

ABSTRACT

Title: A pilot study of the effect of pharmacist led medication counselling on compliance with drug therapy in psychotic patients.

Objective: to determine whether medication counselling by a clinical pharmacist could improve compliance with treatment in acutely psychotic inpatients, and if so, whether the effect persisted three months later. A similar study was carried out by Kemp et al; (1996), which demonstrated improved compliance in a similar group of patients who had undergone 'compliance therapy' undertaken by a psychiatrist.

Design: Randomised controlled trial of medication counselling by clinical pharmacist each comprising 3 sessions lasting 20-30 minutes and brief counselling given by ward nurses/clinician.

Setting: Acute psychiatric admission wards serving xxxxxxxx catchment area.

Subjects: 38 patients with psychosis.

Main outcome measures: Informant and observer reported measure of compliance; observer assessed global functioning; self-rated attitudes to drug treatment and symptom scores. All performed after the intervention and three months later.

Results: 20 patients received medication counselling and showed significantly greater improvements in their attitudes to drug treatment and in their insight into illness and compliance with treatment compared with the control group. The gains persisted for three months.

Conclusion: Medication counselling by a clinical pharmacist is a pragmatic method of improving compliance with drug treatment in psychotic patients and its gains persist for three months.

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INTRODUCTION

Kemp et al (1996) concluded that medication compliance therapy is an effective method for improving compliance with drug treatment in psychotic inpatients and its gains persist for at least six months. An extensive literature search revealed no studies, which had looked at the effect of a pharmacist on influencing compliance in such patients by providing similar medication counselling. This pilot study is designed to look at this intervention, using similar patients, assessments and methodology to determine if such an effect can be achieved by a clinical pharmacist and given the significant problems arising from poor compliance, represent a cost effective way of improving patient care.

THE PROBLEM OF NON-COMPLIANCE

DEFINITION

Non-compliance is defined as suboptimal adherence to treatment regimens. A more appropriate term now used is 'concordance' which represents a new approach to the prescribing and taking of medicines. It is an agreement reached after negotiation between a patient and a healthcare professional that respects the beliefs and wishes of the patient in determining whether, when, and how medicines are to be taken. The Royal Pharmaceutical Society of Great Britain's working party on medicine taking (1997) recommends that 'concordance' should replace the term 'compliance'. Compliance has long been criticized as denoting obedience – "following doctor's orders".

However in most of the literature researched for this study the word compliance is used and for this reason this term is used for the purpose of this study.

Poor compliance with medication is endemic in all areas of medicine and psychiatry is no exception. By its very nature, psychiatric illness may more strongly affect judgement, insight and stability, placing psychiatric patients at increased risk for medication non-compliance. Psychotic patients are particularly vulnerable as discontinuation of medication increases the risk of relapse (Kane 1983), thus impairing insight and judgement and rendering the patient less likely to accept treatment.

PREVALANCE

Rates of poor compliance ranging from 10% to 80% have been cited in various reviews of patients with psychotic disorders (Weiden et al, 1994, Corrigan et al, 1990).

This wide range is most likely the result of differences in the definition of compliance, how it is measured and the populations studied.

THE IMPACT OF POOR COMPLIANCE

Studies have indicated poor compliance as a crucial factor associated with

- Relapse and rehospitalisation (Johnson 1983, Sullivan 1995)
- Length of readmissions
- Eventual outcome (Helgason, 1990; Haywood, 1995).

Non-compliance has also been identified as predictive of violent behaviour in patients with psychotic disorders (Fuller Torrey, 1994). Kissling (1994) concludes that with consistent relapse prevention, including improving medication compliance, the rate of relapse in schizophrenia

could be lowered to about 15% (at present approximately 50% of schizophrenic patients relapse within the first year of remission and about 85% do so within the first 5 years). Bebbington (1995) has estimated the cost of non-compliance in the UK to be over £100 million per annum.

This does not take into account costs to society from

- Lost work output
- Burden of care
- Family and social disruption
- Individual suffering
- Losses and deprivation

FACTORS ASSOCIATED WITH NON-COMPLIANCE

1. Disease related factors

Non-compliance has been associated with psychotic symptomatology e.g. paranoid delusions, thought disorder and grandiosity (Appelbaum, 1980; Marder et al., 1983; Hoge et al., 1990). Impairment of social perception is a fundamental feature of psychotic illness. Perception of emotions is less accurate than in healthy individuals, as is the ability to identify the facial and vocal signs of emotion. Emotional deficits have clinical implications for social function and inadequate social interactions may have implications for compliance. In a double blind trial, Kee et al 1998 compared the effect of the atypical antipsychotic risperidone with haloperidol on the ability to perceive emotions. They found that risperidone may facilitate the patient's ability to accurately perceive emotions. Many patients prefer such an improved mood status and are therefore more compliant with medication.

Cognitive disturbances are not only an adverse effect during treatment with classical antipsychotics but also common symptoms of psychotic disorders e.g. schizophrenia. It has been suggested that the cognitive decline in schizophrenia may be due to a reduction in the dopamine activity in the prefrontal cortex and that typical antipsychotics which reduce the dopaminergic activity even more, can further reduce cognitive function (Green et al, 1999, 1993). Newer atypical drugs with serotonin-dopamine antagonistic properties, such as clozapine, risperidone and olanzapine, have been reported to have a better effect on cognitive functioning than classical antidopaminergic drugs and be more likely to enable the patient to benefit from cognitive training, and consequently better understand the need for drug treatment. (Borison, 1996; Foster et al, 1999; Lindstrom, 1994; Purden 1999).

2. The Treatment

(a) Polypharmacy

Polypharmacy and the complexity of the medication regimen have been shown to adversely affect compliance (Blackwell, 1972). Patients are more likely to adhere to a simple regimen; when multiple medications are prescribed simultaneously or doses are to be taken several times a day, compliance is frequently reduced. Therefore a single daily dosage has increased in popularity, when indicated, in the treatment of many psychiatric conditions.

(b) Physician Behaviour

Physician behaviour can also affect compliance e.g. clinicians attitude towards medication (Irwin et al, 1971). Other clinician factors, which tend to decrease compliance include an authoritarian attitude, aloofness, passive behaviour, indifference, anger, denial, cynicism, hopelessness and ignorance (Baldessarini, 1994).

(c) Antipsychotic Side Effects

Recognition of side effects is an important factor in reducing non-compliance. Common problems with antipsychotic medication include sedation, anticholinergic effects, orthostatic hypotension, cognitive blunting, sexual dysfunction and in particular extrapyramidal syndromes (EPS). EPS effects are especially problematic as they are unique to antipsychotics, present subtly and play a major role in antipsychotic non-compliance. The major EPS effects and other side effects that cause non-compliance are:

- Dystonia.

Acute dystonias are sustained, unopposed muscle contractions that lead to distortions of the face, eyes, neck and extremities. They arise most often early in the course of treatment. Dystonias may be sudden, dramatic, painful and frightening. They most often occur in young male patients. Prompt recognition, treatment and anticholinergic prophylaxis are ways of reducing long term non-compliance from an initial dystonia.

- Akinesia.

Akinesia is a component of parkinsonism that is characterized by a paucity of spontaneous speech, gestures and movements. This side effect can range from virtual mummification to subtle slowing of activities or even just a subjective complaint of “feeling like a zombie”. Akinesia may cause or be mistaken for depression. The primary treatment is dosage reduction or discontinuation. Anticholinergic drugs may be helpful.

- Parkinsonian effects.

Beside akinesia, drug-induced parkinsonism may cause tremor and rigidity experienced as shaking, stiffness or decreased coordination. Specific occupational dysfunction e.g. typing, manual labour may lead to non-compliance after hospital discharge. Anticholinergic medication is useful.

- Akathisia

Akathisia can be intensely distressing. It can present either as psychomotor agitation or an inner sense of restlessness. It can occur after only one dose of

antipsychotic or may persist with chronic treatment. Dosage reduction is the first line of treatment and adjuvant treatments include benzodiazepines, anticholinergics and propranolol.

- Tardive dyskinesia (TD)

This is an involuntary movement disorder usually consisting of choreoathetoid movements of the orofacial musculature or extremities. Although it can be chronic and disabling, the most striking aspect of the relationship between TD and noncompliance is that either the threat or presence of TD usually does not lead to non-compliance (obviously there are exceptions to this). Since TD generally arises in patient populations who in general have complied with antipsychotics for a long time, there may be a tendency for TD to arise within a highly compliant group. TD patients often do not recognise or become distressed by their symptoms (Munetz et al 1985) and even when informed of the presence of TD will continue on their medication. Therefore, often it becomes the responsibility of the clinician/pharmacist to inform the patient of TD and emphasise the risks. Patient and family education is indicated which should include open discussion of the risks and benefits of available treatment options and prognosis.

- Cognitive blunting

Cognitive blunting may result from antipsychotic medication or from the adjunctive anticholinergic treatment. This may present clinically in a wide range of ways, from trouble recalling information to a subjective interference with creative thought. Such medication induced cognitive problems need to be clinically distinguished from the

attentional difficulties arising directly from schizophrenia. Cognitive difficulties are most likely to be reported by working patients involved in task-orientated activities or those patients who are very, aware of their thought processes. Treatment options include reduction or discontinuation of adjunctive anticholinergics, dosage reductions of the antipsychotic or changing to another antipsychotic.

- Affective changes

Depression and dysphoria are reported complications of antipsychotics. A patient who is distressed by this and is able to recognise the onset of depression with the medication may refuse treatment. Depression arising from antipsychotic medication needs to be distinguished clinically from post-psychotic depression, negative symptoms of schizophrenia and a co-existent affective illness.

- Sexual dysfunction

This is a frequently occurring problem with antipsychotic medication, and one, which is often overlooked by the clinician. Antipsychotic medication may cause decreased libido, erectile impotence, retrograde ejaculation and anorgasmia. Hyperprolactinaemia secondary to antipsychotics can cause galactorrhoea, amenorrhoea and infertility in women, and sexual dysfunction in men. This can be quite a major factor in non-compliance especially in the younger patient population and one, which needs to be addressed more readily with careful selection of antipsychotic agent

- Weight gain.

Antipsychotics are often associated with weight gain (Weiden et al 1986). Female patients are more likely to refuse medication on this basis due to growing social pressure towards slimness (Silverstone et al, 1988). Fortunately significant advances have occurred in understanding and managing this problem (Stanton, 1995). Careful choice of medication is required in this group of patients.

