Psychological Preparation for Gastrointestinal Endoscopy

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Abstract

The literature on stress and medical procedures is reviewed. Included are the effects of stress on the individual, psychosocial modifiers of stress and a review of psychological interventions in medical settings. Methodological issues regarding research in the health care setting are discussed and psychological aspects of gastrointestinal endoscopy are explored, including the issue of sedation. All main studies used three types of measures: self-report, physiological and behavioural. The results of these studies and their implications are discussed. Preliminary study 1 is described where patients undergoing a colonoscopy examination were interviewed and information regarding their experiences of colonoscopy and their preferences for psychological intervention is reported.

One of the factors identified as important to an individual's experience of stress is perceived control. Preliminary study 2 piloted patients' responses to two relaxation tapes, with or without coping instructions to enhance the experience of perceived control. Study 1 formally investigated repetitive use of a relaxation procedure on patients undergoing a colonoscopy examination in comparison with a non-intervention control group. Patients listened to the relaxation procedure in their own homes during the week leading up to the examination. Anxiety measures were also taken during this time and analysis revealed different trends between the groups. Dose of analgesia, age and group membership were related to patients' experiences of colonoscopy.

Individual coping style is another important factor when looking at how patients differ in their perception of stress. A further study looked at the effectiveness of a single procedure of relaxation and examined the importance of coping style and locus of control in its effectiveness. Comparisons were made with two control groups: attention control as well as non-intervention control groups. Dose of analgesia, state anxiety and duration of the examination were associated with experience of colonoscopy in this sample of patients. A relaxation group by trait anxiety interaction was also identified as relating to the experience of colonoscopy.

Two further preliminary studies were carried out and consisted of interviews with patients
undergoing different gastrointestinal endoscopy procedures, a) to assess their experience and thoughts on psychological interventions, and b) an attempt to modify a questionnaire concerning patients' experiences of colonoscopy so that patients' endoscopic retrograde cholangio-pancreatography (ERCP) experiences could also be reported. A final study compared an alternative psychological preparation for patients undergoing an ERCP. Patients were randomly allocated to one of four intervention groups: relaxation, provision of information, attention control or non-intervention control groups. Dose of sedation, pred-ERCP oxygen saturation levels and social desirability scores were associated with response to ERCP. No between-group differences were detected in these patients during ERCP.

Specific measures used, particularly the measurement of anxiety and outcome measures, are also explored. Future research is suggested and findings are summarised.
To Stefan
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<tr>
<td>ANCOVA</td>
<td>analysis of covariance</td>
</tr>
<tr>
<td>ANS</td>
<td>autonomic nervous system</td>
</tr>
<tr>
<td>APRT</td>
<td>abbreviated progressive muscle relaxation training</td>
</tr>
<tr>
<td>BIS</td>
<td>behavioural inhibition system</td>
</tr>
<tr>
<td>EMG</td>
<td>electro-myogram</td>
</tr>
<tr>
<td>ERCP</td>
<td>endoscopic retrograde cholangiopancreatography</td>
</tr>
<tr>
<td>GAS</td>
<td>General Adaptation Syndrome</td>
</tr>
<tr>
<td>GI</td>
<td>gastrointestinal</td>
</tr>
<tr>
<td>HAD</td>
<td>Hospital Anxiety and Depression scale</td>
</tr>
<tr>
<td>HLC</td>
<td>Health Locus of Control scale</td>
</tr>
<tr>
<td>HOS</td>
<td>Health Opinion Survey</td>
</tr>
<tr>
<td>MANOVA</td>
<td>multivariate analysis of variance</td>
</tr>
<tr>
<td>MANCOVA</td>
<td>multivariate analysis of covariance</td>
</tr>
<tr>
<td>MBSS</td>
<td>Miller Behavioural Style Scale</td>
</tr>
<tr>
<td>MHLC</td>
<td>Multiple Health Locus of Control scale</td>
</tr>
<tr>
<td>NK</td>
<td>natural killer cells</td>
</tr>
<tr>
<td>OGD</td>
<td>oesophagastroduodenoscopy</td>
</tr>
<tr>
<td>PCA</td>
<td>patient controlled analgesia</td>
</tr>
<tr>
<td>sd</td>
<td>standard deviation</td>
</tr>
<tr>
<td>S.E.</td>
<td>standard error</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Sciences</td>
</tr>
<tr>
<td>STAI</td>
<td>State-trait Anxiety Inventory</td>
</tr>
<tr>
<td>TM</td>
<td>transcendental meditation</td>
</tr>
<tr>
<td>TMAS</td>
<td>Taylor Manifest Anxiety Scale</td>
</tr>
<tr>
<td>UGI</td>
<td>upper gastrointestinal</td>
</tr>
<tr>
<td>VAS</td>
<td>visual analogue scale</td>
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</table>
1 Stress

Chapter overview

The historical development of models which attempt to explain the stress process is discussed after the definitions of stress. This is followed by a detailed description of physiological and psychological responses to stressors. An important aspect of stress is an individual's interpretation of the event or circumstance as stressful. Various factors, physiological, psychological and social that affect this interpretation are presented, giving special attention to coping style. Finally, a brief description is given of the possible psychological interventions available for reducing stress and in particular the anxiety associated with it.

1.1 Definitions and models of stress

Lay definitions of stress commonly refer to it as both the negative force or pressure acting on an individual and the unpleasant tension it creates. Hence, stress is used as a general term including both the cause and the response. Academic writers, however, distinguish between the two. The term stressor refers to the cause, the environmental stress or 'stress as a stimulus'. This includes events or circumstances perceived as threatening. Stress or distress refers to an individual's response to a stressor, i.e. 'stress as a response'. This response can be both physiological (affecting neural and chemical processes in the body) and psychological (influencing behaviour, cognitions and emotions). This distinction will be adopted for the purposes of this thesis. A further aspect of the definition of stress is provided by the transactionist approach, which defines stress in terms of the interaction between an individual and his or her environment. Thus, stress is present only when it is perceived as such by the individual (Lazarus, 1966).

Traditionally, theories on stress have focused on physiological responses (Cannon, 1914, 1929; Selye, 1956). Cannon (1914, 1929) was one of the first to use the term stress and suggested that both physiological and psychological factors were involved, as in the fight/flight response.
However, the focus was on the physiological response to stressors. Thus, an increase in activity rate may result in escape from the stressor. He viewed stress as a potential cause of medical problems. Selye (1956) continued this approach of 'stress as response' and devised a model of stress which he referred to as the General Adaptation Syndrome (GAS).

The GAS consists of three stages (see Figure 1.1). First, is the alarm reaction once the organism becomes aware of the stressor. Second, preparation to resist the stressor occurs and involves various physiological changes. Selye refers to this as the stage of resistance where various coping mechanisms are applied and a suitable state of adaptation is achieved. Resistance to the stressor is continued but resistance to other stimuli is reduced. If the resistance stage is prolonged, the third stage, exhaustion, results which may lead to irreversible physiological damage. According to Selye, the GAS is set off by stressors which are noxious and which result in the same basic response. Repeated, prolonged or sufficiently strong stressors may deplete one's ability to resist further. Thus, adaptive abilities are limited.

**Figure 1.1: Diagram of Selye's GAS**

(Based on Selye, 1956, 1976)

<table>
<thead>
<tr>
<th>STRESSOR</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Organism's Response</th>
</tr>
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<table>
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<tr>
<th>ALARM!</th>
</tr>
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</table>
Increase in activity. Mobilisation to meet and resist stressor.

<table>
<thead>
<tr>
<th>RESISTANCE</th>
</tr>
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</table>
Coping with, and resistance to, stressor.

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<tr>
<th>EXHAUSTION</th>
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</table>
If resistance does not terminate stressor, coping exhausted with repeated exposure.
Criticisms of the above model are that: a) it fails to specifically include any psychological aspects of stress; b) it assumes that all individuals respond in the same way; and c) it is based on studies carried out on rats and so its applicability to humans is questioned. Mason (1975) criticised Selye's model in so far as it portrayed stress as a nonspecific physiological response. These criticisms are taken further by Hobfoll (1989) who accuses Selye of using illogical deductive reasoning in that an organism is considered or observed to be experiencing stress only when part of the GAS is occurring. Thus, we are forced to wait until the outcome to know when stress or distress will occur and cannot predict potential stressful events or situations. Furthermore, there is a wealth of evidence to indicate that the human stress response is far from being uniform in terms of when the response occurs and whether the response is physical or psychological in nature (e.g., Appley and Trumbull, 1986; Lazarus and Folkman, 1984).

Alternatives to explaining 'stress as response' include 'stress as stimulus' theories and transactional or event-perception theories of stress (Hobfoll, 1989). Elliot and Eisdorfer (1982) identify 4 kinds of stressors: i) acute, time-limited stressors, e.g., visit to dentist, awaiting a biopsy; ii) stressor sequences, e.g., divorce, bereavement or job loss; iii) chronic, intermittent stressors, e.g., exams, painful medical treatments; and iv) chronic stressors, e.g., debilitating illness, prolonged marital discord, exposure to occupation related dangers. A stressor is defined as a stimulus which normally leads to emotional upset, psychological distress or physical impairment or deterioration. Hobfoll (1989) argues that it is a good starting point because it has given the researcher a basis for comparing individual reactions to stressful situations by producing a taxonomy of stressful events. Although, such information is useful, it fails to completely account for the process of stress.

The most popular explanation for stress is that which describes stress as an interaction between an individual and his or her environment (Lazarus and Launier, 1978). Such a definition has a three point emphasis on appraisal, known environmental threats and personality traits (Sarason, 1972, 1975). Spielberger (1966, 1972) identifies two types of threat: physical threat and ego threat (the latter being threats to the phenomenological self). A further aspect of this type of model is one of balance. This is where stress is seen in terms of a mismatch - actual or perceived - between the person and his or her environment. That is, when environmental
demands exceed the resources available to cope with such demands as perceived by the individual (McGrath, 1970; Lazarus and Folkman, 1984).

Lazarus (1966) gives a detailed account of how the interaction between the stressor and an individual may occur. Thus, as well as an event potentially causing distress, an appraisal or interpretation of the event as stressful is also required. Lazarus identifies two levels or types of appraisal: Primary and Secondary appraisal (see Figure 1.2). First, a potential stressor is labelled as irrelevant, benign (positive) or threatening (harmful). Secondary appraisal refers to the individual evaluating the advantages and disadvantages of different coping strategies. Types of interpretations or appraisals can be categorised as follows: 1) harm or loss appraisal, where the stressful event has already happened; 2) threat appraisal, where the interpretation is anticipatory and 3) challenge appraisal, where there is a possibility of overcoming the stressor.

**Figure 1.2: Transactionist model of stress**

(Based on Lazarus, 1966; Lazarus and Folkman, 1984; Lazarus and Launier, 1978)
There are a variety of choices of stress responses or coping behaviour. Lazarus and Folkman (1984) divide them into manipulative or accommodating behaviour. An individual may take direct action, attempting to directly manipulate or change his or her relationship to the stressful situation. A second choice may be to take no action. Alternatively, one may seek information to enhance one's understanding of the stressful situation and possibly predict related events. Information may increase one's sense of control and coping efficacy (Baum, Singer and Baum, 1981). Finally, there is what Lazarus and Folkman refer to as palliative or intrapsychic coping, where the individual accommodates the stressful situation by altering themselves in some way. Examples include the use of 'drugs', alcohol, learning to relax, meditation or the use of defence mechanisms. Individual differences, coping styles and coping behaviours are considered in more detail below.

Studies that support this notion of appraisal as important in stress include Mason (1975) who showed differing endocrine responses with a variety of psychosocial stimuli depending whether they elicited uncertainty, anger or fear. Therefore, different types of psychological distress may be necessary for a particular physiological reaction. Thus, it appears that awareness is important in identifying the body's response to a stressor. Patients who were conscious before dying showed more signs of physiological stress, such as enlarged adrenal glands at post-mortem compared with unconscious patients (Symington, Currie, Curran and Davidson, 1955). Speisman, Lazarus, Mordkoff and Davidson (1964) showed that the type of soundtrack (emphasising trauma, denial or intellectualisation) accompanying unpleasant genital surgery influenced subjects appraisal of the event as stressful. Other studies (see Koriat, Melkman, Averill and Lazarus, 1972; Nomikos, Opton, Averill and Lazarus, 1968) indicate that stress cannot be explained as a result of 'stressful' situations alone. Different stress reactions can be observed by altering the appraisals individuals make while viewing films.

One of the main criticisms of the transactional definition of stress is that it is tautological (Hobfoll, 1989; Schafer and Fals-Stewart, 1991). This is because it does not provide distinct definitions of demand and coping capacity, using each term to define the other: "Demand is that which is offset by coping capacity. Yet coping capacity is that which offsets threat or demand" (Hobfoll, 1989, p. 515). Furthermore, demand and coping capacity are identified post hoc and so it is uncertain whether such coping resources will be of use in the future (Hobfoll,
1989). The researcher is confronted with a methodological problem of measuring coping resources and demands in meaningful units that may be balanced, even if they can be identified. Such a task would be difficult and that may be why no attempt has been made. Hence, studies in the stress field have been criticised for not accurately operationalizing terms used, which would facilitate measurement and replication (Schafer and Fals-Stewart, 1991). Studies need to focus on the formulation of precise hypotheses about specific relationships between well-specified variables.

Hobfoll (1989) provides a new model, the 'conservation of resources' model of stress. He aims to bridge the gap between environmental and cognitive viewpoints, claiming that his model is testable and provides a comprehensive explanation of behaviour during stressful circumstances. The conservation of resources model states that individuals strive to retain, protect and build resources and that what is threatening to them is the potential or actual loss of these valued resources. Hobfoll defined psychological stress "...as a reaction to the environment in which there is: a) the threat of a net loss of resources; b) the net loss of resources; or c) a lack of resource gain following the investment of resources. Both perceived and actual ... lack of gain are envisaged as sufficient for producing stress" (p. 516).

Hobfoll (1989) describes resources as the single factor necessary for understanding stress. Resources are additionally defined as those objects, personal characteristics, conditions or energies that are valued by the individual. Examples include mastery, self-esteem, learned resourcefulness, socioeconomic status and employment. Furthermore, resources have instrumental value and symbolic value. These distinctions are similar to Spielberger's (1966, 1972) threat definitions, where symbolic value, in direct comparison with ego threat, helps individuals to define who they are. Like the interaction model, the conservation of resource model emphasises appraisal of resources, which may entail shifting the focus of attention or interpreting threat as challenge (Kobasa, 1979), and reevaluating resources (that are threatened or lost). In this way appraisal is the key to stress resistance. Hobfoll, adds that when individuals are not under stress they are motivated to gain resources in order to enrich their resource pool.
1.2 Effects of stress on the individual

The body responds both physiologically and psychologically to a perceived stressor. The immediate physiological stress response involves the sympathetic branch of the autonomic nervous system (ANS) and the endocrine system. Examples of the physiological response include: an increase in heart rate and blood pressure, constriction of the blood vessels serving the skin and gut with the blood being redirected to tissues, such as skeletal muscles, which are essential for vigorous activity. The immune system is also affected (see Vollhardt, 1991; Dorian and Garfinkel, 1987 for a review of the related literature).

Examples of psychological stress effects include: an increase in anxiety, fear, anger or aggression. In addition, there may be changes in behaviour resulting in an increase in accidents (Johnson, 1986; Quick and Quick, 1984); as well as behaviours which increase an individual's risk of being harmed, e.g., smoking, increased consumption of alcohol or caffeine, changes in diet - such as omitting meals or eating 'junk' food - and a reduction in exercise (Baer, Garmezy, McLaughlin, Pokorny and Wernick, 1987). The psychological and social effects of stress are described after a physiological account of the stress response.

1.2.1 Physiological changes

The sympathetic branch of the ANS prepares the body for 'fight or flight' activities, whereby the blood supply is directed to skeletal muscle and away from the skin and gastrointestinal system. The heart rate increases, as does the respiratory rate (although changes in the breathing pattern during stress are not consistent, Steptoe, 1990). An increase in blood pressure may also be present. As might be expected during periods of acute stress - where the individual is in a prolonged state of potential activity - damage to the myocardium (heart muscle) may occur (Deanfield, Shea, Densett, Horlock, Wilson, DeLandsheere and Selwyn, 1984). Other conditions which may arise from this aspect of the stress response are hyperventilation, producing both affective and somatic symptoms (Grossman and de Swart, 1984), and stomach ulcers, which generally manifest after the stress event when the parasympathetic branch of the ANS is overstimulated as compensation (Kalat, 1988).
Activation in the hypothalamus stimulates the pituitary gland to produce adrenocorticotropic hormone, which in turn stimulates the release of corticosteroids. Corticosteroids influence a number of biochemical activities throughout the body: increased production of glucocorticoids in the liver; the uptake of glucose is inhibited in peripheral tissues; a modification of the body's water balance and vascular reactivity; and there are changes in immune function and gastrointestinal activity. Such changes are compatible with those of the ANS described above.

These two physiological systems also work together in positive feedback. The activity of the sympathetic nervous system stimulates the adrenal medulla to release catecholamines (e.g., adrenalin and nor-adrenalin) which in turn stimulate the activity of the sympathetic nervous system. Catecholamines also mobilise and utilise stored fuel (along with glucocorticoids) and promote the clotting process. Thus, again one could suggest that a prolonged state of acute stress may affect the health of an individual with the production of thrombi (blood clots) which, if mobilised, may lead to a cerebrovascular accident or coronary damage and possibly a heart attack.

Psychological stress has a direct effect on the immune system (Ballieux, 1991). Two types of leucocytes (white blood cells), lymphocytes and granulocytes, are responsible for fighting foreign bodies including bacteria and viruses, foreign cells and tissues in blood transfusions or organ transplantations and tumour cells. Lymphocytes are further subdivided into T-lymphocytes (processed in the thymus), B-lymphocytes (processed in bone marrow) and natural killer (NK) cells. The latter prevent the development of cancer. During states of stress there is a reduction of NK activity and a reduction of T-lymphocytes (Kiecolt-Glaser and Glaser, 1992). There is evidence that stress can influence infectious illnesses, such as the common cold (Cohen, Tyrrell and Smith, 1991) and responses to Hepatitis B vaccination in medical students (Glaser, Kiecolt-Glaser, Bonneau, Malarkey and Hughes, 1992). However, Kiecolt-Glaser and Glaser, (1992) warn against the assumption that changes in the immune system necessarily result in changes in health.
1.2.2 Psychological changes

Catecholamines can affect cognitive and behavioural functions as well as emotions (Frankenhaeuser, 1971). One view of the relationship between physiological arousal and emotions is that individuals seek to understand the source of their arousal. Schachter and Singer (1962) hypothesised that an injection of adrenalin would elicit an emotional response following physiological arousal depending on the subjects' attributions concerning the aroused state. It was predicted that subjects who were told that the injection had no side effects would look for other cues to provide an interpretation of their arousal. In this study the cues were provided by a confederate who behaved either euphorically or angrily. These 'misinformed' subjects reported experiencing the same emotions as displayed by the confederate. In contrast, subjects who were informed that the injection they had received was adrenalin and were told what side-effects to expect did not interpret their arousal as emotion. Thus, cognitive appraisal can affect emotional response as well as perceptions of stress.

Fear is a common emotional reaction to a stressor that involves a combination of psychological discomfort and physical arousal in threatening situations. Two types of fear have been identified: phobia and anxiety (Kaloupek, 1987). Phobias can be defined as intense and irrational fears that are directly associated with specific events. Anxiety refers to a vague feeling of uneasiness or apprehension often involving a relatively uncertain or unspecific threat. Examples of situations in which anxiety may occur include awaiting surgery or the results of diagnostic tests, receiving appraisals likely to provoke feelings of low self-worth and the anticipation of loss of esteem of self or others.

