Adherence to Pharmacological Treatment of Non-Malignant Chronic Pain: The Role of Illness Perceptions and Treatment Beliefs and Research Portfolio

Part One
(Part Two bound separately)

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CONTENTS

Chapter 1: Small-Scale Service Related Project

Characteristics of Anger Problem Referrals made to Clinical Psychology Services in East Glasgow

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Abstract

This study identifies the proportion of anger problems referred to East Glasgow's Clinical Psychology Department. It examines whether the number of anger referrals differs between sectors, referring agent and the client's clinical characteristics. The implications for clinical practice are discussed.

(40 word summary in accordance with Clinical Psychology guidelines)

Introduction

Anger is a powerful normal emotion that is common in everyday life. However, anger is often viewed as a negative construct. The definition of anger and what constitutes problematic anger is debated in clinical and research settings. Researchers have put forward different explanations of anger. Ray Novaco proposed that anger is a cognitively mediated emotional state that may have positive functions e.g. release bodily tension. However, he also argues that it has to be controlled for healthy functioning. Novaco believes anger becomes a clinical problem when it is 'dysregulated' – that is when it's activation, expression and experience occur without appropriate controls (Ramm and Novaco, 2002).

Dysregulated anger interferes with efficient thinking, impairs physiological health and can result in aggressive behaviour towards the self or others (Kay et al. 1988). As well as being a problem in itself, anger is a common feature of other psychiatric problems such as personality disorders (Blackburn 1993), schizophrenia (Levy and Howells 1991) and mood disorders, as well as reactions to trauma such as post-traumatic stress disorder (PTSD) (Chemtob et al. 1997). Clients with anger problems can therefore be expected to make up a standard component of adult clinical psychology practice.

Working with patients who are experiencing anger problems can provide a particular clinical challenge. For example, there is considerable evidence to suggest that anger is a mediator in violent offences in the community and in clinical settings such as psychiatric wards (Levy and Howells 1991). Clients with anger problems may therefore present a danger to staff (Cunningham et al. 2003). Anger problems may also be a long-standing strategy to cope with recurrent adversity (Novaco 1997). The patient may have found this strategy to be, in some ways, a successful way of dealing with life's difficulties, resulting in an ingrained pattern of

behaviour. Patients with anger problems therefore have a reputation of being resistant to treatment (Howells 1998), and may be met with therapeutic pessimism on the part of the therapist (Renwick et al. 1997). Given the difficulties outlined above, there has been growing concern amongst clinicians about how best to manage patients who present with anger problems to clinical psychology departments.

Anger is associated with different aetiological factors and presents along a spectrum of severity. It is therefore helpful to apply criteria to differentiate anger problems when working in clinical settings. It has been suggested that anger problems can be differentiated by the extent to which the client expresses anger towards other people or the environment (anger out), and the extent to which they suppress angry feelings (anger in) (Speilberger, 1983). Determining the client's ability to control anger is another useful way of understanding the differences in anger problems. The State Trait Anger Expression Inventory (Speilberger, 1979) measures anger expression according to the extent to which it is expressed, suppressed and controlled. Adult mental health psychology departments may be better equipped to deal with clients with anger problems who are more in control of their anger, and thus less likely to direct their anger towards others and the environment.

Clients who were experiencing high expressed anger and poor anger control were, until recently, referred to the forensic team in Glasgow. The forensic team provided a specialist service for people with anger problems called the 'Anger Management Fast Track' service (AMFT). However, the number of referrals was found to be unmanageable by the AMFT team and the team also felt that many of the referrals were inappropriate, as not all referrals were forensic in nature (Munro 2002). The service was therefore closed in June 2002.

Whilst it could be argued that the complex needs of patients with anger problems may be best

met by a specialist service, there nonetheless remains the task of identifying how best to manage anger referrals within the more generic adult mental health setting. The East Glasgow adult psychology team believed that they were experiencing a high volume of referrals of patients with anger problems. They were also concerned about the clinical characteristics of people being referred with anger problems. Staff were particularly concerned that the client may have anger that was directed towards others in the environment (anger out) or a forensic history, as such characteristics are associated with greater risk to others.

This project sought to audit the number of patients with anger problems being referred to the psychology department in East Glasgow in order to identify the size of the service need for these patients. Methods of managing the service need could then be developed. This study audits the number of referrals of patients with anger problems relative to other problems. It also identifies whether there are any significant differences in the number of referrals made by General Practitioners (GPs), compared to Community Mental Health Teams (CMHTs), and across the East's 3 sub sectors: City (comprising City Centre, Denniston, Parkhead and Bridgeton), Mid (comprising Riddrie, Carntyne, Shettleston and Carmyle) and Easterhouse (comprising Ballieston, Garthamlock, Easterhouse, Barlanark). The clinical characteristics of the patients with anger problems are also explored.

Aims

The study therefore aimed to address the following exploratory objectives:

1. Describe the relative proportions of problem type referred to the department during the period 1.04.03 – 31.03.04.

2. Identify if there was a significant difference between the number of referrals of

patients with anger problems across the City, Mid and Easterhouse sectors.

3. Identify if there was a significant difference between GPs and CMHTs in the number of referrals made for patients with anger problems.

4. Describe the clinical characteristics of clients referred with anger problems i.e. express 'anger out', compared with 'anger in', gender, comorbid problems and forensic history.

Method

Procedure

a) Information was accessed from the letters referring clients to adult psychology services by GPs and CMHTs in East Glasgow between 01.04.03 and 31.03.04. Four hundred and seventy five referrals were reviewed out of 560 referrals (85% of the referral population).

b) Demographic information such as age, gender, postcode, presenting problems and any mention of forensic history was extracted from referral letters. Presenting problems were categorised according to EPPIC criteria (Urquart 1997). This is a method of categorising presenting problems that was designed in the West Coast of Scotland and validated in community and clinical samples. Up to three categories of problem were recorded for each referral.

c) An anger problem was recorded whenever there was any mention of a loss of control of anger, including descriptions of irritability, loss of temper, aggressive or violent behaviour

such as assaulting others, or an indication that anger was affecting relationships. Anger was classified as 'out' when the anger was described as being expressed towards individuals or the environment. Anger was described as 'in' if the anger was described as being suppressed, or not affecting others or the environment. If both were mentioned, then the problem was categorised as 'anger out'.

d) Data were analysed using descriptive statistics, with Chi-Square tests being employed to examine associations between unrelated categorical data.

Results

The referral population for the year 1.04.03 to 31.03.04 was 560 individuals and the following analyses are based on 475 cases (85%).

1. Relative proportions of problem type referred to the department

The department received referrals for a wide range of problem types during the period assessed (Figure 1). The most frequent referral was for depression (33%). Problems related to anxiety (including GAD, panic, social phobia, agoraphobia, OCD) were the next most common referral (31%), then PTSD (13%), anger (8%), sexual abuse (6%), insomnia (3%) and eating disorders (2%). Additional problems collapsed into 'other' category (4%) included psychosis, intellectual/memory impairment, substance abuse and personality disorder.

Insert figure 1 here

Anger referrals were therefore less common than depression, anxiety and PTSD but more common than eating disorders, sleep problems and psychosis. It is therefore one of the more common referrals totalling 37 out of 475 (8%) referrals.

2. Frequency of anger referrals by sector

The frequencies of anger referrals by sector within the East Psychology Division are illustrated in Table 1. The frequency of anger referrals was highest in the Mid-Sector (9.6%) and Easterhouse sectors (8.4%). Anger referrals were less frequent in the City (5.9%). However, Chi-square analysis did not confirm the difference in anger referrals between sectors as significant ($\chi 2 = 1.52$, df = 2, $p>.05$).

Insert table 1 here

3. Frequency of Anger referrals by referrer

Table 1 also illustrates the frequency of anger referrals by referrer. GPs referred people with anger problems more frequently than CMHTs across all sectors. The CMHT in the Mid-sector referred people with anger problems more frequently than in the City or Easterhouse sectors. Chi-square analyses of data revealed no significant difference overall between GPs and CMHTs in the frequency of anger referrals compared to non-anger referrals ($\chi 2 = 0.53$, df = 1, $p>.05$), and no significant difference when the City and Mid-sectors were analysed individually i.e. City-sector ($\chi 2 = 0.01$, df = 1, >.05), Mid-sector ($\chi 2 = 0.35$, df = 1, $p>0.05$). However, GPs referred people with anger problems significantly more frequently than the CMHT in the Easterhouse sector ($\chi 2 = 6.61$, df = 1, $p<.002$).

4. Clinical characteristics of clients referred with anger problems i.e. gender, comorbid problems, anger in/out and forensic history

Gender

Overall, more females were referred to the department than males (57% female referrals). However, the opposite pattern was shown in the anger referrals with males making up 73% of the anger referrals. This difference was significant ($\chi 2 = 13.18$, df = 1, $p<.001$).

Comorbid Problems

Fifty four percent of people referred with anger problems were also experiencing other mental health problems. The level of comorbidity was similar between sectors (City = 63.6%, Mid = 61.5%. Easterhouse = 53.8%). Problems associated with anger referrals include alcohol/substance abuse (N=6), depression (N=6), anxiety (N=6), PTSD (N=2), relationship/marital problems (N=2), learning disability (N=1) and psychosis (N=1).

Anger In/Out

Ninety one percent of referrals of people with anger problems describe anger that is expressed towards individuals or the environment, rather than suppressed. Therefore the vast majority of referrals were in the 'anger out' category. This information is based on 34 out of the 37 referrals. Comments describing expressed anger problems include: 'violent outbursts', 'loses temper with family' and 'destroys property'. This level was similar across all sectors.

Forensic History

Twenty four percent of people referred with anger problems had a forensic history mentioned in the referral letter. This information is based on 34 out of 37 referrals. This comprised 2 referrals to the City, 3 referrals to the Mid and 3 referrals to the Easterhouse sectors.

Requesting Anger management

It was also noted which referrals of people with anger problems were specifically requesting Anger Management (AM) services. This information is also based on 34 out of 37 referrals. 68% of referrals specifically requested AM. This frequency of requests for AM was higher in the Easterhouse sector (83%) than in the Mid (58%) or City sectors (60%).

Discussion

Service Need

This study has determined the service need for patients with anger problems in adult psychology in East Glasgow. Anger problems make up 8% of total referrals, which is less than anxiety, depression and PTSD, but more common than other mental health problems such as eating disorders, sleep disorders, psychosis and intellectual impairment. Clients experiencing anger constitute a considerable component of patients seen in clinical practice, and this has implications for psychologists working in East Glasgow. The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, APA, 1994) lacks a specific anger diagnosis. Problems with a DSM classification are more easily diagnosed and measurable than unclassified problems. This may partly explain why there is only a small literature on managing anger problems in clinical practice. Psychologists are therefore likely to be more familiar with treatment approaches for problems that have a DSM diagnosis, such as eating disorders, than anger problems. Psychologists in East Glasgow can now be made aware that

they are actually very likely to encounter patients with anger problems and therefore acquaint themselves with approaches to dealing with anger e.g. through continuing professional development (CPD) workshops.

Treatment Implications

Now that a service need has been identified, the question arises regarding how best to manage the clients with anger problems referred to the department. The department could continue to treat anger problems on an individual basis. However, there is increasing evidence that group approaches can be employed to address problematic anger in adult psychology departments (Mayne & Ambrose 1999, O'Loughlin et al. 2004). These groups are either based on a Cognitive Behavioural Therapy (CBT) (Siddle et al. 2003), or on a psycho-educational approach akin to White's Anxiety and Stress Groups (White, 2000). An anger management group would be an evidence-based approach to managing the service need. Alternatively, some clients with anger problems may be suitable for the Stress Management Group that is currently run within the department.

One noteworthy caution in planning services for patients with anger problems is the considerable non-attendance rate. Siddle et al. (2003) reported that 41% of patients referred with anger problems did not attend their first appointment and only 9% of those referred attended for the whole course of CBT. In effect, it is likely that the actual service need for these patients is less than indicated by the number of referrals.

Clinical Characteristics

The clinical characteristics of patients referred with anger problems also have implications for practice. Patients are significantly more likely to be male, typically present with comorbid problems, such as alcohol abuse, and are also likely to express their anger towards others

(anger out). One quarter of those referred with anger problems also had a forensic history. They therefore fit with the clinical challenges associated with anger problems described in the literature (Kay et al. 1988, O'Loughlin et al. 2004), and with the characteristics of patients that are typically met with therapeutic pessimism (Renwick et al. 1997). They also fit with the concerns held by members of staff in the department, which were that the client may have anger that was directed towards others in the environment and that the client may have a forensic history.

Methods of addressing staff concerns should therefore be considered. A teaching session from a forensic clinical psychologist could be arranged at a team meeting, and team meetings could also refresh team members on general safety procedures. It may also be worth considering training interested members of the department in risk assessment, or considering joint assessments when seeing a client referred with expressed anger problems.

Referral Patterns

Anger referrals were more frequent in the Easterhouse and Mid-sectors than the City-sector and this fits with the experience of clinicians in the department. Almost two thirds of referrals of people experiencing anger problems specifically requested Anger Management (AM). The closure of the Douglas Inch AMFT service means that referrals for AM have to be dealt with within the East Psychology Department and the lead clinicians must decide whether they can provide an AM service. This is especially important in the Easterhouse sector, which received the highest percentage of people referred specifically for Anger Management.

Overall, GPs referred people with anger problems more than CMHTs. There was a smaller difference in the frequency of GP and CMHT referrals in the Mid-sector. It may be that psychology involvement in the CMHTs in the City and Easterhouse sectors has resulted in

greater awareness of the type of services provided by the psychology department, whereas there has been less involvement from psychology in the Mid-sector CMHT, as there had been an unfilled post in there for some time.

There are a number of ways the department could utilise the information gathered by this study to influence referral patterns. More information could be provided to GPs in the area with regards to the types of intervention offered to clients with anger problems and what constitutes an appropriate referral. This may be particularly appropriate in the Easterhouse sector where the number of referrals from GPs of people with anger referrals was particularly high. Additionally, the newly appointed psychologist in the Mid-sector could address any queries held by the CMHT as to what constitutes an appropriate anger referral and what type of intervention may be appropriate.

Limitations

One of the limitations of this study was that problems were classified using referral letters. There are some disadvantages associated with using referral letters. Using referral letters means that the number of people with anger problems calculated in this study is an estimation that may either under-reflect or overestimate problematic anger, e.g. patients may not view their anger as problematic and therefore not mention it to their GP, or, GPs may view anger management as an appropriate way to view a clients difficulties where the underlying problem may be relationship difficulties. Similarly, the number of people being referred with a forensic history is also an estimate.

Other limitations include the sampling of referrals i.e. only 85% of those referred to psychology were reviewed in this study. The remaining referrals were either temporarily unavailable or already assigned to treatment. It is important to note that referrals assigned to

early treatment may have differed from the remaining population in terms of urgency but it is not thought that this has impacted on the estimation of anger referrals.

The study's findings have limited generalisability. It is specifically designed to assess the needs of the psychology department in East Glasgow. However, it does raise issues that are relevant to other psychology departments in Glasgow as the closure of the Douglas Inch Anger Management Fast-Track system means that all psychology departments in Glasgow have more responsibility for managing anger referrals.

Action Points

The results of the study were shared with the team at a departmental meeting. Appendix 1.2 contains details of the action plan. Possible interventions suggested by the findings of the study include:

- Staff teaching on managing clients with anger problems and conducting risk assessment.
- Developing an anger management group.
- Screening clients with anger problems for the Stress Management Groups.
- Liasing with referrers to improve knowledge of the services provided and what information to include in referral letters.

Future Research

A future study could audit the number of clients with anger problems actually being seen in clinical practice by gathering information from clinicians. The success of the interventions suggested by this study, such as the Anger Management group, should be audited at a future date.

Conclusions

This study has identified that the department of clinical psychology in the east of Glasgow receives a considerable number of referrals of people with anger problems. It has also identified the clinical characteristics and referral patterns of patients. A number of suggestions arise from this study including liasing more closely with referrers and developing new ways of managing patients with anger problems.

References

American Psychiatric Association (1994). *Diagnostic and statistical manual of mental disorders (4th ed.)*. Washington, DC: American Psychiatric Association.

Blackburn, R. (1993). *The psychology of criminal conduct.* Chichester: Wiley.

Chemtob, C.M., Novaco, R.W., Hamada, R.S., Gross, D.M., Smith G. (1997). Anger regulation deficits in combat-related post-traumatic stress disorder. *Journal of Traumatic Stress*, 10, 17-36.

Cunningham, J., Connor, D.F., Miller, K., Melloni R.H. (2003). Staff survey results and characteristics that predict assault and injury to personnel working in mental health facilities. *Aggressive Behaviour*, 29, 31-40.

Howells, K. Cognitive behavioural interventions for anger, aggression and violence. In Tarrier, N., Wells, A. and Haddock, G. (1998) *Treating complex cases: the cognitive behavioural therapy approach.* Chichester: Wiley.

Kay, S., Wolkenfield, F., Murrill, L. (1988). Profiles of aggression among psychiatric patients II. Covariates and predictors. *The Journal of Nervous and Mental Diseases*, 176, 547-57.

Levy, S. and Howells, K. (1991). Anger and its management. *Journal of Forensic Psychiatry*, 1(3), 305-327.

Mayne, T.J. and Ambrose, T.K. (1999). Research Review on Anger in Psychotherapy. *Journal of Clinical psychology,* 55(3), 353-363.

Munro, F. and Macpherson, G. (2002). Anger Management Fast Track: a waiting list initiative utilizing a large group format. *Clinical Psychology Forum*, 147, 30-34.

Novaco, R.W. (1997). Remediating anger and aggression in violent offenders. *Legal and Criminal Psychology*, 2, 77-78.

O'Loughlin, S., Evans, E. and Sherwood, J. (2004). Providing an anger management service through psychoeducational classes – and avoiding therapy. *Clinical Psychology*, 33, 17-29.

Ramm, M. and Novaco, R.W. (2002). Presentation at South of Scotland Cognitive Behavioural Therapy course, Edinburgh.

Renwick, S.J., Black, L., Ramm, M. and Novaco, R.W. (1997). Anger treatment with forensic hospital patients. *Legal and Criminological Psychology*, 2, 103-116.

Siddle, R., Jones, F. and Awenat, F. (2003). Group cognitive behavioural therapy for anger: A pilot study. *Behavioural and Cognitive Therapy*, 31, 69-83.

Speilberger, C.D. (1979). *Stait-Trait Anger Expression Inventory :* Professional Manual: Psychological Assessment Resources Inc.

Speilberger, C.D., Jacobs, G., Russell, S., & Crane, R.S. (1983). Assesment of anger : The Stait-Trait Anger Scale. In J. N. Butcher & C. D. Speilberger (Eds.), *Advances in personality*

assessment (pp. 161-189). Hillsdale, NJ : Erlbaum.

Urquart, G. (1997). EPPIC project: community case dataset development in Scotland – implications for health care professionals. *British Journal of Occupational Therapy*, 60(1), 29-32.

White, J. (2000). *Treating Anxiety and Stress: A group psycho-educational approach using brief CBT.* Chichester: Wiley.

Figure 1 Spectrum of Referrals

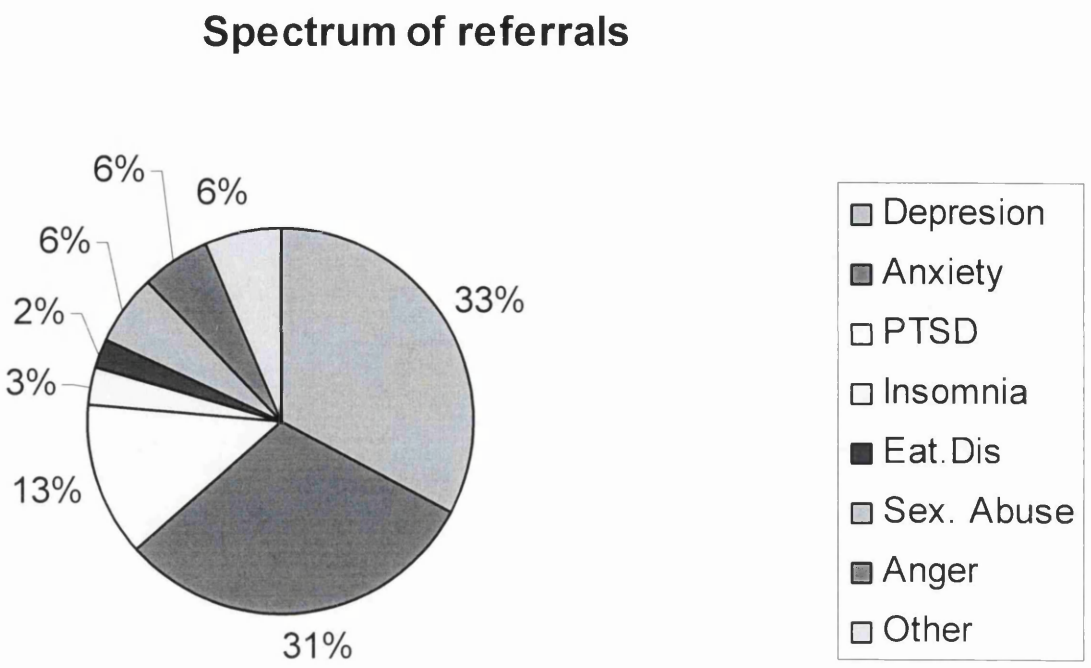

Table 1 Frequency and percentage of anger referrals by sector and referrer

	City		**Mid**		**Easterhouse**	
	Number	**Percentage**	Number	**Percentage**	Number	**Percentage**
Total	11 (184)[1]	**5.9**	13 (136)	**9.6**	13 (155)	**8.4**
GP	9 (118)	**7.6**	9 (91)	**9.9**	12 (91)	**13.2**
CMHT	2 (66)	**3.0**	4 (45)	**8.9**	1 (64)	**1.6**

[1]Numbers in parentheses indicate total sample.

The role of beliefs about medicines in adherence to pharmacological treatment of chronic illness: A systematic review of the literature

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Running title: Review of beliefs about medicines and adherence

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ABSTRACT

Objectives: This paper reviews the psychometric properties of the BMQ, with a particular focus on the strength of the relationship between BMQ scales and adherence to medicines in chronic illness populations.

Data Sources: Electronic searches of the databases: CDSR, MEDLINE, PsychINFO, EMBASE, CINAHL and Google Scholar were conducted. Hand searches were also conducted on three key journals and reference lists of related articles.

Study Selection and Data Extraction: Studies were included when participants were reported as suffering from a chronic illness, were taking medication for that illness and were adults. Studies were published in a peer-reviewed journal, adopted the Beliefs about Medicines Questionnaire to measure treatment beliefs and employed a measure of adherence. Information on reliability, validity and relationship to adherence in bivariate and multivariate analyses were extracted. Methodological issues that may impact on findings were also extracted.

Results: Seventeen studies were included in this review. Studies were too heterogeneous to warrant meta-analysis. The Necessity Scale was significant in 71% of bivariate analyses, had the largest effect sizes and remained a significant predictor in all but one of the multivariate analyses it was entered into. The Concerns Scale was significant in fewer bivariate analyses (58%), had smaller effect sizes and remained significant in fewer regression analyses (43%). The general scales were less strongly associated with adherence in bivariate and multivariate analyses than the specific scales.

Conclusions: Specific scales in the BMQ were found to be associated with adherence in theoretically valid and reliable ways. The Necessity Scale was more strongly related to adherence than the Concerns Scale although there were differences between illness populations. The BMQ general scales were less strongly associated with adherence but have been adopted in fewer studies so limited conclusions regarding their association with adherence can be drawn. The results suggest that peoples' beliefs about medicines are related to adherence. Research now needs to focus on investigating if adherence can be improved by interventions designed to restructure beliefs about medicines.

Key phrases: Beliefs about medicines questionnaire, medicine beliefs, self-regulatory model, adherence

INTRODUCTION

The role of beliefs about medicines in adherence

The prescription of medication is one of the most common forms of modern treatment yet average adherence rates to these medicines have been estimated at a modest 50% (Sackett & Snow, 1979; Millar, 1997), substantially reducing treatment effectiveness (Rogers & Bullman, 1995). Despite this finding, health professionals and pharmaceutical companies have tended to focus on improving the range of medicines available, and efforts to improve adherence have been largely neglected (Shaw, 2003). As the number of effective self-administered treatments increase, the need for a better understanding and management of the factors determining adherence intensifies.

There is no consensus on the factors that best predict adherence. However, the literature currently advocates differentiating between intentional and involuntary non-adherence. Involuntary non-adherence concerns patients failing to follow recommendations because they forget to take them or they do not understand instructions. Intentional non-adherence relates to patients deciding not to take medication as prescribed, in other words, the patient's adherence behaviour is governed by a rational decision (Weintraub, 1990).

Interventions to improve adherence have focused on both non-intentional and, to a lesser extent, intentional adherence (Haynes, McKibbon & Kanani, 1996; McDonald, Garg, & Haynes, 2002). Interventions have ranged from very simple i.e. changing dosing schedule, to complex combinations of techniques (e.g. counselling, patient leaflets, telephone follow up and support group, Bailey, Richards & Brooks, 1990). A recent review concludes that there is little evidence that conventional interventions are effective, or even cost effective, and calls for innovative approaches to improving adherence (McDonald et al. 2002). Few of the studies included in the review expressly focus on intentional non-adherence. None focused

specifically on patients' beliefs about their medicines or illness, although they did provide education on illness and medicines, which may have indirectly altered beliefs.

Shaw (2003) proposes that it is patient's beliefs that govern their adherence behaviour and the present challenge for health professionals is to create an environment that respects patients' personal decisions as well as professional expertise. This opinion has been substantiated by a burgeoning literature on patients' beliefs about illness and treatment. The self-regulatory model (Leventhal, Deifenbach & Leventhal, 1992) is one of a number of models developed in the health psychology literature to explain how psychological factors influence adherence behaviour. The self-regulatory model proposes that the patient's perceptions of their illness affect the way they take their medication. Patients' illness perceptions have been operationalised in the 'Illness Perceptions Questionnaire' (Weinman, Petrie, Moss-Morris & Horne, 1996) and have been successfully used to assess illness perceptions in a range of illnesses. Hagger and Orbell (2003) recently reviewed the evidence and concluded that illness perceptions are indeed related to adherence.

In recent years it has been suggested that including a measure of patients' medication beliefs could increase the value of the self-regulatory model in explaining adherence behaviour. The literature had historically suggested that medication beliefs were also related to adherence (see Horne, 1997 for a review) but there could not be comparisons made between studies, as these beliefs had not been measured in any standardised way. Horne, Weinman and Hankins (1999) published the 'Beliefs about Medicines Questionnaire' (BMQ) to provide a standardised way of measuring treatment beliefs. There have since been a substantial number of authors adopting the BMQ to measure beliefs about medicine in a regimented manner.

Description of the BMQ

Horne et al. (1999) published data on the psychometric properties of the BMQ and it has been used in over 20 studies since. It is an 18-item questionnaire designed to assess the views a person has about their medicines (see Appendix 2.2 for full measure). The questionnaire includes 2 sections:

1) The 'specific' section contains two 5-item scales measuring the concerns one has with specific medication and the perceived necessity of medicines prescribed for a particular condition. An example from the necessity scale is: "My health, at present, depends on my medications". An example from the concerns scale is: "I sometimes worry about the long-term effects of my medicines".