3.Other factors

Treatment adherence may also be affected by:

- Social stability

There is evidence that less socially stable patients are more likely to drop out of treatment in psychiatric populations. Altman et al (1972) found that patients who were single and not earning a salary were more likely to not comply. In their review of the literature Baekeland and Lundwell (1975) conclude that among psychiatric populations, the less socially stable a patient is, the more likely he or she is to drop out of treatment. Occupational and residential stability seem to carry more weight than marital stability and occupational stability is a more potent predictor of dropping out in alcoholics and drug addicts than other groups of psychiatric patient

Living alone strongly correlates with poor compliance (Blackwell, 1976). Intermediate levels of supervision e.g. day programmes may increase compliance. Availability of family

members or concerned individuals may be essential for compliance in patients living in otherwise unsupervised settings.

- Socio-economic status

An association between low socio-economic status and poor compliance has long been recognised both in medical and psychiatric conditions. (Lefebvre et al, 1986, Baekeland et al 1973).

- Age

Numerous studies have examined the impact of age on compliance Waters et al 1976) found that 7% of prescriptions issued were never presented at a chemist. They found that the 25-34 age group were least likely to present their prescriptions whereas older patients complied better. Other studies have given conflicting results (Quinn et al, 1977). The inconsistency of reports in this area reflect the variations in the populations under study. Haynes et al (1979) found no consistent relationship between age and compliance. The majority of studies in this area seem to draw similar conclusions.

A similar picture emerges with regard to psychiatric treatment e.g. Baekeland and Lundwall (1975) looked at 51 studies of which 35 found age to be unrelated to non compliance with treatment. Where an age difference has been identified, the conclusion has usually been that older patients comply better. No studies were found that looked exclusively at a schizophrenic patient population

- Sex

The sex of a patient has not been shown consistently to affect the likelihood of compliance with treatment. Davis (1968) looked at 154 patients in a medical outpatient clinic and found no difference between men and women in the extent to which they followed medical advice. Even when differences have been found, these are often trivial. In certain specialised samples significant differences have been found e.g. Kanzler et al (1976) looking at an anti-smoking programme, found that 57% males were still smoking as compared to 30% females. In psychiatric populations differences have also been noted in specific populations. Craig et al (1974) looking at a relatively deprived inner city population in Baltimore, found that males were less likely to progress successfully from referral by the emergency service to regular outpatient attendance, and also reported that when males do enter treatment they do so under less favourable circumstances, e.g. through the courts. A later study of the same population, however, showed that once patients had entered treatment the drop out rates were the same for males and females. In Britain Caine and Weijesinghe (1976) used a sample drawn from 100 patients referred to a psychotherapy clinic and found no significant differences in age or sex between treatment responders and those who dropped out of therapy.

- Personality and attitudinal factors

Views that are anti-psychiatry; anti-chemicals are common in society. Augermeyer and Matschinger, 1994 have demonstrated the general population's preference for psychological rather than biological explanations for schizophrenia, and a corresponding tendency to favour psychological rather than pharmacological interventions.

Other attitude factors include; prevalent beliefs about the value of alternative cures, or the role of self-control and willpower in overcoming the illness (Weiden, 1986). Fears of addiction or loss of personality are common, as are playing out interpersonal and family conflicts and dependency needs. (Kane, 1983).

IMPROVEMENT STRATEGIES

Various strategies have been proposed and used to improve compliance. The following has been suggested.

- Keeping the regimen simple – reducing the frequency and number of drugs
- Providing explicit written instructions
- Involving the patient in the decision making process
- Encouraging the patient's participation in their own care
- Implementing drug regimens gradually
- Tailoring to daily rituals
- Providing warm positive feedback

The use of depot medications

As an alternative to oral treatment in non-compliant patients, depot antipsychotics offer a valuable and safe method of maintenance therapy (Glazer and Kane, 1992). Although very beneficial in patients who at least comply with this kind of application, relapse rates are not brought down to zero even with this “assured compliance”, and underlying negative attitudes will not be changed. Careful monitoring and supportive therapy are needed to minimise default leading to relapse. (Weiden et al, 1995). Unfortunately, many antipsychotics especially the newer atypicals are not yet available in depot form although work is currently underway in this field.

The role of newer antipsychotics

Following the introduction of the new atypical antipsychotics e.g. clozapine, risperidone, olanzapine - the number of pharmacoeconomic studies has increased considerably. Comparisons have been made between old and new antipsychotics, and new versus new antipsychotics. Some evidence has accumulated that new antipsychotics may reduce hospital stays, increase quality of life and decrease EPS.

In randomised trials it has been shown that clozapine improves psychopathological symptoms and increases quality of life more than conventional antipsychotics (Kane et al, 1998, Balldessarini et al 1991). However clozapine is an expensive drug, partly because of the fact that all patients receiving clozapine must have weekly or monthly blood cell counts. Nevertheless, the results obtained with clozapine indicate that savings in both direct and indirect costs may be achieved (Reid et al, 1994, Melzer et al, 1993, Davis 1994).

Risperidone has been evaluated for its efficacy and possible cost-effectiveness in chronically ill antipsychotic-resistant patients. A potential for cost savings in this group has been identified. (Lindstrom et al, 1995, Keegan et al, 1999, Lecompte et al, 1999).

Comparisons of olanzapine with haloperidol have led to conclusions of cost savings, or at worst neutrality, with olanzapine (Glazer et al, 1997, Almond et al, 1998, Hamilton et al, 1999).

Educational interventions

Patient education is a favoured way of promoting compliance among psychiatric patients (Falvo, 1995) According to Falvo, patient education is a key component in enabling patients to accurately follow the recommendations of the clinician. Patients cannot follow treatments and recommendations if they don't understand or accept them. Patient education has also been

identified as an important preventive intervention to break the cycle of multiple psychiatric rehospitalisations (Haywood et al, 1995).

The pharmacist has an invaluable role to play in educating and counselling psychiatric patients about their medication. However this is likely to be more effective as part of a multi-disciplinary approach. To date there seems to have been no research done as to the effects of a clinical pharmacist providing medication counselling/information. Previous research has looked at psychiatrist, psychiatric nurse, or psychologist input which has given, mostly favourable, but a few mixed results.

Boczkowski et al (1985) compared the effects of a behavior tailoring (BT) and a psychoeducational (PE) intervention in chronic schizophrenics. Follow up after three months showed that the BT group were significantly more compliant, as measured by pill counts.

- The BT intervention included practical guidelines such as stimulus cues to facilitate remembering, and self-monitoring calendars.
- The PE intervention consisted of didactic information on the illness and reasons for taking medication, however its brevity (50 minutes in total) may partially explain its limited effect.

Seltzer (1980) found improved compliance 5 months after a series of lectures together with written information given while inpatients. The intervention was considerably more intensive than Boczkowski et al consisting of nine lectures given in small groups. The content included

- Patient experiences
- Side effects
- The relationship between relapse and premature cessation of drugs
- Reinforcing desirable drug-taking behaviour

In one of the most comprehensive programs to be evaluated, Eckman et al (1990) investigated the potential of a behaviourally orientated program in improving compliance and medication management skills in outpatients with schizophrenia. In a multicentre field trial, patients followed a structured module in groups for about three hours per week over four months.

The four skilled target areas were

- Information on the benefits of antipsychotic medication
- Correct self-administration and evaluation of medication effects
- Identifying side effects
- Negotiating medication issues with healthcare providers.

Compliance assessed independently improved significantly, from about 60% to 80%

Kemp et al (1996) found significant improvements in compliance in psychotic inpatients receiving compliance therapy and that this improvement was sustained over an 18 month follow up period.

In examining the results from educational programs a few points must be considered.

- Paced learning, rehearsal and repetition are important techniques to overcome attention/concentration difficulties.
- Gaining knowledge, especially when abstract, does not necessarily lead to changes in attitude. In Streiker's study (1986) there was an initial improvement in attitudes which decreased over time. This suggests a need for booster or maintenance sessions to consolidate any gains made.
- Diamond (1983) has commented on the importance of tailoring medical recommendations with a patient's own perceptions. Talking in very general terms is less likely to make an

impact than specifically addressing an individual's unique needs. This may suggest a need for more individualised interventions.

- Hogan et al (1983) have commented on the problem in providing positive information about medication, if patients' interoceptive cues from the effects of drugs are decidedly unfavourable.

TABLE 1: PRACTICAL DIFFICULTIES AND POSSIBLE ACTIONS

<u>Problem</u>	<u>Action</u>
Impaired sight	Large print or Braille labels. Tape Recordings of Patient Information Leaflet (PIL)
Reduced manual dexterity	Use non-Child Resistant Containers Check patient can cope with foil or blister packing or liquid medicines.
Problems swallowing solid dose forms	Suggest change to liquid formulations or dispersible forms.
Poor reading skills	Concentrate on verbal counselling Offer continuing information back-up on the telephone
Lack of knowledge/understanding about the disease and/or treatment	Written information Verbal information
Forgetfulness	Prompts and reminders e.g. Precise dosing timing Reminder charts Special containers e.g. Medidos Involve relatives or carers
Confusion over complex regime	Tailor regime to patients lifestyle approach clinician about rationalisation of regimen.

Not all non-compliant people choose to reject their medication; some just forget to take them.

It is generally known that most people prescribed medication, whether mentally ill or not; tend to forget to take their medication from time to time. It is not surprising that patients with mental illnesses frequently forget, as they may be suffering considerable cognitive dysfunction at the time. It is important to involve other family members/carers and to ensure they are counselled on the use of the drugs. Strategies used to help remember to take the medication include integrating the timing into usual routines e.g. getting up, going to bed, eating, shaving, brushing teeth etc. It is important to simplify medication taking as much as possible. If the clinician concurs, drug regimes may be simplified, or dosage forms adjusted. The use of medication aids e.g. Medidos can be of value. Practical advice to cope with any unpleasant side effects include; sugarless gum for dry mouth, the use of sunscreens for photosensitivity.

Patient Counselling

It is important for the pharmacist to assess the patient's understanding of the therapeutic regimen. Gauging the patient's knowledge can help in designing the counselling session to the patient's level of understanding about the disease state or drug therapy. While simplifying is appropriate for most patients, it can be insulting to others (Lewis et al, 1997). The patient's level of understanding can be assessed by asking him to describe the disease and its management in his own terms.

The pharmacist should avoid assuming a particular diagnosis when a patient receives antipsychotic therapy. Often the use of a drug does not necessarily agree with licensed indications. It is important for the pharmacist to respond to this scenario in a professional manner in order to avoid confusing or offending the patient or prescribing clinician. The pharmacist should ask open-ended questions e.g. "what did the doctor tell you the medication is for?" This format can be useful in assessing the patient's understanding of the medication's indication and also the diagnosis. If the patient is unaware of the diagnosis, the pharmacist can shift the discussion to the use of the medication for certain symptoms the patient has experienced.