Stress can also lead to feelings of sadness or depression. Depression becomes a psychological disorder when it is severe, frequent and longlasting. Although responses to stress are not usually so severe, an increase in general negativity, impatience, irritability, feelings of worthlessness, and emotionality may accompany a stress response. Another common emotional reaction to stress is anger, particularly if the situation is perceived as harmful or frustrating. Anger in turn may lead to aggressive behaviour. McCabe and Schneiderman (1985) provide a useful account of psychophysiological reactions to stress, linking psychological effects to biological processes.
Stress may have positive effects on cognition, such as improved performance on some tasks. An explanation for this can be provided by the Yerkes-Dodson law which is represented by an inverted-U to describe the relationship between performance and level of arousal. Stressors, such as noise, have been linked to improved performance in times when productivity is generally low, such as in night-time work or during the post-lunch dip in performance (see Smith, 1990, for a review of the effects of physical stressors, anxiety and drugs on information processing in laboratory settings). However, the consequences of a stressor on cognitive abilities are generally negative. Glass and Singer (1972), for example, report a reduction in problem solving ability. Furthermore, increased levels of stress impair memory and attention during cognitive activities (Cohen, Kiecolt-Glaser, Bonneau, Malarkey and Hughes, 1986).

The type of emotional response experienced, such as anxiety, fear or anger, may affect coping behaviour. For example, if an individual responds with anger to the stressor, then coping is more likely to be direct, active or forceful than with a response of sadness or despair. Distressed individuals are more likely to develop high risk lifestyles, in particular, poorer health habits, such as an inclination for alcohol abuse, poorer sleep, poorer nutrition and low exercise (Verbrugger, 1979), and these behaviours affect immunity (Kiecolt-Glaser and Glaser, 1992).

Psychological aftereffects of stress include a decrease in cognitive ability, a low tolerance for frustration, aggressiveness, helplessness, a reduction in sensitivity to others and withdrawal (Cohen, 1980). These negative effects are consistent with Selye's (1976) notion of limited adaptive energy, causing reductions in subsequent coping ability. Such effects appear to be related to perceived control during the stressful event, i.e., fewer adverse aftereffects follow experiences of greater perceived control (Cohen, 1980). Perceived control, a modifier of stress is described in the next section.

1.3 Psychosocial modifiers of stress

The following factors have been identified as influencing an individual’s perception of stress and their response to it: exercise; dispositional variables, such as sex differences, personality and coping style; social support and perceived control.
1.3.1 Exercise

Evidence suggests that exercise helps to reduce levels of stress. Sinyor, Schwartz, Peronnet, Bisson and Seraganian (1983) showed that subjects who exercised regularly showed hormonal responses to a laboratory stressor which were stronger and recovered quicker compared with those of subjects with infrequent exercise habits. Other beneficial effects of vigorous exercise, compared to less demanding exercise activities, include a reduction in anxiety as well as the benefits of increased fitness (Goldwater and Collis, 1985). Physical fitness has also been associated with the ability to cope with psychosocial stress (Brooke and Long, 1987). Furthermore, subjective reports of positive mood changes are more common among exercisers, and it has been found that anxiety and depression can be reduced with the commencement of exercise (Folkins and Sime, 1981; Markoff, Ryan and Young, 1982). Endorphins associated with exercise may explain how exercise affects the stress response: by reversing and reducing the effects of catecholamines (Steptoe, 1990).

1.3.2 Dispositional variables

Sex differences have been identified in physiological responses to stress. Stoney, Davis and Mathews (1987) found that males respond more strenuously than females, particularly in measures of systolic blood pressure. Females show smaller adrenalin changes than men, but similar nor-adrenalin and cortisol levels during stress (Frankenhaeuser, 1983). Nespor (1985) reports that males generally appear more resistant to stressful life events than females. Such resistance includes a tendency for commitment to involvement, perceived control over life events, the belief that change initiates growth, low fatalism and high flexibility. In studies concerning stressful medical procedures the evidence for differences in levels of anxiety or in coping styles between men and women is not consistent (Schultheis, Peterson and Selby, 1987). Generally, studies which have showed a difference indicate that men report or display less distress than women (e.g., Graham and Conley, 1971; Kaloupek, White and Wong, 1984.

Type A personality, or Type A behaviour, has been associated with stress-related illnesses, in particular, with chronic heart disease. Type A behaviour patterns include time urgency,
competitiveness and hostility (Friedman and Rosenman, 1974). The individuals concerned respond to stressors as a threat to their sense of control. Thus, their interpretation of events is particularly sensitive to anything that might reduce their control (Carver, Diamond and Humphries, 1985; Glass, 1977). In addition, a person displaying Type A behaviour patterns may encounter more stressful events as these individuals tend to seek out demanding situations (Byrne and Rosenman, 1986; Smith and Anderson, 1986). Furthermore, as they are often in a hurry they tend to have more accidents than those who are of a more relaxed, easygoing disposition (Suls and Sanders, 1988).

The 'hardy personality' has also been identified on the basis of individual responses to stressors. In contrast to Type A personalities, hardy individuals differ in their tendency to resist becoming ill under stress (Kobasa, 1979). The characteristics of a hardy personality consist of: i) a sense of control - the belief that they can influence events in their lives; ii) commitment - a sense of purpose and involvement in events or activities; and iii) challenge - the tendency to view changes as incentives or opportunities for growth (and not as a threat to security). In times of stress such individuals turn to others for assistance and resist giving up. Coping styles, although strictly a dispositional variable, will be dealt with in the next section.

1.3.3 Social support

Social support can be defined as the perceived comfort, caring and esteem or help a person receives from others (Cobb, 1976). Types of social support have been divided into emotional, esteem, instrumental and informational support (Wills, 1985). Emotional support refers to the expression of empathy or concern providing a sense of comfort, reassurance and belonging. Esteem support is where other's positive regard, encouragement or agreement helps to build feelings of self-worth, competence and being valued. Instrumental support is the direct assistance with time, chores or finances. Finally, informational support refers to giving advice, directions, suggestions and feedback.

A number of theories attempt to explain how social support acts as a mediating factor. The 'main effect hypothesis' states that social support is beneficial and its absence is
perceived as stressful. Thus, social support is important regardless of whether an individual is stressed or not. In contrast, the 'stress buffering hypothesis' views social support as beneficial because it helps an individual cope with stress (Cohen and McKay, 1984; Cohen and Syme, 1985). There is evidence to support both views (Fleming, Baum, Gisriel and Gatchel, 1982; Wills, 1985). An alternative theory, the 'social comparison theory', has been proposed which explains social encounters as situations where affiliation and help with reappraisal can occur. Thus, comparison with others can provide the introduction to a choice of coping strategies (Schachter, 1959). Finally, 'role theory' explains social support as enabling the individual to change roles and identity according to the stressor (Cobb, 1976).

Cohen and Wills (1985) claim that the effectiveness of social support in the reduction of stress is determined by the degree to which it meets the needs of the situation. In a review of the literature Cohen and Wills (1985) suggest that appraisal of support is more important than the support that is actually available. Negative aspects of social support include a tendency to dependency and hence reduced self-reliance (Kulik and Mahler, 1989), as well as any unwanted effects arising from exposure to the problems of others (Solomon, Mikulincer and Hobfoll, 1987).

1.3.4 Perceived control

A sense of personal control, or perceived control, is the belief that one is able to make decisions and take effective action to produce desirable outcomes and avoid undesirable ones (Rodin, 1986). Thus, having a sense of personal control can reduce the impact of stress by providing individuals with a sense that they can cope effectively and possibly predict events. Baum, Fisher and Solomon (1981) found that accurate expectations reduce stress. It is also important to note that there may be a difference between perceived control and actual control (Wallston, 1989).

One aspect of perceived control is identified in the notion of 'locus of control' (Rotter, 1966). Individuals who believe they have control over their successes and failure are described as
having an internal locus of control; they believe that they are responsible for such events. The opposite, external locus of control, refers to a belief that outside forces, such as fate or luck, have more influence (Rotter, 1966). However, most people vary between these two extremes. With respect to health care settings an extra dimension has been added to external locus of control: the influence of powerful others (Wallston, 1989). That is, an individual may believe that others, such as health care providers, family or friends, are a major influence on one’s health and recovery from illness. This is, of course, often the case when one is acutely or chronically ill and so a high score in this dimension does not necessarily indicate low perceived control of one’s life and health in general (Wallston, 1989).

The relation between perceived control and health is broadly as follows. Individuals with high perceived internal locus of control are more likely to maintain their health and prevent illnesses and once ill, such individuals have a greater ability to adjust to illness and promote their own rehabilitation. If an individual believes that a stressor can be controlled this reduces the perception of stress. However, attempting to control the uncontrollable may result in increased perception of stress.

The related concept of ‘responsibility’ is further explored by Brownell (1991), who argues that some individuals overestimate the control or influence they have over their health. Such beliefs are displayed in behaviours, such as an increase in the consumption of low fat foods, dieting and an increase in health and sport club membership. Thus, the assumption prevails that if health is under one’s control then one is responsible for one’s health. Brownell continues this line of reasoning with the suggestion that the assumption of responsibility can acquire moral overtones: that responsible behaviour leads to good health and irresponsible behaviour leads to bad health. Some suggest that there is a curvilinear relationship between responsibility and controllability: that very little control over a situation has negative effects on health, and that an overestimation of control may have the same effect (Turk, Rudy and Salovey, 1986). Hence, a mismatch between actual control and perceived control may result in a renouncement of all personal responsibility for influencing one’s state of health or illness.
1.4 Coping styles

Menaghan (1983) distinguishes between three broad categories of coping variables: coping resources, coping styles and coping efforts. Resources are defined as the generalised attitudes and skills that are considered beneficial over many situations. Examples include attitudes about oneself and the world, and intellectual and interpersonal skills. Coping styles refer to generalised coping strategies such as the individual's preferred approach for dealing with problems. Coping efforts are specific actions taken in a specific situation intended to reduce a problem or stress. Such action may be covert or overt, for example, in response to a stressor the individual may appraise the problem, begin a new activity, express or exhibit an emotion, ask for help or refuse to think about the problem.

What is considered coping depends on the criteria used for judging its effectiveness. Examples of judgement criteria used to assess the successful management of stress are perceived helpfulness, reduction in emotional distress and reduction in problem level. However, the criterion of perceived helpfulness is problematic as it is difficult to assess the relationship between reports and actual effects of helpfulness. Similarly, studies which take a reduction in emotional distress as a measure of coping do not reflect that a reduction or even a solution to the problem has taken place (Menaghan, 1983). The reduction in the problem level as a criterion may also be problematic as the effectiveness of a coping resource, style or effort may vary depending on one's chosen indicator. As a result of the specificity of many findings, some researchers have questioned the necessity of attempting to identify generally effective coping variables (Turk, 1979). Hackman (1970) argues that the ability to assess how well an individual's coping strategy is working depends on establishing some classifying system of describing task demands.

Menaghan (1983) argues that for those in stress there is a finite number of general adaptive tasks to be carried out and these are reflected in the general criteria used for assessing effectiveness as well as for categorising coping efforts. As noted above, stress may be reflected as a mismatch between environmental demands and the individual's capacities. The coping tasks, therefore, involve the efforts employed to alter stress and this may be done by altering the environment or the individual, either by direct action or by interpretive appraisal. The
mismatch between demands and capacities is often unpleasant, producing anxiety and tension. Therefore, it is possible that efforts to reduce the problem are accompanied by efforts to avoid being overwhelmed by negative affect.

Despite these criticisms a number of measures for assessing individuals' coping style are frequently used in medical settings. Examples of measures include the Repression-Sensitization Scale (Byrne, 1961) and the Miller Behavioural Style Scale (MBSS; Miller, 1987). The Repression-Sensitization scale separates individuals on the basis of their coping styles as 'repressors' and 'sensitizers'. Problems with this scale are discussed in Chapter 7. Repressors appear non-anxious and deal with impending stress by repression or denial. Sensitizers, in contrast, are overtly anxious and alert to threatening cues and tend to seek information about a stressor as a means of preparing themselves for it. The MBSS divides individuals in a similar way: into 'monitors' or 'blunters'. Monitors may be classed as 'high' or 'low' depending on whether they seek or avoid information, respectively. Blunters seek distractions when dealing with a threatening situation. Again blunters may be classed as 'high' or 'low', depending on the extent of distraction sought. Further discussion on coping styles can be found in Schultheis, Peterson and Selby (1987).

1.5 Psychological interventions

Typically psychological interventions carried out to reduce anxiety and fear focus on the cognitive appraisal and coping actions of the individual. Psychological interventions have attempted to manipulate such aspects in various medical settings to reduce the distress and discomfort associated with medical procedures or symptoms of illnesses. Such attempts at 'stress management' include a variety of behavioural and cognitive-behavioural interventions, which aim to provide patients with alternative coping mechanisms as a way of reducing stress. Such an approach often uses a combination of training in muscle relaxation, modification of thoughts and distraction from pain and discomfort.

The rationale for providing information is that it enables the individual to form accurate cognitive expectations about the procedure (Johnson, 1975) and so may increase his or her
sense of control and ability to cope (Janis, 1958). Two types of information may be given: procedural information, consisting of a description of the sequence of events which will occur during the medical procedure; and sensory information, involving the types of sensations likely to be experienced. However, it is often difficult to provide sensory information without describing the procedure as well. After assessing a number of studies Suls and Wan (1989) concluded that combined sensory and procedural information is more affective in reducing pain reports and distress compared with either sensory or procedural information alone.

Although the underlying processes are not fully understood, relaxation has both somatic and cognitive effects which can occur independently of each other (Davidson and Schwartz, 1976). The use of relaxation for reducing stress is based on the premise that muscle tension is closely related to anxiety and that an individual will feel some reduction in experienced anxiety when muscular tension is reduced. The most common form is progressive muscle relaxation, where the individual focuses on tensing and relaxing different muscle groups (Jacobson, 1938). An alternative type of relaxation procedure is passive relaxation. This is where the individual is instructed to focus on various muscle groups and allow the muscles to relax (without tensing them first). Attention may be drawn to the individual's breathing and images of relaxing places, such as lying on the beach, may be introduced. It is important to note that some individuals respond negatively to relaxation: with the onset or increase in anxiety. This may be due to perceived loss of control, especially when physiological changes are observed by the individual (Heide and Borkovec, 1983).

Biofeedback is a technique in which an instrument monitors the status of a person's physiological processes, and immediately reports that information back to the individual. Examples include heart rate or muscle tension. This information allows the person to gain voluntary control over such processes, as changes in feedback indicating success helps to reinforce the efforts of the individual. Lazarus (1975) gives three reasons for accepting the importance of biofeedback processes. These are: i) biofeedback can aid recognition of the possibility of wilfully regulating bodily processes (however small the influence); ii) biofeedback can offer helpful information in a person's quest for self-regulation; and iii) research in biofeedback may answer important theoretical and practical questions regarding the effectiveness of psychological processes individuals use to regulate their emotions.
Biofeedback is useful in treating stress and stress related illnesses, such as chronic tension headaches and stress related hypertension, and can be as useful as progressive muscle relaxation for the treatment of headaches (Holroyd and Penzien, 1985). Criticisms of biofeedback include the cost of the equipment and exaggeration of its effectiveness (Turk, Meichenbaum and Berman, 1979).

The goal of cognitive-behavioural strategies for stress reduction is to directly alter cognitions and appraisals surrounding the noxious event (Ludwick-Rosenthal and Neufeld, 1988). Examples of techniques which have been used include distraction, attention focusing, the use of positive self-statements, sometimes in an effort to enhance perceived control and multiple-strategy packages such as stress inoculation (Meichenbaum, 1977). Stress inoculation involves three stages; first, the establishment of a conceptual framework for understanding stress reactions; second, introduction to a variety of cognitive-behavioural techniques. For example, helping the individual control his/her physiological arousal and substituting positive self-statements for repetitive anxious thoughts; and third, rehearsal of strategies using imagery or actual stimuli.

Modeling approaches often include features of the other interventions such as providing information and coping strategies. It is based on the assumption that the patient can learn how to cope successfully during a noxious medical procedure from exposure to a model who is coping adequately in the same situation. Modeling can have a number of effects including observational learning, response facilitation and inhibition effects (Bandura, 1969). The first involves the acquisition of new coping strategies. Responses already present in the observer’s repertoire may be facilitated and behaviours resulting in negative consequences may be inhibited.

Individuals who practice transcendental meditation (TM) are instructed to do so sitting upright with their eyes closed and repeating a word or sound (referred to as a mantra) to prevent thoughts from occurring. It is generally promoted as improving mental health and reducing stress (Benson, 1984). The purpose is to increase one’s ability to make an alternative, relaxed response in the face of a stressor. Research indicates that TM is as effective as some relaxation procedures, such as autogenic training, in reducing stress as measured by urinary
catecholamines compared with a control group (Gallois, Forzy and Dhont, 1984). However, other research suggests that it is not as effective as progressive muscle relaxation, desensitization (Kirsch and Henry, 1979), behaviour therapy and self-relaxation (Puente and Beiman, 1980) at reducing heart rate under stressful conditions. Furthermore, a review of experimental research failed to show evidence that meditating subjects attained lower levels of somatic arousal that did resting subjects (Holmes, 1984).

Hypnosis is considered by some to be an altered state of consciousness that is induced by special techniques of suggestion and can lead to varying degrees of responsiveness to directions for changes in perception, memory and behaviour (Orne, 1980). Irrespective of its theoretical status, subjects who have been hypnotized describe it as a relaxing experience and it has been used for this and other purposes in medical settings. In particular, hypnosis has been applied to the reduction of pain by dentists and physicians (see Holroyd, 1996) and studies have found that hypnosis can be as helpful as other relaxation techniques in stress management (Wadden and Anderton, 1982). It is important when using hypnosis to take account of patient's misconceptions, particularly of hypnosis as 'mind control' as implied in the popular literature and entertainment. Redd (1986) suggests that misconceptions may change with straightforward discussion of patients' beliefs and expectations regarding this behavioural intervention.

These interventions have been investigated in various medical and laboratory settings and the next chapter contains a review of the evidence for their effectiveness in relation to medical and surgical procedures.
2 Stress and Medical Procedures

Chapter overview

There are numerous review papers evaluating the effectiveness of the various psychological interventions (e.g., Anderson and Masur, 1983; Chapman and Turner, 1986; Kendall and Watson, 1981; Ludwick-Rosenthal and Neufeld, 1988; MacDonald and Kuiper, 1983; O'Halloran and Altmayer, 1995; Salmon, 1993; Schultheis, Peterson and Selby, 1987; Wilson-Barnet, 1984). Therefore, studies or papers which give a summary of the effectiveness of a particular intervention are described. This is followed, where possible, by an account of interventions in gastrointestinal endoscopy or surgical procedures. The patient's experience of endoscopy is described in detail in Chapter 3. Each intervention is addressed in turn and followed by studies which compare two or more interventions, and then the issue of individual differences is explored. Finally, a section describing criticisms and problems in this type of research is also included. Part of this and the following chapter is based on a review paper by Woloshynowycz, Oakley, Saunders and Williams (1996) which is included inside the back cover of this thesis.

2.1 Psychological interventions in medical settings

A variety of psychological interventions have been applied to patients in medical settings to reduce the fear and anxiety associated with medical procedures. Studies with surgical patients indicate that a patient's level of anxiety can determine the amount of medication required to induce anaesthesia (Markland and Hardy, 1993; Williams, Jones, Workhoven and Williams, 1975). Psychological interventions have also been used to reduce both chronic and acute pain, and other medical conditions, such as hypertension (e.g., Blanchard, Applebaum, Randitz et al., 1990; Jacob, Shapiro, O'Hara and Portser, 1992) and irritable bowel syndrome (Blanchard, Greene, Scharff and Schwarz-McMorris, 1993; Creed and Guthrie, 1989). Medical procedures which have been studied vary from blood donations and endoscopic investigations, to biopsies and surgery. Thus, patients in the different studies vary widely in
the duration of hospital stay and whether they will be fully conscious, partially sedated or under general anaesthetic during the procedure.

2.1.1 Provision of information

Suls and Wan (1989) attempted to address the following questions: i) whether all kinds of information are equally beneficial, ii) whether a combination of sensory and procedural information is better than either alone and iii) whether only certain kinds of outcomes are benefited by pre-operative information. To do this they carried out a meta-analysis on 21 studies which used provision of information as a psychological preparation for medical procedures (sixteen studies) or pain induced in laboratories (five studies). Selection criteria for inclusion into the meta-analysis were a) studies which compared sensory, procedural, sensory and procedural and/or no instruction groups; and b) results which were sufficiently reported to enable calculation of effect sizes. Studies were excluded if information conditions also provided subjects with instructions on coping techniques, such as relaxation. The relative effects of sensory, procedural, and combined sensory-procedural information on coping outcomes were evaluated. Suls and Wan report that preparation involving a combination of sensory and procedural information was associated with the largest and most consistent benefits. Such benefits were reflected in self-reported affect and pain measures and in observer ratings of distress. However, there were no significant objective outcome measures such as length of stay and degree of complications as a result of combined preparation. As Suls and Wan indicate, this may be due to few studies measuring such outcomes. Sensory information given alone reduced self-rated pain more than procedural information. However, the study effect sizes were heterogeneous and could not be explained by the authors.

