# ADHERENCE TO A CHRONIC PAIN MANAGEMENT REGIMEN: AN APPLICATION OF THE THEORY OF PLANNED BEHAVIOUR

**KAREN E DAVIS**

SUBMITTED FOR THE DEGREE OF DOCTOR OF CLINICAL PSYCHOLOGY
THE UNIVERSITY OF EDINBURGH
1999

**Declaration**

"This thesis has been composed by myself and the work contained herein is my own"

Signed

**ACKNOWLEDGEMENTS**

There are various people I would like to thank whose assistance has made this work possible. I am most grateful to my supervisors, Deborah Tinson, Frank Charlton and Katherine Cheshire for their guidance, support and encouragement throughout. My gratitude is extended to Kenny Brown and Katherine Hobbs and the rest of the Astley Ainslie Hospital Pain Management Team for putting up with all my requests! Therese Muir, Pharmacist, and Dr. Stewart Donald were of tremendous help with regards to the measurement of drug reduction. I am grateful for the time and effort given by the patients who participated in this study and made it possible. Finally, I would like to thank my parents for their unstinting support throughout my academic pursuits and, in particular, my father with whom useful discussion took place.

**ABSTRACT**

This study assesses the utility of Ajzen's (1988) Theory of Planned Behaviour (TPB) in predicting adherence to drug reduction plans in chronic pain patients. At the beginning of a ten week pain management programme, 40 participants expressed their attitudes, subjective norms, perceived control and intentions with respect to drug reduction. A measure of self-efficacy was also used. Twenty-nine participants opted to work on drug reduction plans and data on adherence and drug reduction was collected throughout the programme and at 1 and 18 month follow-up. Questionnaires were re-administered following pain management intervention to assess whether changes in attitudes and self-efficacy had occurred. Partial support was obtained for the TPB. Attitudes and subjective norms were found to predict intention to reduce and attitudes and, surprisingly, negative intention were found to predict actual drug reduction. The model was unable to explain any of the variance in adherence. It was suggested that this was due to the patient-controlled nature of drug reduction becoming confounded with adherence. More support was obtained for the Self-Efficacy Theory, with this variable predicting adherence, drug reduction and maintenance. Increases in self-efficacy were observed over the course of the programme with perceived barriers being the only TPB variable to change over treatment. Return rates of 100% and 79% were achieved at 1 and 18 month follow-up respectively. Follow-up at 18 months revealed some relapse in drug intake and self-efficacy but not back to pre-treatment levels. No relationship was found between nonadherence to plans and relapse in drug reduction post-treatment. Participants fell into 3 groups: 24% made no progress after intending to reduce, 38% made progress but then relapsed to varying extents and 28% made progress and did not relapse. Implications for practice and future research are discussed.

**CONTENTS**

# 1. INTRODUCTION

## 1.1. INTRODUCTION TO CHRONIC PAIN AND ITS TREATMENT

Chronic pain is most usefully defined as pain lasting six months or more (Williams & Erskine, 1995). It affects over ten per cent of the population and approximately one per cent are severely disabled (von Korff, Dworkin & Le Lesche, 1990). Often the causes are not fully understood and tests fail to identify clear-cut pathology. For many, a wide range of traditional methods of pain relief have failed creating concerns, in addition to human suffering, of excessive use of health service resources and lost industrial output.

The chronic pain patient tends towards rest and avoidance of activity leading to a deteriorated physical state producing further symptoms and multiple losses, eg. work, income, social life. This contributes to feelings of depression, anxiety and low self-esteem which adversely affect the pain experience. Many patients enter an "overactivity-rest" cycle as they try to "catch up" on good days but end up having to rest for increasingly longer periods. Difficulties can also be perpetuated by the medical profession with multiple referrals, surgery and excessive drug use often adding to patients' suffering.

If patients can accept that a cure is unlikely then pain management can help them to cope with their pain more effectively. A multi-disciplinary cognitive-behavioural approach is the predominant model. This approach has been well-established in the USA for some time but has only begun to flourish in the UK over the last ten years, mainly via outpatient groups. The treatment focuses on the behaviours and beliefs which exacerbate and maintain pain. Operant and cognitive techniques are used to increase well behaviours (eg. independent activity) and decrease pain behaviours (eg. prolonged rest, excessive drug use). A typical pain management programme will include education, teaching behavioural and cognitive skills, a stretch and exercise

programme, medication reduction, goal-setting and pacing, relaxation training, relapse prevention and a family and follow-up session.

Appendix A shows the format of the Astley Ainslie Hospital pain management programme (AAH PMP), where the present study was carried out. This programme is run by a multi-disciplinary team including a clinical psychologist, physiotherapist, nurse, occupational therapist and doctor. It aims to teach effective self-help ways of managing and coping with chronic pain, to teach a system that allows patients to resume activities they have given up, to improve quality of life, to increase confidence, to reduce anxiety and depression, to reduce demands on health service resources and to increase understanding about pain and maintaining factors. It does not aim to cure pain. Due to limited understanding about who can be helped, inclusion criteria are kept to a minimum. The AAH Pain Management Team look for evidence of disruption to personal and family life, mood changes, a wish to increase activities and some relief from pain being found from some source. They exclude those with a major psychiatric illness, where further medical treatment is indicated or where the applicant wishes to look for medical treatment.

Amanda Williams has been an important contributor to outcome research in the UK. UK studies of outpatient programmes (eg. Skinner, Erskine, Pearce, Rubenstein, Taylor & Foster, 1990; Luscombe, Wallace, Williams & Griffiths, 1995) and inpatient programmes (eg. Williams, Nicholas, Richardson et al., 1993) have reported significant improvements in such areas as quality of life, physical performance, depression severity and confidence with the Williams study showing these to be well-maintained at one and six month follow-up. As expected, pain intensity was the only measure to show less clear-cut improvements but ratings of how distressing the patients found the pain showed significant reductions (Skinner et al., 1990). Williams, Richardson, Nicholas et al. (1996) compared inpatient and outpatient treatment and found both groups made significant improvements in

physical performance and psychological function and reduced medication use. However, inpatients made greater gains and maintained them better at one year. They noted an inpatient format offers a more intensive programme in a more consistent operant environment but the costs are around four times that of an outpatient programme.

Flor, Fydrich & Turk (1992) conducted a meta-analysis of 65 outcome studies and proclaimed multidisciplinary treatment to be effective and superior to no treatment or conventional, single discipline approaches. However, a number of common methodological problems were acknowledged, eg. lack of randomized design, high rates of attrition at follow-up. Some of these difficulties have been recently addressed by Morley, Eccleston & Williams (1999). These authors conducted the first meta-analysis of 25 randomized controlled trials of cognitive behaviour therapy (CBT) and behaviour therapy for chronic pain. They also concluded that psychological treatments based on the principle of CBT are effective. Cognitive behavioural treatments produced significant effect sizes on all domains of measurement in comparison to waiting list controls and significantly greater changes on half the domains measured compared to alternative active treatments, eg. regular pain clinic attendance, physiotherapy. Morley et al. observed that measurement of domains with economic importance (eg. health service use, drug intake) and process variables (eg. adherence to treatment methods, patients' expectations of change) was generally lacking.

It is still unclear by what therapeutic mechanisms or processes multi-disciplinary programmes achieve their successful outcomes. Jensen, Turner & Romano (1994a) observed, in keeping with cognitive-behavioural theory, that changes in pain-related beliefs and cognitive coping strategies were associated with improvement after multi-disciplinary treatment. This finding cannot be interpreted as proving a causal relationship between changes in cognition and improvement. Functioning may

change as a result of changes in beliefs and coping, beliefs and coping may change as a result of altered functioning, or all may interact dynamically over time. Interestingly, changes in some behavioural coping strategies specifically targeted in multi-disciplinary treatment (eg. exercise, relaxation, decreases in drug use) did not explain significant amounts of improvement. Consequently, Jensen et al. suggest that improvement following multi-disciplinary pain treatment may be more closely associated with changes in what patients think about their pain than what they do about their condition. However, they note that it could take longer than three to six months post-treatment for benefits of some of these behavioural coping strategies to emerge.

The issue of relapse has received little attention in the chronic pain literature. Despite outcome studies consistently reporting initial improvement in many individuals, follow-up data suggest that substantial numbers, typically between 30 per cent and 70 per cent of patients attending chronic pain treatment programmes, relapse over a one year to five year period (Keefe, Gil & Rose, 1986). Dolce, Crocker & Doleys (1986a) found much treatment efficacy outcome data was maintained at 6 and 12 months but that significant amounts of relapse had occurred for medication use and exercising. They reported that 97 per cent of patients in their sample had been free of analgesic medications at time of discharge but this number was reduced by almost one third at follow-up. Similarly, Cinciripini & Floreen (1982) reported a 28 per cent relapse at 6 months and a 39 per cent relapse at 12 months in terms of numbers remaining free of medication. In Cinciripini & Floreen's study 75 per cent and 65 per cent of questionnaires were returned at 6 and 12 months respectively. As follow-up studies are based on only those patients who are available and willing to participate in follow-up assessment they require to be interpreted with caution.

Even less is known about the related topic of patient noncompliance to pain management recommendations which tends to be inferred from outcome. However a complex relationship exists between compliance and treatment outcome and one should not be assumed from the other. This study will investigate compliance during a pain management programme. Lutz, Silbret & Olshan (1983) indicated that compliance rates are more appropriately assessed within each separate therapeutic regimen of pain management, as opposed to an overall compliance measure, since correlations between different behaviours within a regime may be low. Therefore the component of drug reduction, an area of pain management which evokes controversy and difficulty, was selected for investigation here.

## 1.2. DRUG REDUCTION IN PAIN MANAGEMENT PROGRAMMES

A wide variety of drugs are prescribed to chronic pain patients (eg. non-steroidal anti-inflammatories (NSAIDS), opioid analgesics, antidepressants and benzodiazepines) despite a lack of evidence that long term use is beneficial (Spanswick & Main,1989). For many patients, opiates have proven to be ineffective in relieving pain and improving function (Pither & Nicholas, 1991) with patients reporting no increase in pain during drug reduction (eg. Williams et al., 1993). Furthermore, patients frequently experience unwanted side-effects such as impaired cognitive function, drowsiness and constipation, reducing their quality of life even further. Long term consequences include gastric ulcers and liver and kidney problems.

Despite these disadvantages, many continue to look to analgesics for help in managing their pain. In this sense, opiate use can be construed as an obstacle to pain management (Williams, 1993). Drug use may even exacerbate the patients' problems when consumed on an "as required" (prn) basis, only when pain is severe. Fordyce (1976) believes this can reinforce pain behaviour since increased pain and pain

behaviour become associated with (ie. reinforced by) the perceived benefits of pain relief. Therefore, at the very least, taking analgesics time-contingently rather than pain-contingently is advisable.

Reduction of pain-related medication and substitution of other strategies, eg. relaxation, has become an integral part of pain management programmes. The term "drugs" is used intentionally in preference to "medication" or "pills" in order to utilize its negative connotations. There are two main methods of reduction which both involve taking drugs on a time-contingent basis. The first, a staff-controlled approach using a "drug cocktail" (Fordyce, 1976) is commonly chosen for inpatient courses. Here the active ingredient is masked in a flavoured syrup while the concentration is reduced by regular amounts over days or weeks (with the patient being unaware of the reduction schedule) until the cocktail contains no medication. In the second approach, Patient-Controlled Reduction (PCR), the patient holds their own supply of drugs and discusses with a nurse the desired rate of reduction. Plans are reviewed regularly with large deviations being discussed and plans adjusted as appropriate. Staff-controlled reduction, in particular, has abstinence as its goal. However, Turk, Rudy & Sorkin (1993) point out that what constitutes successful drug reduction may vary between the treatment stakeholders. For example, third party payers may desire abstinence whilst patients may aim for judicious use. Patients choose between the two methods on the INPUT inpatient course in London. An INPUT study, offering this choice, showed that reduction of NSAIDS and antidepressants were maintained at one and six month follow-up (Williams et al., 1993). However, opioid analgesics were reduced following treatment but increased markedly prior to one month follow-up with little further change at six months when the mean daily dose was still half that at admission.

A further INPUT study by Ralphs, Williams, Richardson, Pither & Nicholas (1994) compared the effectiveness of the two methods for opiate reduction. Patients were

able to choose which method to employ in aiming for complete withdrawal by discharge. Patients who opted for the cocktail method started at higher morphine equivalents, were less confident in their ability to cope without medication and rated their everyday activities as more disrupted by pain. A greater number of the cocktail group were abstinent at discharge (89 per cent vs. 68 per cent) but this advantage had disappeared at one month follow-up, with abstinence rates being equivalent for the two groups (55 per cent) at six months. Furthermore, at this stage, non-abstinent cocktail group patients were taking significantly larger doses of opiates than PCR patients. Admission opiate dose level was the best predictor of abstinence at discharge and of subsequent opiate dose level in non-abstinent patients. It was suggested that the higher relapse rate with the cocktail method might be due to PCR patients having developed skills of controlling their own intake in the presence of a supply. Szymanski, Epstein, Wimberly & Madtes (1979) argue that PCR will strengthen the maintenance of reduction as patients will attribute progress to their own behaviour. However, the beliefs of the patients who chose the cocktail method were likely to be undermining of maintenance of change. Thus replication of this study with random allocation to the methods would be useful. Whether particular patients would do better with a particular method would be another useful line of research.

The Astley Ainslie Hospital programme uses the PCR approach, largely due to the practical difficulties of employing staff-controlled reduction in an outpatient setting. This approach is also more congruent with the ethos of the programme as it fosters self-control and responsibility.

## 1.3. ADHERENCE

### 1.3.1. DEFINING ADHERENCE

The terms adherence and compliance have been used interchangeably to refer to the degree to which patients carry out the behaviours and treatments recommended by their practitioners (Sarafino, 1990, p308). Authors (eg. DiMatteo & DiNicola, 1982; Meichenbaum & Turk, 1987) have argued that compliance suggests the practitioner using an authoritarian style with the patient obeying passively and reluctantly. Thus adherence is the more satisfactory term, being used to imply a more active, voluntary collaborative involvement of the patient. Despite the emphasis at the Astley Ainslie Hospital programme being on choice and patient participation, the terms adherence and compliance may be used interchangeably throughout this text.

### 1.3.2. MEASUREMENT OF ADHERENCE

A wide variety of criteria and measures of adherence have been used by researchers making comparison across studies difficult. Measures of adherence can be divided into two main categories of subjective and objective measures. Some of the most common approaches within both categories will be outlined, with a view to selecting a suitable measure of adherence to drug reduction plans. In doing so, it should be noted that it is not uncommon for pain management patients to have access to a cabinet full of various back-dated medications.

#### Classification

Adherence and nonadherence are most usefully conceptualized as forming a continuum rather than as a dichotomous construct, with most people probably adhering at an "in between" level (Sarafino, 1990, p309). Various forms of "violation" are possible along this continuum, eg. consumption of too little medication, too much medication or additional nonplanned medication. Perfect

adherence may not be necessary in many cases to achieve the desired health benefits, therefore clear definitions are required about the amount of deviation permitted from the regimen before the patient is judged to be noncompliant.

Subjective Measures

(A) Self-Report

Asking patients directly about adherence is the most frequently used measure in research and clinical practice. This measure is easy to obtain and allows for ongoing assessment which is important as compliance may vary over time. However, intentional distortions may occur with responses likely to be biased in a socially desirable direction (Turk & Rudy, 1991). Unintentional errors, due to comprehension and memory difficulties for example, may also occur and diary records have been used in an attempt to reduce these effects. It should be noted that self-monitoring may enhance adherence by acting as a reminder and encouraging discussion of adherence difficulties (Sarafino, 1990). Ley's (1988) review found that patients' reports yield higher absolute estimates of compliance compared to more objective measures. However he cautiously suggests that patients' report will give similar results to other methods on relative standing on the compliance dimension.

(B) Professional Assessment

There is much evidence (eg. Mushlin & Appel, 1977) that clinicians cannot readily detect noncompliance, even when they feel quite certain of the accuracy of their estimates. Pain management professionals see patients solely in a hospital environment making it difficult for them to estimate rates of adherence to home-based work. It is arguable that GP assessment would simply result in GPs questioning patients about their drug intake. Furthermore, this would be a time-consuming and therefore unfeasible task for GPs on a regular basis.

(C) Independent Observers eg. family, friends

Turk & Rudy (1991) suggest it may also be useful to obtain reports from family or friends in the natural environment. However, these people are unlikely to be present at all times when patients take their often frequent medication, hindering true reporting. During pilot work for the current study, some patients commented that their medication use was private and had nothing to do with family or friends.

Objective Measures

(A) Behavioural Measures

Pill or quantity accounting is the most common behavioural measure. Patients are provided with an over-supply of medication and the remaining medication is counted at a specific time. However, Turk & Rudy (1991) note that pill counts do not increase the reliability of statements concerning medication compliance significantly. This is because this method does not guarantee that those missing were ingested or other sources for prescribed pills were not obtained. Another disadvantage is the lack of information about the pattern of drug consumption.

(B) Biochemical Indices

Biochemical tests, eg. of blood or urine, can accurately assess recent medication use (Turk & Rudy, 1991). However urine tests are only sensitive to medication taken two to three days prior to the test, so would be an inaccurate measure for the full week between hospital attendances in the present study. Further difficulties arise due to individual variation in metabolic conditions and because some drugs possess identical end-products. Finally, high costs and limited practicality and availability prevent wide-scale usage.

(C) Outcome

Clinical outcome is rarely an adequate measure of adherence since adherence does not always have a straightforward linear relationship with clinical outcome, ie. there

are patients who improve without complying and patients who are totally compliant who do not derive significant benefits. This was demonstrated in Lutz et al.'s (1983) study of compliance following multidisciplinary treatment of chronic pain. Despite very low overall compliance rates, they obtained 37-59 per cent improved status on various outcome measures. In correlating outcome with self-reports of compliance, the present study will be able to comment on the appropriateness of using outcome as a means of assessing adherence to drug reduction plans. It may be that adherence to formal plans only has a small impact on the actual quantity of drugs reduced.

Therefore, all of the above methods of measuring adherence to drug reduction plans contain drawbacks. Given ideal resources, self-report would be combined with a more objective measure.

### 1.3.3. RATES OF ADHERENCE

Adherence rates to simple medical regimes, eg. taking prescribed medication, have been estimated to fall between 38 - 58 per cent (Ley, 1976; Sackett & Snow, 1979). More demanding regimens, such as diet, smoking or exercise programmes, tend to have even lower adherence rates, eg. eight per cent in one study by Garb & Stunkard (1974) on diet for weight reduction. Thus prior to entering a pain management programme adherence of chronic pain patients to their long-term drug therapy is likely to be low. They are then expected to make extensive life-style changes to be continued on a regular basis for the rest of their lives.

Lutz et al. (1983) conducted one of the few studies designed specifically to examine compliance following multidisciplinary treatment of chronic pain. Using patient self-report, they found only 12.3 per cent of respondents were complying with their total combination of regimens at an average follow-up of 23.4 months. However, compliance with individual regimens averaged at 42 per cent and compliance with

any one regimen was generally unrelated to the probability of complying with other behaviours. Drug reduction was not one of the five regimens studied but medication use was included as an outcome measure. Decreased medication use was found to correlate significantly with adherence to three regimens: (i) physical therapy and occupational therapy exercises (ii) home treatments eg. electrical stimulation and (iii) relaxation and/or self-hypnosis exercises. (Progressive ambulation exercises and use of proper body mechanics were the other two regimens in this study).

## 1.4. WHY DO PEOPLE ADHERE AND NOT ADHERE?

No studies could be found which investigated predictors of adherence to the drug reduction component of pain management programmes specifically. In fact little has been written about variables relating to adherence to chronic pain management programmes in general, with the majority of work being atheoretical.

Much of chronic pain research has focused on the stage of adjustment to pain and the coping strategies employed. During the past decade studies have focused increasingly on cognitive variables (attitudes, beliefs) as possible mediators of adjustment to intractable pain (eg. Jensen, Turner & Romano, 1991) and numerous measures of these constructs have been developed (eg. The Pain Beliefs and Perceptions Inventory (PBPI); Williams & Thorn, 1989). Probably the best researched instrument has been the Survey of Pain Attitudes (SOPA) which now assesses seven attitudes eg. the controllability of pain; relations between emotionality and pain severity; appropriateness of medication for treating pain (Jensen, Turner, Romano & Lawler, 1994b). Tait & Chibnall (1998) have recently extended work with this scale by looking for attitude profiles to mediate behaviour and psychosocial function. They identified four relatively clear attitude clusters (self-reliant and medically orientated attitudes each with higher and lower emotionality associated with pain) that were associated with meaningful differences

in clinical status. Work on coping strategies has shown "catastrophizing" to be predictive of low treatment gains and poor maintenance (eg. Keefe, Salley & Lefebvre, 1992).

Other studies have tended to be "data-mining" projects producing a rather muddled picture and lacking conclusive information about predictors of treatment success and failure. For example, Painter, Seres & Newman (1980) examined demographic, incentive, attitude and psychological variables in 25 pain treatment successes and 25 failures. They concluded that the failure group demonstrated less incentive for maintaining their gains, most of whom continued to receive financial compensation for their pain. Differences in attitudes were also noted, with the failure group more likely to assume a dependent, passive stance. The groups did not differ on psychological diagnostic interviews or on the MMPI. Curiously, patients in the success group rated themselves as significantly more depressed at the time of admission in comparison to the failure group. More recently, Williams & Erskine (1995) concluded that there are not yet any consistent predictors of performance in treatment or afterwards.

### 1.4.1. CHRONIC PAIN DRUG USAGE: ADDICTION OR COPING STRATEGY?

Looking to models to guide research is likely to prove more useful as the researcher is provided with a coherent framework for interpreting findings (Johnston, Wright & Weinman, 1995). One possibility here would be to view chronic pain drug usage as a form of addiction and obtain guidance from models of addiction. However, on studying the criteria for Substance Dependence (DSMIV, 1995) a good fit is not obtained. For instance, the substance dependent client spends much time using the substance, recovering from its effects, or trying to obtain it. Chronic pain patients spend little time actually taking their drugs which they can obtain relatively easily from their GPs. The substance dependent client reduces or abandons important

work, social or leisure activities because of substance use. In contrast the chronic pain patient may be forced to abandon such activities due to his or her pain but often takes drugs with the aim of being able to maintain these activities. In the substance dependent client the duration of use episodes are often greater than intended whereas chronic pain patients may stick to a regular dose and be wary of taking more than recommended dose levels. The chronic pain patient may be less likely then the substance dependent client to have repeatedly tried without success to control or reduce his or her substance use. Finally, a key point in substance dependence is the continued use of the substance despite evidence of the physical and psychological difficulties it is causing. The chronic pain patient may not experience difficulties in the short term or be aware of the long term hazards. The latter may be less well publicised than those of some substances, eg. nicotine, alcohol. Williams & Erskine (1995) state that it is much more helpful to treat chronic pain drug use as an attempt at coping rather than as an addiction. They liken analgesic-taking to other pain coping strategies in that it can be more a response to cognitive and affective factors rather than to the pain level alone and may worsen rather than improve the situation.

### 1.4.2. MODELS OF ADHERENCE

Recently adherence research has been guided by various models to explain behaviour and it may be more useful to look to these general models of adherence for a framework here. Other "addictive" health behaviours, such as smoking and alcohol use, have been studied using such models (see below). The major theoretical orientations will be reviewed briefly but, given the focus of this study, the cognitive models will be outlined in most detail.