The pharmacist should discuss adverse effects in a positive way, whenever possible. Discussing positive benefits firstly may reduce the patient's anxiety or concern in starting a new medication.

Onset of effect

Within the first few weeks of therapy, antipsychotic medications may only provide calming effects. The patient can feel less agitated, less hostile, and be in a better mood, but may not have any improvement regarding positive or negative symptoms. After 2-6 weeks, the patient may

experience some improvement in socialisation. From about two weeks to a few months, the patient may begin to experience less of the positive symptoms such as hallucinations, delusions or thought disturbances. Depending on how long the patient has experienced psychosis, he may never be symptom-free. He may only experience fewer episodes or they may be less visual. It is important to provide specific information to the patient since without this knowledge; patients may discontinue medication due to disappointment with minimal results.

Expectations

Many patients with psychotic symptoms are not satisfied with their symptom improvement, regardless of how effective their medication may be. This is often due to unrealistic expectations by the patient or family. Unfortunately most psychotic patients do not accept the fact that medication may reduce but not eliminate psychotic symptoms. This frustration leads to discontinuation of medication, exposing the patient to a higher risk of relapse. Realistic goals need to be set for patients regarding the management of their symptoms with antipsychotic drug therapy. If the patient is at an early stage of psychosis, symptoms may be diminished or even eliminated after a few months or years of antipsychotic agents. But if the patient has been having psychotic symptoms for many years, symptoms will most likely never be eliminated, only reduced in severity.

Awareness

Many newer antipsychotic drugs have become available in recent years and others are in the process of being marketed and patients need to be aware of what they are taking and understand any changes that are made. It is important that patients participate actively in drug therapy

selection since this can improve compliance and treatment outcome. A pharmacist can have great impact on the patient's drug therapy by providing appropriate information. Counselling should be individualised in terms of how much information the patient receives.

Attitude

Patients who have a negative attitude to their drug therapy are often non-compliant with their medication regimen. Regardless of selection of the optimal drug regimen, the patient's attitude can easily negate the effectiveness of such. Counselling patients must emphasise balancing the medication risk and benefits, and ways to improve the negative aspects of the therapy. Presenting solutions before patients experience problems may help improve the patient's attitude to drug therapy and thus improve compliance and clinical outcome.

Adverse effects

Although counselling about adverse effects involves discussing a negative aspect of drug therapy, the focus should be on minimising patients' overconcern. When patients experience an adverse effect, they may choose the effective solution of discontinuing the drug. Thus counselling must include discussion of the common, expected adverse effects and what to do if one occurs. Patients must understand that adverse effects can be treated or minimised while drug therapy continues.

The antipsychotic drugs can be separated into typical and atypical categories. For typical drugs e.g. chlorpromazine, haloperidol, adverse effect counselling should focus on sedation, anticholinergic (dry mouth, blurred vision etc) and extrapyramidal effects. Individual atypical drugs possess varying receptor profiles and thus have adverse effects different enough from each

other to warrant counselling by specific agent.

- Sedation can be presented as a positive effect, helping to calm anxiety or nervousness and helping to induce sleep. Sedation is more prominent in the first two weeks of therapy, or in the two weeks after a dosage increase. Thus patients should be instructed that sedation will usually diminish after this time and if it does not a change in the dosage schedule or regimen may be sufficient to resolve the problem.
- Anticholinergic effects are common but can usually be corrected. As with sedation, anticholinergic effects will usually decrease after the initial two weeks of drug therapy.
- Orthostatic hypotension is a particular risk in the elderly patient as it can lead to falls and fractures. Patients should be advised to rise slowly from lying or sitting positions.
- Extrapyramidal effects are quite troublesome and often require additional medication e.g. procyclidine. It is important that the patient is aware of the purpose of this medication i.e. prevent or treat 'muscle side-effects' The patient should also be counselled about tardive dyskinesia.

Atypical antipsychotics

Risperidone – common adverse effects about which patients should be counselled include orthostatic hypotension, some activating effects and extrapyramidal effects. The activating effects may interfere with sleep, making morning or early afternoon dosing preferable. The extrapyramidal effects are much less of a problem than with the older typical drugs and are more likely when the dose reaches 6-8mg or more.

Olanzapine – adverse effects requiring patient counselling include sedation, mild anticholinergic

effects and weight gain. Extrapyramidal effects are very rare and do not require prior counselling.

Quetiapine – effects include sedation, initial orthostatic hypotension, and weight gain.

Clozapine- this is an agent usually reserved for treatment- resistant cases. Although it has a great number of possible side effects, these negatives are counterbalanced when clozapine is the only effective treatment for the patient. The adverse effect of greatest concern is agranulocytosis, which can be explained to the patient as a sudden decrease in white blood cells, which are necessary to fight infection. The risk is greatly reduced by the mandatory weekly blood test. Clozapine also causes sedation, anticholinergic effects, drooling, and orthostatic hypotension.

Maintenance therapy

The danger of relapse has been clearly documented with discontinued antipsychotic therapy after initial response. (Robinson et al, 1999). One study showed that the rate of relapse after 5 years from initial recovery was 81.9%. This risk increased almost five-fold when antipsychotic drug therapy was discontinued and diminished with maintenance antipsychotic drug treatment. (Lewis et al, 1997). This result clearly shows the importance of emphasizing compliance with maintenance treatment. This may not be an easy task, especially with patients experiencing psychotic symptoms. After experiencing improvement of symptoms for a period of time, many patients choose to discontinue their medication if they experience continued adverse effects with no obvious major benefits. The pharmacist should emphasise the importance of compliance with maintenance therapy after symptoms have resolved. Patients also need to understand the danger of relapse associated with non-compliance as well as the benefit of remaining compliant with drug therapy.

MOTIVATIONAL INTERVIEWING

This is a technique, which has been successfully used with ambivalent groups. It was developed, initially, to treat substance abuse, and has been applied to a number of other medical settings. It aims to help people work through ambivalence about behaviour change, and avoids the confrontation and stalemate of many conventional health professional/patient interaction. Elements derived from the principles of motivational interviewing include: (Miller and Rollnick, 1991)

- inductive questioning
- reflective listening
- regular use of summarising
- investigation of the pros and cons of alternative courses of action
- homing –in on and reinforcing adaptive attitudes and behaviour

With specific reference to psychotic patients, the following modifications are used

- A flexible approach to session length with more frequent short sessions to counteract poor concentration and memory difficulties.
- Increasing the educational component, including information about medication uses, side effects etc.
- Dealing with delusions specifically regarding medication
- paced intervention with a defined hierarchy of goals:
 - willingness to discuss treatment
 - acceptance of the need for medication
 - acceptance of regular medication and treatment
 - acceptance of the need to continue treatment even when well

The pharmacist proceeds with what the patient presents, asking open-ended questions. There are three phases:

1. Eliciting the patients stance towards treatment
2. Exploring ambivalence towards treatment
3. Highlighting the need for maintenance treatment

However, moving through these areas depends on the patient's progress. Two key techniques are reflective listening and exploration of the pros and cons of alternatives.

Discrepancy is developed: e.g. the patient feels he should not have to take medication, but realises it may keep him out of hospital. The pharmacist then homes in on the acknowledgement and prompts the patient to amplify it. Important components include:

- Expression of empathy
- Exploring ambivalence
- Dealing with resistance without being confrontational
- Avoidance of blaming

PHASE 1

- Formulate patient's stance toward treatment
- Link medication cessation and relapse
- Acknowledge negative treatment experiences
- Suggest advantage of patient's involvement in own treatment

PHASE 2

- Predict common misgivings about treatment
- Correct misconceptions
- Guide consideration of benefits and drawbacks of treatment
- Feedback symptoms reported by patient as targets for treatment
- Use metaphors e.g. medication as a 'protective layer'
- Highlight indirect benefits of treatment
- Cautiously explore delusional resistance to medication

PHASE 3

- Medication as positive strategy to enhance quality of life
- Analogy to physical illness needing long-term maintenance treatment
- Predict consequences of stopping medication
- Medication as an insurance policy to stay well

DRUG HISTORY

It is important to obtain an accurate drug history as soon as possible after patient admission.

This has become an increasingly important role for the clinical pharmacist. For the purposes of this study a medication history form was devised by the pharmacist (appendix 1).

Sources of information

In taking a medication history, medical notes, referral notes, medication records are all used, as well as information from patients themselves. Each of these has limitations e.g. patients are often poor historians and hospital records, etc are often inaccurate.

Studies have shown that pharmacists' drug histories are more accurate than those taken by other disciplines (Higham, 1987; Gurwich, 1983). However it must be remembered that the patient will only derive benefit if the additional information is of clinical significance. In a study by Badowski et al, a panel judged that 11% of 80 pharmacist acquired drug histories contained clinically important information missed by the doctor.

What information is required?

- Prescribed medicines

Information regarding prescribed medicines is essential to enable the admitting doctor to continue maintenance drugs during hospitalisation. It is important to detail all other drugs prescribed for medical conditions not related to psychiatry, something which can be overlooked in the psychiatric hospital and which pharmacists can be utilised.

- Allergies

Patient's allergies to drugs must be documented in order to avoid unnecessary, expensive and potentially life-threatening reactions. Questions relevant to food and food additive allergies may also have pharmaceutical implications.

- Recently discontinued medications

The action of drugs continues beyond cessation of administration. It is imperative that the physician knows if a patient has recently taken e.g. steroids or monoamine oxidase inhibitors.

- Non-prescribed drugs

Though frequently ignored, this is a very important part of the drug history. Covington (1972) found that the average hospitalised patient consumed 3.8 different non-prescribed remedies during the year prior to admission, while Patel and Jacques (1981) reported usage of non-prescribed by 74.3% of patients interviewed. These drugs are potential sources of drug-drug interactions, adverse reactions, and iatrogenic disorders. In the psychiatric field, the potential for interaction between St John's Wort and other psychotropic drugs, has recently been highlighted, in particular antidepressants and the possibility of inducing a 'Serotonin syndrome' Fugh Berman (1999), Muller et al (1997), Ernst (1999).

- Adverse reactions

It is important to document any previous adverse reactions suffered as these may affect any future treatment regimes.

- Alcohol and tobacco consumption.