2) The 'general' section measures general views about medicines as a whole. It contains two 4-item scales measuring beliefs about the harms associated with medications and beliefs that doctors overuse medicines. An example from the harms scale is: "Medicines do more harm than good". An example from the overuse scale is: "Doctors use too many medicines".

Some studies have combined the BMQ specific scales or general scales into a differential. This is interesting as it relates to models of health behaviour proposing that people weigh up the costs and benefits of health behaviours. For example, patients may consider their beliefs regarding the necessity of their medication in relation to their concerns before deciding whether or not to take the medication.

Application of the BMQ

The BMQ was originally validated on a population of people taking medicines for different health conditions (asthma, renal, cardiac, general medical, diabetes and psychiatric) and compared with people seeking allopathic and complementary treatments. It has since been used on a wider population range including other clinical populations such as HIV and renal transplant patients (e.g. Gellaitry, Cooper, Davies, Fisher, Leake & Horne, 2005; Butler, Peveler, Roderick, Smith, Horne & Mason, 2004) acute conditions (e.g. Bekker, Gough, & Williams, 2003; Lam, Stevenson, Britten & Leventhal, 2001) and healthy students (e.g. Horne, Frost, Hankins & Wright, 2001; Horne, Graupner, Frost, Weinman, Wright & Hankins, 2004).

Although the BMQ is being applied in a wider range of populations, Horne et al. (1999) suggest that beliefs may differ between chronic and acute illness conditions, for example, beliefs about the necessity of medicines are stronger in chronic illness populations than in populations suffering form more acute conditions. Therefore, in order to increase homogeneity and improve comparability of findings between studies it was decided that this review should focus on chronic illness populations only.

Importance of predictive validity

Criterion validity has the closest relationship to what is intuitively believed to be validity. Nunnally (1967) has described criterion validity as "at issue when the purpose is to use an instrument to estimate some important form of behaviour that is external to the instrument itself, the latter being referred to as the criterion". Therefore, one of the most important questions to assess in reviewing the psychometric properties of a measure is the relationship between the measure and the criterion. In this case the criterion is how the BMQ relates to adherence behaviour.

The growing number of studies using the BMQ to measure adherence means it is difficult to assess the available evidence. Systematic reviews can helpfully synthesise the evidence and provide clear and unbiased overviews (Dickson & Entwistle, 1996). This is the first review to focus on how the BMQ scales relate to adherence.

Inclusion/Exclusion Criteria

Studies were included if:

1) Full study details were published in a peer-reviewed journal.
2) Participants were suffering from a chronic illness and were taking medication for that illness. In this review chronic illness was defined as an illness lasting more than three months in line with common medical practice.
3) Beliefs about medicines were measured using the BMQ.
4) Adherence was measured by self-report or objective measures.
5) The relationship between the BMQ and measures of adherence were reported.
6) Participants were over 18 years of age. This criterion was adopted as younger individuals may have assistance with adherence to medicines and this could affect the relationship between medication beliefs and adherence.

Studies were excluded if:

1) The BMQ was altered and the study authors did not report at least minimal psychometric data on the altered measure.

Review Objectives

This paper will review the psychometric properties of the BMQ, with a particular focus on the strength of the relationship between BMQ scales and adherence to medicines in chronic illness samples.

METHODS

Search Strategy

1) An electronic search was conducted of the following electronic databases for the period 1999 (date of publication of the BMQ) to October 2005: CDSR, DARE, CCT, CINAHL, EMBASE, MEDLINE, PsychINFO and Google Scholar.

2) Key search terms included: [BMQ] or [belief$ about medicine$] or [beliefs about medication] or [medication representation$] or [medicines and beliefs] or [self-regulatory model] or [common sense model] or [illness perception$] or [illness perceptions questionnaire].

3) Papers published by the original BMQ authors were also reviewed (Horne R, Weinman J and Hankins M).

4) Hand searches on the following relevant journals were also conducted for the same time period: British Journal of Health Psychology, Psychology and Health, Psychology, Health and Medicine.

5) Reference lists of included papers were also scanned for suitable papers.

6) Conference presentation abstracts were not included, as the full papers had not been subjected to the peer review process (Sharpe, 1997), which would have provided some reassurance regarding minimal levels of study quality. Time constraints made it difficult to guarantee locating unpublished data sets and these were also excluded. This review therefore focuses on published literature. However, it is acknowledged that reviewing published data only may introduce biases in the review conclusions. These potential issues are addressed later.

Computerised Search

The initial search identified 1062 potential papers for inclusion in the review. This was reduced to 714 once limited to English and humans then duplicates removed. Based on title and abstract alone, 679 were excluded. This left 35 papers that were reviewed in more detail. Agreement was reached between the reviewer and an independent rater (also undertaking doctorate level training) on studies that fulfilled the above inclusion criteria (see Figure 1 for details of the exclusion procedure). As a result of this process 17 studies were retained for inclusion in this review.

Insert Figure 1 here

Other search procedures

Other search procedures adopted did not result in any additional papers that matched the inclusion criteria indicating that the search criteria used were comprehensive.

Evaluation of Study Quality

There is debate regarding which critical appraisal tools are most appropriate for which research design. A recent review of critical appraisal tools (Katrak, Bialocerowski, Massy-Westropp, Kumar & Gimmer, 2004) concluded that there is no 'gold standard' critical appraisal tool for any type of research, and there are few specific guidelines for cross-sectional observation studies such as those included in this review. Studies were therefore evaluated using criteria adapted from the Scottish Intercollegiate Guidelines Network (SIGN) 'Guideline Developers' Handbook' (Scottish Intercollegiate Guidelines Network, 2004).

Additionally, because of the design of these studies, there are few criteria that automatically preclude the study from being used as evidence. The criteria were used to determine the level of confidence in the findings of the study. The studies were rated according to 24 facets of design quality and possible scores ranged between 0 and 26. Papers were then ranked according to their percentage score and assigned to one of four quality categories (see Appendix 2.3).

An independent rater (as above) evaluated half of the studies. 100% agreement was reached between reviewer and the independent rater following discussion. The majority of included studies were rated A (65%). No studies were rated D (The findings of the study are thought likely or very likely to be affected by study quality).

Data Extraction

The following data were extracted from included studies:

1) The reliability and validity of the BMQ.

2) The bivariate correlation between the BMQ scales and adherence to medicines.
3) Variables inputted into regression analyses and significant findings.
4) Methodological issues that may limit generalisability of findings.

RESULTS

Results begin by giving an overview of the characteristics of included studies. Findings regarding the reliability and validity of the measure and the relationship between BMQ scales and adherence are then presented, focusing firstly on the specific scales individually, then combined specific scales and, lastly, the general scales.

Due to the observational nature of the studies included in this review, it was decided that a meta-analytic approach would not be adopted as the number of sources of heterogeneity can result in spurious findings (Egger, Davey-Smith & Schneider, 2001).

Characteristics of Included Studies

Characteristics of the 17 studies included can be found in Table 1.

Insert Table 1 here

Study Design

All 17 studies included in this review are of cross sectional design.

Sample

The total number of participants in each study ranged from 43 to 1084. Thirteen studies had under 200 participants, with a mean of 81 participants. The other four studies had large samples (Horne et al. 1999; Ross, Walker & MacLeod, 2004; Byrne, Walsh & Murphy, 2005; Neame & Hammond, 2005). Samples included fourteen chronic illnesses ranging from common disorders such as Asthma and Diabetes to conditions that are relatively rare, such as Marfan Syndrome and Haemophilia. The mean age for participants ranged from 36.4 to 74.2.

Beliefs about Medicines Questionnaire

Sixteen studies used the specific scales (necessity and concerns) of the BMQ. The general scales have been looked at less often in relation to adherence (47% studies). Four studies altered the number of items in the subscales (Webb, Horne & Pinching, 2001; Horne & Weinman, 2002; Butler et al, 2004; Horne, Buick, Fisher, & Leake, 2004). The number of items in scales is detailed in Table 1. These papers report that internal reliability was not impaired by altering scale items. One paper (Butler et al. 2004) added a 'Benefits' scale to the general section of the BMQ following discussion with the BMQ's original authors. This scale was not described in the paper. It was significantly associated with adherence in a bivariate analysis but was not significant in regression analyses. It is not considered in any more detail in this review.

Measures of adherence

Studies used a number of different measures of adherence. Fifteen studies used a self-report measure of adherence and in three studies this measure was a single item (Horne, Sumner,

Jubraj, Weinman & Frost, 2001; Maidment, Livingstone & Katona, 2002; Neame & Hammond, 2005). One study (Byer & Myers, 2000) used objective measures in addition to self-report (prescription uptake) and another (Llewellyn, Miners, Lee, Harrington, & Weinman, 2003) used adherence diaries as an outcome measure. Only one study (Butler et al. 2004) used solely objective measures of adherence (electronic monitoring).

Other variables measured

Six studies (Horne et al. 1999; Byer & Myers, 2000; Peters, Horne, Kong, Francomano & Biesecker, 2001; Horne & Weinman, 2002; Llewellyn et al. 2003; Butler et al. 2004) included the Illness Perceptions Questionnaire (IPQ) and a further two (Ross et al. 2004; Byrne et al. 2005) used the revised version of the IPQ (Moss-Morris, Weinman, Petrie, Horne, Cameron & Buick, 2002). The IPQ has been developed to encapsulate the illness perceptions dimensions of the self-regulatory model. It contains five dimensions measuring identity, timeline, consequences, causal factors and control/curability of the illness. It is particularly relevant to review the BMQ in relation to the IPQ in order to test whether the BMQ adds to the variance explained by illness perception variables. Other, less commonly used, scales are described in Table 1.

Reliability and Validity of the Measure

Reliability

A review of any measure needs to consider its psychometric properties. Scales demonstrated adequate to good internal reliability as measured by Cronbach's alpha. The range and average of Cronbach's alphas (computed by D-STAT, Johnson, 1989) is given in Table 2. Test-retest reliability (repeated measure after two weeks) is given as measured in the original validation study (Horne et al. 1999). It has not been examined in any of the other included studies. The

factor structure of the measure was also explored in the original validation paper but has not been evaluated in any study since.

Insert Table 2 here

Validity

Discriminant validity has been assessed in a number of studies demonstrating that the specific scales are independent from each other in simple bivariate correlational tests (Treharne, Lyons & Kitas, 2004; Aikens, Nease, Nau, Klinkman & Schwenk, 2005; Byrne et al. 2005) and in structural equation modelling (Horne & Weinman, 2002). This illustrates that they are tapping into different constructs and are not just different ends of the same spectrum. The correlation coefficients between the general subscales have been computed less frequently but studies report moderate levels of association between the general harm and overuse scales indicating that they may be tapping into the same construct (Webb et al. 2001; Treharne et al. 2004; Byrne et al. 2005). Only two papers assess the degree of relationship between the specific and general subscales finding a moderate degree of intercorrelation between them. A negative correlation was found between necessity and the general scales, fitting with the hypothesised direction (Horne et al. 1999; Treharne et al. 2004). However, further reporting of the relationships between the subscales and, ideally, testing of the general and specific scales in confirmatory factor analysis is required before conclusions regarding their interdependence can be drawn.

The means, variance and distribution of scores for each subscale were also examined in relation to discriminant validity. Figure 2 provides a pictorial representation of the distribution of beliefs across illness populations. The numbers in brackets in the legend of Figure 2 identify the study as reported in Table 1. Scales have a minimum score of 0 and a

maximum score of 5. There was substantial variance in mean scores between different illness populations. This would be expected given the diversity of illnesses studied. The specific subscales had the largest range of mean scores (Fourteen papers: necessity 1.68[.56] - 4.28[1.21]; concerns 2.26[.53] - 3.8[.86]) whereas there was less variation between mean scores on the general subscales (Five papers: harms 1.42[.48] - 2.1[.57]; overuse 2.12[.51] - 2.28[.80]).

Insert Figure 2 here

Around a third of included studies reported the proportion of subjects scoring over the mid-point on the specific section (Horne & Weinman, 1999; Horne et al. 2001; Horne & Weinman, 2002; Butler et al. 2004; Horne et al. 2004; Neame & Hammond, 2005) and even fewer reported details for the general sections (Horne et al. 2001; Webb et al. 2001). Where details were reported, a substantial percentage of participants scored above the midpoint on the necessity scale (71 - 97%), whereas there were smaller percentages reported for the other scales (concerns; 23 – 52%, harms; 33-34%, overuse 12-60%), indicating that responses on the necessity scales may be positively skewed. However, studies did not report skewness statistics and, as many studies failed to report any details regarding skewness, limited conclusions regarding distribution of scores can be drawn.

The difference in treatment beliefs between illness populations is an area that is not well developed. Only Horne & Weinman (1999) compare the means of different illness conditions within one study. They found significant differences in beliefs between illness conditions i.e. asthmatic patients had stronger concerns about medication than oncology, renal and cardiac patients. They also note that these asthmatic patients also had significantly lower adherence

to medication. The relationship between medication beliefs and adherence are explored further below.

Summary

- The BMQ exhibits satisfactory reliability and validity although further testing and reporting of some aspects of reliability and validity is required.
- There is substantial variation in mean scores across different illness populations although these have only rarely been systematically investigated. More studies should investigate the differences in treatment beliefs by comparing illness groups within one study.

Relationship Between Adherence and the BMQ

The ability of the BMQ to predict adherence in theoretically viable and systematic ways is arguably its most useful function. If beliefs about medicine are related to adherence behaviour then perhaps intervening in order to change these beliefs could improve adherence. The results of the relationships between BMQ scales and measures of adherence are summarised in Table 3 along with effect sizes (ES), significance values and details of regression analyses.

Insert Table 3 here

Bivariate Analyses

Effect size was categorised according to Cohen's (1992) conventions. For correlation coefficients the index of ES was Pearson's product-moment correlation coefficient (miniscule $> .0$, small $\geq .1$, medium $\geq .3$, Large $\geq .5$). Where statistics were not reported as correlation coefficients they were converted from other test statistics, where these were available, using

the DSTAT package (Johnson, 1989). Statistically significant results are reported, as are non-significant results as some studies may have been underpowered. Results were classified as incalculable where papers did not report details of analyses (sometimes these were simply absent, on other occasions it was because results were just reported as non-significant).

A number of papers have more than one analysis i.e. look at more than one population or compare scales against different measures of adherence. These analyses were looked at separately. There are 24 individual analyses for the specific scales and 8 for the general scales in the seventeen papers reviewed.

Multivariate Analyses

BMQ subscales have been entered into regression analyses in 53% studies, although the general subscales were only entered in 18% of studies (as detailed in Table 3). The BMQ scales were entered into regression analyses along with demographic, clinical and illness perception variables although these combinations differed and were sometimes not fully reported. Regression analyses give some indication of the power of the BMQ to predict adherence when potential confounding variables are controlled for. However, different types of regression models were tested, making comparisons between analyses difficult. These different models are each described within the relevant sections.

Results are explored for specific scales individually, combined specific scales and general scales in turn. Discussion focuses first on bivariate analyses before multivarariate analyses. One study has used Structural Equation Modelling to investigate whether or not the BMQ scales mediate between variables from the self-regulatory model in their impact on adherence. This paper is discussed at the end of the results section.

Effect Size in Bivariate Analyses

Necessity is commonly found to be strongly associated with adherence (significant in 71% of analyses). There were 3 large effect sizes for the necessity subscale, 8 medium, 7 small, 2 miniscule and 4 were incalculable. The largest effect sizes were found in studies using an objective measure of adherence. The grounds for the null results are not easy to identify but may be related to shorter measures of adherence. Most of the studies with null results measure adherence using four items or less in self-reported measures and one study used a single item measure of adherence (Horne et al. 2004). There was also a tendency for studies with larger sample sizes to have smaller effect sizes.

Regression Analyses

The necessity scale remained a significant predictor of adherence in six of the seven regression analyses it was entered into. Maidment et al. (2002) found necessity was significant at the bivariate level but it was dropped in a backward stepwise regression where concerns and other variables were significant (as described in concerns section below). Where necessity was significant, two studies used logistic regression, one used forced entry analyses and three used hierarchical regression and these results will be presented in turn.

Logistic Regression

Ross et al. (2004) employed multiple logistic regression and found age, BMQ specific necessity and two elements of the IPQ-R (emotion and personal control) were most predictive of adherence in a population of hypertension patients. This study indicates that aspects of the self-regulatory model i.e. illness perceptions, as well as beliefs about the necessity of medicines, are associated with increased levels of adherence. They also looked at factors

associated with specific beliefs. BMQ necessity beliefs were best predicted by a model consisting of: three aspects of the IPQ-R (namely perceptions of time, consequences of illness and perceptions of cure) as well as age and number of medicines. The authors suggest that medication beliefs may mediate the relationship between some illness perceptions, age and adherence. This study was rated A in quality evaluation, it had a good sample size and the study population was representative of patients attending hospital clinics.

Butler et al. (2004) entered only those variables that were significant in a bivariate screening analysis into a logistic regression model for patients with renal transplants. They found a transplant from a live donor, low BMQ necessity for immunosuppressants as a group and low BMQ necessity for Prednisolone specifically were associated with non-adherence. This study was rated A in terms of quality and used electronic monitoring to measure adherence, however the sample size was small (58) compared to the large number of variables studied.

Forced Entry Regression

Llewellyn et al. (2003) looked at two types of adherence in Haemophiliac patients – adherence to prophylactic treatment and adherence to dose on-demand treatment. Variables were entered into regression using the forced entry method. For both types of adherence their initial regression model, which included all variables (demographic, clinical, illness perceptions and specific BMQ scales) was not significant (see Table 3). However, the variance in prophylactic treatment adherence was partially explained by BMQ necessity (19%) and IPQ Identity (14%) and a model containing these variables only was significant. Adherence to on-demand treatment was only predicted by age (12% variance) and not by BMQ scales.

The results from this study indicate that haemophiliac patients who had stronger perceptions of the necessity of treatment were more likely to be adherent despite concerns over the use of clotting factor. However, it also showed that age had a strong influence on certain types of adherence. This study was rated B in terms of quality. The sample size was small (65) for the number of variables measured and the study population was significantly different from the clinic population (authors report respondents were significantly older and more likely to be HIV positive).

Hierarchical Regression

Treharne et al. (2004) used hierarchical regression analyses to investigate variables related to adherence in patients with rheumatoid arthritis. Three demographic and clinical factors were entered into the first analysis (children at home, taking steroid medication and total number of medications) explaining 21% of the variance in adherence to rheumatology medications. Seven psychosocial factors accounted for an additional 43% of the variance. These included three aspects of satisfaction with the medical consultation and the four BMQ scales. Out of these variables, total number of medicines, increased BMQ necessity and lower BMQ overuse beliefs were most associated with the variance in adherence. This study was rated A, however it had a comparatively small sample size for the number of variables investigated (85).

Byrne et al. (2005) also used hierarchical regression analyses to determine variables associated with adherence in patients with coronary heart disease. They controlled for demographic and clinical variables in step 1, illness perceptions in step 2 and medication beliefs (specific and general) in step 3. They found that older age, eligibility for free health care (including prescriptions) and IPQ-R chronic timeline were significant until the addition of the BMQ. They concluded that illness perceptions were very weakly associated with

treatment adherence (explaining around 1% of the variance) and there was a small to medium effect of medication beliefs on adherence (accounting for about 7% of the variance in adherence scores). This was the study with the largest sample size in the review (1084 participants) and was rated A in terms of its quality.

Horne and Weinman (2002) entered 12 variables into a hierarchical regression analysis based on data from a sample of asthma patients. Demographic variables (age, gender, educational status) explained 6% of the variance in adherence. Clinical factors (number of visits to GP, number of hospital admissions, duration of asthma did not add anything to the variance. Illness perceptions (IPQ identity, timeline, consequences and cure-control scales) added another 13% with medication beliefs (BMQ necessity and concerns) adding a further 17%. The authors observed that specific BMQ scales added to the variance explained on top of illness perceptions, supporting an extended self-regulatory model that includes beliefs about medicines. The authors continued their analysis of the data by looking at relationships using structural equation modelling, described in more detail below.

Summary

- Overall, the necessity subscale remains a significant predictor of adherence after controlling for possible confounding variables.
- It has been suggested that the BMQ necessity scale may mediate the relationship between some illness perceptions, age and adherence.

Effect Size in Bivariate Analyses

More mixed results have been found between adherence and the BMQ concerns subscale. The concerns subscale was significantly related to adherence in 58% of analyses. There were no large effect sizes for the concerns subscale. There were 7 medium, 8 small, 2 miniscule and 6 incalculable effect sizes. Concern scores were not significantly related to adherence in six studies (Byer & Myers, 2000; Llewellyn et al. 2004; Barnes, Moss-Morris and Kaufusi 2004; Butler et al. 2004; Treharne et al. 2004; Aikens et al. 2005). These studies were adopting some of the more objective or substantial self-report measures of adherence.

Regression Analyses

The BMQ Concerns scale was significant in three out of seven regression analyses. As mentioned above, concerns regarding medication were significantly related to adherence, as well as necessity beliefs, illness perceptions and other variables, in both Byrne et al. (2005) and Horne and Weinman's (2002) analyses. Maidment et al. (2002) is the only study to find that medication concerns remained a significant predictor of adherence when necessity beliefs did not. They entered seven variables into a backwards linear regression model using data from a sample of depressed older adults. BMQ Necessity, the general health questionnaire (GHQ) and the Geriatric mental state schedule depression scale (GMSS-DS) were not significant in the model. The model, accounting for 27.1% of the variance in adherence to antidepressant medication, included BMQ concerns, a questionnaire on patient education (QPE), the Mini mental state examination (MMSE) and a global side-effect burden measure. Therefore concerns were more related to adherence than necessity in this population. This study was rated as B as there were some differences between respondents and non-

respondents (respondents were significantly younger), adherence was measured using one item, and sample size was small for the number of variables measured.

Ross et al (2004) investigated the variables that predicted medication concerns. This is perhaps surprising given that the authors found that the association between BMQ concerns and adherence did not remain statistically significant in their multivariate analyses (i.e. when age, BMQ Necessity and aspects of the IPQ were taken into account). However, they found that a model comprising of: BMQ harm, BMQ overuse, IPQ emotional response, IPQ consequences and age best predicted medication concerns. They suggest that general beliefs about medication may indirectly influence adherence through specific concerns. This is in line with the model proposed by Horne et al. (1999).

The finding that concerns were not strong predictors of adherence was contrary to some authors' expectations. Llewelyn et al. (2003) and Butler et al. (2004) were surprised that concerns about medication were not more strongly associated with non-adherence given the risk of infection using clotting factor or the side effects of immunosuppressants. They suggest that a salient belief in the need for the medication may overrule concerns about troublesome side effects.

Summary

- It appears that concerns about medicines are less strongly associated with adherence than necessity but they are more salient in some populations than others.
- Concerns are not predictably associated with adherence in conditions taking medication with greater side effects.
- It has been suggested that concerns may mediate the relationship between general BMQ scales and adherence.

Effect Size in Bivariate Analyses

Some studies have found a stronger association between adherence and the specific scales when they combine the necessity and concerns scales into a differential (NCD). A NCD was employed in 5 of the studies included in this review (Horne & Weinman, 1999; Peters et al. 2001; Horne et al. 2004; Aikens et al. 2005; Neame & Hammond, 2005). These five papers produced 9 separate analyses and in each of these the NCD was always found to be significantly associated with adherence (5 medium effect sizes, 3 small and one incalculable result).

Regression Analyses

A NCD was entered into two analyses and was significant in one (Horne & Weinman, 1999). Their stepwise linear regression model of adherence to medication across a variety of illness groups demonstrated that the necessity-concerns differential explained most of the variance (19%), followed by illness group (asthma and cardiac) and age. This paper was also evaluated as an A grade paper with a large sample overall and no evidence of bias in its sample. The NCD was not significant in Peters et al. (2001), where it was entered into a regression with age, palpitations, chest pain, headaches, BMQ harms, BMQ overuse and BMQ concerns. This study was rated as C on quality criteria. It had a reasonable sample size (174) but a poor response rate (50%) and any differences between the study population and the clinic population were not discussed.

Summary

• Initial investigations suggest that a composite of necessity and concern scores may be a helpful way of understanding cost-benefit decisions regarding adherence behaviour but, as it has been employed only infrequently, further analysis is required before firm conclusions can be drawn regarding its utility.

General Scales

Effect Size in Bivariate Analyses

The overuse scale was significantly related to adherence in 44% of analyses (Horne et al. 1999; Peters et al, 2001; Webb et al. 2001; Aikens et al. 2005). It had a medium effect size in 2 of these analyses, 3 small, 1 miniscule and 3 were incalculable. The harms scale was significantly related to adherence in 22% analyses (Peters et al. 2001; Treharne et al. 2004), producing 1 medium, 4 small, 1 miniscule and 3 incalculable effect sizes. A harms-overuse differential was not significant in the one study that had used it (Aikens et al. 2005).

Regression Analyses

The BMQ general harm subscale was a significant contributor in one out of three regression models (Peters et al. 2001), as was the BMQ overuse subscale (Treharne et al, 2004).

Peters et al. (2001) found younger age, increased palpitations and increased general harms to be the variables most strongly associated with adherence in patients with Marfan syndrome using multivariate analysis. In this study it appears the patient's beliefs about medicines in general as intrinsically harmful are most associated with adherence. The authors relate this finding to medicines being perceived as a threat to self-reliance and a reminder of the permanence of their medical condition. This study was rated C as discussed above.

Treharne et al. (2004) found the BMQ general overuse scale and not specific concerns predicted adherence for patients with rheumatoid arthritis. The authors suggest that participants may have played down the specific concerns about medicines because they believed they were necessary whilst maintaining beliefs that medicines are overused in general.

Summary

- These findings indicate that BMQ general scales are not strongly associated with adherence to current medication, however more studies are required to investigate the general scales in multivariate analyses before firm conclusions can be drawn.
- Patients' beliefs about medicines in general may not always be related to their beliefs about specific medicines.

Structural Equation Modelling

Although the BMQ has been entered into regression analyses and has been shown to add to the variance in predicting adherence, there are limitations to regression analyses that prevent fully testing the extent to which the data fit the predicted pattern of relationships between medication beliefs and adherence. All of the variables that are entered into a regression model are allowed to correlate with all of the other variables. Although this allows the researcher to rule out potential confounding between variables it can have unforeseen and unwanted effects. Even where independent variables do not correlate significantly, the small degree of overlap that does exist can introduce distortions into the model. Perhaps more frustrating for the analyst is when they theorise that some of the independent variables have their effects mediated through some of the other independent variables. In these instances, the

true importance of a variable can be obscured by the multiple regression approach, as only its unique contribution to the variance of the dependent variable is tested. Structural equation modelling, on the other hand, is superior to regression analyses as the analyst can specify precisely which variables are correlated and which are independent. It also allows for direct and indirect effects to be included thus enabling model specification that corresponds exactly to the theoretical model.