(A) The Biomedical Model

Leventhal & Cameron (1987) named the approach which looks for individual factors to explain adherence, the biomedical approach. Much early research was conducted under the umbrella of this approach which is largely atheoretical. Countless studies (eg. Belcon, Haynes & Tugwell, 1984) have failed to find demographic or personality characteristics which are unique to non-compliers. Furthermore, characteristics of the illness have not been found to be important generally. For example, Berndt, Maier & Schutz (1993) reported no consistent correlation between compliance and pain intensity or duration in chronic pain patients. However features of the treatment regimen have been identified as relevant to compliance. A review by Masur (1981) found three factors that were consistently associated with decreased rates of compliance. Firstly, the complexity of the regimen. In Berndt et al.'s (1993) study of chronic pain patients, polymedication (ie. daily intake of three or more preparations) was reported to be a fairly reliable factor for predicting noncompliance. Interestingly, Belcon et al.'s (1984) review of rheumatoid arthritis studies found no consistent correlation between compliance and drug dose frequency but as the mean total daily dose increased there was greater variation in the dose actually taken, ie. as there was more room for error. The other factors identified by Masur were the degree of behavioural or lifestyle change demanded and the duration of the therapeutic regimen. Turk & Rudy (1991) noted that as these are all inherent in pain rehabilitation, chronic pain patients represent a high risk population with regard to treatment nonadherence. Important interactions may be lost in this approach when isolated aspects of a regime are examined in this way.

(B) Learning Theories: Operant Conditioning

The principles of learning theory such as Operant Learning Theory (Skinner, 1953) have been very influential in providing the rationale for behavioural interventions,

eg. goal-setting, self-monitoring. This approach came into vogue as research shifted focus to the behaviours needed for compliance. This model attends to the stimuli or cues that elicit behaviour and the rewards that reinforce the behaviour. One potential source of reward in chronic pain patients may be compensation payments. Some studies (eg. Block, Kremer & Gaylor, 1980) have reported that patients receiving disability payments or compensation are less adherent. However, the evidence is equivocal with a number of studies failing to find such support (eg. Mendelsohn, 1986). Williams & Erskine (1995) point out that the discretionary nature of many welfare benefits is similar in financially rewarding increased disability, but has not been a major focus of research. However these theories fail to address how cognitions interact with skills training to impact on compliance. High relapse rates following behavioural programmes (Cinciripini & Floreen, 1982) suggest that other variables are important.

(C) Knowledge and the Communication Models

Ley (1982) proposed that a substantial amount of the variance in adherence and satisfaction could be explained by comprehension and memory variables. Important factors in his model of communication include the transmission of information from the doctor to the patient, the intelligibility of the doctor's communications and the ability of the patient to recall medical information. Ley suggested simple techniques for improving communication, and thus adherence, many of which are incorporated into pain management programmes, eg. written instructions; increasing the individual's general knowledge about his or her illness. However, while comprehension and retention of the treatment regimen is essential for adherence, it is not sufficient. The patient must also be motivated to act and it may be that education needs to be combined with other strategies such as behavioural interventions (Mazzucca, 1982).

(D) Cognitive Models

Various models have focused on cognitions, eg. attitudes, beliefs, knowledge, to explain and predict health behaviours and outcomes. Several models have developed within the Expectancy Value approach which assumes that health behaviours, decisions or intentions will be based on weighing up of the respective costs and benefits believed to be associated and the likelihood of achieving these (Johnston et al., 1995). The four principal models that are relevant to the population under study will now be discussed.

(1) Social Learning Model: Self-Efficacy Theory

Rotter's version of the Social Learning Theory (1966) focuses on the construct of Locus of Control - a generalized expectancy about whether one's own behaviour or forces external to oneself control reinforcements. However, it is the second version of the Social Learning Theory (Bandura, 1977) which is examined in this study and which has received much attention in both the adherence and pain literature. This version predicts behaviour using two variables: self-efficacy expectancy (the expectation that one is sufficiently competent to perform a desired behaviour) and outcome expectancy (the expectation that a behaviour will lead to particular consequences). For example, Social Learning Theory would posit that people will engage in drug reduction if they have the confidence that they can tolerate or perform the required action to reduce and the understanding that drug reduction will be of benefit to them. It is argued that given the necessary skills and incentives, it is an individual's belief about their efficacy which predominantly determines whether a coping behaviour will be emitted and persisted with in the presence of obstacles and aversive experiences, eg. painful stimuli.

Bandura postulated that self-efficacy varies along three dimensions: magnitude (ie. level of task difficulty), generality and strength. He described efficacy expectations

as being based upon four main sources of information: performance accomplishments, vicarious observation, verbal persuasion and physiological state. However, more important is how this information is appraised by the individual. Despite cognitive variables being the primary determinants of behaviour, techniques that provide performance-based accomplishments (ie. behavioural experience, practice) are the most powerful tools for bringing about behaviour change (Bandura, 1982).

Self-efficacy has been found to predict a range of health-related behaviours, eg. adherence to health recommendations in rheumatoid arthritis patients (Taal, Rasker, Seydel & Wiegman, 1993). There have been several studies examining the relationship between self-efficacy and treatment outcome in the chronic pain population. Nicholas, Wilson & Goyen (1992) found that patients in the cognitive behaviour therapy/physiotherapy treatment condition for chronic pain improved on self-efficacy ratings and these were maintained at follow-up. Both Dolce et al. (1986a) and Kores, Murphy, Rosenthal, Elias & North (1990) have also reported that chronic pain patients' self-efficacy scores significantly improve with pain management input. Furthermore, higher post-treatment self-efficacy ratings were positively related to improved functioning at follow-up (as measured by greater exercise levels, less medication use and better work status in the Dolce et al. (1986a) study). Post-treatment self-efficacy was a better predictor of maintenance than pre-treatment self-efficacy. These studies suggest that self-efficacy expectancies may be useful predictors of treatment outcome among chronic pain patients. Dolce, Crocker, Moletteire & Doleys (1986b) suggest that a subgroup of chronic pain patients exist who fail to display improvements in self-efficacy despite experiencing behavioural success, ie. they may fail to employ newly acquired management skills following treatment due to low efficacy beliefs and are consequently good candidates for relapse. In clinical practice Dolce observed that these patients tend to

attribute their success to external factors (eg. therapist encouragement/guidance) rather than their own skills and abilities.

Dolce (1987) outlined three mechanisms of how perceived self-efficacy could bring relief from pain. First, people who believe they can control pain are likely to mobilize whatever coping skills they have learned. Second, people who are self-efficacious may persevere in their efforts. Finally, a sense of self-efficacy may reduce distressing anticipations that create aversive physiological arousal and bodily tension which may exacerbate pain sensations and discomfort. Meanwhile, Bandura and his colleagues attempted to clarify the relationship between self-efficacy and physiological mechanisms of pain control. Bandura, O'Leary, Taylor, Gauthier & Gossard (1987) found evidence that attenuation of the impact of pain stimulation by cognitive means is mediated by both opioid and nonopioid mechanisms. The stronger the perceived self-efficacy to reduce pain, the greater was the opioid activation. Pain tolerance was greatest when both mechanisms were present (ie. cognitive coping and opioid activation). However, cognitive copers were able to achieve some increase in pain tolerance even when opioid mechanisms were blocked by an opioid antagonist.

The Pain Self-Efficacy Questionnaire (PSEQ) (Nicholas, 1989) is presently in vogue in the UK. It asks patients to rate their confidence in performing an activity whilst in pain and is therefore more a measure of pain tolerance beliefs (Nicholas, 1994). It aims to measure the strength and generality of pain sufferers' beliefs and is disadvantaged by the omission of the third "difficulty" dimension from Bandura's model, according to Skevington (1995). Data has been collected to demonstrate the reliability and validity of the instrument (Nicholas, 1994) and its sensitivity to treatment changes (Nicholas et al., 1992). This 1992 study illustrates that the PSEQ scores are not simply a reflection of mood or pain severity.

However, Dolce et al. (1986a) advocated that self-efficacy ratings are not completely independent of other predictive measures. Lin & Ward (1996) described a positive correlation between self-efficacy and perseverance of coping effort in patients with chronic low back pain and stated that perseverance of coping effort mediated the effect of self-efficacy on pain outcomes. Similarly, Keefe, Kashikar-Zuck, Robinson et al. (1997) found that several pain coping strategies (ignoring pain sensations, coping self-statements and catastrophizing) predicted a significant proportion of the variance in their patients' (with osteoarthritis or persistent knee pain) ratings of self-efficacy, after controlling for pain intensity and demographic variables. While a relationship between efficacy and successful coping has been demonstrated, this research is correlational and the mechanisms which underlie this relationship could be reciprocal and remain unclear. Difficulties arise due to the confounding of different dimensions, eg. coping strategy and outcomes of coping (Williams & Erskine, 1995). Skevington (1995) also discusses the novelty of the self-efficacy concept. She argues that ratings of self-efficacy may be no more than statements of intention (that is decisions to act that are the result of expectations and not expectations as such) because people are often unable to tell whether their performance is living up to expectations. This distinction is utilised in the Theory of Planned Behaviour which will be discussed in 1.4.2.(D)(3).

There has been less research examining the effects of outcome expectancies on coping behaviour in chronic pain. Lin & Ward (1996) also found that outcome expectancies were positively correlated with perseverance of coping effort and that this relationship was not moderated by self-efficacy. They claimed that outcome expectancies and self-efficacy play equally important roles in coping with low back pain. However, the majority of studies have been less supportive of outcome expectancy. Council, Ahern, Follick & Kline (1988) found that beliefs about the effects of specific body movements on pain were related to observed performance of

those movements. However, these relationships were not statistically significant when self-efficacy expectancies were statistically controlled. Furthermore, Jensen et al. (1991) asked chronic pain patients to rate outcome and self-efficacy expectancies for eight coping strategies, including avoidance of opioid medication use. There was support for the self-efficacy theory but beliefs about the consequences of coping efforts and their interaction with beliefs about capabilities were generally unrelated to coping. Therefore, from research with chronic pain patients, outcome expectancy appears, at best, to be associated only weakly with coping behaviour. By way of explanation, Council et al. (1988) found support for their hypothesis that self-efficacy expectancies may mediate the relationship between outcome expectancy and functioning. This fuels critics' arguments that self-efficacy expectancy and outcome expectancy are ambiguous variables which may not be conceptually distinct (Lin & Ward, 1996). These results suggest that treatment should emphasize the actual practice and use of adaptive coping strategies over education about their outcome.

(2) The Health Belief Model

The Health Belief Model (HBM) (Becker, 1974) was specifically developed to explain the various factors influencing preventive health behaviours. The model asserts that the decision to engage in a particular health behaviour will be determined by beliefs about perceived susceptibility to the health threat, perceived seriousness of the health threat, perceived benefit of taking the preventive action and perceived barriers associated with the action. The decision is triggered by an internal or external cue (eg. an invitation to attend screening). Recently other beliefs, eg. efficacy beliefs, and demographic factors have been added to the model.
Much research has been conducted using the HBM or some of its components. The model has consistently received moderate success, at least in the short term, in

predicting health behaviours (eg. giving up smoking, reducing alcohol consumption). Janz & Becker (1984) reviewed 24 studies and found perceived barriers to the behaviour and perceived susceptibility to the condition to be the strongest predictors. The model has been extended to predict adherence to medical advice and treatment in both acutely and chronically ill patients. Becker & Rosenstock's (1984) review of 19 such studies concluded that perceived barriers and benefits were the most powerful dimensions.

The model has been criticised for being unclear as to the precise way in which the variables combine to predict behaviour and because the dimensions are not independent (Marteau, 1995). Furthermore, Weinstein (1987) has suggested that susceptibility and severity beliefs may not even be considered by the individual, describing experimental subjects as often having great difficulty in answering questions about likelihood and severity of a particular health threat. This may be the case with problems relating to continued drug use in chronic pain patients who have often had their pain and been on drugs for many years.

(3) Theories of Reasoned Action and Planned Behaviour

The Theory of Reasoned Action (TRA) (Ajzen & Fishbein, 1977), which was developed by social psychologists, asserts that the primary determinant of behaviour is the person's intention to perform the behaviour. Intention is in turn seen to be determined by two sets of attitudes. First, the person's personal attitudes towards the behaviour, which refers to the extent the person has a favourable or unfavourable evaluation of the behaviour. Second, the subjective norm, or perceived social pressure to perform or not perform the behaviour. These two factors are underpinned by sets of beliefs. For the attitude component these are behavioural beliefs concerned with the likely outcomes of the behaviour and evaluations of these outcomes. For the subjective norm component the beliefs are normative beliefs

which reflect the perceived opinions of key other people about the behaviour and the person's motivation to comply with these opinions. Demographic variables and factors associated with a health condition are generally presumed to be antecedent to attitudes and subjective norms.

However the TRA was only intended to be applied to the prediction of behaviour under voluntary control. Therefore, Ajzen (1988, 1991) put forward the Theory of Planned Behaviour (TPB) (see Fig. 1.1) in order to extend the TRA to the prediction of non-volitional behaviour. Thus the TPB includes an additional component - a measure of perceived behavioural control - which taps the degree to which the behaviour is seen to be under the person's control. This measure is similar to Bandura's (1986) construct of self-efficacy. The set of beliefs underpinning this

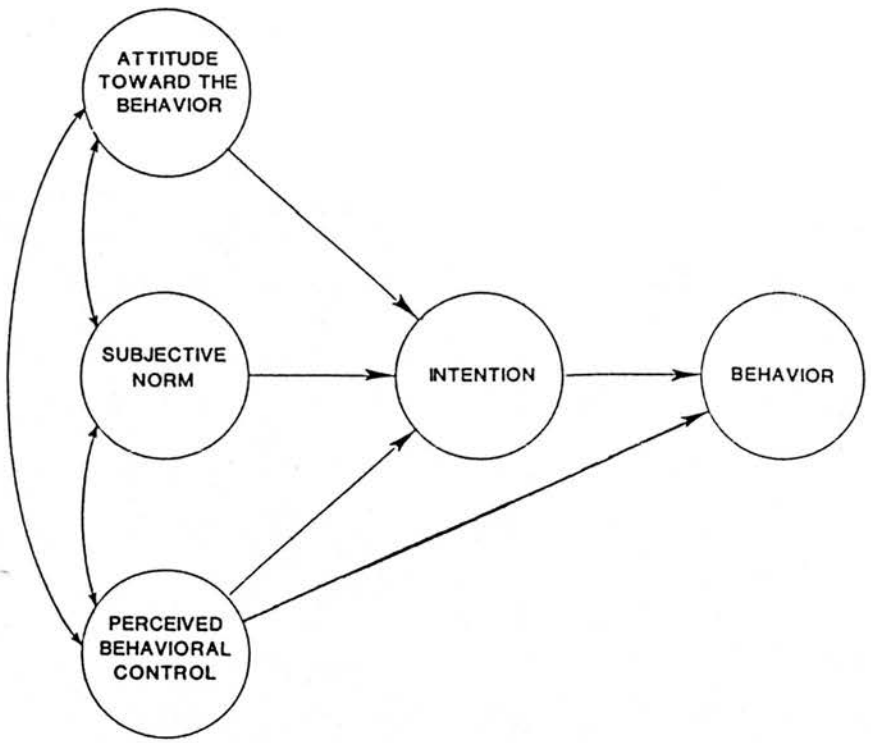



**Fig. 1.1: Ajzen's (1988) Theory of Planned Behaviour**

component focus on perceived barriers to the behaviour, ie. anticipated impediments and obstacles. The relative contribution of the different components of this model will vary from one health behaviour to another.

These models have been less widely applied than the HBM in the health field, despite seeming to have more explanatory power (Johnston et al., 1995). This may be due to the development of appropriate measures being time-consuming as new behaviours have to be assessed for each behaviour and population. The TRA has successfully predicted significant amounts of the variance in intention and behaviour in a variety of areas such as drug and alcohol abuse and smoking cessation (Sheppard, Hartwick & Warshaw, 1988). The addition of the perceived behavioural control component has been found to make a contribution from various studies in the health field, eg. weight loss (Schifter & Ajzen, 1985) and problem drinking (Schlegel, D'Averna, Zanna, DeCourville & Manske, 1992). Madden, Ellen & Ajzen (1992) and Netemeyer, Burton & Johnston (1991) observed perceived behavioural control to influence both behavioural intentions and actual behaviour for behaviours low in perceived control (eg. weight loss) but to influence intentions only for behaviours high in volitional control (eg. voting). Ajzen (1988) stipulated that the direct path between perceived behavioural control and behaviour represented the influence of actual control. However, Pellino (1997) reported that perceived control over taking analgesics was not related to intentions to use postoperative analgesia following elective orthopedic surgery. She looked at perceived control over taking analgesics and perceived control of pain and advocated further study of this complex area. Due to the inpatient status of her patients postoperatively, Pellino was able to study the TPB using a subjective and objective measure of behaviour for the first time. She found intentions to take analgesics did not relate to the actual amount of medication used but did relate to the subjective report of medication use. She hypothesized that this was due to a major event (surgery with the actual occurrence

of pain) taking place between the measure of intent and behaviour producing a change in intentions to take medication.

Recent research has studied some of the theoretical assumptions of the model which previous researchers have been criticized for taking for granted. Richard, van der Pligt & de Vries (1995) and Parker, Manstead & Stradling (1995) have suggested that additional measures of anticipated regret and worry and moral norm can substantially improve the TPB's power to predict (un)safe sexual behaviours and commission of driving violations respectively. As drug reduction is less influenced by emotions than sexual behaviour and is not an antisocial or socially controversial area, these additional variables are less likely to apply. Elliott, Jobber & Sharp (1995) reported that overall attitudes can be predicted much more accurately using personally salient beliefs rather than using only those beliefs which are modally salient for a given population. However, other researchers have found the benefits of this cumbersome procedure to be minimal. Giles & Cairns (1995) found partial support for their suggestion that a multidimensional representation of attitudes (ie. separate measures of positive and negative beliefs) was more accurate and valid than a unidimensional system for representing attitudes about blood donation. Drug reduction is also associated with both positive and negative consequences.

The TPB has been criticized for not taking people's prior experience of the behaviour into account. Ajzen (1988) argued that the addition of perceived behavioural control and perceived barriers into the model dealt with this criticism, as the effects of prior behaviour should be mediated by perceived behavioural control. However, Norman & Smith (1995) and Bagozzi & Kimmel (1995) claimed that the addition of prior behaviour had direct effects on intentions and subsequent exercising and dieting behaviour. In the latter study some predictions were no longer significant after controlling for past behaviour. However, it should be noted that this study was based on survey and not experimental methodology.

Cognitive models are criticized for assuming a causal relationship between cognitions and behaviour when the influences may be bi-directional or involve other processes. One of their major drawbacks is their inability to produce complete explanations of social behaviour due to their overemphasis on attitudes. Cognitions are only one of the many determinants of behaviour and a wider perspective, including environmental and cultural influences, is required. Coping skills are not dealt with except to consider the perceived lack of skills as a barrier. Furthermore, the models focus on conscious, intentional behaviour and ignore the wide range of automatic actions (eg. resulting from habit or custom) that make up much of daily activity. At the level of cognitions, there is a lack of agreement about which are important in which circumstances. Those measured may not be of particular importance to the individual who may not be able to describe or accurately rate these "hidden processes" (Johnston et al., 1995). Finally, there is a lack of standardized measurement tools making proceeding with and comparing across studies difficult.

(4) "Common Sense" Models

More recently cognitive approaches have responded to some of these criticisms with "common sense" models attempting to identify patients own representations of their health and illness threats rather than using experimenter generated concepts. The Self-Regulation Model (Leventhal & Nerenz, 1985) conceptualizes the individual as a problem-solver who is attempting to close the gap between his or her current state and a goal state. Individuals feel motivated to engage in health-protective actions when they notice actual body symptoms or sensations that could be interpreted as warning signs of future or current disease threats. Leventhal proposes adaptive behaviours elicited during a health episode are regulated by: (i) the cognitive representation of the health threat,eg. beliefs about the identity, cause, consequences and duration of an illness (ii) action planning or coping (iii) appraisal. Thus this

model encompasses interacting cognitive, emotional and behavioural aspects of the situation. People's representations may reflect attitudes about prior illness episodes which may not necessarily apply to the current episode, eg. beliefs regarding chronic pain, may be guided by the expectations of conditions being time-limited and curable.

Despite its appeal, there are two major drawbacks with this model. Firstly, there is a paucity of supporting data although isolated studies show promise. For example, Meyer, Leventhal & Gutmann (1985) demonstrated how the illness representations of hypertensive patients can influence their level of adherence to antihypertensive medication as well as other ways of coping. Secondly, methodological problems include an absence of operations to assess specific constructs (Leventhal & Cameron, 1987) and the need to take multiple measures and then make decisions about whether variables are independent or dependent measures.

Williams & Thorn (1989) developed The Pain Beliefs and Perceptions Inventory (PBPI) which attempted to capture patients own conceptualizations of what pain is and what pain means for them. Their inventory was initially comprised of three factors: pain stability, pain as a mystery and self-blame. They found that beliefs in the long duration of pain and the perception of pain as a mystery were associated with lower compliance (as rated by primary therapists from four disciplines) to physical therapy and behavioural interventions for pain management.

(E) Process Models

Other authors have stressed the importance of considering adherence as a process. Prochaska & DiClemente's (1982) Transtheoretical Model of Change and Marlatt & Gordon's (1980) Relapse Prevention Model postulate that the choice to begin to adhere, to continue to do so and to maintain the habit may be influenced by different factors. However, this study focuses on adherence over a narrow time scale and the

main group of participants would all be categorized in Prochaska & DiClemente's "action" stage.

### 1.4.3. MULTI-MODEL STUDIES OF ADHERENCE

Studies have frequently combined variables from more than one cognitive model to look for predictors of adherence. As previously stated, no studies investigating predictors of adherence to drug reduction plans could be found but one cognitive study looked at adherence to taking medication. Brus, van de Laar, Taal, Rasker & Wiegman (1999) looked for predictors of adherence to taking Sulphasizine in rheumatoid arthritis patients. Only self-efficacy regarding the use of this medication correlated with adherence which, on logistical regression analysis, determined 80 per cent adherence. No relationship was found between adherence and outcome expectations, perceived attitudes and perceived support of the social environment, demographic or disease-related variables or perceived barriers.

Granlund, Brulin, Johansson & Sojka (1998) analysed adherence to a five month exercise programme in subjects with low back pain. They studied several factors which are either included in or similar to variables from Self-Efficacy Theory, The Health Belief Model, The Theory of Planned Behaviour and The Transtheoretical Model of Change. They found a combination of age, perceived lack of time to exercise (a perceived barrier), expected consequences of not taking action to relieve the back pain (related to the HBM's "perceived susceptibility") and adherence self-efficacy resulted in a logistical regression model that correctly identified 96 per cent of higher adherers and 84 per cent of lower adherers after five months of participation in the exercise programme. Among the variables studied which were less useful in predicting higher and lower adherers were outcome expectations and level and stability of commitment (likened to intention). Expected ability to adhere to the exercise programme (adherence self-efficacy) was more useful than strength

of self-efficacy to components of the exercise programme which they hypothesized could be highly susceptible to beginners' enthusiasm. They viewed their results as providing partial support for the HBM and obviously conclusions could be drawn with respect to other models. However, they investigated a large number of variables (more than those mentioned here) in relation to a relatively small sample size of 51.

## 1.5. THE PRESENT STUDY

This study will assess the extent to which the Theory of Planned Behaviour can explain adherence to drug reduction plans in chronic pain management patients. The TPB was chosen for testing here as it was felt to have the greatest applicability to drug reduction of the models reviewed which offered tight specification and guidelines for scale construction. Furthermore, it has not been widely applied in the health field and, according to Skevington (1995), needs to be taken seriously in pain research as one of the best models available. Administration of the PSEQ will provide standardized information and allow comment on the blurred concepts of self-efficacy and perceived behavioural control.

Such research is required due to the neglect of the issue of adherence in the growing field of chronic pain management. Unnecessary drug usage is expensive in human and material terms and adherence to drug reduction plans is desirable to cost-conscious healthcare purchasers (in terms of cost of drugs and time in GP consultation) and individual patients. It is hoped that the findings will lead to improved methods of helping patients to achieve their desired reduction in drug use.