It is useful to ascertain alcohol intake to aid the interpretation of liver function tests as well as flagging alcohol as a drug, which can interact with many other drugs. Tobacco consumption should be noted and patients can be counselled about the detrimental health effects and any potential interactions with other medications e.g. theophylline can be detected.

- Compliance

It is also useful especially in the psychiatric situation to ask compliance related questions. These can help ascertain if e.g. forgetfulness is a problem.

METHODS OF MEASURING COMPLIANCE

There are three main methods of measuring medication compliance:

- Patient and clinical self-report
- Pill counts
- Biological measures

Self-report methods are generally the most cost effective and time-efficient way of obtaining an indication of compliance (O'Shea, 1995; Gaebel, 1997), although such methods have been reported to overestimate compliance by over 30% (Piatkowska et al, 1992; Wright, 1993).

In comparison, pill counts have the disadvantage of undermining the therapeutic relationship and are also unreliable since there is no guarantee that the tablets removed from the container were actually consumed (Fenton et al, 1997). Biological measures are less frequently used due to their cost and limited availability (Piatowska et al, 1992; Kane, 1983) As with other methods the accuracy of biological measurement is compromised by individual differences in metabolism and is dependant on the period of time between ingestion of the last tablet and testing. (Cochrane and Gitlin, 1988). None of these methods of compliance measurement is completely accurate (O'Shea, 1995), and the concordance rate across these different measures has been reported to be low (Fenton et al, 1997). None the less self-report measures and clinical judgement are the easiest to administer and the least costly, whereas biological methods are more objective but no more accurate yet more expensive.

Assessments

The Brief Psychiatric Rating Scale (BPRS) (appendix 2) is a scale, which measures the degree of specific types of symptoms such as positive, and negative, and disorganisation, as well as overall pathology. It is the major assessment tool utilised in most efficacy studies of antipsychotic medication. It captures the type of psychopathology that is affected by drug treatments and is sensitive to the changes, which occur in treatment studies. (Lukoff et al, 1986).

The global assessment scale (GAS) (appendix 3) is a rating scale for evaluating the overall social functioning of a subject. The scale values range from one, which is the hypothetically sickest individual, to 100, the hypothetically healthiest with 10 defined anchor points relating to social competence. (Endicott et al, 1976).

A measure devised by David, 1990 (appendix 4) was used to measure the patient's level of insight. This scale measures a patient's willingness to accept that they have an illness, ability to identify psychotic experiences, and acceptance of their treatment.

The Drug Attitudes inventory (DAI) (appendix 6) is a self reported scale predictive of drug compliance. (Hogan et al, 1983). This scale measures the patient's attitude towards taking their medication and was created for use specifically on schizophrenic patients. This scale has demonstrated adequate test-retest reliability with an r-correlation of 0.82. The scale measures whether the patients only take medication when their symptoms intensify, attitudes toward taking their medication, and whether they are aware of the benefits of their medication.

In the research by Kemp et al (1996) two scales were used to assess the side effects of antipsychotics – the Simpson-Angus scale for extrapyramidal side effects (Simpson and Angus, 1970) and the Barnes Akathisia scale (Barnes, 1989). These scales were not used in this research as being quite long, medical staff felt time was not available to perform these on each patient. However the Lunsers side effect rating scale (appendix 7) was used instead. This is a fully validated and comprehensive self- rating scale for measuring the distress from the side effects of neuroleptics at any particular time. (Day et al 1995).

ASSESSING THE SIDE EFFECTS OF ANTI-PSYCHOICS IN CLINICAL PRACTICE.

The efficacy of anti-psychotics in treating schizophrenia and other psychosis is unquestionable. However the efficacy may come at a price; a wide range of side effects, including anticholinergic, extrapyramidal, hormonal, cardiovascular and haematological can occur, some of which are disabling and many of which contribute to non-compliance. Despite this patients do not always report side effects. Moreover health professionals may under estimate the impact of anti-psychotic side effects on the patient's quality of life, particularly those who rely on antipsychotic medication as the mainstay of their psychiatric treatment to enable their daily functioning. The practice of assessing antipsychotic side effects in such patients can therefore be viewed as a significant contribution to the clinical management of psychotic illness.

Assessing a patient for antipsychotic side effects can help improved management by:

- Improving quality of life
 - Encouraging drug choice based on side effect profile
 - Involving patients – this may augment therapeutic alliances and improve compliance
 - Reducing stigma
 - Encourage evidence-based prescribing
-

Because of the benefits, several guidelines now recommend assessing antipsychotic side effects. Until recently this was difficult in routine clinical practice. Previous rating scales examined only a limited range of adverse effects such as EPS (e.g. Simpson- Angus scale (Simpson, Angus 1970), or akathisia (e.g. Barnes Akathisia Rating Scale (Barnes 1989). A trained investigator is needed to administer the most comprehensive scale, the UKU (Udvalg Kliniske Undersogelser) which takes up to an hour to complete (Brenner et al 1990).

Against this background, the Liverpool University Neuroleptic Side-Effect Rating Scale (Lunsers) offers a straightforward fully validated and reliable assessment of antipsychotic side effects (Day et al, 1995) (see appendix 7 for example of the scale). Patients can complete the scale in five to twenty minutes. Lunsers includes 41 established antipsychotic side effects as well as 10 “red herrings”. The patient ranks the extent to which he or she has experienced each side effect over the preceding month. Each side effect falls into one of eight groups:

- Psychic side-effects
- Extra pyramidal side-effects
- Hormonal side-effects
- Anticholinergic side-effects
- Miscellaneous
- Other autonomic
- Red herrings
- Allergic reactions

High red-herring scores may indicate someone who 'over-scores' on the scale generally. The antipsychotic side effects score is the sum of all the items minus the red herrings.

In practice Lunsers is recommended for use before and after changing a drug or dosage, as well as six monthly during maintenance therapy. The pharmacist is the most appropriate health professional to administer this and assess the results and therefore make recommendations regarding the appropriate strategy, which may involve changing the dose or drug or a more specific intervention e.g. use of an anticholinergic. Therefore Lunsers can be a useful tool for the pharmacist to evaluate antipsychotic side effects and can offer the opportunity to improve management and enhance patient's quality of life.

The Role of the Pharmacist in Mental Health

Mental health problems are very common. As many as one in six adults suffer from mental health problems at any one time. This ranges from depression to serious mental illness, such as schizophrenia. Mental health is now a major priority for the Government with the publication of the national service framework (NSF) for mental health. This was developed as part of the governments vision for improving the quality of health care and providing a better service to patients and sets national standards, based on clinical evidence, and sets out best practice for promoting mental health and treating mental illness. Seven standards were set:

- promoting mental health for all and combating discrimination against people with mental health problems.
- identifying the needs of patients with mental health problems and ensuring they are offered effective treatments.
- ensuring all services are available round the clock
- ensuring all mental health service users on the Care Programme Approach (CPA) receive care which prevents or anticipates crisis and reduces risk
- provides a hospital bed or suitable alternative bed for those who need it and in an environment close to home that protects them and the public
- making sure carers who look after someone on the CPA have their own caring, physical and mental needs assessed on an annual basis
- reducing the suicide level.

The NSF was launched in a way that delivered a co-ordinated and constant message on how mental health services should be modernised. Clinical judgement, professional self-regulation and lifelong learning would underpin the delivery of care in mental health. Progress would be monitored by the commission for health improvement and a national survey of patients. People with severe and enduring problems were prioritised, whilst recognising the more common mental health problems still required attention.

Pharmacy and pharmacists received little mention within the mental health NSF. However pharmacists do have a central role to play in getting the treatment element of patient care “right”. In addition to developing drug treatment protocols, the pharmacist’s skills should be used in the management of those individuals who required complex drug treatment and whose needs cannot be met through adherence to these standard protocols

As part of getting drug treatment ‘right’ pharmacists can become involved in clinical audits on the use of medicines within mental health.

They also have an important role to play in educating patients and carers and providing information about psychiatric medicines in a way that is both understandable and relevant. The NSF does note that patients receive inadequate information concerning treatment (page 32). Pharmacists should become involved in offering advice, help and support, running medication education programmes, providing talks, leaflets, books, helplines etc. This should include people requiring rehabilitation receiving education about their treatment and carers, who should have information about medication and any side effects which can be predicted, and services available to them (standard six). This will help improve compliance and hence reduce suicide rates (target of reducing deaths by suicide by one fifth by 2010)(most standards). Indeed non—

compliance is mentioned in the guidelines as being a 'likely contributory factor in many cases of relapsing psychotic illness' (page45). The pharmacist has a major role to play in helping to increase compliance in mental health patients.

Specialist pharmacists can play their part in developing the mental health workforce by passing on their knowledge, skills and awareness of medication to their colleagues through structured training programmes.

People with mental health needs require individualised, co-ordinated, continuing and open pharmaceutical care and education about drugs, drug therapy and the consequences of taking and not taking long-term therapy.

NSF AND ANTIPSYCHOTICS

Issues raised by NSF document:

- Early treatment supported
- lower doses may be as effective as higher doses in preventing relapse
- Atypicals, with a different range of side effects, offer scope for improving the effectiveness of treatment and reducing side effects.
- Side effects may lead to treatment discontinuation, and relapse is higher with non-compliers
- "all service users should be assessed for and receive new antipsychotics where indicated"

THE CASE FOR ATYPICALS

The main side effects of typical antipsychotics, such as thioridazine and haloperidol, include extrapyramidal symptoms, tardive dyskinesia, akathisia and increased prolactin production.

Clinical trials have shown that atypical antipsychotics, such as olanzapine and risperidone, are as effective as older drugs at treating the positive symptoms of schizophrenia and were at least as effective for negative and cognitive symptoms. Atypical antipsychotics have fewer side effects, yet are under utilised in most psychiatric hospitals. Many health authorities are not funding atypical antipsychotics and forthcoming guidance is awaited from the National Institute for Clinical Excellence (NICE). If patients suffering their first episode of schizophrenia were exposed to drugs that caused severe side effects this could affect their attitude to drug treatment for the rest of their life. One local milestone stipulated in the guidelines is that all service users should be assessed for and receive atypical antipsychotics where indicated using clinical guidelines. This would involve a huge project just to identify all the people on antipsychotics and the assessment of whether they should be prescribed new antipsychotics is a role in which the mental health pharmacist can become involved.