Horne and Weinman (2002) used structural equation modelling (SEM) to examine the relationships between illness perceptions and specific medication beliefs in explaining non-adherence to asthma medication. They demonstrated that the specific necessity and concerns scales influence adherence directly. They also found that the relationship between some illness perceptions and adherence were mediated by medication beliefs i.e. individuals who believed their asthma was a less chronic condition were less likely to believe in the necessity of their treatment, and were then less adherent to it.

The findings of Horne and Weinman's (2002) study are interesting as it suggests that illness perceptions may not appear significantly related to adherence in a regression analysis that included medication beliefs. It also suggests that regression analyses that enter illness perception variables before medication beliefs weaken the effect of medication beliefs e.g. Byrne et al. (2005). Taking their results one step further, their SEM implies that targeting an adherence intervention at changing illness beliefs will improve adherence by subsequently changing medication beliefs.

The Horne and Weinman (2002) study suggests that the strength of the self-regulatory model to explain adherence is improved by extending it to include medication beliefs, and provides preliminary empirical support for an extended self-regulatory model of treatment adherence.

Illness perceptions and beliefs about medicines have repeatedly been shown to affect adherence. Structural equation modelling allows the literature to move forward by demonstrating how these variables relate to each other. More studies are required in order to replicate these findings and also to expand this model further.

Summary

- Structural Equation Modelling provided further evidence that BMQ specific beliefs may medicate the relationship between illness perceptions and adherence.
- The model described in Horne and Weinman (2002) also suggests that the strength of the self-regulatory model to explain adherence is improved by extending it to include medicine beliefs.

DISCUSSION

This review set out to investigate the psychometric properties of the BMQ with particular emphasis on criterion validity i.e. how the BMQ scales are associated with adherence to medicines prescribed in chronic illness populations. The BMQ was found to exhibit satisfactory reliability and validity, although it was acknowledged that further testing and reporting of some aspects of reliability and validity is required. There are substantial variations between mean scores across different illness populations, although these cannot be easily summarised due to heterogeneity within the study sample.

Despite the variation in means, the BMQ is consistently associated with adherence across a variety of chronic illness populations and these relationships are, for the most part, in directions that were predicted by theory. The necessity scale appears to be the most strongly associated with adherence in the regression analyses examined here. However there is

variation, in that some regression analyses find other scales are the most potent predictor of adherence. Perhaps this is a consequence of the diverse nature of the illnesses and treatment regimens studied. Nonetheless, the relationships can sometimes seem surprising. For example, the weak relationship between specific concerns and adherence in populations with high medication side-effects or risk. It is also surprising that beliefs that medicines were generally harmful were more predictive of non-adherence than specific concerns in a sample of patients with rheumatoid arthritis, where most other studies have found general concerns to be mediated through specific concerns.

The results of this review have some interesting implications for understanding adherence behaviour. Firstly, regression and SEM analyses appear to indicate that the BMQ mediates the effect of particular variables on adherence. Beliefs about medicines may therefore be more directly related to adherence than other variables such as age and illness perceptions (as measured by the IPQ). Secondly, there is growing evidence that adding the BMQ to the self-regulatory model increases its explanatory power for adherence. These findings highlight the importance of medication beliefs in determining adherence behaviour.

These results would suggest that interventions to improve adherence may profit from focusing on medication beliefs. The literature search that detected the papers included in this review did not discover any papers describing interventions that focused on altering medication beliefs per se. However, studies are starting to use the BMQ to assess whether medication beliefs change when intervening to improve adherence. The few studies that there are found that medication beliefs do change as a result of these interventions (Higgins, Livingston & Katona, 2004; Theunissen, de Ridder, Bensing & Rutten, 2003). Interestingly, Theunissen et al. (2003) found that discussing illness representations in a G.P. consultation reduced concerns about hypertension medicines, fitting with the finding of this review that these

concepts are related to each other and that perhaps illness perceptions are mediated through medication beliefs. Unfortunately, this study did not look if these reductions in medication concerns actually improved the adherence to anti-hypertensive drugs.

Limitations of Reviewed Papers

There are several limitations to the evidence base reviewed above; particularly relating to study design, measures used and statistical power which may limit the conclusions of this review.

Study Design

The cross sectional design of studies only allows for the analysis of the association between beliefs about medicines and adherence at a single point in time therefore limiting inferences that can be made about the direction of cause between variables.

Measure of Adherence

There is debate in the literature as to the relative benefits of self-report compared to objective measures of adherence. Objective measures such as electronic monitoring or blood assays are considered the 'gold standard' but are often impractical and expensive. Self-report measures have been compared to objective measures and have been found to be a useful indicator of adherence (Choo, Rand, Inui, Lee, Cain, Cordeiro-Breault, Canning & Platt, 1999). Self-reports are also the method that clinicians use routinely to measure adherence in practice. In some sense therefore, self-reports may have more ecological validity than more objective measures. It is nonetheless worth noting that the majority of the studies here are using a measure of adherence that may be less sensitive than objective measures. This extra sensitivity may be responsible for the finding that the studies that used more objective

measures of adherence had larger effect sizes. Additionally, some studies included in this review have used only one item to measure adherence. This obviously limits the range of possible responses and is likely to increase the amount of error in the measure thereby affecting statistical power. All studies using a single item to measure adherence had some non-significant results.

Statistical power

It is known that statistical power can be maximised by ensuring an adequate sample size, avoiding score range restriction, using reliable measures, and using homogeneous subjects populations (Hallahan & Rosenthal, 1996). Some of the studies included in this review have limitations in these areas, which are likely to affect the power and validity of results. In particular, some studies had a small sample size for the number of variables analysed which can limit the power of the study to detect a significant effect (Type 2 error).

Limitations of Review

This review may be limited by the following factors:

Guidelines for Evaluating Study Quality

As discussed earlier, there is no concensus on quality evaluation criteria for cross sectional observation studies, and few exclusion criteria, so it is difficult to provide standardised evaluations of study quality. Focusing on published literature provides some reassurance of minimal study quality but this can result in biased results from the publication process itself.

Publication Bias

Publication bias is a common problem in systematic reviews as there is a trend towards the publication of positive results, resulting in effect sizes being an overestimation of the true effect (Easterbrook, 1991). However, because many of the studies included more than one scale of the BMQ, both significant and non-significant results are considered in this review. Nonetheless, the results of this review suggest a trend towards larger studies reporting smaller effect sizes. This may indicate that smaller studies that find smaller effect sizes, and therefore non-significant results, may not have their studies published.

Recommendations for Future Research

Study Design

Studies should adopt longitudinal design, or use structural equation modelling, to allow analysis of whether beliefs about medicines are causal or the result of adherence behaviour.

Intervention Studies

The finding that beliefs about medicines are reasonably predictive of adherence is potentially very important given that reviews highlight the paucity of effective interventions to improve adherence and call for the development of innovative approaches (Haynes et al. 1996, McDonald et al. 2002). Intervention studies are needed to test whether changing medication beliefs can alter adherence behaviour. This review demonstrates that certain beliefs are more strongly associated with adherence than others. It is suggested that focusing on improving the perceived need for medication is likely to have a stronger effect on adherence than reducing medication concerns, although this might vary across illness groups.

- There is evidence that beliefs about medicines can be measured in a systematic way.
- The BMQ scales appear to be related to adherence in correlational studies, although we cannot be certain about the direction of cause as these studies were not prospective.
- Certain aspects of beliefs are more prominent predictors of adherence than others i.e. perceived need for a specific medicine more than concerns or general views on medication, and it would be worth focusing on these beliefs in any future interventions.
- Beliefs about medicines continue to be predictive of adherence after controlling for a variety of potential confounding variables.
- Beliefs about medicines may mediate the effect of other factors, such as age and illness perceptions, in predicting adherence.
- The BMQ should now be used in more intervention studies to assess if altering beliefs can alter medication taking behaviour.

REFERENCES

Aikens, J.E., Nease, D.E., Nau, D.P., Klinkman, M.S. and Schwenk, T.L. (2005) Adherence to maintenance phase antidepressant medication as a function of patient beliefs about medication. *Annals of Family Medicine*, **3**, 23-30.

Bailey W.C., Richards, J.M. Jr and Brooks C.M. (1990) A randomised trial to improve self-management practices of adults with Asthma. *Archives Internal Medicine*, **150**, 1664-1668.

Barnes, L., Moss-Morris, R. and Kaufusi, M. (2004) Illness beliefs and adherence in diabetes mellitus: a comparison between tongan and European patients. *The New Zealand Medical Journal*, **117** (1188), 743-751.

Bekker, H.L., Gough, D. and Williams, M. (2003) Attendance choices about the Influenza Immunization Programme: evidence for targeting patients' beliefs. *Psychology, Health and Medicine*, **8** (3), 279-288.

Butler, J.A., Peveler, R.C., Roderick, P., Smith, P.W.F., Horne, R. and Mason, J.C. (2004) Modifiable risk factors for non-adherence to immunosuppressants in renal transplant recipients: A cross-sectional study. *Nephrology Dialysis Transplantation*, **19** (12), 3144-3149.

Byer, B. and Myers, L. B. (2000) Psychological correlates of adherence to medication in asthma. *Psychology, Health & Medicine*, **5** (4), 389-393.

Byrne, M., Walsh, J. and Murphy, A.W. (2005) Secondary prevention of coronary heart disease: Patient beliefs and health-related behaviour. *Journal of Psychosomatic Research*, **58** (5), 403-415.

Choo, P.W., Rand, C.S., Inui, T.S., Lee, M.T. Cain, E., Cordeiro-Breault, M., Canning, C. and Platt, R. (1999) Validation of patient reports, automated pharmacy records and pill counts with electronic monitoring of adherence to antihypertensive therapy, *Medical Care*, **37**, 846-857.

Cohen, J. (1992) A power primer. *Psychological Bulletin*, **112**, 155-159.

Conn, K.M., Halterman, J.S., Fisher, S.G., Yoos, H.L., Chin, N.P. and Szilagyi, P.G. (2005) Parental beliefs about medications and medication adherence among urban children with asthma. *Ambulatory Pediatrics*, **5** (5), 306-310.

Dickson, R. and Entwistle, V. (1996) Systematice Reviews: keeping up with research evidence. *Nursing Standard*. **10** (19), 32-35.

Easterbrook, P.J. Berlin, P.A., Gopalan, R. and Matthews, D.R. (1991) Publication Bias in Clinical Research. *Lancet*, **337**, 867-872.

Egger, M., Davey Smith, G. and Schneider, M. (2001) Systematic reviews of observational studies. Pp. 211-227. In Systematic reviews in Health Care: Meta-analysis in context. Egger, M., Davey Smith, M and Atman, D.G. 2001 (Eds). BMJ Publishing Group, London.

Engova, D., Duggan, C., MacCallum, P. and Bates, I. (2002) Patients' understanding and perceptions of treatment as determinants of adherence to warfarin treatment. *International Journal of Pharmacy Practice*, **10** (suppl), R69.

Engova, D., Duggan, C., MacCallum, P. and Bates, I. (2004) The role of medication adherence in warfarin anticoagulation control and its cognitive determinants. *British Journal of Haematology Supplement*, **1** (suppl), 57.

Gellaitry, G., Cooper, V., Davis, C., Fisher, M., Leake Date, H. and Horne, R. (2005). Patients' perception of information about HAART: impact on treatment decisions. *AIDS Care*, **17** (3), 367 – 376.

Gill, A. and de C. Williams, A. C. (2001) Preliminary study of chronic pain patients' concerns about cannabinoids as analgesics. *Clinical Journal of Pain*, **17** (3), 245-248.

Hagger M.S. and Orbell S. (2003) A meta-analytic review of the common sense model of illness representations. *Psychology and Health*, **18** (2), 141-184.

Hallahan, M and Rosenthal, R. (1996) Statistical Power: concepts, procedures, and applications. *Behaviour Research and therapy*, **34**, 489-499.

Haynes, R.B., McKibbon, K.A. and Kanani, R. (1996) Systematic review of randomised control trials of interventions to assist patients to follow prescriptions to medications. *Lancet*, **348**, 383-386.

Higgins, N., Livingston, G. and Katona. (2004) Concordance therapy: an intervention to help older people take antidepressants. *Journal of Affective Disorders*, **81** (3), 287-91.

Hobro, N., Weinman, J. and Hankins, M. (2004) Using the self-regulatory model to cluster chronic pain patients: the first step towards identifying relevant treatments? *Pain*, **108** (3), 276-283.

Horne, R. (1997) Representations of medication and treatment: advances in theory and measurement. In Petrie K.J. & Weinman, J.A. Perceptions of Health and Illness: Current Research and Applications, (ed). London: Harwood Academic, pp.155-187.

Horne, R. (1999) Patients' beliefs about treatment: the hidden determinant of treatment outcome. *Journal of Psychosomatic Research*, **47** (6), 491-495.

Horne, R., Buick, D., Fisher, M. and Leake, H. (2004) Doubts about necessity and concerns about adverse effects: identifying the types of beliefs that are associated with non-adherence to HAART. *International Journal of STD & AIDS*, **15** (1), 38-44.

Horne, R., Clatworthy, J., Polmear, A. and Weinman J. (2001) Do hypertensive patients' beliefs about their illness and treatment influence medication adherence and quality of life? *Journal of Human Hypertension*, **15** (Suppl.1), S65-S68.

Horne, R., Frost, S., Hankins, M. and Wright S. (2001) 'In the eye of the beholder': Pharmacy students have more positive perceptions of medicines than students of other disciplines. *International Journal of Pharmacy Practice*, **9** (2), 85-89.

Horne, R., Graupner, L., Frost, S., Weinman, J., Wright, S.M. and Hankins M. (2004) Medicine in a multi-cultural society: The effect of cultural background on beliefs about medications. *Social Science & Medicine*, **59** (6),1307-1313.

Horne, R., Hankins, M. and Jenkins, R. (2001) The Satisfaction with Information about Medicines Scale (SIMS): a new measurement tool for audit and research.

Horne, R., Sumner, S., Jubraj, B., Weinman, J. and Frost S. (2001) Haemodialysis patients' beliefs about treatment: Implications for adherence to medication and fluid-diet restrictions. *International Journal of Pharmacy Practice*, **9** (3), 169-175.

Horne, R. and Weinman, J. (1999) Patient beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. *Journal of Psychosomatic Research*, **47** (6), 555-567.

Horne, R., Weinman, J. and Hankins. M. (1999) The beliefs about medicines questionnaire: the development and evaluation of a new method of assessing the cognitive representation of medication. *Psychological Health*, **14**, 10-24.

Horne, R. and Weinman, J. (2002) Self-regulation and self-management in asthma: exploring the role of illness perceptions and treatment beliefs in explaining non-adherence to preventer medication. *Psychology and Health*, **17** (1), 17-32.

Johnson, B.T. (1989) DSTAT. Software for the Meta-analytic Review of Research literature. Lawrence Erlbaum Associates, Inc.

Katrak, P., Bialocerkowski, A.E., Massy-Westropp, N., Kumar, S. and Gimmer, K.A. (2004) A systematic review of the content of critical appraisal tools. *BMC Medical Research Methodology*, **4** (22), doi:10.1186/1471-2288-4-22.

Kendrew P., Ward F., Buick D., Wright D. and Horne R. (2001) Satisfaction with information and its relationship with adherence in patients with chronic pain. *International Journal of Pharmacy Practice*, **9** (suppl), R5.

Lam, F., Stevenson, F.A., Britten, N. and Stell, I.M. (2001) Adherence to antibiotics prescribed in an accident and emergency department: the influence of consultation factors. *European Journal of Emergency Medicine*, **8** (3), 181-188.

Leventhal, H., Diefenbach, M. and Leventhal, E.A. (1992) Illness Cognition: Using common sense to understand treatment adherence and affect cognitive interactions. *Cognitive Therapy and Research*, **16** (2), 143-163.

Llewellyn, C. D., Miners, A. H., Lee, C. A., Harrington, C. and Weinman, J. (2003) The Illness Perceptions and Treatment Beliefs of Individuals with Severe Haemophilia and their Role in Adherence to Home Treatment. *Psychology and Health*, **18** (2), 185-200.

Maidment, R., Livingstone, G. and Katona, C. (2002) 'Just keep taking the tablets': Adherence to antidepressant treatment in older people in primary care. *International Journal of Geriatric Psychiatry*, **17**, 752-757.

McDonald, H.P., Garg, A.X. and Haynes, R.B. (2002) Interventions to enhance patient's adherence to medication prescriptions: scientific review. *JAMA*, **288** (22), 2868-2879.

Millar, N.H. (1997) Compliance with treatment regimens in chronic asymptomatic diseases. *American Journal of Medicine*, **102**, 43-49.

Moss-Morris, R., Weinman, J., Petrie, K.J., Horne, R., Cameron, L. and Buick, D. (2002) The revised illness perception questionnaire (IPQ-R). *Psychology and Health*, **17** (1), 1-16.

Neame, R. and Hammond, A. (2005) Beliefs about medications: a questionnaire survey of people with rheumatoid arthritis. *Rheumatology*, **44** (6), 762-767.

Nunnally, J.C. (1967). Psychometric Theory. New York: McGraw-Hill.

Peters, K. F., Horne, R., Kong, F., Francomano, C. A. and Biesecker, B. B. (2001) Living with Marfan syndrome II. Medication adherence and physical activity modification. *Clinical Genetics*, **60** (4), 283-292.

Rogers, P.G and Bullman, W.R. (1995) Prescription medicine compliance: A review of the baseline of knowledge. A report of the National Council on Patient Information and Education. *Journal of Pharmacoepidemiology*; 2:3.

Ross, S, Walker, A. and MacLeod, MJ. (2004) Patient compliance in hypertension: Role of illness perceptions and treatment beliefs. *Journal of Human Hypertension*, **18** (9), 607-613.

Sackett, D.L. and Snow, J.C. The magnitude of compliance and noncompliance. In: Haynes RB, Taylor DW, Sackett DL, eds. Compliance in Health Care. Baltimore, Md: John Hopkins University Press; 1979:11-22

Scottish Intercollegiate Guidelines Network (SIGN) 'Guideline Developers' Handbook'. (2004) http://www.sign.ac.uk/guidelines/fulltext/50/ (accessed on 14/11/05).

Sharpe, D. (1997) Of apples and oranges, file drawers and garbage: Why validity issues in meta-analysis will not go away. *Clinical Psychology Review*, **17**, 881-901.

Shaw, J. (2003) Not to be taken as directed: putting concordance fot taking medicines into practice. *British Medical Journal*, **326**, 348-349.

Skingle, S.J. (2004) A study to investigate factors that may be associated with patients' decisions about starting disease modifying anti-rheumatic drugs. *Rheumatology*, **43** (Suppl. 2), ii 153.

Stafkey, D.R., Erickson, S.R., Kline-Rogers, E.M., Smith, D.E., Cooper, J.V., Chang, A. and Eagel, K.A. (2003) Relationship between patient beliefs about medication and self-reported medication adherence six months after discharge for acute coronary syndromes. *Value in Health*, **6** (3), 312.

Theunissen, N,C., de Ridder, D.T., Bensing, J.M. and Rutten, G.E. (2003) Manipulation of patient-provider interaction: discussing illness representations or action plans concerning adherence. *Patient Education and Counselling*, **51**, 247-258.

Treharne, G.J., Lyons, A.C. and Kitas, G.D. (2004) Medication adherence in rheumatoid arthritis: effects of psychosocial factors. *Psychology, Health & Medicine*, **9** (3), 337-49.

Wade, A. N., Farmer, A. J. and French, D. P. (2004) Association of beliefs about illness and medication with self-care activities in noninsulin treated Type 2 diabetes. *Diabetic Medicine Supplement*, **21** (suppl2), 52.

Webb, D. G., Horne, R., Pinching, A. J. (2001). Treatment-related empowerment: preliminary evaluation of a new measure in patients with advanced HIV disease. International Journal of STD & AIDS, **12** (2), 103-107.

Weinman, J., Petrie, K.J., Moss-Morris, R., and Horne, R. (1996) The Illness Perception Questionnaire: A new method for assessing illness perceptions. *Psychology and Health*, **11**, 431-446.

Weintraub, M. (1990) Compliance in the elderly. *Clinics in Geriatric Medicine*, **6**, 445-455.

Figure 1 **Pathway from search procedure to studies included in the review**

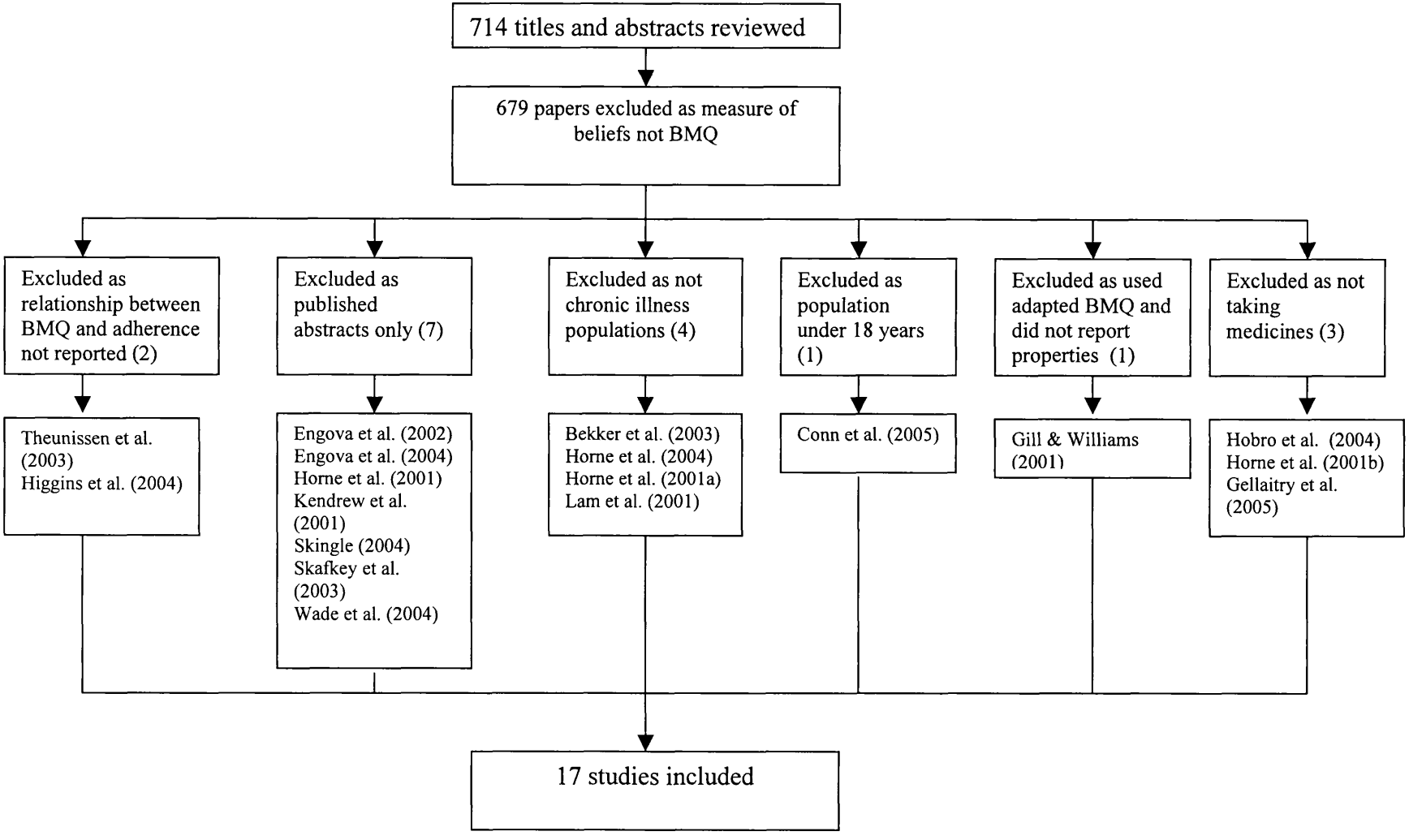

Figure 2 **Mean BMQ scores across chronic illness populations**

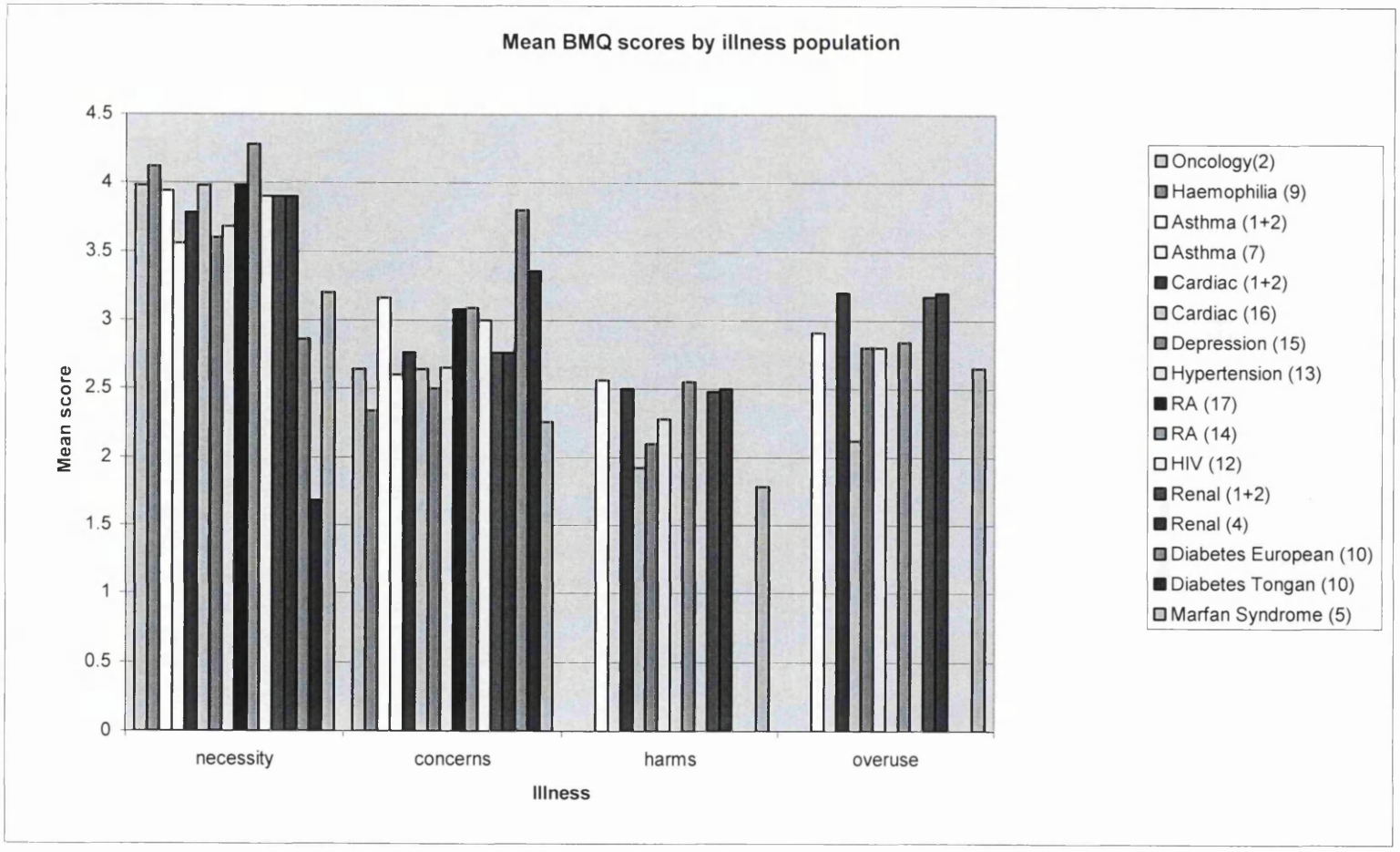

Table 1 Summary characteristics and quality ratings for studies included in the review

No	Study Title and evaluation level	Author and year	Population	Sample (% male)	Demographics Mean age (SD)	Study Design	Measures	Outcome measures
1	The beliefs about medicines questionnaire: the development and evaluation of a new method of assessing the cognitive representation of medication. **A**	Horne, Weinman & Hankins 1999	Asthma Renal Cardiac General medicine Psychiatric Diabetes	78 (37%) 47 (49%) 120 (71%) 91 (50%) 89 (37%) 99 (39%)	45.5 (18.3) 49 (17.3) 63.6 (12.4) 54 (19.8) 45.8 (10.9) 46.6 (18.5)	Cross-sectional	Beliefs about Medicines Questionnaire (BMQ) (general and specific), Illness Perceptions Questionnaire (IPQ), Sensitive Soma Scale	Reported Adherence to Medication Scale (RAM)
2	Patients' beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. **A**	Horne & Weinman 1999	Asthma Renal Cardiac Oncology	78 (37%) 47 (49%) 116 (71%) 83 (51%)	45.5 (18.3) 49 (17.3) 63.6 (12.4) 58.5 (15.84)	Cross-sectional	BMQ (specific)	Reported Adherence to Medication Scale (RAM)
3	Psychological correlates of adherence to medication in asthma. **A**	Byer & Myers 2000	Asthma	64 (50%)	39.63 (13.83)	Cross-sectional	BMQ (specific), IPQ	1) Prescriptions collected for preventer medication 2) Prescriptions collected for reliever medication 3) Self-reported adherence
4	Haemodialysis patients' beliefs about treatment: Implications for adherence to medication and fluid-diet restrictions. **A**	Horne, Sumner, Jubraj, Weinman & Frost 2001	Renal - haemodialysis	47 (49%)	49 (17.3)	Cross-sectional	BMQ (general and specific),	'How often do you deliberately miss a dose of medication'
5	Living with Marfan syndrome II. Medication adherence and physical activity modification. **C**	Peters, Horne, Kong, Francomano & Biesecker 2001	Marfan disease	174 (Not reported)	Not reported	Cross-sectional	IPQ, BMQ (general and specific)	Self-report measure adapted from Horne and Weinman (1999)
6	Treatment related empowerment: preliminary evaluation of a new measure in patients with advanced HIV disease. **B**	Webb, Horne & Pinching 2001	Advanced HIV	43 (93%)	38.6 (7.7)	Cross-sectional	BMQ (general), Treatment-Related Empowerment Scale	2 items 'Some people say they sometimes take less of their medicines, how often do you do this?' 'Some people say they forget to take their medicines, How often do you do this?'