The anticipated beneficial effects of providing information have not been easy to demonstrate in endoscopy settings. Two studies which used only patients' own rating of anxiety failed to show a reduction in anxiety. In one study, Lanius, Zimmermann, Heegewaldt, Hohn, Fischer and Rohde (1990) provided half the patients undergoing gastroscopy or colonoscopy with information booklets. Anxiety levels were measured by a Visual Analogue Scale (VAS) before and after reading the booklets. All patient groups were comparable. No differences
in anxiety levels were found before and after reading the patient information booklet. Agre, Kurtz and Krauss (1994) compared live versus videotaped consent information for colonoscopy. Two hundred and one patients were divided into three groups: video plus discussion, video alone, and discussion alone. Patients were assessed with a knowledge test and the State-Trait Anxiety Inventory (STAI; Spielberger et al., 1970). Planned comparisons showed that patients in the two video groups had significantly better knowledge scores, but that anxiety was not influenced by an increased understanding of the risks and benefits of colonoscopy. The authors claim that such an approach may by used for other medical procedures, saving time for the physicians while providing a basis of understanding of the procedure for further discussion with the patient. Both these studies used patient's own rating of anxiety only.

Levy, Landmann, Stermer, Erdreich, Beny and Meisels (1989) added behavioural ratings by the endoscopist to patients' own ratings and found no effect of information with either measure. They investigated whether more detailed information reduced fear in patients undergoing a gastroscopy. Two hundred and forty three patients were randomly assigned to four groups: a standard brief description of the procedure; a detailed description by the endoscopist; a comprehensive explanation and photographs of each stage of the procedure; or a specially prepared video. A fifth group of patients who had previously undergone a gastroscopy were also included in this study. Except patients in the first group the rest were encouraged to ask questions. Anxiety was measured in the form of self-report questionnaires (STAI; Spielberger et al., 1970) and on the basis of the patients' behaviour: ease of intubation, intensity of retching and degree of cooperation as assessed by the endoscopist. The results failed to show any significant difference between the five groups. Thus, neither the level of information offered nor previous experience of the procedure significantly reduced patient anxiety as indicated by the measures used in this study. Unfortunately, patients' responses to the different types of information (e.g. whether they thought that information helped them) were not reported.

Wilson, Moore, Randolph and Hanson (1982) however, as part of a larger study, did find a beneficial effect of information in upper gastrointestinal endoscopy. They used physiological measures (heart rate and the amount of sedation used) in addition to a variety of self-reported
(fear and mood) and behavioural (gagging, moaning and arm movements) assessments. Information was provided via an audio tape. Wilson et al. (1982) report that compared with the control group, patients in the information group exhibited less distress during insertion of the tube, showed smaller increases in heart rate, reported the procedure as less uncomfortable than expected and said that they would be less frightened in future hospital experiences. Responses to the information tape indicated that it decreased fear in eight patients, increased fear in one, and had no effect on fear as reported by five patients. In addition, the information group were more positive about being informed about future hospital experiences than either the control group or the relaxation group. It is not clear why Wilson et al. achieved different results from the studies described above. One possible explanation may be the content of the information condition. Furthermore, differences in physiological measures were reported, whereas the other studies this did not use physiological measures.

Irrespective of its effectiveness patients vary in their desire for additional information. Probert, Jayanthi, Quinn and Mayberry (1991) looked at patients' perceived information needs prior to an endoscopy. One hundred and two patients took part in the study, 31% of whom had previously undergone an endoscopy. Results revealed that of the new patients 94% were aware of the reason for their investigation, 38% said they would like an information booklet and 18% reported that they would like to see a video of the procedure. Of those having a repeat endoscopy 25% and 18% said they would have liked access to a booklet and video, respectively. Even though the percentage requesting additional information were relatively low, the authors recommended that all patients should be offered an information booklet (Probert et al., 1991).

2.1.2 Relaxation

Carlson and Hoyle (1993) looked at the effectiveness of abbreviated progressive muscle relaxation training (APRT). A meta-analysis was carried out on the association between APRT and outcome measures for 29 studies published since 1980. Studies analysed were restricted to meet certain criteria: that relaxation training was provided according to the
procedure described by Bernstein and Borkovec (1973); that no other therapy was received by the sample; and that an effect size could be extracted. Samples studied included patients with chronic headaches, essential hypertension, cancer chemotherapy stress and lower back pain. The average effect size across all experiments was found to be moderate and ranged from no effect to a very large effect. Analysis suggested that the effectiveness of relaxation training was influenced by additional factors. When the sample size of studies was taken into account, for example, there was a tendency towards a larger effect size with smaller samples. Similar effects were found at follow-up for those studies which included such an assessment, implying that the effectiveness of relaxation training did not diminish with time. Studies which assessed change over time within subjects had more of an effect than those which compared groups. The strongest association of APRT was with studies which delivered relaxation on an individual basis and provided subjects with training tapes for home practice. As expected, the number of sessions and duration of treatment positively influenced the strength of association.

There are many more studies on the effects of relaxation than those assessed by Carlson and Hoyle (1993). One example is Markland and Hardy (1993) who compared a group receiving a brief tape-recorded guided relaxation procedure, to an attention control group (where patients listened to a tape-recorded message about the history of the hospital) and a no treatment control group. The 21 subjects were day-case surgery patients awaiting a variety of procedures. The relaxation group showed significant reduction in pre-operative anxiety and a low rating of difficulty in maintaining anaesthesia as rated by the anaesthetist. Both the relaxation group and the attention control group required less time for the induction and maintenance of anaesthesia. However, though there were no differences in their anaesthetic requirements compared with the relaxation group, the attention control group did not achieve a reduction in pre-operative anxiety.

An example of the use of relaxation as part of a larger study concerning gastrointestinal endoscopy is taken from Wilson et al. (1982). Like the information group in their study, the relaxation group also received their instructions via an audiotape. Compared with those in the control group, patients who underwent the relaxation procedure showed less distress during insertion of the endoscopy tube, showed lower heart rate increases and reported
significant improvement in mood after the endoscopy. It is difficult to assess the significance of between group comparisons in this study, however, as Wilson et al. (1982) were comparing the effects of an eight minute information tape and a 25 minute relaxation tape with a 'no treatment' control group, thus failing to control for the duration of the intervention or for attention effects. It is worth noting nevertheless that all but one patient evaluated the relaxation tape positively. When compared with the provision of information, some studies have shown beneficial effects of relaxation, i.e. a reduction in physiological measures (Gatusso, Litt and Fitzgerald, 1992); whereas other studies (e.g. Wilson et al., 1982) report the benefits of both types of intervention on physiological and behavioural measures. It seems likely that one type of procedure will not benefit all patients and that the coping styles of patients need to be taken into account. This issue is addressed in Section 2.2.

2.1.3 Cognitive-behavioural strategies

On the basis of the small amount of information available concerning endoscopy patients cognitive-behavioural interventions appear to have some beneficial effects for this group of patients. In one study sixty six patients undergoing sigmoidoscopy were divided into three groups (Kaplan, Atkins and Lenhard, 1982). In two self-instructional conditions patients were briefly trained to focus their attention in one group on their own ability to regulate the situation or, in a second group, on the doctor's ability. A third group were not given any instructional training but did receive attention. In addition, half the subjects in each of the above conditions also received relaxation training. Comparisons revealed that subjects in the self-instruction groups rated themselves as less anxious, moved less often during the examination and produced fewer pain utterances than those in the attention control group. Subjects in the external condition perceived that the examination took less time. Although, there was little difference between the two instructional groups in terms of reported anxiety, patients in the internal (personal) group rated their benefits as significantly higher than those in the external (doctor) group. The external group subjects also tended to have elevated heart rates during the procedure. Those who received relaxation training rated themselves as less anxious than patients who did not receive relaxation training. They also showed a tendency to make fewer requests to stop the examination and to overestimate its duration. There were
no interaction effects.

In another study, patients who had experienced relaxation plus coping enhancement reported greater increases in coping self-efficacy and greater decreases in distress before and during gastroscopy than did other patients (Gattuso, Litt and Fitzgerald, 1992). Measures taken included: behavioural ratings of distress; physiological measures of heart rate, EMG and amount of sedation required; and self-reported distress, self-efficacy and credibility of the relaxation intervention. There were no differences in self-efficacy ratings, nor reported distress, between the relaxation and information groups.

Overall, for gastrointestinal endoscopy patients, those who received relaxation training rated themselves as less anxious than patients who did not receive such training (Kaplan et al., 1982) and physiological measures of frontalis EMG and pulse rate were significantly reduced in two relaxation groups compared with an information group (Gattuso et al., 1992).

2.1.4 Modeling

Modeling is rarely used as the sole strategy and approaches featuring modeling often include aspects of the other interventions such as providing information and coping strategies. Two studies have used modeling as an intervention in an endoscopy setting.

Shipley, Butt and Horwitz (1979) showed experienced patients a videotape of a gastroscopy procedure one or three times. Although Shipley et al. tested a different hypothesis, their study will be used here as an example of modeling, as the video tapes used were similar to those employed in the modeling approach and others have used these studies as examples of modeling (Anderson and Masur, 1983; Ludwick-Rosenthal and Neufeld, 1988; Schultheis, Peterson and Selby, 1987). Their research was based on the premise that fear of painful medical or dental procedures results from previous negative experiences or, in their words, "aversive classical conditioning" (p. 485). They tested an extinction/habituation hypothesis, which predicts that a patient's fear of medical procedures could be reduced by repeated exposure to the relevant stimuli in the absence of pain. The design also included a control
videotape which was unrelated to the endoscopy. The experimental video showed a model (patient) experiencing an endoscopy displaying an average amount of distress. All 36 patients received information from the doctor, nurse and experimenter regarding the procedure. Behavioural (e.g., amount of gagging, observer ratings of anxiety), physiological (e.g., heart rate) and self-reported measures of anxiety were taken.

Results showed that the insertion of the endoscope was quicker for patients who viewed the experimental tape three times (compared with the control group), but that they also expressed more annoyance about the procedure than both the other two groups. No group differences were indicated in the other measures. Shipley et al. (1979) concluded that extinction/habituation is beneficial for reducing indices of anxiety, though it seems equally plausible that modeling could account for this finding. A similar experimental procedure carried out on patients who had no prior experience of a gastroscopy produced comparable results (Shipley, Butt, Horwitz and Farbry, 1978).

2.1.5 Hypnosis

Redd (1986) has described how hypnosis may be used to control the aversive effects of chemotherapy. Patients were given audiotapes of relaxation training - either active, in the form of tensing and relaxing different muscle groups, or passive (hypnotic) relaxation. Guided imagery was also included for both types of relaxation training. It is not clear whether patients were given both or just one of the tapes. Patients' comments regarding the intervention were positive and they reported applying the skills they had learned to other problems such as insomnia, headaches, pain and other clinical procedures. However, in the absence of a control group and no mention of any comparisons between the two types of relaxation, the contribution of hypnosis to this outcome is not clear. Other studies suggest that hypnosis helps to reduce the amount of anaesthetic agents required for patients undergoing day-case gynaecological surgery (Goldmann, Ogg and Levey, 1988).

In another study, Hendler and Redd (1986) interviewed 105 patients attending an outpatients department for chemotherapy to assess their views on relaxation and hypnosis and their
effectiveness in helping to reduce the side effects of chemotherapy. Patients were randomly assigned to one of three descriptions of identical procedures labelled as either, "hypnosis", "relaxation" or "passive relaxation with guided imagery". Findings indicate that there was a significant difference in whether patients believed that the treatment procedure would help control their nausea. Patients in the hypnosis condition were less likely to believe that the procedure would help to control their nausea compared with patients in the other two conditions. When patients in the hypnosis conditions were questioned why they felt unsure about the procedure 15 out of 20 said that they felt uncomfortable about it. In addition, one patient in the "relaxation" condition gave the following reason for noncompliance: that the relaxation description sounded like hypnosis. Most patients in the relaxation conditions either could not think of a reason for declining or felt that their symptoms were not severe enough to warrant learning an new procedure. There was no relationship between the amount of reported distress and patients' beliefs and intentions to try the procedures, regardless of the assigned condition. In all, patients' explanations support the hypothesis that patients feel uncomfortable about hypnosis.

Hypnosis has also shown some success in reducing pain intensity for patients undergoing either lower (Cadranel, Benhamou, Zylberberg, Novello, Luciani, Valla and Opolon, 1994) or upper gastrointestinal endoscopy (Jackson and Middleton, 1978). In a preliminary study hypnosis was used on 24 patients undergoing colonoscopy where, the authors report, no alternative premedication was available (Cadranel et al., 1994). Moderate or deep hypnotic relaxation was achieved in 12 patients, who were compared to those patients for whom hypnosis was not successful. This comparison showed that pain was less intense for those patients who had been successfully hypnotised, and that the colonoscopy examination was completed in all these patients compared with a 50% completion rate in the other group. This study could be criticised on the grounds that successful hypnotic subjects were compared with unsuccessful hypnotic subjects rather than with a control group. Furthermore, those unsuccessful subjects should have been included in the analyses of those whose hypnotic session was successful to comply with the 'intention to treat' principle (Newell, 1992). These criticisms could also be applied to the Jackson and Middleton (1978) study described below and are discussed in Section 2.3.
Jackson and Middleton (1978) carried out a study, where patients were invited to undergo an upper gastrointestinal endoscopic examination under hypnosis as an alternative to the usual intravenous sedation and antispasmodic medication. Eighteen agreed to be hypnotised, but six were excluded because of difficulty in achieving hypnotic relaxation or poor motivation. Two of the twelve became distressed during the examination, unable to maintain adequate relaxation. A further two required the antispasmodic medication, but none of the remaining ten patients needed sedation. This study did not compare the outcome of these patients with a control group, because, as the authors stress, the intention was to show the usefulness of hypnosis in the endoscopy setting. Indeed one patient on his subsequent return for a repeat examination refused sedation and successfully underwent the examination using self-hypnosis.

2.1.6 Comparison of psychological interventions

Johnston and Vögele (1993) conducted a meta-analysis on both published and unpublished studies to investigate the benefits from psychological preparation for surgical procedures and to establish whether all forms of preparation are equally effective. Studies which did not use random allocation of subjects to groups were excluded, as were those which were not analysed in accordance with the 'intention to treat' principle. Johnston and Vögele (1993) selected eight outcome measures for comparison: negative affect, pain, pain medication, length of hospital stay, behavioural recovery, clinical recovery, physiological indices and satisfaction. In total 35 studies were analysed which included the following interventions: procedural information, sensory information, behavioural instruction, cognitive intervention, relaxation, hypnosis and emotion-focused intervention. Not all studies used all of the selected outcome measures. Procedural information and behavioural instruction showed benefits on all outcome measures. Relaxation showed benefits in all outcome measures except behavioural recovery and pain medication. Emotion-focused intervention showed beneficial effects in pain medication, length of hospital stay, physiological indices and satisfaction. Cognitive intervention indicated benefits in negative affect, pain, pain medication and clinical recovery. Sensory information showed benefits in length of hospital stay and behavioural recovery. Finally, hypnosis showed benefits in clinical recovery and satisfaction. Thus, in
addition to reviewing studies to find the most effective psychological interventions, this paper demonstrates the importance of including different types of outcome measures. Outcome measures are described in more detail in Section 2.3.

Edelson and Fitzpatrick (1989) attempted to assess the effectiveness of cognitive-behavioural and hypnotic treatments compared to an attention control group in reducing chronic pain. Twenty seven patients were assigned to one of the three groups. The two experimental conditions were identical except for a hypnotic induction. Patients in the experimental conditions were taught to alter their thoughts and verbalizations on pain (from pain to numbness). The attention control condition consisted of a therapist encouraging the patient to talk about his or her pain and its effects on their lives. No suggestions, interpretations or attempts to alter behaviour were given. Measures taken included subjective ratings of pain, the McGill Pain Questionnaire (Melzack, 1975), and an activity log which required the patient to record time spent in three activities: sitting, walking or standing and reclining. The activity log is based on the assumption that chronic pain decreases activity levels and that effective treatment will reverse this process. A follow-up measure of reported pain was also taken one month after the end of the training sessions. No significant changes were noted for patients in the attention control group, as expected. Patients in the cognitive-behavioural condition showed changes in pain behaviour: less time sitting and more time walking or standing. These activities remained similar at follow-up. Reductions in pain were also noted as recorded on the pain questionnaire. Patients in the hypnosis group showed changes only on the pain questionnaire and not in behaviour. The explanation that the authors gave for the lack of effectiveness on the patients' behaviour in the hypnosis condition is that the hypnotic induction may have reduced the patient's perception of responsibility and active participation in treatment.

Wilson, Moore, Randolph and Hanson (1982) allocated 48 upper gastrointestinal endoscopy patients into an information group, a relaxation group or a control group. Both experimental groups received their intervention via an audio tape. Measures taken included self-reported mood, fear, coping style and response to the endoscopy, behavioural measures of distress and physiological measures of heart rate and the amount of sedation used. Compared with the control group, patients in the information condition exhibited less distress during insertion
of the tube, showed smaller increases in heart rate, reported the procedure as less uncomfortable than expected and said that they would be less frightened in future hospital experiences. In addition, they were more positive about being informed about future hospital experiences than both the control group and the relaxation group. Listening to the information tape decreased fear for 8 patients, increased fear for one, and had no effect on fear as reported by five patients. Compared with those in the control group, patients who underwent the relaxation procedure showed less distress during insertion, showed lower heart rate increases and reported significantly greater increase in mood after the endoscopy. All but one patient evaluated the relaxation tape positively.

To summarise, Wilson et al., (1982) reported that both information and relaxation reduced both heart rate increases and observer ratings of distress during tube insertion; and that relaxation increased positive mood change following the endoscopy procedure. However, it is important to note that this study made multiple comparisons and, more importantly, set the acceptable probability level at 0.1 increasing the risk of Type I error. In addition, any effects may have been missed as too few numbers were used, resulting in a risk of Type II error. Hence, the risk of both type I and type II errors puts the reliability of this study into question. These and other criticisms of such research are addressed more fully in Section 2.3.

Gattuso, Litt and Fitzgerald (1992) assigned 48 patients waiting to undergo endoscopy to one of four preparation conditions: relaxation plus coping self-efficacy enhancement; relaxation only; procedural information; and a no preparation control condition. Measures taken included: behavioural ratings of distress; physiological measures of heart rate, EMG and amount of sedation required; and self-reported distress, self-efficacy and credibility of the relaxation intervention. Patients in the relaxation plus coping enhancement condition reported greater increases in coping self-efficacy and greater decreases in distress before and during endoscopy than did other patients. There were no differences in self-efficacy ratings, nor reported distress, between the relaxation and information groups. Physiological measures of frontalis EMG and pulse rate was significantly reduced in the two relaxation conditions compared with the information condition. There were no correlations between previous endoscopies and any of the outcome measures, indicating that previous experience with endoscopies was not associated with better adaptation. When subjects were divided into
experienced (at least one previous endoscopy) versus inexperienced groups, no differences in outcome were found.

2.2 Individual differences

Individuals differ in the way they attempt to cope with stressful situations. Past experiences may influence how one anticipates and responds to a future event. Experiences which are comparable or at least are encountered in a similar setting (e.g., a hospital) are likely to require similar coping skills. As suggested above, individuals also respond differently to psychological interventions. One model, the congruency model, refers to the idea that preparation would be more effective if it was made more compatible with the patient's coping style. For example, patients who use avoidant approaches may not be benefitted or may even be harmed by the provision of additional information (Andrew, 1970). The alternative model, the compensation model, declares that preparatory procedures should compensate for any "deficiencies" in a patient's coping style. For example, patients who usually avoid seeking information would be helped by its provision. Established distinctions of coping style commonly used are between i) "sensitizers" or "monitors", who are overtly anxious and alert to threatening cues and tend to seek information about a stressor as a means of preparing themselves for it, and ii) "repressors" or "blunters", who superficially appear non-anxious and deal with impending stress by repression, denial or distraction (Byrne, 1961; Miller, 1987).

