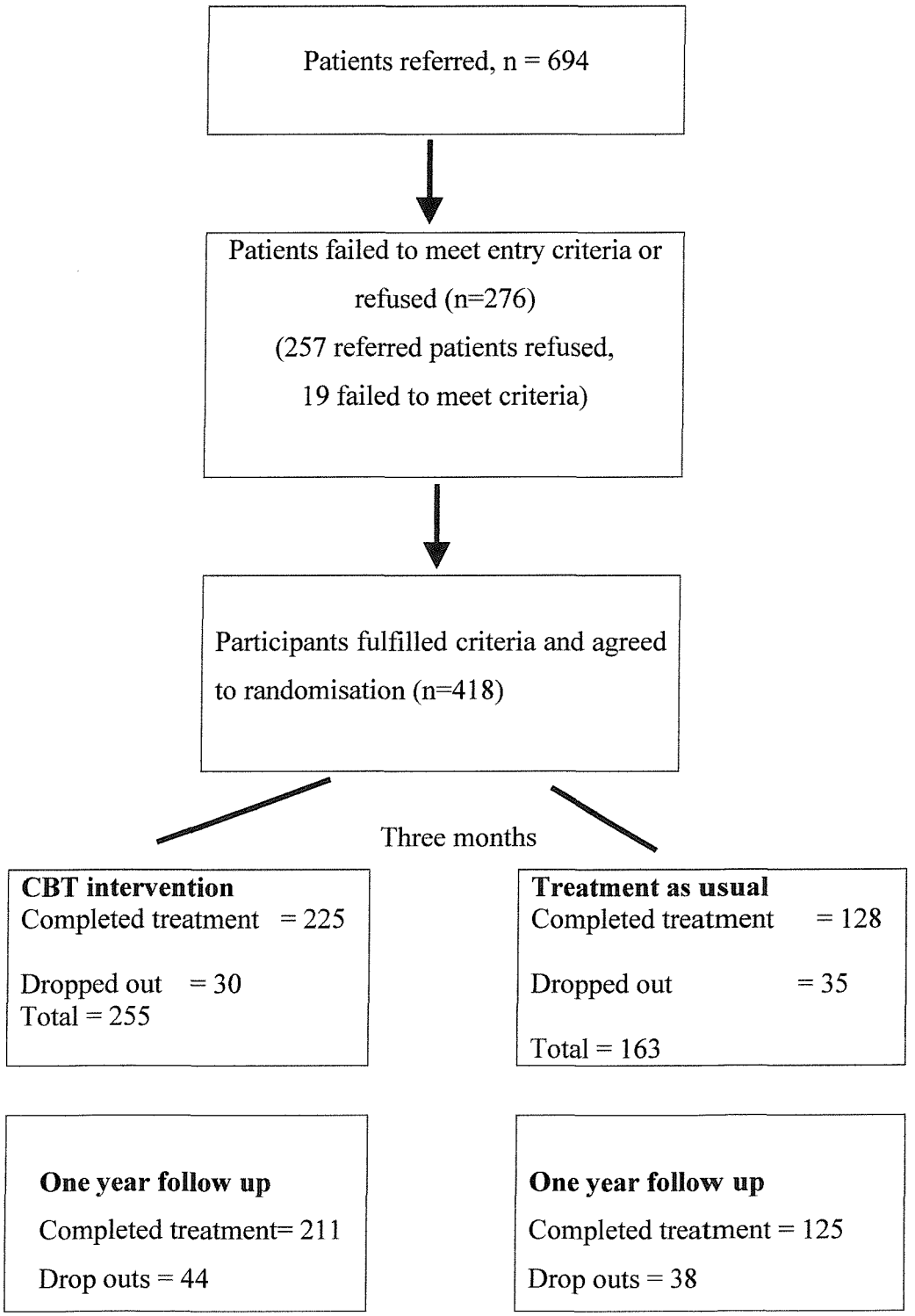
5. Analysis of a correlation between the components of insight and change with therapy and a correlation between components of insight and total psychopathology and change with therapy was by Pearson or Spearman correlation coefficient depending on whether the data was normal or not respectively.

6. Residuals were analysed for normality wherever appropriate.

CHAPTER 4: RESULTS

Participant Recruitment and Treatment Allocation

Fig 4.1: Flow chart showing participant recruitment and treatment allocation



The drop outs after randomisation (at one year) included:

- Participants who deteriorated in mental health (four in the therapy group and nine in the TAU group)
- Participants who moved out of the area (three in TAU group)
- Participants who died (two in TAU group)
- Participants who went on long holiday (two in TAU group and two in therapy group)
- Participants who went to prison (one from TAU group)
- Participants' who did not want to continue in the programme (thirty eight in therapy group and twenty one in TAU group)

Some participants who had left the study at three months returned at one year.

Dates defining periods of recruitment and follow up

The recruitment programme commenced in September 1999 and the entire programme ended following one-year analysis in May 2001.There was some variation in the start date for different participants as there was only one therapist per centre.

Baseline demographic and clinical characteristics

There were no statistically significant baseline differences between the groups. Severity, as estimated by number of previous relapses and by the number of previous days in hospital for schizophrenia was not statistically different between the groups. The intervention group had a mean of 4.71 previous admissions with a mean number of previous days in hospital being 48.53. The TAU group had a mean of 5.18 admissions and mean 52.01 days in hospital. Antipsychotic medication was calculated in chlorpromazine equivalents with the intervention group on a mean of 746.88mg equivalents and the TAU group on 886.58mg equivalents. Of those on atypical neuroleptics, 55 were in the intervention group and 25 were in the TAU group (Turkington *et al*, 2002).The following table describes the baseline characteristics of the participants.

Table 4.1: Baseline characteristics of participants

	Number	Percentage	Intervention	TAU
Gender				
Male	276	66	173	103
Female	142	34	82	60
Age (years) Mean	40.47		39.9	41.07
Marital status				
Single	296	71.09	183	113
Married	58	13.74	37	21
Divorced/widowed	64	15.17	36	28
Ethnic group				
White	354	84.6	219	135
African-Caribbean	20	4.8	14	6
Black African	14	3.3	4	10
Black other	8	1.6	4	4
Asian	7	1.4	3	4
Chinese	1	-	-	1
Other	11	2.6	9	2
Unknown	3		1	2
Employment status				
Unemployed	127	30.3	74	53
Sick/Disabled	241	57.6	150	91
Full	7	1.6	4	3
Part time	6	1.4	4	2
Sheltered workshop	12	3.0	6	6
Training	8	1.8	4	4
Student	6	1.4	3	3
Retired	5	1.3	3	2
Other	2	-	2	-
Housing status				
Independent	187	44.7	110	77
Family	110	26.30	75	35
Staffed home	91	21.56	57	34
Unstaffed home	21	5	7	14
Homeless	3	-	2	1
Unknown	6	-	4	2
Carer participation				
Treated with carer	97	43.10		
Treated without carer	128	56.90		

Table 4.2: Mean baseline scores for outcome measures, Insight, CPRS, MADRS

Measure	Mean	Standard Deviation
Total Insight		
Intervention	8.75	3.1
TAU	8.70	3.3
Component 1		
Intervention	3.25	0.99
TAU	3.31	0.88
Component 2		
Intervention	3.83	1.98
TAU	3.66	1.97
Component 3		
Intervention	1.66	1.51
TAU	1.72	1.61
CPRS		
Intervention	23.23	13.2
TAU	24.43	14.3
MADRS		
Intervention	5.5	3.9
TAU	6.1	4.5

Table 4.3: Baseline Means and Standard deviations of psychotic symptoms

	Feeling Controlled	Disrupted thoughts	Ideas of Persecution	Grandiose ideas	Other delusion	Commenting Voice	Auditory hallucinations
Intervention	0.31	0.69	0.78	0.23	0.37	0.63	0.49
SD	0.73	1.04	1.01	0.68	0.85	1.01	-0.09
TAU	0.37	0.61	0.70	0.20	0.30	0.73	0.47
SD	0.75	0.98	0.91	0.63	0.71	1.15	0.93
Total	0.34	0.66	0.75	0.22	0.34	0.67	0.48
SD	0.73	1.02	0.97	0.66	0.79	1.07	0.94

SD = Standard deviation

As is evident from the above table, the baseline mean scores for the three outcome measures, Insight, CPRS and MADRS are not significantly different in the two treatment groups.

Adverse events

One participant in the treatment as usual group committed suicide.

Drop out Analysis

1. Three month data

The number of dropouts was thirty (11.8%) for participants in the intervention group and thirty five (21.5%) for participants in the treatment as usual group. Dropouts were not more likely to be more severely ill, less insightful or more depressed.

A Pearson chi^2 test for age, gender, marital status and employment was statistically non significant. There was a statistically significantly increased dropout rate in those participants who were not Caucasian ($p<0.001$). This group comprised twenty percent of the African-Caribbean and fifty percent of the Black African participants. The conclusions stated later regarding this group might be biased by the drop out rate. Analysis of the drop out population with housing status revealed that one out of the three homeless dropped out but there were no statistically significant results. The drop out was 60% for participants with five children and this result had borderline significance ($p = 0.06$).

2. One year follow up drop out analysis

From the initial four hundred eighteen participants, at one-year follow up, eighty-two dropped out. Of these, thirty-eight (23.3%) were in the treatment as usual group and forty-four (17.3%) were from the intervention group and had received cognitive behaviour therapy.

The mean age of the dropouts was 41.33 years compared to the mean age of the non-dropouts, which was 40.48 years. The difference was not statistically significant. A Pearson chi^2 test for gender, marital status and employment was statistically non significant. There was a statistically significant dropout rate in those participants who were not Caucasian ($p<0.001$). This group comprised of sixty percent African-Caribbean and fifty percent Black African and the Black other group. The three groups together had a total dropout rate of 54%. None of the Asians dropped out.

Comparison of the mean insight scores of the various ethnic groups between those who stayed in the study and those who dropped out revealed the following information.

Table 4.4: Comparison of mean insight scores of dropouts and non drop outs at one year analysis

	Dropout	Non dropout
White	8.16	9.01
Black	8.09	6.57
Asians	No dropouts	9.43
Other	8.50	8.00

As is evident, the mean insight score for dropout blacks is better than the score for non-dropouts, whereas for the white group it is opposite. It seems that the blacks selectively dropout and this could affect the analysis results. An independent samples T test was performed to determine whether this difference in insight scores between the dropout and non-dropout population was significant. It revealed a P value of 0.06 for White and 0.11 for the Black groups. This suggests that neither difference is significant statistically and in the black group, this may be due to small numbers. An ANCOVA for dropouts in the ethnic group did not reveal statistically significant results. A study powered for the subgroup would be needed to answer this question.

The drop out was 80% for participants with five children and this result had statistical significance ($P < 0.05$). However, the numbers were very small.

CHAPTER 5: ANALYSIS OF CHANGE IN INSIGHT AND COMPONENTS

Introduction

This chapter describes the results of analysis of:

Objective 1: To analyse a difference in change from baseline to follow-up values of each of the three components of insight between the two treatment groups (intervention and TAU) at three months and one year follow up.

Objective 2: To determine if there is a correlation between the components of insight and whether this changes with therapy.

The chapter is divided into three sections.

- Section 5.1 describes the three-month analysis
- Section 5.2 describes one-year follow-up analysis
- Section 5.3 describes correlation between the components of insight

Section 5.1: Three Months Analysis of Change in Insight and components

Case summary

A total number of four hundred eighteen participants fulfilled the criteria for the study, three hundred fifty three of which were assessed at three months. Two hundred twenty five were in the intervention group (30 dropouts) and received cognitive behaviour therapy. One hundred twenty eight were in the TAU group (35 dropouts).

Table 5.1: Case summary of participants in the study at three months analysis

Change in total insight	Cases					
	Included		Excluded		Total	
	N	Percent	N	Percent	N	Percent
TAU group	128	78.5	35	21.5	163	100
Intervention group	225	88.2	30	11.8	255	100

Means and Standard deviations at three months analysis

Mean scores at three months are as follows:

Total insight- Intervention group: 9.91 (SD 3.32); TAU: 8.57 (SD 3.62)

Component 1- Intervention group: 3.54 (SD 0.95); TAU: 3.20 (SD 1.10)

Component 2- Intervention group: 4.31 (SD 1.86); TAU: 3.78 (SD 1.95)

Component 3 –Intervention group: 2.02 (SD 1.50); TAU: 1.66 (SD 1.51)

The change in total insight and its components was calculated by subtracting the initial values from the follow up values. The change in total insight ranges from a value of 0 to 14. For component 1 (treatment adherence) and 3 (relabelling psychotic symptoms), the scores range from 0 to 4, and for component 2 (acceptance of illness) from 0-6.

Table 5.2: Means and Standard Deviation for change in insight and its components at three months

	Intervention group (N = 225) Mean (SD)	TAU group (N = 128) Mean (SD)	Total (N = 353) Mean (SD)
Change in total insight	1.04 (3.37)	-0.07 (3.40)	0.64 (3.42)
Change in component 1	0.31 (1.21)	-0.08 (1.17)	0.16 (1.21)
Change in component 2	0.38 (1.96)	1.10 (1.94)	0.28 (1.95)
Change in component 3	0.36 (1.76)	-0.09 (1.69)	0.19 (1.75)

Independent samples T tests for change in insight at three months

From the frequency distributions of change in insight and components depicted by the histograms and box plots shown in Appendix 7, there are no obvious departures such as pronounced skew ness. Therefore it is reasonable to assume a normal distribution of the data. Components of insight themselves were not found to be normal. Transformation using log was attempted with statistician's assistance but was not found to be possible.

Table 5.3: Independent samples T test for change in total insight and components at three months

	T-test for Equality of Means						
	t	df	P-value	Mean Difference	SE Difference	95% CI of Difference	
						Low	High
Change in Total Insight	-2.99	351	**0.003**	-1.12	0.37	-1.85	-0.39
Change in Component 1 of Insight	-2.96	351	**0.003**	-0.39	0.13	-0.65	-0.13
Change in Component 2 of Insight	-1.30	351	0.194	-0.28	0.21	-0.70	0.14
Change in Component 3 of Insight	2.33	351	**0.020**	-0.44	0.19	-0.83	-0.07

df: degrees of freedom; SE: Standard Error; CI: Confidence Interval;

The above table shows a P value of 0.003, 0.003 and 0.02 for change in total insight and components 1 (insight into treatment adherence) and 3 (insight into relabelling psychotic symptoms) respectively. For component 2 (insight into acceptance of illness), the P value is 0.19. The inference is that the study has demonstrated a significant statistical difference between the two groups for two out of three components.

Section 5.2: Statistical Analysis of Change in Insight and components at One year

Case summary

At one-year follow-up assessment, there were three hundred thirty six participants, with two hundred eleven in the intervention group (44 drop outs) and one hundred twenty five in the TAU group (38 drop outs). Some participants who had dropped out from the initial assessment came back to the study for a follow up assessment.

Table 5.4: Case summary of participants at one year follow up

		Valid		Missing		Total	
		N	Percent	N	Percent	N	Percent
Change in Insight	TAU group	125	76.7	38	23.3	163	100
	Intervention group	211	82.7	44	17.3	255	100

Mean scores of insight and components at one year

Mean scores at one year are as follows:

Total insight- Intervention group: 9.18 (SD 3.61); TAU: 8.47 (SD 3.78)

Component 1- Intervention group: 3.50 (SD 1.03); TAU: 3.16 (SD 1.20)

Component 2- Intervention group: 4.18 (SD 2.06); TAU: 3.90 (SD 1.96)

Component 3 –Intervention group: 1.49 (SD 1.52); TAU: 1.40 (SD 1.53)

Change in Total insight at One-year analysis

Change in total insight was recorded in three time points, i.e. baseline, three-month assessment and one-year assessment. In order to look at change, Analysis of covariance was performed, as the sample was normally distributed (Appendix 8).

The General Linear Model Repeated Measures

This procedure provides analysis of variance when the same measurement is made several times on each subject or case. If between-subjects factors are specified, they divide the population into groups. Using this general linear model procedure, the null hypotheses about the effects of both the between-subjects factors and the within-subjects factors can be tested. Interactions between factors as well as the effects of individual factors can be investigated. In addition, the effects of constant covariates and covariate interactions with the between-subjects factors can be included.

Using the above test, a significant interaction was found between treatment and time for change in total insight. The F statistic is 3.59 on two and three hundred and ten degrees of freedom with a P value of <0.05. There is a significant difference over time and with treatment and there is a time treatment interaction. In order to show the difference, the means of change over time are present in the table below.

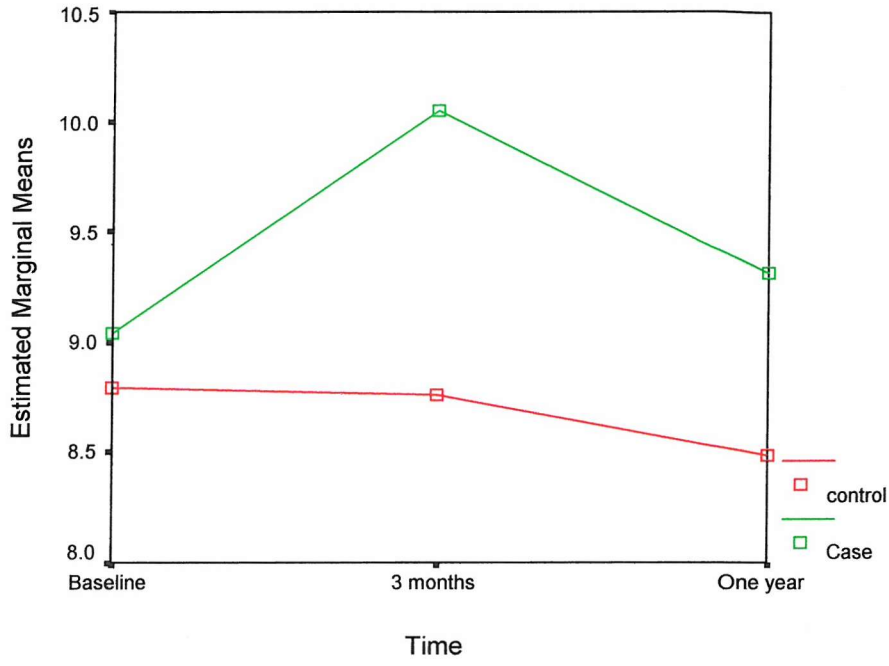
Table 5.5: Means of total insight at various assessments

		Total baseline insight	Total insight at three month follow-up	Total insight at one year follow-up
TAU group	Number	163	128	125
	Mean	8.71	8.57	8.47
	SD	3.28	3.63	3.78
Intervention group	Number	255	225	211
	Mean	8.75	9.92	9.18
	SD	3.10	3.32	3.62
Total	Number	418	353	336
	Mean	8.73	9.43	8.92
	SD	3.17	3.49	3.69

SD = Standard deviation

The above table shows an improvement in insight for the participants in the intervention group from baseline to first assessment (8.75 at baseline and 9.92 at first assessment). The one-year follow-up assessment shows a drop in the total insight score, although it is not to baseline level. There is a consistent drop in insight scores from baseline for the TAU group. In order to further investigate the difference in insight between cases and controls, the means were plotted on the following graph. Another observation from the table of mean insight is that in the case of TAU group, the mean insight has remained nearly the same during the treatment period (8.71 & 8.57).

Fig 5.1: Mean of total insight at different assessments showing change



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The above graph clearly shows a higher insight score for participants who received therapy as compared to TAU group and agrees with the statistically significant P values in the General linear model repeated measures test. It is also known that the difference in change in insight between the two groups at three-month analysis was statistically significant.

In order to analyse whether, following an initial significant difference (three months) between the groups, the rate of decline was statistically significant, Independent samples T test was performed to measure the difference in change in total insight from the three month analysis to the one-year analysis. The analysis revealed: T = 0.01; degrees of freedom = 311; P = 0.26; mean difference = 0.46; Confidence interval = - 0.35 & 1.27. This suggests that once the cases have stopped being treated, the improvement in insight begins to decline.

Change in components of insight at one-year analysis

The General linear model repeated measures test was not appropriate for the components of insight, as the individual components did not represent a normally distributed sample. The change in components of insight did represent a normal distribution (histograms and box plots are presented in Appendix 8). Independent samples T test was used to analyse the difference in change between the groups from baseline to one year assessment scores and from three months to one year assessment.

Means and Standard deviations for Change in Components of Insight at One year

Following is a Table of Means and Standard Deviation for change in components of insight at one-year follow up:

Table 5.6: Table of Means and Standard Deviation (SD) for change in components of insight at one-year follow up

	Intervention group (N = 225) Mean (SD)	TAU group (N = 128) Mean (SD)	Total (N = 353) Mean (SD)
Change in component 1	0.22 (1.25)	-0.15 (1.42)	0.08 (1.33)
Change in component 2	0.30 (2.13)	0.13 (2.09)	0.24 (2.12)
Change in component 3	-0.22 (1.90)	0.39 (1.90)	-0.28 (1.90)

Independent samples T tests for change in components of insight at one year:

From the frequency distributions depicted by the histograms and box plots in Appendix 8, there are no obvious departures such as pronounced skew ness, hence it is reasonable to assume a normal distribution of the data. Independent samples T test was done to detect a significant change in insight and its components at one year follow up.

Table 5.7: Independent samples T test for change in components of insight at one year

	T-test for Equality of Means						
	t	df	P-value	Mean Difference	SE Difference	95% CI of Difference	
						Low	High
Change in Component 1 of Insight	-2.54	334	**0.012**	-0.37	0.01	-0.67	-0.08
Change in Component 2 of Insight	-0.71	334	0.474	-0.17	0.24	-0.64	0.29
Change in Component 3 of Insight	-0.78	334	0.433	-0.17	0.22	-0.59	0.25

From the above table it is evident that the only statistically significant changes in insight for intervention group at one year follow up is for component one or insight into compliance with medication. Change in component three which was significant at three month assessment is statistically non significant at one year follow up. In order

to study the pattern of changes for the components of insight over time and treatment the means have been plotted on a graph.

Component One of Insight (Insight into need for compliance with treatment)

Following is a table of means for component one of insight at baseline, initial and one-year assessment.