NEW ANTIPSYCHOTICS – EVIDENCE-BASED FACTS

- Improved extrapyramidal and endocrine profile
- Equal efficacy in multiepisode patients
- Enhanced efficacy in first episode patients (Lieberman 1996)
- Early treatment improves prognosis (Lieberman, 1996)
- First episode patients react badly to even low doses of typical antipsychotics (Tollefson 1997)
- No evidence for low dose or mega -dose strategies in schizophrenia
- Clozapine is recommended in treatment resistant and treatment intolerant patients
- Atypicals are cost effective (Keegan et al 1999, Walker et al 1997).

In the light of these facts best practice is represented by:

1. Use of an atypical as early as possible in the disease process in all first episodes and subsequent relapses.
2. The numbers needed to treat for a patient to receive benefit from low dose typicals is likely to be high and therefore not justifiable.
3. In the treatment resistant patient use of Clozapine is recommended.
4. When individualising patients consider the individual side effect profile of the drug e.g. weight gain, prolactin, sedation, and endocrinological side effects.

5. Consider benzodiazepines for sedation of the acutely psychotic patient.
6. In the non-compliant patient consider use of depot medication.
7. All patients benefit from compliance therapy, education groups, carer groups etc.

ALGORITHM FOR THE TREATMENT OF SCHIZOPHRENIA

Give atypical antipsychotic at minimum effective dose.

Evaluate over six weeks: after titration, increase dose every two weeks (or longer) only if necessary

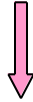
effective



tolerated

Continue with oral therapy as sole agent

ineffective/partly effective



Not tolerated

Change to a different antipsychotic

Consider: amisulpride, olanzapine or risperidone for negative symptoms; quetiapine or olanzapine for EPS; quetiapine or olanzapine for symptomatic hyperprolactinaemia

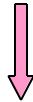
effective



tolerated

Continue with oral as sole agent

poor



compliance

Change to depot

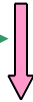
Use lowest known therapeutic dose at maximum allowable interval (unless practical issues demand otherwise. Adjust dose only at 2-3 month intervals.

effective



tolerated

Continue with depot as sole agent



Not tolerated / ineffective

Change to clozapine

Titrate slowly. Assess over at least six months

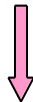
effective



tolerated

If measured improvement continue at same dose as sole agent

Ineffective



Not tolerated

Consider unproven therapies.

Add sulpiride to clozapine. Clozapine with small doses of risperidone, haloperidol or amisulpride. High dose olanzapine (60mg/day).

Omega – 3 marine triglycerides

5g bd, ECT, add nefadazone

effective



tolerated

If clearly measured improvement, Continue.

- Assess efficacy with recognized rating scales e.g. BPRS, GAS
- Use benzodiazepines or promethazine if sedation or behavioural control is required.
(Short term use only: 4-6 weeks maximum)
- Consider augmentation strategies e.g. lithium for schizoaffective disorder: carbamazepine for aggression, valproate for mood disturbance.
- Use compliance therapy as adjunct in non/partly compliant patients.
- Unproven therapies if used must be carefully evaluated using recognized rating scales over a prospectively fixed period (6-8 weeks). If possible gain patient consent and document in patient notes.

AIM

A pilot study to determine if medication counselling by a clinical pharmacist is as effective in increasing compliance in psychotic patients as that demonstrated in the BMJ paper by Kemp et al (1996) where medication compliance therapy was undertaken by a psychiatrist and a psychologist. This was done by performing a single blind randomised controlled trial.

OBJECTIVES

1. Identify patients admitted with acute psychosis to xxxxxx. These patients all having been diagnosed according to the Diagnostic and Statistical Manual of Mental Disorders – fourth edition (DSM IV) as suffering from schizophrenia, schizoaffective disorder, delusional disorders or bipolar disorders with psychotic components.
2. Assess the patients using symptom scores- BPRS, global functioning scores, assessment of insight, compliance with medication, assessment of attitudes to drug therapy and for adverse effects (Lunsers scale).
3. Perform medication compliance counselling on one group of patients and compare with control group which was not counselled by a pharmacist but received standard nursing information about their drug treatment.
4. Re-assess using the same scales after the intervention.
5. Re-assess after three months to see if any improvement is maintained.

METHOD

The study population was drawn from consecutive patients aged 20- 67 who were admitted with a diagnosis of acute psychosis to one of two wards at xxxxxxxx (180 bed psychiatric unit). Subjects with a low intelligence quotient or organic brain disease were excluded leaving 40 eligible patients from whom consent to take part was sought. Consent was also obtained from their psychiatrists. Patients were assessed as soon as possible after admission, all within one week. One patient refused to take part and one patient was deemed too ill by their clinician leaving 38 patients.

The remaining patients suffered from schizophrenia, schizoaffective disorders, delusional disorders and bipolar disorders with psychotic components. (Diagnosis according to the criteria of DSM-IV). All subjects were in relapse. All were receiving antipsychotic drugs and 9 patients were also receiving anti-depressants and 7 mood stabilisers.

Patients were randomly assigned to medication compliance therapy or control treatment. The intervention consisted of 3 sessions of medication compliance therapy, lasting approximately 20-25 minutes over a period of 5-8 days. The control group consisted of general counselling as provided normally by nursing staff.

The pharmacist counselled the patients in the intervention group using the motivational interviewing technique. Information was given about the individual medications and details of any possible side effects and the importance of compliance with drug treatment. The patient was encouraged to ask questions about their medication and to engage in conversation about their drug therapy. Various printed information sheets were provided (see appendix 8 for examples).

ASSESSMENTS

Before intervention all patients completed a number of assessments to establish a baseline situation.

- Drug history
- Brief psychiatric rating scale (BPRS)
- The global assessment scale (GAS)
- Insight scale (IS)
- The drug attitudes inventory (DAI)
- Lunsers scale of neuroleptic side effects (LSE)
- Compliance scale (CS)

OUTCOME MEASURES

Initial compliance was rated (appendix 5) blind to intervention by the patients' primary nurse on a seven point rating scale. Complete refusal was scored as 1. Partial refusal – for example, refusing depot drugs or accepting only the minimum dose- was scored as 2. Reluctant acceptance- accepting only because treatment was compulsory or questioning the need for treatment often (every two days)- was scored as 3. Occasional reluctance about treatment- questioning the need for treatment once a week- was scored as 4. Passive acceptance was scored as 5. Moderate participation- some knowledge of and interest in treatment and no prompting needed to take the drugs- was scored as 6. Active participation, ready acceptance, and taking some responsibility for treatment was scored as 7.

All ratings were repeated after the intervention as before and at three months later based on corroboration from the psychiatrist at the outpatients clinic, and the patient's community psychiatric nurse.

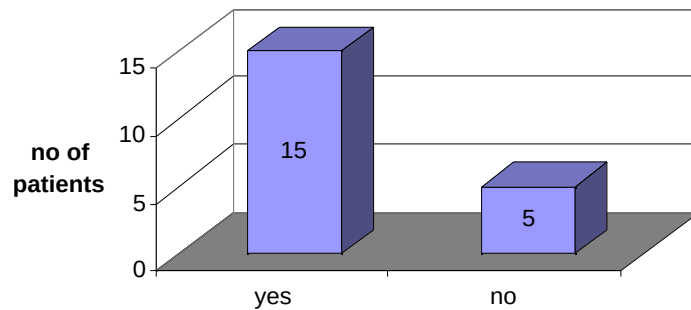
RESULTS

TABLE 2: Characteristics of the intervention and control groups.

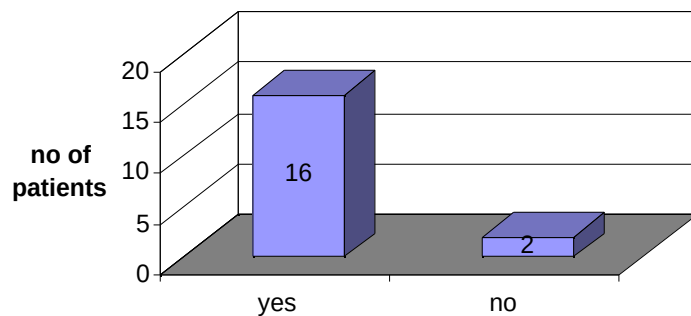
	Intervention (n=20)	Control (n=18)
Mean (SD) age (years)	38.0(15.6)	41.0(12.3)
Men	13	14
Mean (SD) no of years of illness	10.1(10.0)	12.5(8.8)
First admissions	3	1
No on Atypicals	14	12

MEDICATION HISTORY

As part of the initial assessments in this study a medication history was taken from each patient in each of the two groups (see appendix 1 for sample copy). Histories were mainly taken from the patient themselves, however in some cases additional information was acquired using hospital medical records, GP referral letters and from relatives/carers. As part of this information patients were assessed on their knowledge at the start of this research to establish if there was any difference in the two groups.

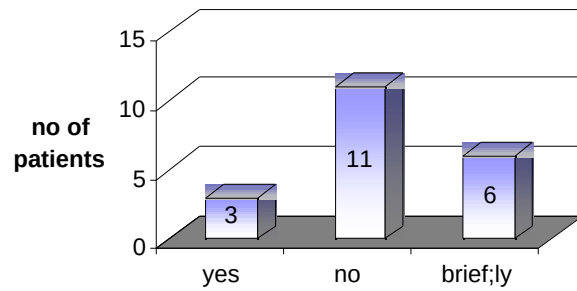


GROUP 1(intervention n=20)

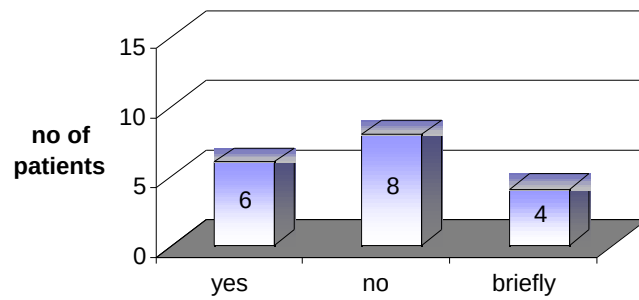


GROUP 2 (non-intervention n=18)

FIGURE 1: Have you received any information about your current medication?