Main effects for coping style has been reported in some studies, but not found by others. Examples include Avants, Margolin and Salovey (1991), who found main effects of coping style in students, where those with a 'blunting' coping style were more likely to find all stress management techniques used appealing; Wilson (1981), who found main effects of their own measure of an avoidance coping style, denial, in surgical patients, where high scorers had a shorter post-operative stay in hospital and used fewer pain-reducing medications; and Millar and Mangan (1983), who found main effects for coping style in patients undergoing colposcopy, with blunters indicating less subjective arousal and less behavioural arousal than monitors. With a different medial procedure, cardiac catheterization, two studies failed to
find a main effect of coping style (Davis, Maguire, Haraphongse and Schaumberger, 1994a; Ludwick-Rosenthal and Neufeld, 1993). Interaction effects in such studies have also been of interest and are sometimes found where there are no main effects of either coping style or treatment group (Schultheis et al., 1987). Studies which report 'information by coping style' interactions are described in detail in Chapter 9.

Gastrointestinal endoscopy studies indicate that sensitizers/monitors benefit from additional information (Wilson et al., 1982), including modeling (Shipley et al., 1978, 1979) and specific psychological preparation in the form of coping enhancement (Gattuso, Litt and Fitzgerald, 1992). The beneficial effects have been seen on measures of gagging (Gattuso et al., 1992); as a lower increase in heart rate (Shipley et al., 1978, 1979) and in patients being rated as less anxious by the physician and nurse during and after endoscopy (Shipley et al., 1979).

Patients who are categorised as repressors or blunter on the other hand cope better in a control or relaxation group than in an information group (Gattuso et al., 1992) and those who score high in emotional control and avoidance benefit more from a relaxation procedure by showing lower distress (Wilson et al., 1982). In the modeling studies, increased viewing of the model produced greater increases in heart rate, indicating an increased stress response, in repressors (Shipley et al., 1978, 1979).

### 2.3 Methodological considerations

Studies carried out in this area of research typically compare the effectiveness of one or more of the above interventions with a 'no treatment' control group (e.g., Cottier, Shapiro and Julius, 1984). Occasionally, interventions are combined and compared with their separate components. For example, Johnson and Leventhal (1974) compared four experimental groups: sensory information alone, behavioural instruction alone, sensory information with behavioural instruction and a 'no treatment' control. Wilson (1981) also used four similar groups, comparing information with relaxation to information alone, relaxation alone and a control group. Such comparative designs are extremely useful, but frequently, treatment
components are not clearly defined (Anderson and Masur, 1983) and sometimes not all components of a combined intervention are applied alone as illustrated by Edelson and Fitzpatrick (1989). As a result it is difficult to identify the source of any group differences observed (Ludwick-Rosenthal and Neufeld, 1988). Ludwick-Rosenthal and Neufeld (1988) suggest, for example, that the two types of information should be separated and that a 'no treatment' control group should also be included. However, withholding information from patients raises ethical concerns (Salmon, 1993) and procedural information is frequently provided as part of a sensory description, thus making it difficult to separate the treatment components.

For future research in this area to be effective a clear definition of attention control is required and treatment components need to be systematically varied (Anderson and Masur, 1983). In particular, attention effects and other non-specific factors associated with receiving treatment need to be accounted for by appropriate control groups. Such control groups are referred to as 'attention control' or 'attention placebo control'. Before discussing the issue of attention placebo control, it is important to note that past attempts to compare different treatment interventions have not systematically varied certain aspects of the treatment components. For example, as noted earlier, Wilson, Moore, Randolph, and Hanson (1982) compared the effects of an eight minute information tape and a 25 minute relaxation tape with a 'no treatment' control group thereby failing to control for the duration of the intervention. Furthermore, most studies have not controlled for the possible placebo effects produced by interaction with a concerned professional.

'Placebo', 'attention control' and 'placebo attention control' are all terms that have been used to describe a control group in a variety of studies. The common notion of a placebo is that of an inert substance prescribed to patients as part of a medical treatment. Applied to psychology, a placebo is defined as a theoretically inert treatment or study condition (O'Leary and Borkovec, 1978). However, even such treatments or definitions may need to be reexamined if placebo effects are found. In fact, O'Leary and Borkovec (1978) suggest that an alternative term is used such as a "component control condition" or "neutral (compared with positive) expectancy". Although O'Leary and Borkovec argue from a psychotherapeutic perspective their ideas have been applied to health psychology (Anderson and Masur, 1983).
Two types of attention control groups have been identified: i) attention as distraction and ii) attention as interest or concern from another person, such as medical staff or researchers. The former is increasing in its importance in relaxation studies by researchers such as Markland and Hardy (1993), who use a fairly innocuous story, and Levin, Malloy and Hyman (1987), who gave their subjects a taped recording of a history of the hospital as an attention-distraction control. Kaplan, et al. (1982) adopted the second definition and patients received attention from one experimenter of the same duration as the self-instructional training (in focusing attention externally or internally). Even 'placebo' (taken as the medical definition above) has been referred to as an attention control condition by a number of authors (e.g., Blanchard et al., 1990; Blanchard, Schwarz, Suls and Gerardi, 1992). Hence, studies have defined attention control in at least three ways. This variation in definition demonstrates the difficulty of evaluating and comparing research in this area. Furthermore, some studies refer to no-treatment control groups as 'attention control', which actually consist of no psychological intervention but subjects do receive the usual medical preparation for procedures (Shaw and Enrich, 1987; Cottier, Shapiro and Julius, 1984). Therefore, a major criticism of these type of studies is a failure to include proper control groups to account for the attention effects and other non-specific factors associated with receiving treatment (Ludwick-Rosenthal and Neufeld, 1988; Anderson and Masur, 1983). O'Leary and Borkovec (1978) reflect the preoccupation of this issue of control groups with the suggestion that "...a study is not worthy of publication or funding because a placebo group was not included" (p. 822). Despite these ongoing criticisms, recent studies continue to omit systematically varied components of interventions, particularly where different psychological preparations are compared. Gattuso, Litt and Fitzgerald (1992) for example, compared provision of information, relaxation and a 'no treatment' control condition.

Random allocation to treatment groups is considered an important design aspect in intervention studies (Johnston and Vögele, 1993) and clinical trials (Brewin and Bradley, 1989; Pocock, 1983). It is assumed that any potential systematic bias is reduced by randomizing subjects to treatment groups so that comparisons can be made. Alternatives to randomization include sequential or alternating allocation of subjects to experimental groups and other non-random allocation, such as matching subjects on variables of interest or importance. This has occurred in studies where the researchers in clinical areas were
concerned that patients in different groups should not mix on the wards (Martelli, Auberbach, Alexander and Mercuri, 1987; Wallace, 1984). Despite randomization, differences in some background measures may still be present, although it is not expected to be the case.

A related issue to group allocation is that of patients' preferences for treatment, particularly where coping style may be an important factor. Brewin and Bradley (1989) present the case for considering patients' preferences for a particular treatment. They discuss the importance of motivational factors and the extent of subjects' participation, paying special attention to patients being informed about their participation in clinical trials. Ideally, only those patients who have no preference regarding which group they are allocated to should be included in such studies. However, there are practical considerations in that it might be difficult to find sufficient subjects given the constraints of various factors such as funding. Furthermore, such a sample would not be representative and it is probable that subjects who are allocated to a treatment not to their liking will drop out of the study (Brewin and Bradley, 1989). However, outside experimental studies patients do drop out of certain treatments and this is an important factor when considering their effectiveness. Despite subjects' preferences, and as mentioned earlier, the 'intention to treat' principle is an important consideration when analysing data where subjects have dropped out or have, for one reason or another, been switched to other treatment groups (Newell, 1992). Newell (1992) provides interesting examples to illustrate the differences between including and excluding subjects which have failed to complete a particular treatment. This issue may also relate to group allocation, especially, where subjects find themselves in a treatment which is in conflict to their preferred coping style. However, as discussed above, it is important to systematically vary the treatment components, including expected interactions.

Various outcome measures are taken in order to assess the effectiveness of psychological interventions as "good" recovery from surgery is not a single concept (Wilson, 1981) and cannot be measured by a single index. Examples of the types of measures which might be used include: physiological measures of the respiratory and cardiovascular system; measures of muscle tension and endocrine measures; numerous self-report measures, typically about anxiety, fear, denial and/or aggression; and behavioural measures such as facial or vocal expressions of pain during procedures and physical resistance to the progression of the
procedure. Moreover, the amount of pain-killers and sedation required is also taken into account as well as time spent recovering. Not all studies use the three types of outcome measures outlined above, though many researchers do recognise the importance of recording them (Anderson and Masur, 1983; Kaplan et al., 1982; Salmon, 1993; Wilson, 1981).

A further criticism is failure to assess the effectiveness of the different interventions (Ludwick-Rosenthal and Neufeld, 1988; O'Halloran and Altmaier, 1995). That is, failure to take manipulation checks to demonstrate that the intervention techniques being provided are valid and are actually being utilized (such as the relaxation procedure used in Markland and Hardy's study). The measures themselves have also been subject to criticism. Ludwick-Rosenthal and Neufeld (1988) question the validity of dependent measures "... especially those regarding self-reports of anxiety and adjustment that are sometimes based on responses to a single item" (p. 338). Despite such criticism, a recent comparison of measures of pain indicates that the one item question (asking patients to write a number from 0 to 100 which best describes the intensity of their pain, where 0 would mean "no pain" and 100 would mean "pain as bad as it could be") is the most practical index. The variety of pain measures including visual analogue scales, behavioural rating scale and verbal rating scales all yielded similar results (Jensen, Karoly and Braver, 1986). Other considerations include the state of alertness of patients when asked to report distress during a medical procedure. Self-report data had to be discarded from one study as many subjects failed to accurately recall their feelings during the procedure as a result of sedatives used (Johnson and Leventhal, 1974).

The characteristics of subjects also raise important methodological considerations. In particular, the type of medical procedure (Wilson, 1981; Anderson and Masur, 1983), the age of the patient, previous experience, and severity of the patient's overall medical condition need to be controlled for (Anderson and Masur, 1983). The nature or seriousness of procedures is important in the effectiveness of psychological interventions. Patients facing cancer surgery, mutilating surgery, kidney transplant surgery and cataract surgery show higher levels of preoperative anxiety than patients facing less threatening surgery (see Anderson and Masur, 1983). Although wide age ranges have usually been included, several studies have found varying results for different ages (Johnson and Leventhal, 1974; Melamed,
Studies indicate that patients who have already undergone an invasive procedure will respond differently compared with naïve individuals (Melamed et al., 1978; Shipley, Butt and Horwitz, 1979). Yet, some studies fail to control for differences in previous experience with the medical procedure in their subjects. This is particularly important when information is used as a preparation. Content and style of information presented to patients is also important (Wilson, 1981). Specifically, this might relate to the explicitness of procedural information and extent to which behaviour modification is emphasized. Inconsistencies when reporting procedures has also been observed such as Gattuso et al. (1992), who in their abstract imply that assignment to experimental conditions was based on preferred coping style of the patient and yet it is apparent from the reported procedure that subjects were randomly assigned to one of four experimental conditions. Future research needs to address more systematically the question: which interventions are effective for which patients?

Despite the above criticisms a great deal of emphasis is placed on statistical significance and not enough on the clinical effectiveness of psychological interventions. Demonstrated statistical significance of treatment effects has sometimes been weak, but these outcomes need to be seen in a broader applied context. Thus, "...the extent to which these statistical differences are apparent and meaningful to the health care team and to the patients themselves is an issue that should not be overlooked" (Ludwick-Rosenthal and Neufeld, 1988, p. 338). As a result of successful interventions, however defined, the cost to the health service may be reduced if they are reflected in a reduction in the length of stay in hospital or a reduction in the amount of medication required. Indeed, cost effectiveness of psychological interventions needs to be considered as part of an overall clinical evaluation. Individualised treatments that require repeated professional contacts however effective are not likely to be employed on a large scale. As indicated, audiotapes and other materials such as leaflets have been used which do not require excessive amounts of staff time.

In summary, a major methodological consideration for research in health care settings is the need to systematically vary component factors and in particular to include attention placebo controls, which take account of both attention as distraction and attention as contact with a
concerned professional. One of the drawbacks to carrying out research in medical settings is the difficulty in obtaining subjects. However, subjects' characteristics continue to require consideration; particularly important is whether they have had previous experience with the particular medical procedure being studied. Although many interventions are designed to reduce anxiety the outcome measures do not fully assess the multidimensional nature of anxiety and should do so by including physiological, behavioural and self-report measures (Anderson and Masur, 1983; Salmon, 1993). Finally, the usefulness of any proposed intervention to the clinical setting must be considered. In other words, clinical as well as statistical significance is required.
3 Psychological Aspects of Gastrointestinal Endoscopy

Chapter overview

This chapter begins with an introduction to the different types of gastrointestinal endoscopy procedures, including their indications and preparation. Related areas of research are mentioned. Research and discussion from the patient's perspective on how the experience of endoscopy can be improved appears to be less well represented in the literature, apart from the work on acceptance and tolerance of bowel preparation. Thus, this chapter explores patients' experiences, their preferences concerning sedation and information and opinions on interventions. It concludes with a report of the first preliminary study of interviews with patients following a colonoscopy examination.

3.1 Introduction

Unexplained gastrointestinal symptoms, many of which may prove to be dysfunctional in origin, may require further investigation by endoscopy. All forms of gastrointestinal (GI) endoscopy involve some discomfort and may be experienced as stressful by the patient both in anticipation of the procedure and during it (Wilson-Barnet, 1984). An endoscopy examination is a diagnostic procedure which involves the passage of a long, flexible tube either through the oesophagus, the stomach and into the duodenum or, in the case of colonoscopy, the large intestine. A sigmoidoscopy refers to the examination of the sigmoid colon only. Once inside the appropriate part of the digestive system the fibre-optic tube enables the physician to visually inspect, photograph and biopsy the inner lining. A more complicated gastrointestinal endoscopy procedure is endoscopic retrograde cholangiopancreatography (ERCP) during which a radio opaque liquid is inserted into the bile and pancreatic ducts enabling the physician to take detailed X-rays.

Reasons for patients undergoing an upper gastrointestinal (UGI) endoscopy or oesopagagogastroduodenoscopy (OGD or gastroscopy) include persistent upper abdominal distress despite appropriate medication, suspected ulcer, family screening for polyposis coli
and symptoms such as bleeding, weight loss, loss of appetite and persistent vomiting of unknown cause. Indications for a colonoscopy examination include a family history of bowel cancer or the presence of polyps, colitis, Crohn's disease or symptoms of pain, a change in bowel habit or bleeding. The patient is usually partially sedated, but remains conscious throughout the procedure for both these types of endoscopy. ERCP, in contrast, requires the patient to be completely still while X-rays are being taken, and the procedure itself may be uncomfortable or prolonged, requiring the patients to be more heavily sedated. Indications for ERCP are pre-operative assessment or evaluation of persistent or recurrent symptoms which suggest biliary tract disease, such as jaundice, or pancreatic disease including pancreatitis.

In general, preparation for most types of gastrointestinal endoscopy consists of fasting for up to six hours before the examination. Patients undergoing a colonoscopy examination have the added inconvenience or distress of undergoing a process of bowel preparation prior to the procedure itself. An empty bowel is important to ensure good visual examination, thus preventing needlessly prolonged procedures and reducing patient risks (Bianchi Porro and Lazzaroni, 1992). However, not all patients tolerate the preparation procedure well and, for this or other reasons, bowel preparation is not always successful resulting in an incomplete or compromised colonoscopy. This problem is reflected in the literature, notably in studies comparing different types of preparation for effectiveness in bowel cleaning (e.g., Rosch and Classen, 1987; Adams, Meagher, Lubowski and King, 1994). The general issue of patient acceptance of such procedures has also been addressed by some writers (Thomas, Brozinsky and Isenberg, 1982; Cohen, Wexner, Binderow et al., 1994) and in more detail by DiPalma, Brady and Pierson (1986).

Patients undergoing ERCP may require prophylactic antibiotics, in addition to fasting, in case therapeutic procedures are additionally carried out once the diagnostic ERCP has commenced. Often patients who undergo ERCP do so as part of a series of investigations or prior to surgery. Consequently, they are commonly admitted to a hospital ward, unlike patients undergoing one of the more straight-forward endoscopy examinations who tend to attend the endoscopic unit as a day case.

Before specifically looking at psychological aspects of gastrointestinal endoscopy, it is worth
noting briefly other areas of research connected with these procedures in the medical literature. Recently, two comprehensive review articles (Bianchi Porro and Lazzaroni, 1992; Lazzaroni and Bianchi Porro, 1994) have explored bowel preparation and other aspects of endoscopy, such as sedation and physiological monitoring. Additional areas of interest include issues of providing services and advice on the running of endoscopy units (Seifert and Weismuller, 1986; Lennard Jones, Williams, Axon et al., 1991), complications (Aliperti, 1996; Kuhlman, Fishman, Milligan and Siegelman, 1989; Kulik and Mahler, 1989; Macrae, Tan and Williams, 1983; Waye, Lewis, and Yessayan, 1992), techniques and successful completion of total colonoscopy (Farmer and Church, 1992; Church, 1994) and ERCP (Zuckerman, 1996), and technological changes such as flexible sigmoidoscopy, polypectomy (Rodney, 1992) and imaging (Williams, Guy, Gillies and Saunders, 1993).

3.2 The experience of endoscopy

The majority of descriptions of patients' experience of gastrointestinal endoscopy have been in the nursing literature (Beck, 1981; Hadley, 1984; Murphy, 1993; Parker, 1992) focusing on the nurse's role in reducing any distress or anxiety experienced by the patient. No studies concerning patient's experience of ERCP have been found. Parker (1992) uses a model based on a 'human responses framework' in an attempt to understand the complete range of responses to a colonoscopy examination. These include physiological, pathophysiological, behavioural and experiential reactions. When reporting their experience of colonoscopy, patients focus on the amount of pain, some expressing also how relieved they felt when it was over and how anxious they felt beforehand, including their inability to sleep the night before (Parker, 1992).

Hadley (1984) interviewed patients before and after a gastrointestinal endoscopy and found that patients report two sources of anxiety: the examination itself and its findings. More specifically, patients undergoing UGI endoscopy expressed fear of the endoscopy tube restricting breathing, fear of not being able to swallow the tube and apprehension about the level of sedation. Anxieties for patients undergoing a colonoscopy examination included the degree of pain involved, embarrassment and fear of uncontrolled bowel movement during the examination. Anxieties common to both types of procedure also include apprehension felt
following a previous negative hospital experience. Much of the discomfort and fatigue experienced by the majority of the patients undergoing colonoscopy was due to the preparation and to unpleasant after-effects of the examination, including tight wind-like pains due to air inserted during the procedure, though these usually ended after an hour. Hadley (1984) noted that the degree of pain a patient was likely to experience depended a great deal on the skill of the doctor performing the examination. A more formal study suggested that the experience of the endoscopist may also affect the anxiety of patients, with those examined by the most experienced endoscopist appearing to be less worried (Salmon, Shah, Berg and Williams, 1994). However, contrary to Hadley's suggestion Salmon et al. (1994) found that physical discomfort was not related to how experienced the endoscopist who carried out the procedure was.

Relatively few formal studies have been conducted to assess how stressful a gastrointestinal endoscopy is. In an audit of the experience of patients following an upper gastrointestinal endoscopy, 25% reported the experience as unpleasant (Meredith, Quine, Burridge and Bell, 1993). In a different study of 98 patients about to undergo a gastroscopy or a colonoscopy examination 67% stated that they felt anxious; with half reporting intense anxiety (Gebbensleben and Rohde, 1990). Sixty percent of these patients had previously experienced an endoscopy. Explanations given by the patients as to the cause of their anxiety included: unpleasant previous experiences of endoscopy (24%), alarm over what they had heard about such procedures (22%) and concern about what the procedure might reveal (24%). Patients having a colonoscopy for diagnostic reasons, because of symptoms such as bleeding, report more worry than those referred for cancer prevention screening or for follow-up after cancer surgery (Salmon et al., 1994).