### 1.5.1. HYPOTHESES UNDER INVESTIGATION

#### Exploring the Measures of Adherence

Adherence will be measured using two methods (see Appendix E) which are expected to correlate highly, as are the two ways of calculating drug reduction. It is predicted that adherence to drug reduction plans and amount of drug reduction will correlate moderately and not highly.

#### Accounting for the Variance in Adherence and Drug Reduction

Demographic/background factors are not expected to be associated with adherence to drug reduction plans and amount of drug reduction with the exception of the complexity of the regimen. The main hypotheses being tested involve the Theory of Planned Behaviour. It is hypothesized that the variables from the theory (ie. attitudes, subjective norms, perceived behavioural control and perceived barriers towards drug reduction), collected prior to the decision to opt in/out of drug reduction, will predict intention to reduce one's drugs. The same variables, plus intention to reduce, will then predict the behaviours of (i) deciding to opt into drug reduction work (ii) adhering to drug reduction plans and (iii) reducing drugs. Self-efficacy variables (PSEQ and drug SE) are also expected to correlate with adherence to drug reduction plans and amount of drug reduction. A further hypothesis involves a Decisional Balance variable (TPB Questionnaire Q12). It is predicted that those who feel the advantages of taking drugs outweigh the disadvantages will be less likely to adhere to reduction plans and reduce their drugs.

#### Change During the Programme

The TPB variables and the Decisional Balance variable are expected to become more favourable towards drug reduction over the course of the programme in those who opt into drug reduction work. Increases in self-efficacy variables (PSEQ and drug SE) are also predicted over the course of the programme. These changes are

predicted on the basis of pain management input and positive experiences of drug reduction.

Maintenance of Change

Self-efficacy variables and drug intake scores are expected to show some relapse (as defined in 4.5) at 1 and 18 month follow-up. It is predicted that nonadherence during the group will be related to relapse at 1 and 18 month follow-up due to nonadherers failing to learn strategies for dealing with setbacks or trying to reduce too much too soon. Finally, self-efficacy variables will be associated with maintenance at 1 and 18 month follow-up with post-treatment SE being a better predictor than pre-treatment SE.

## 2. METHODOLOGY

Approval for this study was sought and obtained from the Lothian Area Ethics of Medical Research Committee.

### 2.1. DESIGN

A prospective, naturalistic design was employed with patients deciding whether to opt in or out of drug reduction. The study used a standardised questionnaire format.

### 2.2. SETTING

The setting is the Health Psychology Department, Astley Ainslie Hospital, Edinburgh. Its PMP consists of a 12 session multidisciplinary cognitive-behavioural approach to the outpatient treatment of chronic pain over ten weeks. It is aimed at controlling pain as opposed to curing it. The AAH is representative of major outpatient clinics in its scope and structure (see Appendix A). On the third session, the doctor held an education session which explored the use of medication in chronic pain and strongly recommended the desirability of drug reduction as part of the PMP.

### 2.3. SUBJECTS

Subjects were taken from a consecutive series of patients attending the AAHPMP between October 1995 and April 1996. Inclusion and exclusion criteria for the AAHPMP are presented in 1.1. All those who were taking pain-related medication and agreed to participate took part in the study.

## 2.4. MEASURES

### 2.4.1. TPB QUESTIONNAIRE

TPB variables as applicable to pain-related drug reduction were measured using the TPB Questionnaire. This measure was designed by the author specifically for the present study (see 2.5.1.).

(A) Questionnaire (Long Form) (See Appendix B)

The long form of the questionnaire contained the following measures. Unless otherwise stated, all items were rated on seven-point Likert scales with scores ranging from one to seven.

*Attitudes*

Attitudes were measured in two ways. The concept "drug reduction" was rated on three bipolar adjective scales which were summed to provide a direct measure of attitude (Q23-25). For the second measure, the belief strength associated with ten possible positive and negative consequences of drug reduction was assessed (Q1-10) and evaluations of each of the ten possible consequences were obtained (Q13-22). Five clinical psychologists were asked to indicate whether agreement or disagreement with the beliefs was likely to predict drug reduction and whether most people with pain would be likely to think the consequence good or bad. Mixed responses were obtained for three items (Q4, 5 &9) which were consequently omitted from the data set. The products of the remaining seven items were then summed to produce a belief-based measure of attitude.

*Subjective Norms*

Subjects indicated their beliefs that each of three referents (if applicable) would approve or disapprove of their reducing their drugs on a scale ranging from -3 to +3 (Q28-30) and their motivations to comply with each referent (Q32-34). The products of these ratings were summed to produce a belief-based measure of subjective norm.

*Perceived Behavioural Control (PBC)*

Two measures of PBC were obtained. The first measure of PBC required subjects to indicate how likely 12 factors would be in preventing them from reducing their drugs (Q35(a)-(l)) with responses being summed to produce the *Perceived Barriers* score. A second, more direct measure, was obtained by assessing the degree to which subjects believed they had control over reducing their drugs (Qs26 & 31) and their self-efficacy to reduce, using Q7 of the PSEQ (see 2.4.2.) to avoid repetition, with responses to these three items being summed.

*Intention*

Intention was assessed by one item(Q27) dealing with the likelihood of drug reduction.

*Decisional Balance*

In addition to the TPB items, subjects were asked to respond 'yes' or 'no' as to whether the advantages of taking drugs for their pain outweighed the disadvantages (Q12).

(B) Questionnaire (Short Form) (See Appendix C)

The short form of the questionnaire repeated the items for attitudes (excluding evaluations), PBC and the decisional balance question. The tense was altered for the perceived barriers items. In addition, subjects were asked how much support they got on the course to help them reduce their drugs (Q20).

2.4.2. PAIN SELF-EFFICACY QUESTIONNAIRE

Confidence in performing a range of roles and activities despite the pain was measured using the PSEQ (Nicholas, 1989) (see Appendix D).

### 2.4.3. ADHERENCE

Self-report measures of adherence to drug reduction plans were calculated from weekly recording sheets (see Appendix E for method of calculation).

### 2.4.4. DRUG REDUCTION

Drug reduction scores were calculated by comparing the final week recording sheets with the details of drug intake collected at Time 1 (see Appendix E for method of calculation).

## 2.5. PROCEDURE

### 2.5.1. Pilot Work

The questionnaire to assess the TPB variables as applicable to pain-related drug reduction was devised by referring to studies which had used this model to test other behaviours and by interviewing chronic pain patients and pain management staff to identify key issues relating to drug reduction. Four patients and four members of staff were asked to list the advantages and disadvantages of reducing pain-related medication, the people who might approve or disapprove of reduction and the factors that might help or prevent reduction. Responses to these questions were used to develop behavioural, normative and control belief items respectively.

The provisional questionnaire was piloted on four chronic pain patients and was read by four members of the pain management team who were asked for comments. This process resulted in the finalized questionnaire. As pilot work was limited due to time constraints, the finalized questionnaire included two open-ended questions (Q11&36) to assess whether any common behavioural or control belief items had been overlooked.

2.5.2. Main Study

At the session following the medication education session, subjects taking pain-related medication who had agreed to participate completed the TPB and PSEQ questionnaires (Time 1). Questionnaires were completed during the session in the presence of the experimenter. Following questionnaire completion patients met individually with the nurse who oversees drug reduction. Initial details of drug intake were recorded and it was ascertained whether the patient wished to work on drug reduction.

Those opting to work on drug reduction plans met the nurse on a weekly basis to review and specify their plan for the forthcoming week, and monitored their daily medication use on a drug recording sheet designed specifically for the study (see Appendix F/G). At discharge from the group (Time 2), all subjects who were on pain-related medication at Time 1 (including those who had opted in and out of drug reduction work) completed the short form of the TPB questionnaire and the PSEQ. The group who had opted into working on drug reduction plans during the programme were followed up by post at 1 month (Time 3) and 18 months (Time 4). They completed the PSEQ and a record of their drug intake over one week. Subjects who failed to respond within three weeks were contacted by telephone and encouraged to return the information or provide it verbally over the telephone.

# 3. RESULTS

The main data analysis was conducted using SPSS for Windows: Version 6. Version 7 was used to analyse the 18 month follow-up data. Throughout the results section significance levels have been coded in the tables as follows: * = $p<0.05$, ** = $p<0.01$, *** = $p<0.001$.

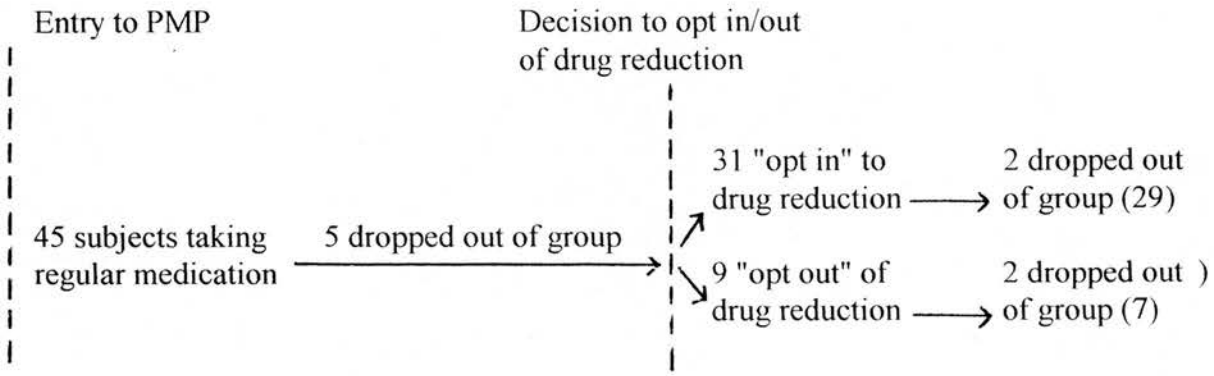
## 3.1. DESCRIPTION OF THE SAMPLE AND THE DATA SET

### 3.1.1. CHARACTERISTICS OF THE PATIENTS IN THIS STUDY

Of 60 patients attending six groups during the period of study, 45 subjects were taking regular pain-related medication. Fig. 3.1 illustrates behaviour over the course of the group for these 45 subjects. Data from the two patients who dropped out of the programme after opting into drug reduction was not examined due to the small drop out rate. No patients dropped out of the research but continued to attend the group. At one month follow-up (Time 3) a 100 per cent return rate was achieved from the 29 subjects who had opted into drug reduction. Details of these 29 patients (ie. the main group on which analysis was conducted) are provided in Table 3.1. The majority (23) had back pain (with nine of these suffering additional pains), three had neck/shoulder pain, one had abdominal pain, one had leg pain and one had pain all over.

Table 3.1 provides demographic and other background information for patients in this study who opted into drug reduction and patients from a large INPUT evaluation study (Williams et al., 1993) in order to establish how far the current patients are representative of the chronic pain population. This data is collected routinely at the start of the AAH PMP, with the exception of the self-efficacy scores which were collected as part of the present study. The current sample was slightly younger and

**Fig. 3.1: Flow chart of subject behaviour**




---

**Table 3.1: Demographic/background characteristics for current and comparison samples**

| | Current "opting in" sample (n=29) | | | INPUT sample* (n=212) | | |
|---|---|---|---|---|---|---|
| Sex (% female) | 83 | | | 65 | | |
| | Mean | SD | Range | Mean | SD | Range |
| Age (Years) | 43.9 | 12.7 | 23-74 | 50.0 | 13.3 | 20-84 |
| Years in pain | 12.5 | 10.7 | 1-35 | 10.5 | 9.9 | 1-47 |
| Dysfunction score (SIP) (%) | 64.7 | 14.2 | | 28.4 | 11.4 | |
| Depression score | 10.4 | 3.6 (HAD) | | 18.5 | 8.7 (BDI) | |
| Self-efficacy score (PSEQ) | 23.0 | 8.0 | | 24.1 | 11.4 | |
| n prior to drop outs | 31 | | | 243 | | |
| % dropped out | 6 | | | 9 | | |

SIP = Sickness Impact Profile (AAH = short form, INPUT = long form)
HAD = Hospital Anxiety and Depression Scale (range 0-21)
BDI = Beck Depression Inventory (range 0-63)
PSEQ = Pain Self-Efficacy Questionnaire (range 0-60)
* Williams et al. (1993)

---

contained markedly more females than the INPUT group. Duration of pain, depression scores, self-efficacy scores and drop out rates are similar for this sample and the INPUT programme (with Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983) and Beck Depression Inventory (Beck, Ward, Mendelsohn, Mock & Erbaugh, 1961) means both representing mild depression). Unfortunately, the long form of the Sickness Impact Profile (Bergner, Babbit, Carter & Gilson, 1981) and the short form (Roland & Morris, 1983) are not directly comparable. Therefore, conclusions about differences in self-reported dysfunction in the two samples cannot be made.

### 3.1.2. MISSING QUESTIONNAIRES AND MISSING DATA

One subject failed to complete the Self-Efficacy questionnaire at Time 2. The specific item relating to medication use (Q7) was replaced with the overall series mean.

The TPB questionnaires of one subject were judged inadequate for use. This man, who was known to abuse alcohol, responded by circling "7" for the vast majority of items whilst frequently placing ticks at the opposite end of the scale. It was decided to remove him from the main analysis. His Self-Efficacy questionnaires were judged to be satisfactory for inclusion.

Only one question (TPB questionnaire Time 2, Q18(h)) was omitted by one subject. The missing value was replaced with the overall series mean.

The TPB questionnaire required subjects to provide normative opinion regarding their hospital consultant if applicable on a scale of -3 (disapprove) to 3 (approve). 20 of the 29 subjects had a current hospital consultant. Those without were given a score of 0 on the basis that no such person existed to provide either an approving or disapproving influence.

## 3.2. EXPLORING THE DATA

Exploration of the data was based on the sample who opted to work on drug reduction for which parametric analysis was planned (n=28).

### 3.2.1. THE FREQUENCY DISTRIBUTIONS OF THE VARIABLES

The frequency distributions of the main variables being studied were examined in order to determine how far they approximated a normal curve and therefore met the assumptions of parametric statistics. In most cases the sample distributions did not differ substantially from normal. The exceptions were the subjective norms and PBC scores. Scores on these variables were clustered around one end of the scale and more items would be required to adequately differentiate the participants. It was therefore felt that transformation of the data was unlikely to help. Summary data is presented in Table 3.2.

### 3.2.2. FURTHER EXPLORATION OF THE NEWLY DEVISED QUESTIONNAIRE

Responses to the open-ended questions, designed to pick up any missed concepts, suggest that most ideas were covered by the questionnaire. Two subjects mentioned "becoming more angry or bad-tempered" as an additional consequence of reducing and "cold and damp weather conditions" was suggested as a barrier which had not been included. Of course other important consequences/barriers may exist which the subjects either could not write down (due to lack of awareness) or chose not to write down (eg. because to do so would require effort or personal disclosure). However, an open-ended question was not used to check the subjective norms measure and opinions of other people not included in the questionnaire (eg. employers, friends, pain management group members and staff) may be influential. Employers (where applicable) may have strong views about their employees taking medication to

**Table 3.2: Comparison of subjects opting in and out of drug reduction**

| | OPT OUTS (n=7) | | | OPT INS (n=29) | | |
|---|---|---|---|---|---|---|
| | Mean | SD | Range | Mean | SD | Range |
| Age | 49.86 | 13.37 | 29-63 | 43.86 | 12.72 | 23-74 |
| No. of different drugs | 2.00 | 0.82 | 1-3 | 2.45 | 1.30 | 1-7 |
| Sex ratio | 1:6 | | | 5:24 | | |
| TIME 1: | | | | | | |
| TPB VARIABLES* | | | | | | |
| Intention | 4.29 | 1.80 | 2-6 | 5.11 | 1.42 | 2-7 |
| Attitudes (direct) | 13.14 | 4.56 | 7-20 | 16.14 | 4.04 | 9-21 |
| Attitudes (belief-based) | 22.14 | 9.12 | 10-37 | 27.89 | 6.80 | 16-45 |
| Subjective Norms | 1.29 | 3.09 | -2-6 | 4.04 | 3.52 | -2-9 |
| PBC | 12.29 | 5.79 | 3-18 | 14.36 | 2.77 | 9-19 |
| Perceived Barriers | 41.14 | 6.01 | 29-46 | 48.21 | 9.48 | 34-70 |
| SE VARIABLES | | | | | | |
| PSEQ Total | 25.43 | 6.40 | 17-35 | 23.04 | 8.01 | 8-45 |
| Drug SE (Q7) | 1.43 | 1.40 | 0-3 | 1.79 | 1.08 | 0-4 |
| TIME 2: | | | | | | |
| TPB VARIABLES* | | | | | | |
| Attitudes (direct) | 12.00 | 5.66 | 4-21 | 16.54 | 4.01 | 8-21 |
| Attitudes (belief-based) | 23.29 | 7.34 | 15-38 | 29.25 | 6.51 | 5-45 |
| PBC | 12.71 | 4.39 | 6-20 | 15.02 | 3.34 | 7-20 |
| Perceived Barriers | 45.00 | 18.32 | 21-76 | 56.87 | 13.09 | 25-84 |
| SE VARIABLES** | | | | | | |
| PSEQ Total | 30.00 | 13.49 | 5-44 | 31.43 | 12.24 | 10-55 |
| Drug SE (Q7) | 2.00 | 1.53 | 0-5 | 2.64 | 1.93 | 0-6 |
| OUTCOME VARIABLES: | | | | | | |
| Compliance (Days) | | | | 72.79 | 24.25 | 28-100 |
| Compliance (Pills) | | | | 87.19 | 19.37 | 0-100 |
| Drug Reduction (Excl. flare-up days) | | | | 0.48 | 0.59 | -0.22-2.50 |
| Drug Reduction (Incl. flare-up days) | | | | 0.40 | 0.54 | -0.27-1.85 |

* n=28 (1 TPBquestionnaire judged inadequate)
** n=28 (1 SE questionnaire not completed)

facilitate work and overactivity or about reducing medication to decrease side-effects.

Due to the limited time available for the pilot phase, the newly devised TPB questionnaire could not be validated before the study. However, some attempts were made to check the reliability after the study had been completed. There is a lack of existing measures available from which to assess the concurrent validity of the new questionnaire.

Firstly, the internal consistency was examined using Cronbach's alpha coefficient of reliability. This was calculated for the two variables consisting of more than three items using the Time 1 questionnaires (n=28). An alpha coefficient of 0.61 was obtained for the summed belief-based attitudes score and 0.67 for the perceived barriers score. No individual items were negatively correlated with the variable total. These coefficients demonstrate that internal consistency is just acceptable for the two variables tested.

On examining the correlations between the variables one would expect the direct and indirect measures of attitude and the direct and indirect measures of PBC to be more closely correlated with each other compared to the other variables. Table 3.3 shows that the attitude scores are correlating reasonably well with each other, although they are correlating equally well with intention and perceived barriers. Of more concern is the lack of correlation between the two measures of PBC. Furthermore, the PBC total does not correlate significantly with the other variables in the model.

The predictive validity of the questionnaire will be assessed later in the results section.

**Table 3.3: Pearson's product moment correlations between TPB variables - 1 tailed sig. (n=28)**

| Variable | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|
| 1. Intention | - | | | | | | | |
| 2. Attitudes (direct) | 0.75*** | - | | | | | | |
| 3. Attitudes (summed beliefs) | 0.57** | 0.48** | - | | | | | |
| 4. Attitudes x Evaluations | 0.61*** | 0.62*** | 0.89*** | - | | | | |
| 5. Subjective Norms (summed) | 0.58*** | 0.59*** | 0.09 | 0.21 | - | | | |
| 6. Subjective Norms x Evaluations | 0.47** | 0.48** | -0.06 | 0.05 | 0.87*** | - | | |
| 7. PBC | 0.19 | -0.03 | 0.12 | 0.02 | 0.06 | 0.03 | - | |
| 8. Perceived Barriers | 0.42* | 0.43* | 0.51** | 0.57** | 0.25 | 0.08 | 0.11 | - |

### 3.2.3. FURTHER EXPLORATION OF THE MEASURES OF ADHERENCE

Measures of adherence were calculated using the days method and the pills method. Drug reduction was calculated including and excluding days in flare-up in the week of discharge (see Appendix E). Mean scores are presented in Table 3.2.

In the absence of an observation method or similar studies enabling comparison of adherence scores, the measures of adherence were validated by correlating the various methods employed. Table 3.4 shows a highly significant correlation between the two direct measures of adherence ($r = 0.69$, $p<0.001$, 1 tailed). The days measure was selected as the primary measure of compliance for use in future correlations and in the main analysis for reasons outlined in Appendix E and because the scores better approximate a normal curve and do not contain an outlier.

As one would expect, the scores calculating drug reduction with and without leniency to flare-up are very highly correlated ($r = 0.97$, $p<0.001$, 1 tailed) (Table 3.4). The score excluding days in flare-up was selected as the primary measure of drug reduction for use in future correlations and in the main analysis in keeping with the policy implemented when calculating the measures of adherence.

Outcome (ie. drug reduction) is often used as a crude measure of adherence and the direct measures of adherence were expected to correlate moderately, rather than strongly, with the drug reduction scores. No correlation was observed. However the scores in brackets are consistent with this hypothesis. These were obtained on removing the subject who abuses alcohol (who achieved the largest reduction whilst being noncompliant) from all the correlations and an outlier (who was not following group principles) from the compliance (pills method) correlations.

## 3.3. COMPARISON OF SUBJECTS OPTING IN AND OUT OF DRUG REDUCTION

There were seven people in the study who were taking drugs but who opted out of working on drug reduction plans. Due to the small number these data will not be tested statistically and the following description is based on impression only. Study of Table 3.2 shows that the means for those opting in and out of drug reduction differ in the expected direction for all the TPB variables, ie. more favourable towards drug reduction in those who opted to work on drug reduction plans. However PSEQ was greater in those opting out suggesting a generally low pain self-efficacy is not the reason for their decision to opt out of drug reduction. As expected there is little change in the TPB variables between Times 1 and 2 in the group opting out, with the exception of a small increase in perceived barriers. The SE measures show an increase between Times 1 and 2.

## 3.4. ACCOUNTING FOR THE VARIANCE IN ADHERENCE AND DRUG REDUCTION

### 3.4.1. DEMOGRAPHIC AND BACKGROUND VARIABLES

Table 3.5 illustrates that, as hypothesized, demographic variables (age, sex) and illness characteristics (self-reported dysfunction (SIP), duration of pain) were not significantly associated with compliance or drug reduction. Masur (1981) demonstrated that adherence decreases with the complexity of the regimen, however number of drugs and adherence were not significantly correlated here.

A significant association was found between higher pre-treatment HADS Depression scores and lower compliance ($r = -0.43$, $p<0.05$, 2 tailed) but not between these scores and drug reduction. Subjects were asked at the end of the group how much support they had received on the course to help them reduce their drugs on a scale of one (none at all) to seven (very much). Their responses ranged from four to seven

**Table 3.4: Pearson's product moment correlations amongst measures of compliance - 1 tailed sig. (n=29)**

| Measure | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| 1. Compliance, (Days method) | | - | | |
| 2. Compliance, (Pills method) | 0.69*** (0.81***) | - | | |
| 3. Drug reduction, (Excluding flare-up) | 0.15 (0.43*) | 0.06 (0.35*) | - | |
| 4. Drug reduction, (Including flare-up) | 0.23 (0.44*) | 0.05 (0.31) | 0.97*** (0.98***) | - |

Scores in brackets n=28. Note n=27 for measure 3 (see text for explanation).