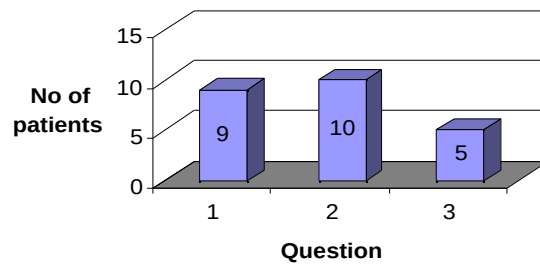


GROUP 1 (intervention n = 20)

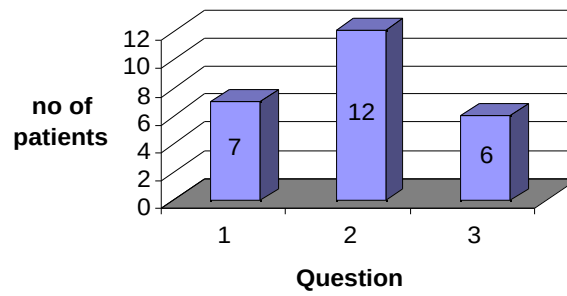


GROUP 2 (control n = 18)

FIGURE 2: Have you read the patient information leaflet supplied with your medication?



GROUP 1 (intervention n=20)



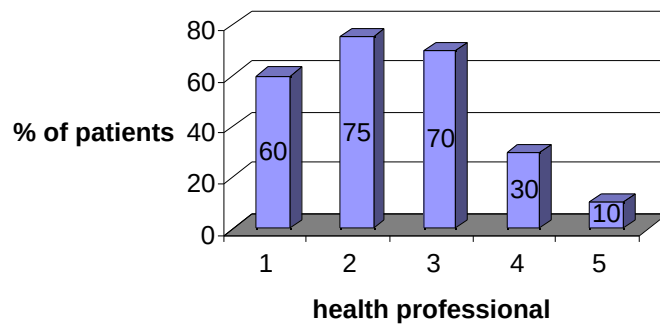
GROUP 2 (control n = 18)

Question 1: Do you know the names of your medication?

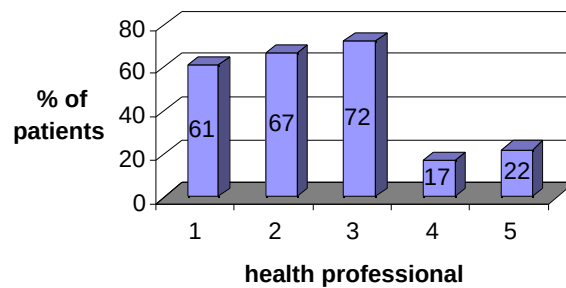
Question 2: Do you know what your medication is for?

Question 3: Are you aware of any possible side effects of your medication?

Figure 3: Patients knowledge of their medication



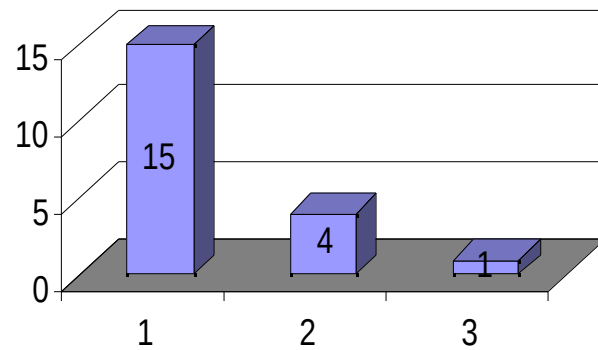
GROUP 1(intervention n = 20)



GROUP 2 (control n = 18)

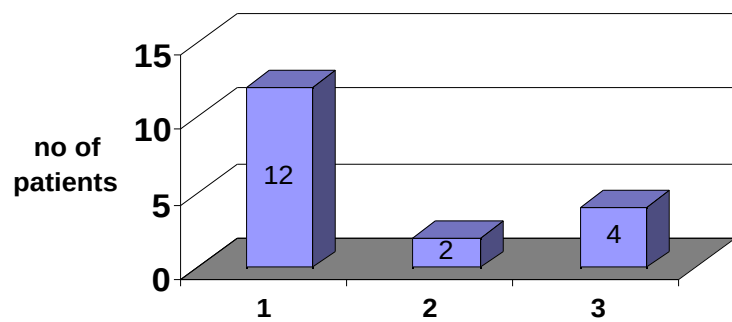
1 = GP, 2 = NURSE, 3 = PHARMACIST, 4 = PSYCHIATRIST, 5 = OTHER

Figure 4: Which healthcare professionals have you received information from?



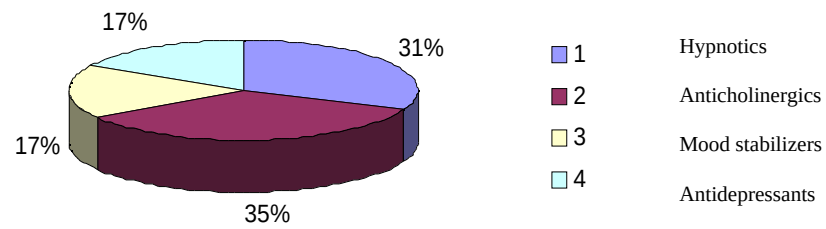
GROUP 1 (intervention n=20)

1= yes
2= no
3= don't care

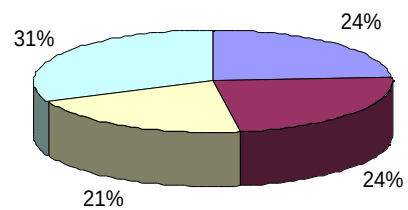


GROUP 2 (control n = 18)

Figure 5: Would you like to receive more information about your medication?

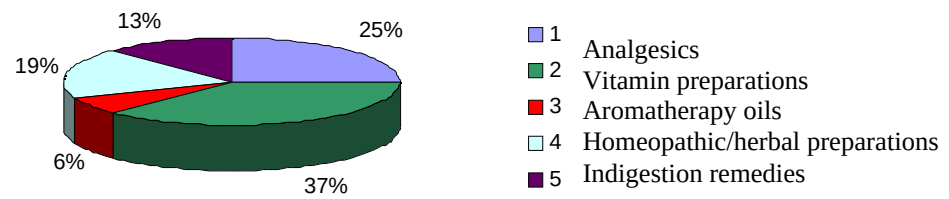


GROUP 1 (intervention n=20)

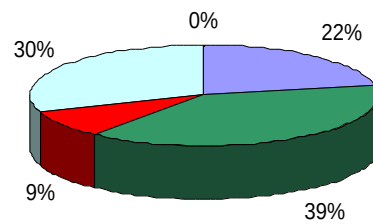


GROUP 2 (control n=18)

Figure 6: Usage of other drugs



Group 1 (intervention n=20)



Group 2 (control n = 18)

Figure 7: Usage of non-prescribed drugs

TABLE 3: RESULTS OF OUTCOME MEASURES BEFORE AND AFTER INTERVENTION

Measure	Intervention		Control	
	Mean (SD) Score	No of patients	Mean (SD) score	No of patients
<u>BPRS</u>				
Before intervention	57.9 (9.4)	20	52.7 (10.6)	18
After intervention		39.4 (7.8)		20
			37.7 (6.4)	18
At 3 months			41.3 (8.0)	
		18		
		41.1 (7.3)		17
<u>GAS</u>				
Before intervention	36.1 (9.0)	20	39.2 (7.2)	18
After intervention	51.2 (6.9)	20	52.8 (7.2)	18
At 3 months	50.8 (6.8)	18	52.0 (6.7)	17
<u>DAI</u>				
Before intervention	41.2 (7.3)	20	43.3 (6.9)	18
After intervention	51.1 (5.1)	20	45.0 (7.6)	18
At 3 months	48.8 (5.5)	18	44.0 (7.5)	17
<u>INSIGHT</u>				
Before intervention	36.3 (17.1)	20	30.1 (18.3)	18
After intervention	49.3 (19.5)	20	38.1 (18.5)	18
At 3 months	47.2 (17.2)	18	37.4 (17.9)	17
<u>COMPLIANCE</u>				
Before intervention	2.7 (1.5)	20	3.1 (1.8)	18
After intervention	4.7 (1.3)	20	3.2 (1.8)	18
At 3 months	4.6 (1.2)	18	3.1 (1.6)	17