Fox, O'Boyle and Lennon (1987) assessed 60 patients undergoing a sigmoidoscopy or a left-sided colonoscopy without medication. They recorded physiological, observational and self-reported measures. As expected, patients were significantly more anxious before the procedure than after. Overall they concluded that the examinations were highly unpleasant and painful experiences for the majority of patients.

Salmon, Shah, Berg and Williams (1994) provide an additional perspective to the above studies by exploring other aspects of the experience of colonoscopy in addition to negative
mood associated with such medical procedures. They acknowledged the recent tendency towards a consumer-orientated approach in health care by including patient satisfaction as part of their overall assessment. A questionnaire, based on patients' descriptions of colonoscopy, revealed three independent aspects: satisfaction with the experience, emotional distress relating to the procedure and the physical discomfort experienced during it. In addition to their findings mentioned above, Salmon et al. (1994) found that satisfaction was not related to which endoscopist carried out the procedure and that female patients reported more physical discomfort than male patients. Perhaps this may be subsequently explained by the more tortuous nature of the female colon (Saunders, Fukumoto, Halligan, Jobling, Moussa, Bartram and Williams, 1996). However, no sex differences where found in relation to satisfaction or emotional distress (Salmon et al., 1994). Another study also reported no differences in relation to age, sex or social class in patients' attitude to endoscopy or initial concerns about their illness (Meredith, Quine et al., 1993).

3.2.1 Informed consent

In addition to the above anxieties concerning GI endoscopy, Hadley (1984) found that patients were poorly informed about the procedure. This lack of information is also reflected by Lydeard (1989) who gives a case account of colonoscopy from her own experiences as a patient.

Legally, doctors are required to provide informed consent before every medical procedure. However, one concern is that too much information may result in an increase in anxiety for the patient. The evidence concerning this in other medical procedures is conflicting, where some studies support this concern (e.g., Alfidi, 1971), whilst others refute it (e.g., Flam, Spice-Cherry and Ansel, 1989).

Newton, Hawes, Jamidar, Harig and Lehman (1994) carried out a survey of physicians' preferences on informed consent for ERCP. Physicians are generally required to inform patients of the potential risks, benefits, and alternatives to the procedure. Ideally, consent should be voluntary, the patient be sufficiently mentally capable to engage in rational decision-making and 'adequate information' should be conveyed. However, there are
controversies in both medical and legal literature concerning the definition of 'adequate information.' From their sample of 81 academic and private practice physicians, more than 90% of physicians believed that the risk of pancreatitis must be mentioned when consenting for diagnostic ERCP and in addition bleeding and perforation risks when therapeutic ERCP is being undertaken. There was variation of opinion as to whether patients must be informed of the potential need for surgery, prolonged hospital stay or death. The timing of the consent procedure seems to have little influence on its effectiveness as a more general source of information. Elfant, Korn, Mendez, Pello and Peikin (1995) compared the amount of information retained following endoscopic procedures between patients who were consented immediately before the procedure to those who were consented between 24 and 72 hours before and found no significant difference between the two groups.

More direct research on the effects of providing information prior to gastrointestinal endoscopy adds to this confusion. To recapitulate, two studies which used only patients' own rating of anxiety (Lanius, Zimmermann, Heegewaldt, Hohn, Fischer and Rohde, 1990; Agre, Kurtz and Krauss, 1994) and one that also included ratings by others (Levy, Landmann, Stermer, Erdreich, Beny and Meisel, 1989) failed to show a reduction in anxiety following the provision of information. These findings may be due to the measures used, i.e. patients' reports, as when physiological measures were taken into account significant differences as a result of the provision of information were found (Johnson, Morrisey and Leventhal, 1973; Johnson and Leventhal, 1974; Wilson, Moore, Randolph and Hanson, 1982).

### 3.3 The need for sedation

It seems, unsurprisingly, to be generally agreed that both upper and lower gastrointestinal endoscopy can be unpleasant and distressing procedures and that pre-procedural anxiety is common. As a result patients frequently request some form of sedation (Fox et al., 1987; Gebbensleben and Rohde, 1990; Probert, Jayanthi, Quinn and Mayberry, 1991) but vary in their preference for information (Levy et al., 1989; Probert et al., 1991). The question of sedation warrants further discussion before looking at ways in which staff can help to promote a more positive experience for the patient.
Medication commonly administered to the patient undergoing colonoscopy ranges from a general anaesthetic, to intravenous conscious sedation and/or analgesia, to antispasmodic alone or no medication whatsoever. In a review of 5000 cases Macrae, Tan and Williams (1983) recommended, amongst other things, the avoidance of oversedation, as this may lead to clinical complications. There is an ongoing debate in the literature on whether sedation for GI endoscopy is required (Bianchi Porro and Lazzaroni, 1991) and which type of sedation is the most effective (e.g., Chokhavatia, Nguyen, Williams, Kao and Heavner, 1993; Holloway and Logan, 1990). Schütz, Lee, Schmitt, Almon and Baillie (1994) found that 15% of patients undergoing colonoscopy were dissatisfied with conscious sedation and that this dissatisfaction was determined by education (at least one year of college) and by the procedure lasting longer than 60 minutes.

Some endoscopists take the question of sedation further by suggesting that with advances in technology and expertise, sedation can be avoided completely for the majority of endoscopy examinations (Al Atrakchi, 1989; Herman, 1990; Ueno, Takahashi, Arakawa and Mitsushima, 1991). Al Atrakchi (1989) carried out 2000 upper gastrointestinal endoscopies without any sedation. Measures taken included anxiety, ease of introduction of the gastroscopy tube, tolerance of the procedure, and the overall success of the procedure. Al Atrakchi found that 81% tolerated the procedure well and that 92% were completely successful. However, sedation had to be used in 32 patients (1.6%) because of 'excess anxiety'. In addition, Solomon, Kajla and Banerjee (1994) found that 73% of unsedated elderly patients, who had undergone gastroscopy, did not want to be sedated for future examinations because of the inconvenience of the recovery period. Hadley (1984) states that pain is rare in OGDs, but severe discomfort can result if the patient was not prepared or sedated enough.

Herman (1990) offered the view that sedation and analgesia are not necessary for a colonoscopy and that pain is a symptom which may serve as a valuable "barometer" of the safety of the procedure. In his study of 211 patients, 82% of colonoscopy examinations were carried out without any form of medication. Of the remaining 18% of patients, who were given medication, this was in the form of sedation with benzodiazepines without opiate analgesia. Herman reported minimal or no discomfort in patients who were not given any medication; however, it is not clear how pain was assessed. Fox et al. (1987) have argued
that patients' tolerance for such procedures is overestimated by the medical staff. This has important implications, as research investigations often use only physicians' impressions of patients' distress. As a consequence, Fox et al. (1987) suggested that analgesia may be more appropriate than sedation for colonoscopy, since the pain endured is a major factor in the reported experience. Chatrenet, Friocourt, Ramain, Cherrier and Maillard (1993) noted that in a selective elderly population colonoscopy was better tolerated with analgesia. Furthermore, using patient self-report measures, Saunders, Fukumoto, Halligan, Masaki, Love and Williams (1994) reported that a placebo control group in their study on colonoscopy patients who received neither sedation nor analgesia showed what the authors described as "unacceptably high pain scores despite all examinations being performed by experienced endoscopists" (p. 420). They agreed with Herman that some pain may act as a useful warning of problems arising within the procedure, such as loop formation or overdistension, but stressed that the experience of pain should be kept to a minimum. Studies indicate that sedation in colonoscopy is associated with a higher percentage of complete examinations (Rodney, Dabov, Orienrale and Reeves, 1993) and that patients receiving sedation tolerate UGI endoscopy better than those not receiving sedation (however, the additional use of a local anaesthetic spray did not effect patients' tolerance) (Meredith, Quine, Burridge and Bell, 1993).

Patients' preferences for sedation, or additional sedation, depend on whether the patient is interviewed before or after the procedure, whether sedation was routinely used during the examination and on the type of examination (Meredith, Quine et al., 1993; Fox et al., 1987; Gebbensleben and Rohde, 1990). The relevant figures vary from 11%, who after the procedure indicated that they would have preferred additional sedation for OGD (Meredith, Quine et al., 1993); to 63% for both types of endoscopy, when asked about their anxiety and methods of reducing it before the procedure (Gebbensleben and Rohde, 1990); up to 94.7% for patients who had experienced a sigmoidoscopy or left-sided colonoscopy without medication (Fox et al., 1987).

Prior to a gastroscopy or a colonoscopy examination Gebbensleben and Rohde (1990) interviewed 98 patients, 60% of whom had previously experienced a gastrointestinal endoscopy, and looked at the prevalence of anxiety, its causes and the patients' thoughts on its reduction. Sixty seven percent of patients interviewed stated that they felt anxious; with
half reporting intense anxiety. Explanations given by the patients as to the cause of their anxiety were as follows: unpleasant previous experiences of endoscopy (24%); alarm by what they had heard about such procedures (22%); and concern about what the procedure might reveal (24%). Overall, 63% said they would like a sedative and 21% suggested more detailed information about the procedure may help to reduce anxiety. Others suggested a calm, relaxed atmosphere (19%) or the presence of a relative during the procedure (7%). Gebbensleben and Rohde conclude by suggesting that greater effort should be made to reduce patients' fears and worries.

For patients undergoing sigmoidoscopy or left-sided colonoscopy 94.7% reported that they would have liked sedation compared with endoscopists' report that sedation was indicated in only 28% of patients. The authors report that the latter assessment was based on the endoscopists' perceptions of patients' pain. Like endoscopists, nurses also underestimated the distress and pain expressed by the patient, although in general the nurses' assessments were more accurate (Fox et al., 1987).

When offered a choice of a general anaesthetic, light intravenous sedation, hypnosis or acupuncture for upper gastrointestinal endoscopy 1.4% of new and 10% of returning patients refused any sort of sedation (Probert et al., 1991). Approximately a third of patients (both new and returning) opted for a general anaesthetic; 53% of new and 36% of returning endoscopy patients chose light intravenous sedation and 18% of each type of patient expressed no preference for type of sedation. No patient specifically chose hypnosis or acupuncture. Probert et al. concluded by recommending that all patients should be offered sedation. In a similar study Pereira, Hussaini, Hanson, Wilkinson and Sladen (1994) offered patients a choice between a local anaesthetic throat spray or sedation to patients undergoing OGD to one group of patients and the same choice to another group, where those who were anxious were encouraged to have the sedation. Whether anxious or not, over 70% of patients who chose throat spray found the examination comfortable and would choose the same in the future. Pereira et al. (1994) recommended giving all patients an informed choice.

A study including some form of personality testing was conducted by Webberley and Cuschieri (1982) where 69% of patients were given sedation for UGI endoscopy. They found that patients who scored high on a neuroticism scale (Eysenck and Eysenck, 1963) also
tolerated the procedure poorly and were less likely to agree to future tests. Patients were more likely to agree to a repeat endoscopy when diazepam was given - although the authors reported that this made no difference to the degree of tolerance observed during the procedure. Webberley and Cuschieri (1982) recommended offering pre-medication (sedation) to all patients. Obviously, more research is needed to explore the accuracy of this finding, specifically whether it can be related to other types of endoscopy. Such use of personality inventories have been criticized by Jones (1982) for being unnecessary, lacking any predictive power, and therefore sedation, with its amnesic qualities, should be given to all patients. Charitopoulos, Karkanias, Dimitraki, Charitopoulos, Vostanis and Alexandropoulos (1995) took opinions and measures of patients' personality profiles (anxiety, depression, introversion and extraversion) and a variety of behavioural measures. Patients' opinion for gastroscopy was found to be independent of all personality ratings, although insertion of the endoscope was less difficult in patients having higher scores of extraversion.

Irrespective of patient preference the effects of sedation and analgesia are not clear cut. Analgesics that are generally used for colonoscopy and other medical and surgical procedures do have some sedative qualities and conversely when patients are sedated their perception of pain is reduced (Gilman, Goodman and Gilman, 1975; Loebel and Danzig, 1970). Due to unwanted side effects of intravenous medication, alternatives such as nitrous oxide/oxygen (Entonox) inhalation (Lindblom, Jansson, Jeppsson, Tornebrandt, Benoni and Hedendro, 1994; Saunders et al., 1994), acupuncture (Cahn, Carayon, Hill and Flamant, 1978; Li, Nauck, Loser, Folsch and Creutzfeldt, 1991) and hypnosis (Cadranel et al., 1994; Jackson and Middleton, 1978) have all been explored.

In the Saunders et al. (1994) study nitrous oxide/oxygen inhalation (Entonox) provided similar analgesia and sedation compared with intravenous medication, consisting of diazepam and pethidine. In addition, patients in the Entonox group were able to leave the endoscopy department much earlier than those receiving conventional intravenous sedation. The colonoscopy examinations in this study were however performed by skilled endoscopists and the results may not be replicable with less experienced endoscopists.

As Entonox is administered by the patient it is considered a form of Patient Controlled Analgesia (PCA). This type of pain relief and sedation has been used in other hospital
settings, including childbirth (e.g., Brownridge, 1991) the relief of cancer pain (Keating and Kundrat, 1996), sickle-cell-related pain (Shapiro, Cohen and Howe, 1993) and post-operative pain (Katz, Clairoux, Kavanagh, Roger, Nierenberg, Redahan and Sandler, 1994). Types of administration include bolus doses of analgesia into infusions, whether intravenous, intramuscular, subcutaneous or epidural (Lehmann, 1995), as well as the inhalation of Entonox. PCA pumps can be programmed to deliver a preset dose of sedation or analgesia when the patient depresses the control button. A lockout time can also be programmed where once the button is pressed no more medication is delivered within a given time. See Smythe (1992) for a review of PCA.

Jowell, Eisen, Onken, Bute and Ginsberg (1996) explored intravenous patient controlled analgesia for conscious sedation during ERCP and found that it was comparable to the standard form of administration in terms of patient satisfaction. There were no differences between the two groups in the amount of additional sedation and analgesia received and the duration of the procedure. The only group difference reported was that the PCA group required less initial sedation when titrated to the same clinical end point as the control group. The authors did not find an explanation for this. It is possible that anxiety levels may have played a part in the amount of sedation required. Unfortunately, anxiety levels were not reported in this study. Chapter 8 explores the relationship between anxiety levels and sedation. Jowell et al. (1996) concluded that PCA was no better than standard sedation in this group of patients. They acknowledged that further studies are required to assess the cost and which patient groups are more likely to benefit from such forms of analgesia and sedation.

Studies involving acupuncture as a preparation for colonoscopy have reported significantly lower pain sensitivity and less need for sedation and analgesia during the examination in the acupuncture group than in groups without acupuncture or with pretend acupuncture (Li et al., 1991). Cahen et al. (1978) found similar results with gastroscopy patients. Preliminary studies using hypnosis are described in Chapter 2 and indicate that hypnosis is useful in reducing pain intensity for patients undergoing either lower (Cadranel et al., 1994) or upper gastrointestinal endoscopy (Jackson and Middleton, 1978).

Although nitrous oxide/oxygen inhalation, acupuncture and hypnosis appear to be successful
- at least for some patients and some endoscopists - more research and information is required on their possible usefulness. As noted above, when offered a choice between pharmacological sedation, hypnosis or acupuncture, no patients in Probert et al.'s (1991) study chose alternative forms of 'sedation' for upper gastrointestinal endoscopy.

Attempting to reduce discomfort by giving medication with amnesic qualities does not necessarily result in a more satisfactory experience for the patient. Salmon et al. (1994) concluded that patient satisfaction with experience of colonoscopy is most related to a caring approach of the staff involved, minimising embarrassment and humanising the event. Cheli (1993) also emphasised the importance of the psychological as well as the technical training of gastroenterologists. In a meta-analysis of 107 studies on consumer satisfaction with medical care Hall and Dorman (1988) also found that humaneness and technical quality of medical care were ranked near the top.

3.3.1 Conclusion

One problem with questioning patients about their thoughts and feelings is the reliability of their responses. Individuals may respond in terms of what they think the researcher wants to hear or what is socially desirable. Whilst some readily admit to feeling extremely anxious, others deny being in such an emotional state. Obviously, there are individuals who are truly low in anxiety prior to colonoscopy, who report a decrease in anxiety following such a procedure; whereas those failing to admit to anxiety prior to their procedure cannot show any reduction following it (Fox et al., 1987).

Patients respond differently to endoscopy, including their desire for additional information (Probert et al., 1991). Individual differences have been categorised as a result of their responses on various coping style measures or personality inventories. In one study, patients who scored high in neuroticism were less likely to agree to future tests (Webberley and Cuschieri, 1982).

In places where satisfaction of the experience of colonoscopy is high, patients report that the bowel preparation is the worst part of the whole experience (see interviews at St. Marks...
Hospital endoscopy unit reported in Section 3.4). However, little research has been carried out to examine how this aspect of colonoscopy can be made less distressing, from a psychological perspective. As noted in the introduction, the majority of studies on bowel preparation focus on the efficiency or effectiveness of achieving an empty bowel with often just a passing comment on the patient's acceptance or tolerance (Rosch and Classen, 1987; Adams et al., 1994). What is required is first, more research on psychological aspects in colonoscopy; and secondly, more specifically, some kind of coping strategy or intervention to commence before the colonoscopy examination and possibly even before the administration of bowel preparation.

3.4 Preliminary study 1: Interviews with colonoscopy patients

3.4.1 Background

The usual procedure for out-patient colonoscopy at St. Marks Hospital was as follows: four to six weeks before the examination, patients received their appointment date and bowel preparation sachets via the post. At this point they were not given any specific information regarding the examination, only detailed instruction about the bowel preparation, including possible side effects, and the advice that they should arrange to be escorted home afterwards. It was generally assumed that the procedure would have been explained or described to them before this. Patients were instructed to contact the hospital to confirm their appointment and some took this opportunity to ask about any queries they may have had. Thus, a colonoscopy differs from other investigative procedures because it involves a potentially noxious preliminary preparation procedure which patients carry out in their own homes.

If the bowel preparation proves to be a source of distress for the patients then any intervention would need to be carried out in their own homes. Interventions which might be considered are: the provision of sensory information or procedural information for patients who are undergoing a colonoscopy for the first time; or a relaxation procedure to be carried out at some point before the examination. Relaxation instructions could take the form of an audio tape to be sent to the patient's home. As well as the usual anxieties of the medical procedure, patients may be concerned about the outcome of their investigation or, as
suggested, be upset by the preparation. In order to explore their anxieties interviews were carried out with patients following their colonoscopy.

Thus, the aim of interviewing colonoscopy patients was to identify anxieties and establish whether any of the potential interventions considered would be acceptable to the patient, as well as to gain any other information which may be relevant to this study.

3.4.2 Methods

Subjects

Thirty two patients attending St. Marks Hospital for colonoscopy were interviewed, their age ranged from 27 to 73 years (mean of 47). Nineteen (59%) had previous experience of colonoscopy and 13 (41%) patients were male. Indications for colonoscopy were as follows: family history of cancer (44%); previous diagnosis of ulcerative colitis or Crohn's disease (14%); examination for possible ulcerative colitis (10%); previous presence of polyps (19%); the rest had symptoms, such as rectal bleeding (10%) or changes in bowel habit (3%).

Procedure

Consecutive patients were approached at St. Marks Hospital endoscopy unit following their colonoscopy examination and were asked to talk about their experience in order to help with a study aimed at reducing patients' concerns. Unstructured interviews were conducted with 22 patients in order to identify the issues which needed to be explored. The following themes were identified, although these were not of concern to all patients: expectations of colonoscopy, feelings about the amount of information received, thoughts on receiving their appointment for a colonoscopy examination, feelings about bowel preparation, anxieties about any part of the process, including feelings of embarrassment and identifying the "worst part" of the procedure, accounts of how uncomfortable or painful the examination was and any other descriptions of colonoscopy, views on the purpose and necessity of medication, thoughts about the monitor, the staff, the prospect of another examination in the future and opinions on the effectiveness of a relaxation tape to help with preparation for colonoscopy.
The interviews generally lasted ten to fifteen minutes. During this first unstructured phase of the study not all patients were asked about all issues. Therefore, a further 10 patients were interviewed using the themes identified above. Responses to questions and comments were noted by the interviewer.