Table 1 (Continued) Summary characteristics and quality ratings for studies included in the review

No	Study Title and evaluation level	Author and year	Population	Sample (% male)	Demographics Mean age (SD)	Study Design	Measures	Outcome measures
7	Self-regulation and self-management in asthma: exploring the role of illness perceptions and treatment beliefs in explaining non-adherence to preventer medication. **A**	Horne & Weinman 2002	Asthma	100 (39%)	49.3 (18.1)	Cross-sectional	IPQ, BMQ (specific)	Medication Adherence Report Scale (MARS)
8	'Just keep taking the tablets': adherence to antidepressant treatment in older people in primary care. **B**	Maidment, Livingstone & Katona 2002	Depression	67 (49%)	74.2 (6.1)	Cross-sectional	BMQ (general and specific), General Health Questionnaire (GHQ-28), Geriatric Mental State Schedule – Depression (GMSS-DS), Questionnaire on Patient Education (QPE), Mini-Mental State Examination (MMSE), National Adult Reading Test (NART), 'UKU side effects rating scale', 'Schedule for Assessing the Three Components of Insight'	Global Adherence Measure (GAM)
9	The illness perceptions and treatment beliefs of individuals with severe haemophilia and their role in adherence to home treatment. **B**	Llewellyn, Miners, Lee, Harrington & Weinman. 2003	Haemophiliacs (44% HIV-positive)	65 (100%)	36.4 (12.2)	Cross-sectional	IPQ, BMQ (specific),	Adherence diaries
10	Illness beliefs and adherence in diabetes mellitus: a comparison between Tongan and European patients. **A**	Barnes, Moss-Morris & Kaufusi 2004	Diabetes (European origin and Tongan origin)	39 European 43 Tongan (not reported)	59.6 (12.7) 59.2 (11.2)	Cross-sectional	BMQ (specific) IPQ-R	MARS
11	Modifiable risk factors for non-adherence to immunosuppressants in renal transplant recipients: a cross-sectional study. **A**	Butler, Peveler, Roderick, Smith Horne & Mason 2004	Kidney transplant	58 (66%)	48 (13)	Cross-sectional	IPQ, BMQ (general, specific and 'benefits' scale) revised Clinical Interview Schedule (CIS-R), Short Form 36 (SF-36), Expectations of transplant scale, Significant Others Scale (SOS)	Electronic monitoring

Table 1 (Continued) Summary characteristics and quality ratings for studies included in the review

No	Study Title and evaluation level	Author and year	Population	Sample (% male)	Demographics Mean age (SD)	Study Design	Measures	Outcome measures
12	Doubts about necessity and concerns about adverse effects: Identifying the types of beliefs that are associated with non-adherence to HAART. **A**	Horne, Buick, Fisher, Leake, Cooper and Weinman 2004	HIV	109 (97.2%)	41.2 (9.0)	Cross-sectional	BMQ (specific)	'How much of your HAART medication did you take within two hours of when you were supposed to?'
13	Patient compliance in hypertension: Role of illness perceptions and treatment beliefs. **A**	Ross, Walker and MacLeod 2004	Hypertension	515 (51.9%)	59.92 (12.16)	Cross-sectional	BMQ (specific and general), IPQ-R	Morisky Medication Adherence Scale (MMAS)
14	Medication adherence in rheumatoid arthritis: effects of psychosocial factors. **A**	Treharne, Lyons & Kitas 2004	Rheumatoid Arthritis	85 (25%)	58.88 (12.64)	Cross-sectional	Medical Interview Satisfaction Scale (MISS), BMQ (specific and general) Social Support Questionnaire (SSQ-6), Life Orientation Test (LOT)	Compliance Questionnaire – Rheumatology (CQ-R) plus two items from RAM
15	Adherence to Maintenance-Phase Antidepressant Medication as a Function of Patient Beliefs About Medication. **A**	Aikens, Nease, Nau, Klinkman & Schwenk 2005	Depression	81 (21%)	<40 = 31% 41-50 = 41% 51-60 = 13 >60 = 5%	Cross-sectional	BMQ (general and specific), Patient Health Questionnaire (PHQ-9), Medical Outcomes Study SF-12 Health Survey, Marlow-Crowne Social Desirability Scale	MMAS plus three items from the Brief Medication Questionnaire
16	Secondary prevention of coronary heart disease: Patient beliefs and health-related behaviour. **A**	Byrne, Walsh & Murphy 2005	Coronary Heart Disease	1084 (65%)	66 (9.1)	Cross-sectional	IPQ-R, BMQ (general and specific)	MARS
17	Beliefs about medications: a questionnaire survey of people with rheumatoid arthritis. **C**	Neame & Hammond 2005	Rheumatoid Arthritis	344 (33%)	49.5% over 65	Cross-sectional	BMQ (specific), Multidimensional Health Assessment Questionnaire (MDHAQ), Psychological Distress Scale, Rheumatology Attitudes Index (RAI), Arthritis knowledge Questionnaire (ARQ),	'I often do not take my medicines as directed'

Table 2 **Summary of reliability of BMQ**

	Specific scales		General scales	
	Necessity	**Concerns**	**Harm**	**Overuse**
Range	.74-.88	.51-.82	.62-.83	.60-.82
Average alpha	R=.84	R=.75	R=.63	R=.75
Retest reliability	$\rho = .77$	$\rho = .76$	$\rho = .78$	$\rho = .60$
Spearman's	($p<0.001$)	($p<0.001$)	($p<0.001$)	($p<0.001$)
correlation (n=31)				

Table 3 **Results of the relationships between BMQ and measures of adherence (effect sizes, significance values, multivariate statistic [B, β, OR, adjusted R^2])**

Author and date	Patient Group	N	Adherence measure (number of items)	BMQ scales (number of items)	Pearsons r (ES)*	P value	Regression Model used	Variables entered into analysis (significant results in bold)	P value	Multivariate Statistic (%variance explained)
Horne et al. (1999)	Cardiac and General Medical	210	RAM (4)	Necessity (5)	.19	0.01				
				Concerns (5)	-.28	0.001				
				Harms (4)	-.06	N/S				
				Overuse (4)	-.19	0.01				
Horne & Weinman (1999)	1) Asthma	78	RAM (4)	Necessity (5)	.28	0.05	Backwards	**BMQ NCD**	0.001	R^2 0.19 (19%)
				Concerns (5)	-.21	0.05	Linear	**Asthma illness group**	0.001	R^2 0.26 (7%)
				NCD (10)	.39	0.01	Regression	**Age**	0.001	R^2 0.30 (4%)
	2) Renal Dialysis	47	As above	Necessity (5)	.03	N/S		**Cardiac illness group**	0.001	R^2 0.33 (3%)
				Concerns (5)	-.41	0.01		Gender	N/S	
				NCD (10)	.39	0.01		Educational experience	N/S	
	3) Cardiac	116	As above	Necessity (5)	.21	0.05		Renal illness Group	N/S	
				Concerns (5)	-.27	0.05		Oncology illness Group	N/S	
				NCD (10)	.32	0.05		Number of medicines	N/S	
	4) Oncology	83	As above	Necessity (5)	.30	0.01				
				Concerns (5)	-.34	0.01				
				NCD (10)	.43	0.01				
	5) Group total	324		Necessity (5)	.21	0.01				
				Concerns (5)	-.33	0.01				
				NCD (10)	.41	0.01				
Byer & Myers (2000)	Asthma	64	1) Prescriptions collected for preventer medication	Necessity (5)	.44	0.01				
				Concerns (5)	Incalculable	N/S				
			2) Prescriptions collected for reliever medication	Necessity (5)	.30	0.05				
				Concerns (5)	Incalculable	N/S				
			3) Self-report of adherence (not reported)	Necessity (5)	.44	0.01				
				Concerns (5)	Incalculable	N/S				
Horne et al. (2001)	Renal - Haemodialysis	47	'How often do you deliberately miss a dose of medication' (1)	Necessity (5)	Incalculable	N/S				
				Concerns (5)	-.39	0.001				
				Overuse (4)	Incalculable	N/S				
				Harms (4)	Incalculable	N/S				

Table 3 (Continued) Results of the relationships between BMQ and measures of adherence

Author and date	Patient Group	N	Adherence measure (number of items)	BMQ scales (number of items)	Pearsons r (ES)*	P value	Regression Model used	Variables entered into analysis (significant results in bold)	P value	Multivariate Statistic (%variance explained)
Peters et al. (2001)	Marfin Syndrome	174	adapted from Horne & Weinman (1999) (3)	Necessity (5)	Incalculable	N/S	Multivariate Regression	**Age**	0.001	B – 3.24 Age 18-29
				Concerns (5)	-.14	0.01				B – 1.78 Age 30-39
				NCD	.14	0.009		**Palpitations**	0.04	B -2.59
				Harms (4)	-.16	0.003		**BMQ harms**	0.002	B – 0.3
				Overuse (4)	-.14 (estimated from significance)	0.007		BMQ overuse	N/S	
								BMQ concerns	N/S	
								BMQ NCD	N/S	
								Chest pain	N/S	
								Headaches	N/S	
Webb (2001)	Advanced HIV	43	a) Intentional non-adherence 'Some people say that they sometimes take less of their medicines, how often do you do this' (1)	Overuse (3)	-.34	0.05				
				Harms (3)	-.23	N/S				
			b) Unintentional non-adherence 'Some people say that they forget to take their medicines, how often do you do this' (1)	Overuse (3)	-.02	N/S				
				Harms (3)	-.11	N/S				
Horne & Weinman (2002)	Asthma	100	MARS (9)	Necessity (6)	.32	0.01	Hierarchical Linear Regression	Gender	0.06	β - 0.19
				Concerns (11)	-.43	0.001		Age	0.14	β 0.18
								Educational status	0.29	β - 0.12 R^2 0.06 (6%)
								Visits to GP	0.07	β 0.20
								Hospital admissions	0.03	β - 0.24
								Duration of asthma	0.45	β - 0.08 R^2 0.00 (0%)
								IPQ identity	0.92	β 0.01
								IPQ timeline	0.43	β 0.09
								IPQ consequences	0.007	β - 0.31
								IPQ cure/control	0.31	β 0.11 R^2 0.13 (13%)
								BMQ necessity	0.01	β 0.28
								BMQ concerns	0.001	β - 0.35 R^2 0.17 (17%)
Maidment et al. (2002)	Depression in older adults	67	GAM (1)	Necessity (5)	.29	0.05	Backward Linear Regression	**QPE**	0.05	β - 0.128
				Concerns (5)	-.36	0.01		**BMQ concerns**	0.05	β 0.0173
				Overuse (4)	-.16	N/S		**MMSE**	0.05	β 0.01
				Harms (4)	-.07	N/S		**Global side effect burden**	0.05	β 0.0682
								Overall model	0.001	R^2 0.271 (27%)
								GHQ	N/S	Dropped in stepwise regression
								BMQ necessity	N/S	
								GMSS-DS	N/S	

Table 3 (Continued) Results of the relationships between BMQ and measures of adherence

Author and date	Patient Group	N	Adherence measure (number of items)	BMQ scales (number of items)	Pearsons r (ES)*	P value	Regression Model used	Variables entered into analysis (significant results in bold)	P value	Multivariate Statistic (%variance explained)
Llewellyn et al. (2003)	Haemophiliacs	65	a) Prophylactic frequency of infusion with clotting factor (n=32)	Necessity (5)	.44	0.01	Forced entry	Age	N/S	β - 0.081
				Concerns (5)	-.14	N/S	Regression	HIV status	N/S	β - 0.133
								IPQ identity	0.05	β - 0.659
							Model 1	IPQ timeline	N/S	β 0.155
								IPQ consequences	N/S	β - 0.161
								IPQ control	N/S	β - 0.118
								BMQ necessity	0.01	β - 0.534
								BMQ concerns	N/S	β 0.213
								Overall Model	N/S	R^2 0.187
							Model 2	**BMQ necessity**	0.01	β - 0.444
								IPQ identity	0.05	β - 0.379 R^2 0.291
			b) Adherence to recommended 'on-demand' dose of clotting factor (n=33)	Necessity (5)	.37	0.05	Model 1	**Age**	0.05	β 0.524
				Concerns (5)	-.03	N/S		HIV status	N/S	β 0.375
								IPQ identity	N/S	β - 0.330
								IPQ timeline	N/S	β 0.189
								IPQ consequences	N/S	β - 0.158
								IPQ control	N/S	β 0.120
								BMQ necessity	N/S	β - 0.285
								BMQ concerns	N/S	β 0.176
								Overall Model	N/S	R^2 0.072
							Model 2	**Age**	0.05	β 0.339 R^2 .086
			c) Adherence to dose of clotting factor		Incalculable	N/S				
Barnes et al. (2004)	Diabetes	72	MARS (not reported)	Necessity (5)	.36	0.01				
				Concerns (5)	-.14	N/S				
Butler et al. (2004)	Renal transplant	58	Electronic monitors±	Necessity (5)	.51	0.01	Stepwise Logistic Regression	**BMQ necessity immunosuppressants**		OR 2.0
			Adherence Prednisolone	Concerns (7)	Incalculable	N/S		**Transplant from live donor**		OR 31.6
			Adherence Immunosuppressants	Necessity (5)	.55	0.01		**BMQ necessity prednisolone**		OR 1.8
				Concerns (7)	Incalculable	N/S		Lives alone	N/S	
				Benefits scale (added after correspondence with BMQ author)	.52	0.01		Education	N/S	
								BMQ benefits Scale	N/S	
								SF-36 scale	N/S	
								IPQ emotions scale	N/S	

Table 3 (Continued) Results of the relationships between BMQ and measures of adherence

Author and date	Patient Group	N	Adherence measure (number of items)	BMQ scales (number of items)	Pearsons r (ES)*	P value	Regression Model used	Variables entered into analysis (significant results in bold)	P value	Multivariate Statistic (%variance explained)
Horne et al. (2004)	HIV	109	'How much of your HAART medication did you take within two hours of the time you were supposed to?' ± (1)	Necessity (8) Concerns (11) NCD (19)	.17 -.18 .25	N/S 0.05 0.008				
Ross et al. (2004)	Hypertension	515	MMAS (4)	Necessity (5) (dichotomised) Concerns (5) (dichotomised) Harms (4) Overuse (4)	Incalculable -.07 Incalculable Incalculable	0.001 0.028 N/S N/S	Multiple Logistic Regression	**Age** **BMQ necessity** **IPQ emotion** **IPQ personal Control** IPQ consequences IPQ cure BMQ concerns Gender Diastolic BP control	0.001 0.001 0.008 0.012 N/S N/S N/S N/S N/S	OR 4.82 OR 3.06 OR 0.65 OR 0.59
Treharne et al. (2004)	RA	85	CQ-R (19) plus items from RAM (2)	Necessity (5) Concerns (5) Overuse (4) Harms (4)	.69 -.13 -.47 -.40	0.001 N/S 0.001 0.001	Hierarchical Regression Step 1 Step 2	Children at home Taking steroid medication **Number of medications** MISS affective MISS cognitive MISS behavioural **BMQ necessity** BMQ concerns BMQ harms **BMQ overuse**	N/S N/S 0.05 N/S N/S N/S 0.05 N/S N/S 0.05	β - 0.13 β 0.21 β 0.27 R^2 0.21 (21%) β 0.22 β 0.14 β 0.09 β 0.28 β - 0.06 β 0.03 0.43 (0.001) β - 0.25 R^2 0.43 (43%)
Aikens et al. (2005)	Depression	81	General adherence: MMAS (4) plus items from Brief medication Recent adherence: Brief Medication Questionnaire (3)	NCD (10) Overuse Harm differential (8) Necessity (5) Concerns (5) Overuse (4) Harms (4)	Incalculable Incalculable Incalculable Incalculable Incalculable Incalculable	0.001 N/S N/S N/S N/S N/S				

Table 3 (Continued) Results of the relationships between BMQ and measures of adherence

Author and date	Patient Group	N	Adherence measure (number of items)	BMQ scales (number of items)	Pearsons r (ES)*	P value	Regression Model used	Variables entered into analysis (significant results in bold)	P value	Multivariate Statistic (%variance explained)
Byrne et al. (2005)	Coronary Heart Disease	1084	MARS (5)	Necessity (5)	.25	0.001	Hierarchical	Age	N/S	β - 0.3
				Concerns (5)	-.11	0.01	Linear	Sex	N/S	β 0.02
				Overuse (4)	-.16	0.001	Regression	GMS eligibility	N/S	β 0.06
				Harms (4)	-.17	0.001	Step 3	GP consultations in 6mths	N/S	β - 0.02
								Months since diagnosis	N/S	β 0.01
								Previous Myocardial Infarction	N/S	β - 0.02
								IPQ cause – stress	N/S	β < 0.01
								IPQ cause – heredity	N/S	β - 0.05
								IPQ cause – behaviour	N/S	β 0.02
								IPQ identity	N/S	β - 0.01
								IPQ timeline – chronic	N/S	β - 0.03
								IPQ consequences	N/S	β 0.04
								IPQ personal control	N/S	β 0.05
								IPQ treatment control	N/S	β 0.01
								IPQ illness coherence	N/S	β - 0.04
								IPQ timeline - cyclical	N/S	β 0.07
								IPQ emotional representations	N/S	β - 0.06
								BMQ necessity	0.001	β - 0.23
								BMQ concerns	0.01	β 0.11
								BMQ harm	N/S	β 0.05
								BMQ overuse	N/S	β 0.07
								Total Model	0.001	R^2 0.09 (7% increase attributable to BMQ)
Neame & Hammond (2005)	Rheumatoid Arthritis	344	'I often do not take my medicines as directed'± (1)	Necessity (5)	.03	N/S				
				Concerns (5)	-.30	0.002				
				NCD	.26	0.008				

* All results were in theoretically valid directions but altered according to study design. The direction of effect sizes has been adjusted so that all results are in the same direction.

± Adherence scores were dichotomised into adherent and non-adherent groups.

Chapter 3: Major Research Proposal

Adherence to Pharmacological Treatment of Non-Malignant Chronic Pain: The Role of Illness Perceptions and Treatment Beliefs

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Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology

Prepared in accordance with University of Glasgow requirements (see Course handbook Guidelines in Appendix 3.1). An amendment to recruitment procedure was made and this has been appended on page 96.

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Summary of Project

Objective. The aim of this study is to identify the degree to which illness perceptions and treatment beliefs explain variations in reported adherence to medication prescribed for the treatment of non-malignant chronic pain. It will also test the applicability of an extended version of the self-regulatory model to the chronic pain population.

Design and method. A cross-sectional design will be employed. Patients attending chronic pain clinics will complete validated questionnaires assessing their illness perceptions, beliefs about medication and reported adherence to medication. Data will be analysed using structural equation modelling and hierarchical regression analyses.

Keywords. Illness perceptions: Treatment beliefs: Chronic pain: Adherence: Self-regulatory model: Structural equation modelling

Chronic Pain

Chronic pain has been defined as 'pain that either persists beyond the point at which healing would be expected to be complete or that occurs in disease processes in which healing does not take place' (Clinical Standards Advisory Group, 2000). The term is used to encapsulate a variety of conditions such as fibromyalgia, chronic low back pain and rheumatoid arthritis. Conditions such as chronic low back pain are increasing in prevalence in industrial society and are considered to be a major source of lost income due to disability (Karjalainen et al, 2004). Chronic pain is resistant to treatment (Guzman et al, 2004), and a significant problem with non-adherence to prescribed medication has been identified (Kendrew et al. 2001). Non-adherence to prescribed medications is well documented in the general medical literature (WHO, 2003), and a recent review indicates that around 50% of patients fail to receive the full benefit of prescribed medications through non-adherence (Rogers & Bullman, 1995).

Adherence Research

Until recently, research into medication use focused on the concept of compliance. Compliance is defined as the extent to which a patient's behaviour coincides with medical advice (Haynes, 1979). It reflects the traditional biomedical model of healthcare, and neglects the psychological and social aspects of illness. The term adherence is more associated with the psychosocial model of health care, which sees adherence as an intricate series of behaviours (Ley, 1997). There has been a corresponding shift in research from an atheoretical focus on patient characteristics (e.g. sociodemographics, clinical factors), which ignores patient's views, to the development of theory driven models of health behaviour.

Factors Predicting Adherence in Chronic Pain

Although there is evidence that many chronic pain patients do not adhere to their prescribed medicines, the literature examining why this is the case is under-developed, compared to research that has examined non-adherence in other medical populations. Proposed reasons for non-adherence in chronic pain are largely related to patient characteristics and include demographic (age, socio-economic status), clinical (illness severity, chronicity of illness) and practical (collection of prescriptions) factors. The influence of psychological factors (beliefs about illness and medication) has been barely explored. However, clinical and health psychology research has made considerable advances in exploring the psychological factors that determine people's adherence behaviour in other chronic conditions.

The Application of Theoretical Frameworks to Adherence Behaviour

A number of theories have been proposed to explain how psychological factors influence health behaviours such as adherence. Expectancy-value models, such as the Health Belief Model, propose that the likelihood of a particular behaviour will depend on the individual's expectation that the behaviour will result in a positive outcome and on the value of that outcome. Much research has applied the Health Belief Model to health behaviours but there is growing evidence to suggest that cognitive models, such as the Theory of Planned Behaviour (TPB), explain more of the variance in health behaviours (Connor and Armitage, 2000). The TPB describes the relationships between beliefs, attitudes and behaviours, and postulates that peoples' intentions are the best predictors of their health behaviours. A review by Sheeran (2005) provides evidence that the TPB reliably predicts around 28% of variance in behaviour. These models have been successfully applied to peoples' adherence to a variety of medical regimens, from attendance at breast cancer screening (e.g. Rutter 2000), to dietary and exercise adherence in diabetes (e.g. Glasgow et al. 1986).

The Self-Regulatory Model

However, these models have been criticised as not providing complete explanations of specific illness behaviours (Marteau, 1995) and other models have been put forward which aim to address this criticism by including these variables. The best example of this is the illness representation model developed by Leventhal and colleagues (Leventhal et al. 1980; Leventhal et al. 1992). This model is often described as a self-regulatory model (SRM), as it proposes that the individual attempts to regulate their behaviour during an illness threat, such as perceiving a symptom (see Figure 1).

Insert Figure 1 here

Two interacting parallel processing pathways are proposed in the SRM. It is suggested that the first processing pathway is a cognitive representation of the illness and the coping strategies that are employed as a result of the illness representation. The second pathway is an emotional representation of the illness and the coping strategies employed to deal with it. It is proposed that coping effectiveness is appraised, impacting on cognitive and emotional representations, and future coping responses. As a result, the SRM is a dynamic system explaining the representation of the illness, and coping strategies employed as a result of an illness threat.

Evidence Supporting the Application of the SRM to Adherence

A review by Hagger and Orbell (2003) indicates that there are theoretically predictable relationships between illness cognitions, coping and outcomes (highlighted in bold in figure 1). The SRM has been applied to explore adherence to treatment in various chronic illness populations (e.g. Jessop and Rutter, 2003, Ross et al. 2004, Whitmarsh et al. 2003), with

adherence being viewed as a coping response. However, there is a paucity of research examining illness representation variables, and their effects on treatment adherence, in the chronic pain literature.

The Dimensions of Illness Representations

Illness representations are proposed to be structured around 5 dimensions – that is the identity, timeline, consequences, causal factors and control/curability of the illness. The relative role of each dimension in predicting adherence has been investigated in a number of studies. Horne and Weinman (2002) and Walsh et al. (2004) found that negative perceived consequences of illness were more associated with non-adherent behaviour, whereas Ross et al. (2004) found that belief in personal ability to control illness was the most important dimension in predicting adherence to hypertension medication.

Hagger & Orbell (2003) looked at the relationship between illness cognitions and illness outcomes in their review and conclude that it could be predicted that a chronic timeline, more serious consequences, a strong illness identity and high symptomatology are associated with poorer adjustment and outcomes, whereas a higher perceived level of controllability/curability would be associated with better adjustment. However, Hagger and Orbell (2003) also highlight that the pattern of beliefs vary across illnesses and ought to be explored for different illness groups.

Most papers in this review use the Illness Perceptions Questionnaire (Weinman et al. 1996) to measure cognitive representations. Studies have more recently used the revised version of this scale to measure emotional representations as well as the cognitive dimensions described above, enabling a comprehensive assessment of the SRM (Moss-Morris et al. 2002). One

such study indicated that higher emotional reactions are linked to poorer adherence (Ross et al. 2004).