**Table 3.5: Pearson's product moment correlations between demographic/ background variables and compliance/drug reduction - 2 tailed sig. (n=29)**

| | Compliance | Drug Reduction |
|---|---|---|
| Age | -0.21 | -0.02 |
| Sex | -0.15 | -0.23 |
| SIP | -0.24 | -0.03 |
| Duration of pain | -0.22 | 0.31 |
| HADS - Anxiety | -0.11 | 0.27 |
| HADS - Depression | -0.43* | -0.07 |
| No. of different drugs | -0.24 | -0.06 |
| Perceived support | 0.26 | 0.45* |

**Table 3.6: Pearson's product moment correlations between variable choices and dependent variables - 1 tailed sig. (n=28)**

| | Intention | Compliance | Drug Reduction |
|---|---|---|---|
| Summed Beliefs | 0.57** | 0.23 | 0.33* |
| Beliefs x Evaluations | 0.61*** | 0.07 | 0.30 |
| Summed Subjective Norms | 0.58*** | 0.13 | 0.22 |
| Subjective Norms x Evaluations | 0.47** | 0.09 | 0.12 |

with an average of 6.1 indicating that all subjects at least felt obliged to report that they had received adequate-good support. A significant correlation was obtained between perceived level of support and drug reduction ($r = 0.45$, $p<0.05$, 2 tailed). Group attendance was not examined as little variance was observed in attendance with the vast majority of subjects who did not drop out attending 11 or 12 sessions.

### 3.4.2. TPB VARIABLES

#### Selection of Independent Variables

Several studies (eg. Chassin, Presson, Sherman, Corty & Olshavsky, 1984) have indicated that using the simple sum of attitudinal and normative beliefs is as successful in predicting behaviour as the multiplicative scores (ie. beliefs x evaluations). The summed and multiplicative totals from the present study were correlated with the dependent variables and are presented in Table 3.6.
On examining the correlations it was decided to use the simple summed normative beliefs measure in the multiple regression analyses. Likewise the simple summed beliefs measure was the preferred belief-based measure of attitude. In order to keep the number of independent variables as low as possible, the significantly correlated direct and belief-based measures of attitude ($r = 0.48$, $p<0.01$, 1 tailed) were combined to provide one measure of attitude (see Table 3.3). A decision was made not to sum the two measures of PBC (PBC and perceived barriers) due to the lack of significant correlation between these variables.

#### (A) Accounting for the Variance in Intention

Table 3.7 shows that intention to reduce drugs correlated significantly with attitude, subjective norm and perceived barriers. No association was obtained for PBC with intention. In order to assess the predictive value of these components on intention in more detail a multiple regression analysis was conducted on the data.

Attitudes, subjective norms, PBC and perceived barriers were entered in one step in keeping with the TPB. This resulted in these variables explaining 65 per cent of the variance. (Total equation: Ad R Sqd = 0.65, F = 13.29, df = 4,23, $p<0.001$) Attitudes (beta = 0.67, $p<0.001$) and subjective norms (beta = 0.28, $p<0.05$) made independent contributions to the prediction of intention (see Fig. 3.2 and Appendix H).

(B) Accounting for the Variance in Adherence

One can see in Table 3.8 that intention and perceived barriers are weakly but not significantly correlated with compliance to drug reduction plans. No association was found for attitudes, subjective norms or PBC. A hierarchical regression analysis was performed to examine ability to account for compliance. In accordance with the model, intention was entered on the first step, PBC and perceived barriers on the second step and attitudes and subjective norms on the third step. The results of the multiple regression revealed no significant effects and none of the variance was explained (see Appendix H).

(C) Accounting for the Variance in Drug Reduction

On analyzing drug reduction, Table 3.8 shows that perceived barriers was the best single predictor of the amount of drugs reduced over the programme. Attitudes also correlated significantly with drug reduction, but the weak correlation with subjective norms was not significant. No correlation was observed for intention or PBC. A hierarchical regression analysis was performed to examine the ability of these variables to account for drug reduction with the variables entered in three steps as above. The intention measure accounted for none of the variance in drug reduction. The addition of PBC and perceived barriers accounted for 13 per cent of the variance, with only perceived barriers (beta = 0.49, $p<0.05$) making a significant

**Table 3.7: Correlations among TPB variables entered in MRA - 1 tailed sig. (n=28)**

| Variable | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| 1. Attitudes | - | | | | |
| 2.Subjective Norms | 0.44* | - | | | |
| 3. PBC | 0.03 | 0.06 | - | | |
| 4. Perceived Barriers | 0.54** | 0.25 | 0.11 | - | |
| 5. Intention | 0.78*** | 0.58** | 0.19 | 0.42* | - |

**Table 3.8: Correlations between TPB Variables and Compliance/Drug Reduction entered in MRA - 1 tailed sig. (n=28)**

| | Compliance | Drug Reduction |
|---|---|---|
| Attitudes | 0.13 | 0.34* |
| Subjective Norms | 0.13 | 0.22 |
| PBC | 0.09 | 0.15 |
| Perceived Barriers | 0.21 | 0.44* |
| Intention | 0.21 | 0.06 |

**Table 3.9: Pearson's product moment correlations between Self-Efficacy and dependent variables (n=28)**

| | Intention | Compliance | Drug Reduction |
|---|---|---|---|
| Total PSEQ | 0.12 | 0.38* | 0.41* |
| Drug SE (Q7) | 0.30 | 0.16 | 0.04 |

**Fig. 3.2: TPB variables contributing to prediction of intention**

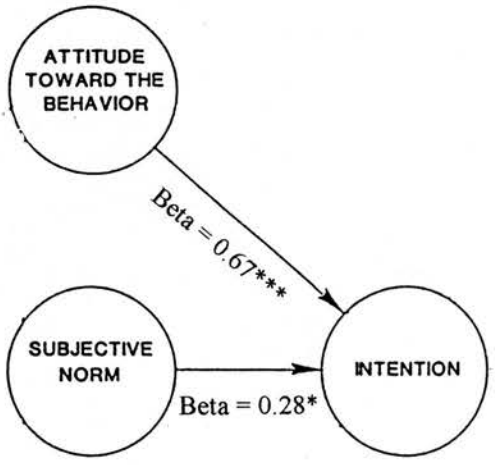
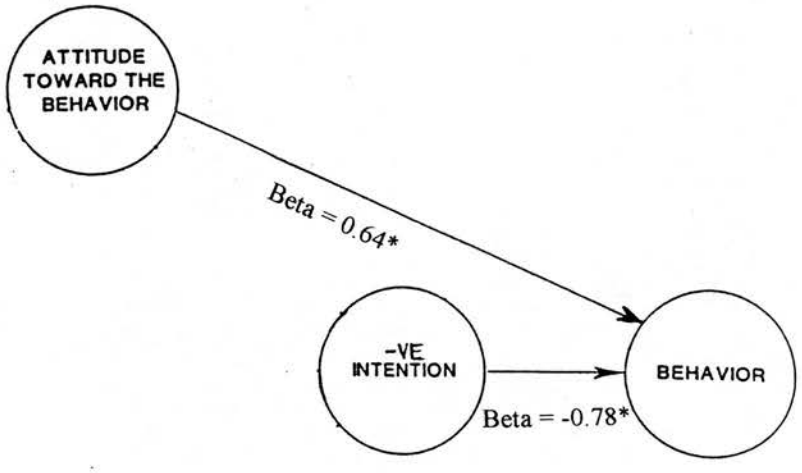



**Fig. 3.3: TPB variables contributing to prediction of drug reduction**



contribution to the equation at this stage. The addition of attitudes and subjective norms increased the amount of variance explained by 14 per cent bringing the total amount of variance explained to 27 per cent. When all the variables were entered, the analysis revealed a significant negative effect of intention (beta = -0.78, $p<0.05$) with attitudes (beta = 0.64, $p<0.05$) making a positive contribution to the final equation (see Fig. 3.3 and Appendix H).

The ability of each equation to meet the assumptions of multiple regression analysis was investigated. Since some of the independent variables were inter-correlated it was important to assess the impact of multicollinearity. On doing so no tolerance levels were found to be unacceptably small. Furthermore, a random pattern was observed on plotting the standardised residuals against the predicted residuals increasing confidence in the results.

### 3.4.3. SELF-EFFICACY VARIABLES

Question 7 (Drug self-efficacy) had the lowest mean score of 1.8 on the PSEQ and lowest item-total correlation of 0.34. Therefore the patients confidence in being able to cope with their pain without medication was low and was only weakly related to their general PSEQ score.

In order to assess the contribution of the self-efficacy variables, specific drug self-efficacy (DSE) and general pain self-efficacy (PSEQ) were correlated with intention to reduce, compliance with drug reduction plans and amount of drug reduction. Table 3.9 indicates that DSE at Time 1 is a better predictor of intention than PSEQ but PSEQ is a better predictor of compliance and drug reduction than DSE.

### 3.4.4. DECISIONAL BALANCE VARIABLE

21 of the 29 subjects felt that the advantages of taking drugs outweighed the disadvantages. No correlation was found between the decisional balance type question (TPB questionnaire Q12) and compliance (0.06) or drug reduction(0.07).

## 3.5. CHANGE DURING PROGRAMME

### 3.5.1. TPB VARIABLES

In order to see if the variables in the TPB became more favourable towards drug reduction over the course of the group, t-tests were conducted on the data. Table 3.10 indicates that there was no change in attitudes or PBC between the beginning and end of the group. A significant change in the perceived barriers measure was observed ($t = -3.59$, $df = 27$, $p<0.01$, 1 tailed). However, the tense of this question was changed between the Time 1 and 2 questionnaires. The Time 1 questionnaire asked "How likely are the following to prevent you from reducing your drugs?" and the Time 2 questionnaire read "How much did the following prevent you from reducing your drugs?". Therefore the change obtained represents a decrease between initial prediction of barriers and actual report of barriers at discharge.

In order to see which individual barriers changed significantly Table 3.10 reports t-tests conducted on the individual items. A significant decrease between initial prediction and actual report was obtained for eight of the perceived barriers with the other four items showing no change.

### 3.5.2. SELF-EFFICACY VARIABLES

T-tests were also carried out on the SE measures in order to see if there had been an increase in these scores over the course of the group. Table 3.10 indicates that there was weak evidence of an increase in the Drug SE between Times 1 and 2 ($t = -2.31$,

**Table 3.10: T-tests of changes over time**

**T-tests of changes between Time 1 and Time 2 - 1 tailed sig.**

| | TIME 1 | | TIME 2 | | |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | t |
| TPB VARIABLES (n=28) | | | | | |
| Attitudes (direct) | 16.14 | 4.04 | 16.54 | 4.01 | -0.70 |
| Attitudes (belief-based) | 27.89 | 6.80 | 29.25 | 6.51 | -1.43 |
| PBC | 14.36 | 2.77 | 15.02 | 3.34 | -0.93 |
| Perceived Barriers | 48.21 | 9.48 | 56.87 | 13.09 | -3.59** |
| Individual Perceived barriers | | | | | |
| (a) pain flare-up | 2.64 | 1.66 | 3.68 | 2.04 | -2.89** |
| (b) stress | 3.82 | 1.70 | 4.64 | 1.52 | -2.35* |
| (c) low mood | 3.79 | 1.77 | 4.68 | 1.70 | -2.20* |
| (d) new pain/injury | 3.54 | 1.71 | 4.96 | 1.40 | -4.21*** |
| (e) do less | 3.57 | 1.77 | 4.46 | 1.64 | -2.16* |
| (f) low confidence | 4.43 | 1.50 | 5.21 | 1.42 | -2.35* |
| (g) little time/energy | 4.18 | 1.49 | 5.29 | 1.21 | -3.67*** |
| (h) something new | 4.86 | 1.63 | 5.40 | 1.50 | -1.77* |
| (i) pressure from family | 5.50 | 1.50 | 5.61 | 1.55 | -0.28 |
| (j) poor sleep | 3.29 | 2.02 | 3.82 | 1.83 | -1.21 |
| (k) withdrawal effects | 4.32 | 1.93 | 4.71 | 1.74 | -1.00 |
| (l) conflicting advice | 4.29 | 1.54 | 4.39 | 1.57 | -0.38 |
| SE VARIABLES | | | | | |
| PSEQ Total (n=28) | 23.36 | 7.94 | 31.43 | 12.24 | -4.47*** |
| Drug SE (Q7) (n=29) | 1.79 | 1.08 | 2.64 | 1.93 | -2.31* |

**T-tests of changes between Time 2 and Time 3 - 2 tailed sig.**

| | TIME 2 | | TIME 3 | | |
|---|---|---|---|---|---|
| SE VARIABLES | | | | | |
| PSEQ Total (n=28) | 31.43 | 12.24 | 31.64 | 13.28 | -0.16 |
| Drug SE (Q7) (n=29) | 2.64 | 1.93 | 2.34 | 2.09 | 1.01 |

df = 28, $p<0.05$, 1 tailed) and strong evidence of an increase in Pain SE over the same period ($t = -4.47$, df = 27, $p<0.001$, 1 tailed).

In order to examine the role of drug reduction in accounting for these increases, drug reduction was correlated with change in SE. Table 3.11 shows that increases in SE were not associated with experiences of drug reduction.

### 3.5.3. DECISIONAL BALANCE VARIABLE

Exactly the same number of subjects (21 out of 29) felt that the advantages of taking drugs outweighed the disadvantages at the end of the group as the beginning. However, eight subjects (mainly unexpected to the author) had changed their answers from Time 1.

### 3.5.4. DRUG INTAKE SCORES

During the programme 22 of the participants reduced their drugs, five did not alter their intake and two increased their drugs. Three of the 22 who had made reductions became medication free (two during the course and one during the first month of follow-up). Table 3.2 illustrates the range of scores on the drug reduction measure (see Appendix E). Referring to the case descriptions in 3.8 will help to put these scores into context. Drug reduction scores were 0.9 (John), 0.75 (Jean), 2.5 (Brian) and 0.0 (Janet).

## 3.6. MAINTENANCE OF CHANGE: ONE MONTH FOLLOW-UP

At one month follow-up data was collected on drug intake and SE from 100 per cent of the 29 reducing subjects. Drug intake records were not used for one subject for whom the follow-up week had been extremely atypical.

### 3.6.1. SELF-EFFICACY SCORES

In order to test the hypothesis that SE scores would show some relapse over the one month follow-up period, t-tests were carried out. Results are shown in Table 3.10. The results indicate no change in either DSE or PSEQ over the follow-up period. Thus the improvements made on the SE measures during the group were maintained at one month follow-up.

### 3.6.2. DRUG INTAKE SCORES

During the programme seven of the 29 participants failed to reduce their drugs after planning to do so. The issue of relapse is pertinent to the remaining 22 participants who made a reduction. Nineteen of these 22 provided information at follow-up and will be categorized here.

Relapse is defined at this stage as any increase in drug intake between the end of treatment and one month follow-up. By comparing the weekly records of drug intake which were completed at one month follow-up with the end of programme recording sheets, subjects were categorized as "maintainers of abstinence", "maintainers of partial reduction" (both no change over follow-up), "reducers following partial reduction" (a decrease over follow-up) and "relapsers" (an increase over follow-up). The original method of calculating drug reduction (see Appendix E) was used except "change in dose over one month follow-up" was the numerator in the equation. Those with increases/decreases of less than 0.1 were categorized as maintainers with the exception of one subject, whose reduction was small due to an overall low intake, who was classed as a reducer. In keeping with previous policy odd days in flare-up were omitted. This led to seven subjects being classed as maintainers of partial reduction, six as relapsers and there were four reducers. Of the two participants who had reduced to zero during the group, both were maintainers of abstinence.

### 3.6.3. RELATIONSHIP BETWEEN RELAPSE AND NONADHERENCE

It was hypothesized that those who were nonadherers during the programme would be more likely to relapse than the adherers due to failing to learn strategies for dealing with setbacks or trying to reduce too much too soon. To explore this hypothesis the group was split into adherers and nonadherers on the basis of the natural division observed on the compliance (days method) graph (see Appendix I) ie. <65 = nonadherence and >75 = adherence. For those who had made a reduction during the programme and for whom follow-up data was available, this division resulted in 15 compliers and four noncompliers. Follow-up behaviour is provided for these two groups in Table 3.12.

A Chi-squared Test for Independence could not be performed due to three of the four expected values being less than five. A Fisher Exact Test was therefore carried out. This failed to reach significance ($p>0.30$) and supports the null hypothesis that compliance and relapse are independent.

### 3.6.4. RELATIONSHIP BETWEEN RELAPSE AND SELF-EFFICACY

Pain management studies by Dolce et al. (1986a) and Kores et al. (1990) suggested that self-efficacy expectancies could usefully predict maintenance with post-treatment SE being a better predictor than pre-treatment SE. This hypothesis was tested here by coding relapsers (1) and nonrelapsers (0) to obtain a maintenance variable which was correlated with pre and post treatment SE scores (see Table 3.13). In line with the two papers mentioned above, the present study found SE expectancies were associated with maintenance with post-treatment SE being more strongly associated with maintenance than pre-treatment SE. Once again PSEQ was found to be a more useful variable than DSE.

**Table 3.11: Pearson's product moment correlations between drug reduction and Time 1-2 Self-Efficacy change**

| | Drug Reduction |
|---|---|
| Change in Total PSEQ (n=28) | 0.13 |
| Change in Drug SE (Q7) (n=29) | 0.17 |

**Table 3.12: Compliance during group by maintenance during 1 month follow-up (n=19)**

| | Compliers | Noncompliers |
|---|---|---|
| Relapsers | 4 | 2 |
| Non-relapsers | 11 | 2 |

**Table 3.13: Spearman's rho correlation coefficients between Self-Efficacy and maintenance - 1 tailed sig. (n=19)**

| | TIME 1 | | TIME 2 | |
|---|---|---|---|---|
| | Total PSEQ | Drug SE (Q7) | Total PSEQ | Drug SE (Q7) |
| Maintenance | 0.42* | 0.13 | 0.68** | 0.63** |

## 3.7. EIGHTEEN MONTH FOLLOW-UP

At 18 month follow-up data was collected on drug intake and SE from 23 of the 29 reducing subjects (a 79 per cent return rate). Two further subjects provided partial information. In one case drug intake data had to be discarded as the participant had just had a baby and had been warned against taking analgesic medication. On telephoning the other, who had not responded by post, she said she could not be bothered to provide the information and did not want to face up to the amount of drugs she was consuming. However, she indicated that she was taking "a whole mixture of different drugs that varied from day to day". This allowed her to be classed as having relapsed between the end of the programme (when she had been taking set drugs consistently as advised) and 18 months. No data was obtained from four subjects. Three did not respond by post and could not be reached by telephone and one replied that she was ill with another problem and had had to come off all pain-related medication whilst tests were being carried out.

One of the 23 responders had started taking MST Continus (Morphine Sulphate) over the 18 month follow-up period. This drug may be increased according to needs and there is no maximum recommended daily dose. This meant it was not possible to use the calculation devised (see Appendix E) to calculate whether this lady was a relapser or non-relapser over the 18 month follow-up period. However, it was decided to class her as a relapser as morphine is a strong opiate (prescribed as a last resort) and its use is clearly a move in the opposite direction from drug reduction.

### 3.7.1. SELF-EFFICACY SCORES

In order to test the hypothesis that SE scores would show some relapse over the 18 month follow-up period, two repeated measures analyses of variance with one factor (time) were performed on the data (see Table 3.14). As sphericity tests failed to

**Table 3.14: Repeated measures ANOVA of changes in Self-Efficacy over time**
**(n=29, except Time 4 n=24 and Time 2 PSEQ n=28)**

| | Mean (Standard Deviaton) | | | | | |
|---|---|---|---|---|---|---|
| | Time 1 | Time 2 | Time 3 | Time 4 | F | df |
| PSEQ Total | 22.8 (8.3) | 31.4 (12.2) | 31.0 (13.5) | 26.0 (12.6) | 8.18 | 3,66*** |
| Drug SE (Q7) | 1.8 (1.1) | 2.6 (1.9) | 2.3 (2.1) | 2.0 (2.0) | 2.60 | 3,69 |

**Table 3.15: Paired sample T-tests of changes in Self-Efficacy over time using the Bonferroni method- 2 tailed sig.**

| | MEAN | SD | MEAN | SD | t |
|---|---|---|---|---|---|
| | Time 1 | | Time 2 | | |
| PSEQ Total (n=28) | 23.36 | 7.94 | 31.43 | 12.24 | -4.47* |
| Drug SE(Q7) (n=29) | 1.79 | 1.08 | 2.64 | 1.93 | -2.31 |
| | Time 1 | | Time 3 | | |
| PSEQ Total (n=29) | 22.83 | 8.30 | 30.97 | 13.54 | -4.15* |
| Drug SE(Q7) (n=29) | 1.79 | 1.08 | 2.34 | 2.09 | -1.66 |
| | Time 1 | | Time 4 | | |
| PSEQ Total (n=24) | 23.42 | 8.86 | 26.04 | 12.55 | -1.34 |
| Drug SE(Q7) (n=24) | 1.92 | 1.10 | 2.04 | 1.99 | -0.35 |
| | Time 2 | | Time 3 | | |
| PSEQ Total (n=28) | 31.43 | 12.24 | 31.64 | 13.28 | -0.16 |
| Drug SE(Q7) (n=29) | 2.64 | 1.93 | 2.34 | 2.09 | 1.01 |
| | Time 2 | | Time 4 | | |
| PSEQ Total (n=23) | 32.17 | 13.18 | 26.61 | 12.52 | 2.64 |
| Drug SE(Q7) (n=24) | 2.77 | 2.00 | 2.04 | 1.99 | 1.87 |
| | Time 3 | | Time 4 | | |
| PSEQ Total (n=24) | 30.88 | 13.69 | 26.04 | 12.55 | 2.48 |
| Drug SE(Q7) (n=24) | 2.54 | 2.06 | 2.04 | 1.99 | 1.66 |

* significant beyond the 0.008 level set using the Bonferroni method

indicate inequality of variance across repeated measures no modifications were required.

(i) Pain Self-Efficacy Scores

On analysing the Total PSEQ scores a significant effect of Time was revealed ie. the time when SE was measured affected the Total PSEQ scores obtained ($F=8.183$; 3,66df; $p<0.001$). To find out where the differences lie paired sample t-tests using the Bonferroni method were carried out (see Table 3.15). These showed SE scores at Time 4 (26.0) to be similar to Time 1 (22.8) and Time 2 (31.4). However, there was a significant difference between Time 1 and Time 2 ($t = -4.47$, $df = 27$, $p<0.008$, 2 tailed). Differences between Time 1 and Time 4 did not approach significance ($p=0.194$) whereas comparison between Time 2 and Time 4 ($p=0.015$) was closer to significance but failed to reach the requirement for the Bonferroni method involving six comparisons of showing significance beyond the 0.008 level. Although the differences were not significant, inspection of the means (see Table 3.14) indicates that SE scores fell over the18 month follow-up period but Time 4 SE remained slightly superior to Time 1 SE.

(ii) Drug Self-Efficacy Scores

There was no effect of Time on analysing the DSE (Q7) data, ie. the time when SE was measured did not affect the DSE scores obtained ($F=2.598$; 3,69df; ns). Although there were no significant differences between the means, these illustrate the predicted trend with a gradual return over follow-up to close to, but not reaching, pre-treatment levels.

### 3.7.2. DRUG INTAKE SCORES

Relapse behaviour will be described as in 3.6.2 for the 19 participants who made a reduction during the programme and for whom follow-up data is available.

The 18 month drug intake data will be discussed more extensively than at one month. Firstly, relapse is defined in terms of any increase in drug intake between the end of treatment and 18 month follow-up. This led to 11 subjects being classed as relapsers, five as reducers and one as a maintainer of partial reduction. The two participants who had reduced to zero during the group were again maintainers of abstinence.

Relapse is also investigated here by comparing 18 month follow-up with pre-treatment levels. This produced four relapsers, 13 reducers and two maintainers who were taking the same amount of medication at 18 months as at the start of the programme.

Of the seven participants who did not make a reduction during the programme, four returned information at 18 month follow-up. Three of these four were taking more medication in comparison to pre-treatment levels and one was taking the same amount of medication as at the start of the programme.