PSYCHIATRIC SYMPTOMS

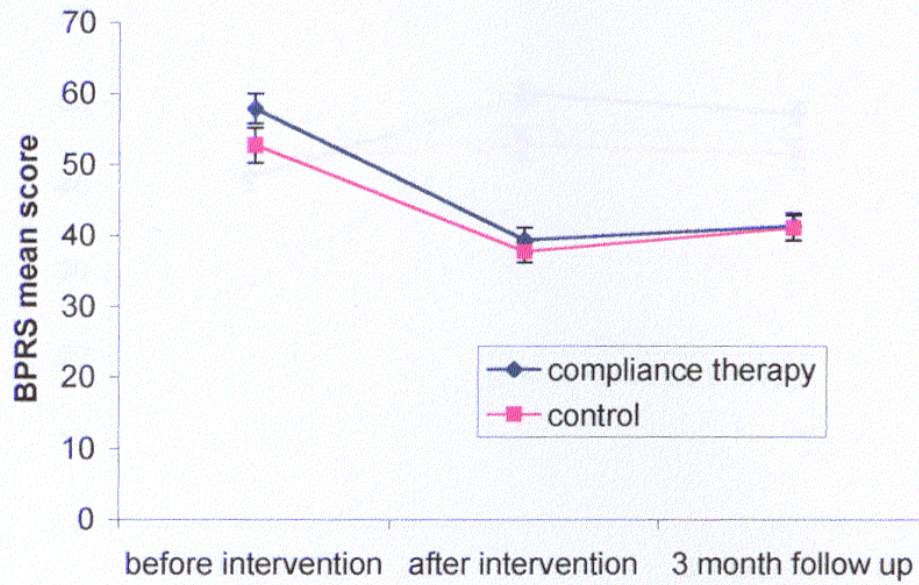


Figure 8: Graph showing changes in Brief Psychiatric rating scores over time¹

GLOBAL FUNCTION

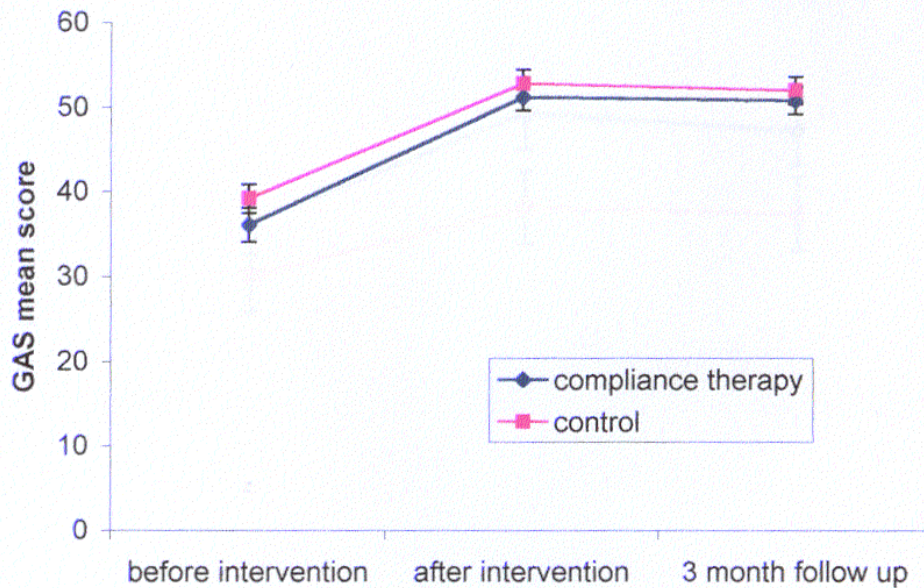


Figure 9: Graph showing changes in Global Assessment scores over time

¹ Error bars are Standard Error of the Mean for each data set

DRUG ATTITUDE INVENTORY

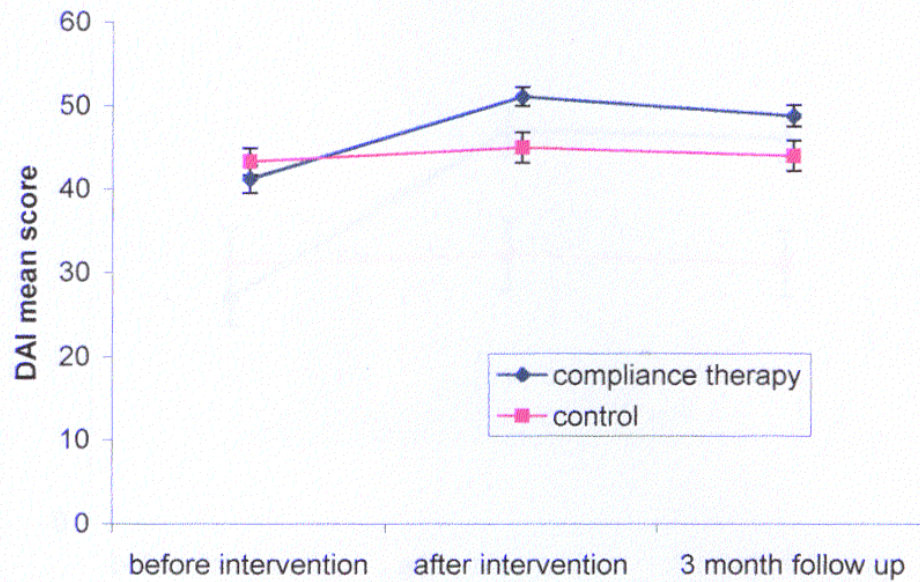


Figure 8: Graph showing changes in mean Drug Attitude Inventory Scores over time

INSIGHT

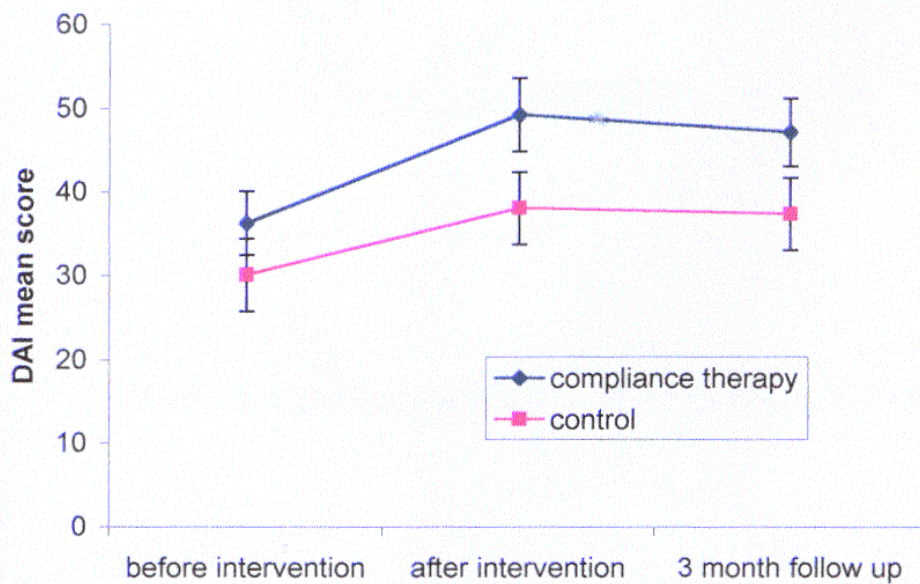


Figure 9: Graph showing changes in mean Assessment of Insight scores over time

COMPLIANCE SCORES

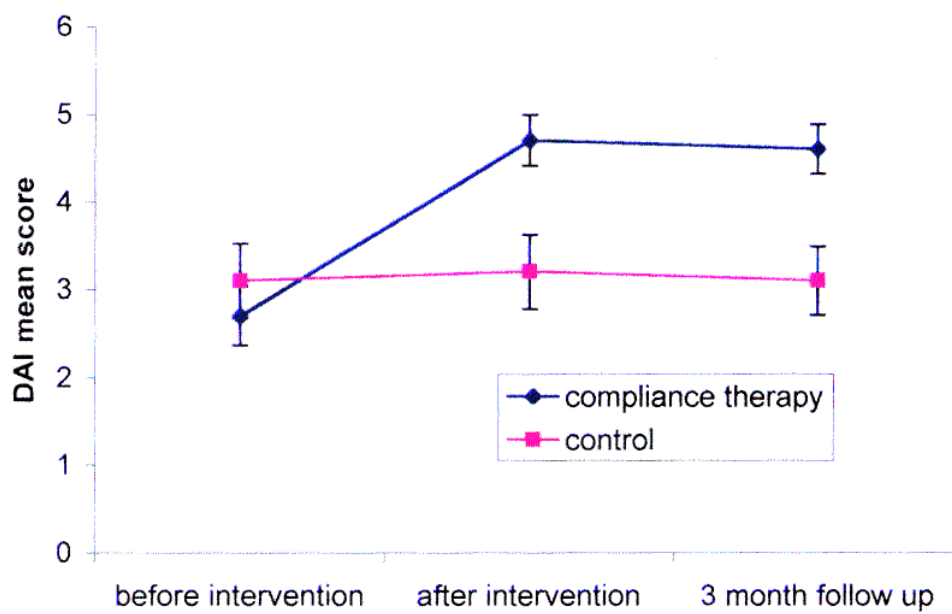
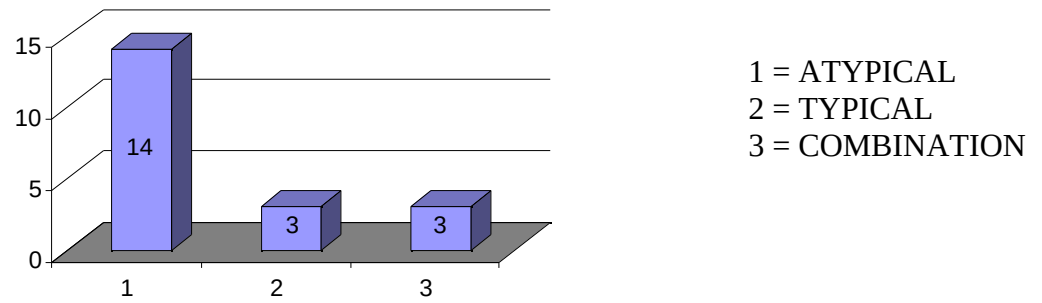
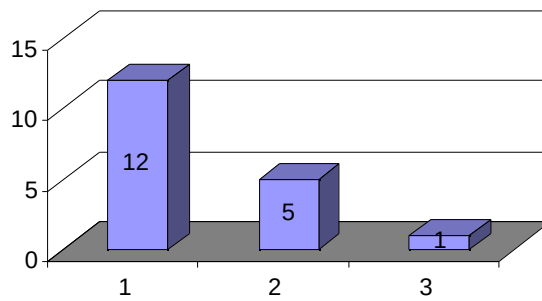


Figure 12: Graph showing changes in mean Compliance Scores over time



GROUP 1 (intervention n= 20)



GROUP 2 (control n = 18)

Figure 13: Comparison of antipsychotics used

LUNTERS SIDE EFFECT SCORES

Table 4: Mean Lunters scores per group

<i>Group</i>	<i>Mean Score</i>
Intervention n = 20	35.3 (SD = 16.50)
<u>Control n= 18</u>	35.2 (SD= 15.8)

Table 5: Mean Lunters scores according to type of antipsychotic

<i>Type of Antipsychotic</i>	<i>Mean Score</i>
<u>A Typical</u>	30.9 (SD = 14.8)
<u>Atypical</u>	45.1 (SD = 15.7)
<u>C Combination</u>	43.5 (SD = 12.9)

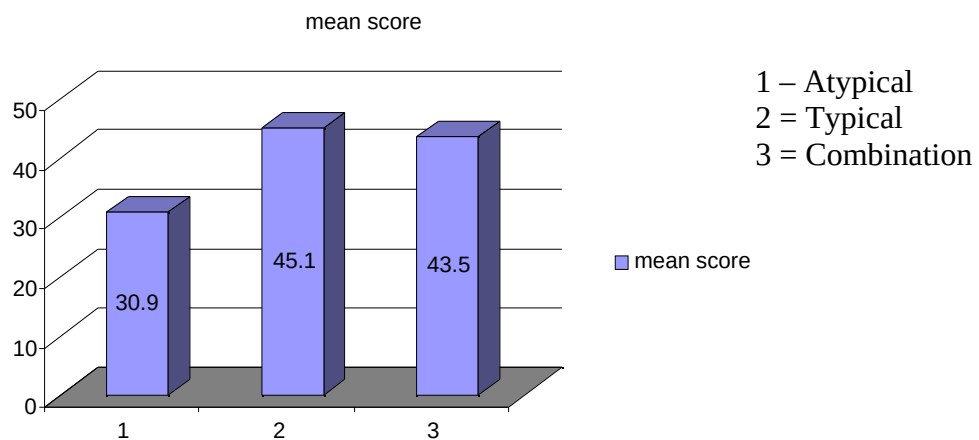


Figure 14: Bar Chart showing Mean Lunters Scores According to Type of Antipsychotic used.

DISCUSSION

In this study each of the patients in the two groups were asked a series of questions (appendix 1) to establish initially if there was any difference between the intervention and control groups.