Table 5.8: Table of means for component one of insight at baseline, initial and one-year assessment

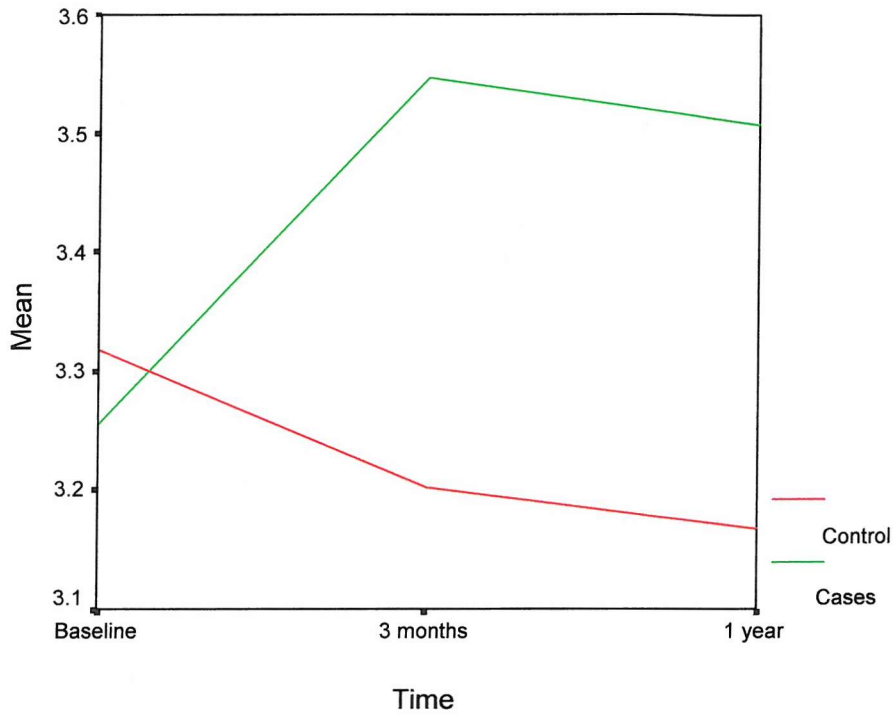
		Total baseline insight, component1	Total insight 1at three month follow-up	Total insight 1at one year follow-up
TAU group	Number	163	128	125
	Mean	3.32	3.20	3.17
	SD	0.88	1.10	1.20
Intervention group	Number	255	225	211
	Mean	3.25	3.55	3.51
	SD	0.99	0.95	1.04
Total	Number	418	353	336
	Mean	3.28	3.42	3.38
	SD	0.95	1.02	1.11

SD = Standard deviation

The above table shows an improvement in the mean component 1 of insight for participants in the intervention group following therapy at three-month assessment. There is a small drop at one-year follow-up although it is above the baseline mean. In the case of TAU group, the mean component 1 of insight progressively declines with time from baseline assessment.

This result is reinforced by the significant P value of 0.012. This difference is shown in the following graph of means for component one of insight.

Fig 5.2: Graph of means for component one of insight



It is already known from previous analysis that the difference in change in Component 1 of insight between the two groups is significant at three-month analysis. There is a drop in mean score at one-year follow up. A regression to mean would have been expected over time as the effect wears out. This seems to have maintained in this component.

In order to detect whether this decline is significant between the two groups a T test was done on the change in scores from three months to one year. Analysis revealed, T = 5.92; degrees of freedom =311; P = 0.95; mean difference = 0.01; CI = -0.27 & 0.26; suggesting that the rate of decline following therapy is not statistically significant, although the difference in mean scores at one year follow-up remains statistically significant.

Component Two of Insight (Acceptance of mental illness)

Following is a table of means for baseline, initial and one-year assessment for component two (acceptance of mental illness) of insight:

Table 5.9: Means for baseline, initial and one-year assessment for component two (acceptance of mental illness) of insight

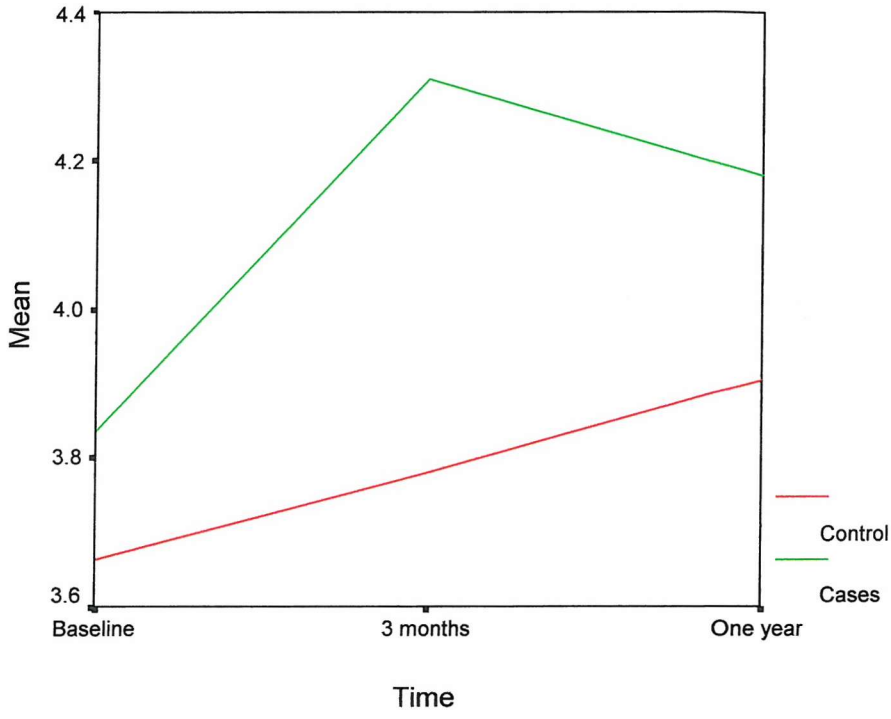
		Total baseline insight, Component 2	Total insight 2at three month follow-up	Total insight 2at one year follow-up
TAU group	Number	163	128	125
	Mean	3.66	3.78	3.90
	SD	1.98	1.95	1.96
Intervention group	Number	255	225	211
	Mean	3.84	4.31	4.18
	SD	1.99	1.87	2.06
Total	Number	418	353	336
	Mean	3.77	4.12	4.08
	SD	1.98	1.91	2.02

SD = Standard deviation

The above table shows some interesting trends for the means of component two of insight. The mean score for component two for participants in the intervention group improves following therapy but at one year follow-up assessment shows a minor decline although it is still higher than baseline. In the case of TAU group, the trend is upwards from baseline at three-month assessment and at follow up assessment. This could be the effect of time or the fact that these participants were included in the study and saw an assessor.

The following graph shows the change in mean insight for component two at the various time points.

Fig 5.3: Graph of mean scores for component two of insight



In order to detect whether the change in trend from three months to one-year analysis was statistically significant between the two groups a T test was performed. Analysis revealed, T = 0.36; degrees of freedom =311; P = 0.66; mean difference = 0.09; CI = -0.33 & 0.52; suggesting that the decline following therapy in the intervention group is not statistically significant.

Component Three of Insight (Relabelling psychotic symptoms)

Following is a table of means for baseline, initial and one-year assessment for component three of insight (Relabelling psychotic symptoms):

Table 5.10: Means for baseline, initial and one-year assessment for component three of insight (Relabelling psychotic symptoms)

		Total baseline insight, Component 3	Total insight 3 at three month follow-up	Total insight 3 at one year follow-up
TAU group	Number	163	128	125
	Mean	1.72	1.66	1.40
	SD	1.62	1.51	1.54
Intervention group	Number	255	225	211
	Mean	1.66	2.02	1.50
	SD	1.52	1.51	1.52
Total	Number	418	353	336
	Mean	1.68	1.89	1.46
	SD	1.56	1.52	1.53

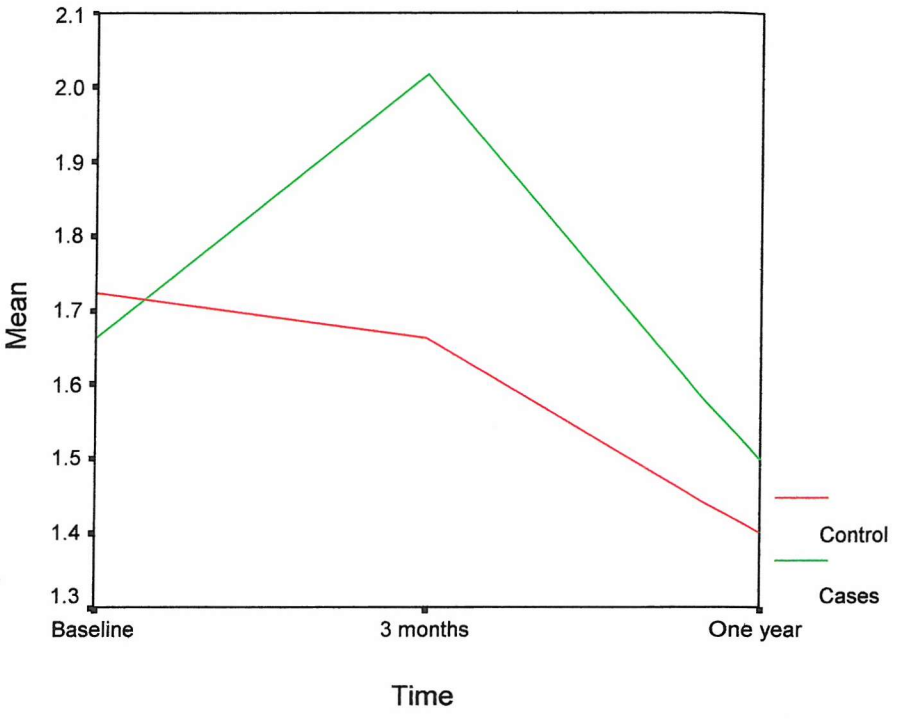
SD = Standard deviation

Change in the mean for component three of insight is very interesting. The mean score for participants in the intervention group improved following therapy, as there is a higher mean score at three month assessment. This is also depicted by the statistically significant P-value (0.02). This improvement is not sustained and the score is lower than baseline at one-year assessment.

The TAU group started with a higher mean score but the score has consistently dropped over time.

The following results are plotted in the graph of means at the various time points for component three of insight.

Fig 5.4: Graph of mean scores for component three of insight



Analysis of the changes between three months and one year follow up using T test reveals: T = 1.97; degrees of freedom =311; P = 0.27; mean difference = 0.23; CI = -0.18 & 0.64; suggesting that the rate of decline following therapy is not different.

The above results and their implications will be discussed further in the discussion.

Section 5.3: Correlation for Components of Insight

In order to examine the correlation between the three components of insight Spearman's rank correlation co-efficient test was performed (as the three components of insight were not normally distributed). As the number of correlations was large, a significance of $P < 0.01$ was used to determine significance.

In the baseline data, there was no significant correlation between treatment compliance and relabelling symptoms but there was a correlation between treatment compliance and acceptance of illness ($r = 0.18$) and a correlation between acceptance of illness and relabelling symptoms component ($r = 0.34$).

Analysing the dataset at three-month follow-up, there was again a correlation between treatment compliance and acceptance of illness (0.42), treatment compliance and relabelling symptoms ($r = 0.21$) and acceptance of illness and relabelling symptoms ($r = 0.49$). As is evident, the correlations have changed following therapy. When controlled for therapy, the correlation between the components has strengthened in case of both groups, although it is slightly stronger for the intervention group.

Similar significant results were found for the dataset at one year follow-up: treatment compliance and acceptance of illness, $r = 0.43$; treatment compliance and relabelling symptoms, $r = 0.29$ and acceptance of illness and relabelling symptoms to be 0.51.

CHAPTER 6: INSIGHT AND DEMOGRAPHICS THREE MONTH AND ONE YEAR ANALYSIS

Introduction

This chapter deals with

Objective 3: After controlling for treatment effect to determine if there is a differential change in total insight scores with the demographics of participants at three months and one year follow up.

The demographics described include:

- Age
- Gender
- Ethnicity
- Employment
- Marital Status
- Housing status
- Confounding between significant variables

Boxplots and histograms describe the data and regression is used to analyse the data.

The chapter is divided into two sections:

- Section 6.1: Analysis of three-month data
- Section 6.2: One-year analysis

Section 6.1: Three-month analysis of change in insight and demographics

1. Age

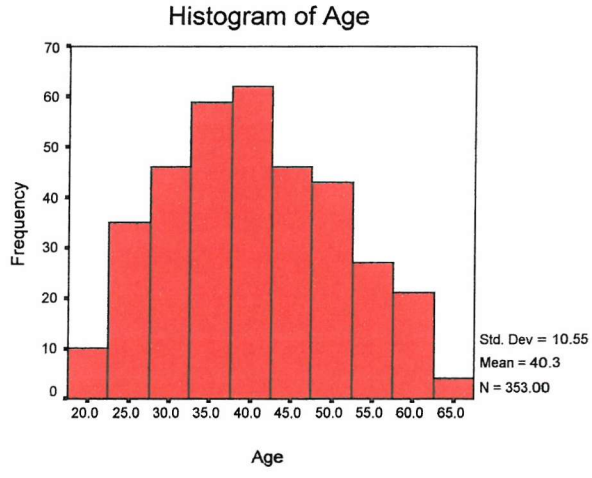
Four hundred and eighteen participants fulfilled the criteria for the study. Three hundred fifty three participants were assessed at three-month follow up assessment. Age range varied from 18 to 65years. Mean age was 40.25years and standard deviation was 10.55.

Table 6.1: Table of Means and Standard deviations (SD) for age at three months

	Number	Mean	SD
Intervention group	225	39.80	10.84
TAU group	128	41.04	10.01
Total	353	40.25	10.55

Following is a histogram for age, which depicts the frequencies and supports the assumption of a normal distribution.

Fig 6.1: Histogram of age at three months



Linear Regression was performed to determine whether age had a direct impact on change in insight.

Table 6.2: Regression of change in insight and age at three months

	Unstandardized coefficients		Standardized coefficients	t	P-value	Confidence interval	
	B	SE	Beta			Low	High
TAU group	1.89	0.75		2.50	0.013	0.40	3.37
Intervention group	1.06	0.37	0.150	2.86	0.004	0.33	1.79
Age	-0.05	0.02	-0.148	-2.8	**0.005**	-0.08	-0.01

B = Estimate; SE = Std Error; Sig = Significance; df =350; Predictors: Controls, Age; Dependent variable: Change in total insight

The interpretation is that a change in insight is expected to increase by -0 .05 (i.e. decrease) with every increase of one year in age. In other words, there is a decline in change in insight with increasing age.

2. Gender

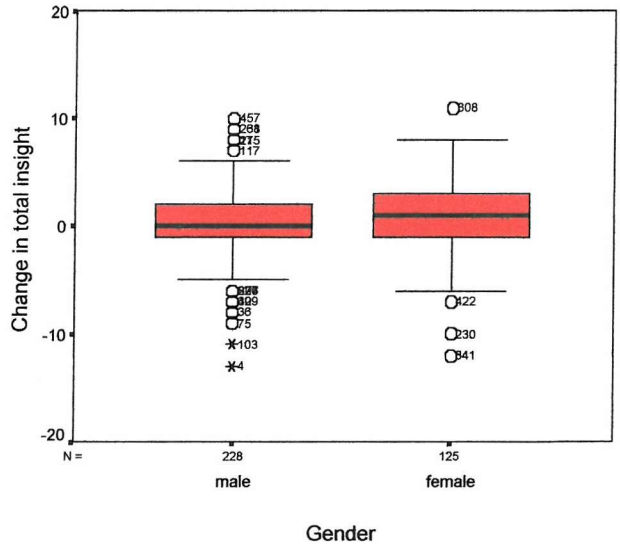
The case summary for data on gender at three months is as follows:

Table 6.3: Case summary for gender at three months

	Frequency	Percent	Valid Percent	Cumulative Percent
Male	228	64.6	64.6	64.6
Female	125	35.4	35.4	100
Total	353	100	100	

A boxplot for the same in relation to change in insight is as follows:

Fig 6.2: Box Plot of change in insight and gender at three months



A Regression to determine the relationship between change in insight and gender after allowing for the groups is as follows:

Table 6.4: Regression of change in insight and gender at three months

	Unstandardized coefficients		Standardized coefficients	t	P- value	Confidence interval	
	B	SE	Beta			Low	High
Constant	-0.26	0.34		-0.76	0.44	-0.92	0.40
Cases	1.16	0.38	0.16	3.09	0.00	0.424	1.90
Gender	0.44	0.38	0.06	1.16	0.25	-0.30	1.18

B = Estimate; SE = standard error; Predictors: Gender, cases; Dependent variable: Change in total Insight; df = 350

The analysis suggests that the observed difference maybe purely by chance or there is not enough data to show a significant difference.

3. Ethnicity

The case-processing summary of various ethnicities is as follows:

Table 6.5: Case summary of ethnicity at three months

Ethnicity	Number	Mean	SD	SEM
Caucasian	312	0.80	3.36	0.19
Black Caribbean	16	-1.50	3.96	0.99
Black African	7	2.00	3.41	1.29
Black other	5	-2.00	4.30	1.92
Asian Indian	4	0.50	2.38	1.19
Asian Pakistani		-3.00	–	–
Other Asian	1	-2.00	–	–
Other	4	-1.25	2.87	1.44
Total	351	0.64	3.43	0.18

SD = Standard Deviation; SEM = Std Error of Mean

Two people have not disclosed their ethnicity.

In order to compare the change in insight in the various ethnic groups, *dummy variables* were created. This allowed comparison between various groups. Since the white population was largest, it was the reference category. The Black and Asian populations were not grouped together respectively because of the cultural differences within each subgroup (i.e. Black Caribbean, Black African and Black other), as highlighted above and their identity as such in the Office for National statistics.

Regression of the groups revealed:

Table 6.6: Regression of change in insight and ethnicity at three months

	Coefficients		t-value	P-value	95% CI for B	
	B	SE			Lower bound	Upper bound
Constant	0.00	0.31	-0.09	0.921	-0.64	0.57
Cases	1.25	0.38	3.32	0.001	0.51	1.99
Black Caribbean	-2.41	0.86	-2.81	**0.005**	-4.09	-0.72
Black African	1.85	1.29	1.43	0.153	-0.69	4.39
Black other	-2.72	1.51	-1.80	0.072	-5.69	0.24
Asian Indian	-.01	1.68	-0.06	0.955	-3.41	3.22
Asian Pakistani	-4.22	3.35	-1.26	0.209	-10.81	2.37
Other Asian	2.77	3.35	0.83	0.408	-3.82	9.37
Other	-1.97	3.36	-0.59	0.558	-8.58	4.64

B = Estimate; SE = Std Error; CI = Confidence Interval; df = 342

The Black Caribbean group shows significantly poor change in insight compared with the white group.

4. Employment

The case summary of various groups is as follows:

Table 6.7: Case summary of employment at three months

Employment status	Number	Mean	SD	SEM
Full-time	7	0.00	1.82	0.69
Part-time	6	4.66	3.56	1.45
Unemployed	105	0.90	3.36	0.32
Training	5	1.80	2.05	0.92
Sheltered work	11	-0.73	4.45	1.34
Student	2	4.00	0.00	0.00
Retired	4	-2.25	5.56	2.78
Sick/disabled	207	0.48	3.33	0.23
Other	1	2.00	–	–
Total	348	0.65	3.42	0.18

SD = Standard Deviation; SEM = Standard Error of Mean

Five participants have not disclosed their employment status. The largest group is of participants registered as sick/disabled. This was used as a reference group and dummy variables were created for the other groups. Although this group would be unemployed as well, it was decided not to combine it with the unemployed group following advice from the statistician. Again, participants in the student and training group were not combined as the 2 male students were in their early twenties compared with those in training who were above thirty. The part time group was predominantly females compared with those in full time employment and it was felt that biases could be introduced by combining them although statistical power would have increased by doing so. A regression on the variables, after allowing for cases and controls revealed:

Table 6.8: Regression of change in insight and employment at three months

	Coefficients		t-value	P-value	95% CI of B	
	B	SE			Lower bound	Upper bound
Constant	-0.21	0.34	-0.62	0.538	-0.88	0.46
Cases	1.04	0.37	2.77	0.006	0.30	1.78
Full time	-0.38	1.28	-0.29	0.765	-2.91	2.14
Part time	4.18	1.38	3.26	**0.003**	1.46	6.90
Unemployed	0.51	0.40	1.27	0.204	-0.28	1.30
Training	1.38	1.51	0.91	0.360	-1.69	4.36
Sheltered work	-0.99	1.03	-0.95	0.340	-3.03	1.05
Student	3.17	2.38	1.32	0.183	-1.50	7.84
Retired	-2.80	1.69	-1.67	0.095	-6.14	0.49
Other	1.17	3.35	0.34	0.727	-5.42	7.76

B = Estimate; SE = Std Error; CI = Confidence Interval; df = 338; Dependent variable = *change in total insight*

The regression for employment reveals that participants in part time employment do significantly better than the other groups. The unemployed group appears similar to the sick/disabled group. The lack of significance in the training and student group may be due to small numbers in these classes.

5. Marital status

The case distribution for marital status at three months is as follows:

Table 6.9: Summary of case distribution for marital status at three months

Marital status	Number	Mean	SD
Married	50	1.02	3.39
Single	253	0.58	3.44
Divorced	42	0.83	3.03
Widowed	7	-1.29	5.22
Total	352	0.64	3.42

Marital status is not available for one participant. Since the single group is the largest, it was used as baseline and dummy variables were created for the other groups. It was decided not to combine the single group with divorced and widowed due to large numbers in the single group. Regression was then done, allowing for the groups.

Table 6.10 Regression of change in insight and marital status at three months

	Coefficients		t-value	P-value	95% CI of B	
	B	SE			Lower bound	Upper bound
Constant	-0.13	0.32	-0.39	0.69	-0.76	0.51
Cases	1.11	0.38	2.95	0.00	0.37	1.85
Married	0.41	0.52	0.79	0.43	-0.62	1.44
Divorced	0.27	0.56	0.48	0.63	-0.84	1.38
Widows	-1.79	1.29	-1.38	0.17	-4.35	0.76

B = estimate; SE = Std Error; CI = Confidence Interval; df = 347; Dependent variable: Change in total insight

The analysis indicates that there is no difference in change in insight between the various groups.