Modelling the SRM

Although the value of the SRM in explaining adherence in chronic illness has been demonstrated by a number of studies, these studies have used regression analyses, which despite being depicted using path diagrams, do not allow for formal tests of mediating relationships. Few studies have tested fully the extent to which the data fit the predicted relations between illness representations and adherence. However, Horne and Weinman (2002) used structural equation modelling to examine the direct and indirect relationships between illness perceptions and medication beliefs in explaining non-adherence to asthma medication. They demonstrated that illness perceptions influence adherence both directly and indirectly through medication beliefs i.e. individuals who believed their asthma was a passing condition were less likely to support the necessity of their treatment, and were less adherent to it. Figure 2 reproduces their model.

Insert Figure 2 here

The weakest correlation was between Illness Timeline and Illness Consequences (.19). Other correlation coefficients ranged from .25 to .38 (small to moderate correlations). This study suggests that the strength of the SRM to explain adherence is improved by extending it to include a measure of treatment beliefs, and provides preliminary empirical support for the extended self-regulatory model of treatment adherence.

The results of a search of the literature indicate that there have been no studies using the SRM to predict adherence to treatment in chronic pain, although the findings of a study by Hobro et

al. (2004) support the use of the SRM to cluster chronic pain patients. This study will follow a similar design to that applied in Horne and Weinman (2002), in that it will examine the role of illness perceptions and treatment beliefs in explaining adherence. However, the extended self-regulatory model will be applied to a chronic pain population, thus initiating the empirical testing of this model in a new population.

Hypotheses:

1) Adherence to prescribed medication will be explained by illness perceptions: with perceptions of a chronic timeline, more serious consequences, a strong illness identity and more symptoms and higher emotional response being associated with poorer adherence, and higher perceived levels of controllability/curability being associated with better adherence.

2) Adherence to prescribed medication will be related to beliefs about medication. Adherence will be positively correlated with patients' perceptions of the necessity of prescribed medication and negatively correlated with concerns about potential negative effects.

3) Beliefs about medication will add to the proportion of variance in adherence that is explained by illness perceptions, clinical factors and demographic variables.

4) The extended SRM model, as proposed in Horne and Weinman (2002), will be a good fit to the data (as judged by a variety of fit indices).

Study Design

a) Participants

Inclusion criteria:

1) Participants will include all patients with non-malignant chronic pain that are attending a pain clinic and receiving prescribed medication for pain at one of the Glasgow hospitals. In terms of the types of pain conditions sampled, the population is likely to be heterogeneous. However, it will be an ecologically valid sample of the pain clinic population. Furthermore, there are no a-priori, theoretical reasons for thinking that the model is more relevant to certain non-malignant pain conditions than it is to others.

Exclusion criteria:

1) Patients with pain that is associated with malignant disease will be excluded, as their illness perceptions are likely to be different from the rest of the pain population and they are a minority of the pain population seen in the chronic pain clinics.

2) Age limits will be set. Recruited patients will be over 18 and under 65, as adherence behaviours have been found to differ in children and older adults (e.g. Hughes, 2004), and there are different consent issues in these populations.

3) As this is a self-completion questionnaire study, patients will be excluded if they cannot understand spoken and written English. Time pressures on the consultant anaesthetists make it impractical for questionnaires to be read out to patients with

literacy difficulties. However, if the patient has a translator or interpreter with them who is prepared to help the patient complete the questionnaire, the patient will be included in the study.

b) Recruitment

Patients will be accessed from the weekly chronic pain clinics that run at a number of hospitals in Glasgow (Gartnavel General, Stobhill, Royal Infirmary, Victoria and Southern General Hospitals), focusing recruitment on 3 sites (Gartnavel General, Royal Infirmary and Stobhill). All patients who have been prescribed medication for their pain by their consultant anaesthetist will be invited to take part in the study. An audit of patients being seen by anaesthetists has been conducted. Results estimate an average recruitment rate of 15 patients per clinic, per week. Based on this estimate, recruitment will take place over an 8 week period, approximately.

c) Measures

A major difficulty in this area of research is the variety of instruments used to measure the independent and dependent variables. This diversity limits cross-study comparisons, and impedes the progress of research. Consequently, this study will adopt standardised measures to address the independent variables of illness perceptions and treatment beliefs. It will also adopt a standardised self-report measure of adherence. Self-report measures of adherence have been found to differ from objective measures of adherence by around 30% in chronic pain patients. For example, Berndt et al. (1993) found 70% correspondence between self-reports of adherence to medication in chronic pain and urine toxicology screening. Whilst toxicology screening would provide the most accurate way of measuring adherence, self-

report is recognised as an acceptable estimate of adherence when objective measures are ethically inappropriate, or practically unviable (Stephenson, 2003).

At assessment patients would be asked to complete a questionnaire pack including:

1) *The Illness Perceptions Questionnaire – Revised, IPQ-R* (Moss-Morris et al. 2002).

The Illness Perceptions Questionnaire (IPQ) has encapsulated the illness perception components of the SRM. The IPQ-R was chosen over the original Illness Perceptions Questionnaire (Weinman et al. 1996) as it has been validated on chronic pain patients and found to have good reliability and validity (Cronbach's alpha's for each of the subscales range from .79 to .89 and test-retest correlations from .46 to .88). The IPQ-R evaluates the 5 original dimensions of the SRM but breaks timeline and control beliefs into two scales and includes a measure of emotional response to illness. Scores for eight of the nine scales (identity, timeline, timeline cyclical, consequences, personal control, treatment control, coherence and emotional representation) are summed individually to assess the relative contributions they make to adherence. The cause section is not treated as a scale but analysed as separate items in accordance with authors' recommendations (Moss-Morris et al. 2002). This study will use the standardised Chronic Pain version of the IPQ-R. The questionnaire therefore does not need to be altered to suit the client group.

2) *Beliefs about Medicines Questionnaire, BMQ (Horne et al. 1999)*

The BMQ will be employed to measure patients' beliefs about prescribed medication for pain. The BMQ contains two scales: one assessing the patient's concerns about their medication the other their beliefs about the necessity of their medication. It has been validated on other chronic illness populations and shows good reliability and validity (Cronbachs alpha .75 and .80 and test-retest .76 and .77 when validated on asthmatic patients). It has been used to

assess treatment beliefs in previous studies (e.g. Horne and Weinman, 2002), and has also been used to assess chronic pain patients' beliefs about their medication (Hobro et al. 2004).

3) *Medication Adherence Report Scale. MARS* (Horne and Hankins, 2001).

The MARS is a 5 item self-report questionnaire that has been used in published papers to assess the degree of adherence to medications prescribed for chronic pain (Horne and Weinman, 2002). The frequency of non-adherent behaviours (deciding to miss a dose, forgetting to take a dose, altering the dose, stopping taking doses for a while and taking less than instructed) is measured on a 5-point Likert-type scale. Scores are summed to give a continuous measure of adherence or can be split into categories of 'high' and 'low' adherence.

The scale can produce both continuous and dichotomised (good/poor adherence) scales. This study will use a continuous scale, as important material is lost when the scale is dichotomised (Oppenheim, 1992). Convergent validity has been assessed between the BMQ and MARS with negative correlations between the BMQ-concerns and MARS and positive correlations between BMQ-necessity and MARS (Horne and Hankins, 2001).

4) *Pain Numerical Rating Scale. PNRS*

Numerical rating scales have been recommended by a leading international group of pain researchers to measure pain in chronic pain trials (McQuay, 2004). The PNRS provides a measure of the severity of the patient's pain by asking them to rate their pain on a scale of 0 to 10, where ten indicates the most severe pain.

d) Design and Procedure

All patients receiving a clinic appointment during the recruitment phase of the study will be sent information about the study and a consent form no later than two weeks before their appointment. Anaesthetists will ask patients who are currently taking medication for chronic pain to take part in the study during their routine consultation. Participants will be given the opportunity to ask questions about the study before signing the consent form and completing the questionnaires detailed above.

e) Settings and Equipment

Recruitment will be carried out in the pain clinics. The researcher will require access to paper and a photocopier. A computer package will also be required for statistical analysis such as EQS (ver 6.1: Bentler, 1995).

f) Power Calculation

Bentler and Chou (1987) recommended 15 participants per variable as a guideline for sample size in structural equation modelling. Horne and Weinman (2002) have 5 variables in their model (timeline, consequences, necessity, concerns, adherence rating) so replicating their model would require 75 participants.

A more formal calculation of sample size of 216 patients has been determined using the UCLA website. This is based on a Null hypothesis value of 0, an alternative hypothesis value of .19 (using the weakest correlation from Horne and Weinman, 2002), and using

participants will be aimed for to allow for attrition and missing data.

g) Data Analysis

The study will employ:

1) Descriptive statistics and Cronbach alpha values will be provided for each scale to demonstrate whether scales were internally reliable.
2) Scores on scales will be checked to see if they are normally distributed.
3) Pearson correlation coefficients will test the relationship between illness perception dimensions and adherence (hypothesis 1).
4) Correlation coefficients will also be employed to test hypothesis 2 i.e. adherence will be positively correlated with beliefs about the necessity of medication and negatively correlated with concerns.
5) Hypothesis 3 will be tested by hierarchical multiple linear regression.
6) The relationships between the SRM variables that are specified in Horne and Weinman's (2002) model, will be tested using a Structural Equation Modelling approach using the statistical package EQS (ver 6.1: Bentler, 1995). This approach also allows the overall fit of the model to be evaluated as well as testing the significance of mediated pathways.

Practical Applications

This study is the first to explore the specific illness and treatment representations that most strongly affect adherence in the chronic pain population. It is also the first stage of a continuing research programme in the Glasgow chronic pain service. The results of this study

can be used to improve practice. For example, clinicians working with chronic pain patients could improve adherence to prescribed medication by identifying and challenging problematic representations. The impact of altering illness and treatment representations on adherence could be evaluated by further studies.

Ethical Issues

1) The proposed study will involve patients filling out a number of straightforward questionnaires. It is proposed that each set of responses will be coded to retain confidentiality and entered onto a secure computer database. Original transcripts will be kept in a locked filing cabinet.
2) The study will not affect the treatment that participating patients receive.
3) It is likely that non-adherent behaviour will be reported on the Medication Adherence Scale. This information will be a general overview of the way a patient uses medication and not specific details on what medication they are not taking correctly. We will therefore be unable to identify any specific concerns about medication. Thus patients will be informed that no action will be taken if they report non-adherent behaviour. The information collected is providing a snap shot of patient's behaviours and no intervention will be offered to alter behaviour. This will also be made clear in the patient information leaflet.
4) Access to details i.e. age, gender, diagnosis for patients who opt out of study would be preferable to allow for comparison but may pose ethical problems. Guidance notes for the Local Research Ethics Committee state that anonymised, aggregrated patient information can be used in NHS studies without the patient's express consent.

References

Bentler, P.M. & Chou, C. (1987). Practical issues in structural modelling. Sage: Beverly Hills, CA.

Bentler, P.M. (1995). EQS Structural Equations Program Manual. Multivariate Software, inc: Encino, CA.

Berndt, S., Maier, C. & Schutz, H.W. (1993). Polymedication and medication compliance in patients with chronic non-malignant pain. Pain. 52(3): 331-339.

Clinical Standards Advisory Group (2000). Services for people with pain. Her Majesty's Stationary Office, London.

Connor, M. and Armitage, C.J. (2000). Efficacy of the Theory of Planned Behaviour: A meta-analytic review. British Journal of Social Psychology, 40, 471-499.

Glasgow R.E., McCaul K.D. & Schafer L.C (1986). Barriers to regime adherence amongst person with insulin dependent diabetes. Journal of Behavioral Medicine. 9(1): 65-77.

Guzman, J. Esmail, R., Karjalainen K., Malmivaara, A., Irvin, E. and Bombardier, C. (2004). Multidisciplinary bio-psycho-social rehabilitation for chronic low back pain. The Cochrane Database of Systematic Reviews, The Cochrane Library, Volume 4.

Hagger M.S. & Orbell S. (2003). A meta-analytic review of the common sense model of illness representations. Psychology and Health, 18(2), 141-184.

Haynes, R.B., Sackett, D.L. and Taylor, D.W. (Eds.). *Compliance in Health Care.* Baltimore, MD: John Hopkins University Press, 1979.

Hobro, N., Weinman, J. & Hankins M. (2004). Using the self-regulatory model to cluster chronic pain patients: the first step towards identifying relevant treatments? Pain. 108(3): 276-283.

Horne, R., Weinman, J. (1999). Patient beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. Journal of Psychosomatic Research. 47(6): 555-567.

Horne, R., Weinman, J. and Hankins. M. (1999). The beliefs about medicines questionnaire: the development and evaluation of a new method of assessing the cognitive representation of medication. Psychological Health. 14: 10-24.

Horne, R & Hankins, M. (2001). The MARS-5: An instrument to assess self-reported adherence to medication prescriptions. University of Brighton, UK.

Horne, R. & Weinman, J. (2002). Self-regulation and self-management in asthma: exploring the role of illness perceptions and treatment beliefs in explaining non-adherence to preventer medication. Psychology and Health. 17(1): 17-32.

Hughes, C.M. (2004). Medication non-adherence in the elderly. Drugs Aging. 21(12): 793-811.

Jessop, D.C. & Rutter, D.R. (2003). Adherence to Asthma Medication: The role of Illness representations. Psychology and Health. 18(5): 595.

Karjalainen, K., Malmivaara, A., van Tulder, M., Roine, R., Jauhiainen, M., Hurri, H., Koes, B. (2004). Multidisciplinary biopsychosocial rehabilitation for subacute low-back pain among working age adults. The Cochrane Database of Systematic Reviews, The Cochrane Library, Volume 4.

Kendrew P., Ward F., Buick D., Wright D. & Horne R. (2001). Satisfaction with information and its relationship with adherence in patients with chronic pain. International Journal of Pharmacy Practice. 9(suppl): R5.

Leventhal, H., Meyer, D. and Nerenz, D. (1980). The common sense representation of illness danger. In: Rachman, S. (Ed.). Contributions to medical psychology. Pp. 7-30. Pergamon Press, Oxford.

Leventhal, H., Diefenbach, M. & Leventhal, E.A. (1992). Illness Cognition: Using common sense to understand treatment adherence and affect cognitive interactions. Cognitive Therapy and Research. 16(2): 143-163.

Ley, P. Compliance among patients. In A. Baum, S. Newman, J. Weinman, et al. (Eds.), Cambridge Handbook of Psychology, Health and Medicine. Cambridge, UK: Cambridge University Press, 1997: 281-284.

Marteau, T. (1995). Health beliefs and attributions. In Broome, A.K. and Llewelyn, S. (Eds.) Health Psychology: Processes and Applications. London: Chapman and Hall.

McQuay, H. (2005). Consensus on outcome measures for chronic pain trials. Pain. 113: 1-2.

Moss-Morris, R., Weinman, J., Petrie, K.J., Horne, R., Cameron, L. and Buick, D. (2002). The revised illness perception questionnaire (IPQ-R). Psychology and Health. 17(1): 1-16.

Oppenheim, A.N. (1992). Questionnaire design, interviewing and attitude measurement. Pinter, London.

Rogers P.G & Bullman W.R. (1995). Prescription medicine compliance: A review of the baseline of knowledge. A report of the National Council on Patient Information and Education. Journal of Pharmacoepidemiology; 2:3.

Ross, S, Walker, A. and MacLeod, MJ. (2004). Patient compliance in hypertension: Role of illness perceptions and treatment beliefs. Journal of Human Hypertension. 18(9): 607-613.

Rutter, D.R. (2000). Attendance and reattendance for breast cancer screening: A prospective 3-tyear test of the Theory of Planned Behaviour. British Journal of Health Psychology, 2, 199-216.

Sheeran P. (2005). Implementation Intentions and health behaviours. In M. Conner & P. Norman (Eds). Predicting heath behaviour: Research and practice with social cognition models (2nd ed.). Buckingham, UK: Open University Press, in press.

Stephenson B.J., Rowe B.H., Macharia W.M., Leon, G. & Haynes, R.B. (1993). Is this patient taking their medication as prescribed? JAMA. 269:2779-81.

UCLA website accessed on 15/01/05. http://calculators.stat.ucla.edu/powercalc/

Walsh, J.C., Lynch, M., Murphy, A.W. and Daly, K. (2004). Factors influencing the decision to seek treatment for symptoms of acute myocardial infarction: an evaluation of the self-regulatory model of illness behaviour. Journal of Psychosomatic Research. 56(1): 67-73.

Weinman, J. Petrie, K.J., Moss-Morris, R., & Horne, R. (1996). The Illness Perception Questionnaire: A new method for assessing illness perceptions. Psychology and Health, 11, 431-446.

Whitmarsh et al. (2003). Illness perceptions, mood and coping in predicting attendance at cardiac rehabilitation. Health Psychology. 8(2): 209-221.

World Health Organisation. (2003). Adherence to long-term therapies: Evidence for action. WHO, Geneva.

Figure 1 The self-regulatory model

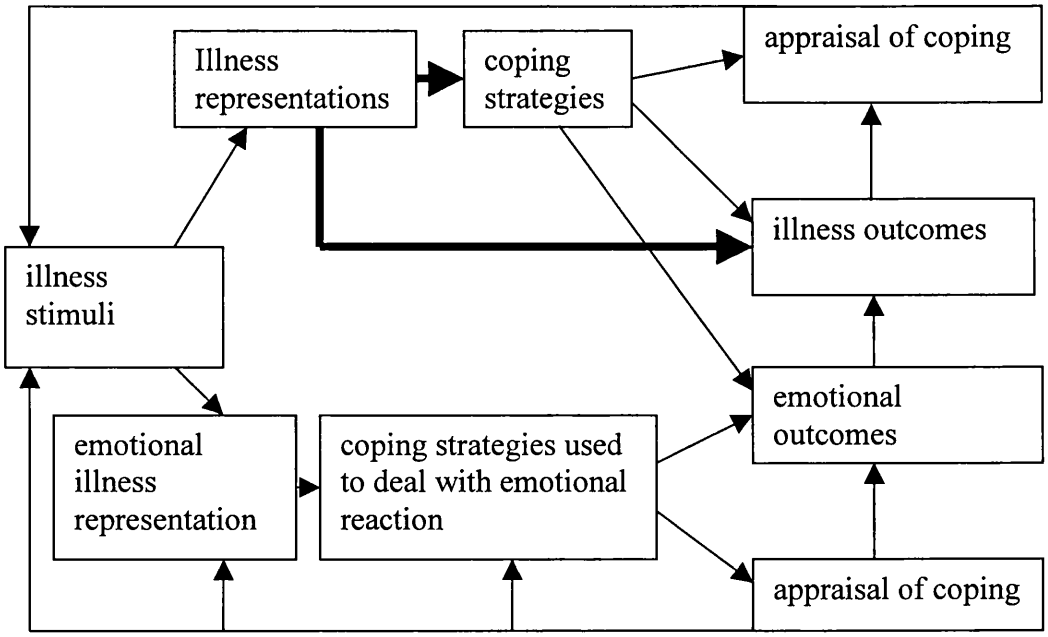
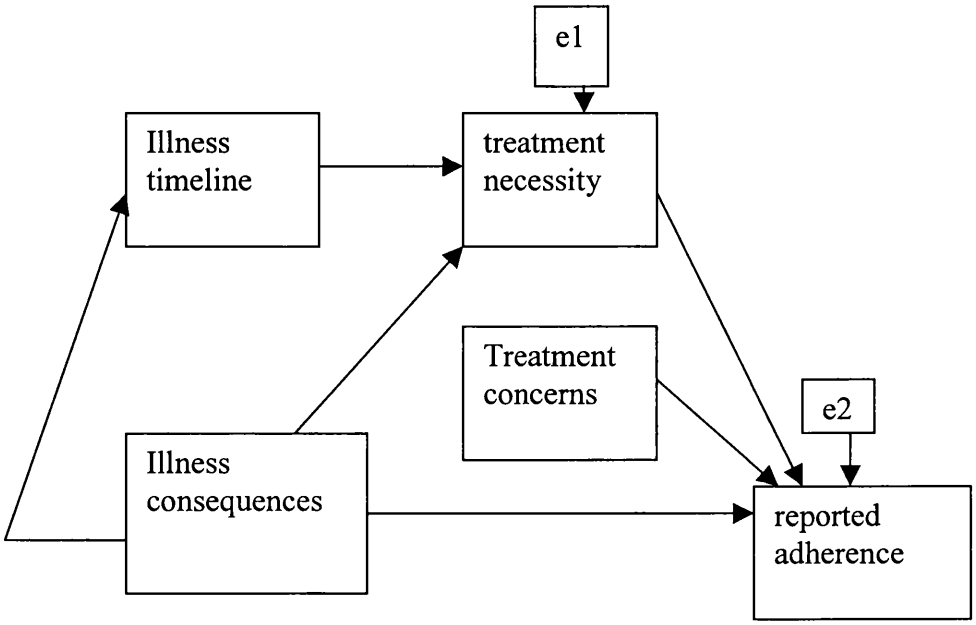


Figure 2 **A Structural Equation Model of the extended SRM (Horne and Weinman, 2002)**



Amendments to proposed project

Amendment 1: *'Age limits will be set. Recruited patients will be over 18 and under 65, as adherence behaviours have been found to differ in children and older adults (e.g. Hughes, 2004), and there are different consent issues in these populations.'*

The upper age limit for participants was removed as a substantial proportion of clinic patients were over 65 and it was felt that excluding these patients would reduce the ecological validity of the study. Approval for the change was granted from the Ethics Committee (appendix 4.3). There was not thought to be any different consent issues but the literature has mixed findings on rates of adherence in older adults, therefore the effects of age on adherence were explored in the study's results.

Amendment 2: *'All patients receiving a clinic appointment during the recruitment phase of the study will be sent information about the study and a consent form no later than two weeks before their appointment. Anaesthetists will ask patients taking medication for chronic pain to take part in the study during their routine consultation. Participants will be given the opportunity to ask questions about the study before signing the consent form and completing the questionnaires detailed above.'*

The local ethics committee recommended that patients be given the option of opt-in to the study as opposed to informed consent to reduce the likelihood of influence from the doctor-patient relationship. Patients therefore received a patient information sheet (appendix 4.2) before clinic attendance and could opt-in to the study at their clinic appointment.

Chapter 4: Major Research Project

Adherence to Pharmacological Treatment of Non-Malignant Chronic Pain: The Role of Illness Perceptions and Medication Beliefs

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Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology

Prepared in accordance with guidelines for submission to Pain (Appendix 4.1)

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Abstract

Objective. To identify the degree to which illness perceptions and medication beliefs explain variations in reported adherence to medication prescribed for the treatment of non-malignant chronic pain and to test the applicability of an extended version of the self-regulatory model (SRM) to the chronic pain population.

Design and method. A cross-sectional design of 217 patients attending a chronic pain clinic, who completed validated questionnaires assessing their illness perceptions, medication beliefs and reported adherence to medication.

Results. Perceptions of illness (pain) as chronic, uncontrollable and unremitting (not cyclical) were associated with greater adherence to medication, fewer concerns about medication and a belief that treatment was necessary. Illness and medication beliefs each added 3% to the variance in adherence explained by demographic and clinical variables in a regression analysis. Structural equation modelling supports an extended SRM for chronic pain. It suggests that patients holding perceptions of serious consequences of pain and high levels of emotion have more concerns about medication and are less adherent. Perceptions of serious consequences of illness are also associated with stronger beliefs about the necessity of medicines and greater adherence.

Discussion. Beliefs about illness and medication are associated with adherence to treatment in chronic pain and this can be explained by an extended SRM. These results are preliminary and require replication. Further studies should further explore the role that emotion has on coping strategies in chronic pain. Interventions should focus on altering unhelpful beliefs that reduce adherence.

Keywords. Illness perceptions: Medication beliefs: Chronic pain: Adherence: Self-regulatory model: Structural equation modelling

Introduction

Chronic Pain

Chronic pain has been defined as 'pain that either persists beyond the point at which healing would be expected to be complete or that occurs in disease processes in which healing does not take place' (Clinical Standards Advisory Group 2000). The term is used to encapsulate pain associated with a variety of conditions such as fibromyalgia, chronic low back pain and rheumatoid arthritis. Chronic pain has a high prevalence and an influential report asserts that it affects 18% of Scottish people (McEwan, 2004). The Clinical Standards Advisory Group (2000) advised that although 'cure' is seldom an option in chronic pain, a great deal can be done to treat pain and alleviate its effects.

Patients experiencing chronic pain in Scotland have high rates of mental health problems, high utilisation of health services and high unemployment (Haetzman et al. 2003). Chronic pain has proved resistant to treatment (Guzman et al, 2004), and this is associated with significant non-adherence to prescribed medication (Kendrew et al. 2001). There is a clear requirement to investigate factors that predict non-adherence in this population, thereby facilitating interventions to improve adherence. Improving the management of chronic pain would have substantial benefits to the patient, health services and the economy.

Factors Predicting Adherence in Chronic Pain

The literature examining non-adherence in chronic pain is under-developed, compared to research that has examined non-adherence in other medical populations. In the wider literature, patient characteristics (e.g. demographic and clinical factors) and practical factors (e.g. collection of prescriptions) have been proposed to influence adherence. Psychological factors

(e.g. beliefs about illness and medication) are important and are related to adherence to treatment in other chronic conditions (Weinman and Petrie, 1997).

The Self-Regulatory Model

A number of models have been proposed to explain how psychological factors influence adherence. One model that has proved popular with researchers is Leventhal and colleagues' self-regulatory model (SRM), as it can be applied to a wide range of specific illness conditions (Leventhal et al. 1980; Leventhal et al. 1992). Cognitive and emotional representations of the illness ('illness perceptions') are of key importance in the SRM. It is proposed that illness perceptions influence coping behaviours, including adherence to treatment regimens, and health outcomes in people experiencing illness. The SRM is a dynamic system and it is proposed that coping effectiveness is reappraised, impacting on cognitive and emotional representations, and future coping responses.

Evidence Supporting the Application of the SRM to Adherence

A meta-analysis of forty-five studies using the SRM indicated that there was a reliable empirical basis for the proposed relationships between illness perceptions, coping and outcomes (Hagger & Orbell, 2003). Illness perceptions are proposed to be structured around 5 dimensions – that is the identity, timeline, consequences, causal factors and control/curability of the illness. Hagger and Orbell looked at the relationship between these dimensions and illness outcomes in their review and concluded that a chronic timeline, more serious consequences, a strong illness identity and a high number of symptoms were associated with poorer adjustment and outcomes, whereas a higher perceived level of controllability/curability was associated with better adjustment.

Most papers use the Illness Perceptions Questionnaire (Weinman et al. 1996) to measure cognitive representations. Studies have more recently used the revised version of this scale to measure emotional representations as well as the cognitive dimensions described above, enabling a comprehensive assessment of the SRM (Moss-Morris et al. 2002). Such studies indicated that higher emotional reactions were linked to poorer adherence (Ross et al. 2004) and reduced quality of life (Fowler & Baas, 2006).