### 3.7.3. RELATIONSHIP BETWEEN RELAPSE AND NONADHERENCE

A further test of the hypothesis that those who were nonadherers during the group would be more likely to relapse than the adherers was carried out. The subjects for whom relapse was pertinent had been split into noncompliers and compliers in 3.6.3. Compliers and noncompliers were then categorized as relapsers or non-relapsers by comparing their drug intake at 18 months to their drug intake at (i) the end of the programme and (ii) the start of the programme (see Table 3.16). As before, Chi-squared Tests would be invalid and two Fisher Exact Tests were performed. Both tests failed to reach significance: $p>0.34$ and $p>0.16$ with relapse being calculated by method (i) and (ii) respectively. Therefore, as with the one month data, compliance and relapse scores were found to be independent.

**Table 3.16: Compliance during group by maintenance during 18 month follow-up (n=19)**

| | Compliers | Noncompliers |
|---|---|---|
| TIME 4 - 2: | | |
| Relapsers | 8 | 3 |
| Non-relapsers | 7 | 1 |
| | | |
| TIME 4 -1: | | |
| Relapsers | 2 | 2 |
| Non-relapsers | 13 | 2 |

**Table 3.17: Spearman's rho correlation coefficients between Self-Efficacy and maintenance - 1 tailed sig. (n=19)**

| | TIME 1 | | TIME 2 | |
|---|---|---|---|---|
| | Total PSEQ | Drug SE (Q7) | Total PSEQ | Drug SE (Q7) |
| Maintenance: | | | | |
| Time 4 - 2 | 0.22 | 0.45* | 0.42* | 0.41* |
| | | | | |
| Maintenance: | | | | |
| Time 4 - 1 | 0.30 | 0.15 | 0.60** | 0.68** |

### 3.7.4. RELATIONSHIP BETWEEN RELAPSE AND SELF-EFFICACY

The hypothesis that self-efficacy expectancies can usefully predict maintenance with post-treatment SE being a better predictor than pre-treatment SE was tested further using the 18 month follow-up data. Initially, a maintenance variable was calculated using two methods: relapsers and nonrelapsers were coded with relapse being (i) any increase in drug intake between post-treatment and 18 month follow-up and (ii) any increase between pre-treatment and 18 months. The two maintenance variables were then correlated with pre and post treatment SE scores (see Table 3.17). This supports, once again, the hypothesis that post-treatment SE is a useful predictor of maintenance, with SE being more strongly correlated with maintenance when calculated by method (ii) ($r = 0.60$, $p<0.01$, 1 tailed). PSEQ and DSE appear to be equally useful measures post-treatment. However, the use of pre-treatment SE to predict maintenance is no longer supported.

## 3.8. QUALITATIVE DATA

Participants tended to fall into four categories. Those who complied with their drug reduction plans and reduced successfully over the course of the programme did so by two methods: (i) systematic and gradual reduction (ii) sudden and complete cessation. The majority reduced using method (i). Noncompliant participants either (iii) reduced successfully (therefore by haphazard means) or (iv) failed to reduce. A small number of participants were able to comply with their plans and reduce little due to reduction plans being self-paced and flexible. This point is explained further in 4.3.2.(B).

### 3.8.1. ILLUSTRATIVE EXAMPLE - METHOD (i)

John was a 51 year old man who worked part-time in a legal office. He had suffered neck pain for three years. At the start of the programme he was taking 50mg of

Froben, 500mg of Carbamazepine, 100mg of Imipramine and two Co-proxamol (see Appendix J) tablets daily. He was 100 per cent compliant with his plans which involved weekly step-by-step reductions. Firstly, he stopped his Froben which he believed was not helping his pain. He then reduced from two to one to zero Co-proxamol tablets. Next he reduced his Carbamazepine by 100mg a week. At the end of the programme he had reduced to 100mg of Carbamazepine and 100mg of Imipramine. At one month follow-up he was taking only 50mg of Imipramine. Eighteen months later he had stopped his Imipramine but was taking, on average, two Co-proxamol tablets every other day which he put down to increased working hours.

### 3.8.2. ILLUSTRATIVE EXAMPLE - METHOD (ii)

Jean was a 36 year old social care nightshift worker who had suffered back pain for 17 years. Pre-treatment she was taking between four and eight Co-dydramol tablets a day depending on whether she was working or not. She decided to stop taking her drugs "cold turkey". During the first week of this plan she took two Co-dydramol tablets on the four nights she was working and for the remaining six weeks of the course she took no pain-related drugs. This produced a compliance score of 92 per cent (ie. she was compliant with her plan on 92 per cent of days). At 1 and 18 months follow-up she remained medication-free.

### 3.8.3. ILLUSTRATIVE EXAMPLE - METHOD (iii)

Brian, a 49 year old man who was medically retired, had experienced back pain for 30 years. He made the largest reduction in his medication over the course of the programme. He did so in a haphazard fashion, adhering to his reduction plan on only 42 per cent of 'non-flare-up' days. Interestingly, he suffered a flare-up of his pain on more days than any other participant, probably because he also adhered poorly to

principles of pacing. Obtaining an estimate of Brian's initial intake was difficult as he reported taking "handfuls" of pills. Detailed questioning produced an estimate of 1900mg of Zydol (for which the recommended maximum daily dose is 400mg) and 3500mg of Paracetamol daily. We suspected this man was also consuming some alcohol. Post-treatment Brian had stopped his Paracetamol and was taking 600mg of Zydol daily. At one month follow-up he had increased his intake by less than one Zydol and one Paracetamol tablet a day. However, 18 months later he was off Zydol and Paracetamol and had started on four new medications: 800mg Sulindac daily (twice the recommended maximum daily dose), 180mg of Dihydrocodeine, 50mg of Imipramine and 150mg of Voltarol daily! It would have been interesting to know how much of this change had been instigated by his GP/Consultant and if they were aware of his daily consumption. Unfortunately, Brian had to be excluded from the analysis of TPB data due to inadequate questionnaire completion (see 3.1.2).

### 3.8.4. ILLUSTRATIVE EXAMPLE - METHOD (iv)

Janet was a 42 year old housewife who had suffered rheumatic pain in multiple joints for ten years. On an average day at the start of the programme she was taking 1500mg of Paracetamol, 90mg of Codeine and 10mg of Amitriptyline with much day to day variation. She decided to reduce her Amitriptyline initially and cut down to 5mg for two days before returning to 10mgs. Early in the programme her Paracetamol and Codeine were swapped for Co-proxamol by her GP. Although the programme's Charge Nurse called this a "sideways move" in terms of amount of analgesic, being on one rather than two tablets should have made establishing a pattern easier. That was her next plan - to take a regular amount of Co-proxamol each day. This was never achieved and she continued to take between zero and eight tablets a day (with an average of six a day at the end of the programme). She was judged to have adhered to her plan on 35 per cent of days. It should be noted that

Janet travelled a round trip of 150 miles to attend the programme. Her average daily intake at one month follow-up was 10mg of Amitriptyline and 4.5 Co-proxamol tablets and she had started on 4mg of Diazepam daily. Eighteen months later her Amitriptyline was unchanged and her Co-proxamol had been switched for Co-codamol of which she was taking five a day (still variable). Diazepam had been discontinued. Thus she had no greater success in applying the principles of drug reduction when travelling was no longer an issue.

# 4. DISCUSSION

## 4.1. COMMENTS AND CRITICISMS OF METHODOLOGY

### 4.1.1. SAMPLE

It is important to note how far the present sample was representative of chronic pain management patients who take drugs for their pain. The INPUT programme, used for comparison purposes, is the largest UK programme to collect background measures which are similar to the AAH. It should be noted that this is an inpatient programme although selection criteria are similar to the AAH programme. It should also be noted that the INPUT population includes all patients who completed treatment regardless of medication use. The age, duration of pain and depression and self-efficacy scores of the current sample appear to be reasonably representative of chronic pain management patients but the sex ratio is less so. It is possible that the present sample is more representative of pain management patients who use medication. However generalisation from the present sample requires caution as this small sample may include more females and it is not possible to conclude how representative it is in terms of self-reported dysfunction. Comparison of participants opting in and out of drug reduction in the current study would have been useful but was not carried out due to the small number opting out.

### 4.1.2. TPB QUESTIONNAIRE: HOW VALID IS THIS NEWLY DEVISED MEASURE?

Reliability analysis provided weak support for the belief-based measure of attitude and the perceived barriers scores. However reliability analysis was not conducted on the other variable totals due to them being comprised of three items or less. The inter-variable correlations provided some support for the questionnaire. The direct measure of PBC seems to be of little predictive value and had no significant

associations with other measures in the model. The perceived control part of the score was measured by two items of which one did not adequately differentiate the participants. The SE part of the score was measured using Q7 of the PSEQ. This assessed confidence in ability to cope without medication rather than ability to reduce medication. Using an item such as "For me to reduce my drugs will be easy - difficult" would have been more in line with previous studies. Unfortunately it was not possible to extensively validate the questionnaire due to lack of time and availability of existing materials. Test-retest reliability analyses were not carried out. Whilst these results provide some initial optimism, much caution is required in interpreting results. Handling of the PBC variable, in particular, requires care. Future research would be strengthened if this measure included more items.

Ajzen (1991) suggested that assessment of perceived barriers should cover the presence or absence of resources and opportunities, together with obstacles and impediments to performance of the behaviour and be weighted by their perceived power to facilitate or inhibit performance. Many of the research papers referred to by the author when the questionnaire was being designed (eg. Norman & Smith, 1995; Winkelstein & Feldman, 1993) assessed perceived barriers using only one of these two steps. The present subjects were provided with a set of perceived barriers (eg. sleeping badly) which they interpreted in one of two ways: "If I am sleeping badly would that prevent me reducing my drugs?" or "Do I or do I not sleep badly?" Hopefully, despite this inconsistency, both interpretations provide useful information about the extent the factor is perceived to be a barrier.

There were some general ways in which the questionnaire and its administration could be improved. A few questions used long words (eg. "outweigh" in Q9) or double negatives (Q7) and would benefit from simplification. The wording used in one or two of the items could be tightened, eg. the addition of "unwanted" side-effects to Q10 would be helpful. It was necessary when devising the questionnaire to

achieve a balance between item inclusiveness and length so as not to overburden the subjects. Nevertheless, concentration problems, as a result of pain, medication or fatigue, may have affected questionnaire responses. Due to a lack of free time during the groups patients were sometimes completing the questionnaires in haste. Thus, allowing completion at home may have been the preferable option although this had been decided against initially due to anticipated problems of non-return.

### 4.1.3. MEASUREMENT OF ADHERENCE: HOW VALID ARE THE METHODS EMPLOYED?

Measurement of compliance turned out to be a complex process. Comments on the strategies employed are contained in Appendix E. Unfortunately the use of other non-prescribed substances (eg. alcohol, cannabis) to control pain was not measured. However, the one participant who was known to abuse alcohol was omitted from the main analysis due to inadequate questionnaire completion.

Given the points raised in the introduction, the compliance scores are surprisingly high suggesting that the drug reduction plans were realistic and appropriate. Compliance may be increased as a result of the self-monitoring procedure. In contrast drug reduction scores were generally quite low with some subjects failing to reduce and even increasing their medication intake. There were three subjects who came off their drugs completely during the programme. They all chose to stop "cold turkey" as opposed to gradual reduction.

Measurement of compliance can be criticised for relying solely on self-report which may be biased by such factors as memory and social desirability, as discussed earlier. Again adherence figures from existing studies are not available to assist validation. Overall reports of compliance are quite high in the present study, compared to other demanding regimes, possibly providing grounds for suspicion.

Nevertheless, there are reasons to have confidence in the self-report data. Firstly, as the main purpose of recording was for use in negotiation of drug reduction plans, dishonesty would result in future plans being meaningless and even less achievable. Furthermore, weekly discussions with the nurse about the plans allowed for verification. A "no fault approach" was taken with it being acknowledged that participants might take more than the agreed dosage at times. There was no evidence of subjects having difficulty understanding the recording form or attending with their weekly records incomplete. Self-report was likely to be less accurate with the one or two subjects on a large number of pills. For example, the participant on seven prescribed medications found the recording sheet too small and a larger format would be useful for such subjects in the future. Also, recording of intake initially and at follow-up may be more questionable when verification was not possible. Finally, it was a concern initially that participants would report being in flare-up for much of the time. However, as no participant claimed to be in flare-up for more than 40 per cent of the time, it was assumed that participants were being appropriate in their flare-up reporting.

The moderate correlation (obtained on removing the atypical subject) between the measures of drug reduction and compliance was expected. It was possible for subjects to comply and reduce little as the speed of reduction was self-paced and flexible. It was also feasible for participants to reduce effectively whilst paying little attention to their plans (see 3.6.5.- Brian). Thus inferring compliance from clinical outcome, as is generally done in pain management studies, may be a fairly inaccurate procedure.

## 4.2. COMPARISON OF SUBJECTS OPTING IN AND OUT OF DRUG REDUCTION

The small numbers who opted out of drug reduction prevent any firm conclusions being drawn. It is disappointing that the ability of the TPB to predict opting in and out of drug reduction could not have been examined using regression analysis, as looking at the means of these two groups show that all differences are in the expected direction, ie. those opting in expressed more favourable attitudes towards drug reduction. It was expected that this group would be very much against reduction given that they opted out despite a strong recommendation to reduce. The subjective norm difference is especially marked suggesting that those opting out of drug reduction might be particularly encouraged to do so by perceiving drug reduction to be against the wishes of their families and doctors. Unfortunately attendance at the family sessions tends to be low and therefore changing the views of family members is likely to be difficult. Surprisingly, intention to reduce is reasonably high in the group opting out who shortly after completing the questionnaire refused to participate in a drug reduction plan. However, as the question measuring intention did not specify a time span it is possible that these people did hope to reduce eventually without intending to do so immediately. Unexpectedly, two or three members of this group did go on to reduce a small amount of medication without reporting this to the group until discharge. Therefore they may have intended to reduce but, possibly due to an expectation of failure or a fear of pressure, wanted to work independently.

Conclusions regarding the increase in perceived barriers and self-efficacy variables over the course of the group in the subjects opting out are confounded by the two or three patients who went on to reduce independently. If this had not occurred the 'opt out' group could have served as a 'control group' who had attended the programme but had no experience of reducing their drugs.

## 4.3. ACCOUNTING FOR THE VARIANCE IN ADHERENCE AND DRUG REDUCTION

### 4.3.1. DEMOGRAPHIC AND BACKGROUND VARIABLES

The lack of a moderate correlation between the demographic variables and compliance/drug reduction is consistent with the literature but a stronger association with number of drugs was expected. This correlation may be weaker than anticipated since subjects were advised to target one drug at a time whilst keeping the rest of their medication stable. A moderate association was observed between perception of support received for drug reduction and amount of drugs reduced. There are at least two explanations for this correlation. Firstly, some patients received more attention and not surprisingly their reduction scores were higher. This seems unlikely since, if anything, those reducing well tended to receive less attention. Perhaps, more likely, people's perception of support relates to their satisfaction with the drug reduction component of the course. This is likely to be higher if the subject reduced successfully. If so the correlation would represent an effect and not a cause of drug reduction.

### 4.3.2. TPB VARIABLES

(A) Accounting for the Variance in Intention

Partial support was obtained for this part of the model with the measures of attitude and subjective norm making significant contributions to the prediction of intention (see Fig. 3.2, page 50). Therefore, as expected, favourable attitudes to reduction and approval of reduction from significant others relate to positive intentions to reduce. The amount of perceived control over drug reduction and the number of perceived barriers was not found to influence intention to reduce. Therefore, in effect support has been obtained for the Theory of Reasoned Action and not the TPB. The lack of

support for PBC could be due to inadequate measurement in the current study (see 4.1.2) and is discussed in more detail in 3.2.3.

(B) Accounting for the Variance in Adherence

No support was obtained for the model in this case, with these variables failing to predict adherence. One explanation for this failure is that the newly designed questionnaire measured attitudes towards drug reduction and not attitudes towards adherence with drug reduction plans. The reason for this was to facilitate ease of completion. Obviously it is simpler for people to rate, for example, "If I reduce my drugs my self-confidence will improve" compared to "If I stick to my drug reduction plans, my self-confidence will improve". It is very unlikely that entirely different sets of attitudes would predict drug reduction and adherence but possible for people to intend to reduce without intending to go about it in the style recommended by the programme. There appeared to be a few subjects who felt that aspects of the method of reduction (eg. time-controlled intake, reducing one drug at a time) were not appropriate for them.

However a stronger reason for the theory's lack of success may be that the patient-controlled nature of drug reduction has become confounded with adherence. Since patients held an element of control over how quickly they worked through their plans, it was possible for subjects (perhaps with less positive attitudes about drug reduction) to move through their plans more slowly whilst remaining compliant. In fact it may even have been easier for these patients to be compliant if their reduction plans were less demanding and involved fewer changes. A few subjects were noted to have high compliance scores whilst reducing little. Thus the TPB should be better able to explain the speed of progress through plans or actual drug reduction as opposed to compliance.

(C) Accounting for the Variance in Drug Reduction

Unusual results were obtained here, with the measure of attitude making a significant positive contribution to the prediction of drug reduction and the measure of intention making a significant negative contribution to this prediction (see Fig. 3.3, page 50). Therefore, as expected, favourable attitudes to reduction and, surprisingly, negative intent to reduce relate to greater drug reduction. Subjective norms and perceived control were not found to influence drug reduction.

Firstly, to explore the unusual result of negative intention, drug reduction and intention were plotted as in Appendix K. This failed to show a direct negative relationship between the two variables but obviously does not shed light on what happens to intention when the other TPB variables are present. Suppressor variables are sometimes discussed when attempting to explain seemingly unreasonable variables. It may be that intention is acting here as a suppressor variable which enhances the importance of other variables by suppressing irrelevant variance in other independent variables or the dependent variable.

It should be noted that the measure of intention was based on one item (I am going to reduce my drugs) which despite providing a good overall range of responses (two to seven), the vast majority (26 of the 28) fell between four and seven. The majority of studies referred to used two or three items to assess intention and use of, for example, "I intend to reduce my drugs" and/or "I will try to reduce my drugs" at different points in the questionnaire may have been preferable.

Another possibility for the lack of a positive association between drug reduction and intention is that general traits such as confidence and optimism were influencing how people responded to the intention question. There was a feeling that those who had low intent but went on to reduce were cautious about their chance of success. They may have scored more highly if the intention question had been rephrased as "I am going to try to reduce my drugs". In contrast, those who had a high intent but

reduced little may have had a rather unrealistic, overconfident approach, believing that reduction would be easy. In fact, these styles may have reflected whether people approached reduction methodically or haphazardly possibly influencing their success on reduction. However, if this is the case, it is not clear why these traits have contributed to this behaviour but not to others studied.

A further reason to explain why people with strong intentions to reduce may not have done so is that the item did not specify a time span. The item may have been more useful in predicting drug reduction if it had included a time frame, ie. "I am going to reduce my drugs during the programme". Many chronic pain patients may believe that one day their pain or their management of it will improve and therefore they may have a positive long term intention to reduce with little immediate motivation. Bagozzi & Kimmel (1995) observed that a gap in time exists between the decision to act and the opportunity for action. Time gaps were present in this study between completing the questionnaire and meeting the nurse to specify a plan and actually carrying out a reduction step. In some cases this process was quite lengthy if patients initially worked towards time-controlled intake. Thus once activated the intention is likely to undergo further processing and elaboration, eg. planning, monitoring. Therefore models that deal with process and appraisal, eg. The Self Regulation Model (Leventhal & Nerenz,1985), Transtheoretical Model of Change (Prochaska & DiClemente, 1982) may be better able to explain the negative effect of intention.

A lack of support was obtained for subjective norms which is in keeping with much of the literature. Subjective norms failed to significantly predict behaviours in 10 of 19 investigations summarized by Ajzen (1991). Ajzen (1988) is able to deal with these inconsistent results by stating that the contribution of attitudes and subjective norms will vary from situation to situation. Terry & O'Leary (1995) suggest that even though people may perceive that others would wish them to reduce in this case, the fact that failing to do so is unlikely to have immediate detrimental effects may

mean that they are not particularly motivated to comply with this social pressure. Informal comments made by some patients in the present study indicated that they felt quite strongly that the views of others were not important to them, eg. "it's not up to them, it's up to me", "they don't know how much I take". Possibly because of the nature of suffering pain and the strong desire for relief, the approval or disapproval of others is less important here than with some behaviours. Furthermore, drug intake may be one area where the patients feel they can retain some independence.

Perception of fewer barriers to drug reduction was related to greater drug reduction prior to the entry of attitudes and subjective norms into the analysis. However, when these variables were entered, they (effectively attitudes) explained all of the variance that the perceived barriers variable had been explaining. On devising the questionnaire I had been aware that many concepts could have been expressed as a barrier (eg. Not being able to do as much) and/or a belief-based attitude (eg. If I reduce my drugs, I will not be able to do as much). This may illustrate poor interpretation of the theory on my part but provides an explanation for the shared variance. It is not possible to comment on whether a causal relationship exists between perceived barriers and attitudes.

The lack of support for the PBC measures is difficult to interpret as the method of measuring PBC may have been poor in the present study. This result is in keeping with the Theory of Reasoned Action and not the TPB. The former was intended for application of behaviours under voluntary control but drug reduction is a domain in which voluntary control was anticipated to be incomplete. Even if its execution is not dependent on other people, it is conceivable that the person will lack the alternative coping skills required to perform the behaviour.

The PBC - behaviour link in the model is hypothesized to represent actual control. De Vries, Dijkstra & Kuhlman (1988) argued that the correspondence between actual and perceived control could be low if individuals are not familiar with the task

or when behaviour is complex and dependent on several variables. Many of the subjects may not have tried to reduce in the past, and the second explanation referred to may also be true, given the importance of developing alternative coping strategies and the presumed contribution of pharmacological and biological factors.
Finally, Terry & O'Leary (1995) criticized Ajzen for confounding variables by combining the notions of perceived control and self-efficacy into the concept of perceived behavioural control. They found evidence for incorporating the concepts of perceived behavioural control and self-efficacy as two separate variables in the model and reported that the effects of the two components on intentions and actual behaviour differed. These interesting results require replication. Previous evidence in support of a PBC effect may have been due to previous measures primarily assessing efficacy expectancies (Terry & O'Leary, 1995). Therefore SE alone may have been influential here but was being masked by the use of a combined variable.

A final possible reason for the overall weak and variable support for the TPB is that other variables, not included in the theory, may be of greater importance in accounting for compliance and drug reduction. Some feelings were gleaned from the subjects about which other cognitive and noncognitive variables might be influential. In keeping with Leventhal & Nerenz's (1985) Self-Regulation Model, there was some suggestion that patients' own "common sense" notions about their pain and medication were interfering with drug reduction planning and compliance. For example, two or three subjects resisted taking their medication on a time-controlled basis believing that to do so would not suit their particular condition. Effects of prior experience, which Bagozzi & Kimmel (1995) claim contribute over and above the TPB, seem likely to be important. Subjects' comments indicated that these experiences served as reference points for them, sometimes influencing the way plans were drawn up. For instance, one patient wanted to reduce two drugs in

tandem which she knew from past experience only worked if taken together. Prior experiences appear to have been variable with some patients having reduced successfully on their own and others encountering difficulties such as withdrawal symptoms.

Other noncognitive variables could also be important. On looking at some of the reasons provided for nonadherence, Ley's (1982) comprehension and memory variables were mentioned. Occasionally a subject admitted to forgetting to follow a medication instruction. Failures in communication were observed between staff and patients in both directions. Once or twice, due to time pressures on staff, plans were not specified as clearly as possible. On speaking to a patient's spouse it transpired that the patient had reasons for believing that the plan he negotiated was not appropriate for him but he failed to articulate this effectively to the nurse. Finally some miscellaneous reasons were provided for nonadherence. These included taking less tablets to compensate for taking additional medication for another ailment or because a couple of glasses of wine had been consumed.