6. Housing status

The participants were divided into the following groups according to housing status:

Table 6.11: Case summary of housing status at three months

Housing status	Number	Mean	SD
Missing	5	0	4.00
Independent living	154	1.66	2.95
Family	98	1.14	3.48
Staffed home	76	-0.01	4.00
Unstaffed home	18	-0.17	3.95
Homeless	2	-0.50	0.70
Total	353	0.64	3.42

SD= Standard deviation

Dummy variables were created with participants living independently being constant. None of the groups were combined following advice from the statistician as there is evidence that housing status can have an association with outcome in schizophrenia. For e.g. participants living with families may experience high expressed emotions (Leff and Vaughn, 1981). Again, compliance may be better in staffed accommodation (Kinane and Gupta, 2001). Homelessness and mental illness are associated independently (Scott, 1993). It was felt that combining groups might introduce biases. Regression on these variables revealed:

Table 6.12: Regression of change in insight and housing status at three months

	Coefficients		t-value	P-value	95% CI of B	
	B	SE			Lower bound	Upper bound
Constant	0.06	0.36	0.18	0.86	-0.64	0.77
Cases	1.08	0.38	2.86	0.00	0.34	1.82
Family	0.34	0.43	0.79	0.43	-0.51	1.19
Staffed home	-0.79	0.47	-1.67	0.09	-1.71	0.14
Unstaffed home	-0.65	0.84	-0.77	0.44	-2.31	1.01
Homeless	-1.10	2.40	-0.46	0.65	-5.83	3.62

df = 347; Dependent variable: Change in Total insight

None of the results above are statistically significant.

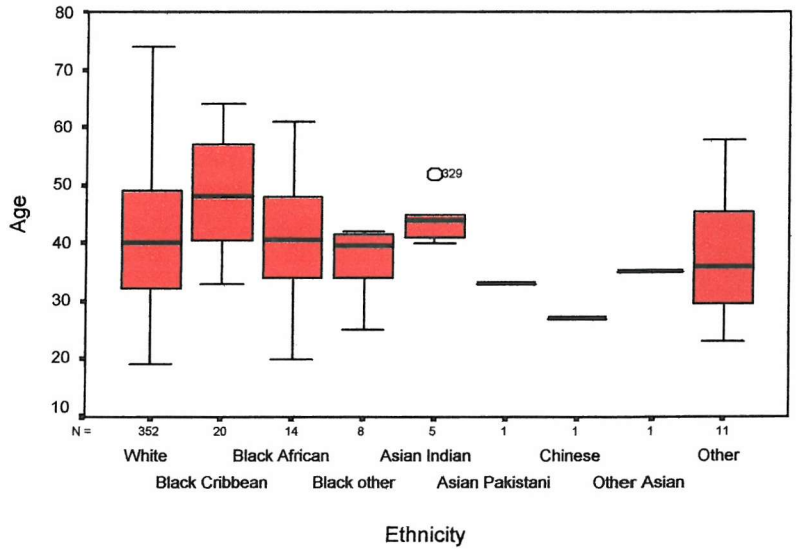
6. Confounding Variables

From the analysis of the above demographic variables, the factors that show a statistical significance to change of insight are:

- Age: With increase in age, change in insight is less
- Ethnicity: Black Caribbean group show a significantly poor change in insight compared with the white group
- Employment: The group in part time employment showed a statistically significant improvement in insight compared with the others

It is possible that the effect of age could explain the significant results of ethnicity and employment. The observed effect for Black Caribbean's could be due to their older age (mean age 47.75 compared to 40.39 of the white population). But this does not explain the nearly significant results (for change in insight) in the Black other group whose mean age is 37.13 years. A box plot to explain this further follows:

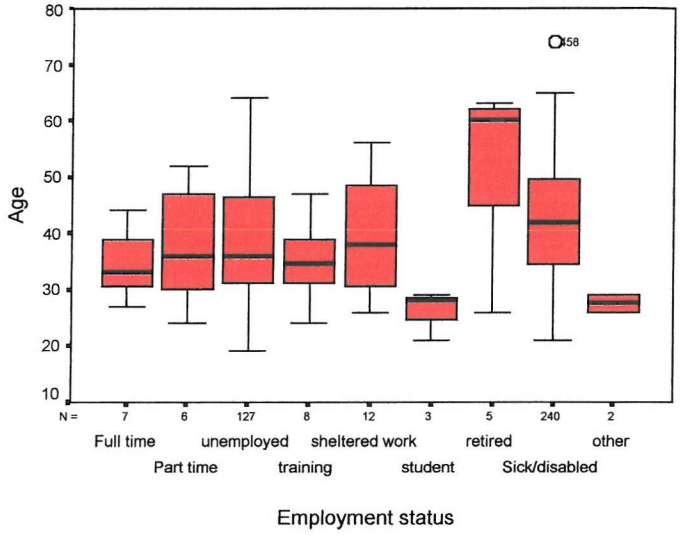
Fig 6.3 Box plot of ethnicity and age with change in Insight at three months



Similar arguments can explain the effect of age on the significance of employment. Mean age of the group in part time employment is 37.50 years compared to

42.25years for the sick and disabled group, which was taken as reference. Again, the mean age for the group in full time employment is 34.71 years and 26 years for students although they do not show a significant change in insight.

Fig 6.4: Box plot showing the relationship of age and employment status



In order to identify any confounding between these three significant variables, a multiple regression was performed.

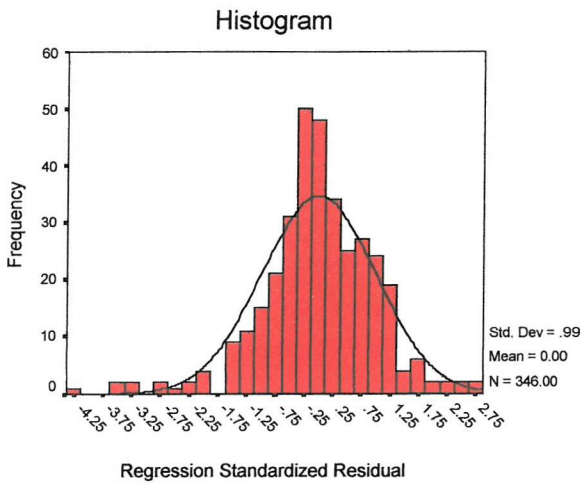
Table 6.13: Table of multiple regressions for confounding between variables

	B	Std Error	Beta	t	P-value
Constant	1.59	0.76		2.10	0.04
Cases	1.06	0.37	0.15	2.88	0.00
Part time Employment	3.84	1.36	0.15	2.82	0.00
Black Caribbean	-2.04	0.85	-0.13	-2.38	0.02
Age	-0.04	0.02	-0.12	-2.30	0.02

As is evident from the table, there does not seem to be a confounding effect between the three variables. None of the interactions was significant.

A residual analysis follows.

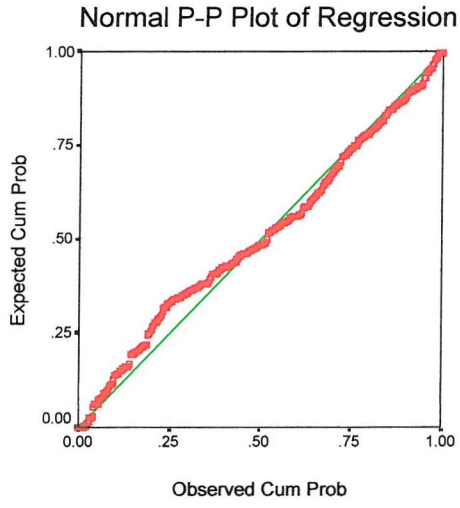
Fig 6.5: Histogram of Residuals for confounding at three months



The histogram of the standardized residuals revealed nothing too unusual. There were five people with a big drop (>= 10 points) in insight but there was no reason to believe that this had influenced the results.

The normal P-P plot for regression is plotted below which confirms the above.

Fig 6.6: Normal P-P Plot of Regression for confounding at three months



Section 6.2: Insight and demographics: one year follow up analysis

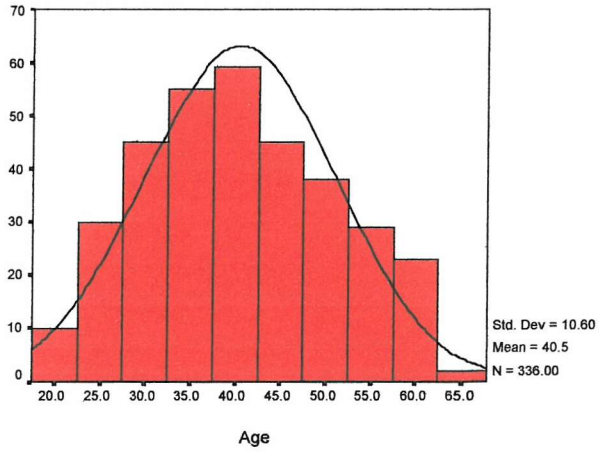
1. Age

Four hundred eighteen participants fulfilled the criteria for the study. Final analysis was carried out on three hundred fifty three participants at three months follow up assessment and three hundred thirty six patients at one-year follow-up assessment. Age range varied from 18 to 65 years. Mean age was 40.48 years and standard deviation was 10.60. Table 8.1 and Figure 8.1 summaries the age distribution at one year.

Table 6.14: Table of Means and Standard deviations (SD) for age at one year

	Number	Mean	Standard Deviation
Intervention group	211	39.99	10.87
TAU group	125	41.32	10.11
Total	336	40.48	10.60

Fig 6.7: Histogram for age at one year



A Linear regression revealed:

Table 6.15: Regression of change in insight at one-year follow-up with Age

	Unstandardized coefficients		Standardized coefficients	t	P-value	Confidence interval	
	B	SE	Beta			Low	High
Constant	0.87	0.86		1.01	0.31	-0.8	2.55
Cases	0.68	0.42	0.09	1.62	0.11	-0.1	1.50
Age	-0.03	0.02	-0.09	-1.6	0.11	-0.1	0.01

B = Estimate; SE = standard error, df = 333; Predictors: Age, cases

Dependent variable: Change in total insight

At one year, the association of age and change in insight is not evident.

2. Gender

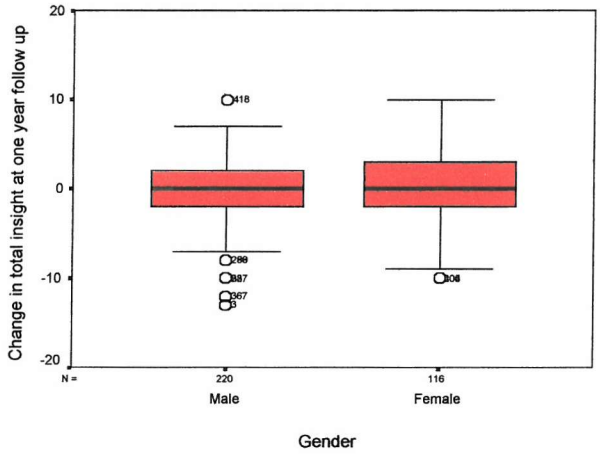
The case summary for gender in the sample at one year is as follows:

Table 6.16: Case summary for gender at one year

	Frequency	Percent	Valid Percent	Cumulative Percent
Male	220	65.5	65.5	65.5
Female	116	34.5	34.5	100
Total	336	100	100	

A box plot for the same in relation to change in insight is as follows:

Fig 6.8: Box Plot for gender with change in insight at one year



The above plot shows that the number of females that have improved in insight is greater. Whether this difference is statistically significant and is due to therapy will be determined by performing a linear regression. The result of a regression to determine the relationship between change in insight and gender after allowing for the two groups is as follows:

Table 6.17: Regression for change in insight and gender at one year

	Unstandardized coefficients		Standardized coefficients	t	P- value	Confidence interval	
	B	SE	Beta			Low	High
Constant	-0.61	0.38		-1.6	0.10	-1.4	0.12
Cases	0.77	0.42	0.10	1.84	0.07	-0.05	1.60
Gender	0.49	0.43	0.06	1.15	0.25	-0.34	1.34

B = Estimate; SE = standard error; Predictors: Gender, cases; df = 333

Dependent variable: Change in total insight

The result is not statistically significant.

3. Ethnicity

The case-processing summary of various ethnicities at one year is as follows:

Table 6.18: Case summary of ethnicities at one year

Ethnicity	Number	Mean	SD
White	298	-0.06	3.76
Black Caribbean	8	0.13	4.09
Black African	7	3.00	4.35
Black Other	4	2.25	0.50
Asian Indian	5	-0.40	2.07
Asian Pakistani	1	3.00	
Chinese	1	0.00	
Other Asian	1	-2.00	
Other	9	0.11	3.44
Total	334	0.05	3.72

Two participants had not disclosed their ethnicity. In order to compare the change in insight in the various ethnic groups, dummy variables were created. This allowed comparison between various groups. Since the white population is the largest, it was kept as the reference category. A regression was performed on all the groups to reveal:

Table 6.19: Regression for ethnicity with change in insight at one year

	Coefficients		t-value	P-value	95% CI for B	
	B	SE			Lower bound	Upper bound
Constant	-0.58	0.35	-1.68	0.09	-1.26	0.09
Cases	0.86	0.43	2.01	0.05	0.02	1.69
Black Caribbean	0.17	1.33	0.13	0.89	-2.44	2.79
Black African	3.34	1.43	2.34	0.02	0.53	6.14
Black Other	2.40	1.87	1.29	0.19	-1.27	6.08
Asian Indian	-0.16	1.68	-0.09	0.92	-3.46	3.14
Asian Pakistani	2.73	3.72	0.73	0.46	-4.59	10.04
Other Asian	-0.27	3.72	-0.07	0.94	-7.59	7.04
Other	-1.42	3.72	-0.38	0.70	-8.74	5.91

B = Estimate; SE = standard error; CI = confidence interval; Caucasian -reference gp; df = 323

The result is interesting because, at three month follow up the Black Caribbean group showed a significantly poor change in insight compared to the white group, which is not sustained at one-year follow-up. An analysis for confounding and interaction with other variables, which follows later in the chapter, may make the picture clearer.

4. Employment

The case summary of various employment groups at one year is as follows:

Table 6.20: Case summary for employment at one year

Employment status	Number	Mean	SD
Full time	7	-0.86	2.27
Part time	5	0.60	5.32
Unemployed	104	0.55	3.25
Training	5	2.00	1.22
Sheltered work	12	-2.00	5.53
Student	3	4.67	2.08
Retired	4	-1.50	1.00
Sick/disabled	190	-0.09	3.83
Other	1	-2.00	
Total	331	0.05	3.72

Five participants have not disclosed their employment status.

The largest group is of participants registered as sick/disabled. This was kept as a reference group and dummy variables were created for the other groups. A regression test was done on the variables.

Table 6.21: Regression of change in insight and employment at one year

	Coefficients		t-value	P-value	95% CI of B	
	B	SE			Lower bound	Upper bound
Constant	-0.56	0.39	-1.44	0.15	-1.32	0.20
Cases	0.69	0.42	1.65	0.10	-0.14	1.53
Full time	-0.69	1.41	-0.49	0.62	-3.48	2.09
Part time	0.74	1.66	0.45	0.66	-2.53	4.02
Unemployed	0.72	0.45	1.59	0.11	-0.17	1.61
Training	2.28	1.67	1.37	0.17	-0.99	5.56
Sheltered work	-1.79	1.09	-1.63	0.10	-3.94	0.37
Student	4.53	2.14	2.12	0.04	0.32	8.74
Retired	-1.29	1.86	-0.69	0.49	-4.94	2.36
Other	-2.14	3.68	-0.58	0.56	-9.39	5.11

B = Estimate; SE = standard error; CI = confidence interval; Sick/disabled - reference gp; Dependent variable: change in total insight; df = 320

At three-month analysis participants in part time employment did significantly better than the other groups following therapy. This effect is lost at one-year follow up.

5. Marital Status

The case distribution for marital status at one year is as follows:

Table 6.22: Case distribution for marital status at one year

Marital status	Number	Mean	SD
Married	51	-0.05	3.92
Single	240	0.08	3.77
Divorced	38	0.18	3.18
Widowed	6	-1.33	3.98
Total	335	0.04	3.72

Marital status is not available for one participant. Since the single group is the largest, it was kept as baseline and dummy variables were created for the other groups. Regression was performed.

Table 6.23: Regression for marital status with change in insight at one year

	Coefficients		t-value	P-value	95% CI of B	
	B	SE			Lower bound	Upper bound
Constant	-0.41	0.36	-1.13	0.26	-1.12	0.30
Cases	0.76	0.42	1.79	0.07	-0.07	1.58
Married	0.02	0.58	0.03	0.97	-1.12	1.15
Divorced	0.13	0.65	0.21	0.84	-1.14	1.41
Widowed	-1.30	1.54	-0.85	0.39	-4.33	1.72

B = Estimate; SE = standard error; CI = confidence interval;

The analysis does not reveal a statistically significant result.

Housing status

The participants were divided into the following groups according to housing status:

Table 6.24: Table of means and Standard deviation of housing status at one year

Housing status	Number	Mean	SD
Missing	5	-1.20	3.56
Independent	142	0.23	3.43
Family	95	0.34	3.71
Staffed home	74	-0.26	4.06
Unstaffed home	17	-1.71	4.09
Homeless	3	3.67	3.06
Total	336	0.04	3.72

Dummy variables were created with participants living independently being the reference group. A regression test on these variables revealed:

Table 6.25: Regression for housing status with change in insight at one year

	Coefficients		t-value	P-value	95% CI of B	
	B	SE			Lower bound	Upper bound
Constant	-0.23	0.39	-0.56	0.57	-1.01	0.56
Cases	0.67	0.42	1.59	0.11	-0.16	1.49
Family	0.11	0.49	0.23	0.82	-0.84	1.07
Staffed	-0.45	0.53	-0.86	0.39	-1.49	0.52
Unstaffed	-1.76	0.95	-1.85	0.07	-3.62	0.11
Homeless	3.45	2.15	1.61	0.11	-0.77	7.67

B = Estimate; SE = standard error; CI = confidence interval

None of the results above is statistically significant.

Confounding between Significant variables

The significant variables from the above analysis revealed that, at the P<0.05 but not P<0.01 levels

- Black African patients did significantly better than the white patients
- Students did significantly better (p<0.05) than the sick/disabled group

In order to look for confounding effect, ethnicity and employment status were included in a multiple regression after controlling for treatment.

Table 6.26: Multiple regressions of significant variables at one year

	B	Standard Error	Beta	t	P-value
Constant	-0.39	0.34		-1.18	0.24
Cases	0.71	0.42	0.09	1.69	0.09
Black African	3.52	1.41	0.14	2.49	**0.01**
Sheltered work	-2.25	1.08	-0.11	-2.08	0.03
Student	4.35	2.12	0.11	2.04	0.04

The Black African group show a statistically significant association to change in insight. The analysis did not rule out interactions between the variables and with treatment.

Further analysis of interactions, revealed:

Table 6.27: Table of interactions of significant variables at one year

	B	Standard Error	Beta	t	P-value
Constant	-0.47	0.34		-1.406	0.16
Cases	0.84	0.42	0.11	1.99	0.04
Sheltered work	-2.41	1.07	-0.12	-2.24	0.03
Student	4.29	2.11	0.11	2.04	0.04
Black African	5.56	1.66	0.22	3.34	0.00
Cases: Black African	-6.92	3.07	-0.15	-2.25	0.02

There is an interaction between the treatment group and ethnicity (Black African).

- A black control's change in insight is on average 5.556 more than a white control's.
- A black case's change in insight is on average 5.556-6.924 = 1.368 less than a white case's.
- A white case's change in insight is on average 0.841 more than a white control's
- A black case's change in insight is on average 0.841-6.924 = 6.083 less than a black control.

Hence, although initial linear regression of ethnicity and change in insight revealed that the Black African group did better than the white group, in reality the result was due to the confounding effect of the treatment group. The conclusion is that the change of insight in the Black African group is significantly lower than the white reference group. Normality in the above data is tested by a Residual analysis.

Fig 6.9: Residual Analysis for confounding in variables at one year

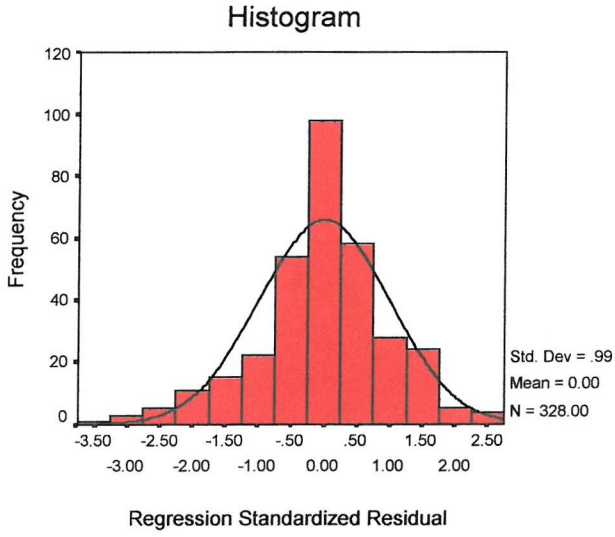
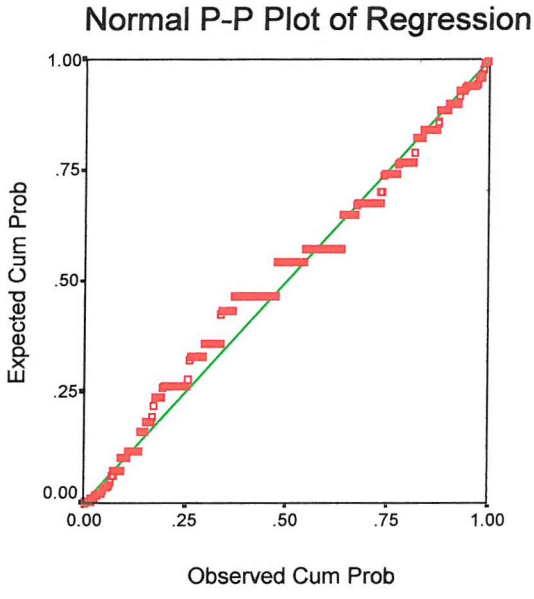


Fig 6.10: Normal P-P Plot of Regression



CHAPTER 7: INSIGHT AND PSYCHOTIC SYMPTOMS: THREE MONTH AND ONE YEAR ANALYSIS

Introduction

This chapter deals with following objectives.

Objective 4: To determine if there is a correlation between baseline scores of psychotic symptoms and baseline insight scores (Section 7.1).

Objective 5: To determine if there is an association between baseline scores of individual psychotic symptoms and change in total insight after controlling for therapy at three months and one year (Section 7.2).

Objective 6: To determine if there is an association between changes in individual psychotic symptoms and change in insight and its components after controlling for therapy at three months and one year follow up (Section 7.3 & 7.4).

Objective 7: To determine if there is a correlation between insight, components and total psychopathology measured by the Comprehensive psychopathological rating scale and whether this changes with therapy (Section 7.5).

The psychotic symptoms are part of the Comprehensive psychopathological rating scale:

- Feeling controlled
- Disrupted thoughts
- Ideas of persecution
- Ideas of grandeur
- Other delusions
- Commenting voices
- Other auditory hallucinations

They are scored on a scale from 0 to 3, 0 being no symptom. For each of these symptoms, the difference between follow up scores and baseline scores was calculated in order to detect a change in the symptoms. Thus, a positive difference would mean a higher follow-up score or deterioration in the particular symptom.