Content analysis was used to provide a description of patients' experiences. This form of analysis has been described as comprising of both a mechanical (physically organising the data into categories) and an interpretive (determining which categories are meaningful in terms of the questions being asked) component (Krippendorf, 1980). The approach used in this thesis was to focus on the first of these components. The categories used to organise patients' responses were exclusive (i.e. responses were allocated to one category only) and exhaustive (i.e. all responses were categorised). Where the emphasis is on meaning rather than on quantification a more qualitative form of content analysis may be used. For a description of the different types of content analysis see Millward (1995). The preliminary studies reported in this thesis were intended to assist the investigator in understanding patients' experiences of endoscopy and so to help in planning the main studies. As content analysis was used only in the preliminary studies and did not form a main method in this thesis only one coder (the investigator) was used. The numbers and percentages of patients who responded and how they were categorised are presented in the results section along with additional comments.

3.4.3 Results

Expectations. Twenty five patients who commented on their expectations of colonoscopy were separated into the following categories: nine (36%) said that the procedure was as they expected, eleven (44%) indicated that the procedure went better than they expected and five (20%) said that it was worse (i.e., more painful or uncomfortable) than they expected. Eight of the nine who said that the procedure was as they expected had experienced the procedure before, and two of them added that they were "not bothered" nor "distressed by it". Four of the eleven who indicated that the procedure went better than they expected were having a colonoscopy for the first time. One patient in particular had been given negative information by relatives who had had this procedure in the past. One patient of the five who reported that the procedure was worse than she expected said that it was more painful than on previous
occasions but also stated that if she had to describe it to someone else then she would say "it isn't as painful as one expects."

Information. Seventeen patients gave comments about the information received. Fourteen (82%) patients felt that the information provided by the hospital was adequate. Actual words used consisted of the following: 'helpful' (one patient), 'good or accurate description' (four patients), 'very good' (three patients), 'excellent' (two patients), 'excellent and clear' (one patient), 'clear guidance' (one patient), 'enough information' (one patient) and 'adequate information' (one patient). Three (18%) patients thought that the wording used should be less blunt or less direct and that the descriptions of some of the side effects of the bowel preparation were too severe, indicating that they did not experience these effects.

Thoughts on receiving appointment. When 16 patients were asked about their thoughts and feelings on receiving the letter from the hospital, nine (56%) patients stated that they were relieved to know that an investigation would take place. Eight of these patients were keen to know the cause of, or treatment for, their symptoms, and the ninth had a history of cancer in the family and so was 'happy' to be screened. Three (19%) expressed 'dread' at the thought of the impending procedure, but added that they had not expected the procedure to be so easy. "Not at all looking forward to it", was an expression used by four (25%) patients, especially if they'd had a painful experience in the past.

Preparation. On the whole responses to bowel preparation were unfavourable, where 20 of 23 (87%) gave the following comments: 11 had difficulty with the large volume they were required to drink, two complained about the unpleasant taste, and five disliked having to go without food for so long, especially, as one expressed it, when cooking for other members of the family. One patient said that the difficult part was taking medication and having to act normally. Another patient commented that it wasn't the pain, but running to the toilet that was most distressing. Two (9%) patients gave favourable statements about the preparation, one was that it was "good for the system" and the other, "I would like to lose weight". Finally, one (4%) patient simply said that the preparation was inevitable. Of eleven who spoke of side effects, five patients felt nauseous, one of whom also suffered cramps and another felt quite faint and six patients complained of disturbed sleep. Twelve (52%) patients added that the bowel preparation was the worst part.
**Anxiety.** Patients responded in two ways to the issue of anxiety: 21 commented on whether they felt anxious about the examination itself and 17 reported specific concerns about some aspect of the process. Four (19%) patients reported that they did not feel anxious on this occasion, whereas seventeen (81%) reported being anxious or nervous. Of these seventeen, eight patients stated that anxiety was worse immediately before the examination. Three of these eight also felt anxious the night before. Five felt anxious when they received the letter from the hospital or when they realised they had to undergo such a procedure.

Specific concerns included the following: one (6%) patient reported a dislike of hospitals in general and two (12%) reported a fear of injections. A further two (12%) patients said that they were worried about the instructions and being able to carry them out. Nine (53%) patients were anxious about the results, although the extent of anxiety varied from 'concern' to 'being scared'. When patients were specifically asked if they had any thoughts or concerns regarding the results, five out of ten had already been given the results at the time of the interview. It is assumed that others may have been awaiting biopsy reports which they would receive at the follow-up consultation, generally 2-3 weeks following their examination. Another anxiety for three (17%) patients who used public transport was the possibility of a mishap during travelling and the embarrassment that this might have caused. In fact none of the patients interviewed had had such an "accident".

**Embarrassment.** Of 16 patients who gave comments on feelings of embarrassment, one (6%) patient felt vulnerable and only three (19%) reported the procedure as embarrassing. Another (6%) patient remarked that it helps to know that others feel the same. Eleven (69%) patients said that they were not embarrassed, with three patients attributing this to having experienced other embarrassing investigations or experiences (including the experience of childbirth). One patient said that she was sedated and so was "**not bothered with any thoughts of embarrassment.**"

**Worst part.** Eighteen patients gave their comments about the worst part of the whole process. In addition to the twelve (67%) patients who reported that the preparation was the worst part (see preparation paragraph above), a further two (11%) patients said that fasting for so long was the worst part. Other negative aspects of the whole experience of a colonoscopy are as follows: one (5.5%) follow-up patient didn't like the thought of having...
it done and a new patient (5.5%) disliked not knowing what to expect. Only two (11%) patients reported that pain and discomfort during the procedure as the worst part of it all.

Pain or discomfort. Reports from 21 patients of physical aspects of the examination varied and have been separated into four categories: four (19%) patients described the examination as 'totally comfortable' or 'not painful'; eight (38%) used the words 'discomfort' or 'minimal pain', five (24%) said that they experienced 'intense discomfort' or 'sharp pain' and the final four (19%) patients reported 'intermittent pain' or 'intermittent discomfort'. The experience may have depended on other factors such as the anatomical variations of each patient. The colon is particularly sensitive when inflamed.

There was some discrepancy when ten patients were asked to describe what the experience of colonoscopy was like. Two (20%) patients compared the discomfort to 'holiday tummy' or cramps; whereas two (20%) others totally disagreed with this description when it was offered to them. One (10%) patient said that it was "nothing to worry about," another (10%) said that she would "encourage others to have it", and a third (10%) stated that one's "expectations are not justified." However, such comments do not give any indication what the procedure may be like. Other descriptions were as follows: one (10%) patient said that "it was like a bad period" and two (20%) reported having the "...intense urge to push it [the endoscope] out".

Sedation. When patients were asked why they were given an injection, five (50%) out of ten stated that it helps them to feel relaxed, one (10%) referred to it as an anaesthetic, another (10%) that it relaxed the muscles, two (20%) added that it was calming and another (10%) patient said the injection relaxed the bowel.

When 12 were asked if the injection was essential, two (15%) patients indicated that they had no way of knowing how essential it was; another two (15%) said that without sedation the procedure would be difficult and one (8%) patient thought that it was important that the injection should be administered prior to commencement of the colonoscopy examination to prevent any pain or discomfort. Five (39%) reported that the injection was essential, one (8%) complained that it didn't stop the pain and two (15%) patients implied that it might not be essential for all patients. Their comments were "how essential the injection was depended
Monitor. Patients at St. Marks had the opportunity to look at a monitor screen which displayed the interior of their colon. Twenty seven patients were asked about this. Although four (15%) patients disliked the idea of this, they were encouraged to watch. Only two of these reported that they didn't look. Thirteen (48%) patients stated that they were interested in the monitor and three (11%) said that they were impressed. Three (11%) patients liked it as it provided a distraction during the procedure. Four (15%) patients, both new and returning, stated that it was a good idea and interesting "...as long as they didn't see anything." As the purpose of the examination is to screen for abnormalities in the colon it is assumed that these patients were referring to seeing abnormalities such as tumours.

Staff. When asked their opinions of the staff, all twenty patients responded positively. Examples of comments include: 'kind and gentle' (10%), 'very nice' (5%), 'brilliant' (25%), 'warm and friendly' (15%) and 'reassuring' (5%). Three (15%) patients expressed the importance of the staff's approach or manner. Five (25%) patients said that the endoscopist helped to put them at ease.

Prospect of a future colonoscopy. Mixed responses were given at the prospect of a future colonoscopy, although no-one said that they wouldn't have one. Ten (83%) out of twelve patients simply replied 'fine', 'o.k.' or "happy to be checked". One (8%) patient didn't like the thought of another colonoscopy. Another (8%) patient would be happy as long as she had the same physician performing the examination.

Relaxation tape. Seventeen (68%) of 25 patients said that a relaxation tape is a good idea. However, six of these said that it probably wouldn't help them, only those of a nervous disposition. One patient (4%) thought that every patient waiting for an examination is a little nervous and so it would be helpful. Another (4%) patient thought that it would help just before the colonoscopy examination, while waiting to go in. Three (12%) patients, one of which had just experienced his first colonoscopy, thought that it would only be beneficial to patients who are undergoing colonoscopy for the first time. One (4%) patient expressed concern that the offer of a relaxation tape may indicate that the procedure was 'not nice' and that it may cause anxiety. Two (8%) patients added that just chatting to others helps, as long
as they were not discussing negative experiences.

3.4.4 Discussion

From the results it is apparent that the experience of colonoscopy can vary between individuals, as well as within one individual on different occasions. Although some patients dislike the thought of a colonoscopy, on the whole patients appreciate the necessity of the investigation and the encouragement of the staff.

One of the possible psychological preparations considered for a future study was to compare sensory with procedural information. However, the majority of patients were happy with the information they received from the hospital, despite lack of procedural and sensory details. One explanation may be that focusing on the bowel preparation may have distracted from any thoughts about the procedure. Alternatively, it could be that as the preparation is something that is the responsibility of the patients, then details of the preparation is all they want to or need to concern themselves with.

In attempting to obtain an accurate description of the experience of colonoscopy some problems were encountered. There was a discrepancy in descriptions of the experience and patients didn't seem to want to talk about, or accurately describe, the sensations in any detail. Rather some patients resorted to giving encouraging comments, as if trying to convince or reassure a potential patient. Not many subjects reported being embarrassed. Whether this was in fact the case was difficult to assess.

It appears that a relaxation procedure may help both new and returning patients. Those who thought that only new patients would benefit possibly felt that once an accurate indication of what to expect was established then any concerns or worries would disappear. It is obvious that this is not always the case, as even returning patients felt nervous or anxious.

Because the monitor in the examination room may act as a distraction, any attempts for patients to undergo a relaxation procedure during a colonoscopy may be difficult, inappropriate or even unnecessary. In addition, it may be that patients feel some involvement
in their care by paying attention to the screen, especially when the endoscopist guides them round the various particulars of their colon. Sometimes, music is played in the examination room, but patients are not always aware of this. It would seem from all these observations that any relaxation procedure would have to be introduced before the examination.

As mentioned above, perceived control is a mediating factor in an individual's perception of stress. Patients interviewed do perceive the prospect of a colonoscopy as unpleasant. Wilson-Barnet (1992) describes negative responses of medical procedures in general as: "...often feeling vulnerable and exposed, being handled as a body rather than as a person and sensing a lack of control of what is happening to them" (p. 119). Although, patients interviewed at St. Mark's Hospital didn't report sensing a lack of control directly, introducing the notion of patient control into a relaxation procedure, may enhance the beneficial effects which can be achieved by relaxation alone.

An important outcome of the interviews is the finding that anxiety commences much before the day of colonoscopy and so as Domar, Noe and Benson (1987) suggest for maximum effects, interventions, such as relaxation training intended to reduce anxiety need to begin well before the patient arrives at the hospital. Thus, in the case of out-patient procedures, such as a colonoscopy, a home based intervention is suggested, to commence approximately a week prior to their appointment and before the process of bowel preparation. It is important that patients have the opportunity to learn such a skill, before they need to use it. This may even help with any negative side effects from the bowel preparation, even if it only acts as a distraction.

Thus, it is suggested that three groups of patients may be compared: a 'relaxation alone' group, a 'relaxation plus suggestions of control' group and a 'no treatment' control group. It is hoped that the enhanced relaxation procedure may give the patients a sense of contribution to the procedure itself with greater ability to cooperate with position change, and possibly reduce the need for sedation resulting in a reduced stay in the recovery area and the need for an escort home.
4 Relaxation: A Validation Study

Chapter overview

Having described some of the causes of anxiety experienced by patients undergoing GI endoscopy in the previous chapter, this chapter first outlines the objectives of conscious sedation, then two different techniques for relaxation. Finally, an account of the second preliminary study conducted to validate the relaxation procedures proposed for use in this thesis is presented.

4.1 Conscious sedation

As already discussed, the prospect of undergoing a medical investigation may be interpreted as highly stressful, resulting in increased anxiety in the individual (Johnston, 1980; Leventhal, 1990). Since anxiety increases pain perception (Fordyce and Steger, 1979) the result may be an increase in discomfort perceived during medical procedures. Insufficient treatment of pain and anxiety can cause cardiovascular strain and restlessness, which may jeopardize the success of the procedure (Lang and Hamilton, 1994). As a result more sedation and/or analgesia may be required during the examination. This inevitably prolongs a patient's stay in the recovery area. For patients who are attending the hospital as day cases this is contrary to the desired outcome and expectation.

The objective of using intravenous sedation for medical and surgical interventions is to ensure a safe and efficient procedure both for the patient and the physician or surgeon. Ideally, patients under conscious sedation are able to independently maintain their airway and respond appropriately to verbal commands. Such patients will nevertheless have a depressed level of consciousness, and decreased pain and anxiety (Covell and Annand, 1994). Amnesia, relaxation, and cooperation should be the achieved objectives when using intravenous sedative medication for endoscopic procedures and not drowsiness or anaesthesia (McCloy and Pearson, 1990; Nagengast, 1993). Signs of oversedation are hypotension, bradycardia.
and respiratory depression (Nagengast, 1993), thereby increasing the procedural risks and delaying the patient's recovery (Lang and Hamilton, 1994). As indicated in Chapter 3, most of the complications associated with endoscopy, particularly UGI endoscopy, are associated with medications used for conscious sedation (Chan, 1996).

### 4.2 Aspects of anxiety and relaxation

A study conducted by Domar, Everett and Keller (1989) attempted to identify, and possibly predict, the potential causes of preoperative anxiety. Findings indicated that female patients were more anxious than male patients, and, contrary to social support theories, individuals accompanied by a support person were more anxious than those not accompanied. However, it is important to add that one reason that such individuals were accompanied by a support person may be because they were anxious (Domar et al., 1989). Furthermore, other factors such as previous surgical experience, the possibility of cancer and demographics did not contribute to anxiety. Thus, in this study patient anxiety did not reflect the assumptions of surgical and anaesthesia staff. Domar et al. concluded that preoperative anxiety may reflect a patient's personality and coping style more than medical data. In a similar study, again anxiety was reported to be higher in females but also in those not having had a previous anaesthetic. Furthermore, levels of anxiety remained constant from the afternoon of the day before surgery to the immediate preoperative period. Anaesthetists were also found to be poor assessors of anxiety unless they specifically questioned their patients about it (Badner, Nielson, Munk, Kwiatkowska and Gelb, 1990).

As mentioned in the previous chapter, Johnston (1980) indicated that patients' highest level of anxiety was on the day before the procedure, although anxiety commenced much before this. Therefore for maximum effects, interventions, such as relaxation training intended to reduce anxiety, need to begin well before the patient arrives at the hospital (Domar, Noe and Benson, 1987).

Despite these reports of the early commencement of anxiety, relaxation interventions frequently begin on the day of the procedure, especially when applied to day cases (e.g.,
Markland and Hardy, 1993; Lamb and Strand, 1980). Home-based relaxation interventions in the form of audiotapes have been used to treat medical disorders such as hypertension (Hoelscher, Lichstein, Fischer and Hegarty, 1987; Sherman, 1982), tension headaches, chronic anxiety (Sherman, 1982) and irritable bowel syndrome (Blanchard, Greene, Scharff and Schwarz-McMorris, 1993). Studies commonly use progressive muscle relaxation (Jacobson, 1938), where the individual focuses on tensing and relaxing different muscle groups (e.g., Blanchard et al., 1990; Burish and Jenkins, 1992). However, this may be inappropriate to practice during some medical procedures (Wilson-Barnet, 1992), such as during a colonoscopy examination, where the nature of the procedure does not allow systematic freedom of movement.

Passive relaxation with, or without, guided imagery is another type of relaxation procedure. This also focuses on reducing muscle tension in different parts of the body, but without tensing the muscles first. Additionally, the individual is encouraged to pay attention on his or her breathing and to relax (e.g., to let any tension drain away) when exhaling. Images suggested can be of a place such as a beach or a garden associated with being calm and relaxed.

4.3 Preliminary study 2: Validation of two relaxation tapes

4.3.1 Background

Perceived control is an important aspect of an individual's perceptions of stress. Wilson-Barnet (1992) reports a number of negative responses of patients undergoing a variety of medical procedures as: "often feeling vulnerable and exposed, being handled as a body rather than as a person and sensing a lack of control of what is happening to them" (p. 119). For some time, situations involving uncertainty have been associated with different patterns of stress hormone production (Mason, Sacher, Fishman, Hamburg and Handlon, 1965). Lack of personal control has been linked to helplessness and depression (Seligman, 1975). As well as negative psychological states being associated with poor health, the opposite, i.e., positive psychological states and optimism have likewise been linked to good
Control as a positive outcome can be particularly useful for some patients whose response to relaxation may induce anxiety due to perceived loss of control (Braith, McCullough and Bush, 1988; Heide and Borkovec, 1983). Therefore, introducing the notion of patient control or active coping into a relaxation procedure, may be expected to enhance the beneficial effects which can be achieved by relaxation alone (Kaplan, Atkins and Lenhard, 1982).

Another consideration when devising an intervention is the timing of it. With colonoscopy a crucial initial stage is when patients are complying with their bowel preparation instructions. Preparation takes a number of days, starting with the discontinuation of certain medications and foods high in fibre and ending with intake being restricted to clear fluids only. Patients are also given strong laxatives to take during this time which, they are informed, may give them cramps. Patients who were interviewed at St. Mark's Hospital also reported feeling weak and faint, especially whilst travelling on the day of their appointment for colonoscopy.

The aims of this study were to evaluate the appropriateness of the relaxation intervention and to gain feedback on the tapes prepared. In assessing relaxation interventions a comparison was made between the anticipated enhanced 'relaxation plus control' procedure and a simple relaxation procedure. Thus, two tapes were prepared: relaxation alone and relaxation with suggestions of control for patients to use whenever they need to feel relaxed or calm.

4.3.2 Methods

Subjects

Forty five patients attending St. Mark's Hospital for colonoscopy were approached to take part in the study. One patient refused, stating that he wasn't tense and four patients who listened to the tapes following colonoscopy were dropped from the analysis because they found it difficult to ascertain whether any feelings of relaxation were due to the sedation they had received. Twenty patients listened to the 'relaxation alone' tape and 20 listened to the 'relaxation plus control' tape, before their colonoscopy examination. Their ages ranged from
19 to 74 years, with a mean age of 48, and 70% were female. Sixty four percent had experienced colonoscopy before and reasons for colonoscopy were as follows: family history of cancer (38%); family history of polyps (5%); ulcerative colitis or Crohn's disease (20%); previous diagnosis of polyps (15%); and symptoms (10%), such as rectal bleeding. Fifty eight percent reported that they had no past experience of a relaxation procedure.

Materials

Materials consisted of the two relaxation tapes described above and a questionnaire devised for patients' evaluation of the tapes. The texts of both are included in Appendix A.

The two relaxation procedures were based on various scripts (Karle and Boys, 1987; Waxman, 1989). Due to the change in position required during the colonoscopy examination a passive relaxation procedure was chosen, where patients were asked to think about their breathing and to relax on exhalation. Towards the end of the procedure they were invited to think of a place where they feel comfortable or relaxed, to imagine being there and were then given time to enjoy it.