The patients were questioned regarding their initial knowledge of their medication. 25% of patients in the intervention group and 12% in the control group stated that they had not received any information about their medication prior to this study. This is quite surprising, as supply of Patient Information Leaflets (PIL) is now required with all dispensed medication. The patients were then asked if they had read the PIL - 55% in the intervention group and 44% in the control group said they had not read the information leaflet. In a study by Raynor and Knapp (2000) similar results were found. They concluded that patients do not gain full benefit from PIL. Key issues relate to the lack of awareness of the leaflets, a low perception of their importance and the inability of health professionals to incorporate them into the wider information giving process. PILs have also been criticised for including long lists of side effects with no clear explanation of their likelihood, for excessive use of technical and medical jargon and for including vague and sometimes contradictory statements. Indeed recent studies by the Consumer Association concluded that some PILs confuse and alarm patients. So some PILs may need to be rewritten to make them more user friendly and perhaps a more individualised, computer generated information sheet may have a place in the future along with verbal reinforcement and explanation.

The patients were asked who had given information about their drug therapy. The GP, nurse and pharmacist were all important in providing information and all have a role in improving patient's knowledge and compliance.

Results also showed that 55% of patients in the intervention group and 61% in the control group were not aware of the correct name of their medication. 50% and 44% respectively did not know what their medication was for and 75% and 67% were not aware of possible side effects of their medication. This shows an immense lack of knowledge among this patient group and the extent of education that is required. This is a role for which the clinical pharmacist is ideally and uniquely placed as it is clear that most patients would desire to have more knowledge (75% of the intervention group and 67% of the control group stated they would like more information).

Usage of other drugs was also looked at. Similar results were seen for each group. It is important to look at the usage of OTC and any of the various alternative therapies available from chemist shops, health food shops or even through the internet. Patients often do not think of such items as drugs and often need questioning to offer the information. In this study 40% of the intervention group and 55% of the control group stated that they frequently bought OTC /alternative remedies.

Psychiatric Symptoms

Initially the control group had a slightly lower mean score on the brief psychiatric rating scale (52.7 v 57.9) i.e. they were slightly less ill. After the intervention, scores in both groups decreased as is expected, as the patient's condition improves after hospital treatment. The non-parametric Mann Whitney U Test was performed to compare Group 1 scores before and after the intervention and the difference was found to be significant ($U = 30$ $p < 0.05$). For the control group, using the same statistical test, significance was also reached ($U = 40$ $p < 0.05$). After the 3-month follow-up the scores rose slightly in both groups. This was a similar finding to Kemp et

al although the follow up in their paper was after six months and a shorter version of the BPRS (seven item version) was used.

Global Function

The global function scores again improved after the intervention in each group with little difference between groups at each time interval. The results in both groups were found to be significant after the intervention. (Group 1 $U = 359.5$ $p < 0.05$, Group 2 $U = 328$ $p < 0.05$). Kemp et al did see an improvement in the compliance group as time went by (the groups were assessed at 3 and 6 months).

Insight

With the assessment of insight scale there is a significant increase in scores the intervention group ($U = 275$ $p < 0.05$), but not in the control group ($U = 116.5$ $p < 0.05$) and both groups show little effect of time at follow up. Patients who received compliance therapy showed greater insight after the intervention and retained this improvement after three months.

Drug Attitude

The results for the drug attitude show a significant rise in scores for the intervention group i.e. they had a better attitude to and understanding of their medication after the counselling sessions. ($U = 337.5$ $p < 0.05$). The control group scores did not increase significantly ($U = 186.5$ $p < 0.05$).

The scores fell slightly at the 3-month follow up in both groups but was still greater in the intervention group.

Compliance

A significant rise was found in the compliance scores for the intervention group ($U = 65$ $p < 0.05$) and it was sustained during the follow up. The mean difference between the intervention group and the control group was 1.5, which is equivalent to a 21.5% improvement.

Lunser's side-effect scores

These results show that patients taking antipsychotic medication do often suffer side effects. A Mann Whitney U test was performed to find out if there was any difference between the intervention group and the control group and no difference was found. ($U = 112$ $p < 0.05$).

Although most of the patients in this study are receiving atypical drugs (70% in the intervention group and 67% in the control group), those who are receiving monotherapy with typicals do appear to suffer a greater number of side effects (45.1 v 30.9). Those receiving a combination of typical and atypical also suffer an increase in side effects (43.5 v 30.9). Although in this pilot study time and patient numbers did not allow investigation to determine if the occurrence of side effect had an influence on compliance, other studies have found this to be the case (Van Putten 1974, Hoge et al, 1992). Of particular note is the occurrence of sexual side effects, which presented in quite a few cases. This is an adverse effect, which is often overlooked by health professionals and something, which warrants further study.

Social Habits

22 of the patients (58%) in this study smoked and 30 (79%) admitted to drinking alcohol. Studies have indicated that alcohol abuse may be more common in schizophrenic patients than in the general population (Drake 1989, Pristach 1989). In another study alcohol abuse among schizophrenic patients was associated with the use of illegal street drugs, increased hospitalisations and symptomatology, lack of social support and medication non-compliance (Drake 1989) These studies are consistent with studies of chronic psychiatric patients with a variety of diagnoses (Safer 1987).

In another study by Pristach and Smith 1990, a high prevalence of both alcohol abuse and medication non-compliance was found before hospital admission among acute schizophrenic in-patients. The majority of patients studied admitted to drinking alcohol in the 30 days previous to admission and most of these patients also discontinued their psychotropic medication while drinking.

Studies have revealed a striking prevalence of smoking in psychiatric settings (Hughes et al, Munetz et al, 1987)) and patients seem to be ambivalent at best about curtailing their use of tobacco. Concerns about smoking in the psychiatric setting, as well as the obvious health risks to the patients, include fire starting and its sequelae and self-inflicted injuries (Resnick et al 1989).

Clinical pharmacists in counselling sessions are in an ideal situation to reinforce the anti-smoking message and perhaps advise on the appropriateness of the use of nicotine replacement therapies, bupropion etc and also to educate patients on the safe use of alcohol, recommended limits, any possible interactions with medication and the necessity to comply with treatment at all times.

Poor adherence to treatment is a huge problem in all areas of medicine. In the treatment of psychiatric disorders, in particular psychosis, the problem of non-compliance may be even more extensive and more complex because of the nature of the illness and the potential impact on the patients' judgement, insight and stability. An enormous amount of research and resources go into the development of new pharmacological treatments and it is often assumed that the giving and taking of medication is relatively uncomplicated process. Compliance is frequently discussed as an "all or nothing" phenomenon when in fact it is most often partial. Many patients take less medication than prescribed, taken it erratically or take excessive amounts at certain times.

The most serious potential consequence of discontinuing a prescribed antipsychotic medication is that psychotic symptoms will emerge or worsen. As many as 75% of patients who stop taking their antipsychotic medication experience significant symptom exacerbation over the course of a year, compared with only 25% of those who continue to take their medication. (Ayuso-Gutierrez and del Rio 1997). The consequences of symptom exacerbation can be serious. Of particular concern is the increased risk of potentially dangerous behaviour such as aggression towards oneself and others (Steadman et al 1998) In addition numerous studies suggest that repeated symptom exacerbations, especially early in the course of a psychotic illness, can worsen the course and prognosis of the disease (Wyatt 1991) Symptom exacerbations can also lead to antipsychotic treatment resistance and development of chronic psychosis (Lieberman et al 1998) Worsening symptoms increase the healthcare costs associated with the illness, because of the greater need for hospitalisation and use of emergency services. Given the high rates of medication non-compliance, together with the high risk of symptom exacerbation and its resulting consequences, clearly this is an issue, which needs to be addressed.

Drugs are one of the most cost-effective health interventions therefore failure of the patient to follow adequately prescribed instructions turns this valuable asset into an inefficient and dangerous liability. Although being informed about medications is no guarantee of medication compliance, it is generally recognised that increasing the patients knowledge about his or her medication regime tends to improve compliance (Dow 1991).

This pilot study looked at the impact of medication compliance therapy undertaken by a clinical pharmacist on the medication compliance in a group of patients suffering from a psychotic illness. The research was based on work by Kemp et al, 1996; which showed an increase in patient compliance in an inpatient group given compliance therapy by a psychiatrist and psychologist. A similar favourable result has been demonstrated here with an increase in compliance found in the group receiving the medication counselling by the pharmacist compared with the control group receiving brief information from nursing staff, which is the common practice on the wards studied. This could have a considerable impact in psychiatric hospitals, if a suitably trained pharmacist was responsible for providing medication counselling to patients possibly in groups and individually in selected patients and also to their carers where appropriate. This would prove more economically viable as psychiatrists rarely, on their own admission have time to spend counselling patients and the pharmacist is in an ideal role to perform this task, which if properly performed would have a huge impact on the treatment of these patients.

However it must be remembered that the most effective and efficient mechanism for improving compliance is that of a multiprofessional effort. The mental health profession has widely accepted a team approach in which psychiatrists, nurses, social workers and pharmacists share responsibility. For this reason neither physicians, nurses nor pharmacists can hope to improve

compliance individually. The most effective and efficient mechanism for improving compliance is a concerted interprofessional effort.

CONCLUSION

The results obtained in this small scale study have shown that medication counselling by a clinical pharmacist specialising in mental health is at least as effective as compliance therapy undertaken by a psychiatrist. Patients' attitudes to medication improved, as did their understanding of their specific drug therapy. The efficacy of antipsychotic treatment is undisputed in psychotic patients and is the mainstay of routine treatment. The results obtained show the effectiveness of medication counselling by a pharmacist using motivational interviewing techniques in improving insight, attitudes and compliance in the short term. These gains are maintained for three months. It cannot be assumed that these effects will be maintained for longer periods and this is something, which requires further study.

The study has also highlighted the scale of side effects suffered by patients receiving antipsychotic medication, especially in the patients receiving typical drugs, although further studies are required with larger groups of patients. Nevertheless it does highlight the question over whether the use of typical drugs should be continued. The occurrence of side effects has as expected a huge effect on compliance with treatment and the high occurrence of extrapyramidal and endocrine effects with these drugs suggest that it may be more cost effective in the long term to preferentially use atypical drugs in most patients and to avoid the use on combinations of both classes of drug.

The study highlights an important role, as per NSF guidelines, for the clinical pharmacist in medication counselling, advising on choice of therapy, implementing and drawing up protocols, assessing patients for occurrence of side effects and advising thereof and along with other health professionals, helping to increase the quality of life in mentally ill patients.

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