Section 7.1: Correlation between baseline scores of psychotic symptoms and baseline insight scores

a) Total baseline insight and baseline psychotic symptoms

Pearson correlation coefficient test was performed as the total insight and baseline psychotic symptoms were found to be normally distributed.
The results are presented in Table 7.1:

Table 7.1: Correlation between baseline scores of psychotic symptoms and total baseline insight

Symptom	Correlation coefficient with Insight	Significance
Feeling controlled	0.09	0.04
Disrupted thoughts	-0.06	0.21
Ideas of persecution	-0.02	0.64
Other delusions	-0.12	0.01
Commenting voices	-0.00	0.95
Grandiose ideas	-0.14	0.002
Auditory hallucinations	-0.04	0.37

It is evident that the symptom that correlates to insight at the $P < 0.01$ level of significance is Ideas of grandiosity.

b) Baseline components of insight and baseline psychotic symptoms

Spearman's correlations coefficient test was used, as the components of insight were not normally distributed. Ideas of grandiosity and other delusions were significant at the 0.05 level and auditory hallucinations were significantly correlated at the 0.01 level ($r = -0.123, -0.123, -0.128$ respectively) to insight into relabelling psychotic symptoms.

The number of correlations was large and their significance could be questioned specially at the $p < 0.05$ levels.

Section 7.2: Baseline psychotic symptoms and change in total insight after controlling for therapy at three months and one year

Regression was performed in order to determine the association between baseline psychotic symptoms scores and change in insight.

Table 7.2: Regression of baseline psychotic symptoms and change in total insight at three months

Symptom	B	Standard Error	Beta	t	P-value
Feeling controlled	-0.76	0.24	0.00	0.00	0.99
Disrupted thoughts	0.13	0.18	0.39	0.73	0.46
Ideas of persecution	-0.92	0.19	0.03	0.49	0.63
Other delusions	-0.98	0.23	-0.23	-0.44	0.66
Commenting voices	-0.87	0.17	-0.03	-0.52	0.61
Grandiose ideas	-0.16	0.27	-0.03	-0.60	0.54
Auditory hallucinations	0.16	0.19	0.04	0.79	0.43

B = Estimate; Dependent variable: Change in total insight

As is evident there is no statistically significant association between psychotic symptoms and change in insight at three months.

Table 7.3: Regression of baseline psychotic symptoms and change in total insight at one year

Symptom	B	Standard Error	Beta	t	P-value
Feeling controlled	0.37	0.29	0.07	1.27	0.20
Disrupted thoughts	0.21	0.21	0.06	1.04	0.29
Ideas of Persecution	0.25	0.22	0.06	1.13	0.26
Other delusions	0.27	0.27	0.06	1.02	0.31
Commenting voices	0.18	0.19	0.05	0.96	0.33
Grandiose ideas	0.24	0.36	0.04	0.67	0.50
Auditory hallucinations	0.26	0.22	0.06	1.14	0.25

B = Estimate; Dependent variable: Change in total insight

Again, at one year none of the results were statistically significant.

Section 7.3: Changes in individual psychotic symptoms and change in insight and its components after controlling for therapy at three months

This section describes the results of three-month analysis for association between change in insight and components with change in psychotic symptoms following therapy.

Case summary at three months

Mean CPRS at three months:
Intervention group (IG): 19.75 (SD 14.30)
Treatment as Usual (TAU): 22.76 (SD 15.03)
Total: 20.84 (SD 14.62)

Table 7.4: Means and Standard deviations (SD) of psychotic symptoms at three months

	Feeling Control	Disrupted thoughts	Ideas of persecution	Other delusion	Commenting Voice	Grandiose ideas	Auditory hallucinations
IG	0.34	0.56	0.73	0.31	0.63	0.19	0.41
SD	0.68	0.93	0.99	0.73	1.00	0.63	0.86
TAU	0.35	0.59	0.65	0.30	0.59	0.16	0.28
SD	0.72	0.98	0.92	0.73	1.07	0.56	-0.07
Total	0.35	0.58	0.69	0.31	0.62	0.18	0.37
SD	0.69	0.94	0.96	0.60	0.72	1.03	0.81

Change in psychotic symptoms and change in total insight at three months

Regression was carried out, allowing for the groups, for the difference (at 0 and 3 months) in score for each of the symptoms and compared to change in Insight (being the dependent variable). The following results were obtained:

Table 7.5: Regression of change in psychotic symptoms and change in total insight at three months

	Change in Insight				
	B	Std Error	Standardised Coefficients, Beta	t	P-value
Feeling Controlled	-0.13	0.24	-0.03	-0.55	0.58
Disrupted Thoughts	-0.08	0.19	-0.02	-0.47	0.64
Ideas of persecution	-0.37	0.19	-0.10	-1.88	0.06
Grandiose ideas	-0.07	0.28	-0.01	-0.26	0.79
Other delusions	0.13	0.22	0.03	0.60	0.55
Commenting voices	0.40	0.23	0.09	1.74	0.08
Other hallucinations	-0.09	0.18	-0.02	-0.47	0.64

The relationship between change in insight with cognitive behaviour therapy and change in individual psychotic symptoms is not statistically significant.

Components of Insight and Symptoms of Psychosis at three months

A regression for change in components of Insight and change in total CPRS revealed:

Table 7.6: Regression of change in components of insight and change in total CPRS at three months analysis

	B	Std Error	Beta	t	P-value
Component 1	0.08	0.01	0.07	1.28	0.20
Component 2	-0.01	0.01	-0.07	-1.28	0.20
Component 3	-0.05	0.01	-0.03	-0.56	0.58
Total Insight	-0.06	0.02	-0.02	-0.35	0.73

B = Estimate; Dependent variable: Change in insight and components

The above table indicates no statistically significant results.

Change in components of insight and change in individual symptoms of psychosis at three months

A number of regressions were performed to detect an association between change in individual psychotic symptoms and components of insight. There is a statistically significant deterioration in component 1(compliance) of insight with deterioration in ideas of persecution. Detailed descriptions of these regressions are presented in Appendix 9.

Section 7.4: Changes in individual psychotic symptoms and change in insight and its components after controlling for therapy at one year

This section looks at the results of one-year analysis for association between change in insight and components with change in psychotic symptoms following therapy.

Case summary at one year

Mean CPRS at one year:

Intervention group (IG): 18.23 (SD 13.93)

Treatment as Usual (TAU): 20.63 (SD 16.73)

Total: 19.13 (SD 15.05)

Table 7.7: Means and Standard deviations (SD) of psychotic symptoms at one year

	Feeling Controlled	Disrupted thoughts	Ideas of persecution	Grandiose ideas	Other delusion	Commenting Voice	Auditory hallucinations
IG	0.30	0.54	0.65	0.22	0.13	0.62	0.35
SD	0.68	0.88	0.94	0.65	0.46	1.04	0.81
TAU	0.32	0.50	0.66	0.20	0.08	0.56	0.31
SD	0.68	0.90	0.93	0.61	0.42	1.08	0.80
Total	0.31	0.53	0.65	0.21	0.12	0.59	0.34
SD	0.68	0.88	0.93	0.63	0.45	1.05	0.81

A regression was performed for the difference (at baseline and one year) in score for each of the symptoms and compared to change in Insight.

Table 7.8: Regression of psychotic symptoms and change in total insight at one year follow up

	Change in Insight				
	B	Standard Error	Standardised Coefficients, Beta	t	P-value
Feeling controlled	-0.51	0.27	-0.10	-1.84	0.07
Disrupted thought	-0.14	0.23	-0.03	-0.59	0.55
Ideas of persecution	-0.07	0.22	0.02	-0.32	0.75
Grandiose ideas	-0.24	0.34	-0.04	-0.69	0.49
Other delusions	-0.15	0.25	-0.03	-0.59	0.56
Commenting voices	0.18	0.22	0.05	0.83	0.41
Other hallucinations	-0.08	0.22	-0.02	-0.36	0.72

B: Estimate; Dependent variable: Change in insight at one year follow up.

The change in insight with cognitive behaviour therapy for individual symptoms is not statistically significant.

Components of insight and psychotic symptoms at one year

A regression for change in components of Insight and change in total CPRS was performed in order to analyse whether a change in CPRS caused a change in components of insight following therapy.

Table 7.9: Regression of change in components of insight and change in CPRS at one-year analysis

	B	Std Error	Beta	t	P-value
Component 1	0.013	0.006	0.11	1.95	0.032 CI 0.0, 0.02
Component 2	0.05	0.01	0.03	0.49	0.623
Component 3	0.01	0.01	0.07	1.36	0.176
Total Insight	0.03	0.02	0.09	1.67	0.095

B = Estimate; Dependent variable: Change in insight and components
None of the results are significant at the $P<0.01$ level.

Change in components of insight and change in individual symptoms of psychosis at three months

A number of regressions were performed to detect a change in individual psychotic symptoms and components of insight. None of the results were statistically significant. A detailed description of the regressions is presented in Appendix 10.

Section 7.5: Correlation between insight, components and CPRS

To establish a correlation between total insight and CPRS at baseline and subsequent follow-up, Pearson correlation coefficient test was used.

- At baseline, there was no correlation between the two ($r = -0.08$).
- At three months this correlation had changed and was significant at the $p< 0.001$ level ($r = -0.21$).
- At one year, this correlation was still significant but at the $p< 0.01$ level ($r = -0.15$).

The relationship seems to be influenced by therapy.

Spearman's correlation of the CPRS scale with components of insight in order to verify the relationship between the two was calculated. Spearman's r coefficient was used as the three components of insight were not normally distributed. As the number of correlations was large, $p< 0.01$ was chosen to determine significance.

- At baseline, only insight into compliance was correlated with the CPRS ($r = -0.163$).
- At three months, insight into compliance and relabelling symptoms were correlated to CPRS ($r = -0.253$ in both cases).
- At one year, all the components of insight were correlated to CPRS ($r = -0.152$; $r = -0.150$; $r = -0.142$ respectively).

The results suggest effect of therapy and are discussed further in the discussion chapter.

CHAPTER 8 DEPRESSION AND CHANGE IN INSIGHT – THREE MONTHS AND ONE YEAR

In this chapter the following objective is described:

Objective 8: To determine if there is an association between change in total insight and its components and change in symptoms of depression after controlling for treatment (Depression assessed by the Montgomery Asberg Depression scale, appendix 4).
Section 1 describes the results of three months analysis and section 2 of one year analysis.

Ten items from the CPRS scale make up the Montgomery and Asberg Depression rating scale (MADRS). A total score for depression was calculated at baseline and follow-up assessments for the cases and controls.

Case Summary

MADRS score at three months:
Intervention group: 4.50 (SD = 3.93)
Treatment as usual group: 5.71 (SD = 4.27)
Total: 4.94 (SD = 4.09)

Section 8.1: Three months analysis of depression and insight

To calculate a change in depression score following therapy, an analysis of covariance was performed.

Table 8.1:Coefficients of analysis of covariance of change in depression following therapy at three months analysis

	B	Std Error	Beta	t	P-value
Constant	1.95	0.38		5.14	0.000
Cases	-0.89	0.35	-0.104	-2.51	0.01
Total MADRS initial	0.61	0.04	0.617	14.85	0.00

Dependent variable: Total follow up MADRS; df = 350 Predictors: Initial MADRS, control

The results suggest an improvement in symptoms of depression following therapy.

Components of insight and depression at three months

For the change in depression scores following therapy with change in components of insight, the difference between follow-up and baseline scores of depression was calculated. A positive score for the difference would hence indicate deterioration in depression. Regression was done with the dependent variable being change in depression and predictors being change in components of insight and controls. The following results were obtained:

Table 8.2: Change in depression with change in components of insight following CBT at three months follow up

	Change in Depression				
	Unstandardized Coefficients		Std Coefficients, Beta		
	B	Std Error		t	P-value
Change in component 1 of Insight	-0.12	0.16	-0.04	-0.76	0.44
Change in component 2 of Insight	0.21	0.09	0.11	2.16	**0.01 C.I: 0.18-0.40**
Change in component 3 of Insight	0.09	0.11	0.04	0.79	0.43

B = estimate; Dependent variable: Change in Depression

There is a suggestion that with change in component 2 of insight, depression gets worse. The same test when applied to check if change in insight for individual psychotic symptoms varies with or without depression, with cognitive behaviour therapy (Depression assessed by the Montgomery Asberg Depression scale) did not reveal any significant results.

Section 8.2: Depression and change in insight and its components at one year

In this section the change in depression, following therapy and the relationship between change in insight and depression has been analysed.

Case summary of MADRS scores at one year

Intervention group: 4.06 (SD = 3.97)

Treatment as usual group: 4.88 (SD = 4.34)

Total: 4.37 (SD = 4.13)

To calculate a change in depression score following therapy, at one-year assessment, an analysis of covariance was performed (dependent variable: Total follow up MADRS).

Table 8.3: Coefficients of analysis of covariance of change in depression following therapy

	B	Standard Error	Beta	t	P-value
Constant	1.45	0.39		3.68	0.000
Cases	-0.55	0.38	-0.06	-1.48	0.14
Total MADRS initial	0.56	0.04	0.59	13.35	0.000

df = 334; Predictors: Initial MADRS, cases

There is no treatment effect at one year.

For the change in depression scores following therapy with change in components of insight, at one year follow up the difference between one-year follow-up and baseline scores of depression was calculated. A positive score for the difference would hence indicate deterioration in depression. Regression was done, allowing for cases and controls with the dependent variable being change in depression and predictors being change in components of insight and controls. The following results were obtained:

Table 8.4: Change in depression with change in components of insight following CBT at one year

At one year follow up	Change in Depression				
	Unstandardised coefficients		Std Coefficients, Beta		
	B	Std Error		t	Sig
Change in component 1 of insight	-0.36	0.16	-0.13	-2.29	**0.02 CI: -0.67 & -0.05**
Change in component 2 of Insight	0.15	0.10	0.08	1.52	0.13
Change in component 3 of Insight	-0.03	0.11	-0.02	-0.27	0.78

B: Estimate; CI: Confidence Interval; Dependent variable: Change in depression

There is a suggestion that with change in component 1 of insight (insight into compliance), depression gets better.

The same test when applied to check if change in insight for individual psychotic symptoms varies with or without depression, with cognitive behaviour therapy (Depression assessed by the Montgomery Asberg Depression scale) did not reveal any significant results.

CHAPTER 9: SUMMARY OF RESULTS

Dropouts

At three months analysis there was a significant drop out rate in the Black African group and at one year, there was a significant number of dropouts from the total Black group (Afro Caribbean, Black African and Black other group).

Insight and components

1. At three months, there was a significant improvement in total insight and in component one (insight into compliance with treatment) and three of insight (insight into relabelling psychotic symptoms as pathological).
2. The significant improvement in component 1 of insight at three months is sustained at one year.
3. Correlation between components of insight improves with therapy.

Demographics and Insight

At three months analysis:

1. Age: There was a decrease in change in insight with increase in age.
2. Ethnicity: The Afro Caribbean group showed a significantly poor change in insight compared with the white group.
3. Employment: Participants in part time employment did significantly better than the other groups.

At one year analysis:

1. Ethnicity: The Black African group does significantly worse than the white group did.

Psychosis symptoms and Insight

1. Ideas of grandiosity are significantly correlated (inversely) to total insight.
2. Auditory hallucinations (baseline) are significantly correlated to component three of insight (baseline).
3. A number of regressions were performed to detect an association between change in individual psychotic symptoms and change in components of insight. There is a statistically significant deterioration in component one (compliance) of insight with deterioration in ideas of persecution at three months.
4. Correlations between components of insight and with psychopathology improve with therapy.

Depression and Insight

1. At three months analysis, there was some suggestion that with an increase in component two of insight, depressive symptoms get significantly worse.

CHAPTER 10: DISCUSSION

Discussion is divided into four sections:

- The first section discusses the results taking into account sources of bias and generalisability of the findings
- The second section focuses on the interpretation of results in the context of literature and evidence
- The third section discusses implications of the findings for patients, services and future research
- The last section is the conclusion that highlights gains in knowledge from this project

Section 10.1: Interpretation and Generalisability

The results need interpretation in the light of methodological strengths and weaknesses, which have been highlighted in this section. The main findings of this sub analysis are that a short, insight-focused CBT programme, delivered by trained nurses in the community effects significant improvement in two out of the three components of insight in the short term. These are insight into treatment adherence and relabelling of psychotic symptoms as pathological. At the end of one year, improvement in insight into treatment adherence remained significant. The suggestion would be that this type of short insight focussed educational cognitive behaviour therapy module is successful in improving the patient's insight into the need for treatment.

Participants in whom there was an improvement in insight into acceptance of mental illness, symptoms of depression got worse. The other main finding includes poor change in insight in the Afro Caribbean and Black African groups compared with the white group with therapy.

The analysis of components of insight described in this thesis is a sub analysis from the main insight study. The insight study was designed to measure changes in total insight and CPRS as the main outcome measures. This is reflected in the fact that although the therapy was broad and included issues of compliance, normalisation and reattribution of symptoms, it was not aimed at improving components of insight specifically. This sub analysis was not powered for, although the sample size was large. Therefore, the results of the sub analysis predominantly serve to generate further hypotheses.

Participant enrolment

The multi-centre design of the study, the cross sectional and longitudinal assessments increase the external validity and generalisability of the results. There may be a clustering effect due to the large number of patients in each centre. Due to practical

difficulties and financial constraints, it would have been difficult to include more centres and fewer participants at each.

Selection of participants from various lists to form a representative sample was systematic and aimed to reduce selection bias. Participants from Clozapine clinics were included at any stage of treatment as long as their mental state was stable. Patients on Clozapine can improve in their mental state on the medication for up to six months after commencing it and this could have potentially affected the outcome for these participants.

It could be argued that only the motivated patients would consent to enter the study, patients who have less insight may not participate at all and they would be less likely to change. This is true for most research. However, the analysis suggested that for the Black Caribbean group, dropouts were participants with higher insight scores at baseline.

Recruitment was not time limited and therefore participants were enrolled from existing lists. Participants with different lengths of illness would have variable understanding of their symptoms and potential for improvement in insight, which could bias the outcome.

There was no provision for non-English speaking patients and this was not considered in the exclusion criteria. In areas with high proportions of non-English speaking ethnic minorities, the practicality of intervention would be questionable.

The exclusion of patients with a primary diagnosis of drugs and alcohol dependence affects the external validity of the results. Often it is difficult to determine which is the primary diagnosis, which could potentially lead to exclusion of participants with a dual diagnosis and would affect generalisability of the results to this group in actual clinical practice.

There were no set criteria for withdrawal of a participant who deteriorated while in the trial. It depended on the individual therapist leading to potential for inconsistency.

In summary, the overall direction of selection bias is towards an uncomplicated and stable population with schizophrenia in the community. Therefore, generalisation of the results to the wider group with schizophrenia may be less favourable.

Intervention

Therapy did not focus solely on insight and its components. It was broad but individualised and aimed to improve insight, psychotic symptomatology and depressive symptoms. The generalisability of the results of this sub analysis, which show an improvement in insight into compliance, and reattribution of symptoms (at three months) based on the above can be questioned.

The insight study did not take into account variables like attitudes and training of the therapist in issues of race; education level and personality characteristics of the participants as these are likely to determine the success or failure of therapy and introduce bias. It could also have an influence on the drop out rate. The results regarding ethnicity need interpretation considering this aspect.

The treatment as usual group was a potential source of performance bias, as there were six centres in the study and treatment as usual could vary in different centres. The study did not account for whether patients saw a psychologist or CBT therapist as part of their usual treatment. This would have had an influence on the insight scores of TAU group. From the data, it was apparent that there was no significant difference in distribution of subgroups (e.g., ethnicity) across the centres and therefore differences in TAU may not have significantly affected the results of the subgroups.

There was no provision for face-to-face therapist time in the TAU group. This design has advantages and disadvantages as it could measure the effect of actual therapy but on the other hand does not account for Hawthorne effect that would favour positive results for the intervention group.

The researchers had no control over medication changes and these changes were not accounted for in the data. It can be concluded that there are some inconsistencies in

the intervention delivery and in the TAU group, which need consideration when interpreting the results.

Outcome measures

The outcome measures for this sub analysis were not the primary outcome measures for the main insight study. The power of the study and interrater reliability of assessors were calculated based on CPRS as opposed to the insight scale. Although inter-scale reliability and concurrent validity for the insight scale (with SAI-expanded, ITAQ and PANSS insight item) have been demonstrated by Sanz *et al* (1998), one aspect of assessment of insight through this schedule is that it is based on the participants' responses to set questions and depends on their capacity to word their responses in a particular fashion. There was no validation of these responses in the study design by checking notes at a later date. Assessment tools were used without cross-cultural validation. This could potentially bias the results especially on ethnicity.

In the insight study, there was no record of compliance. There was limited evidence of reduced admission rate. Although the results showed an improvement in insight in compliance, translation of this into actual compliance with treatment was not validated by other measures. On the other hand, previous studies have demonstrated a discrepancy between compliance assessed at interview and that confirmed by urine analysis (Gordis *et al*, 1969) or that measured by pill count (Park and Lipman, 1964).

Sample size

Statistical power was calculated from a previous study where befriending was used as the control group, whereas in the insight study the control was TAU, which could have led to inaccurate calculation of the required sample size. It can be argued that the large sample size allowed detection of small differences in outcome with reasonable power.

Randomisation and blinding

The process of randomisation was robust and an independent observer remote from the unit using computer codes carried out the randomisation to reduce selection bias. As far as possible, raters were blind to the participant's allocation group. Other attempts were made to blind the raters, as the raters were told that some participants in the TAU group had received support material as well. The participants were not blind to their group. Assessing all participants at the beginning also helped the blinding process. In spite of this, elimination of the Hawthorne effect was difficult because participants and community teams were not blind to treatment. None of the assessors was involved in outcome data analysis. However, data was not coded; therefore, the analysts were not blind to the participants allocation group.

Baseline measures

There was some difference between the groups at baseline in terms of general characteristics, medication dose or type, or severity of illness as indicated by number of hospitalisations or days hospitalised although this was not statistically significant. This may have been the result of stratification only by centre.

The number of female participants recruited to the trial was almost half of male participants and could potentially be a source of recruitment bias towards male. Epidemiology of the illness cannot explain this difference, as the incidence of schizophrenia is equal between the two genders.

It was morally difficult to analyse the differences between the centres. The reason was that there was only one therapist per centre. On the other hand, more therapists per centre could have potentially been another source of bias due to differences in style and delivery of therapy. The influence of centre on change in total insight at one year was assessed by doing an Analysis of covariance, which was non-significant ($p = 0.12$) suggesting some uniformity across centres.