The SRM has been used to explore adherence to treatment in diverse chronic illness populations and there is good evidence that the dimensions are stable across illnesses. However, Hagger and Orbell (2003) highlighted that the pattern of beliefs varies across illnesses and ought to be explored for different illness groups. There is a paucity of research examining illness perception variables, and their effects on treatment adherence, in the chronic pain literature.

Modelling the SRM

Studies demonstrating the value of the SRM in explaining adherence in chronic illness have mostly used regression analyses, which despite being depicted using path diagrams, do not allow for formal tests of mediating relationships. Few studies have fully tested the extent to which the data fit the predicted relations between illness perceptions and adherence. Horne and Weinman (2002) used structural equation modelling to examine the direct and indirect relationships between illness perceptions and medication beliefs in explaining non-adherence to asthma medication. They demonstrated that illness perceptions influence adherence both directly and indirectly through medication beliefs i.e. individuals who believed their asthma was a passing condition were less likely to support the necessity of their treatment, and were, as a consequence, less adherent to it. Figure 1 reproduces their model.

Insert Figure 1 here

Horne and Weinman's (2002) study suggested that the strength of the SRM to explain adherence was improved by extending it to include medication beliefs, and it provided preliminary empirical support for an extended self-regulatory model of treatment adherence.

Modelling the SRM in Chronic Pain

Moss-Morris et al. (2002) validated the IPQ-R on a sample of chronic pain patients and found that people with chronic pain had stronger perceptions of their illness as chronic, cyclical and uncontrollable with serious consequences and a high emotional impact than people with acute pain. To date there have been no studies using the SRM to predict adherence to treatment in chronic pain, although Gill and de C. Williams (2001) investigated whether illness and medication beliefs were related to the willingness of pain patients to try Cannabinoids as a pain reliever (Gill & de C.Williams et al. 2001) and Hobro et al. (2004) used the SRM to cluster chronic pain patients into subgroups. This study examines the role of illness perceptions and medication beliefs in predicting adherence, testing the applicability of the extended self-regulatory model for the first time in the chronic pain population.

Hypotheses

1) Adherence to prescribed medication will be explained by illness perceptions as described by Hagger and Orbell (2003): Perceptions of a chronic timeline, more serious consequences, a strong illness identity, more symptoms and higher emotional response will be associated with poorer adherence, and higher perceived levels of controllability/curability will be associated with better adherence.

2) Adherence to prescribed medication will correlate positively with patients' perceptions of the need for prescribed medication and correlate negatively with concerns about potential negative effects.
3) Beliefs about medication will add to the proportion of variance in adherence that is explained by illness perceptions, clinical factors and demographic variables.
4) The extended SRM model, as proposed in Horne and Weinman (2002), will be a good fit to the data (as judged by a variety of fit indices).

Study Design

Participants

Participants were adults with non-malignant chronic pain who were prescribed medication for pain at hospital-based pain clinics in Glasgow. Participants could understand written and spoken English. Pain conditions sampled were heterogeneous.

Recruitment

All patients attending pain clinics in north Glasgow across a four-month period (November 2005-February 2006) received study information (Appendix 4.2) before clinic attendance and could opt-in to the study at their clinic appointment. Participants had the option of completing the questionnaires at the clinic or returning them in the SAE provided. Approval was granted from the local ethics committees (Glasgow Primary Care and North Glasgow Hospital Committees, approval letters Appendix 4.3).

Measures

This study adopted four standardised self-report measures in addition to questions regarding relevant demographic and clinical variables (questionnaire pack, Appendix 4.4).

1) *The Illness Perceptions Questionnaire – Revised, IPQ-R* (Moss-Morris et al. 2002).

The IPQ-R was chosen over the original Illness Perceptions Questionnaire (Weinman et al. 1996) as it has been validated on chronic pain patients and found to have good reliability and validity (Cronbach's alpha's for each of the subscales range from .79 to .89 and test-retest correlations from .46 to .88). The IPQ-R also includes a measure of emotional response to illness, enabling evaluation of emotional representations. The IPQ-R includes the 5 original dimensions of the SRM but breaks timeline and control beliefs into two scales. Scores for eight of the nine scales (identity, timeline, timeline cyclical, consequences, personal control, treatment control, coherence and emotional representation) are summed individually to assess the relative contributions they make to adherence. The cause section is not treated as a scale but analysed as separate items in accordance with authors' recommendations (Moss-Morris et al. 2002).

2) *Beliefs about Medicines Questionnaire, BMQ (Horne et al. 1999)*

The specific section of the BMQ was employed to measure patients' beliefs about medication prescribed for pain. The BMQ specific section contains two scales: one assessing the patient's concerns about their medication the other their beliefs about the necessity of their medication. It has been validated on other chronic illness populations and shows good reliability and validity (Ramsay et al. 2006, unpublished thesis).

3) Medication Adherence Report Scale. MARS (Horne and Hankins, 2001).

The MARS is a self-report questionnaire that assesses the degree of adherence to prescribed medications (Horne and Weinman, 2002) The frequency of 5 non-adherent behaviours (deciding to miss a dose, forgetting to take a dose, altering the dose, stopping taking doses for a while and taking less than instructed) is measured on a 5-point Likert-type scale. A sixth item

('I take more than instructed') was added following discussion with the authors to capture an additional element of non-adherence relevant to the pain population. Scores were summed to give a continuous measure of adherence. Convergent validity has been assessed between the BMQ and MARS with negative correlations between the BMQ-concerns and MARS and positive correlations between BMQ-necessity and MARS (Horne and Hankins, 2001).

There are limitations to using a self-report measure of adherence, however, due to practical reasons, it was the only clinically viable option in this study. Self-report has been found to differ from objective measures of adherence by around 30% in chronic pain patients (Berndt et al. 1993). Whilst toxicology screening would provide the most accurate way of measuring adherence, self-report is recognised as an acceptable estimate of adherence when objective measures are ethically inappropriate, or not viable for practical reasons (Stephenson, 2003).

4) *Pain Numerical Rating Scale. PNRS*

Numerical rating scales have been recommended to measure pain in chronic pain trials by a leading international group of pain researchers (McQuay, 2005). The PNRS provides a measure of the severity of the patient's pain by asking them to rate their pain on a scale of 0 to 10, where ten indicates the most severe pain.

Power Calculation

A formal calculation of sample size indicated that 216 patients were required for the study to be adequately powered (UCLA website). This is based on a Null hypothesis value of 0, an alternative hypothesis value of .19 (using the weakest correlation coefficient from Horne and Weinman, 2002), and using conventional significance levels of .05, a power of .8 and a 2-tailed design. However, the sample size required is reduced to 171 using the one-tailed design used here.

Statistical Methods

Statistical analysis was carried out using the SPSS for Windows statistical software Package (version 13, SPSS Inc. 2004). The reliability and distribution of scales was checked before performing bivariate and multivariate analyses. Pearson correlation coefficients were employed to examine the relationship between demographic, clinical, illness perceptions and medication belief variables with adherence. Hierarchical linear regression was then used to identify the variables predicting adherence, using only variables identified as significant at the bivariate level. This methodology is often used when there are a large number of variables measured and is a procedure used in similar study designs (e.g. Butler et al. 2004, Ross et al. 2004). The extended SRM model proposed in a previous chronic illness sample (Horne and Weinman, 2002) was tested using Structural Equation Modelling analysis (statistical package EQS, version 6.1: Bentler, 1995). This approach also allows the overall fit of the model to be evaluated as well as testing the significance of mediated pathways between elements of the model.

Results

The results will be presented in the following order: firstly, missing data procedure, demographic details, scale descriptives and the relationships between demographic variables and adherence are described. Findings relating to the study hypotheses are then addressed directly.

Missing data

Questionnaires were rejected if more than 30% of items were missing or illegible (following the methodology of Horne et al. 2001). Eighteen percent of questionnaires were rejected. Missing data on the IPQ-R were addressed using the mean imputation method advised by the scale developers (see website for scoring details: www.uib.no/ipq). The same procedure was adopted for the BMQ and MARS scales.

Participants

The demographic and clinical characteristics of 217 participants are presented in Table 1. The participants represent a broad range of age and education, although it is worth noting that they represent inner city clinics and around one third of participants left school without formal qualifications. Participants had been experiencing pain for a mean of 10 years but this ranged from 6 months to 42 years. Pain ratings were high with an average of 8 out of 10. Two thirds of participants rated more than one location of pain. The lower back was the most common site of pain (44%), followed by legs (22%) and neck (12%). Participants were taking a very wide range of medicines with 51 different brands reported. The most common type of medication taken was Tramadol, a moderately strong, opiate-based analgesic (28%).

Ethics recommendations precluded access to details of non-respondents, but participants were compared with the demographics of an audit of new patients attending Glasgow pain clinics (Rae et al. 1999). Participants did not differ in terms of age, gender or location of pain. However, despite the poor education status of participants in this study, twice as many (62%) of participants in the audit left school without formal qualifications. There are therefore a considerable proportion of clinic attendees that may have literacy problems. The impact of education on adherence is further investigated below.

Insert Table 1 here

Scale Descriptives

The internal consistency and distribution of scales were checked before performing bivariate and multivariate analyses (see Table 2). Internal consistency (as measured by Cronbach's alpha) was acceptable for all scales except IPQ-R personal control (0.66), IPQ-R treatment control (0.65) and BMQ concerns scales (0.62), which were borderline. Scales were normally distributed except the MARS scale, which was positively skewed (skewness statistic 1.520, SE 1.74). It was therefore transformed before being entered into analyses.

Insert Table 2 here

Illness Perceptions Scales

The means for scales and percentage of participants scoring above the scale mid-point (participants agreeing or strongly agreeing with statements) are given in Table 2. Most people saw their pain as a chronic (84%), and a cyclical (55%) condition. Participants reported that their pain had serious consequences on their life (72%). Only 36% reported that they felt in control of their pain and had confidence in the efficacy of medication in controlling their pain. Over half the sample (58%) reported a strong emotional response to their pain.

The IPQ-R Cause subscale was not treated as a cohesive scale in line with authors' recommendations and items were looked at individually. Participants most commonly rated 'bad luck' (42% sample agreeing or strongly agreeing with this as a causal agent), an accident (41%), aging (33%), or emotional state e.g. feeling down, lonely, anxious (28%) as related to their illness. However, there was a wide range of causal attributions endorsed by participants. The relationship between these four causal attributions and adherence was investigated

(applying the methodology of Horne and Weinman, 2002) using Independent sample t-tests. None of the four causal beliefs were significantly related to adherence and this scale was therefore dropped from further analysis.

Beliefs about Medicines

Sixty four percent of participants agreed or strongly agreed that their medicines were necessary, 42% agreed or strongly agreed that they had concerns about their medicines and 22% held both necessity and concern beliefs about medication.

MARS

As mentioned above, scores on the MARS were positively skewed (mean 1.69, SD 0.71). Twenty five percent of participants scored over the mid-point on the scale. The percentages of the sample endorsing individual MARS items are described in Table 3.

Insert Table 3 here

Relationships between demographic and clinical variables and adherence

Pearson correlation coefficients between study variables and adherence are shown in Table 4. Age was highly significantly correlated with adherence ($r = -.24$, $p<0.01$) indicating that older participants were more adherent to their pain medication than were younger participants. Participants with more education were also more adherent ($r = .12$, $p<0.05$). Gender was not significantly associated with adherence. The participants ratings of the severity of their pain was the only significant variable out of the clinical variables ($r = -.22$, $p<0.01$) indicating that those with greater pain were more adherent to their medication.

Insert Table 4 here

Testing the study hypotheses

Hypothesis 1. Adherence to prescribed medication will be explained by illness perceptions as described by Hagger and Orbell (2003): with perceptions of a chronic timeline, more serious consequences, a strong illness identity, more symptoms and higher emotional response being associated with poorer adherence, and higher perceived levels of controllability/curability being associated with better adherence.

Pearson correlation coefficients between IPQ-R scales and reported adherence are displayed in Table 4. Higher scores on the timeline cyclical subscale ($r = .16$, $p<0.05$) were associated with poorer adherence, as hypothesised. Perception of a chronic timeline ($r = -.13$, $p<0.05$) was associated with greater adherence. Higher perceived levels of control were associated with poorer adherence ($r = .15$, $p<0.05$). The findings for the timeline and control subscales differ from the hypothesised direction of the relationships. Consequences, illness identity, treatment control, illness coherence and emotional subscales were not significantly associated with adherence. Hypothesis 1 was therefore only partially supported as some IPQ-R subscales were not significantly related to adherence, and not all associations were in the predicted direction.

The IPQ-R subscales that were not related directly to adherence were significantly related to the BMQ scales, except treatment control. Increased identity ($r = .19$, $p<0.01$), consequences ($r = .24$, $p<0.01$) and emotion ($r = .31$, $p<0.01$) scores were highly correlated with increased concerns about pain medications whereas increased illness coherence was significantly associated with fewer concerns ($r = -.21$, $p<0.01$). Increased consequences ($r = .47$, $p<0.01$), timeline ($r = .28$, $p<0.01$) and emotion ($r = .32$, $p<0.01$) scores were highly significantly correlated with increased treatment necessity, whereas increased personal control was associated with lower necessity scores ($r = -.12$, $p<0.05$).

Hypothesis 2. Adherence to prescribed medication will be related to beliefs about medication. Adherence will be positively correlated with patients' perceptions of the necessity of prescribed medication and negatively correlated with concerns about potential negative effects.

Table 4 also illustrates that necessity was highly significantly correlated with adherence ($r = -.19$, $p<0.01$) with those who held higher necessity beliefs being more adherent. Concerns were significantly correlated with adherence, indicating that those with higher concerns were less adherent to their medication ($r = .12$, $p<0.05$). Hypothesis 2 is supported but it is acknowledged that these correlations are low and the large sample size of this study, combined with multiple comparisons, increases the chance of type 1 error.

Hypothesis 3: Beliefs about medication will add to the proportion of variance in adherence that is explained by illness perceptions, clinical factors and demographic variables.

A hierarchical linear regression (Table 5) demonstrated that 5% of the variance in adherence scores was explained by the demographic variables 'age' and 'educational status'. A further 2% of the variance was explained by considering the clinical variable 'pain rating'. Illness perceptions (timeline, timeline cyclical and personal control) and beliefs about medicines (necessity, concerns) each add a further 3% to the variance explained. Hypothesis 3 is supported, as beliefs about medication add to the proportion of the variance explained by illness perceptions, clinical factors and demographic variables. However the amount of added variance is small and the overall the regression model explains only 9% of the variance. Regression analysis did not provide strong evidence that illness and medication beliefs explain variance in adherence. Structural equation modelling provided a stronger explanatory model and this is outlined below.

Insert Table 5 here

Hypothesis 4: Structural Equation Modelling – The extended SRM model, as proposed in Horne and Weinman (2002), will be a good fit to the data (as judged by a variety of fit indices).

The model proposed by Horne and Weinman (2002) was tested (see Figure 1), but it was not confirmed as a good fit for the current data (CFI = 0.78, RMSEA = 1.45, $\chi^2 = 27.42$, d.f. = 4, p = 0.00002). Appendix 4.5 provides further information on calculating goodness-of-fit in structural equation modelling. This model indicated that consequences were highly predictive of necessity scores and timeline was not related to the other variables. A modified model using the same variables without the timeline subscale was therefore tested, but did not fit the data (CFI = 0.79, RMSEA = 0.184, $\chi^2 = 21.75$, d.f. = 3, p = 0.00007). These models were conducted on the basis of past empirical results but were not representative of this population. An alternative model was proposed after revisiting the correlation coefficient matrix. The IPQ-R emotional representation and consequences scales had the largest relationships at the bivariate level with BMQ scales. The emotional representation scale was not included in Horne and Weinman's (2002) analysis and so its role in predicting adherence had not been tested. It was therefore theorised that emotion, as well as perceived consequences of pain, played an important role in affecting the treatment beliefs of this pain population.

A model including the IPQ-R scales of emotion and consequences and the BMQ scales of necessity and concerns was a good fit for the data (CFI = 0.974, RMSEA = 0.058, Satorra Bentler Scaled $\chi^2 = 8.15$, d.f. = 5, p = 0.15). The model is presented in Figure 2. To summarise this model, the IPQ-R scales influence adherence indirectly through medication beliefs. Higher consequence scores are associated with increased emotion, necessity and concern scores. Increased emotion is associated with increased concerns scores. Higher necessity scores predict better adherence while higher concerns score predict non-adherence. This model provides support that an extended SRM can be applied to chronic pain populations.

It is similar to the model proposed by Horne and Weinman (2002) as medication beliefs directly influence adherence whereas illness perceptions indirectly affect adherence. However, the significant illness beliefs differ in this population from those found in their asthma sample. Hypothesis 4 is therefore supported, although with some modification regarding the specific illness perceptions that influence adherence in this chronic pain population.

Insert Figure 2 here

Discussion

Study results

The main aim of this study was to examine the roles of illness and medication beliefs in reported adherence to medication prescribed for chronic pain. The study hypotheses were largely upheld. Illness and medication beliefs were related to adherence at the bivariate level, added to the variance explained in a regression analysis, and a structural equation model that included these variables was found to be a good fit to the data. The results relating to each hypothesis will be discussed before the study limitations and practical implications are examined.

Illness Perceptions and adherence

Participants viewed their pain as having a chronic, cyclical, uncontrollable course with serious consequences and a high emotional impact. This pattern of beliefs is consistent with the beliefs of chronic pain patients described by Moss-Morris et al. (2002). Hypothesis 1 was not fully confirmed, as although some illness perceptions were significantly related to adherence, others were not in the predicted direction or were non-significant. It is not surprising that the overall pattern of relationships differs from those described by Hagger and Orbell (2003), as studies of

different illness populations have found variations in patterns of illness perceptions (e.g. Ross et al. 2004). Indeed, although Hagger and Orbell (2003) conclude that illness representations are consistent in terms of dimensions across illnesses, they assert that significant differences remain between illness groups depending on severity, chronicity and illness type. This study is the first to describe the pattern of relationships between illness perceptions and adherence in chronic pain. Perceptions of a chronic, uncontrollable and unremitting (not cyclical) illness were associated with greater adherence to pain medications at the bivariate level.

It is interesting that illness perceptions that were not significantly associated with reported adherence were, with the exception of treatment control, related to medication beliefs. This finding is consistent with other papers that propose that the impact of the IPQ variables on adherence is mediated through the BMQ (Horne and Weinman, 2002, Ross et al. 2004). One might speculate that the treatment control scale would be associated with medication beliefs, however it was not in this study, suggesting that this scale may be measuring a different construct.

Beliefs about medicines and adherence

Two thirds of this sample believed their medicine was necessary, yet 42% also held concerns about their medication. It has been suggested that people weigh up their relative medication beliefs and are adherent if the necessity of their medicine is perceived more strongly than their concerns (Horne and Weinman, 1999). It is therefore possible for individuals to hold concerns about their medication and still be adherent. However, this study found that people who report stronger concerns and doubts about the necessity of their medication were more likely to have problems with adherence. This finding fits with the relationships between beliefs about medicines and adherence described in the other chronic illness samples (Ramsay et al. 2006, unpublished thesis).

Medication beliefs will add to the variance in adherence explained by other variables

Although illness and medication beliefs added to the amount of variance in adherence explained overall, the total amount of variance explained by psychological variables was less than expected given the findings of other studies. Horne and Weinman (2002) found medication beliefs explained 17% more variance than illness perception, demographic and clinical variables alone. The considerably weaker effect found in this study could be attributable to making only a minor adjustment to the MARS scale and not tailoring the other scales to be more specific to this population. It could also be a consequence of the larger impact of the demographic variables found in this study, or, and perhaps most likely, it could be due to the differences between this population and other chronic health conditions.

Horne and Weinman (2002) added seven asthma specific items to the BMQ and four to the MARS. Although this study added one item to the MARS ('I take more than instructed'), adding further items specific to chronic pain may have increased the variance explained by these measures. However, adding too many items may 'conflate' results and undermine confidence in the reliability and validity of these scales. Furthermore, there is a great deal of heterogeneity in the types of medicine taken for pain, which varies from analgesics to anti-epileptics. Therefore, it is difficult to make simple adjustments to the measures of medication beliefs so that they tie in with all the medicines used in the chronic pain population. Horne and Weinman (2002), on the other hand, could specify questions relating to the two main types of asthma medicines (preventer and reliever inhalers).

The results of this study suggest that age has an important relationship with adherence in chronic pain and this is surprising given that other studies, such as Horne and Weinman (2002), have found that demographic variables have a negligible association with adherence. A

significant relationship between age and adherence has been often observed in chronic illness samples (see Ramsay et al. 2006, unpublished thesis for a review). The interaction between age and adherence is well explained by the SRM, as it is inherent in self-regulatory theory that illness representations change over time. Leventhal and Crouch (1997) discuss the manner in which illness representations change across the lifecourse. It is suggested that older age is associated with overestimating chronicity, morbidity and mortality and therefore has the effect of increasing treatment seeking and compliance.

An extended self-regulatory model will be a good fit to the data

The structural equation model describes the ways in which patients' models of illness perceptions and treatment beliefs relate to adherence. Patients were more likely to have concerns about their medication if they believed that chronic pain had serious consequences and they were experiencing a greater emotional response to their illness. The consequence scale has been shown to be related both to expressing emotions and to avoidance coping strategies in other studies (Hagger and Orbell, 2003). It is perhaps unsurprising that people who are anxious will worry more about the effects of their medicines, what is more unexpected is the dual relationship between adherence and consequences i.e. people who experience serious consequences are also more likely to hold beliefs about the necessity of their medicines.

These results may indicate the appraisal process inherent in the self-regulatory model. For some people experiencing serious consequences, beliefs in the necessity of medication will outweigh concerns, resulting in better adherence. For others, concerns will outweigh necessity. Horne and Weinman (2002) suggest that illness consequences may be the result of adherence behaviour rather than a determinant and highlight the need for prospective studies to determine the causal direction of these effects. This model confirms a direct relationship between

necessity and concerns and adherence. This study therefore adds to the growing literature providing support for an extended self-regulatory model that includes beliefs about medicines as well as illness perceptions (Horne and Weinman, 2002; Byrne et al, 2005, Ross et al, 2005).

Limitations

It is important to acknowledge that the SEM model depicted in this study was derived from a post hoc analysis after the replication of a model that was a good fit in an asthma population did not fit this pain population. This study used the revised version of the Illness Perceptions Questionnaire and therefore had illness belief variables available for inclusion that were unavailable in Horne and Weinman's study (2002). They, particularly, were unable to measure the emotional representations of illness that proved important in this study population. Nonetheless, the model proposed here requires replication to determine the reliability of these results.

This study has a number of other limitations. Firstly, the cross-sectional design prevents exploration of the direction of causality. This would have been interesting, given that the pattern of associations between illness perceptions and adherence differed from those expected. Secondly, it may have been limited by measuring adherence through self-report. This study did not have the resources to use toxicology screening, which can be regarded as the gold standard. Self-report is less accurate than objective measures of adherence, but it has been shown to be a useful way to measure adherence when objective measures are unavailable (e.g. Choo et al. 1999, Dimtteo et al. 2002). Furthermore, it is the most practical and inexpensive measure to use in everyday practice.

Another consideration, regarding the reliability and validity of these results, is the poor educational status of many of the participants taking part in the study. It is possible that

question wording effects or simple literacy problems influenced the responses of this sample. Poor literacy may also have influenced the participants' adherence through increasing involuntary non-adherence i.e. through not understanding written dosage instructions. There is evidence that low levels of education are very common in pain clinic populations and it is therefore important to consider this in practice or when designing further research. Around one third (35%) of participants had no formal qualifications; this is less than a previous audit of Glasgow pain clinics, but similar to those described in another study investigating the SRM in a UK pain clinic sample (Hobro et al. 2004).

Practical Applications

This study is the first to explore the specific illness and medication representations that most strongly affect adherence in the chronic pain population. The direct cost of back pain is estimated to be £1632 million in the UK (Maniadakis and Gray, 2000). In financial terms alone, there is an obvious need to develop services that manage chronic pain more efficiently. A systematic review of outpatient services for chronic pain concluded that, while there is evidence that chronic pain clinics use interventions that provide pain relief for patients, there is little known about why treatment does not work for some (McQuay et al, 1997). It is acknowledged that problems with adherence are reducing the efficacy of pain treatments and that improving adherence will improve pain control within this population.

Despite the above limitations, the results of this study can be used to improve practice by providing a model for understanding non-adherence. Firstly, this study demonstrates that medication beliefs have a salient and direct effect on chronic pain patients' adherence. On an individual basis, clinicians could therefore use the BMQ to detect problematic medication beliefs in patients with poor adherence and then challenge these beliefs through discussion with the patient. A more global and less specific approach could be designing an information sheet

that highlights the necessity and discusses the concerns, e.g. side effects that patients may hold about pain medication. However, it is worth considering the low levels of education in clinic patients when designing any written information. The efficacy of both these approaches could be evaluated in future studies. Secondly, challenging the illness representations that influence medication beliefs may also enhance the impact of interventions. For example, highlighting the relationship between good adherence and fewer consequences of pain (e.g. better able to perform activities of daily living) may increase the perceived need for medicines and improve adherence.

It would be interesting to further explore the role that emotion has on coping strategies in chronic pain by including a comprehensive measure of anxiety and depression in a longitudinal study. There are many ways in which mood may affect illness representations and adherence. Increased levels of anxiety can inflate concerns about medication as found in this study. Stress management skills may reduce emotional response and prove helpful in improving adherence in chronic pain patients by reducing their treatment concerns. However, mood could also affect adherence through other routes that are not as well represented by the emotions scale of the IPQ-R e.g. depression could increase pessimism regarding treatment effectiveness. Indeed a recent study found that patients with coronary heart disease that were depressed were less adherent than those that were not depressed (Bane et al. 2006). Levels of depression and their impact on adherence in chronic pain should be assessed in future studies.

References

Bane C, Hughes CM, McElnay JC. The impact of depressive symptoms and psychosocial factors on medication adherence in cardiovascular disease. PEC 2006;60(2):187-193.

Bentler PM. EQS Structural Equations Program Manual. Encino, CA. Multivariate Software Inc. 1995.

Berndt S, Maier C, Schutz HW. Polymedication and medication compliance in patients with chronic non-malignant pain. Pain 1993;52(3):331-339.

Butler JA, Peveler RC, Roderick P, Smith PWF, Horne R, Mason JC. Modifiable risk factors for non-adherence to immunosuppressants in renal transplant recipients: A cross-sectional study. Nephrol Dial Transplant 2004;19(12):3144-3149.

Clinical Standards Advisory Group. Services for people with pain. HMSO, London. 2000.

Choo PW, Rand CS, Inui TS, Lee MT, Cain E, Cordeiro-Breault M, Canning, C, Platt R. Validation of patient reports, automated pharmacy records and pill counts with electronic monitoring of adherence to antihypertensive therapy. Med Care 1999;37:846-857.

Dimtteo MR, Giordani PJ, Lepper HS, Croghan TW. Patient adherence and medical treatment outcomes: a meta-analysis. Med Care 2002;40:794-811.

Fowler C, Baas LS. Illness representations in patients with chronic kidney disease on maintenance haemodialysis. Nephrol Nurs J 2006;33(2):173-186.

Gill A, de C. Williams AC. Preliminary study of chronic pain patients' concerns about cannabinoids as analgesics. Clin J Pain 2001;17(3):245-248.