### 4.3.3. SELF-EFFICACY VARIABLES

Scores on the PSEQ suggest drug reduction is an area where people are particularly lacking in confidence and this is not strongly related to their full PSEQ score. These findings are consistent with Nicholas' (1994) validation report on the PSEQ.

Terry & O'Leary's (1995) adaptation of the TPB predicts separate effects of PBC and SE with SE having an effect on intention with no direct effect on behaviour. Some support was obtained for this model. The correlation of 0.30 between Drug Self-efficacy (DSE) and intention is higher than that of 0.19 between PBC and intention suggesting that SE could be more influential on intention but is being masked by PBC. Furthermore, DSE was weakly associated with intention but not behaviour. However, the correlations involving DSE were weak and, like PBC, may not have

been significant if tested as part of the model with the present sample. Research involving a larger number of subjects would allow testing of Terry & O'Leary's model.

The significant contribution of PSEQ to compliance and drug reduction provides some support for the Self-Efficacy Theory and is in line with pain management studies which suggest that self-efficacy expectancies may be useful predictors of treatment outcome (Dolce et al., 1986a, Kores et al., 1990). It is interesting that this general pain measure has one of the highest simple correlations with drug reduction obtained in this study. This is likely to be because high PSEQ scores should reflect greater confidence in developing the alternative coping strategies required if drug reduction is to be successful. This also explains why DSE is a better predictor of intention (which does not require action) but behaviour, which is hypothesized to require skills in addition to intention, is better predicted by PSEQ.

#### 4.3.4. DECISIONAL BALANCE VARIABLE

The lack of association between the decisional balance type question and compliance/drug reduction is perhaps not surprising since it asks nothing about the person's confidence or ability to reduce. Furthermore, little detailed information is obtained as patients score zero or one and we do not gain information on whether the decision was a difficult or clear-cut one. Finally, several people were observed to have difficulty understanding the rather wordy question.

## 4.4. CHANGE DURING PROGRAMME

### 4.4.1. TPB VARIABLES

Interpretation of change in TPB variables is especially difficult given the lack of test-retest reliability data for the new questionnaire. The following discussion is therefore preliminary.

Disappointingly, the experience of attending the programme and working on a drug reduction plan failed to bring about a change in attitudes. This may reflect the rather small amounts of drugs reduced, if at all, resulting in few experiences of success. It is possible that the attitudes of people who succeeded in reducing have become more positive towards drug reduction whilst the attitudes of those who have experienced failure have become more negative. If so, the two changes could have cancelled each other out. However, if this were the case one would expect to see an increase in the range of scores obtained but this was not apparent.

A more likely explanation is that expectations of change may have been somewhat unrealistic given the limited time spent on directly challenging attitudes during the programme. The lack of change could, in fact, be viewed as providing support for the model. As the model predicts that people with positive attitudes will succeed in drug reduction and vice versa, then those experiencing success should be the ones whose attitudes were initially favourable.

Initial perception of barriers was found to be significantly higher than reports of actual occurrence of barriers at discharge. Individualized item analysis demonstrated that this difference was present for eight items and that four items had been perceived accurately, with the initial anticipated barriers being rated similarly to the actual occurring barriers.

The eight items could represent an inaccurate initial perception of how likely potential barriers are in preventing drug reduction or they could have been anticipated correctly but attending the programme /working on a drug reduction plan altered how much these items prevented reduction. This possibility is supported by looking at which barriers were scored differently at Time 2. The eight items were all things which the programme would hope to influence with the possible exception of suffering a new pain or injury (which is quite likely not to have occurred over the short time span of the group.) In contrast three of the four non-changing items are

barriers which the programme has little control over, ie. family pressure, other medical professions and withdrawal symptoms. However improvement on the barrier "sleeping badly" would have been hoped for.

Further examination of the mean scores illustrates that suffering a pain flare-up and sleeping badly were rated as the most likely to have prevented drug reduction. It seems the group may be of some use in reducing flare-ups but is not improving sleep difficulties. Being pressurized by families was rated as one of the least likely factors to have prevented drug reduction which is fortunate given the difficulties encountered in trying to alter the behaviour of families.

It may have been more interesting to have readministered the same question to assess whether there had been a change in the perception of barriers. Given the results of the regression analyses it may be less important to try to change perceived barriers than attitudes. However, given the strong simple correlation between perceived barriers and drug reduction and the possible influence of barriers on attitudes, it seems worthwhile to try to effect a change and encouraging that one has occurred.

### 4.4.2. SELF-EFFICACY VARIABLES

As hypothesized there were significant increases in DSE and PSEQ over the course of the group and working on a drug reduction plan. This will be of interest to the AAH PMP staff when considering how best to demonstrate group effectiveness to their funders. These results are consistent with other studies (eg. Dolce et al., 1986a; Kores et al., 1990) which reported significant increases in self-efficacy following pain management input. However, the increases are not as impressive as those achieved by the INPUT sample (Williams et al., 1993). They report a change in mean PSEQ score of 16.6 over the course of their inpatient programme compared to a mean increase of 8.4 at the AAH PMP. Change on the DSE item was relatively small with the mean score failing to reach the midpoint of three (meaning neither

confident or unconfident about coping with pain without medication). This may be suggestive of a rather weak intervention.

Change in PSEQ was not found to correlate with drug reduction suggesting that the increases in self-efficacy had more to do with such factors as receiving general pain management input, success or failure on other course regimens and nonspecific treatment effects than success or failure on drug reduction. It was more surprising that change in DSE was not more closely related to drug reduction. However, this too may reflect the increase in alternative coping strategies (eg. relaxation, pacing) available following group attendance.

### 4.4.3. DRUG INTAKE SCORES

Studies of pain management programmes have used different criteria for success making comparison of results difficult. Medication behaviour is frequently described in terms of "numbers remaining medication free". To use this stringent description here would indicate little success. In contrast, the more liberal criterion (eg. any reduction) shows that around three-quarters of participants made a positive, albeit small, change. The extent of this change is less favourable than in many of the published studies. For example, Dolce et al. (1986a) reported 97 per cent of their subjects becoming medication free over the course of the programme compared to just ten per cent in this study. Some of this variation may reflect differences between inpatient and outpatient treatment and Patient-Controlled Reduction and Staff-Controlled Reduction. Also, the mean duration of pain, and therefore likely duration of drug use, in this study is longer than in many other studies. The mean duration of pain in the Dolce study was 3.2 years compared to 12.5 years in the present study.

## 4.5. MAINTENANCE OF CHANGE: ONE MONTH FOLLOW-UP

It is necessary to first of all define "relapse" before discussing it more fully in this section of the study. Strictly, relapse could be considered to be any increase in drug use (after planning a period of reduction) or, more conventionally, it could be defined as a return (in the follow-up period) to pre-treatment levels of morbidity (Saunders & Allsop, 1987). Both definitions have weaknesses according to Saunders & Allsop. The former fails to acknowledge any notion of gradation in the severity or duration of the relapse and the latter involves the end point of a process and does not consider those moving towards that point. Turk & Rudy (1991), therefore, advise comparing post-treatment with follow-up with the pre-treatment data as an anchor. The one month data will be analysed here using the former approach, ie. relapse being any increase in drug intake between the end of treatment and one month follow-up. However, the more useful 18 month data will be analysed more extensively following Turk & Rudy's (1991) advice. Firstly, relapse will be discussed in terms of any increase in drug intake between the end of treatment and 18 month follow-up. It will then be investigated by comparing 18 month follow-up with pre-treatment levels.

Follow-up studies require to be interpreted with caution as they are based on only the percentage of the sample who are available and willing to participate in follow-up assessment. Results can vary depending on how studies deal with those who do not respond. Turk & Rudy (1991) differentiate between a "best case" strategy (where relapse rates are completed using available cases only with those not available being discarded) and the more cautious "worst case" strategy (were all nonresponders are counted as failures). They argue that the "truth" is likely to lie somewhere in between the conclusions based on these two approaches. The "best case" strategy appears to be the most commonly used method in evaluating pain management programmes and was employed in this study. This allows comparison with other

pain management studies but may underestimate the extent of relapse, as those who did not comply with follow-up requests may be more likely to have been noncompliant with treatment and fallen into the relapse category. However, this is a minimal problem here as relapse rates were obtained from a 100 per cent return rate at 1 month and from 79 per cent of subjects at 18 months. This compares very favourably with other chronic pain treatment follow-up studies in which the percentage of patients included ranged from 12 - 70 per cent (Turk & Rudy, 1991). This is likely to be due to the present researcher pursuing the participants, with whom she was acquainted, by telephone. Furthermore, three of the six excluded subjects at 18 months did respond to the follow-up request but their case was ignored because of inaccurate record completion or life events (eg. illness, giving birth) resulting in atypical abstinence from drugs. Two of the remaining three had adhered poorly to their drug reduction plans during the programme.

Nicholas (1992) highlights the danger that follow-up results in a given patient may simply reflect the natural fluctuations in this chronic condition rather than the effects of treatment. As is often the case in follow-up studies, individuals were targeted at fixed points in time (ie. 1 month and 18 months) and it is not possible to judge the representativeness of these weeks for each individual. It is hoped, however, that those experiencing atypically good or bad weeks (in terms of drugs consumed) would even out across the sample. Interviewing would allow more detailed process information to be gathered such as whether a relapser had increased his or her drugs steadily or attempted further reduction but encountered problems. Finally, as with earlier stages of the study, the follow-up assessment relies on self-report and is therefore subject to the concerns discussed in 1.3.2. and 4.1.3. Self-report may be more questionable at follow-up when the participants are no longer attending the PMP, which had allowed for some verification of self-report through discussion with

the nurse. Alternatively, it could be argued that this would reduce pressure for social desirability and facilitate honesty.

### 4.5.1. SELF-EFFICACY SCORES

No changes were observed in drug or pain self-efficacy between subjects being discharged from the group and one month follow-up. These results are consistent with other pain management studies (eg. Williams et al. (1993) noted improvements in mean SE scores were maintained at one and six months) and will also provide reassurance to the pain management team. However, a follow-up period of one month is extremely short and the results at 18 months are of greater interest.

### 4.5.2. DRUG INTAKE SCORES

Of the 76 per cent who progressed with drug reduction during the group, the largest subgroup (seven of the 19 - 37 per cent) did not change their level of drug intake over the follow-up period having made a partial reduction on the programme. One of this group had to deal with travelling and family stress in the month following the group.

A disturbing number (six of the 19 - 31.5 per cent) had relapsed to some extent (although one had managed to maintain much of a large reduction). This is in keeping with other pain management studies. For example, Dolce et al. (1986a) noted a relapse figure, in terms of numbers remaining medication free, of almost one third at 6 and 12 month follow-up. The fact that a similar relapse rate was obtained in this study after only one month could be viewed more negatively, ie. further relapse might be predicted. However, Williams et al. (1993) reported an initial relapse in opioid analgesics at one month but no further decrease at six months.

A subgroup of four subjects (21 per cent) reduced their intake over the month. This included people who had been reducing systematically during the course and had

been able to continue to implement a reduction plan by themselves and people who had reduced in a rather haphazard and independent fashion on the course and continued to do so successfully. The two participants (10.5 per cent) who had reduced their drugs entirely whilst on the programme both maintained this gain. Of interest, one participant who failed to make a reduction during the programme made a significant reduction during the one month follow-up period. The physical demands on this person had eased during the follow-up month as she no longer had to travel a long distance to attend the course and had given up her job.

### 4.5.3. RELATIONSHIP BETWEEN RELAPSE AND NONCOMPLIANCE

The results of the Fisher Exact Test suggest that noncompliers are no more likely to relapse than compliers. However, the number of non-compliers was small after those who had not made a reduction were removed. Interestingly, five of the seven participants who did not reduce their drugs were noncompliers. This fact and the moderate correlation reported in 3.2.3 suggests that compliance with plans is more closely related to drug reduction during the group than later relapse. In those that do make a reduction, complying with the PCR method of reduction which is implemented at the AAH PMP may not be any more effective in preventing relapse than haphazard reduction. Only preliminary conclusions can be drawn at this stage due to the shortness of the follow-up period and this area will be discussed in more detail with the 18 month data.

### 4.5.4. RELATIONSHIP BETWEEN RELAPSE AND SELF-EFFICACY

In keeping with previous pain management studies (eg. Dolce et al., 1986a; Kores et al., 1990) post treatment SE was found to be associated with maintenance in the current study.

Dolce et al. (1986b) had suggested that a subgroup of chronic pain patients exist who fail to display improvements in SE despite experiencing success and who are good candidates for relapse. In the current sample, of the five subjects who did not show SE increases despite experiencing some success, three relapsed. Little can be concluded from these small numbers and experiences of success or failure on the other programme regimens requires to be taken into account. However, this trend does not contradict Dolce et al.'s hypothesis.

## 4.6. EIGHTEEN MONTH FOLLOW-UP

### 4.6.1. SELF-EFFICACY SCORES

No change (ie. no relapse or further improvement) was observed in PSEQ scores over the 18 month follow-up period. However, an anomaly exists in the statistics that reduces optimism. Although PSEQ scores increased significantly between Time 1 and 2 and did not relapse thereafter, there is no difference in the PSEQ scores at pre-treatment and 18 month follow-up. Analysis of the drug SE scores now indicates no change over time. Thus there was no increase during the programme and no change in follow-up. This result goes against the finding of 3.5.2. where drug SE was shown to have increased during the programme.

Williams (1998) raised the distinction between statistical and clinical significance and highlighted the need to think of alternative ways of analysing data. The raw data is of interest clinically to the staff at the AAH. These show, despite lack of significance, some relapse in drug and pain SE between subjects being discharged from the group and 18 months later, in keeping with the relapse literature (see 1.1). Therefore, the optimism held at one month follow-up should not be maintained following a lengthier time interval. However, on comparing the SE scores at 18 months with pre-treatment SE, overall progress, albeit not statistically significant, has been made. Given the therapeutic importance of self-efficacy, this small

improvement may be of clinical significance in improving outcome. The concern is whether this improvement will continue to be eroded with time.

### 4.6.2. DRUG INTAKE SCORES

On initially investigating relapse by comparing drugs taken at 18 month follow-up with the end of the programme the data is not encouraging. The majority, 11 of the 19 subjects (58 per cent) had increased their drug intake over the 18 months. These results are typical of the chronic pain relapse literature (see 1.1). Keefe et al. (1986) suggested between 30 per cent and 70 per cent of patients attending chronic pain treatment programmes relapse over a one year to five year period. In the current study more people were found to have relapsed by this definition at 18 months (58 per cent) compared to one month (31.5 per cent). This increase in relapse over time supports the findings of Cinciripini and Floreen (1982), who found numbers remaining free of medication increased between 6 and 12 months, but is contradictory to the more optimistic results of Williams et al. (1993). They reported an initial relapse in opioid analgesics at one month but no further decrease at six months. Extrapolating from the current results would suggest further relapse over a longer time period.

One of the 19 subjects (5 per cent) was taking the same amount of drugs at 18 months as at the end of the programme with five of the 19 subjects (26 per cent) actually reducing their medication over the 18 months. Few of the patients had stopped taking medication completely during the programme (unlike in many of the comparison studies) but one quarter, as hoped, used the skills they had learnt on the programme to continue with their reductions. Impressively, the two achievers of abstinence during the programme (11 per cent) had maintained this abstinence at 18 months.

There is an expectation, from writing on relapse and chronic pain, that people will relapse to a certain extent following treatment. The key question is therefore whether this relapse is back to pre-treatment levels making redundant the time and cost expended. On comparing intake at 18 months with pre-treatment levels the data is more encouraging. Now only four of the 19 subjects (ie. 21 per cent) are categorized as relapsers. These four were taking more drugs at 18 month follow-up compared to pre-treatment.

Two of the 19 subjects (10.5 per cent) were taking the same quantity of drugs 18 months after treatment compared to pre-treatment. It would have been interesting to have compared these results with the chronic pain patients who did not chose to work on drug reduction plans. If there is a tendency to gradually increase drug intake over time, it may be that these two subjects would have increased their drug use without the input they received on drug reduction. This argument could even be extended to those who relapsed - the extent of relapse may be less as a result of attempted work on drug reduction. A study involving a control group is required to shed light on these speculations.

A healthier 13 out of 19 subjects (68.5 per cent) were taking less medication at 18 months compared to pre-treatment. Overall these patients appear to have benefited from the programme although it may be that some or all of them will relapse back to pre-treatment levels over a longer period. However, it could be argued that even if they do revert back to pre-treatment levels they will still have benefited from taking less toxic medication for a period of time although this work may not have been cost-effective to the NHS. In addition, they will possess the skills which may enable them to re-attempt reduction at a later date.

It might have been hoped that those who did not progress during the programme would find the period after treatment more conducive to reduction, eg. when the pressures of attending the hospital had been removed. The follow-up return rate at

18 months in this group (four out of seven - 57 per cent) was poorer than in the full sample (79 per cent). None of the four cases had success in maintaining a reduction post-treatment.

In summary, seven of the full sample of 29 (24 per cent) demonstrated a problem getting started with drug reduction. A further 11 (38 per cent) showed some problem with relapse (in five (17 per cent) relapse was partial and in six cases (21%) all of the treatment gain was eroded). Eight of the 29 (28%) made progress and did not relapse afterwards. Finally, three of the 29 (10%) made a reduction but were excluded from 18 month follow-up due to special factors or non-return (see 3.7).

### 4.6.3. RELATIONSHIP BETWEEN RELAPSE AND NONCOMPLIANCE

Regardless of the method for calculating relapse, the 18 month results are consistent with the conclusions drawn at one month, ie. noncompliers during the group are no more likely to relapse than compliers. These conclusions are now less tentative due to the reasonable length of follow-up period, however, numbers remain small, especially of those failing to comply. Also, if compliers and noncompliers were categorized by a different strategy, perhaps resulting in a greater number of noncompliers who had made a reduction, different conclusions may be reached. However, there is not another natural division in the compliance scores and it seems just as likely that relapse is related to a different set of factors than compliance. Therefore, compliance with the drug reduction plans advocated at the AAHPMP appears to be important in whether participants end up making or not making a reduction in their drugs after planning to do so. Relapse in drug intake, however, seems to be influenced by additional factors pertinent to the post-treatment stage of the process. For example, there may be a loss of positive verbal reinforcement from staff and group members and an increase in unhelpful responses from GPs and family members. Other factors beyond a person's control (eg. injury, illness,

negative life events) may also contribute to the part reversal in treatment gains. The question of who relapses and why (like the related work on prediction of adherence) remains unclarified.

### 4.6.4. RELATIONSHIP BETWEEN RELAPSE AND SELF-EFFICACY

As hypothesized, post self-efficacy expectancies were found to be associated with maintenance at 18 months, ie. there is further support for participants with higher PSEQ and DSE after the course being more likely to maintain reductions in their drug intake. Post-treatment self-efficacy was more closely associated with maintenance when pre-treatment levels of drug intake were used to judge relapse. This measure of maintenance incorporates more information about extent of relapse and takes account of progress during the group. At post-treatment, PSEQ and DSE are equally useful measures suggesting the quick, one item DSE score could be used fruitfully at Time 2. Thus a general confidence in being able to perform activity whilst in pain appears to be at least as important in maintaining drug reduction as specific confidence in being able to cope with pain without medication. These results emphasize the importance of finding methods during treatment to increase SE in chronic pain patients.

There was support for the superiority of post-treatment SE compared to pre-treatment SE as a predictor of maintenance. However, the current study failed to find support for the use of pre-treatment PSEQ. Drug self-efficacy may be of some use at this stage.

## 4.7. IMPLICATIONS FOR PRACTICE

Some suggestions of ways to improve the delivery of chronic pain management, and the drug reduction regimen in particular, can be made on the basis of this study. Adherence to drug reduction plans was associated with amount of drug reduction

illustrating the importance of improving adherence. Some poor compliers did not feel that paced reduction or time-controlled drug use was appropriate for them and repetition of the rationale (perhaps by the PMP doctor) may be useful in such cases. This study also identified a relationship between some cognitive variables and adherence and/or drug reduction. This information could be used to help select people at the start of treatment for work on drug reduction or, preferably, to target those requiring extra support to increase their chances of success.

Attitudes and perceived barriers appear to be the most important TPB variables to change to facilitate drug reduction. Unfortunately the AAH programme did not succeed in altering attitudes (at least between the end of the medication education session and the end of the programme). Further analysis to specify particular attitudes for targeting would be helpful. The PMP was successful in reducing the number of perceived barriers to drug reduction. However there is a suggestion that sleeping difficulties, one of the most likely barriers to prevent reduction, would benefit from more attention.

Current results suggest that pain self-efficacy is associated with adherence, drug reduction and maintenance in line with other studies. Consequently, one of the most important tasks for PMPs is to increase patients' confidence in their ability to use strategies to manage pain and to reduce their drugs. Bandura (1986) discusses methods for maximising SE. We are advised to focus on increasing patients' use of ignoring pain sensations and coping self-statements (Keefe at al., 1997) and encouraging attribution of this improvement to personal skills and abilities rather than external factors (Dolce et al., 1986b). Matching different interventions to different patients may be beneficial eg. intensive training in cognitive therapy techniques might be especially helpful for patients prone to catastrophizing (Keefe et al., 1997). Fortunately, measurement of SE is easy to perform. Re-assessing,

perhaps midway through and at the end of the group, would highlight subjects who could benefit from additional input.

A significant proportion (24 per cent) of participants failed to reduce their drugs at all after planning to do so, illustrating a problem other than relapse. It may be that this group were coerced into an action phase before they were ready. If so, more time spent discussing the advantages of reducing initially may be useful in increasing patients' motivation to work on drug reduction. Another 38 per cent of participants who did make a reduction require more work on relapse prevention to facilitate generalisation of treatment effects. Offering booster sessions is a strategy being considered. Post-group drug self-efficacy (a single item) would be useful in identifying patients who would benefit from such sessions. Finding ways of changing unhelpful responses elicited from families and GPs remains a pressing problem and more effort is required to discover what are the other important influences in the patients' environments.

As drug reduction was not found to be a speedy process, it would seem more appropriate at the AAH to aim for continued reduction post-treatment rather than maintenance. Tackling reduction at this time may suit some (eg. who found travelling to the group arduous). In fact, the initial stages of the programme may not be the best time to target drug reduction when patients' view drugs as facilitating group attendance and acquisition of coping strategies (which may in turn replace the use of drugs). However, continued work post-treatment would require more detailed long-term planning and, in some cases, GP involvement. Kerns, Bayer & Findley (1999) suggest tailoring interventions based on an individual's SE and priorities for change. They believe identifying one or two primary goals followed by stepwise interventions may enhance SE and minimize information overload. Obviously, this type of flexibility is more difficult to manage in a group format.

Finally, on at least five occasions GPs introduced additional drugs or suggested dose increases during the PMP. Improved liaison between the programme and GPs about drug reduction is essential and these links are currently being developed. Ways of dealing with conflicting advice could also be discussed with the patients.
Further clarification of the patients' goals and those of the programme in terms of drug reduction is needed in order to devise clearer strategies.

## 4.8. IMPLICATIONS FOR FUTURE RESEARCH

A further important stage of the present study, given the present climate, would be to calculate a cost-benefit analysis. Estimation of money saved in terms of cost of drugs and possibly fewer GP appointments could be compared to the cost of the PMP nurse's time.
Repetition of this study taking account of the highlighted weaknesses would be useful. If a larger sample was employed it would be possible to analyse those that opted out of drug reduction and efforts could be made to control for drug class and pain diagnosis. In addition, more variables, such as prior experience of drug reduction, could be examined. Finding a way of assessing Prochaska & Diclemente's (1982) 'stage of change' prior to opting into reduction could be useful in identifying those who seem to require more motivational work initially. The crucial role of self efficacy was emphasized in this study. However, urgent research is warranted into the variables which influence self-efficacy and the mechanisms mediating its effect. Further research into which treatment strategies and method of reduction is best for which patients is required. It could be that those patients who reduced little here would have done better using the cocktail method. Self-change methods could also be investigated by comparing a PMP group receiving drug reduction supervision with a group receiving PMP minus supervised reduction. Those who were not on regular medication were not investigated here. Many PMP attenders may have reduced

successfully by themselves in the past and study of their attitudes and the methods they employed could prove worthwhile.