Statistical analysis

An intention to treat analysis was not performed as explained previously. It could be argued that this could introduce bias (usually in favour of the intervention group), but on the other hand, it also has problems of mean imputations. Participants who dropped out of the study were followed up by telephone or letter but no further in order to decide the reasons for the same. It is possible that some believed that they were not ill anymore to remain in the study. Further data on dropouts was desirable.

A number of tests have been performed on the sample leading to a potential increase in the chances of false positive results. In order to reduce this chance of type one errors, statistical significance has been accepted at the $P<0.01$ level where repeated tests have been performed.

Despite the above weaknesses, the insight study had a large sample size and a comprehensive design. The study was aimed towards a stable sample with schizophrenia in the community and the results could be generalised to a similar population.

Section 10.2: Key findings and interpretation in the light of current evidence: Components of Insight

The key findings of the sub analysis need interpretation in the light of existing literature and related research in order to determine generalisability of the results. A shortcoming of the insight study was a lack of booster sessions in the study design. This suggestion is also supported by the fact that at three-month analysis, the dropouts were greater from the TAU group as compared to the intervention group. The collaborative approach as used in CBT, may have contributed to this outcome in the insight study. Participants who received therapy seemed to enjoy the input and found it acceptable. The number of dropouts at one-year follow-up is greater in the intervention group compared with the TAU group, again, probably because there were no more therapy sessions. The number of dropouts may have been different if there were booster sessions, i.e. the participants had sessions to look forward to attend. At this stage, this assumption remains speculative.

On a smaller scale, a similar analysis used the schedule for assessment of insight (David, 1990) in a study of CBT for psychosis (Garety *et al*, 1994), in which the 11 subjects included in the study were highly deluded at the beginning of therapy. Analysis of data on the components of insight before and after twenty sessions of therapy showed substantial changes in component three (correct re-labelling of psychotic experiences; mean = 1.04 at onset and mean = 3 at endpoint).

The two studies are not comparable. In Garety's study, the participants received 20 sessions of therapist time who used general CBT techniques aimed at improving psychotic symptoms. The improvement in insight may have been a desired side effect of therapy. Techniques used by the insight therapists focussed on insight primarily in addition to psychotic symptoms. Following therapy, the insight study found an improvement in component three as well although it was not significant at one-year follow-up. Insight into compliance with treatment was significant post therapy and at one year follow-up.

Lecompte and Pelc (1996), in a randomised controlled trial with sixty-four patients responsive to neuroleptic medication, used a cognitive behaviour programme aimed at improving compliance. They reported that the length of admissions dropped in the first year: 53.3 days to 30.2 days in the CBT group and 48.9 to 43.4 days in the control group. Although their sample resembled that of the insight study in some ways, their outcome measure was different to the insight study that aimed at improving insight as a whole.

Kemp and colleagues (1998) devised compliance therapy, based on CBT principles, motivational interviewing and psycho education and studied its effectiveness in a randomised controlled trial. In their study, seventy four patients admitted to an acute inpatient unit received four to six sessions of either compliance therapy or non specific counselling and were followed up over eighteen months. They found that the participants in the compliance therapy group improved in insight and observer rated compliance.

The therapy package in the compliance study is probably the closest to the insight study compared to other trials. However there are many differences. Besides a larger sample size, insight study participants were in the community and the control group received treatment as usual as opposed to non-specific counselling. Again, in Kemp and colleagues' study the focus of therapy was medication compliance whereas the insight study was pragmatic and individualised based on education regarding the illness, understanding symptoms and benefits of treatment. The insight study did not have booster sessions. Outcome measures were different in the two studies. Both studies have a common suggestion that short educational packages based on CBT techniques improve insight into compliance with medication.

Although not based on the principles of Cognitive behaviour therapy, a number of other programmes have attempted to improve patient's compliance through different models of psycho education. Introduction has highlighted some of them. The common theme is that behavioural training may be more effective than general psycho education (Boczkowski *et al,* 1985). In a multicentre trial, Eckman and colleagues (1990) used a behaviourally orientated programme to improve compliance and

medication management skills in outpatients with schizophrenia. They used videotaped demonstrations, role-play with feedback, focussed instruction, and practice, for about three hours per week over four months, and showed an improvement in compliance. This was a very comprehensive and intense programme, leading to the same conclusion that behaviour oriented educational packages have a role in improving medication compliance.

In this sub analysis, insight into acceptance of illness did not show a significant change following therapy. An explanation may be that failure of recognition of illness may be a core, perhaps biological component of the illness or that patients operate with prominent denial in the face of this most stigmatised of diagnoses. Nevertheless, they would be prepared to accept the need for treatment. The finding that participants in whom this component improved showed a significant increase in depressive symptoms supports this argument.

Another explanation for the lack of significant change in component two (acceptance of illness) may be that a change in this component may need more therapy time by the therapist. For many participants with a delayed response in engagement, by the time the window to work on this aspect is reached, therapy may be over. In other words, it may take longer and more faith in the system for many patients to acknowledge the presence of illness which supports the argument of denial due to stigma. This aspect is further discussed in the section of insight and depression.

At post therapy assessment there was a significant change in insight into relabelling psychotic symptoms as pathological, contradicting earlier thinking that – since psychotic by definition means being out of touch with real events and experiences – it is incompatible for such people to have knowledge of (or be aware of) the true changes taking place within themselves and the environment (Markova and Berrios, 1992). The results suggest that delusions and hallucinations have the potential to be reasoned with, using the right techniques.

Although insight into acceptance of illness did not show a significant change following therapy, insight into compliance did. It may be argued that adherence does

not equate with insight, and many patients will comply with treatment while not regarding themselves as ill; supporting the concept that insight is better understood as consisting of several independent and overlapping components rather than being a unitary concept. The insight study results support an argument in favour of possibility of partial insight in psychosis.

Literature supports this hypothesis. In an interview of 45 patients with chronic schizophrenia on whether they felt they were ill and required treatment, thirteen percent agreed they were ill and twenty seven percent accepted a need for treatment (McEvoy *et al*, 1981). Similar findings were discussed by McPherson and colleagues (1993) – here, a group of long-stay patients showed a willingness to take medication, irrespective of their own views about whether they had an illness or not.

Insight into need for treatment aids compliance, but results regarding acknowledgement of illness are more equivocal. The insight study was unique in a number of ways and, measuring these overlapping constructs of insight separately is perfectly justified as they have implications for management.

From the above discussion on components of insight it can also be concluded that although acceptance of illness in a patient with schizophrenia has a bearing on their help seeking behaviour and treatment adherence, many patients adhere to their treatment regimes without acknowledging their illness. Engaging patients may be the key to successful management.

Measurement of Insight

David's (1990) schedule for assessment of insight describes insight as embracing different dimensions. The scale is composed of related yet independent components. In their later study with 91 psychotic patients, David and colleagues (1992) have demonstrated the value and applicability of the scale. A principal components analysis gave a single factor solution and treatment compliance did not seem strongly related to the ability to recognise psychotic symptoms and relabel them as pathological.

Peralta and Cuesta (1994), in a comparable analysis with 115 inpatients with schizophrenia found that unawareness of symptoms and unawareness of illness shared common features. The correlation of refusal of treatment with other two insight components showed that this component was a differentiated aspect of the lack of insight construct.

Examination of the correlations between the three components of insight from the insight study data showed interesting changes. The baseline data showed no significant correlation between treatment compliance and relabelling symptoms but there was a correlation between treatment compliance and acceptance of illness and a correlation between acceptance of illness and relabelling symptoms component. Analysing the dataset at three-month and one year follow-up, there was again a correlation between insight into treatment compliance and acceptance of illness, treatment compliance and relabelling symptoms and acceptance of illness and relabelling symptoms. As is evident, the correlations have changed following therapy. When controlled for therapy, the correlation between the components has strengthened in both groups, although it is slightly stronger for participants in the intervention group.

There is some amount of overlap and inconsistencies in the way questions are asked in the insight scale (Appendix 2). For e.g., question 2c (on the scale) asks the patient 'How do you explain your illness'? A high score of 2 is rated if the patient is able to answer the question appropriately based on their social, cultural and educational background, e.g. excess stress, chemical imbalance, family history etc. In patients with a specific belief system, this would not be very different to question 3b where the patient is asked ' How do you explain these phenomenon'. However, an explanation of tiredness/ stress would give them a lower score of one on this question. The inconsistency in scoring affects the correlation between the components.

Cognitive behaviour therapy uses principles of the stress vulnerability model and normalising rationale, for e.g. describing stressful situations like sleep deprivation, bereavement, delirium through physical illnesses in which voices can arise, in order to normalise the experience of the symptom. Using the above scale following therapy, if

the patient were to give a similar explanation of the symptom in question 3b, they would score low although it would be 'successful therapy' as the patient would have retained the information given.

In question 3, a patient who responds 'never' to the question that the symptom was *not* actually happening would not be asked question 3b: 'How would you explain these phenomenon'? It is possible for a patient to believe that their symptoms are real although they may be a reaction to outside events as explained through the CBT model.

Thus, the use of the scale to assess change in components of insight following CBT may have its limitations, or there may be a need for a revised scale to account for the above.

Insight and Depression

In the insight study, at three-month analysis, there was no significant improvement in component two (insight into acceptance of illness) of insight. Those participants who showed an improvement in this component also showed a significant increase in depressive symptoms. This result was not significant at one-year follow-up. The finding supports the assumption of denial being the reason for non-acceptance of illness and supports theories to suggest that poor insight may protect against depression (Carroll *et al*, 1999).

Certain life events are depressogenic (Gilbert, 1992) and psychosis is one of them. Awareness of one's psychotic illness and its implications can cause a sense of loss, low self-esteem and helplessness in patients. Iqbal and colleagues (2000) argue that the context for post psychotic depression is provided by the patient's appraisal of psychosis which embodies loss, humiliation and entrapment and the patients consequent 'down ranking' of themselves. They followed up one hundred and five patients over twelve months following an acute episode of psychosis and evaluated measures of depression, working self-concept, cognitive vulnerability, insight and

appraisal of psychosis. They found that during the period of depression, patients reported greater insight into their illness and further lowering of self-esteem.

In a short, focussed educational programme, aimed to improve insight, depression may have been an undesirable side effect in some participants. For the same reason, some clinicians (Goffman, 1961)) feel that attempts to foster insight in psychotic patients could prove destructive and promote the acceptance of the sick role. The finding raises the issue of diagnostic labelling with the term 'schizophrenia', and associated stigma. Stigma does not exist simply in the name and changing the terminology may not reduce the stigma. It lies in societies perception of the illness.

The study participants were in different stages of their illness, as it was not a first onset study. The possibility that the participants who did become depressed were in their early phases of psychosis, as there is greater distress and conflict regarding the diagnosis following first onset, was not analysed and needs further investigation.

On the other hand, the above finding can be explained on the principle of depressive realism, i.e. a hypothetical claim that depressed individuals are 'sadder but wiser' than their non-depressed counterparts. The hypothesis suggests that nondepressed people show illusory cognitions that seem to bolster psychological well-being, while depressed people may be more realistic than nondepressed people, thus reflecting more accurate perceptions and judgments (David *et al*, 2001). The explanation would be that the participants in the study who suffered from depression had a more accurate response to questions regarding illness. Therefore, the conclusion that insight into acceptance of illness leads to depression may be incorrect.

Both the above explanations for the findings are hypothetical. In either case, aim of therapy should be to empower the patient with confidence to deal with their symptoms, relapse, distress and develop better coping strategies. CBT is based on an evaluation of the individuals appraisal of self, others and future but in some patients it may not be possible to work on all these issues in six sessions aimed for a specific purpose. Improving insight should not seem like a process of labelling to the patient. The process of guided discovery through Socratic questioning as used in CBT is an

ideal approach for sensitive issues like insight. Patients who develop signs of depression may need more specialised CBT to work on their negative evaluations. The finding emphasises the role of an individualised approach, as there are other contributing factors to depression. These include genetic influences (Galdi *et al*, 1981), family history and personality characteristics (Birchwood *et al.* 1993).

Insight and Psychopathology

Introduction suggests that insight and psychopathology may not have a linear relationship. In the insight study, although there was an improvement in insight following therapy, there was no significant improvement in psychotic symptoms in the intervention group compared to TAU group. A short CBT programme may not be adequate to achieve this change and as the participants were stable and in the community, for some, there may not be much scope for change.

The baseline scores of ideas of grandiosity were inversely correlated to baseline total insight. These results are not different to what would be expected as being grandiose to some extent means being insightless and similar findings have been documented in literature (Bartko *et al*, 1988; Rossell *et al*, 2003; Mintz *et al*, 2003).

A number of regression analyses were performed in order to assess the association of change in components of insight with change in individual psychotic symptoms following therapy. The only statistically significant result was deterioration in insight into compliance with deterioration in ideas of persecution. This result mirrors previous literature (Hoge *et al*, 1990; Marder *et al*, 1983) and can be explained as a direct consequence of paranoia.

There were no other significant associations. As there was no significant change in psychopathology through therapy, it is reasonable to conclude that a study designed specifically to assess these associations would be needed to answer this question. The change in insight in this sub analysis is independent of change in psychopathology.

Correlation analysis between components of insight and total psychopathology revealed that at baseline, only insight into compliance showed correlation to CPRS. At three months, insight into compliance and relabelling symptoms showed correlation to CPRS. At one year, all the components of insight showed a correlation to CPRS. A similar pattern is observed for total insight and CPRS.

The results show that there may be an effect of therapy or time or both on the variables and the relationship has changed. Since we know that therapy has improved components of insight, it may be reasonable to conclude that although change in components of insight is not associated with change in CPRS, but following a change in insight with therapy, the correlation between components of insight and CPRS improves and suggests a therapy effect.

Demographics

In this section, the key findings of insight and demographics, their relevance and comparisons to other studies are discussed. Emphasis is on ethnicity as it is one of the main findings of the study.

Age

The analysis indicates that the younger the patient the better the improvement in insight at least post therapy. Evidence suggests that early diagnosis and treatment of schizophrenia leads to better prognosis (Pelosi and Birchwood, 2003). Hence, medical treatment complemented by psychological therapy early in the course of illness may have added benefits. This result supports literature that suggests health professionals – both primary and secondary – should concentrate their efforts on the young and acute patients (Harrison *et al*, 1997; Byford *et al*, 2001).

The implications could be criticised as it promotes discrimination based on age. If evidence suggest an improvement in the younger group, it may be because there are not enough trials to contradict this theory and it only highlights the need for more research into the usefulness of CBT in the elderly population.

Ethnicity

In the insight study, the African Caribbean group at three months and the Black African group at one year follow up analysis showed higher dropout rates and significantly poor change in insight compared with the Caucasian group. The results mirror the findings of previous studies over the years (Bhugra *et al*, 1997; Johnson and Orrell 1995).

The unexpected finding was that the mean baseline insight score of the Black patients that dropped out of the study was higher than for those who stayed on. Afro Caribbean patients may be more at risk of developing this particular style of interaction, because of their experience of social disadvantage, racial discrimination

and ascription of inferior identity due to continuing overt prejudice, high levels of unemployment, poorer access to housing, welfare and healthcare facilities together with inability to achieve shared goals. All the above could result in a sense of low self-esteem and a threat in their everyday social life. This view is supported by the fact that affective symptoms are more commonly found among African Caribbean than White patients with psychosis are, and paranoid attributions may be employed as a defence against depression and negative social evaluation (Sharpley *et al*, 2001). As a result, the black community is perhaps less likely to seek psychiatric help from predominantly white services (Robertson *et al*, 2000). A negative experience of the health service in any area of medicine, would lead to reluctance to further contact unless in an emergency (Lloyd and Louis, 1996).

Various explanations attempt to explain the results of the study. These include difficulty in engaging the patients adequately (Rosenthal and Frank 1958), stereotyping of this group as 'hostile, impulsive and not psychologically minded' (Sabshin *et al*, 1970), perceptions and attitudes of the professionals (Byford *et al*, 2001), historical assumptions (Thomas and Sillen, 1972; Lewis, 1965) and lack of understanding of other cultures, their perceptions of illness and help seeking behaviour.

Political, social and ideological pressures current in society impinge on the diagnostic process in western psychiatry and criteria for outcomes (Fernando, 1991). In many non-Western societies, hallucinatory experiences may not be considered bizarre, and may be considered 'real' as opposed to 'as if real' (al-Issa, 1995; Johns *et al*, 1998; Sharpley and Peters, 1999). Another example is an acute psychotic reaction as described by Littlewood and Lipsedge (1978) and compared to the French concept of 'bouffees delirantes'. The Rastafari movement confirms the same. Clinicians involved in caring for Rastafari are encouraged to diagnose and manage based on phenomenological grounds rather than on social behaviour (Hickling and Griffith, 1994).

The above argument does not suggest that the presentation of psychotic symptoms and their implications to society varies between countries and cultures (WHO, 1973).

Afro Caribbean have traditionally believed in witchcraft, voodoos and consult their traditional healers for help. Traditional Yoruba healers in Nigeria distinguish a wide variety of psychological abnormalities, which bear close parallels to Western systems of classification. Among the psychosis they identify are chronic hallucinatory psychosis (*were*), acute psychotic episodes (*asinwin*), chronic withdrawn psychosis (*dindinrin*), regressed psychosis (*danidani*), psychosis with good preservation of personality (*were alaso*), congenital psychosis (*were dile*), and psychosis with childbirth (*abisinwin*), old age (*were agba*), and epilepsy (*ipa were*) (Prince, 1964).

Again, within similar cultures, concepts vary. Among four very similar rural East African societies, the concept of mental illness differs considerably. In one community, sixty percent of people interviewed believed that psychosis was caused by witchcraft compared with only one percent in another. While in some, none believed that psychosis was an illness, in another two thirds said it was an illness caused by a worm in the front of the brain accompanied by stress. Interestingly, those communities which believe that illness is caused by witchcraft, also believe it is curable and pursue a policy of treatment and care, while those who believe in an underlying organic cause leave the patient to starve and beat them (Edgerton, 1966). For similar reasons, diagnosis among the Ganda (East Africa) is negotiable – mentally ill or eccentric. Mentally ill would mean a divine punishment as one of their proverb suggests 'a Lubaale punishes with reason'. This could explain why patients would not want to accept the concept of mental illness.

In summary, the results of the study when compared to available literature suggest that there is a need for greater sensitivity in approaching and managing these issues as logic for accepting treatment between different ethnicities may vary. This view is further supported by the strategy known as 'black psychology' devised by black professionals in the United States (Fernando, 1991). Americans have also pioneered the notion of the 'cultural broker'. A 'cultural broker' is a member of the minority group who works with mental health professionals and who is able to mediate between lay and biomedical ideas and practice, particularly in the area of family therapy. If psychotherapy is a new experience for a particular group, the practice offered is based on appropriate existing models like clergy and traditional healer

(Littlewood and Lipsedge, 1978). This type of intervention is aimed to achieve better engagement of patients of minority groups. The success of the Nafsiyat Intercultural therapy centre further supports the same. Black clients have a good attendance rate here. (Accharya *et al*, 1989).

In conclusion, the suggestion is that different cultural beliefs need understanding and alternative explanations used in CBT may need cultural modification. Style of engagement and language may have a role.

Employment

Participants in part-time employment at three months did significantly better than the other groups. Better educational backgrounds, premorbid adjustment and better use of time may explain these results. However, the numbers of participants in part-time employment were small and the results need to be interpreted in this light. Literature supports the finding that employment is associated with a better quality of life for patients with schizophrenia (Priebe *et al*, 1998) and satisfaction with employment status has significance for health in these patients (Eklund *et al*, 2001).

In conclusion, there is a suggestion that an effective rehabilitation programme and supportive work may have a role for a better prognosis in stable patients with schizophrenia. It helps to build their confidence, self worth and optimism for the future. Such programmes should be paced at an individual's level of ability and potential.

Gender

Although there were no statistically significant differences in change in insight associated with gender in the insight study, differences are reported consistently in literature. Male patients have a poor functional outcome, greater negative symptoms and cognitive impairment with less positive symptoms (Goldstein *et al*, 1990; Moriarty *et al*, 2001). Female patients with schizophrenia have higher overall levels of social functioning across the disease course compared to men (Seaman, 1981); they

have greater work competence (McGlashan and Bardenstein, 1990), are more often parents, living with a partner and heterosexually active than men (Test *et al*, 1990). These observations suggest that there is a global difference between the two genders with schizophrenia and can have important implications for therapy. Women have to cope with many losses such as relationships and professional, and hence the focus needs to be on maintenance, reestablishment, of these roles whereas in men the goal is often to attain these in the first place. Therapy needs to be sensitive to differences in symptom perception and illness concept, in coping, and help seeking behaviour, and the influence of gender specific socialisation and 'gendered' role behaviour (Rossler *et al*, 2000).

In the insight study, the number of male participants was almost twice compared to female participants. This bias may have affected the results. In conclusion, the results cannot be generalised without further validation.

Marital Status

There was no statistically significant change in insight associated with marital status in the insight study. Literature suggests that a positive change in clinical and functional outcome is most prominent among patients who live with their spouse (Salokangas, 1997). A stable 'social milieu' in the form of a supportive spouse may contribute to better compliance and outcome in schizophrenia. The results of this sub analysis cannot be generalised without evidence from further research.

Housing status

Evidence suggests that housing status is associated with the social outcome in patients with schizophrenia (Prudo and Blum, 1987). Patients with schizophrenia often prefer to live alone in independent settings of low behavioural demand (Owen *et al*, 1996). The results of the sub analysis cannot be generalised without further corroborative evidence.

Section 10.3: Implications of the Study

The Cochrane Review (Jones *et al*, 1998) states that although CBT is an effective therapy, it is currently inaccessible to most people with schizophrenia. This situation is unlikely to change until CBT skills are adapted for use by community nurses, or until there is increased availability of specialists. The insight study emphasises the role of a short psycho educational and insight-focused CBT package in not only improving patients' compliance with treatment but also in their developing a better understanding of psychotic symptoms and illness at least in the short term. This could help in alleviating patients' level of distress due to symptoms and aid improved coping, build confidence, and improve quality of life. Adherence with treatment has further implications, such as reduced relapse rates and re-hospitalisation (McEvoy *et al*, 1989b), which may lead to better use of NHS resources.

The form of treatment used in this study appears to be acceptable to patients and has the advantage of delivery in the community setting. CBT is an effective and cost-effective therapy (Knapp and Healey, 1998) and given the availability of trained healthcare professionals, could make a positive difference to patients with schizophrenia in the future.