The relaxation scripts were recorded on audio-cassette by the same person. They were very similar in content and delivery but differed in that one included control suggestions in the form of positive self-statements, such as "more and more confident and in control" and "as we become calmer in our minds, our bodies know automatically how to relax and work how they should...". These type of statements were taken from Karle and Boys (1987) and Waxman (1989) in order to enhance patients' sense of control by way of ego-strengthening and suggestions of body wisdom. Ego-strength refers to the notion that the stronger the ego the more able the individual will be at coping with difficult situations (Waxman, 1989). To control for the extra time taken up by the additional control suggestions in the 'relaxation plus control' script, the relaxation alone tape contained short periods of silence, during which the subject was encouraged to continue relaxing, so that both tapes were of the same duration.

The questionnaire consisted of the following:

i) items to describe their mood state, taken from words used in both tapes;
ii) questions on the duration of the silence periods and patients' ability to visualise; and
iii) questions about whether patients thought that they could use skills learnt on such a
relaxation tape to prepare for, and to use during, a colonoscopy examination. For patients
who listened to the 'relaxation alone' tape an extra item about the gaps in the main part of the
tape was included.

After the questionnaires were compiled two further questions were thought to be helpful and
were asked verbally after completion of the questionnaire. These two questions were: "How
did you feel before listening to the tape?" and "Were you distracted by any noise whilst
listening to the tape?"

Procedure

Patients waiting for their colonoscopy examination were approached and asked to listen to
a relaxation tape and give their comments. They were led to a small room in the endoscopy
department next to the reception area to listen to the tapes. Information whether they had
any experience of colonoscopy as well as any relaxation or similar procedure was recorded.
A brief description of the relaxation procedure was given. After listening to one of the tapes,
patients were requested to fill in the questionnaire and encouraged to ask any questions or
add any comments about the tape or the proposed study. Patients were additionally asked to
describe how they felt beforehand and whether they were distracted by any noises after filling
in the questionnaire. Patients' responses were categorised on the basis of content analysis.
These data may give an indication of the extent of relaxation that patients were able to reach.

Statistical analysis

Demographic variables were checked for differences between groups, using Analysis of
Variance, Mann-Whitney and Chi-square tests. Patients' responses to the question of how they
felt before listening to the tapes and awareness of noise during the relaxation were categorised
using content analysis. T-tests were conducted on the list of mood items between the two
relaxation groups, vividness of the experience, effectiveness of the relaxation tapes and a
Mann-Whitney was conducted to test whether they were distracted by any noise. The
relationship between how relaxed patients felt and how similar the imagery experience to actually being there; and the association of noise with relaxation, imagery and the effectiveness of the tape were explored using Spearman's rank order correlation.

4.3.3 Results

**Background variables**

The two relaxation groups were not significantly different in terms of age, \( t(35) = 0.50, ns \), sex, \( \chi^2(1) = 0.48, ns \), indication, \( \chi^2(2) = 1.06, ns \), previous experience of colonoscopy examinations, \( \chi^2(1) = 1.76, ns \), and previous relaxation experience, \( \chi^2(1) = 0.08, ns \). The means and standard deviations or frequencies are presented in Table 4.1.

<table>
<thead>
<tr>
<th>Table 4.1: Means and standard deviations or frequencies of background variables for each group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background variable</td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Indication</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Previous colonoscopy examinations</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Previous relaxation</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>How patients felt before listening to the tapes</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

* researchers have shown that values as low as two are acceptable for chi-square (Camelli and Hopkins, 1978; Delucchi, 1983)
After listening to the tape and having filled in the questionnaire patients were asked how they had felt immediately before the relaxation procedure. Their responses were categorised using content analysis and are also displayed in Table 4.1. Responses given varied from 'calm' and 'relaxed' to 'anxious' and 'very nervous'. Sixty percent reported some anxiety, ranging from 'a little anxious' to 'very nervous'. The two groups were not significantly different in how they felt before listening to the tapes, $\chi^2(4) = 0.20$, ns.

**Comparison of the two relaxation tapes**

T-tests conducted on the list of descriptive words showed no significant difference between the two groups after listening to either tape. As not one item was significantly different there was no need to apply the Bonferroni correction. The means, standard deviations and $t$ values are displayed in Table 4.2. Furthermore, there were no differences with other measures, specifically, whether noise was noticed, $U(39) = 181$, ns, how patients rated the effectiveness of the relaxation tapes, $t(38) = 1.08$, ns, nor how similar the imagery experience was to actually being in their special place, $t(38) = 0.55$, ns.

In response to the question regarding the short periods of silence in the main part of the relaxation alone procedure 66% of patients who listened to that tape, thought that the periods or gaps were helpful in helping them to relax. Additional comments were as follows: some thought that the gaps were helpful e.g., "... allowed my mind to wander." Others did not notice the gaps and thought that they seemed natural. However, for three patients the gaps were not helpful; for example, one patient reported that, "...it required the need to concentrate and sort of breaks that [relaxing] feeling."

As there were no differences between the two groups the remainder of the analysis was conducted on the combined data for both groups.
Table 4.2: Means, standard deviations and $t$ values of questionnaire items for each group

<table>
<thead>
<tr>
<th></th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
<th>$t$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calm</td>
<td>3.00</td>
<td>2.60</td>
<td>0.76</td>
</tr>
<tr>
<td>Relaxed</td>
<td>3.20</td>
<td>2.80</td>
<td>0.76</td>
</tr>
<tr>
<td>Comfortable</td>
<td>2.60</td>
<td>2.60</td>
<td>0</td>
</tr>
<tr>
<td>In control</td>
<td>2.60</td>
<td>2.45</td>
<td>0.27</td>
</tr>
<tr>
<td>Confident</td>
<td>3.20</td>
<td>3.05</td>
<td>0.25</td>
</tr>
<tr>
<td>Positive</td>
<td>3.30</td>
<td>2.50</td>
<td>1.58</td>
</tr>
<tr>
<td>Safe</td>
<td>2.60</td>
<td>2.35</td>
<td>0.45</td>
</tr>
<tr>
<td>Warm</td>
<td>2.35</td>
<td>1.95</td>
<td>0.87</td>
</tr>
<tr>
<td>Content</td>
<td>2.89</td>
<td>2.84</td>
<td>0.09*</td>
</tr>
<tr>
<td>Pleased</td>
<td>3.42</td>
<td>3.20</td>
<td>0.39*</td>
</tr>
<tr>
<td>Unconcerned</td>
<td>3.40</td>
<td>3.95</td>
<td>-1.02</td>
</tr>
<tr>
<td>Supported</td>
<td>2.55</td>
<td>2.60</td>
<td>-0.10</td>
</tr>
<tr>
<td>Alert</td>
<td>2.80</td>
<td>2.65</td>
<td>0.24</td>
</tr>
<tr>
<td>Peaceful</td>
<td>2.95</td>
<td>2.70</td>
<td>0.42</td>
</tr>
<tr>
<td>Able to Move Easily</td>
<td>2.05</td>
<td>1.85</td>
<td>0.47</td>
</tr>
<tr>
<td>Good</td>
<td>3.25</td>
<td>2.80</td>
<td>0.83</td>
</tr>
<tr>
<td>Pleasant</td>
<td>2.80</td>
<td>2.68</td>
<td>0.22*</td>
</tr>
<tr>
<td>Secure</td>
<td>2.60</td>
<td>2.80</td>
<td>-0.36</td>
</tr>
<tr>
<td>At Ease</td>
<td>3.00</td>
<td>2.95</td>
<td>0.09</td>
</tr>
<tr>
<td>Rested</td>
<td>2.65</td>
<td>2.75</td>
<td>-0.17</td>
</tr>
<tr>
<td>Able to Move Effortlessly</td>
<td>2.25</td>
<td>2.85</td>
<td>-1.17</td>
</tr>
</tbody>
</table>

* degrees of freedom = 37    ** degrees of freedom = 36  degrees of freedom = 38 for all other tests

Effectiveness of the tapes

Patients' responses to how effective they thought the tape was, are indicated in Figure 4.1 and show that the majority thought that the tape was effective. Six (15%) patients marked the scale to indicate that the tape was not effective (using the median as the cut-off point).

Whether patients thought that the tape was effective in helping them to relax was related to how relaxed patients felt after listening to the tape, $r(38) = 0.63, p<0.001$, and to their
ability to use imagery, $r_{(38)} = -0.35, p < 0.05$. Table 4.3 shows which patients found the tape effective in relation to their reported imagery experience. Apart from one patient whose reported imagery was 'much the same', patients who indicated that the tape was not very effective in helping them to feel relaxed also reported low similarity of imagery to a real experience.

Table 4.3: Numbers of patients who found the tape effective in helping them to feel relaxed in relation to how similar their imagery experience was to actually being in their chosen place

<table>
<thead>
<tr>
<th>Effectiveness of tape on relaxation</th>
<th>Similarity of experience to actually being there</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not at all</td>
</tr>
<tr>
<td>Totally effective</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Not at all</td>
<td>7</td>
</tr>
</tbody>
</table>
**Imagery in the special place**

Figure 4.2 illustrates that the reported similarity of the imagery experience to actually being there is almost normally distributed. When questioned about the duration of time spent in the special place, 3% of patients indicated that they would have preferred less time whereas 7% wanted more. The vast majority were pleased with the amount of time allocated.

![Figure 4.2: Frequency of responses to patients' rating of the similarity of the imagery experience to a real experience](image)

**Awareness of noise**

When patients were asked whether they found any noise which occurred during the relaxation procedure disturbing, 44% reported that they didn't notice any noise; 28% were aware of some background noise, but were not distracted by it; and 21% were distracted by noise, such as the telephone ringing or people talking as they passed the door of the room. The remainder were only distracted (5%), or noticed (2%) the noise, at the beginning of the relaxation procedure.

Awareness of noise did not correlate with how relaxed patients felt, \( r_{(37)} = -0.0006, \ ns \), nor how highly they rated the effectiveness of the tape, \( r_{(37)} = 0.27, \ p < 0.05 \) but was related to the similarity of their imagery to a real experience, \( r_{(37)} = -0.37, \ p < 0.01 \).
*Application of the relaxation tapes*

When asked whether the tapes would help them to prepare for a colonoscopy: 77% replied 'yes' (that they thought it would) and 3% didn't know. As indicated in Table 4.4 both patients undergoing a colonoscopy for the first time and follow-up patients responded similarly, \( \chi^2(1) \) = .01, *ns.

<table>
<thead>
<tr>
<th>Relaxation would help with preparation</th>
<th>Previous colonoscopy</th>
<th>First colonoscopy</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes</td>
<td>20 (77%)</td>
<td>11 (79%)</td>
<td>31 (77%)</td>
</tr>
<tr>
<td>don’t know</td>
<td>1 (4%)</td>
<td>0 (0%)</td>
<td>1 (3%)</td>
</tr>
<tr>
<td>no</td>
<td>5 (19%)</td>
<td>3 (21%)</td>
<td>8 (20%)</td>
</tr>
</tbody>
</table>

With respect to whether such relaxation skills would help them during a colonoscopy: 60% thought that it would and 18% didn't know, approximately half of those indicating that they 'didn’t know' were undergoing a colonoscopy for the first time.

*Open ended responses*

Thirty three (83%) patients of the 40 who took part in this study were asked for their comments regarding the proposed study and the following responses were identified using content analysis. Of these 33, 27 (82%) patients thought that it was a good idea, to which four patients added, "*if able to relax*"; another patient added "*especially for those having a colonoscopy for the first time*" and a sixth patient wrote that "*guidance should be given about when to use tape, i.e., before bed and sleep or after a hard day at the office*"; two (6%) patients were unsure whether such a procedure would help them and four (12%)

---

1 The 'don't know group were not included in the analysis due to low cell frequencies.
thought that it might help others rather than themselves.

Twenty (50%) of all 40 patients added further spontaneous comments as a result of having just listened to the tapes. Specific statements regarding the tapes ranged from favourable (5 patients) e.g., "...love the tape"; to indifference (one patient) such as "...it probably had more effect than I am conscious of"; to annoyance (2 patients), where one patient said she was "...slightly irritated by the tape, ...once at hospital just wanted to get the examination over and done with as soon as possible, go home and eat!"

Two patients reported that they had problems relaxing, though one of them thought that others might benefit more from the procedure. Three other critical comments were that: "...a little longer would have been more beneficial"; it was "...fine at the beginning, but found it difficult to relax my shoulders, ...then other thoughts intruded"; and that attending to breathing diverted from the process of relaxing. One patient was preoccupied with the thought of undergoing a colonoscopy for the first time and stated that "at the moment, fear of the unknown is the problem."

One patient found that being approached by the investigator was very helpful, compared with the usual process of "...being passed on from one person to another". Another commented that he, "...found it beneficial, as [he] was tense before due to driving though London." A third commented, "I have never experienced any relaxation methods like this before and have found this unexpected, but beneficial". "I'm more aware of my body, ...think that's better!" was another remark.

Two patients who reported feeling already relaxed stated, "I'm sure relaxation will help if you are tense. In my case I feel no apprehension, therefore, quite relaxed beforehand"; and "perhaps it would be more useful if...had a stressful journey. I was brought by my husband and felt calm beforehand." One patient suggested that the tapes "...should have some music beneath the voice."
4.3.4 Discussion

On the whole, patients responded favourably to the relaxation tapes. The questionnaire data suggest that the tapes had an influence on reported mood state, as the majority of patients indicated that they thought that the tape was effective. As may be expected, rated effectiveness of the tape was correlated with state of relaxation afterwards and strength of experienced imagery. However, contrary to expectation, awareness of, or disturbance by noise did not correlate with patients' state of reported relaxation though it was related to strength of imagery and patients' reports of the effectiveness of the tape.

No differences between the effects of the two relaxation procedures were found. However, it is possible that any differences there may be are not evident after just one occasion, and at a time when thoughts and concerns are elsewhere. Also, other measures not taken in this study, such as those taken in connection with colonoscopy itself, may show outcome differences between the two relaxation procedures. The present results suggest that patients were more confident regarding application of the relaxation procedures to preparation for colonoscopy, rather than to the examination itself. Perhaps, this may be understood in terms of influence or control over the situation as perceived by the patient: the preparation is the patient's responsibility, whereas, once at the hospital, they can place themselves in the expert hands of the doctors and nurses.

Other factors which may influence any preference with respect to the type of relaxation procedure may include the extent to which the individual wishes to take part in his or her medical care. Research indicates that patients vary in their desire to be involved in decisions regarding their medical care as well as in their coping styles (e.g., Wilson et al., 1982). As indicated by some of the comments, not everyone wants to undergo such a relaxation procedure. Individuals have their own ways of coping with the situation. In addition, not everyone will find that such a procedure results in the intended effect. Future research could include relevant measures in the assessment of patients to explore this possibility.

Overall the tapes seemed to have produced the desired effect and although there were no differences between the two relaxation procedures, one may emerge if they are used over a
longer period of time. It was decided, therefore, to retain both procedures for the next study and to look for longer term differences. It would also be informative to compare the effects of the two types of relaxation procedures on distress and discomfort felt by patients during the colonoscopy. Outcome measures could include patients' tolerance of the procedure, the length of stay in the recovery area and the amount of sedation required, as well as a number of self-reported measures, in particular anxiety, prior to the examination. An anticipated benefit of one or both of the relaxation procedures may be to provide the patient with a greater sense of personal wellbeing and control. This should facilitate the endoscopy through greater ability to cooperate with position change, etc. Patients may require less sedation, with a consequent reduction in their stay at the hospital and disruption to their lives (e.g., time off work, the need for an escort, etc.). The first major study of the thesis, reported in Chapter 6, directly explores these possibilities.

On the basis of this pilot study the use of music as background on a relaxation tape was also considered as it may enhance its effectiveness. Music has been shown to be effective in reducing anxiety in patients undergoing flexible sigmoidoscopy (Palakanis, Denobile, Sweeney and Blankenship, 1994). However, all the different components of the intervention would have to be considered and controlled for. This would require experimental conditions including a music only tape and a verbal instruction only tape, as well as a combined verbal instruction and music tape. It was considered that this number of groups would be impractical in terms of numbers of subjects available and it was decided not to explore the effect of music as a background to the relaxation tapes at this stage.
5 Measures

Chapter overview

Before giving an account of the studies included in this thesis it is necessary to explore the common measures used in each study and some related issues. First, the types of self-report anxiety measures that have been used in clinical settings and studies which have tested the concurrent validity of visual analogue scales are discussed. This is followed by a brief account of the importance of physiological and behavioural measures in health care settings. Finally, a preliminary analysis of measures relating to patients' experience of colonoscopy is reported and discussed.

5.1 Measures of anxiety

As indicated in Chapter 2, relaxation has been successful in reducing anxiety related to endoscopy and other medical and surgical procedures. Reported anxiety is widely used as a measure of the effectiveness of a relaxation procedure. Typically, two types of anxiety have been measured: trait anxiety, referring to an individual’s predisposition or proneness to anxiety; and state anxiety - the individual’s response to a specific situation. Examples of anxiety measures include the Spielberger State-Trait Anxiety Inventory (STAI; Spielberger, Gorsuch and Lushene, 1970; Spielberger, 1983), the Taylor Manifest Anxiety Scale (TMAS; Taylor, 1953) and the Hospital Anxiety and Depression scale (HAD; Zigmond and Snaith, 1983). There are reviews which give detailed descriptions of the different measures of anxiety and their development (e.g., Endler and Parker, 1990; Kellner and Uhlenhuth, 1991; Spielberger, 1985). Furthermore, there have been attempts to explore the nature of anxiety and consequently multidimensional measures of anxiety have been developed (Bystritsky, Linn and Ware, 1990; Endler, Parker, Bagby and Cox, 1991; Wells, 1994).

A number of studies have used linear analogue or visual analogue scales (VAS) to measure state anxiety in medical settings (e.g., Cella and Perry, 1986; Egan, Ready, Nessly and Greer, 1992; Goldmann, Ogg and Levey, 1988; Hicks and Jenkins, 1988). Such scales have been
used when frequent ratings are required (Bond, Shine and Bruce, 1995) or when individuals are distressed and would find completing longer questionnaires very taxing (Cella and Perry, 1986). VAS responses generally involve the use of a 100 mm line, with statements or words at the 0- and 100- mm points. The wording for the scales vary, either having i) words with opposite meanings, such as: 'anxious'- 'relaxed' (Goldmann et al., 1988) or 'calm'- 'terrified' (Hicks and Jenkins, 1988); or ii) instructions for patients to indicate the extent to which they feel anxious, with labels such as 'absent'- 'very severe' (Bond et al., 1995) and 'no anxiety or worry'- 'worst possible anxiety or worry' (Egan et al., 1992). Not all studies which have used VAS to measure anxiety have reported or referred to the reliability of these measures (e.g., Goldmann et al., 1988).

To test concurrent validity some studies have compared their versions of state anxiety VAS with established anxiety measures such as the Spielberger STAI-state (Bond et al., 1995; Cella and Perry, 1986) or the anxiety section of the HAD (Hicks and Jenkins, 1988) or both (Millar, Jelicic, Bonke and Asbury, 1995). Studies which have compared state anxiety VAS with the TMAS have been criticised by Hornblow and Kidson (1976) because the TMAS contains trait rather than state anxiety items. Not all studies have found a significant correlation between state anxiety VAS and the Spielberger STAI-state (e.g., Ahles, Ruckdeschel and Blanchard, 1984) although a greater number have (Bond et al., 1995; Cella and Perry, 1986; Hornblow and Kidson, 1976; Millar et al., 1995).

Examining the relationship between state anxiety VAS and STAI-state, Bond et al. (1995) report correlations for a non-anxious situation, before the commencement of their study, $r = 0.63$, and following the administration of 500mg caffeine in order to raise anxiety levels, $r = 0.90$. Bond et al. (1995) also compared STAI-state with a two-item VAS: the anchor words being: 'calm'- 'excited' and 'relaxed'- 'tense'. These were also highly related with STAI-state, before the study $r = 0.75$ and following 500mg caffeine $r = 0.85$. Cella and Perry (1986) report a correlation of 0.52 with their state anxiety VAS measure and the Spielberger (1983) STAI-state and test-retest coefficients as 0.50 on measures taken on two out of four occasions in one day for hospital patients. Overall, it seems that two separate measures of anxiety are more likely to correlate when anxiety levels are high than when subjects are tested in non-anxious situations.
In general, a test-retest correlation coefficient less than 0.80 suggests that either some subjects have poor comprehension of the items or that the scale contains state measures (Kellner and Uhlenhuth, 1991). In fact, Spielberger (1983) reports the median test-retest reliability coefficient for the STAI-state as 0.33. Regarding the reliability of state anxiety scales, Spielberger (1983) notes that measures of internal consistency, such as the alpha coefficient, provide a more meaningful index than test-retest correlations given the transitory nature of anxiety states.