This study did not investigate adherence to recommendations other than drug reduction and little is known about how adherence to drug reduction covaries with adherence to the other PMP regimens (eg. relaxation, exercise) during and after treatment. Knowing which regimens are necessary and sufficient for change might allow a reduction in the number and frequency of recommendations which should improve adherence to the most important ones. Knowing the level of adherence required for successful drug reduction would also be helpful.

Ultimately, research needs to focus less on simple outcome measures and more on the processes of change to aid our understanding of who adheres (and relapses) and why.

## 4.9. CONCLUSIONS

Some support was obtained for the Theory of Reasoned Action instead of the Theory of Planned Behaviour. Attitudes and subjective norms were found to predict intention to reduce drugs and favourable attitudes to drug reduction were associated with actual amount reduced. Perceived barriers was the best single predictor of amount reduced but the addition of attitudes into the multiple regression model explained all of this variance. Oddly, negative intention was also associated with drug reduction. The failure of the TPB to explain any of the variance in adherence to drug reduction plans was attributed to the patient-controlled nature of drug reduction enabling patients to make little progress whilst complying with their plans. The overall failure to explain large amounts of the variance could be due to weaknesses in the measurement of the TPB variables, adherence or drug reduction.

Alternatively, the TPB may have poor generalizability to this domain and other models may be more useful. For instance, in keeping with previous research, self-

efficacy was found to be related to adherence, drug reduction and maintenance and other variables, not measured here, such as biological and pharmacological factors are also likely to contribute.

As expected, follow-up data illustrated a trend towards relapse in drug reduction and self-efficacy over 18 months but not back to pre-treatment levels. However, nearly a quarter of participants never made any drug reduction, indicating a problem of motivation rather than relapse. Adherence to plans was found to be important for drug reduction during the group but nonadherence was not associated with relapse thereafter. Pre and post treatment self-efficacy were related to relapse in drug reduction at 1 and 18 months. To improve outcome it seems important to find methods of increasing favourable attitudes to drug reduction, self-efficacy and adherence to plans. These variables could be used by the PMP to target individuals for drug reduction intervention or to receive additional support.

Despite the lack of strong results, this study has highlighted some of the difficulties of carrying out such research in the pain management field and produced some suggestions for practice. Further adherence research is warranted in this area and expansion of current models (eg. to include interactions between behavioural, physiological and cognitive events) may make this task more fruitful.

## REFERENCES


Ajzen, I. (1988) *Attitudes, Personality and Behaviour*, Open University Press, Milton Keynes.

Ajzen, I. (1991) The theory of planned behaviour. *Organizational Behaviour and Human Decision Processes*, 50, 179-211.

Ajzen, I. & Fishbein, M. (1977) Attitude-behaviour relations: a theoretical analysis and review of empirical research. *Psychological Bulletin*, 84, 888-918.

American Psychiatric Association (1995) *Diagnostic and Statistical Manual of Mental Disorders*, 4th rev.edn., American Psychiatric Association, Washington DC.

Bagozzi, R.P. & Kimmel, S.K. (1995) A comparison of leading theories for the prediction of goal-directed behaviours. *British Journal of Social Psychology*, 34, 437-461.

Bandura, A. (1977) Self-Efficacy: towards a unifying theory of behaviour change. *Psychological Review*, 84, 191-215.

Bandura, A. (1982) Self-efficacy mechanism in human agency. *American Psychologist*, 37, 122-147.

Bandura, A. (1986) *Social Foundations of Thought and Action: A Social Cognitive Theory*, Prentice Hall, Englewood Cliffs, New Jersey.

Bandura, A., O'Leary, A., Taylor, C.B., Gauthier, J. & Gossard, D. (1987) Perceived self-efficacy and pain control: opioid and nonopioid mechanisms. *Journal of Personality and Social Psychology*, 53, 563-571.

Beck, A.T., Ward, C.H., Mendelsohn, M., Mock, J. & Erbaugh, J. (1961) An inventory for measuring depression. *Archives of General Psychiatry*, 4, 561- 571.

Becker, M.H. (ed) (1974) The health belief model and personal health behaviour. *Health Education Monographs*, 2, 324-508.

Becker, M.H. & Rosenstock, I.M. (1984) Compliance with medical advice, in *Health Care and Human Behaviour*, (eds A. Steptoe & A. Mathews), Academic Press, London, pp.175-208.

Belcon, M.C., Haynes, B. & Tugwell, P. (1984) A critical review of compliance studies in rheumatoid arthritis. *Arthritis and Rheumatism*, 27, 1227-1233.

Bergner, M., Babbit, R.A., Carter, W.B. & Gilson, B.S. (1981) The Sickness Impact Profile: development and final revision of a health status measure. *Medical Care*, 19, 787.

Berndt, S., Maier, C. & Schutz, H. (1993) Polymedication and medication compliance in patients with chronic non-malignant pain. *Pain*, 52, 331-339.

Block, A.R., Kremer, E.F. & Gaylor, M. (1980) Behavioural treatment of chronic pain: variables affecting treatment efficacy. *Pain*, 8, 367-375.

Brus, H., van de Laar, M., Taal, E., Rasker, J. & Wiegman, O. (1999) Determinants of compliance with medication in patients with rheumatoid arthritis: the importance of self-efficacy expectations. *Patient Education and Counselling*, 36, 57-64.

Chassin, L., Presson, C.C., Sherman, S.J., Corty, E. & Olshavsky, R.W. (1984) Predicting the onset of cigarette smoking in adolescents: a longitudinal study. *Journal of Applied Social Psychology*, 14, 224-243.

Cinciripini, P.M. & Floreen, A. (1982) An evaluation of a behavioural programme for chronic pain. *Journal of Behavioural Medicine*, 5, 375-389.

Council, J.R., Ahern, D.K., Follick, M.J. & Kline, C.L. (1988) Expectancies and functional impairment in chronic low back pain. *Pain*, 33, 323-331.

de Vries, H., Dijkstra, M. & Kuhlman, P. (1988) Self-efficacy: the third factor besides attitude and subjective norm as a predictor of behavioural intentions. *Health Education Research*, 3, 273-282.

DiMatteo, M.R. & DiNicola, D.D. (1982) *Achieving Patient Compliance: The Psychology of the Medical Practitioner's Role*, Pergamon Press, New York.

Dolce, J.J. (1987) Self-efficacy and disability beliefs in behavioural treatment of pain. *Behaviour Research and Therapy*, 25, 289-299.

Dolce, J.J., Crocker, M.F. & Doleys, D.M. (1986a) Prediction of outcome among chronic pain patients. *Behaviour Research and Therapy*, 24, 313-319.

Dolce, J.J., Crocker, M.F., Moletteire, C. & Doleys, D.M. (1986b) Exercise quotas, anticipatory concern, and self-efficacy expectancies in chronic pain: a preliminary report. *Pain*, 24, 365-372.

Elliott, R., Jobber, D. & Sharp, J. (1995) Using the theory of reasoned action to understand organizational behaviour: the role of belief salience. *British Journal of Social Psychology*, 34, 161-172.

Flor, H., Fydrich, T. & Turk, D.C. (1992) Efficacy of multidisciplinary pain treatment centres: a meta-analytic review. *Pain*, 49, 221-230.

Fordyce, W.E. (1976) *Behavioural Methods for Chronic Pain and Illness*, CV Mosby and Co., St Louis, Missouri.

Garb, J.R. & Stunkard, J.A. (1974) Effectiveness of a self-help group in obesity control: a further assessment. *Archives of International Medicine*, 134, 716-720.

Giles, M. & Cairns, E. (1995) Blood donation and Ajzen's theory of planned behaviour: an examination of perceived behavioural control. *British Journal of Social Psychology*, 34, 173-188.

Granlund, B., Brulin, C., Johansson, H. & Sojka, P. (1998) Can motivational factors predict adherence to an exercise program for subjects with low back pain? *Scandinavian Journal of Behaviour Therapy*, 27, 81-96.

Janz, N.K. & Becker. M.H. (1984) The health belief model: a decade later. *Health Education Quarterly*, 11, 1-47.

Jensen, M.P., Turner, J.A. & Romano, J.M. (1991) Self-efficacy and outcome expectancies: relationship to chronic pain coping strategies and adjustment. *Pain*, 44, 263-269.

Jensen, M.P., Turner, J.A. & Romano, J.M. (1994a) Correlates of improvement in multidisciplinary treatment of chronic pain. *Journal of Consulting and Clinical Psychology*, 62, 172-179.

Jensen, M.P., Turner, J.A., Romano, J.M. & Lawler, B.K. (1994b) Relationship of pain-specific beliefs to chronic pain adjustment. *Pain*, 57, 301-309.

Johnston, M., Wright, S. & Weinman, J. (1995) *Measures in Health Psychology: A User's Portfolio*, NFER-Nelson, Windsor.

Keefe, F.J., Gil, K.M. & Rose, S.C. (1986) Behavioural approaches in the multidisciplinary management of chronic pain: programs and issues. *Clinical Psychology Review*, 6, 87-113.

Keefe, F.J., Salley, A.N. & Lefebvre, J.C. (1992) Coping with pain: conceptual concerns and future directions. *Pain*, 51, 131-134.

Keefe, F.J., Kashikar-Zuck, S., Robinson, E. et al. (1997) Pain coping strategies that predict patients' and spouses' ratings of patients' self-efficacy. *Pain*, 73, 191-199.

Kerns, R.D., Bayer, L.A. & Findley, J.C. (1999) Motivation and adherence in the management of chronic pain, in *Handbook of Pain Syndromes* (eds A.R. Block, E.F. Kremer & E. Fernandez), Lawrence Erlbaum Associates, New Jersey.

Kores, R.C., Murphy, W.D., Rosenthal, T.L., Elias, D.B. & North W.C. (1990) Predicting outcome of chronic pain treatment via a modified self-efficacy scale. *Behaviour Research and Therapy*, 28, 165-169.

Leventhal, H. & Cameron, L. (1987) Behavioural theories and the problem of compliance. *Patient Education and Counselling*, 10, 117-138.

Leventhal, H. & Nerenz, D. (1985) The assessment of illness cognition, in *Measurement Strategies in Health Psychology*, (ed P. Karoly), Wiley & Sons, New York, pp. 517-554.

Ley, P. (1976) Towards better doctor-patient communications: contributions from social and experimental psychology, in *Communication between Doctors and Patients*, (ed A.E. Bennett), University Press, Oxford.

Ley, P. (1982) Understanding, memory, satisfaction and compliance. *British Journal of Clinical Psychology*, 21, 241-254.

Ley, P. (1988) *Communicating with Patients*, Croom Helm, London.

Lin, C. & Ward, S.E. (1996) Perceived self-efficacy and outcome expectancies in coping with chronic low back pain. *Research in Nursing and Health*, 19, 299-310.

Luscombe, F.E., Wallace, L., Williams, J. & Griffiths, D.P.G. (1995) A District General Hospital pain management programme. *Anaesthesia*, 50, 114-117.

Lutz, R.W., Silbret, M. & Olshan, N. (1983) Treatment outcome and compliance with therapeutic regimens: long-term follow-up of a multidisciplinary pain programme. *Pain*, 17, 301-308.

Madden, T.J., Ellen, P.S. & Ajzen, I. (1992) A comparison of the Theory of Planned Behaviour and the Theory of Reasoned Behaviour and the Theory of Reasoned Action. *Personality and Social Psychology Bulletin*, 18, 3-9.

Marlatt, G.A. & Gordon, J.R. (1980) Determinants of relapse: implications for the maintenance of behaviour change, in *Behavioural Medicine: Changing Health Lifestyles* (ed P.O. Davidson), Brunner/Mazel, New York.

Marteau, T.M. (1995) Health beliefs and attributions, in *Health Psychology; Processes and Applications* 2nd edn (eds A. Broome & S. Llewelyn), Chapman & Hall, London, pp.3-20.

Masur, F.T. (1981) Adherence to health care regimens, in *Medical Psychology: Contributions to Behavioural Medicine*, (eds C. Prokop & L.A. Bradley), Academic Press, New York, pp. 441-462.

Mazzucca, S.A. (1982) Does patient education in chronic disease have therapeutic value? *Journal of Chronic Diseases*, 35, 521-529.

Meichenbaum, D. & Turk, D.C. (1987) *Facilitating Treatment Adherence: A Practitioner's Guidebook*, Plenum, New York.

Mendelsohn, G. (1986) Chronic pain and compensation: a review. *Journal of Pain Symptom Management*, 1, 135-144.

Meyer, D., Leventhal, H. & Gutmann, M. (1985) Common-sense models of illness: the example of hypertension. *Health Psychology*, 4, 115-135.

Morley, S., Eccleston, C. & Williams, A. (1999) Systematic review and meta-analysis of randomized controlled trials of cognitive behaviour therapy and behaviour therapy for chronic pain in adults, excluding headache. *Pain*, 80, 1-13.

Mushlin, A.I. & Appel, F.A. (1977) Diagnosing potential noncompliance. *Archives of International Medicine*, 137, 318-321.

Netemeyer, R.G., Burton, S. & Johnston, M. (1991) A comparison of two models for the prediction of volitional and goal-directed behaviours: a confirmatory analysis approach. *Social Psychology Quarterly*, 54, 87-100.

Nicholas, M.K. (1989) The Pain Self-Efficacy Questionnaire: self-efficacy in relation to chronic pain. Paper presented at the BPS Annual Conference, St Andrews.

Nicholas, M.K. (1992) Chronic pain, in *Principles and Practice of Relapse Prevention*, (ed P.H. Wilson), Guilford Press, New York, pp. 255-289.

Nicholas, M.K. (1994) Pain Self-Efficacy Questionnaire(PSEQ): preliminary report.

Nicholas, M.K., Wilson, P.H. & Goyen, J. (1992) Comparison of cognitive-behavioural group treatment and an alternative non-psychological treatment for chronic low back pain. *Pain*, 48, 339-347.

Norman, P. & Smith, L. (1995) The theory of planned behaviour and exercise: an investigation into the role of prior behaviour, behavioural intentions and attitude variability. *European Journal of Social Psychology*, 25, 403-415.

Painter, J.R., Seres, J.L. & Newman, R.I. (1980) Assessing benefits of the pain centre: why some patients regress. *Pain*, 8, 101-113.

Parker, D., Manstead, A.S.R. & Stradling, S.G. (1995) Extending the theory of planned behaviour: the role of personal norm. *British Journal of Social Psychology*, 34, 127-137.

Pellino, T.A. (1997) Relationships between patient attitudes, subjective norms, perceived control, and analgesic use following elective orthopedic surgery. *Research in Nursing and Health*, 20, 97-105.

Pither, C.E. & Nicholas, M.K. (1991) The identification of iatrogenic factors in the development of chronic pain syndromes: abnormal treatment behaviour? in *Proceedings of the VIth World Congress on Pain*, (eds M.R. Bond, J.E. Charlton & C.J. Woolf), Elsevier, Amsterdam, pp. 429-434.

Prochaska, J.O. & DiClemente, C.C. (1982) Transtheoretical Therapy: toward a more integrative model of change. *Psychotherapy: Theory, Research and Practice*, 19, 276-288.

Ralphs, J.A., Williams, A.C.deC., Richardson, P.H., Pither, C.E. & Nicholas, M.K. (1994) Opiate reduction in chronic pain patients: a comparison of patient-controlled reduction and staff controlled cocktail methods. *Pain*, 56, 279-288.

Richard, R., van der Pligt, J. & de Vries, N. (1995) Anticipated affective reactions and prevention of AIDS. *British Journal of Social Psychology*, 34, 9-21.

Roland, M. & Morris, R. (1983) A study of the natural history of back pain, Part 1. Development of a reliable and sensitive measure of disability in low back pain. *Spine*, 8, 141-144.

Rotter, J.B. (1966) generalised expectancies for internal versus external control of reinforcement. *Psychological Monographs*, 80 (1, whole no. 609).

Sackett, D.L. & Snow, J.C. (1979) Magnitude of compliance and non-compliance, in *Compliance in Health Care*, (eds R.B. Haynes, D.W. Taylor & D.L. Sackett), John Hopkins University Press, Baltimore.

Sarafino, E.P. (1990) *Health Psychology: Biopsychosocial Interactions*, John Wiley & Sons Ltd., Chichester.

Saunders, B. & Allsop, S. (1987) Relapse: a psychological perspective. *British Journal of Addiction*, 82, 417-429.

Schifter, D.E. & Ajzen, I. (1985) Intention, perceived control, and weight loss: an application of the theory of planned behaviour. *Journal of Personality and Social Psychology*, 49, 843-851.

Schlegel, R.P., D'Averna, J.R., Zanna, M.P., DeCourville, N.H. & Manske, S.R. (1992) Problem drinking: a problem for the theory of reasoned action? *Journal of Applied Social Psychology*, 22, 358-385.

Sheppard, B.H., Hartwick, J. & Warshaw, P.R. (1988) The theory of reasoned action: a meta-analysis of past research with recommendations for modifications and future research. *Journal of Consumer Research*, 15, 325-343.

Skevington, S.M. (1995) *Psychology of Pain*, John Wiley & Sons Ltd., Chichester.

Skinner, R. (1953) in K.D. O'Leary & G.T. Wilson (1975) *Behaviour Therapy: Application and Outcome*, Englewood Cliffs, Prentice Hall, New Jersey.

Skinner, J.B., Erskine, A., Pearce, S., Rubenstein, I., Taylor, M. & Foster, C. (1990) The evaluation of a cognitive-behavioural treatment programme in outpatients with chronic pain. *Journal of Psychosomatic Research*, 34,13-19.

Spanswick, C.C. & Main, C.J. (1989) The role of the anaesthetist in the management of chronic low back pain, in *Back Pain: New Approaches to Rehabilitation*, (eds M. Roland & J.R. Jenner), Manchester University Press, Manchester, pp.108-128.

Szymanski, H., Epstein, L.H., Wimberly, T. & Madtes, D. (1979) Self-regulation of analgesics: a single case study. *Addictive Behaviors*, 4, 253-258.

Taal, E., Rasker, J.J., Seydel, E.R. & Wiegman, O. (1993) Health status, adherence with health recommendations, self-efficacy and social support in patients with rheumatoid arthritis. *Patient Education and Counselling*, 20, 63-76.

Tait, R.C. & Chibnall, J.T. (1998) Attitude profiles and clinical status in patients with chronic pain. *Pain*, 78, 49-57.

Terry, D.J. & O'Leary, J.E. (1995) The theory of planned behaviour: the effects of perceived behavioural control and self-efficacy. *British Journal of Social Psychology*, 34, 199-220.

Turk, D.C. & Rudy, T.E. (1991) Neglected topics in the treatment of chronic pain patients - relapse, noncompliance, and adherence enhancement. *Pain*, 44, 5-28.

Turk, D.C., Rudy, T.E. & Sorkin, B.A. (1993) Neglected topics in chronic pain treatment outcome studies: determination of success. *Pain*, 53, 3-16.

von Korff, M., Dworkin, S.F. & Le Lesche, L. (1990) Graded chronic pain status: an epidemiologic evaluation. *Pain*, 40, 279-291.

Weinstein, N. (1987) The precaution adoption process. *Health Psychology*, 7, 355-386.

Williams, A.C.de C. (1993) Inpatient management of chronic pain, in *Psychological treatment in human diseases and illnesses*, (eds M. Hodes & S. Moorey), Gaskell Press, London, pp.114-139.

Williams, A.C.de C. (1998) What is effective in pain management? Paper presented at the BPS Division of Clinical Psychology (Scottish Branch) Conference on Psychological Approaches to the Management of Pain, Edinburgh.

Williams, A.C.de C. & Erskine, A. (1995) Chronic Pain, in *Health Psychology; Processes and Applications* 2nd edn (eds A. Broome & S. Llewelyn), Chapman & Hall, London, pp.353-376.

Williams, A.C.de C., Nicholas, M.K., Richardson, P.H., et al. (1993) Evaluation of a cognitive behavioural programme for rehabilitating patients with chronic pain. *British Journal of General Practice*, 43, 513-518.

Williams, A.C.de C., Richardson, P.H., Nicholas, M.K., et al. (1996) Inpatient vs. outpatient pain management: results of a randomised controlled trial. *Pain*, 66,13-22.

Williams, D.A. & Thorn, B.E. (1989) An empirical assessment of pain beliefs. *Pain*, 36, 351-358.

Winkelstein, M.L. & Feldman, H.L. (1993) Psychological predictors of consumption of sweets following smoking cessation. *Research in Nursing and Health*, 16, 97-105.

Zigmond, A.S. & Snaith, R.P. (1983) The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica*, 67, 361- 370.

# APPENDIX

## APPENDIX A

## PROGRAMME FOR CHRONIC PAIN MANAGEMENT GROUP

| Session | Topic |
|---|---|
| **Session 1** | Introduction<br>What is pain?<br>Relaxation & Breathing<br>Introduction of exercise and stretching |
| **Session 2** | Why being active is good for you<br>Over Activity Rest Cycle |
| **Session 3** | Drugs and Pain |
| **Session 4** | "How to move" Session 1 |
| **Session 5** | "How to move" Session 2<br>Lifting and movement |
| **Session 6** | How do we feel pain?<br>Gate control theory and thresholds for pain<br>**Show video** |
| **Session 7** | Adrenalin and arousal |
| **Session 8** | How thinking influences pain<br>Introduce GSR machines |
| **Session 9** | How thinking influences pain<br>Introduce Watches |
| **Session 10** | Pain behaviour and dealing with families,<br>including assertion techniques.First Aid pack |
| **Session 11** | How to set long term goals |
| **Session 12** | Relapse prevention and dealing with<br>flare-ups |

**DRUG REDUCTION QUESTIONNAIRE** **APPENDIX B**

**(LONG FORM)**

NAME: _____

This questionnaire contains general statements about your beliefs about reducing the drugs you take for your pain. There are no right or wrong answers, I am interested in your views. For each item, please circle one of the numbers on the line below the statement.