The following points need consideration from the study:

- Engaging patients is an important aspect of a psycho educational programme.
- Repetition can benefit the long-term success of a psycho education programme.
- It is possible to have partial insight in psychosis.
- Changing attitudes regarding illness may take time. Short interventions may not successfully change patient's attitudes towards illness. Labelling can lead to stigmatisation and despair.
- Enhancing help seeking behaviour and attitudes towards adherence with treatments is central to effective outcomes in psychosis and they depend on the way people conceptualise their illness and perceive the mental health system.

- Therapists recommendations need tailoring to the patient's perceptions, i.e., these interventions would be more successful if they were tailored to the individuals rather than only the diagnosis.
- A short CBT approach (as used in the programme) may be of benefit in a large number of patients although some may need further specialised CBT input.

Implications for patients

Insight into adherence with treatment is beneficial for the patient's long-term prognosis (Loebel *et al*, 1992). When translated into actual compliance with treatment, patients experience an improvement in symptoms, reduced relapse rates and rehospitalisation (Vaughn and Leff, 1976), better control over their illness and a better quality of life in terms of employment, relationships and their role in the community (McEvoy *et al*, 1989b).

The insight study seemed to be well received by the participants partly because it was delivered in the community. Often patients are reluctant to attend in the hospital or outpatient setting due to the perception of stigma. With an emphasis on community care, this may be a way forward.

One outcome of the insight study was that the schizophrenia nurses prepared an individual treatment recommendation, which was sent to the consultant psychiatrist of the patient and key worker as an exit letter at the end of therapy. Pelton (2001) has published some of this data and highlighted that forty seven percent patients received a recommendation of review of medication. This may be due to side effects, ineffectiveness of current medication or the patient's unhappiness with treatment. Forty four percent patients received a recommendation for further CBT sessions and forty four percent needed further social support. Fourteen percent received a recommendation for family therapy and twenty-one percent needed more reading material. These recommendations form the basis of a needs analysis for treatment.

Implications for services

In spite of the chronicity of schizophrenia, there are treatment and support modalities available for patients like CBT, which can improve compliance with treatment, reduce distress, improve personal functioning, raise quality of life and lessen the burden on families in schizophrenia. Research shows that these treatments are cost-effective (Knapp and Healey, 1998).

The National Service Framework (NSF) for mental health (1999) recommends that all mental health users should receive care that optimises engagement with the services. It recommends psychological therapies including cognitive approaches for patients with schizophrenia in order to improve compliance, reduce relapse and hospitalisation.

The NICE guidelines for schizophrenia (2002) recommend availability of CBT for patients with schizophrenia. Unfortunately, there are barriers in the way of achieving these desirable interventions — notably those associated with fragmentation and inequalities — that national policy attention and local action urgently need to address (Haddad *et al*, 2000). In the current state of mental health services, which are under resourced and inadequately staffed, the dissemination of skills in psychosocial interventions is patchy. Uniform implementation of CBT will involve a gap analysis, training of staff and maintaining use of the skills through supervision and appraisal.

Another important suggestion from the study is that psychosocial therapy manuals need to focus on explanations that are in tune with the culture rather than focus on diagnostic labels. Patient's explanatory models of their illness need appraisal based on cultural backgrounds. Greater emphasis needs to be on engaging patients. Training in the adaptation of CBT models for different ethnic groups would be beneficial especially in areas densely populated with ethnic minorities. This suggestion is endorsed by the NSF (1999), which recommends the need to develop and demonstrate cultural competence with staff having the knowledge and skills to work effectively with diverse communities.

Implications for further research

As stated earlier, this thesis presents a sub analysis from the insight study. Therefore, the results of the analysis serve to generate hypotheses for further research. Further research on the same subject with fewer methodological limitations would validate the results. It would also be useful to know which components of CBT were most beneficial.

In the insight study, insight was measured by questionnaire responses. A study of other measures of compliance for e.g. Hayward scale & pill bottles with chip in- and their effectiveness would be useful.

Within this sub analysis, there was no statistically significant difference in change in insight scores between different genders and participants living conditions like housing and marital status. From a practical perspective and evidence from previous literature, the prominence of these differences and their association with outcome following CBT needs research.

The short-term results of the study indicate that CBT should be focused in the first instance on young patients with schizophrenia. It may have a role in early intervention but there is no evidence yet.

As discussed in detail already, more research is required into ways of engaging patients of ethnic minorities more effectively. It may be that their cultural beliefs need understanding and used in therapies such as CBT.

Section 10.4: Conclusion

Gain in knowledge resulting from this project

The *National Service Framework for Mental Health* (Department of Health, 1999) emphasises the need for increased training and implementation of high quality psychosocial interventions in schizophrenia.

The insight study showed that a short focussed CBT based psycho-educational programme improved insight into need for treatment (at three months and one year) and relabelling of psychotic symptoms as pathological (at three months). Insight into acceptance of illness may correlate with increasing depression (at three months). These outcomes suggest that the future might hold an increased role for psychological treatments like CBT for patients with schizophrenia that are cost effective, acceptable to patients and can be delivered through nurses who have received appropriate training and in the community.

Compliance with treatment is an important prognostic factor in patients with schizophrenia. The results of the sub analysis can be generalised to a stable population with schizophrenia in the community and through increased insight into the need for compliance may have a role in relapse prevention. It also highlights that labelling patients with a diagnosis can have implications and needs handling sensitively.

This sub analysis has highlighted problems in engaging patients from ethnic minorities and the influence of culture on insight. It forms the basis for further development in services and research in this area.

Appendix 1

Literature searches

Database: EMBASE <1980 to 2003 Week 11>
Search Strategy:

1	Insight.mp.	25330
2	Schizophrenia	37007
3	1 and 2	327
4	Psychotic Disorders	14840
5	1 and 4	147
6	limit 3 to english language	283
7	limit 5 to english language	134
8	Patient Compliance	21206
9	2 and 8	814
10	limit 9 to english language	689
11	4 and 8	285
12	limit 11 to english language	253
13	Acceptance of illness.mp.	24
14	Acceptance of mental illness.mp.	5
15	Belief systems.mp.	166
16	Mental Disorders	32772
17	15 and 16	10
18	limit 17 to english language	10
19	exp Demography	17298
20	2 and 19	366
21	limit 20 to english language	330
22	exp Ethnic Groups	20343
23	2 and 22	249
24	limit 23 to english language	244
25	psychoeducation.mp.	243
26	2 and 25	84
27	limit 26 to english language	53
28	4 and 25	15
29	limit 28 to english language	10
30	Cognitive behavioural therapy.mp.	302
31	2 and 30	24
32	Cognitive behavioral therapy.mp.	709
33	2 and 32	23
34	4 and 30	13
35	4 and 32	10
36	treatment outcome	142070
37	2 and 36	1394
38	limit 37 to english language	1225

Database: MEDLINE <1966 to March Week 2 2003>
Search Strategy:

1	Insight.mp.	27343
2	Schizophrenia	44315
3	1 and 2	328
4	Psychotic Disorders	16384
5	1 and 4	121
6	limit 3 to English language	287
7	limit 5 to English language	111
8	Patient compliance	23428
9	2 and 8	561
10	limit 9 to English language	502
11	4 and 8	200
12	limit 11 to English language	185
13	Acceptance of illness.mp.	33
14	Acceptance of mental illness.mp.	4
15	Belief systems.mp.	230
16	Mental Disorders	70499
17	15 and 16	13
18	limit 17 to english language	13
19	exp Demography	431431
20	2 and 19	2233
21	limit 20 to english language	1984
22	exp Ethnic Groups	64207
23	2 and 22	500
24	limit 23 to english language	480
25	Psychoeducation.mp.	226
26	2 and 25	73
27	limit 26 to english language	58
28	4 and 25	18
29	limit 28 to english language	16
30	Cognitive behavioural therapy.mp.	211
31	2 and 30	19
32	Cognitive behavioral therapy.mp.	575
33	2 and 32	15
34	4 and 30	8
35	4 and 32	2
36	Treatment outcome	150860
37	2 and 36	1473
38	limit 37 to english language	1350

Database: PsycINFO <1872 to March Week 2 2003>
Search Strategy:

1	Insight.mp.	10450	
2	Schizophrenia	35652	
3	1 and 2	339	
4	Psychosis	9048	
5	1 and 4	107	
6	limit 3 to English language	309	
7	limit 5 to English language	99	
8	Treatment Compliance	4506	
9	2 and 8	294	
10	limit 9 to English language	264	
11	4 and 8	50	
12	limit 11 to English language	46	
13	Acceptance of illness.mp.	39	
14	Acceptance of mental illness.mp.	12	
15	Belief systems.mp.	1068	
16	Mental Disorders		28323
17	15 and 16		15
18	limit 17 to English language	14	
19	exp Demographic characteristics	18087	
20	2 and 19	353	
21	limit 20 to English language	290	
22	exp Ethnic Groups	42178	
23	2 and 22	262	
24	limit 23 to English language	260	
25	Psychoeducation.mp.	1308	
26	2 and 25	183	
27	limit 26 to english language	145	
28	4 and 25	20	
29	limit 28 to english language	15	
30	Cognitive behavioural therapy.mp.	167	
31	2 and 30	18	
32	Cognitive behavioral therapy.mp.	2045	
33	2 and 32	68	
34	4 and 30	12	
35	4 and 32	30	
36	Treatment outcome	8685	
37	2 and 36	539	
38	limit 37 to English language	479)	
39	from 38 keep 1-10	10	

Appendix 2

Schedule for Assessment of Insight

1a. Does the patient accept (includes passive acceptance) treatment (medication and/ or other physical and psychological therapies)

2 Often
1 Sometimes
0 Never (ask why)

If 1 or 2, proceed to 1b.

1b. Does patient ask for treatment unprompted.

2 Often (excludes inappropriate requests for medication)
1 Sometimes
0 Never (accepts treatment after prompting)

2a. Ask patient: ' Do you think you have an illness?' or ' Do you think there is something wrong with you?' (Mental, physical, unspecified)

2 Often (present most of the day, most days)
1 Sometimes (thought present occasionally)
0 Never (ask why doctors/others think they do)

If 1 or 2 proceed to 2b.

2b. Ask patient: ' Do you think you have a mental/psychiatric illness?'

2 Often
1 Sometimes
0 Never

If 1 or 2 proceed to 2c.

2c. Ask patient: ' How do you explain your illness?'

2 Reasonable account given based on plausible mechanisms (appropriate given patients social cultural and educational background, e.g. excess stress, chemical imbalance, family history, etc)

1 Confused account given, repetition of overheard explanation without adequate understanding or ' don't know'

0 Delusional explanation

3a. Ask patient: ' Do you think the belief that.... (delusion)... is not really true/happening?' or ' Do you think that..(delusion) is not really there/ happening?'

2 Often

1 Sometimes

0 Never

If 1 or 2 proceed to 3b

3b. Ask patient: ' How do you explain these phenomenon?'

2 Part of my illness

1 Reaction to outside events (e.g. tiredness, stress etc)

0 Attributed to outside forces (may be delusional)

Appendix 3

Symptoms of Psychosis from the Comprehensive Psychopathological Rating scale

Feeling controlled

Representing the feeling of being in the literal sense influenced or controlled from without, and the experience that feelings, impulses or volitions are imposed from without. Also rated under this heading is the experience of being able to control others in a similar manner.

0 Ordinary influence from social forces

1 Vague or unconvincing report of being unnaturally influenced from without

2 Occasional but clear experiences of being controlled from without, e.g. by means of hypnosis

3 Continuous experiences that feelings or impulses do not derive from oneself but are forced into one, say by means of rays.

Disrupted thoughts

Representing the experience of a sudden stoppage of thoughts (thought blocking), or thoughts being put into one's head, or being taken out, or listened to or broadcast.

0 No thought interruptions

1 Vague or unconvincing reports of episodes of interruptions to thought

2 Occasional but clear thought blocking or occasional episodes of thought insertion or withdrawal. Feeling that thoughts are being read.

3 Disturbing or disabling thought interruptions. Thought broadcasting.

Ideas of persecution

Representing suspiciousness, exaggerated self-consciousness, the conviction of being talked about or watched or persecuted with malicious intent.

0 No undue suspiciousness or self consciousness

1 Vague feelings of being observed. Occasional suspicions of malice.

2 Pervasive feelings of being talked about, threatened or persecuted.

3 Unalterable conviction of being a victim of systematic persecution. Delusional misinterpretation of ordinary events or 'cues'. Conviction of being referred to beyond the realm of likelihood.

Ideas of Grandeur

Representing exaggerated opinion of self-importance, capabilities or good health.

0 No ideas of grandeur.

1 Self assured with an inflated sense of one's own importance.

2 Clearly exaggerated opinion of self-importance and capabilities. Grandiose, facile and unrealistic plans for the future.

3 Absurd, delusional ideas of grandeur.

Other delusions

Representing any other delusions.

0 No other delusions.

1 Vague and unconvincing descriptions.

2 Definitely pathological ideas, approaching delusional strength.

3 Absurd delusions, which may be reflected in behaviour.

Commenting voices

Representing the experience of hearing one's own thoughts spoken or repeated aloud, or hearing voices, commenting or arguing about one in the third person.

0 No hallucinated commenting voices.
1 Vague or unconvincing report of commenting voices.
2 Definite, but not disabling hallucinated voices.
3 Frequent, disabling hallucinated voices.

Other auditory hallucinations

Representing all hallucinated sounds or voices except commenting voices. Also includes auditory hallucinations in keeping with the predominant mood such as depression or elation.

0 No auditory hallucinations, except for hypnogogic phenomenon.
1 Misinterpretations of auditory stimuli. Vague or unconvincing reports of auditory hallucinations.
2 Definite hallucinations, which may be persistent but not intrusive.
3 Loud or unpleasant hallucinations. Forceful commands.

Appendix 4

Montgomery Asberg Depression Rating Scale

The MADRS scale consists of ten items from the CPRS.

Sadness

Representing subjectively experienced mood, regardless of whether it is reflected in appearance or not. Includes depressed mood, low spirits, despondency, and the feeling of being beyond help and without hope. Rate according to intensity, duration and the extent to which the mood is influenced by events.

0 Occasional sadness may occur in the circumstances.
1 Predominant feelings of sadness, but brighter moments occur.
2 Pervasive feelings of sadness or gloominess. Mood is hardly influenced by external circumstances.
3 Continuous experience of misery or extreme despondency.

Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to panic, dread and anguish.

0 Placid. Only fleeting inner tension.
1 Occasional feelings of edginess and ill-defined discomfort.
2 Continuous feelings of inner tension or intermittent panic, which the patient can only master with some difficulty
3 Unrelenting dread or anguish.

Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

0 Normal interest in surroundings and in other people.

1 Reduced ability to enjoy usual interests. Reduced ability to feel anger.

2 Loss of interest in surroundings. Loss of feelings for friends and acquaintances.

3 The experience of being emotionally paralysed, inability to feel anger or grief, and a complete or even painful failure to feel for close relatives or friends.

Pessimistic thoughts

Representing feelings of guilt, inferiority, self- reproach, sinfulness, remorse and ruin.

0 No pessimistic thoughts.

1 Fluctuating ideas of failure, self-reproach or self-depreciation.

2 Persistent self-accusations or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.

3 Delusions of ruin, remorse and unredeemable sin. Absurd self-accusations.

Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

0 Enjoys life or takes it as it comes.

1 Weary of life. Only fleeting suicidal thoughts

2 Much better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intentions.

3 Explicit plans and active preparations for suicide with opportunity.

Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

0 Hardly any difficulty in getting started.

1 Difficulties in starting activities.

2 Difficulties in starting simple routine activities, which are carried out only with effort.

3 Complete inertia. Unable to start activity without help.

Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.

0 No difficulties in concentrating.

1 Occasional difficulties in collecting one's thoughts.

2 Difficulties in concentrating and sustaining thought, which interfere with reading or conversation.

3 Incapacitating lack of concentration.

Reduced appetite

Representing the feeling of a loss of appetite compared with when well.

0 Normal or increased appetite.

1 Slightly reduced appetite.

2 No appetite. Food is tasteless. Need to force oneself to eat.

3 Must be forced to eat. Food refusal.

Reduced sleep

Representing a subjective experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

0 Sleeps as usual

1 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep.

2 Sleep reduced or broken by at least 2 hours.

3 Less than two or three hours sleep.

Apparent sadness

Representing despondency, gloom and despair, reflected in speech, facial expression and posture. Rate by depth and inability to brighten up.

0 No sadness.

1 Looks dispirited but brighten up occasionally.

2 Appears sad and unhappy all the time.

3 Extreme and continuous gloom and despondency.

Appendix 5: Overview of Therapy Sessions, Support material and Case Study

Therapy Sessions

The following CBT techniques were used in the therapy sessions by the SSN.

- Engagement and assessment

Engagement and assessment are essentials at the beginning of therapy. A key element of the assessment procedure was to develop a shared problem list on which the participant was willing to work. In doing this, the therapist enhanced the process of engaging the participant, and managed to avoid a number of potential problems that could arise later in therapy.

Gentle and superficial questioning approaches were recommended in session 1. The approach was to gradually gather evidence through sensitive questioning rather than confronting delusional beliefs, which could lead to weakening of the therapeutic alliance and often entrenchment of the delusion. The aim was to gradually work towards developing a shared and agreed explanation of symptom emergence, which would allow further work.

The basics of the cognitive model for emotional disturbance if required, would be taught in the early sessions. This was done with the help of reading material, case examples and often-personal examples. The model describes how thoughts can cause feelings and behaviour, and serves as both an educational and a normalising tool.

- Normalising

A normalising rationale helps to provide an explanation for puzzling psychotic symptoms and to deal with catastrophic cognitions. This also helps with the process of engagement. For example, as psychotic patients are often sleep deprived, this can be

taken as part of the explanation of what is happening, as there is evidence that lack of sleep can lead to hallucinations (Oswald, 1974). Psychological reactions to extreme stress could be discussed and so could the explanations of the label of schizophrenia, prognosis and the best chance of recovery with medication.
The aim of the normalising rationale was to improve the therapeutic relationship with the participant, and allow work on their personal symptoms, so that alternative explanations could be discussed later in therapy.

- Formulation

Formulation of the participant's problems, their causes and effects helped with appropriate treatment focus and prevented the random use of cognitive techniques. An intervention point could then be chosen, as it was unrealistic to attempt to eliminate all symptoms. The main purpose of a formulation was that it improves insight, guides treatment planning, helps offer most appropriate intervention strategy and helps prioritise patient problems. It also helps the therapist to maintain the therapeutic relationship and understand non-compliance.

- Symptom management

There needed to be agreed symptoms for management. Socratic questioning was used to introduce doubt. This provided the opportunity to explore the participant's evidence for thoughts and beliefs and for them to generate alternative solutions.

Peripheral questioning, a technique involving guided discovery of the basis of evidence and a variation of Socratic questioning, was commonly used (Kingdon and Turkington 1994).

Education on a range of topics was part of symptom management.
Diaries and homework were used to help the participants to consider evidence relevant to the delusion or hallucination and to reinforce the key points of therapy at home.

Generation of alternative explanations by the participants for the delusion and relevance and evidence of each alternative would then be discussed. Rating Beliefs was used to measure a shift in conviction.

Reality testing experiments were done with the participants to test the reality of delusions or hallucinations. This followed on from the content of the session and was aimed at helping to consolidate ideas, which were already at least to some extent established. It was important for the therapist to have considered what could go wrong and why and what would be achieved.

Coping Strategies and rational responses were used. They help by introducing doubt regarding the delusion by questioning the evidence, and serve to reassure by de-catastrophising the implications of the delusion even if it were true. These rational responses were written on a card to study in crises, or recorded for use in crises or learned. Other coping strategies included distraction, counting and sensory focus (Tarrier *et al*, 1990) or even taking additional or perhaps prescribed medication if helpful. Even in instances where only a small percentage improvement had been obtained, coping strategies served to increase the patient's efficacy and sense of empowerment.

In the case of auditory hallucinations, analysis of voice origin, explanations, voice diaries and coping strategies followed by schema change approaches were used.

- Adherence

Presenting the medication as one component of an integrated treatment strategy is helpful. If the patient was sleep deprived, presenting medication as an aid to sleep could be useful. Clear explanations of side effects can sometimes improve compliance. Attitudes to medication were flagged up and ameliorated into a more accepting style.

- Schema based interventions

Schema based interventions are built upon the formulation. The therapists aimed for slight changes or movement along the continuum. Establishment of the origins of the schemas and understanding their development with the patient would help improve insight. This could be a sensitive issue. Time charts, life event charts along with personal disclosure could help here to bring forward ideas as well as making the process of change a more relaxed and collaborative affair. Once the patient was agreeable to consider changing their schemas, current evidence would be examined. Rational responses and written information was used to help the patients cope with anxiety when changing schemas.

Diaries to monitor critical self-comments were used. Automatic negative thoughts were explored, and their evidence challenged. Approval and encouragement were used. Small achievements were acknowledged. Sometimes, giving examples through personal experiences was found to be useful. Activity scheduling, and increasing activities especially those resulting in mastery or pleasure were used to help lift the patient's mood.

- Relapse prevention

Individual relapse signatures (early warning signs of illness) and individualised risk periods varied among participants. An individualised plan was organised for each participant with them and written information given to consolidate the sessions. This involved: generalised advice, contact numbers, the participants own warning signatures, and a personalised action plan. Tapes were used as a revision aid and for supervision.

Humouring, confrontation, collusion, too fast a pace, using techniques in a wrong sequence, agreeing to stop medication and antagonising relatives were avoided.

Support Material

Following is a brief description of the support material used for the study.

- About your treatment

This module focuses on the symptoms of schizophrenia and the different drug and non-drug treatments currently available. It includes valuable information on side effects and reasons to continue with treatment.

- Self care and lifestyle:

Self care and lifestyle is aimed to help people with schizophrenia look at their lifestyles and ways they might improve them to reduce the risk of relapse, such as making sure they eat well, get enough sleep and make time to relax. The module also raises awareness of the early warning signs of relapse.

- Leisure time and relationships:

This module is designed to help people with schizophrenia to develop a daily routine that will enable them to get more out of each day. As people with schizophrenia may have trouble maintaining relationships with friends and family, the module also improves their understanding of other people's reactions to the illness. Advice on relationships and some of the problems encountered by people with the illness is also included.

- Drug and alcohol advice:

Drug and alcohol advice aims to raise awareness of the problems that illegal street drugs and alcohol can cause. It also helps people understand their medication and why it should be taken regularly.

- Managing your symptoms:

Recognising the symptoms of schizophrenia and the early warning signs of the illness are vital for prevention of relapse. This module helps people understand symptoms, the reasons to take medication or attend therapy sessions, and how to avoid symptom triggers.