Guzman J, Esmail R, Karjalainen K, Malmivaara A, Irvin E, Bombardier C. Multidisciplinary bio-psycho-social rehabilitation for chronic low back pain. CDSR, The Cochrane Library, Volume 4. 2004.

Haetzman M, Elliott AM, Smith BH, Hannaford PC, Chambers WA. Chronic pain and the use of conventional and alternative therapy. Fam Pract 2003;20(2):147-54.

Hagger MS, Orbell S. A meta-analytic review of the common sense model of illness representations. Psychol Health 2003;18(2):141-184.

Hobro N, Weinman J, Hankins M. Using the self-regulatory model to cluster chronic pain patients: the first step towards identifying relevant treatments? Pain 2004;108(3): 276-283.

Horne R, Hankins M. The MARS-5: An instrument to assess self-reported adherence to medication prescriptions. University of Brighton, Brighton, UK. 2001.

Horne, R., Sumner, S., Jubraj, B., Weinman, J. and Frost S. Haemodialysis patients' beliefs about treatment: Implications for adherence to medication and fluid-diet restrictions. International Journal of Pharmacy Practice 2001; 9(3): 169-175.

Horne R, Weinman J. Patient beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. J Psychosom Res 1999;47(6):555-567.

Horne R, Weinman J. Self-regulation and self-management in asthma: exploring the role of illness perceptions and treatment beliefs in explaining non-adherence to preventer medication. Psychol Health 2002;17(1):17-32.

Horne R, Weinman J, Hankins M. The beliefs about medicines questionnaire: the development and evaluation of a new method of assessing the cognitive representation of medication. Psychol Health 1999;14:10-24.

Kendrew P, Ward F, Buick D, Wright D, Horne R Satisfaction with information and its relationship with adherence in patients with chronic pain. Int J Pharm Pract 2001;9(suppl):R5.

Leventhal EA, Crouch M. Are there differences in Perceptions of Illness Across the Lifespan. In Petrie K.J. and Weinman, J.A. Perceptions of Health and Illness: Current Research and Applications, (ed). London: Harwood Academic, 1997. pp.77-102.

Leventhal H, Meyer D, Nerenz D. The common sense representation of illness danger. In: Rachman, S. (Ed.). Contributions to medical psychology. Pergamon Press, Oxford, 1980. pp. 7-30.

Leventhal H, Diefenbach M, Leventhal EA. Illness Cognition: Using common sense to understand treatment adherence and affect cognitive interactions. Cog Ther Res 1992;16(2):143-163.

Maniadakis N, Gray A. The economic burden of back pain in the UK. Pain 2000;84:95-103.

McEwan J. Chronic Pain Services in Scotland. HDL, Scottish Executive: Edinburgh. 2004.

McQuay H J, Moore RA, Eccleston C, Morley S, Williams A C de C. Systematic review of outpatient services for chronic pain control. Health Technology Assessment 1997;1(6).

McQuay H. Consensus on outcome measures for chronic pain trials. Pain 2005;113:1-2.

Moss-Morris R, Weinman J, Petrie KJ, Horne R, Cameron L, Buick D. The revised illness perception questionnaire (IPQ-R). Psychol Health 2002;17(1):1-16.

Rae CP, McGlone S, Asbury AJ. The social burden of chronic pain: a profile of new patients attending pain management clinics in Glasgow. Unpublished audit. University Department of Anaesthesia, Western Infirmary, Dumbarton Road, Glasgow, G11 6NT. 1999.

Ramsay LB, Dunbar M, Wild M. The role of beliefs about medicines in adherence to pharmacological treatment of chronic illness: A systematic review of the literature. Unpublished Doctoral Thesis, University of Glasgow. 2006.

Ross S, Walker A, MacLeod MJ. Patient compliance in hypertension: Role of illness perceptions and treatment beliefs. J Hum Hypertens 2004;18(9):607-613.

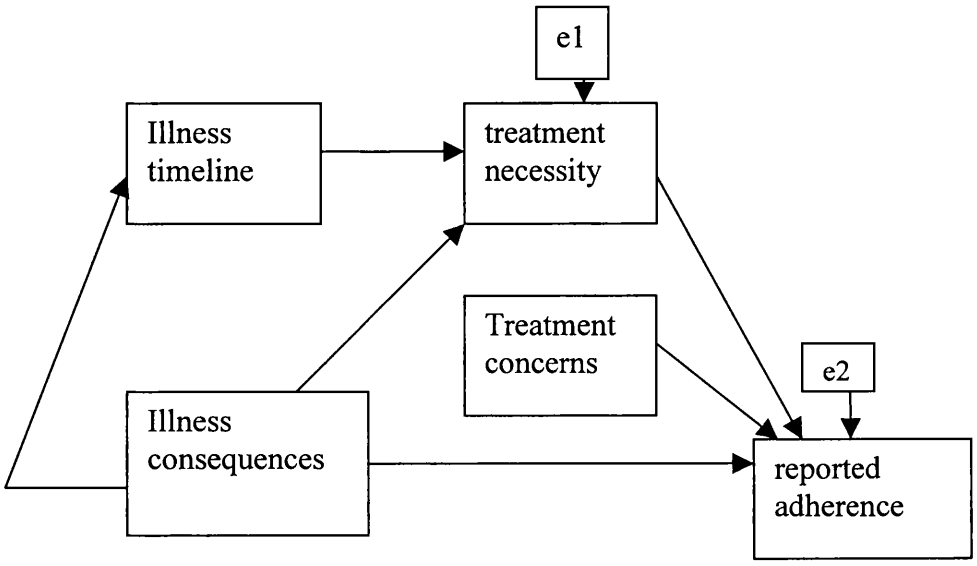
Statistical package for the Social Sciences. Version 13. Chicago, IL: SPSS Inc. 2004.

UCLA website accessed on 15/01/05. http://calculators.stat.ucla.edu/powercalc/

Weinman, J. Petrie, K.J., Moss-Morris, R., & Horne, R. (1996). The Illness Perception Questionnaire: A new method for assessing illness perceptions. Psychology and Health, 11, 431-446.

Weinman JA, Petrie KJ. Perceptions of Health and Illness. In Petrie KJ, Weinman JA. Perceptions of Health and Illness: Current Research and Applications, (ed). London: Harwood Academic, 1997. pp.1-17.

Figure 1 **A Structural Equation Model of the extended SRM (Horne and Weinman, 2002)[2]**



[2] e1 and e2 indicate error values in the model.

Table 1 **Demographic information and illness features (N = 217)**

Gender (% female)	65
Age	
Mean (SD)	50.6 (14.1)
Range	19-86
Education: (%)	
No Formal Qualifications	35
Secondary	30
Tertiary	25
Higher	10
Duration of pain (years)	
Mean (SD)	9.5 (8.5)
Range	0.5-42
Pain rating	
Mean (SD)	8 (6.5)
Most frequent locations of pain (%)	lower back (44)
	legs (22)
	neck (12)
Patients rating >1 location (%)	66
No of pain medications	
Mean (SD)	2.8 (1.8)
Range	1-10
Type of Pain Medication	Tramadol
(5 most common)	Amitriptyline
	Paracetamol
	Gabapentin
	Co-codamol

Table 2 Scale Descriptives

Scale	No. items in Scale	Cronbach's Alpha (N*)	Mean	SD	Scores over mid-point (%)
IPQ-R Identity	14	NA	5.15	3.41	NA
IPQ-R Timeline	6	0.81 (185)	4.1	0.69	84
IPQ-R Consequences	6	0.79 (199)	3.91	0.79	72
IPQ-R Timeline cycle	4	0.74 (205)	3.24	0.94	55
IPQ-R Personal Control	6	0.66 (199)	2.94	0.70	36
IPQ-R treatment control	5	0.65 (200)	2.94	0.64	36
IPQ-R coherence	5	0.89 (203)	3.1	1.04	47
IPQ-R Emotion	6	0.83 (203)	3.62	0.84	58
IPQ-R Cause	17	NA	NA	NA	NA
BMQ necessity	5	0.85 (209)	3.81	0.9	64
BMQ concerns	5	0.62 (208)	3.28	0.83	42
MARS	6	0.78 (195)	1.69	0.71	25

* Numbers vary as individual scales may have been missing for some participants.

Table 3 Responses to items on the Medication Adherence Report Scale (MARS)

Type of non-adherence to pain medication	% Sample admitting type of non-adherence (sometimes, often, always)
I forget to take them	19
I alter the dose	34
I stop taking them for a while	21
I decide to miss a dose	26
I take less than instructed	24
I take more than instructed	26

Table 4 Pearson Correlation Coefficients between illness perceptions, treatment beliefs and adherence

	Age	Gender	Ed. Status	Duration of Pain	Pain Rating	Number of medicines	IPQ-R identity	IPQ-R time-line	IPQ-R time-cycle	IPQ-R personal control	IPQ-R treatment control	IPQ-R conse-quence	IPQ-R coherence	IPQ-R emotion	BMQ necessity	BMQ concerns
Age																
Gender	.07															
Educational Status	-.25**	.13														
Duration of Pain	.18**	.12*	-.003													
Pain Rating	.06	.004	-.25**	.08												
Number of Medicines	-.06	.004	-.03	.01	.19*											
IPQ-R identity	-.01	.02	.10	.14*	.06	.15*										
IPQ-R timeline	.14*	.12*	-.06	.31**	.23**	.12*	.17**									
IPQ-R timecycle	-.13*	-.03	.10	.00	-.14*	-.08	-.03	-.18**								
IPQ-R personal control	-.09	-.002	.15*	-.03	-.21**	-.02	.07	-.2**	.05							
IPQ-R treatment control	.007	-.13*	.06	-.15*	-.24**	-.04	-.14*	-.43**	.04	.39**						
IPQ-R conse-quence	.002	.04	-.14*	.004	.33**	.26**	.28**	.34**	-.08	.06	-.24**					
IPQ-R coherence	-.01	-.04	.23**	.18**	-.14*	.06	.06	.12*	-.18**	.16*	.13*	-.08				
IPQ-R emotion	-.06	.12*	-.15*	-.27**	.27**	.26**	.17**	.11	.02	.06	-.14*	.59**	-.28**			
BMQ necessity	.26**	.16*	-.14**	.08	.31**	.32**	.09	.28**	-.05	-.12*	-.10	.47**	-.04	.32**		
BMQ concerns	.05	-.17**	-.21**	-.19**	.11	.007	.19**	-.05	.06	.01	-.07	.24**	-.21**	.31**	.3**	
MARS	-.24**	-.09	12*	-.06	-.22**	-.12	.12	-.13*	.16*	.15*	.05	-.06	.04	-.05	-.19**	.12*

Significance P<.05*

P<.01 ** (one tailed)

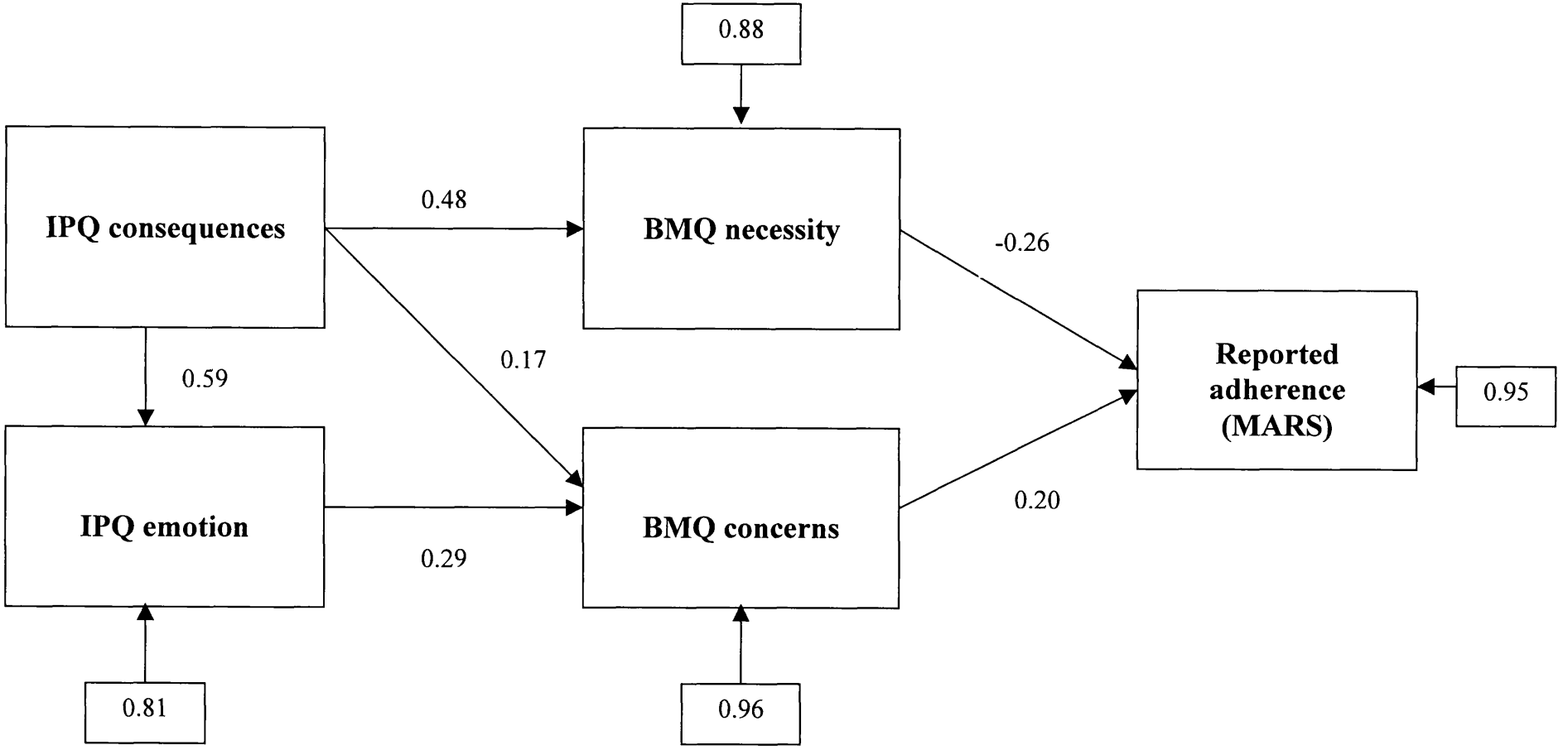
Table 5 Hierarchical linear regression model of predictors of reported adherence to pain medicines

Predictor Block	Variables entered	r	β	Adjusted R^2	Increase in R^2
Demographic variables				0.04	0.05
F (2,176) = 4.96, p = 0.008	Age		-.222**		
	Educational Status		.028		
Clinical Factors				0.06	0.02
F (3,175) = 4.77, p = 0.003	Age		-.214**		
	Educational Status		.000		
	Pain rating		-.152*		
Illness perceptions				0.07	0.03
F (7,171) = 2.99, p = 0.05	Age		-.173*		
	Educational Status		-.004		
	Pain rating		-.116		
	Timeline		-.092		
	Personal control		.065		
	Timeline Cyclical		.088		
Treatment beliefs				0.09	0.03
F (9,169) = 2.91, p = 0.003	Age	-.24**	-.141		
	Educational Status	.12*	.027		
	Pain rating	-.22**	-.098		
	Timeline	-.13*	-.057		
	Personal control	.15*	.057		
	Timeline Cyclical	.16*	.078		
	Necessity	-.19**	-.130		
	Concerns	.12*	.157*		

Significance P<.05*

P<.01 ** (one tailed)

Figure 2 **EQS structural equation model of reported adherence to chronic pain medication.**



Chapter 5: Experimental Case Study – Abstract

Behavioural versus cognitive techniques in the treatment of Chronic Fatigue Syndrome: The contribution of single case methodology

(full document bound separately)

Leeanne B. Ramsay[1]

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology

Prepared in accordance with guidelines for submission to Behaviour research and Therapy (Appendix A)

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Abstract

Background: Cognitive Behavioural Therapy (CBT) for Chronic Fatigue Syndrome highlights the interplay between activity, beliefs, mood and fatigue and is the psychological treatment of choice for this illness. However, there is debate whether it is the behavioural or cognitive components that are most significant in alleviating symptoms.

Design and analysis: This case assesses the relative contributions of behavioural and cognitive components of CBT in improving sleep, activity, depression, illness cognitions and fatigue, using an ABC design with repeated measures. Data were analysed using visual inspection and time series analysis.

Results: The behavioural phase impacted on time of sleep onset at a statistically significant level. Activity, depression and two illness beliefs ('My symptoms are out of my control' and 'if I can't do my work at a 100% level then I can't do it at all') improved at a clinically significant level. Another illness belief ('I am to blame for my symptoms') and fatigue were not affected by the behavioural phase. Illness cognitions did not prevent behavioural treatment impacting on outcome variables, but further change was seen in all variables except fatigue following the cognitive phase. Overall, there were clinically significant changes in sleep onset, activity, depression and beliefs by end of treatment. Subjective experience of fatigue did not change.

Discussion: The findings highlight the potential of single case methodology to investigate the process of change in therapy. In this study the behavioural components of therapy resulted in quick clinical change and improved engagement in therapy. Additional cognitive work strengthened and stabilised the change. Further research could investigate this finding using more generalisable methodology. Study limitations are discussed.

Key words: Chronic Fatigue Syndrome; cognitive behavioural therapy; process

Appendix 1: Appendices for Small Scale Service Related Project

Contents Pages

Guidelines for Submitting to Clinical Psychology

- Articles of 1000-2000 words are welcomed. Send two hard copies of your contribution.
- When sending copy, make sure it is double spaced, in a reasonably sized font and that all pages are numbered.
- Give a 40-word summary at the beginning of the paper.
- Contributors are asked to use language which is psychologically descriptive rather than medical and to avoid using devaluing terminology; i.e. avoid clustering terminology like 'the elderly' or medical jargon like 'person with schizophrenia'. If you find yourself using quotation marks around words with dubious meaning, please use a different word.
- Articles submitted to Clinical Psychology will be sent to members of the Editorial Collective for refereeing. They will then communicate directly with the authors.
- We reserve the right to shorten, amend and hold back copy if needed.
- Include a word count at the end (including references).
- Spell out all acronyms the first time they appear.
- Include the first names of all authors and give their employers, and remember to give a full postal address for correspondence.
- Give references in Clinical Psychology style, and if a reference is cited in the text make sure it is in the list at the end.
- Don't include tables and figures unless they save space or add to the article.
- Ask readers to request a copy of your questionnaire from you rather than include the whole of it in the article.

Appendix 1.2 Action Plan Arising from Project

Action Plan

July

- Presentation at team meeting to update on findings of study. Preliminary findings discussed at June meeting (LR)
- Commence screening of anger referrals on waiting lists of all 3 sub-sectors for Anger Management group (RS)
- Contact Forensic Clinical Psychologist to arrange teaching session (LR)

August

- Possible presentation by forensic clinical psychologist on how to manage anger referrals (FS)
- Liasing with Community Mental Health Team in the Mid-sector regarding appropriate referrals to clinical psychology (JP).

September

- Screen suitable referrals for next Stress Management group (JD)
- Possible start of Anger Management group (RS)

January 2005

- Repeat audit of number of anger referrals for comparison with present numbers (AJ)
- Evaluate Anger Management group (RS)

Appendix 2: Appendices for Systematic Literature Review

Contents | Pages

Appendix 2.1 Guidelines for Submitting to Psychology and Health

PSYCHOLOGY AND HEALTH: INSTRUCTIONS FOR AUTHORS

INTRODUCTION

Submission of a paper to *Psychology & Health* will be taken to imply that it represents original work not previously published, that it is not being considered elsewhere for publication, and that if accepted for publication it will not be published elsewhere in the same form, in any language, without the consent of editor and publisher. It is a condition of the acceptance by the editor of a typescript for publication that the publisher automatically acquires the copyright of the typescript throughout the world.

SUBMISSION OF MANUSCRIPTS

One hard copy of each manuscript, and an electronic version, should be sent to **Paul Norman**, Department of Psychology, University of Sheffield, Sheffield, S10 2TP, UK. Each paper will be read by at least two referees.

FORMAT OF MANUSCRIPTS

Manuscripts should be typed according to the guidelines in the Publication Manual of the American Psychological Association (4th edition, 1994); however, please follow the present Instructions for Authors in cases of contradiction with the APA guidelines. Manuscripts should not exceed 30 pages (including references, tables, figures, etc).

Title page: This should contain the title of the paper, a short running title, the name and full postal address of each author and an indication of which author will be responsible for correspondence, reprints and proofs. Abbreviations in the title should be avoided.

Abstract: This should not exceed 150 words and should be presented on a separate sheet, summarizing the significant coverage and findings.

Key words: Abstracts should be accompanied by up to six key words or phrases that between them characterize the contents of the paper. These will be used for indexing and data retrieval purposes.

TEXT HEADINGS

All headings in the text should be set over to the left-hand margin, and the text should begin on the next line. Type first level (sectional) headings all in capitals. For second and third level headings, only the first letter of the first word should be a capital. Underline third level headings. For example:

FIRST LEVEL TEXT HEADINGS

Second Level Text Headings

Third level text headings

REFERENCES

References should be indicated in the text with the author's name and year of publication in parentheses. If there are two authors, both names should be given. If there are more than two authors, all should be given on the first occasion, and then the first author "et al." should be used subsequently. Use "and" between author names mentioned in the text and an ampersand (&) when mentioned in parentheses and in the reference section. The full list of references should be given in alphabetical order on a separate sheet, with titles of books and journals given in full. Generally, the APA guidelines should be followed for the references. Examples:

1. Johnston, M. (1984) Dimensions of recovery from surgery. *International Review of Applied Psychology*, **33**(4), 505-520.

2. Smith, A.P., Tyrrell, D.A.J., Coyle, K.B., Higgins, P.G. and Willman, J.J. (1990) Individual differences in susceptibility to infection and illness following respiratory virus challenge. *Psychology and Health*, **4**, 201-211.

FIGURES

All figures should be numbered with consecutive arabic numerals, have descriptive captions and be mentioned in the text. Figures should be kept separate from the text but an approximate position for each should be indicated in the margin. It is the author's responsibility to obtain permission for any reproduction from other sources.

Preparation: Figures must be of a high enough standard for direct reproduction. They should be prepared in black (india) ink on white card or tracing paper, with all the lettering and symbols included. Axes of graphs should be properly labelled and appropriate units given. Photographs intended for halftone reproduction must be high quality glossy originals of maximum contrast. Redrawing or retouching of unsuitable figures will be charged to authors.

Size: Figures should be planned so that they reduce to 10.5 cm column width. The preferred width of submitted drawings is 16-21 cm, with capital lettering 4 mm high, for reduction by one-half. Photographs for halftone reproduction should be approximately twice the desired size.

Captions: A list of figure captions should be typed on a separate sheet and included in the typescript.

TABLES

Tables should be clearly typed with double spacing. Number tables with consecutive arabic numerals and give each a clear descriptive heading. Avoid the use of vertical rules in tables. Table footnotes should be typed below the table, designated by superior lower-case letters.

PROOFS

Authors will receive proofs (including figures) by air mail for correction, which must be returned within 48 hours of receipt. Authors' alterations in excess of 10% of the original composition cost will be charged to authors.

Early Electronic Offprints:

Corresponding authors can now receive their article by e-mail as a complete PDF. This allows the author to print up to 50 copies, free of charge, and disseminate them to colleagues. In many cases this facility will be available up to two weeks prior to publication. Or, alternatively, corresponding authors will receive the traditional 50 offprints. A copy of the journal will be sent by post to all corresponding authors after publication. Additional copies of the journal can be purchased at the author's preferential rate of £15.00/$25.00 per copy.

REPRINTS

Twenty-five reprints per article will be sent to the senior author free of charge. Additional copies may be purchased when returning proofs.

PAGE CHARGES

There are no page charges to individuals or to institutions.

Appendix 2.2 The Beliefs about Medicines Questionnaire

Beliefs about Medicines Questionnaire

Rated: strongly agree, agree, uncertain, disagree, strongly disagree

Specific Section

Necessity
My health, at present, depends on my pain medications.
My life would be impossible without my pain medicines.
Without my pain medicines I would be very ill.
My health, in the future, depends on my pain medicines.
My pain medicines protect me from becoming worse.

Concerns
Having to take pain medicines worries me.
I sometimes worry about the long-term effects of my pain medicines.
My pain medicines are a mystery to me.
My pain medicines disrupt my life.
I sometimes worry about being too dependent on my pain medicines.

General Section

Overuse
Doctors use too many medicines.
Doctors place too much trust on medicines.
If doctors had more time with patients they would prescribe fewer medicines.
Natural remedies are safer than medicines.

Harms
Most medicines are addictive.
All medicines are poisons.
Most medicines are addictive.
People who take medicines should stop their treatment for a while every now and again.

Appendix 2.3 Quality Evaluation Criteria

Quality Evaluation Criteria

Study	Score
Study title	
What is the outcome of interest?	
1) Objectives	
Was the research question clearly stated?	Yes-1 No-0
2) Selection of subjects	
Was the population defined?	Yes-1 No-0
Were the sample demographics stated?	Yes-1 no-0
Were all inclusion /exclusion criteria stated?	Yes-1 no-0
Was the sample representative?	Yes-1 no-0
Was sample size justified? (Power Calculation mentioned)	Yes-1 No-0
3) Assessment	
What measures used?	
Was the BMQ used in a reliable and valid way?	Yes-1 No-0
Was adherence measured;	Self-report – 1 Objective measure – 2
Were other outcomes measured in a standard, valid and reliable way?	Yes-2, Some-1 No-0
4) Design	
Is the study design relevant to the question?	Yes-1 No-0
5) Statisical Analysis	
Was the data screening (e.g. abnormal distributions) described?	Yes-1 No-0
Were appropriate statistical methods applied?	Yes-1 No-0
Were all subjects used in analysis?	Yes-1 No-0
Was the analysis of missing data reported?	Yes-1 No-0
6) Results	
Were appropriate summary measures reported?	Yes-1 No-0
Were the results clearly stated?	Yes-1 No-0
7) Discussion	
Were conclusions supported by data?	Yes-1 No-0
Did they consider/explain bias?	Yes-1 No-0
Did they consider alternative reasons for results?	Yes-1 No-0
Are the data supported by other research?	Yes-1 No-0
8) Overall assessment of the study?	Yes-1 No-0
Are the results of the study generalisable?	Yes-1 No-0
Does this study help to answer your key question?	Yes-1 No-0
Is there a statement of funding?	Yes-1 No-0
TOTAL SCORE (max 26)	
Grading (A-D):	

A = 70-100%;
B = 60-70% (Where criteria have not been fulfilled they are thought very unlikely to alter the reliability and validity of study findings).