**For example:**

strongly disagree 1 2 3 4 (5) 6 7 strongly agree

**1. If I reduce my drugs, I will experience a lot more pain.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**2. If I reduce my drugs, my self-confidence will improve.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**3. If I reduce my drugs, I will feel that I am more in control of my pain on my own.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**4. If I reduce my drugs, other people will think I am not really suffering pain.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**5. If I reduce my drugs and then start taking more again, I will have failed with my drugs.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**6. If I reduce my drugs, I will feel more anxious.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**7. If I reduce my drugs, I will have stopped taking things which are not helping my pain.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**8. If I reduce my drugs, I will lose the one thing that gives me some control over my pain.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**9. If I reduce my drugs, I will see my GP or Consultant less.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**10. My current level of drugs causes me side-effects.**

very much 1 2 3 4 5 6 7 not at all

**11. Is there anything else that might happen if you reduce your drugs?**

| |
|---|
| |

**12. For you personally, do you think the advantages of taking drugs for your pain outweigh the disadvantages?**

YES / NO (please delete)

**13. Experiencing a lot more pain would be**

extremely bad 1 2 3 4 5 6 7 extremely good

**14. An improvement in my self-confidence would be**

extremely bad 1 2 3 4 5 6 7 extremely good

**15. Other people knowing that I am suffering pain would be**

extremely bad 1 2 3 4 5 6 7 extremely good

**16. Feeling that I am more in control of my pain on my own would be**

extremely bad 1 2 3 4 5 6 7 extremely good

**17. Failing with my drugs would be**

extremely bad 1 2 3 4 5 6 7 extremely good

**18. Feeling more anxious would be**

extremely bad 1 2 3 4 5 6 7 extremely good

**19. Stopping taking drugs which are not helping my pain would be**

extremely bad 1 2 3 4 5 6 7 extremely good

**20. Losing the one thing that gives me some control over my pain would be**

extremely bad 1 2 3 4 5 6 7 extremely good

**21. Seeing my GP or Consultant less would be**

extremely bad 1 2 3 4 5 6 7 extremely good

**22. Being without side-effects would be**

extremely bad 1 2 3 4 5 6 7 extremely good

**23. For me to reduce my drugs is**

bad 1 2 3 4 5 6 7 good

**24. For me to reduce my drugs is**

harmful 1 2 3 4 5 6 7 beneficial

**25. For me to reduce my drugs is**

foolish 1 2 3 4 5 6 7 wise

**26. Organizing how I take my drugs is almost entirely up to me.**

false 1 2 3 4 5 6 7 true

**27. I am going to reduce my drugs.**

extremely unlikely 1 2 3 4 5 6 7 extremely likely

**28. If I reduce my drugs my family would**

disapprove 1 2 3 4 5 6 7 approve

**29. If I reduce my drugs my GP would**

disapprove 1 2 3 4 5 6 7 approve

**30. If I reduce my drugs my Hospital Consultant (if applicable) would**

disapprove 1 2 3 4 5 6 7 approve

**31. It is mostly up to me whether or not I succeed in reducing my drugs.**

false 1 2 3 4 5 6 7 true

**32. I wish to do what my family thinks I should do.**

not at all 1 2 3 4 5 6 7 very much

**33. I wish to do what my GP thinks I should do.**

not at all 1 2 3 4 5 6 7 very much

**34. I wish to do what my Hospital Consultant (if applicable) thinks I should do.**

not at all 1 2 3 4 5 6 7 very much

**35. How likely are the following to prevent you from reducing your drugs?**

**a) Suffering a flare-up of pain.**

prevent me 1 2 3 4 5 6 7 not prevent me

**b) Being under stress.**

prevent me 1 2 3 4 5 6 7 not prevent me

**c) Feeling low in mood.**

prevent me 1 2 3 4 5 6 7 not prevent me

**d) Suffering a new pain or injury.**

prevent me 1 2 3 4 5 6 7 not prevent me

**e) Not being able to do as much.**

prevent me 1 2 3 4 5 6 7 not prevent me

**f) Having little confidence in other strategies to help deal with your pain.**

prevent me 1 2 3 4 5 6 7 not prevent me

**g) Having little time/energy to use other strategies.**

prevent me 1 2 3 4 5 6 7 not prevent me

**h) Feeling uncertain about trying something new.**

prevent me 1 2 3 4 5 6 7 not prevent me

**i) Being pressurized by your family to take your drugs.**

prevent me 1 2 3 4 5 6 7 not prevent me

**j) Sleeping badly.**

prevent me 1 2 3 4 5 6 7 not prevent me

**k) Suffering withdrawal effects.**

prevent me 1 2 3 4 5 6 7 not prevent me

**l) Receiving conflicting advice from other medical staff.**

prevent me 1 2 3 4 5 6 7 not prevent me

**36. Is there anything else which might stop you from reducing your drugs?**

| |
|---|
| |

**FOR READERS' ATTENTION**

Qs. 1, 6, 8, 10, 13, 18 & 20 were scored by substituting 7 to 1 scale.

Qs. 28, 29 & 30 were scored by substituting a -3 to 3 scale.

Qs. 4, 5, 9, 15, 17 & 21 were excluded from attitude scores.

**DRUG REDUCTION QUESTIONNAIRE** **APPENDIX C**

**(SHORT FORM)**

NAME: _____

This questionnaire contains general statements about your beliefs about reducing the drugs you take for your pain. There are no right or wrong answers, I am interested in your views. For each item, please circle one of the numbers on the line below the statement.

**For example:**

strongly disagree 1 2 3 4 (5) 6 7 strongly agree

**1. If I reduce my drugs, I will experience a lot more pain.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**2. If I reduce my drugs, my self-confidence will improve.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**3. If I reduce my drugs, I will feel that I am more in control of my pain on my own.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**4. If I reduce my drugs, other people will think I am not really suffering pain.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**5. If I reduce my drugs and then start taking more again, I will have failed with my drugs.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**6. If I reduce my drugs, I will feel more anxious.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**7. If I reduce my drugs, I will have stopped taking things which are not helping my pain.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**8. If I reduce my drugs, I will lose the one thing that gives me some control over my pain.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**9. If I reduce my drugs, I will see my GP or Consultant less.**

strongly disagree 1 2 3 4 5 6 7 strongly agree

**10. My current level of drugs causes me side-effects.**

very much 1 2 3 4 5 6 7 not at all

**11. Was there anything else that happened when you tried to reduce your drugs?**

| |
|---|
| |

**12. For you personally, do you think the advantages of taking drugs for your pain outweigh the disadvantages?**

YES / NO (please delete)

**13. For me to reduce my drugs is**

bad 1 2 3 4 5 6 7 good

**14. For me to reduce my drugs is**

harmful 1 2 3 4 5 6 7 beneficial

**15. For me to reduce my drugs is**

foolish 1 2 3 4 5 6 7 wise

**16. Organizing how I take my drugs is almost entirely up to me.**

false 1 2 3 4 5 6 7 true

**17. It is mostly up to me whether or not I succeed in reducing my drugs.**

false 1 2 3 4 5 6 7 true

**18. How much did the following prevent you from reducing your drugs?**

**a) Suffering a flare-up of pain.**

prevent me 1 2 3 4 5 6 7 not prevent me

**b) Being under stress.**

prevent me 1 2 3 4 5 6 7 not prevent me

**c) Feeling low in mood.**

prevent me 1 2 3 4 5 6 7 not prevent me

**d) Suffering a new pain or injury.**

prevent me 1 2 3 4 5 6 7 not prevent me

**e) Not being able to do as much.**

prevent me 1 2 3 4 5 6 7 not prevent me

**f) Having little confidence in other strategies to help deal with your pain.**

prevent me 1 2 3 4 5 6 7 not prevent me

**g) Having little time/energy to use other strategies.**

prevent me 1 2 3 4 5 6 7 not prevent me

**h) Feeling uncertain about trying something new.**

prevent me 1 2 3 4 5 6 7 not prevent me

**i) Being pressurized by your family to take your drugs.**

prevent me 1 2 3 4 5 6 7 not prevent me

**j) Sleeping badly.**

prevent me 1 2 3 4 5 6 7 not prevent me

**k) Suffering withdrawal effects.**

prevent me 1 2 3 4 5 6 7 not prevent me

**l) Receiving conflicting advice from other medical staff.**

prevent me 1 2 3 4 5 6 7 not prevent me

**19. Was there anything else which stopped you from reducing your drugs?**

| |
|---|
| |

**20. How much support did you get on the course to help you reduce your drugs?**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| none at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | very much |

# PAIN: S-E QUESTIONNAIRE

MKN (1988) Pain Management Centre

St Thomas' Hospital London.

**NAME:**_____ **DATE**_____

Please rate **how confident** you are that **you can do** the following things at present, **despite the pain.** To answer circle one of the numbers on the scale under each item, where 0 = "Not at all confident" and 6 = "Completely confident"

**FOR EXAMPLE:-**

0 1 2 (3) 4 5 6

Not at all Confident — Completely Confident

Remember, this questionnaire is not asking whether or not you have been doing these things, but rather, **how confident you are that you can do them** at the present, despite the pain.

1) **I can still enjoy things, despite the pain.**

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

2) **I can still do most of the household chores (e.g. tidying up, washing dishes etc.) despite the pain.**

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

3) **I can socialise with my friends or family members as often as I used to, despite the pain.**

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

4) I can cope with my pain in most situations.

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

5) I can do some sort of work, despite the pain
("Work" includes housework, paid or unpaid work)

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

Turn over the page.

6) **I can still do many of the things I enjoy doing, such as hobbies or leisure activities, despite the pain.**

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

7) **I can cope with my pain without medication.**

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

8) **I can still accomplish most of my goals in life, despite the pain.**

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

9) **I can still live a normal lifestyle, despite the pain.**

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

10) **I can gradually become more active, despite the pain.**

0 1 2 3 4 5 6

Not at all Confident — Completely Confident

# APPENDIX E

CALCULATION OF MEASURES OF ADHERENCE

1. Days Method

Adherence = (No. of days adhere) / (No. of days working on plans) %

2. Pills Method

Adherence = (No. of deviations from plan over course) / (No. of planned pills over course) %

Notes

1. It is acknowledged that patients may increase their medication when in flare-up (ie. suffering more than their usual level of pain) and, ideally, patients should negotiate a "flare-up plan". This would enable adherence with flare-up plans to be measured. As flare-up plans were not negotiated early in treatment, days when additional drugs were taken in flare-up had to be excluded from the total number of days.

2. On several occasions GPs interfered with plans and subjects were scored as adhering if they followed their GP's advice. This may not have been justified if the patients had explicitly or implicitly suggested the medication change to their GPs rather than, as the patients claimed, the doctor advised it.

3. Any deviation from the plan (eg. more planned or nonplanned tablets, less tablets) was scored equally. Some may argue that taking less medication is not as serious as taking more. However, the PMP advocates paced reduction on a time-controlled basis. By taking less on some days drugs will continue to be reinforcing and reducing too quickly may be more likely to lead to failure.

4. Any additional medications taken for other ailments were excluded from calculations. Size of dose was used to determine whether antidepressants,

anticonvulsants and muscle relaxants had been prescribed for analgesia or other purposes.

5. Adherence to the spread of drug intake throughout the day was measured when the step of the plan involved changing from prn to time-contingent use. If the step involved making a reduction, spread of drug intake throughout the day was not assessed.

6. The plan to which adherence was being measured involved the abolition or reduction of drug use. Substitution of other strategies (eg. relaxation, planning of activity) was advocated as part of the Pain Management Programme but was not measured as part of drug reduction plans.

CALCULATION OF MEASURE OF DRUG REDUCTION

(Change in dose over course) / (maximum daily dose*) calculated for individual drugs. Proportions summed for those on >1 drug.

* provided by AAH pharmacist from the British National Formulary (BNF)

This measure was calculated (i) excluding days when additional drugs were taken in flare-up and (ii) including such days.

REMARKS

Using the days method to measure adherence is rather crude in that on noncompliant days the extent of the deviation from the plan is not calculated. This is accounted for by the pills method. However, the pills method is influenced by the number of pills someone is taking, ie. if someone is on 12 pills daily and takes an extra one this contributes less to the adherence score as opposed to someone who is on one tablet and takes an extra one (being unlikely to take an extra quarter tablet). Thus it may be easier for the big pill takers to be compliant. Furthermore, it may be preferable to

use number of doses rather than the absolute number of pills to calculate this method to cater for people taking two pills together (because of the size of pills).

The validity of the two methods of calculating adherence were supported by their significant correlation. In addition, they appeared to be intuitively appropriate. It is expected that using other self-report methods to calculate adherence would also correlate.

The major difficulty in calculating drug reduction is that equivalence tables of analgesic potency across different drug classes do not exist. Thus some of the drugs may be easier or harder to reduce than others and this is not being fully controlled for. Opiates might be considered the hardest and consideration was given to coding subjects on these drugs until it transpired that all subjects were using opiates. Using maximum daily doses for each drug is an attempt to control for some of the pharmacological variance.

However, even if equivalence tables had been available their applicability for chronic pain would be uncertain as they would be based on acute pain. Furthermore, the varying responses of individuals and the interactions of different types of drugs when taken together could not be controlled for. Obviously these are additional problems with the method employed. If time and resources had permitted, an alternative method would be to ask a small number of physicians to rank the various drug combinations according to difficulty to reduce.

However, on discussion with medical and pharmacy colleagues it was felt to be meaningful to calculate a measure of drug reduction <u>across</u> drug classes. Chronic pain patients may be more "psychologically dependent" on their drugs meaning that any reduction would be equally difficult. Feelings of control, hope, etc. are common across drug classes and require to be given up on reduction. However, these results should be interpreted with caution due to the inability to completely control for analgesic potency.

The measure of drug reduction involved adding the reduction proportions of each drug, if someone was taking more than one compound. Therefore it could be argued that someone who is on more drugs has a greater opportunity to reduce. An alternative method would be to use the average reduction proportion for each drug in an attempt to control for opportunity. However, as drug reduction is recommended to be done one drug at a time, the averaging method would penalize someone who had targeted one drug but in the short time span of the group had not reduced the others. Opportunity to reduce may be less of a problem than anticipated as people were not generally running out of drugs to reduce! Only three subjects had reduced completely by stopping instantly and one had done this with two drugs simultaneously. Finally, adherence scores were calculated on the basis of adherence to multiple drugs if applicable without controlling for greater opportunity to be nonadherent.

**DRUG REDUCTION PLAN**

NAME: _____ WEEK BEGINNING: _____

| DRUG | DOSE | TIMES: | TUES | WED | THURS | FRI | SAT | SUN | MON |
|---|---|---|---|---|---|---|---|---|---|
| 1.<br>2.<br>3.<br>4.<br>5. | | | | | | | | | |
| ANY ADDITIONAL DRUGS TAKEN | | | | | | | | | |
| COMMENTS/PROBLEMS<br>E.g. pain flare-up (more than your usual level of pain) | | | | | | | | | |

Please write on the line below the number between 0 and 100 that best describes your pain over the last week. A '0' would mean 'no pain' and a '100' would mean 'pain as bad as it could be'.

0 100

APPENDIX F

EXAMPLE

**DRUG REDUCTION PLAN**

NAME: Joe Bloggs WEEK BEGINNING: 10 Sept '95

| DRUG | DOSE | TIMES: 8am 12 4pm 8pm | THURS | FRI | SAT | SUN | MON | TUES | WED |
|---|---|---|---|---|---|---|---|---|---|
| 1. Ibuprofen<br>2. Co-proxamol<br>3.<br>4.<br>5. | 400mg | 1 1 0 1<br>2 2 1 2 | 1 1 0 1<br>2 2 1 2 | 1 1 0 1<br>2 2 1 2 | 1 1 0 1<br>2 2 2 2 | 1 1 1 1<br>2 2 2 2 | 1 1 0 1<br>2 2 1 2 | 1 1 0 1<br>2 2 1 2 | 1 1 0 1<br>2 2 1 2 |
| ANY ADDITIONAL DRUGS TAKEN | | | | | DF118 - 60mg | DF118 - 60mg | | | |
| COMMENTS/PROBLEMS e.g. pain flare-up | | | | | overacture at weekend - at a wedding. Pain very bad. | | | | |

APPENDIX G

Please write on the line below the number between 0 and 100 that best describes your pain over the last week. A '0' would mean 'no pain' and a '100' would mean 'pain as bad as it could be'.

## APPENDIX H

**TableA1: Results of Multiple Regression Analyses**

**Multiple Regression Analysis of Intention**

| Step | R Sqd | Adj R Sqd | Predictor | beta | T | sig T |
|---|---|---|---|---|---|---|
| 1. | 0.70 | 0.65 | Attitudes | 0.67 | 4.55 | 0.00*** |
| | | | Subjective Norms | 0.28 | 2.18 | 0.04* |
| | | | PBC | 0.15 | 1.30 | 0.21 |
| | | | Perceived Barriers | -0.29 | -0.21 | 0.84 |

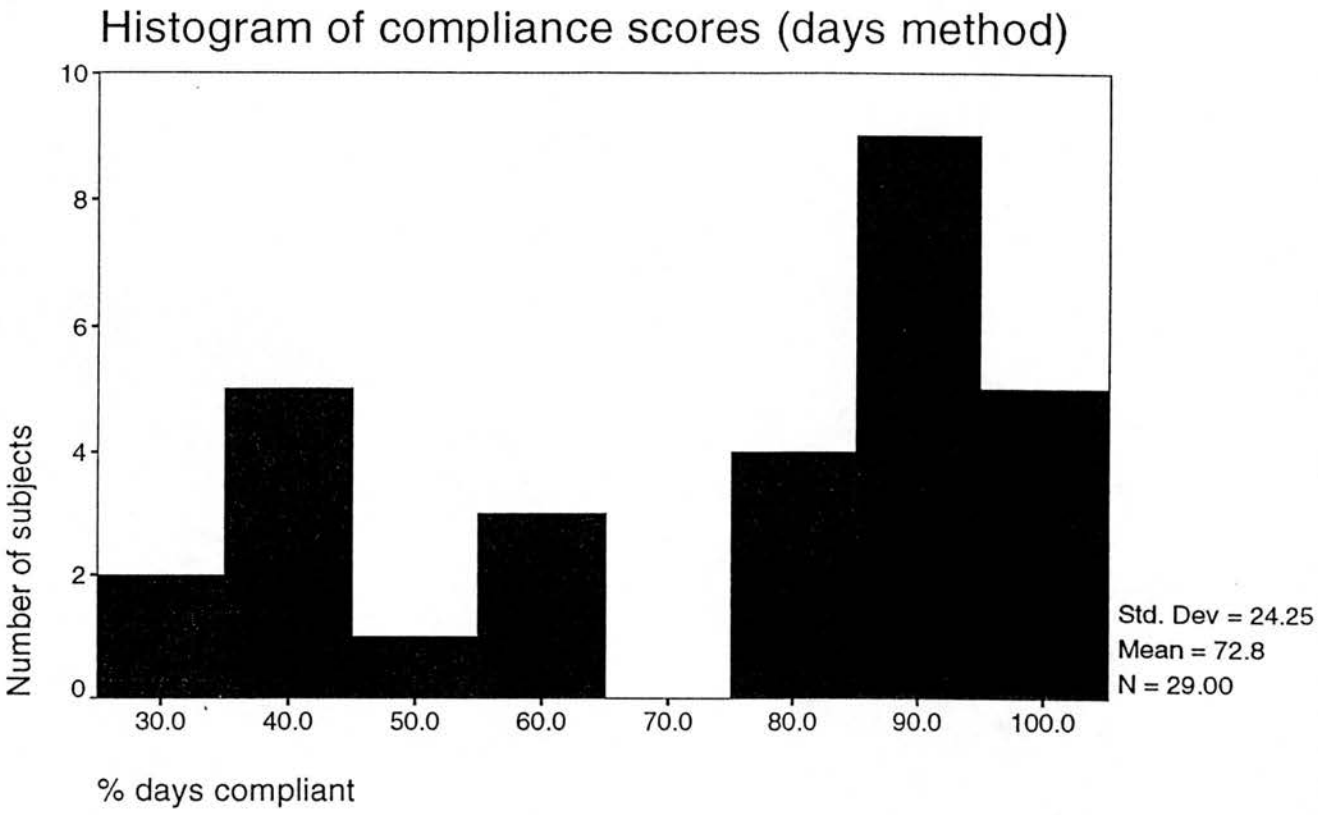
**Multiple Regression Analysis of Compliance**

| Step | R Sqd | Adj R Sqd | Predictor | beta | T | sig T |
|---|---|---|---|---|---|---|
| 1. | 0.04 | 0.01 | Intention | 0.21 | 1.07 | 0.29 |
| 2. | 0.06 | -0.05 | PBC | 0.05 | 0.23 | 0.82 |
| | | | Perceived Barriers | 0.15 | 0.69 | 0.50 |
| 3. | 0.07 | -0.14 | Attitudes | -0.17 | -0.46 | 0.65 |
| | | | Subjective Norms | 0.01 | 0.04 | 0.97 |

**Multiple Regression Analysis of Drug Reduction**

| Step | R Sqd | Adj R Sqd | Predictor | beta | T | sig T |
|---|---|---|---|---|---|---|
| 1. | 0.00 | -0.03 | Intention | 0.65 | 0.33 | 0.74 |
| 2. | 0.22 | 0.13 | PBC | 0.12 | 0.68 | 0.51 |
| | | | Perceived Barriers | 0.49 | 2.48 | 0.02* |
| 3. | 0.41 | 0.27 | Attitudes | 0.64 | 2.21 | 0.04* |
| | | | Subjective Norms | 0.29 | 1.46 | 0.16 |

**APPENDIX I**


Histogram of compliance scores (days method)
Number of subjects
10
8
6
4
2
0
30.0
40.0
50.0
60.0
70.0
80.0
90.0
100.0
% days compliant
Std. Dev = 24.25
Mean = 72.8
N = 29.00

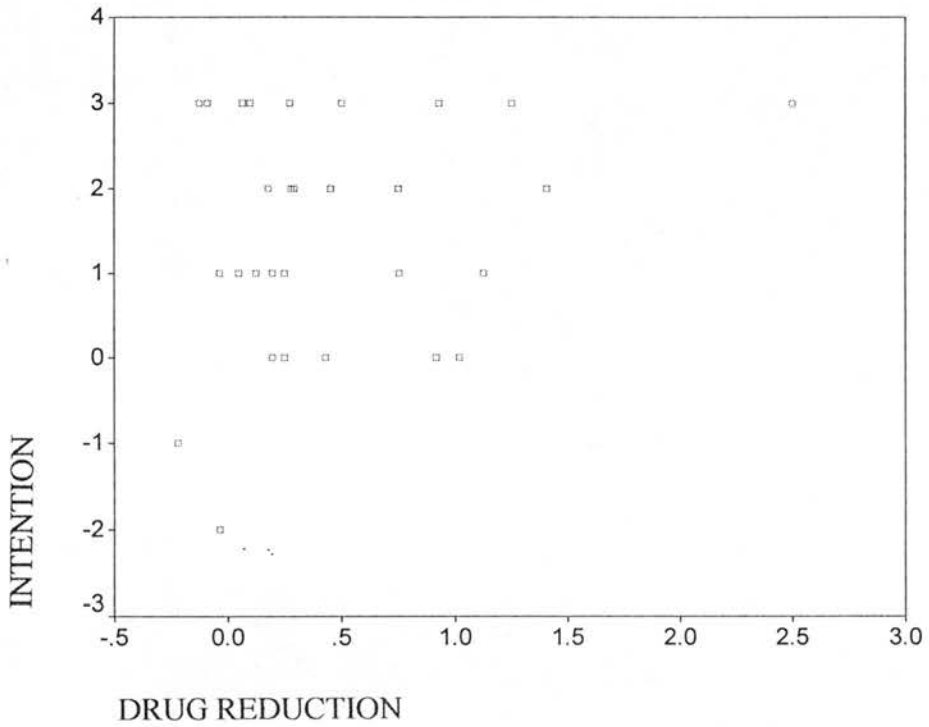
# APPENDIX J

## COMPOUND ANALGESIC PREPARATIONS

Many chronic pain patients are prescribed tablets which are a standardized mixture of opiates, anti-inflammatories or Paracetamol. Common examples are Co-proxamol, Co-dydramol and Co-codamol with Co-codamol tablets, for instance, being comprised of 8mg Codeine Phosphate and 500mg Paracetamol. Prescribed dose is simply 'number of tablets per day' with a maximum daily dose of 8 tablets for all compound analgesics being consumed by participants in this study.

## APPENDIX K

GRAPH OF DRUG REDUCTION VS. INTENTION



## APPENDIX L

LIST OF ABBREVIATIONS

| | | |
|---|---|---|
| AAH | - | Astley Ainslie Hospital |
| PMP | - | Pain Management Programme |
| PCR | - | Patient-Controlled Reduction |
| TRA | - | Theory of Reasoned Action |
| TPB | - | Theory of Planned Behaviour |
| PBC | - | Perceived Behavioural Control |
| HBM | - | Health Belief Model |
| SE | - | Self-Efficacy |
| PSEQ | - | Pain Self-Efficacy Questionnaire |
| DSE | - | Drug Self-Efficacy (Q7 of PSEQ) |
| HADS | - | Hospital Anxiety and Depression Scale |
| BDI | - | Beck Depression Inventory |
| Time 1 | - | Pre drug reduction work |
| Time 2 | - | End of programme |
| Time 3 | - | 1 month follow-up |
| Time 4 | - | 18 month follow-up |