Case study

Short history of illness

Jim, a forty-year-old Caucasian male had a diagnosis of schizophrenia. He suffered auditory hallucinations that he believed were the voice of Hitler and Napoleon. He was residing in a private care home where social services staff supported him. He attended the depot clinic for his monthly depot of Flupenthixol Decanoate, which he had been receiving for some years.

Therapy review

Whilst working with Jim it was noticed that he was not able to keep his legs still for more than a few seconds and had a marked tremor in his hands. The staff stated that he spent long periods asleep showing little interest in the daily happenings in the home, often only showing up for meals.

Whilst working with the staff and Jim the insight nurse became aware that the staff knew very little about side effects of psychotropic medication and that there were alternatives to the medication that Jim was receiving at present. Jim was unwilling to ask the consultant himself for a review of medication but requested that the nurse might have a word on his behalf. With staff approval, the nurse requested a meeting with the consultant and asked if he would review Jim's medication when he next attends his out patient appointment.

Process of therapy

Session 1: Engagement

An agenda was set at the first session.
Jim's level of insight into his illness and diagnosis was assessed and the stress vulnerability model was introduced.
A definition of schizophrenia was agreed between Jim and the nurse and the principal problems were identified as isolation and side effects of his medication. Homework was set at reading psycho-educational materials on the negative symptoms of schizophrenia.

Session 2: Formulation

The links between symptoms and significant life events were established and used as a formulation as Jim identified periods in his life where the times of taking drugs and loss of sleep were the times of emerging symptoms.
Homework entailed keeping a voices diary for a fortnight.

Session 3: Symptom Management

The introduction of doubt surrounding the origin of Jim's voices was achieved through examining the content of the voice diaries. Jim stated that the voices were in English. Through the use of Socratic questioning the question was asked " Could Hitler or Napoleon speak English?'' The nurse set himself a task of finding out if they could speak English and Jim was set the task of noting down the level of his voices as he did different tasks (i.e. watching TV, cooking etc).

Session 4: Adherence

The homework had led Jim to realise that when he was concentrating on something his voices were less severe than when he sat in silence on his bed.

He developed some rational responses to his voices after finding out that Hitler and Napoleon could not speak English. The rest of the session was spent looking at how anti-psychotics work using the dopamine hypothesis as an explanation. Homework was set to read psycho-educational material on anti-psychotics.

Session 5: How I See Others and Myself

After reading the materials left for homework the agenda for the session consisted of role-playing a meeting with Jim's consultant where Jim would ask for a review of his medication to see if there was an antipsychotic with fewer side effects. He set his own task as setting up a meeting with the consultant.

Session 6: Relapse Prevention

Jim had managed to get his medication changed and felt very satisfied with his achievements. With the understanding of his ability to reduce the intensity of his voices when he was actively concentrating on something, he could see the benefit of spending more time with others in the hostel. A relapse prevention plan was compiled with him and actions were agreed for all of the scenarios he could envisage happening. This was shared with his key workers and consultant.

How did therapy affect Jim's life?

There was an almost immediate improvement in Jim within a couple of weeks. The staff commented on how much more interest Jim showed in activities in the home and that he had started taking an interest in his appearance for the first time that they could remember. Jim showed fewer side effects with each of the subsequent visits the nurse made and although there was little reduction in his positive symptoms his quality of life had been markedly improved.

Appendix 6

Tables used for calculating power of the study

Following are tables from the British journal of psychiatry article (Turkington & Kingdon, 2000) used to calculate the power for the insight study.

Table A6.1: Demographic characteristics:

		Cognitive Therapy Group	Befriending Group
Mean age (yrs)		37.4	44.2
Sex (male: female)		7:5	2:4
Marital status	Single	8	4
	Married	2	2
	Divorced	1	1
	Widowed	1	0
Live with:	Parents	5	3
	Alone	5	1
	Spouse	1	2
	Son	1	0
Mean length of illness (yrs)		9.2	13.0
Mean length of hospitalisation		11.3	14.3

Table A 6.2: DSM IIIR group (mean scores)

	Cognitive techniques (n=12)			Befriending (n=6)		
	Start	1 mths	2 mths	Start	1 mths	2 mths
MADRS score	8.1	5.8	4.1	7.8	7.8	6.8
CPRS – global	2.5	1.85	1.25	2.6	2.0	2.4
CPRS - Total	31.3	19.8	14.8	36.0	28.4	26.4

Power is calculated based on the difference between the two groups.

Appendix 7: Histograms and Box Plots for Insight and components at three months

A histogram is a simple diagram representing a frequency distribution. The area of each column represents frequency in a histogram. Hence, the total area of the rectangles represents the whole sample, and the combined area of several adjacent rectangles represents the number of observations within a given range.

Intervention group is referred to as cases and TAU group as controls.

Fig A7.1a: Histogram of Change in Total Insight for Cases:

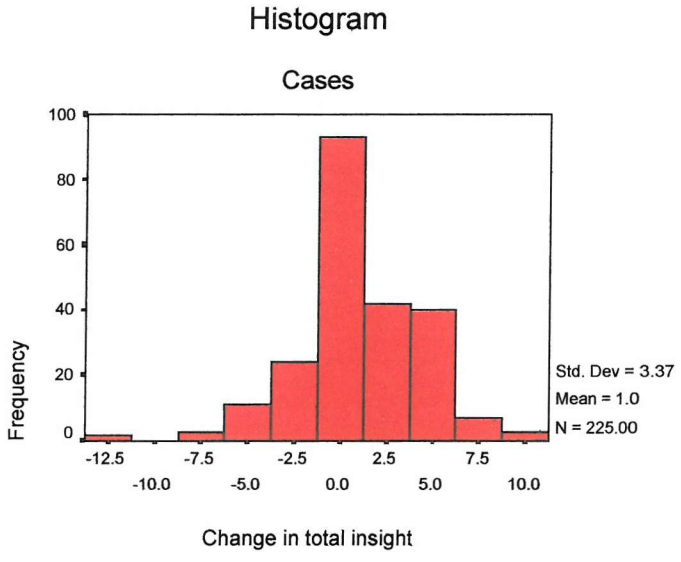


Fig A7.1b: Histogram of Change in Total Insight for Controls:

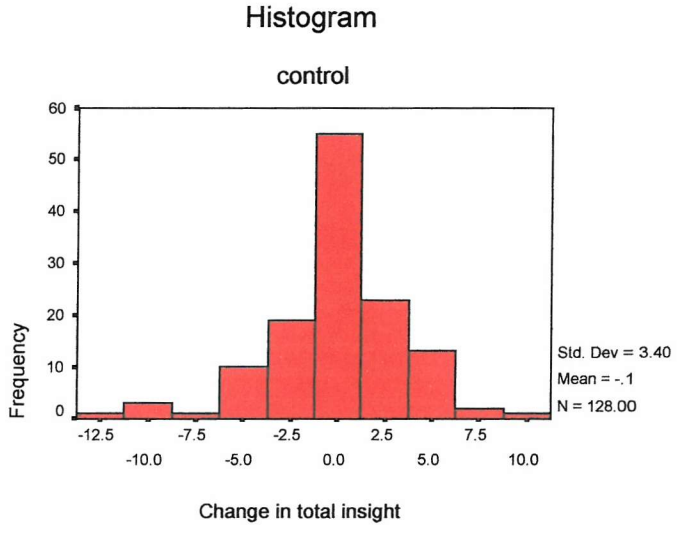


Fig A7.2a: Histogram of change in component One of insight for Cases:

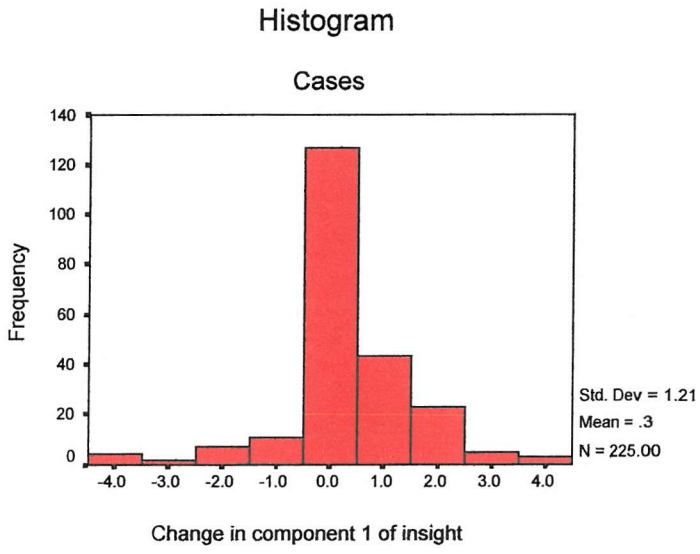


Fig A7.2b Histogram of Change in Component One of Insight for Controls:

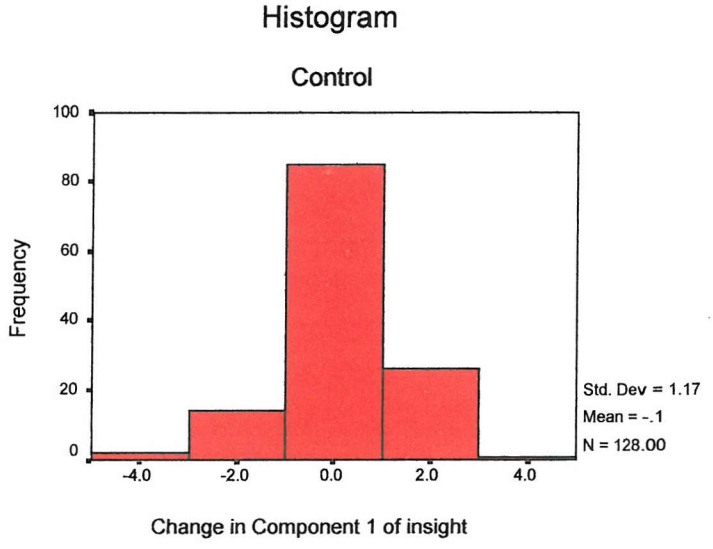


Fig A7.3a: Histogram of change in component Two of Insight for Cases:

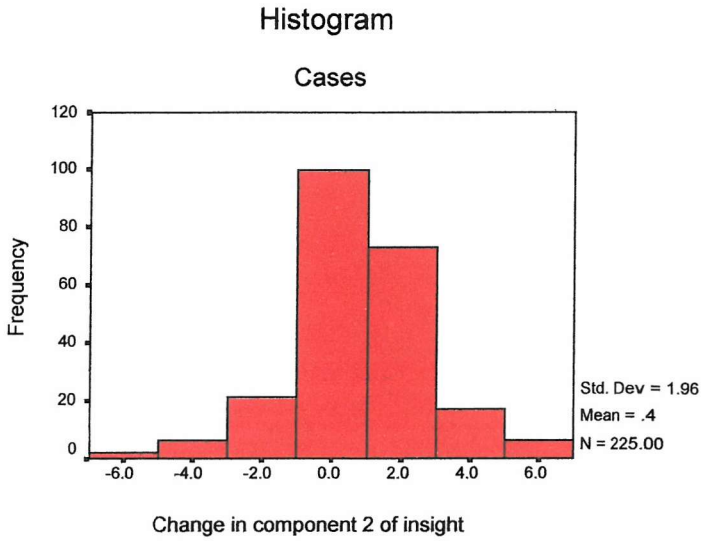


Fig A7.3b: Histogram of change in component Two of Insight for Controls:

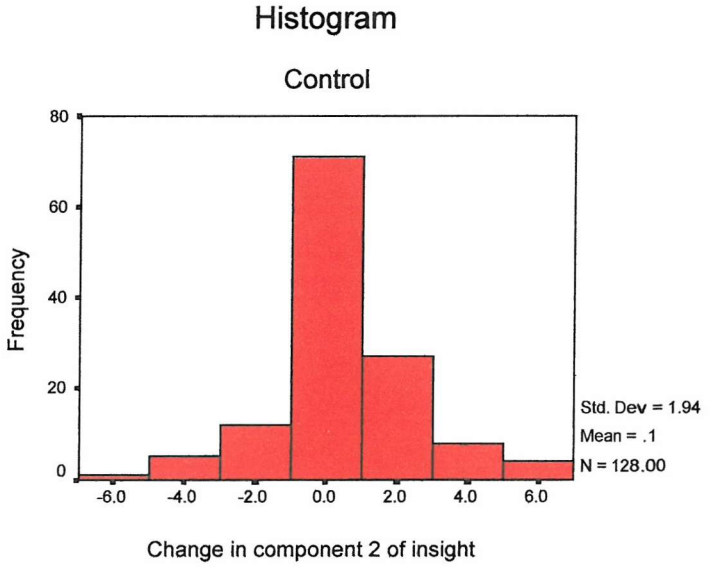


Fig A7.4a: Histogram of Change in Component Three of Insight for Cases:

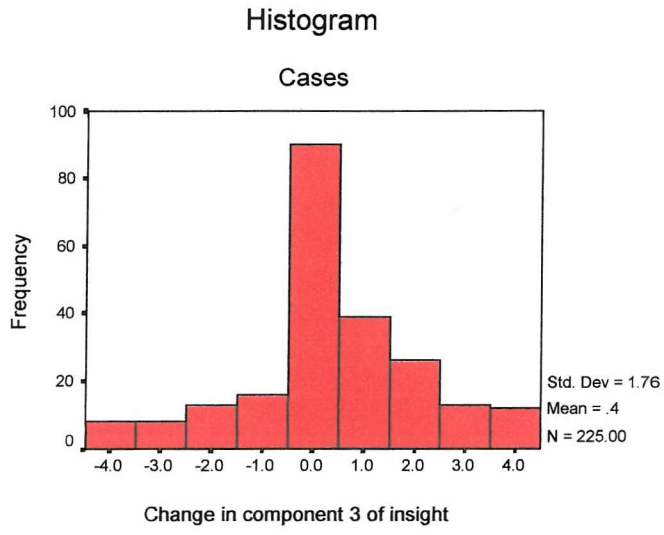
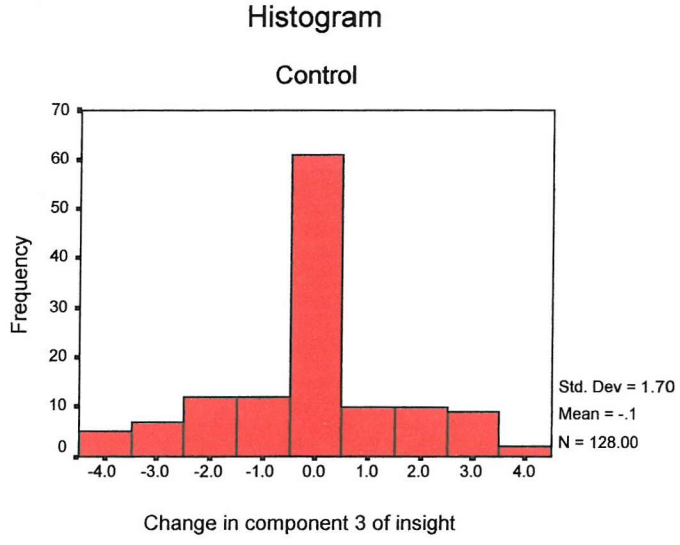


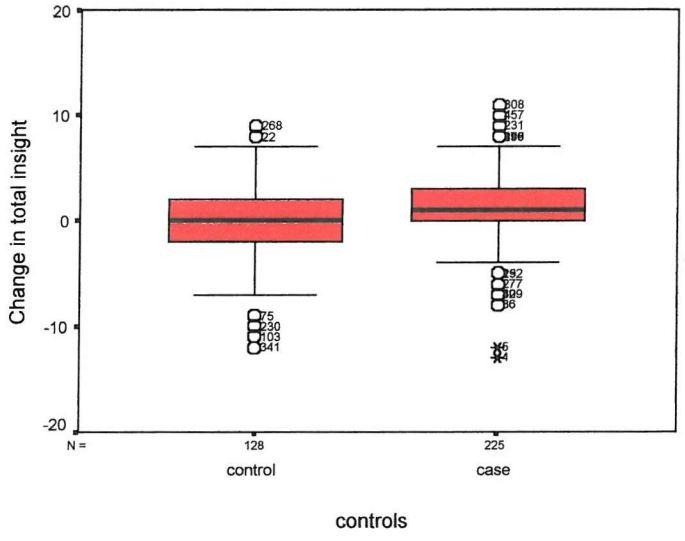
Fig A7.4b: Histogram of Change in component Three of Insight for Controls:



Box Plots of change in Insight at three months:

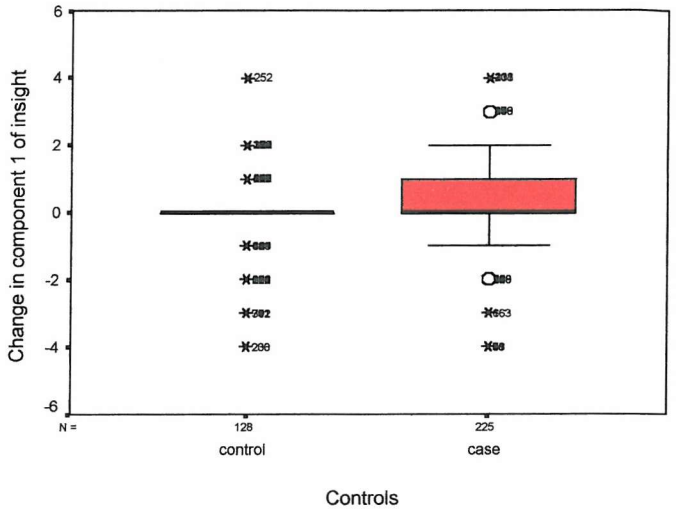
Boxplots display summary statistics rather than observed data. The central line in the box gives the median and the box shows the inter-quartile range. In the following boxplot, the general trend of scores (i.e. change in insight) for cases is upward compared to controls. This effect is more pronounced taking into account the number of cases is 228 whereas the number of controls is 129 and hence may indicate a difference in change in insight between cases and controls.

Fig A7.5: Box Plot of Change in Total Insight:



The box plot for the first component of insight displays similar trend.

Fig A7.6: Box Plot of change in component One of Insight:



There is very little change for controls on this component.

The means and distribution of scores in the following boxplot for component 2 of insight are very similar for cases and controls.

Fig A7.7: Box Plot of change in component Two of Insight:

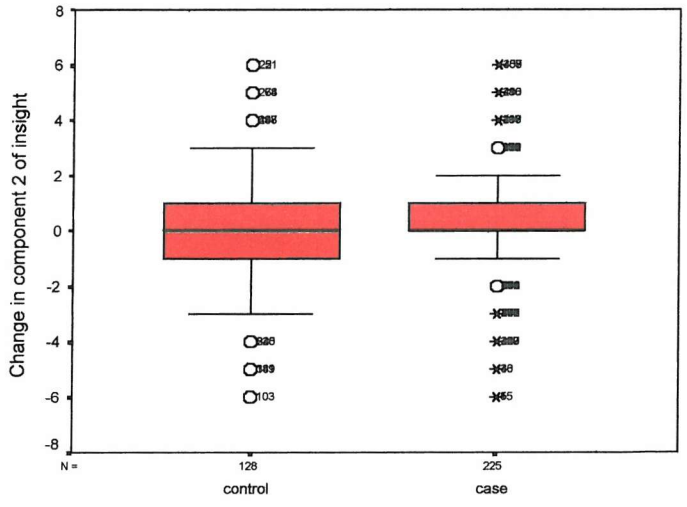
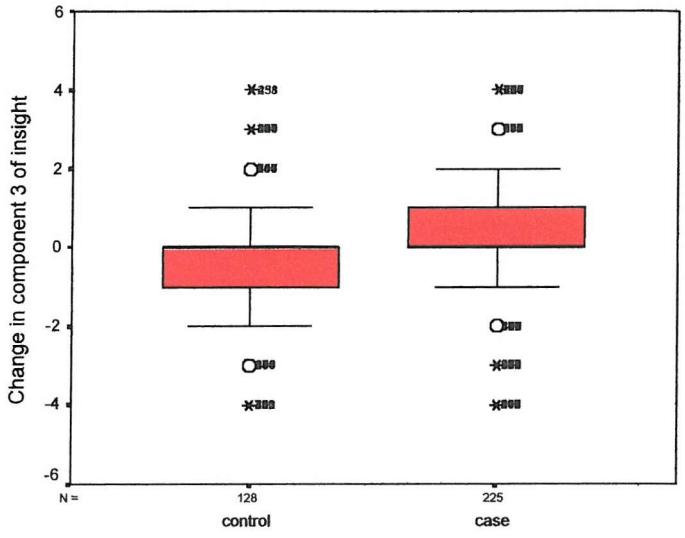


Fig A7.8: Box Plot for change in component Three of Insight:

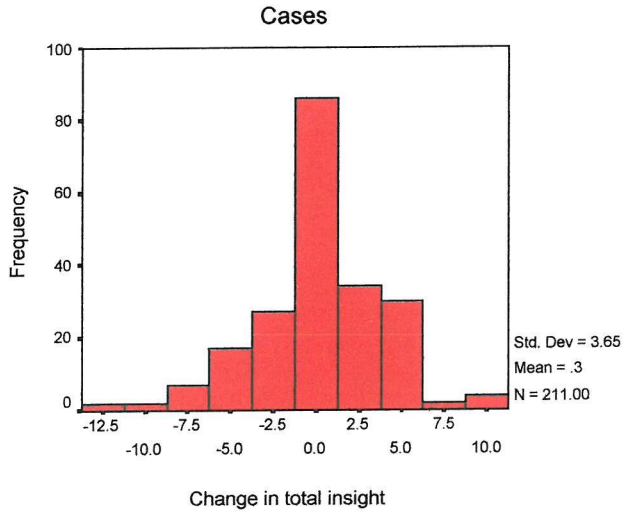


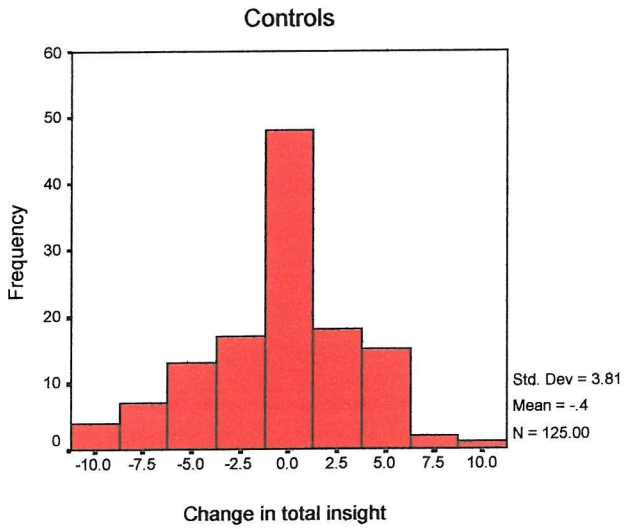
For component 3 of insight, the change for cases and controls appear to be in opposite directions.