C = 50-60% (Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the study findings)

D = 0-49% (The findings of the study are thought likely or very likely to be affected by study quality);

Appendix 3: Appendices for Major Research Proposal

Appendix 3.1 Course Handbook Guidelines for Submission

Course Handbook Guidelines for Submission - Major research Project Proposal

The Major research Project Proposal should include the following headings:

- Full title of project
- Summary of Project
- Introduction
- Aims and Hypotheses
    i. Aims
    ii. Hypotheses
- Plan of Investigation
    i. Participants
    ii. Recruitment
    iii. Measures
    iv. Design and Procedures
    v. Settings and Equipment
    vi. Power Calculation
    vii. Data Analysis
- Practical Applications
- Ethical Approval
- Timescale
- References

Appendix 4: Appendices for Major Research Project

Contents | Pages

GUIDELINES FOR SUBMITTING TO PAIN

1. General

Submission of a paper to PAIN is understood to imply that it has not previously been published (except in abstract form) and that it is not being considered for publication elsewhere. Manuscripts submitted under multiple authorship are reviewed on the assumption that

(1) all authors listed concur with the submitted version of the manuscript and with the listing of the authors;
(2) authorship credit is based on important contributions in one or more of the following areas: conception and design, analysis and interpretation of data, drafting of the manuscript or making intellectual contributions to its content;
(3) the final manuscript has been tacitly or explicitly approved by the responsible authorities in the laboratory or institution where the work was carried out.

If illustrations or other small parts of articles or books already published elsewhere are used in papers submitted to PAIN the written permission of author and publisher concerned must be included with the manuscript. The original source must be indicated in the legend of the illustration in these cases. The letter accompanying the manuscript should include a statement of any financial or other relationships that might lead to a conflict of interest, the recommended Section Editor to which the manuscript should be assigned to, and the names of four potential reviewers with complete contact details. The Publisher and Editors-in-Chief regret that they are unable to return copies of submitted manuscripts.

Articles should be written in English and should be complete in all respects. The layout and style should adhere strictly to the instructions given under 'Organisation of the Article' and, in particular, the reference style of PAIN. No revisions or updates will be incorporated after the article has been accepted and sent to the Publisher (unless approved by the Editors). For all types of papers the preferred method of submission is electronic via the WWW using the SMART Works website http://www.smartworks2000.com/smart2000/start/start.asp. However, if you are having difficulty with the on-line submission, please contact Pain at: tinay@iasp-pain.org. If you are not able to make e-mail contact, you may send one hardcopy of the manuscript, inculding copies of all illustrations, accompanied by a disk containing files of all the text and illustrations, to the attention of the Editor-in-Chief at the Editorial Office.

2. Preparing electronic manuscripts

Keep text and graphics (and any other items) as separate files — do not import the figures into the text file. Name your files using the correct extension, e.g. text.doc, fig1a.eps, fig1.tif, Fig1.cdr, tbl_16.xls, etc. Text files should be supplied in one of the following formats: Microsoft Word or WordPerfect, Windows or Macintosh formatted. The native format is preferred over ASCII text or Rich Text Format (RTF). Ensure that the letter "l" and the digit "1" (also letter "O" and digit "0") have been used properly, and format your article (tabs, indents, etc.) consistently. Characters not available on your word processor (Greek letters, mathematical symbols, etc.) should not be left open, but indicated by a unique code (e.g. gralpha, @, #, etc. for the Greek letter alpha). Such codes should be used consistently throughout the entire text. Please make a list of such codes and provide a key. When accepted articles are processed, most formatting codes will be removed or replaced so there is no need for you to use excessive layout styling. In addition, do not use options such as automatic word breaking, justified layout, double columns or automatic paragraph numbering (especially for numbered references). However, do use bold face, italic, subscripts, superscripts etc. for

scientific nomenclature. When preparing tables, if you are using a table grid, please use only one grid for each separate table and not a grid for each row. If no grid is being used, use tabs to align columns, not spaces. Graphic files: See Elsevier Science's website for guidelines for preparing electronic artwork: http://www.authors.elsevier.com/artwork The following are preferred formats: native formats of Adobe Photoshop and Adobe Illustrator. If this is not possible, the graphic files may also be supplied in either TIFF, JPEG or GIF format (with SMARTWorks submissions). All type fonts used in studio-created artwork must be either "embedded" in the file or supplied separately. All graphic files supplied as bitmap format (not vector format) in native Adobew Photoshop, TIFF, JPEG or GIF must be submitted in sufficiently high resolution (240–300 dpi for greyscale or colour images and 600–1000 dpi for line art) to allow for printing.

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4. Submission of manuscripts
Manuscripts originally submitted as hardcopy: Provide the final form of the accepted article on an electronic storage medium (floppy-disk, ZIP/JAZ disk, or CD ROM). Save text and graphics files on separate disks. Label all disks with your name, journal to be published in, and file names. Please also include details of the word-processing software, compression software, and platform (PC, Mac, UNIX etc) used in the creation of your files. N.B. A hardcopy of both text and illustrations is also required – it is essential that these are identical to the electronic files supplied.

5. Organization of the article
The manuscript should be in English, typed with double spacing with at least 4 cm margin on pages of uniform size. They should include a brief summary on a separate page, and should be in the usual form: Introduction, Methods, Results, Discussion, Acknowledgements, Reference List; not more than 6 keywords.

Title page.
The title page should contain the following items: (i) complete title (preferably no chemical formulas or arbitrary abbreviations); (ii) full names of all authors; (iii) complete affiliations of all authors; (iv) the number of text pages of the whole manuscript (including figures and tables) and the number of figures and tables; (v) the name and complete address of the corresponding author (as well as telephone number, facsimile number and E-mail address, and

if available URL address) to whom correspondence and proofs should be sent; (vi) acknowledgements.

Literature references.
Citation of literature references in the text should be included in parentheses and should be by author(s) and year in chronological not alphabetical order. When papers written by more than two authors are cited in the text, the abbreviation 'et al.' should be used following the name of the leading author, even if the subsequent authors are not the same in all references. All references cited in the text must be listed at the end of the paper, should be typed double-spaced, and arranged alphabetically by author. References must be complete, including initial(s) of author(s) cited, title of paper referred to, journal, year of publication, volume and page numbers. If more than two references with the same year and author(s) are cited, use lowercase letters after the year (Cousins 1982a,b; Melzack et al. 1984a,b). Journal titles should be abbreviated according to Index Medicus, List of Journals Indexed, latest edition. For citations of books, the following uniform sequence should be maintained: author(s), title of article, editor(s), complete title of book, place of publication, publisher, year and page numbers. Manuscripts in preparation and submitted but not accepted as well as 'personal communications' should not appear in the reference list but should be cited at the appropriate place in the text.

Examples:
Adams CWM. Neurohistochemistry. Amsterdam: Elsevier, 1965.
Goldenberg DL. Psychiatric and psychological aspects of fibromyalgia syndrome. Rheum Dis Clin N Am 1989a; 15:105–115.
Goldenberg DL. Fibromyalgia and its relation to chronic fatigue syndrome, viral illness and immune abnormalities. J Rheumatol 1989b;16:91–93.
Turner JA. Coping and chronic pain. In: Bond MR, Charlton JE, Woolf CJ, editors. Pain research and clinical management. Proc. VIth World Congress on Pain, Vol. 4. Amsterdam: Elsevier, 1991., pp. 219–227.
URLs should be included for all references that are publicly accessible via the Internet.

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Authors should consult Elsevier Science's website for guidelines for preparing (electronic) artwork: http://www.authors.elsevier.com/artwork It should be borne in mind that in the journal illustrations will appear either across a single column (=8.4 cm) or a whole page (=17.6 cm). The illustrations should be numbered in Arabic numerals according to the sequence of appearance in the text, where they are referred to as Fig. 1, Fig. 2, etc. Accepted manuscripts submitted on diskette that include electronic files of the illustrations must be accompanied by a hardcopy set of the final illustrations. All hardcopy illustrations should bear the author's name, the orientation (top, bottom, etc.) and be numbered. Hardcopy colour figures should be submitted as separate prints and not be mounted on cardboard. Slides taken from labelled prints are also acceptable. Colour reproduction. Reproduction in colour will have to be approved by the Editor. Authors will be required to pay a fee towards the extra costs incurred in colour reproduction. The charges are E300.00 (approx. US $300) for the first page involving colour, and E200.00 (approx. US $200) per page for all subsequent pages involving colour in a given article (all prices include sales tax).

Figure legends.
Each illustration must have a title and an explanatory legend. The title should be part of the legend and not be reproduced on the figure itself. The legends should be numbered consecutively in Arabic numerals and should be placed on a separate page at the end of the

manuscript and begin with the number of the illustration they refer to. All symbols and abbreviations used in the figure must be explained.

Tables.
Tables should be so constructed that they, together with their captions and legends, will be intelligible with minimal reference to the text. Tables of numerical data should each be typed (with double-spacing) on a separate page, numbered in sequence in Arabic numerals (Table 1, 2, etc.), provided with a heading, and referred to in the text as Table 1, Table 2, etc. A detailed description of its contents and footnotes should be given below the body of the table.

Acknowledgements.
Acknowledgements should be placed at the end of the text before the Reference List and should specify: (1) contributions that need acknowledging but do not justify authorship; (2) acknowledgements of technical help; (3) acknowledgements of financial and material support, specifying the nature of the support; (4) financial arrangements that may represent a possible conflict of interest.

Policy issues.
Ethics of animal experiments. Authors will be required to show that they have paid attention to the proposals of the Committee for Research and Ethical Issues of IASP published in PAIN 16 (1983) 109–110. Authors should indicate if the experimental work was reviewed by an institutional animal care and use committee or its equivalent.
Ethics of human experiments. Authors reporting on experimental work on humans should, where relevant, submit evidence that the work has been approved by an institutional clinical research panel or its equivalent.

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Appendix 4.2 Study Invitation Letter and Patient Information Sheet

Invitation Letter (25/07/05)

Dear Sir/Madam,

Re: Chronic pain patient's views on their illness and medication and how that affects the way they take their medication.

The pain clinic is conducting a research study over the next three months. This study will look at the views people with chronic pain have about their illness and medication and how these views affect the way they take their medication.

All patients who are due to attend the pain clinic are being sent this invitation letter and information sheet. However, not all patients attending the clinic will be selected to take part.

You may be invited to take part in the study when you attend your clinic appointment. In order for you to decide whether you wish to take part it is important for you to understand why the research is being done and what it will involve.

Please take the time to read the attached information sheet (Version3, 25/07/05) carefully and discuss it with others if you wish. You may ask the consultant at the clinic questions if you wish any further information or call the contact at the end of the information sheet.

Thank you for taking the time to consider the study.

Yours faithfully,

Leeanne Ramsay
Principal Investigator

Patient Information Sheet

Version 3 (25/07/05)

Study Title:

Chronic pain patients' views on their illness and medication and how that affects the way they take their medication.

Thank you for taking the time to read this information.

What is the purpose of the study?
This study will explore the views people with chronic pain have about their illness and the views they have about their medication. It will look at whether views about illness and medication affect the way people take their medication.

It is hoped that through understanding the way people think about their illness and medication we can improve the service provided to people suffering from chronic pain.

Why have I been asked to take part?
We are sending this information sheet to all people who are attending the Pain Clinic in the coming months, however not everyone attending the clinic will be asked to take part in the study. We are hoping to have 250 people take part in this study.

What do I have to do if I take part?
You may be given a study questionnaire pack at your clinic appointment. It is your choice to decide whether you would like to take part. The pack contains four brief questionnaires that you can fill in before you leave the clinic or complete at home and post back to us. This should take no longer than 30 minutes. The questionnaires will ask questions about your chronic pain, your views on medication and how you take your medication.

Do I have to take part?
No, you do not have to take part and you are free to change your mind and withdraw from the study at any time. Your decision to take part or not will not affect the standard of care you receive.

What are the possible benefits of taking part?
There is a growing recognition that the care people receive is improved when we understand people's views about their medical condition and its treatment. It is hoped that the results of this study will improve the care people with chronic pain receive in the future.

What are the possible disadvantages of taking part?
We don't anticipate there being any disadvantages to taking part. It is unlikely that you will find answering the questionnaires upsetting, however if you do feel you need to discuss any of the issues raised by the questionnaire you may contact Dr Dunbar, a Clinical Psychologist

attached to the Chronic Pain Service. His contact number is 0141-201-3005. Remember you are free to withdraw from the study at any time if you decide you no longer wish to take part.

If you have any complaints about the way you were approached about this study or treated during the study then you can complain through the normal NHS complaints process.

What will happen to the results of the study?
The research will be completed as part of a Doctorate in Clinical Psychology and the results will be available from the library at the University of Glasgow. It is also aimed that the results will be published in an appropriate scientific journal. If you would like a copy of the results once the study is finished you can contact the principal investigator at the address below.

Who will know what I have said?
If you decide to take part in the study your responses will be completely anonymous and no personal or identifying information will be available to anyone. This means that no action will be taken as a result of the answers given on your questionnaires.

Who is organising the funding for the study?
The study is being funded by the University of Glasgow.

Who has reviewed the study?
The study has been reviewed by the Ethics Committee at Greater Glasgow NHS primary care division and at Gartnavel General, Royal Infirmary and Stobhill hospitals.

Contact for further information:
Leeanne Ramsay (Principal Investigator)
Trainee Clinical Psychologist
Department of Psychological Medicine
Gartnavel Royal Hospital
Glasgow, G12 0XH
Telephone: 0141 211 0607

Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 0XH
Tel: 0141 211 3600
www.nhsgg.org.uk

NHS
Greater Glasgow

Miss Leanne Ramsay
Trainee Clinical Psychologist
University of Glasgow
Department of Psychological Medicine
Gartnaval General Hospital
Glasgow
G12 0XH

Date 16 August 2005
Your Ref
Our Ref

Direct line 0141 211 3824
Fax 0141 211 3814
E-mail anne.mcmahon@gartnavel.glacomen.scot.nhs.uk

Dear Miss Ramsay

Full title of study: **The Role of Illness Perceptions and Treatment Beliefs in Explaining Adherence to Pharmacological Treatment of Chronic Pain**

REC reference number: **05/S0701/51**

Thank you for your letter of 25 July 2005, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Committee held on 11 August 2005. A list of the members who were present at the meeting is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

The favourable opinion applies to the research sites listed on the attached form.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application		22 April 2005
Investigator CV	Supervisor CV	22 April 2005
Investigator CV		22 April 2005
Protocol		22 April 2005
Covering Letter		25 April 2005
Letter from Sponsor		22 April 2005
Compensation Arrangements	Indemnity	22 April 2005

	Arrangements	
Interview Schedules/Topic Guides		22 April 2005
Copy of Questionnaire		22 April 2005
Letters of Invitation to Participants		22 April 2005
Letters of Invitation to Participants	tw0	20 May 2005
Participant Information Sheet	two	20 May 2005
Participant Information Sheet	three	25 July 2005
Participant Information Sheet		22 April 2005
Participant Consent Form		22 April 2005
Response to Request for Further Information	two	25 July 2005
Response to Request for Further Information	one	14 June 2005

Management approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final management approval from the R&D Department for the relevant NHS care organisation.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Notification of other bodies

The Committee Administrator will notify the research sponsor that the study has a favourable ethical opinion.

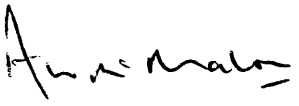
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/S0701/51	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project,

Yours sincerely



A W McMahon
Research Ethics Co-ordinator (Manager) on behalf of Dr Paul Fleming, Chair

Email: Anne.McMahon@gartnavel.glacomen.scot.nhs.uk

Cc Attendance at Committee meeting on 11 August 2005
Standard approval conditions
Site approval form (SF1)

Primary Care Division

Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 0XH
Tel: 0141 211 3600
www.nhsgg.org.uk

NHS
Greater Glasgow

Miss Leanne Ramsay
Trainee Clinical Psychologist
University of Glasgow
Department of Psychological Medicine
Gartnaval General Hospital
Glasgow
G12 0XH

Date 07 September 2005
Your Ref
Our Ref

Direct line 0141 211 3824
Fax 0141 211 3814
E-mail anne.mcmahon@gartnavel.glacomen.scot.nhs.uk

Dear Miss Ramsay

Full title of study: **The Role of Illness Perceptions and Treatment Beliefs in Explaining Adherence to Pharmacological Treatment of Chronic Pain**

REC reference number: **05/S0701/51**

The REC gave a favourable ethical opinion to this study on 11 August 2005.

Further notification(s) have been received from local site assessor(s) following site-specific assessment. On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s). I attach an updated version of the site approval form, listing all sites with a favourable ethical opinion to conduct the research.

Management approval

The Chief Investigator or sponsor should inform the local Principal Investigator at each site of the favourable opinion by sending a copy of this letter and the attached form. The research should not commence at any NHS site until management approval from the relevant NHS care organisation has been confirmed.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/S0701/51	**Please quote this number on all correspondence**

Yours sincerely

Mrs Anne W McMahon
Research Ethics Committee Co-ordinator

Primary Care Division

Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 0XH
Tel: 0141 211 3600
www.nhsgg.org.uk

NHS
Greater Glasgow

Miss Leanne Ramsay
Trainee Clinical Psychologist
University of Glasgow
Department of Psychological Medicine
Gartnaval General Hospital
Glasgow
G12 0XH

Date 18 January 2006
Your Ref
Our Ref

Direct line 0141 211 3824
Fax 0141 211 3814
E-mail anne.mcmahon@gartnavel.glacomen.scot.nhs.uk

Dear Miss Ramsay

Full title of study: **The Role of Illness Perceptions and Treatment Beliefs in Explaining Adherence to Pharmacological Treatment of Chronic Pain**

REC reference number: **05/S0701/51**

Thank you for the amendment regarding the above named submission in which you indicate the alteration to the upper age limit.

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Research governance approval

All investigators and research collaborators in the NHS should notify the R&D Department for the relevant NHS care organisation of this amendment and check whether it affects research governance approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

[REC reference number]: 05/S0701/63 Please quote this number on all correspondence

Yours sincerely

A W McMahon

A W McMahon
Research Ethics Co-ordinator (Manager) on behalf of Dr Paul Fleming, Chair

UNIVERSITY
of
GLASGOW

CHRONIC PAIN PATIENT'S VIEWS ON THEIR ILLNESS AND MEDICATION AND HOW THAT AFFECTS THE WAY THEY TAKE THEIR MEDICATION

Thank you for agreeing to take part in this study. Please answer the following questions carefully and please try to answer **ALL** the questions.

When you are finished please place your pack in the box marked pain questionnaires in the waiting room.

If you would like more time you may take the pack home and post it back to us at the following address:

Leeanne Ramsay (Principal Investigator)
Trainee Clinical Psychologist
Department of Psychological Medicine
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow, G12 0XH

ABOUT YOU

1) What is your age: ☐☐

(Please write your answer in the boxes provided.)

2) Are you: **male** ☐ **female** ☐

(Please tick box.)

3) Please tell us a bit about your education:

(Please tick all boxes that apply.)

Left school before standard grade or equivalent ☐

Standard grade or equivalent ☐ SCOTVEC certificate ☐

Access course after leaving school ☐ HNC or HND ☐

First or higher degree ☐ Other ☐

4) Where do you have pain? (e.g. lower back, neck, legs)

_____

5) How long have you had your pain condition?

Please indicate number of: years ☐☐ months ☐☐

6) How would you rate the pain you've had in the last week?

(please circle the appropriate number)

None *Pain as bad as it could be*

0 1 2 3 4 5 6 7 8 9 10

ABOUT YOUR MEDICATION

- We would like to know a little about the medication that you are currently prescribed for your pain.
- Don't worry if you can't remember all details just fill in what you can.

7) How many types of medication do you currently take for your pain? (Please write in box provided.) ☐

8) Please tell us about your pain medication by completing the table below.

Name of Pain Medication	How many times do you take it a day?

QUESTIONS ABOUT USING YOUR MEDICINES

- We would like to ask you a few questions about how you use your medicines.
- Many people find a way of using their medicines that suits them.
- This may differ from the label or from what the doctor has said.
- Here are some ways that people have said they use their medicines.
- For each of the statements please tick the box which best applies to you.

Your own way of using your medicines	**Always**	**Often**	**Sometimes**	**Rarely**	**Never**
I forget to take them					
I alter the dose					
I stop taking them for a while					
I decide to miss a dose					
I take less than instructed					
I take more than instructed					

YOUR VIEWS ABOUT MEDICINES PRESCRIBED FOR YOUR CHRONIC PAIN

- We would like to ask about your personal views about medications prescribed for your chronic pain. Below are statements other people have made about their medicine.

- Please indicate the extent to which you agree or disagree with them by ticking the appropriate box. *There are no right or wrong answers.* We are interested in your personal views.

Views about your pain medication	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
My health, at present, depends on my pain medications					
Having to take pain medicine worries me					
My life would be impossible without my pain medicines					
Without my pain medicine I would be very ill					
I sometimes worry about the long-term effects of my pain medicines					
My pain medicines are a mystery to me					
My health, in the future, depends on my pain medicines					
My pain medicines disrupt my life					
I sometimes worry about being too dependent on my pain medicines					
My pain medicines protect me from becoming worse					

YOUR VIEWS ABOUT YOUR CHRONIC PAIN SYMPTOMS

- Listed below are a number of symptoms that you may or may not have experienced since your chronic pain.
- Please indicated by circling Yes or No, whether you have experienced any of these symptoms since your chronic pain, and whether you believe that these symptoms are related to your chronic pain (CP).

	I have experienced this since my CP		This symptom is related to my CP	
Pain	Yes	**No**	Yes	**No**
Sore Throat	Yes	**No**	Yes	**No**
Nausea	Yes	**No**	Yes	**No**
Breathlessness	Yes	**No**	Yes	**No**
Weight Loss	Yes	**No**	Yes	**No**
Fatigue	Yes	**No**	Yes	**No**
Stiff Joints	Yes	**No**	Yes	**No**
Sore Eyes	Yes	**No**	Yes	**No**
Wheeziness	Yes	**No**	Yes	**No**
Headaches	Yes	**No**	Yes	**No**
Upset Stomach	Yes	**No**	Yes	**No**
Sleep Difficulty	Yes	**No**	Yes	**No**
Dizziness	Yes	**No**	Yes	**No**
Loss of Strength	Yes	**No**	Yes	**No**

YOUR VIEWS ABOUT YOUR CHRONIC PAIN

- We are interested in your personal views of how you see your current chronic pain (CP).
- Please indicate how much you agree or disagree with the following statements about your chronic pain by ticking the appropriate box.

Views about your CP	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
My CP will last a short time					
My CP is likely to be permanent rather than temporary					
My CP will last a long time					
This CP will pass quickly					
I expect to have this CP for the rest of my life					
My CP is a serious condition					
My CP has major consequences on my life					
My CP does not have much effect on my life					
My CP strongly affects the way others see me					
My CP has serious financial consequences					
My CP causes difficulties for those who are close to me					

Views about your CP (cont.)	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
There is a lot I can do to control my symptoms					
What I do can determine whether my CP gets better or worse					
The course of my CP depends on me					
Nothing I do will affect my CP					
I have the power to influence my CP					
My actions will have no effect on the outcome of my CP					
My CP will improve in time					
There is very little that can be done to improve my CP					
My treatment will be effective in curing my CP					
The negative effects of my CP can be prevented (avoided) by my treatment					
My treatment can control my CP					
There is nothing which can control my condition					
The symptoms of my condition are puzzling to me					

Views about your CP (cont.)	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
My CP is a mystery to me					
I don't understand my CP					
My CP doesn't make sense to me					
I have a clear picture or understanding of my condition					
The symptoms of my CP change a great deal from day to day					
My symptoms come and go in cycles					
My CP is very unpredictable					
I go through cycles in which my CP gets better and worse					
I get depressed when I think about my CP					
When I think about my CP I get upset					
My CP makes me feel angry					
My CP does not worry me					
Having this CP makes me anxious					
My CP makes me feel afraid					

CAUSES OF YOUR CHRONIC PAIN

- We are interested in what you consider to be the cause of your chronic pain.
- As people are very different, there is no correct answer to this question.
- We are most interested in your own views about the factors that caused your chronic pain rather than what the doctors or family may have suggested to you.
- Below is a list of possible causes for your chronic pain.
- Please indicate how much you agree or disagree that they were causes for your chronic pain by ticking the appropriate box.

Possible Causes	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
Stress or Worry					
Hereditary – it runs in the family					
A germ or virus					
Diet or eating habits					
Chance or bad luck					
Poor medical care in my past					
Pollution in the environment					
My own behaviour					

Possible Causes (cont.)	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
My mental attitude i.e. thinking about life negatively					
Family problems or worries					
Overwork					
My emotional state e.g. feeling down, lonely, anxious					
Aging					
Alcohol					
Smoking					
Accident or injury					
My personality					
Altered immunity					

Please rank order the three most important factors that you now believe caused your chronic pain. You may use the items from the box above, or you may have additional ideas of your own.

The most important causes for me are:

1) _____

2) _____

3) _____

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE.

Please could you look back to check that you haven't missed any questions by mistake.

PLEASE PUT YOUR COMPLETED QUESTIONNAIRE IN THE BOX PROVIDED IN THE CLINIC.

YOU CAN ALSO CHOOSE TO POST THIS QUESTIONNAIRE BACK TO ME AT THE ADDRESS PROVIDED ON THE FRONT PAGE.

Appendix 4.5 Calculating 'goodness of fit' in Structural Equation Modelling

Calculating 'goodness of fit' in Structural Equation Modelling (SEM)

Models can be tested for 'goodness of fit' using a number of different criteria. It is possible to use just a chi-square statistic (χ^2) but it is recommended that a range of statistics be used to evaluate model fit (Bentler, 1995). This is because of limitations with individual indices e.g. χ^2 is rarely non-significant.

The following three criteria were adopted to assess goodness of fit in this study:

1) The chi-square statistic (χ^2) is a measure of whether the residual correlations obtained by comparing the observed and predicted values differ from 0. If the χ^2 is small in reference to the degrees of freedom the statistic is *not significant* and the model is considered to be a plausible representation of the causal processes in the underlying data. However it is recommended that the χ^2 is not the sole measure of model fit because it is affected by sample size e.g. larger samples produce larger chi-squares that are more likely to be significant (Type I error), as well as model size and distribution of variables.
2) The second criterion is the confirmatory fit index (CFI), which is a measure of the fit between the theorized model and the data. This index can assume a value between 0 and 1, and is independent of sample size and relatively robust against departures from normality. The index is closer to one when the model fits closely with the data.
3) The third criterion takes into account the population error of approximation (expressed as the root-mean-square error of approximation, RMSEA), which is a measure of the degree to which the model holds in larger samples (i.e., is a measure of generalisability). Values up to 0.05 indicate a close fit in larger populations, and values up to 0.08 represent reasonable errors of approximation in smaller populations.

Hu and Bentler (1999) empirically examined various cutoffs for measures in SEM, and their data suggest that to minimize Type I and Type II errors under different conditions, one should use a combination of a relative fit index i.e. CFI and the RMSEA (good models < .06). Therefore, the model was said to fit the data if the χ^2 statistic was not significant (p= >0.05), the adjusted goodness-of-fit index (CFI) was high (preferably > 0.90) and the RMSEA was 0.05-0.08.

A model may be respecified and the fit of the revised model evaluated (Kline, 1998). The specification should be guided by the researcher's hypothesis.

References:

Bentler, P.M. (1995). EQS Structural Equations Program Manual. Encino, CA. Multivariate Software Inc. 1995.

Hu, L., & Bentler, P. M. (1999). Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. *Structural Equation Modeling, 6*, 1-55.

Kline, R.B. (1998). *Principles and Practice of Structural Equation Modelling.* Guilford Press: NY.