APPENDIX 8

Histograms and Box plots of Change in Insight at One year

Fig A8.1: Histograms of Change in Total Insight at one year: Cases and Controls

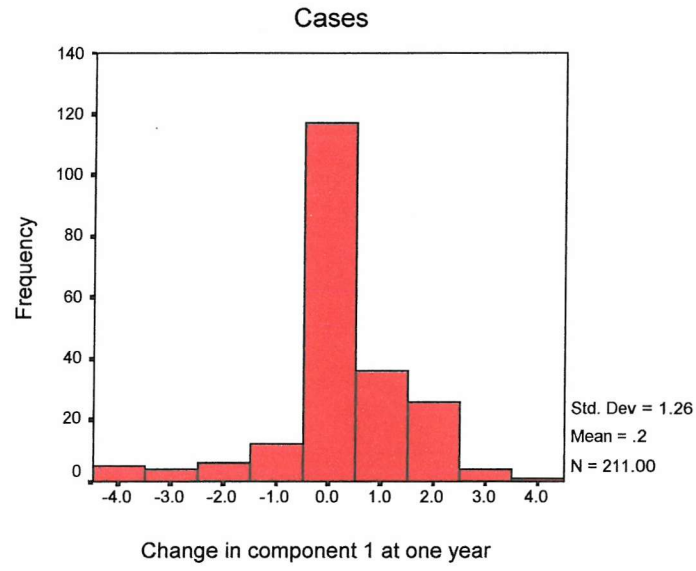




Histograms of Change in Components of insight at one year:

Following are histograms of the above data, which show a normal distribution for change.

Fig A8.2: Histogram of Change in Component One of insight at one-year follow up:



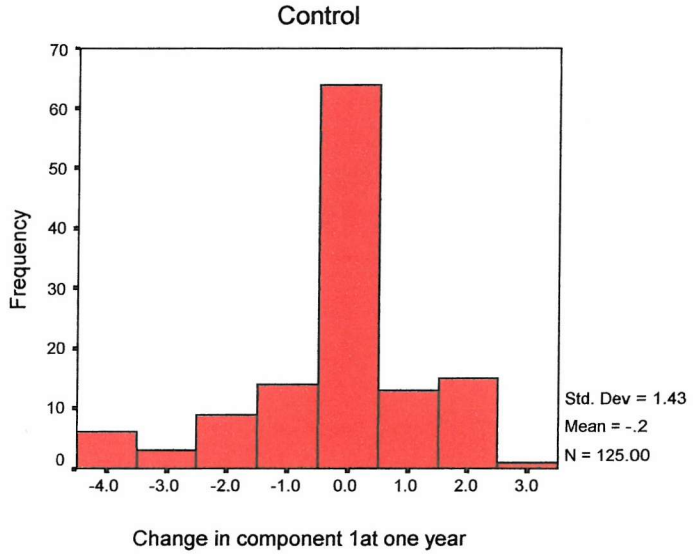
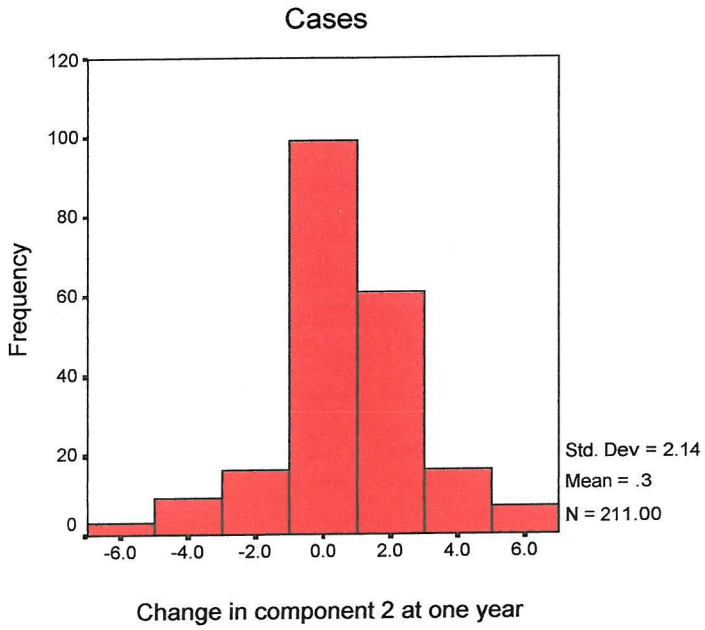


Fig A 8.3: Histogram of Change in component Two of insight at one-year follow up:



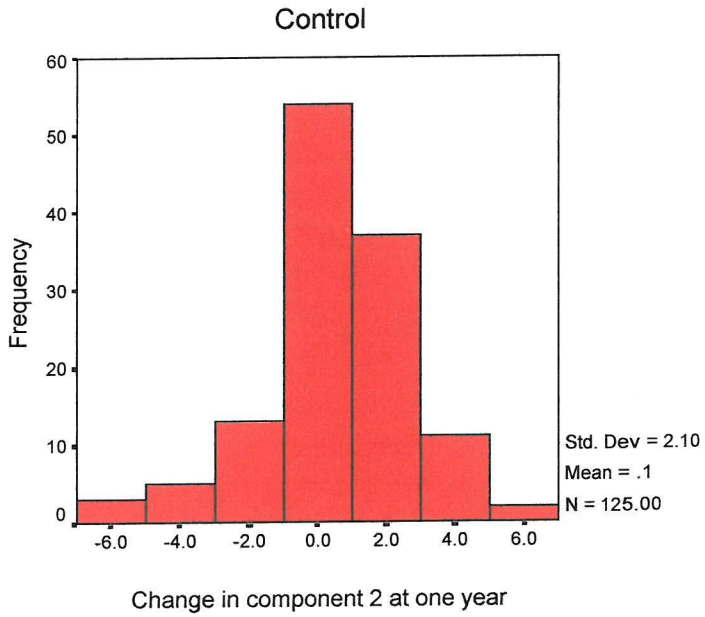
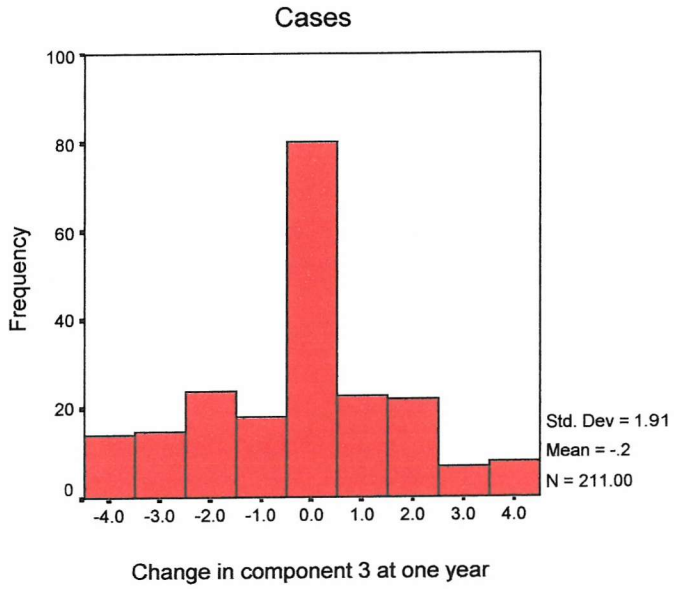
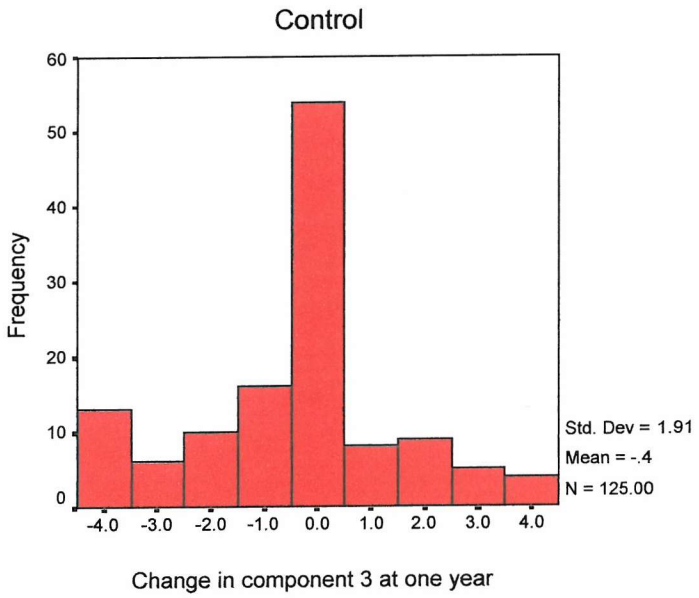


Fig A 8.4: Histogram of Change in component Three at one-year follow up:

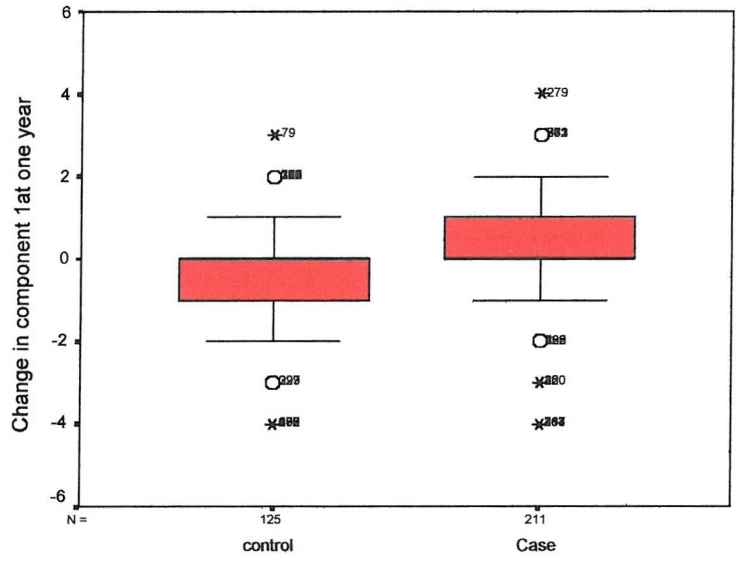




Box Plots of Components of insight at one year:

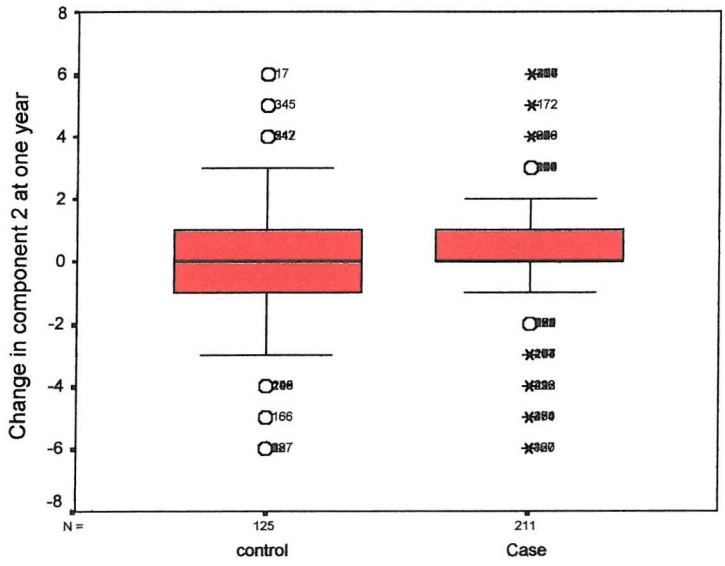
Summary statistics for one-year follow up data are displayed through the following box plots. In the following boxplot, the general trend of scores (i.e. change in insight) for cases was upward meaning they show an improvement compared to controls.

Fig A8.5: Box Plot of Change in Component One of Insight at one year



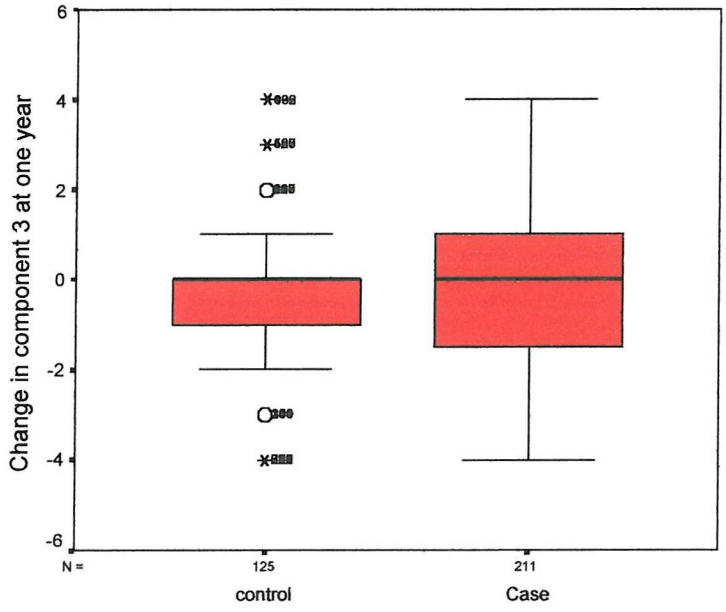
The means and distribution of scores in the following boxplot for component 2 of insight are very similar for cases and controls.

Fig A8.6: Box Plot of Change in Component Two of Insight at one year



For component 3 of insight, the change for the groups appear to be in opposite directions for some of the cases that show an upward trend.

Fig A8.7: Box Plot of Change in Component Three of Insight at one year



Appendix 9

Regressions of change in components of insight and psychotic symptoms at three months

1. **Feeling controlled:**

Table A9.1: Regression of change in components of Insight and Feeling controlled

	B	Std Error	Beta	t	Sig
Comp1	0.12	0.08	0.07	1.39	0.16
Comp2	-0.15	0.14	-0.05	-1.10	0.27
Comp3	-9.71E-02	0.12	-0.04	-0.79	0.43

B = Estimate; Dependent variable: Change in components of insight

None of the results are statistically significant.

2. **Disrupted thoughts:**

Table A9.2: Regression of Change in components of Insight and Disrupted thoughts

	B	Std Error	Beta	t	Sig
Comp1	-0.08	0.07	-0.01	-0.12	0.90
Comp2	0.12	0.11	0.06	1.15	0.25
Comp3	-0.20	0.09	-0.11	-2.13	0 .03 CI -0.39 & -0.02

B = estimate; Dependent variable: Change in components of Insight

With deterioration in disrupted thoughts, comp.3 (relabelling symptoms) of insight gets worse.

3. **Ideas of Persecution:**

Table A9. 3: Regression of change in insight components and persecutory ideas

	B	Std Error	Beta	t	Sig
Comp1	-0.17	0.07	-0.13	-2.48	0.01 (CI = -0.30 & -0.03)
Comp2	-2.95E-02	0.11	-0.01	-0.26	0.79
Comp3	-0.17	0.10	-0.09	-1.78	0.07

B = estimate; Dependent variable: Change in components of Insight

There is a statistically significant deterioration in component 1(compliance) of insight with deterioration in ideas of persecution.

4. Ideas of Grandeur

Table A9.4: Regression of change in insight components and grandiose ideas

	B	Std Error	Beta	t	Sig
Comp1	-0.07	0.10	-0.04	-0.73	0.46
Comp2	-0.03	0.16	-0.01	-0.19	0.85
Comp3	-0.03	0.15	0.01	0.23	0.82

B = estimate; Dependent variable: Change in components of Insight

None of the results in this table are statistically significant.

5. Other Delusions:

Table A9.5: Regression of change in insight components and other delusions

	B	Std Error	Beta	t	Sig
Comp1	0.08	0.07	0.05	1.03	0.31
Comp2	0.13	0.12	0.06	1.04	0.29
Comp3	-0.07	0.11	-0.04	-0.69	0.49

B = estimate; Dependent variable: Change in components of Insight

There are no statistically significant results in the above table.

6. Commenting Voices:

Table A9.6: Regression of change in insight components and commenting voices

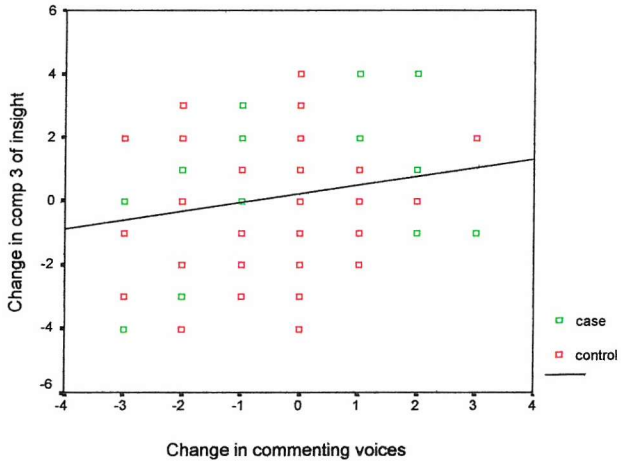
	B	Std Error	Beta	t	Sig
Comp1	-0.05	0.08	-0.00	-0.06	0.95
Comp2	0.16	0.13	0.06	1.19	0.23
Comp3	0.25	0.12	0.11	2.10	**0.04 (CI 0.02 & 0.48)**

B = estimate; Dependent variable: Change in components of Insight

The p value for Component 3 of insight is statistically significant at $p<0.05$ level.

Increase in commenting voices shows a linear association with improvement in insight. This result is confirmed by plotting a scatter plot showing the relationship between the two as follows:

Fig A9.1: Scatter plot showing relationship between component 3 of insight and commenting voices



7. Other Auditory Hallucinations:

Table A9.7: Regression of change in insight components and other auditory hallucinations

	B	Std Error	Beta	t	Sig
Comp1	0.12	0.06	0.09	1.88	0.06
Comp2	-0.08	0.11	-0.04	-0.79	0.42
Comp3	-0.12	0.09	-0.07	-1.30	0.19

B = estimate; Dependent variable: Change in components of Insight

There are no statistically significant results in the above.

Appendix 10

Regressions of change in components of insight and psychotic symptoms at one year

1. Feeling controlled:

Table A10.1: Regression of change in components of Insight and Feeling controlled

	B	Std Error	Beta	t	Sig
Comp1	-0.87	0.098	-0.048	-0.891	0.374
Comp2	-0.120	0.157	-0.042	-0.764	0.445
Comp3	-0.297	0.140	-0.115	-2.115	0.035 CI: -0.57 & -0.02

B: Estimate; CI: Confidence Interval; Dependent variable: Change in individual component of insight.

The p value is significant ($p<0.05$) for component three of insight meaning, with deterioration in the symptom of feeling controlled; there is deterioration in component three of insight.

2. Disrupted thoughts:

Table A10.2: Regression of Change in components of Insight and Disrupted thoughts at one year

	B	Std Error	Beta	t	Sig
Comp1	-0.021	0.082	-0.014	-0.257	0.797
Comp2	0.067	0.131	0.028	0.515	0.607
Comp3	-0.183	0.117	-0.085	-1.556	0.121

B: Estimate; Dependent variable: Change in component of insight.

None of the above results were found to be statistically significant.

3. Ideas of Persecution:

Table A10.3: Regression of change in insight components and persecutory idea at one year

	B	Std Error	Beta	t	Sig
Comp1	-0.018	0.078	-0.013	-0.242	0.809
Comp2	-0.029	0.125	-0.013	-0.235	0.814
Comp3	-0.021	0.112	-0.010	-0.191	0.849

B: Estimate; Dependent variable: Change in individual component of insight.

None of the above results are statistically significant

4. Ideas of Grandeur

Table A10.4: Regression of change in insight components and grandiose ideas at one year

	B	Std Error	Beta	t	Sig
Comp1	0.031	0.123	0.001	0.026	0.979
Comp2	-0.173	0.197	-0.048	-0.881	0.379
Comp3	-0.067	0.177	-0.021	-0.380	0.704

B: Estimate; CI: Confidence Interval; Dependent variable: Change in individual component of insight.

None of the results in this table are statistically significant.

5.Other Delusions:

Table A10.5: Regression of change in insight components and other delusions at one year

	B	Std Error	Beta	t	Sig
Comp1	-0.074	0.090	-0.045	-0.826	0.409
Comp2	0.02	0.145	0.008	0.138	0.890
Comp3	-0.09	0.130	-0.040	-0.724	0.470

B: Estimate; CI: Confidence Interval; Dependent variable: Change in individual component of insight.

There are no statistically significant results in the above table.

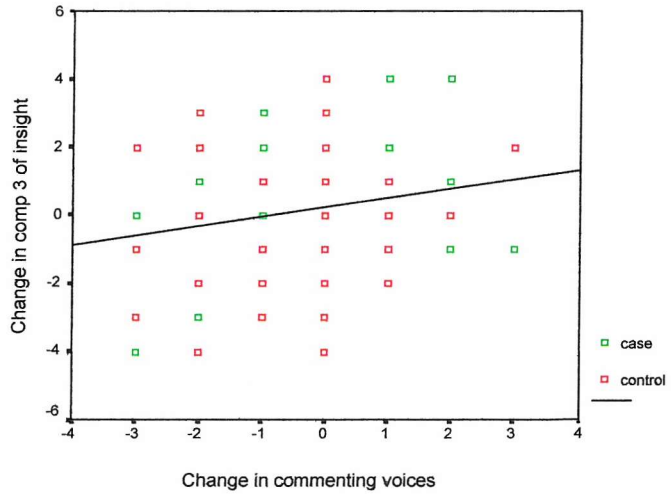
6.Commenting Voices:

Table A10.6: Regression of change in insight components and commenting voices at one year

	B	Std Error	Beta	t	Sig
Comp1	-0.098	0.078	-0.007	-0.125	0.900
Comp2	-0.052	0.126	-0.023	-0.418	0.676
Comp3	0.246	0.112	0.119	2.189	0.029 CI: 0.02 & 0.46

The P value for Component three(relabelling psychotic symptoms) of insight is statistically significant at $p<0.05$. Increase in commenting voices shows a linear association with improvement in insight. This result is further explored by plotting a scatter plot showing the relationship between the two as follows:

Fig A10.1: Scatter plot showing relationship between component 3 of insight and commenting voices at one year



7. Other Auditory Hallucinations:

Table A10.7: Regression of Change in insight components and other auditory hallucinations

	B	Std Error	Beta	t	Sig
Comp1	0.102	0.078	0.071	1.308	0.192
Comp2	-0.197	0.125	-0.086	-1.577	0.116
Comp3	0.015	0.113	0.008	0.140	0.889

B: Estimate; Dependent variable: Change in individual component of insight.

There are no statistically significant results in the above.

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