The State-Trait Anxiety Inventory (Spielberger, Gorsuch and Lushene, 1970) is a widely used measure of anxiety, has reported reliability and validity (Spielberger, 1983) and was selected for use in the present studies. Because at least five consecutive measures of state anxiety were required in the first study, a state anxiety VAS was used to reduce time taken to complete the scales. Two mood VAS items, one anxiety and one calmness item, were used in the studies to avoid suggesting that patients may expect to feel anxious prior to their colonoscopy examination or to remind them how unpleasant the examination can be. It is assumed that by including an item about calmness any selective suggestion of anxiety will be avoided. Concurrent validity of this scale is reported in Chapters 6 and 7, and modifications to this scale - in Chapter 9.

5.2 Physiological and behavioural measures

As previously mentioned, recovery from, and experience of, medical and surgical procedures cannot be measured by a single index. Physiological and behavioural measures can add to the understanding and assessment of patients' experience above that provided by self-report measures. Such measures can also help in distinguishing between the experiences of patients in two or more groups of psychological or pharmacological interventions. Research has indicated a difference, for example, in heart rate increases in two groups of patients undergoing gastroscopy (Wilson et al., 1982). Another physiological indication of distress or discomfort is the amount of sedation and analgesia required to ensure a safe and trouble-free examination; it is generally assumed that the more distressed an individual is the more sedation and analgesia is required to maintain the required level of sedation or anaesthesia.
(Johnston, 1980). Thus, where the intervention attempts to reduce anxiety, this may be reflected in the amounts of sedation and analgesia administered.

How patients respond to, or tolerate, particularly painful aspects of the examination can be assessed by the physician conducting the medical procedure or by other observers (e.g., Shipley et al., 1978, 1979; Wilson et al., 1982). Where more than one observer is used to rate patients' behaviour there is a potential problem of discrepancies in their assessments of the patients. Some studies have established inter-rater reliability by pre-training the raters to overcome this problem (Gattuso et al., 1992; Wilson et al., 1982). However, in the setting in which the studies reported in this thesis were carried out it was not possible to know which particular medical staff would be assessing patients' behaviour and pre-training them in the use of the scales was not feasible. Furthermore, it would be desirable to ensure that raters were counterbalanced across groups, but for the same reason this was also not possible. However, as the medical staff were blind to the group to which the patient was randomly allocated it was hoped that there would be no systematic bias and statistical analysis supported the view that there was no significant difference between the groups in terms of which endoscopists carried out the examinations and hence conducted the ratings for those patients. (These results are reported in the relevant sections of each study.) Nevertheless, results which include observational measures need to be treated with caution.

For the present research a questionnaire, the Endoscopy Questionnaire, was devised comprising of the following items: pulse recordings at five minute intervals following commencement of the examination; the start and completion time of the colonoscopy examination to indicate its duration; the amount of sedation and analgesia given prior to colonoscopy and additional doses as required (recorded by the nurse); patients' tolerance of the colonoscopy examination (recorded by the endoscopist in Study 1 and by both the endoscopist and nurse in Studies 2 and 3) and the endoscopists' assessment of the technical difficulty (recorded by the endoscopist in all 3 studies). This questionnaire can be found on pages 237 and 253.
5.3 Experience of colonoscopy measures

The Post-colonoscopy Questionnaire (Salmon, Shah, Berg and Williams, 1994) is comprised of three components of patients' experience of colonoscopy: satisfaction, emotional distress and physical discomfort. Salmon et al. (1994) used a 7-point scale, however the scale was changed to a VAS in the studies reported here as it was assumed that such a scale might give a more detailed distribution. Salmon et al. (1994) claim that these three components were independent in their sample. For example, patients' level of satisfaction was not necessarily related to the amount of distress or discomfort experienced. Data from the present two studies were analysed separately and in combination with data from the Salmon et al. study. Principal components analysis yielded the following first 10 eigen-values: 5.84, 2.20, 2.02, 1.66, 1.50, 1.45, 1.21, 0.96, 0.90 and 0.82 (Study 1); 6.12, 2.94, 1.96, 1.56, 1.42, 1.32, 1.14, 1.05, 0.94 and 0.80 (Study 2); 5.25, 2.67, 1.85, 1.24, 1.17, 1.16, 1.08, 1.03, 0.89 and 0.84 (data from the three studies combined). The Post-colonoscopy Questionnaire can be found in Appendices B and C.

The corresponding scree tests suggest that there are three factors. To compare the analyses of the two studies with that of Salmon et al. (1994), 3 factors were retained for varimax rotation and loadings are displayed in Table 5.1, along with those of Salmon et al.'s study. Items which yielded a loading value of greater than 0.35 on more than one factor are included in parentheses. The majority of items for Studies 1 and 2 have loaded on the same factors as Salmon et al.'s study. Three items, 'worried about findings', 'not what I expected' and 'relieved when it was over', yielded loadings of less than 0.30. For the remaining analyses the three original components were retained and explored in relation to the other variables for interpretation of patients' experience.

5.3.1 Preliminary analysis of outcome measures used in Study 1

In Study 1 the three components of the Post-Colonoscopy Questionnaire were highly

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1 Eigen values give an indication of how much variance in the original set of variables a factor accounts for (for a more detailed interpretation see Tabachnick and Fidell, 1989).
Table 5.1: Post-Colonoscopy questionnaire factor loadings for the Salmon et al. (1994) study, Study 1, Study 2 and all three studies combined

<table>
<thead>
<tr>
<th>Item</th>
<th>Satisfaction</th>
<th></th>
<th>Emotional distress</th>
<th></th>
<th>Physical discomfort</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Salmon et al.</td>
<td>Study 1</td>
<td>Study 2</td>
<td>3 Studies Combined</td>
<td>Salmon et al.</td>
</tr>
<tr>
<td>Satisfied</td>
<td>0.71</td>
<td>0.53</td>
<td>0.75</td>
<td>0.68</td>
<td></td>
</tr>
<tr>
<td>Staff interested in me</td>
<td>0.69</td>
<td>0.77</td>
<td>0.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pleased with how it went</td>
<td>0.63</td>
<td>-0.38</td>
<td>0.62</td>
<td>0.61</td>
<td></td>
</tr>
<tr>
<td>Staff were warm</td>
<td>0.59</td>
<td>0.31</td>
<td>0.35</td>
<td>0.42</td>
<td></td>
</tr>
<tr>
<td>Staff were informative</td>
<td>0.59</td>
<td>0.64</td>
<td>0.74</td>
<td>0.64</td>
<td></td>
</tr>
<tr>
<td>Dignified</td>
<td>0.55</td>
<td>-0.38</td>
<td></td>
<td>(-0.36)</td>
<td>0.51</td>
</tr>
<tr>
<td>Interested</td>
<td>0.46</td>
<td></td>
<td>-0.47</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confident in the staff</td>
<td>0.44</td>
<td>0.66</td>
<td>0.88</td>
<td>0.65</td>
<td></td>
</tr>
<tr>
<td>Frightened</td>
<td></td>
<td></td>
<td></td>
<td>0.8</td>
<td>0.56</td>
</tr>
<tr>
<td>Worried</td>
<td>0.68</td>
<td>0.64</td>
<td>-0.36</td>
<td>0.56</td>
<td>(-0.45)</td>
</tr>
<tr>
<td>Agitated/calm</td>
<td>0.67</td>
<td>0.41</td>
<td>-0.45</td>
<td>-0.44</td>
<td>(-0.35)</td>
</tr>
<tr>
<td>Worried about findings</td>
<td>-0.34</td>
<td></td>
<td></td>
<td>0.6</td>
<td>0.24</td>
</tr>
<tr>
<td>Not what I expected</td>
<td></td>
<td>-0.19</td>
<td></td>
<td>0.46</td>
<td>0.38</td>
</tr>
<tr>
<td>Did not understand what was happening</td>
<td>(-0.39)</td>
<td>-0.7</td>
<td>(-0.44)</td>
<td>0.45</td>
<td>0.41</td>
</tr>
</tbody>
</table>
Table 5.1 (Continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Satisfaction</th>
<th>Emotional distress</th>
<th>Physical discomfort</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Salmon et al.</td>
<td>Study 1</td>
<td>Study 2</td>
</tr>
<tr>
<td>Puzzled</td>
<td>-0.57</td>
<td>0.43</td>
<td>0.64</td>
</tr>
<tr>
<td>Confused</td>
<td>0.4</td>
<td>0.53</td>
<td>0.48</td>
</tr>
<tr>
<td>Painful</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weary afterwards</td>
<td></td>
<td>-0.71</td>
<td>-0.34</td>
</tr>
<tr>
<td>Preferred to have been less awake</td>
<td>(-0.40)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncomfortable</td>
<td>(-0.40)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bad experience</td>
<td>(-0.48)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Felt out of control</td>
<td>(-0.43)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soreness</td>
<td></td>
<td>-0.55</td>
<td></td>
</tr>
<tr>
<td>Afraid of making a fool of myself</td>
<td>(-0.35)</td>
<td>-0.65</td>
<td>-0.71</td>
</tr>
<tr>
<td>Relieved when it was over</td>
<td>-0.29</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
correlated with each other and with the two measures assessed by the endoscopist carrying out the examination, that is, patients' tolerance and the technical difficulty. These five variables were selected to be the main outcome measures of the study. Table 5.2 displays this set of correlations which have both strong (e.g., $r(73) = -0.605$, $p < 0.001$, emotional distress and physical discomfort) and weak (e.g., $r(73) = 0.219$, $p = 0.06$, satisfaction and difficulty) associations. Principal components factor analysis was conducted to check whether these outcome measures were related in this sample. One factor was extracted accounting for 53.3% of the variance. Combining the measures resulted in a single score with an alpha reliability coefficient of 0.70. Eigen-values for each item are as follows: 2.67, 0.87, 0.61, 0.48 and 0.38, indicating one major factor for this sample, that the five outcome measures are related. The factor loadings are also shown in Table 5.2. Thus, a high score on the factor indicated great difficulty for the endoscopist performing the examination, poor patient tolerance, low patient satisfaction, high emotional distress and high physical discomfort.

Table 5.2: Correlations and factor loadings of the outcome measures for Study 1

<table>
<thead>
<tr>
<th>Tolerance</th>
<th>Satisfactiona</th>
<th>Emotional Distressa</th>
<th>Physical Discomfort</th>
<th>Factor loadings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty</td>
<td>-0.303*</td>
<td>0.219</td>
<td>0.231†</td>
<td>0.299*</td>
</tr>
<tr>
<td>Tolerance</td>
<td></td>
<td>-0.415**</td>
<td>0.408**</td>
<td>-0.464**</td>
</tr>
<tr>
<td>Satisfactiona</td>
<td></td>
<td></td>
<td>-0.528**</td>
<td>0.566**</td>
</tr>
<tr>
<td>Emotional Distressa</td>
<td></td>
<td></td>
<td></td>
<td>-0.605**</td>
</tr>
<tr>
<td>Physical Discomfort</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* reverse score
† $p < 0.05$  * $p < 0.01$  ** $p < 0.001$

2 reversed scored variable
5.3.2 Preliminary analysis of outcome measures used in Study 2

Study 2 differed from Study 1 with the addition of an extra behavioural item: the assessment of patients' tolerance of the colonoscopy examination by the attending nurse. Therefore, the relationship between six outcome measures, chosen to represent patients' experiences of colonoscopy, was examined. Correlations, displayed in Table 5.3, varied from strong (e.g., \( r(85) = 0.665, \ p < 0.001 \), tolerance independently assessed by the endoscopist and nurse) to hardly any association (e.g., \( r(82) = 0.022, \ p > 0.05 \), patients' satisfaction and technical difficulty). Satisfaction was associated with the other self-report measures of emotional distress and physical discomfort but not with the observed measures independently assessed by the endoscopist and nurse. The difficulty of the examination was associated with physical discomfort but not with emotional distress. Although there was a strong association between assessment of tolerance by the endoscopist and nurse, the latter was associated with the endoscopist's assessment of the difficulty of the examination, whereas the endoscopists's assessment of patients' tolerance was not.

Table 5.3: Correlations and factor loadings of the outcome measures for Study 2

<table>
<thead>
<tr>
<th></th>
<th>( T_E )</th>
<th>( T_N )</th>
<th>Satisfaction(^a)</th>
<th>Emotional Distress(^a)</th>
<th>Physical Discomfort</th>
<th>Factor loading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty</td>
<td>-0.168</td>
<td>-0.271†</td>
<td>0.022</td>
<td>0.041</td>
<td>0.359**</td>
<td>-0.41</td>
</tr>
<tr>
<td>Tolerance, assessed by endoscopist (( T_E ))</td>
<td>-</td>
<td>0.665**</td>
<td>-0.043</td>
<td>0.214†</td>
<td>-0.337*</td>
<td>0.70</td>
</tr>
<tr>
<td>Tolerance, assessed by nurse (( T_N ))</td>
<td>-</td>
<td>-0.070</td>
<td>0.248†</td>
<td>-0.399**</td>
<td>0.76</td>
<td></td>
</tr>
<tr>
<td>Satisfaction(^a)</td>
<td>-</td>
<td>-0.337*</td>
<td>0.358**</td>
<td>0.40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional Distress(^a)</td>
<td>-</td>
<td>-0.484**</td>
<td>0.60</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Discomfort</td>
<td>-</td>
<td>-</td>
<td>-0.79</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) reverse scored
\(† \ p < 0.05 \quad * \ p < 0.005 \quad ** \ p < 0.001 \)
Principal components factor analysis was conducted to check whether these outcome measures were related in this second sample. One factor was extracted accounting for 39.9% of the variance. Combining the measures resulted in a single score with an alpha reliability coefficient of 0.67. Eigen-values for each item are as follows: 2.39, 1.32, 0.96, 0.64, 0.37 and 0.32, and also suggest that one major factor exists for this sample. The factor loadings are also shown in Table 5.3. Thus, a high score on total experience indicated high patient tolerance, high patient satisfaction, low emotional distress and low physical discomfort.

The previously established measure of the experience of colonoscopy (Salmon et al., 1994) indicated three components, and the analysis of data from subsequent studies reported in this thesis (Study 1 and Study 2) has supported this. However, in the latter studies the three components were found to be related to each other and to observational measures. As this is the case, reducing the data from these measures to one outcome variable provides a reliable measure of the overall experience of colonoscopy, which is made up of both self-report and observational measures. Therefore, this combined measure was used to assess outcome in the studies reported in Chapters 6 and 7. Chapter 6 provides an account of Study 1 and Chapter 7 reports the findings of Study 2, after giving a description of additional measures used.
6 Study 1: Home-based Psychological Preparation for Colonoscopy

Chapter overview

Having reported patients' responses to the two proposed relaxation procedures and discussed the measures used, this chapter first provides a brief summary of previous relaxation interventions, followed by an account of the ways in which the manipulation of relaxation procedures have been checked. The main part of this chapter reports the findings of Study 1: an investigation of a home-based psychological preparation for a colonoscopy examination.

6.1 Background

Benefits of relaxation procedures for patients undergoing day-case surgery have been reported as consisting of significantly reduced pre-operative anxiety and reduced time needed to induce and maintain anaesthesia (Markland and Hardy, 1993). Regarding endoscopy examinations, relaxation has also been shown to have beneficial effects for gastroscopy patients, with less distress during tube insertion, lower heart rate increases during the procedure, elevation in mood following the procedure (Wilson et al., 1982) and reductions in muscle tension and heart rates (Gattuso et al., 1992). Less anxiety was also reported by those patients undergoing sigmoidoscopy who had been allocated to a relaxation procedure compared to those not receiving relaxation instruction (Kaplan et al., 1982). No previous studies testing the effects of relaxation on patients undergoing a full colonoscopy appear to have been reported.

As mentioned in Chapter 3, the first main study reported in this thesis involves a home-based relaxation intervention with colonoscopy patients. An important related issue, that of the extent of compliance with such interventions, has been investigated and the relevant studies are described below.

Home-based interventions have been used previously with patients suffering from hypertension (Hoelscher et al., 1987; Sherman, 1982), tension headaches and chronic anxiety (Sherman,
1982). However, the extent to which patients comply with instructions is not easy to assess. Using a hidden microelectronic device that stored a real-time record of taped relaxation practice, Taylor, Agras, Schneider and Allen (1983) found that 71% of patients reported full compliance, whereas only 39% actually practised as instructed (five times per week). Similarly, Hoelscher, Lichstein and Rosenthal (1984) found only 25% of subjects performed the instructed daily relaxation practice and that overall they reported more than twice their measured practice. Another study using relaxation tapes reported similar findings even with an intervention to improve compliance over a ten week treatment period (Hoelscher, Lichstein and Rosenthal, 1986). However, in that study relaxation practice which occurred without the use of the tapes was excluded from the analyses. Furthermore, there is no report of how effective the subjects thought the tapes were in helping them to relax. Therefore, questions regarding how often patients listened to the tapes and whether they were able to relax when using them were included in the present study.

Although, no differences were found between the two proposed relaxation procedures (Appendix A), they were both effective in reducing anxiety (see Chapter 4). It was anticipated that a difference might emerge when the procedures are used repetitively in the week before a colonoscopy examination, and when outcome measures relating to the experience of colonoscopy itself are used. The extent to which patients desire information or wish to be involved in their own medical care may play a part in determining any differences in outcome between these two tapes and these two patient variables were measured in the present study using the Health Opinion Survey (Krantz, Baum and Wideman, 1980).

As discussed in Chapter 3 the amount and type of medication used for colonoscopy across endoscopy departments is not standardised (Lazzaroni and Bianchi Porro, 1994). Patients may receive sedation, analgesia, an anti-spasmodic, any combination of these or no medication at all. A recent study has shown that it is feasible to commence colonoscopy with an anti-spasmodic alone (Saunders, Fukumoto, Halligan, Masaki, Love and Williams, 1994) and so, to test the amount of sedation or analgesia required by patients, it was proposed that the routine pre-medication in the present study should consist solely of an anti-spasmodic. Sedation or analgesia were administered at the patients' request or at the endoscopist's discretion.
This study used a non-intervention control group to compare the effects of the two types of relaxation procedures on distress and discomfort experienced by patients during a colonoscopy examination and its preparation. These two procedures are 'relaxation alone' and 'relaxation plus control' as described in Chapter 4. Outcome measures, such as patients' experience of colonoscopy and changes in anxiety, in the two relaxation groups and the non-intervention control group were compared. Ethical approval was obtained for each of the main studies reported in this thesis from the corresponding Hospital Ethics Committees. Although the importance of an attention control groups has been discussed it proved difficult to find material which subjects would find acceptable to listen to repetitively on four occasions and for this reason an attention control group was not included in this study.

The aims of this study were: i) to record levels of anxiety leading up to a colonoscopy procedure; ii) to test the effectiveness of a home based psychological preparation; and iii) to compare two types of relaxation procedures, with and without control instructions. Furthermore, it is expected that the groups will differ in their preferences for health care, as measured by the Health Opinion Survey, as a result of the interventions.

6.2 Methods

6.2.1 Subjects

One hundred and three patients who received appointments to attend the endoscopy department of St. Marks Hospital for a colonoscopy examination agreed to take part in the study. However, 8 of these failed to return their consent forms in time to send out the materials for intervention and ten patients received the relevant materials, but subsequently cancelled their appointments. Two patients had forgotten, or were not able, to listen to the tape, five were having procedures in addition to colonoscopy and two patients incorrectly completed the VAS. Thus, 75 patients remained in the study. Unfortunately, a record was not kept of how many information sheets/consent forms were sent out to patients and so it was not possible to ascertain the number of refusals. Patients' ages ranged from 21 to 75 years with a mean of 54.3. Twenty eight (37%) patients were male and 45 (60%) had previous experience of
colonoscopy. Reasons for colonoscopy were as follows: family history of cancer (30.7%); family history of polyps (2.7%); diagnosed ulcerative colitis or Crohn's disease (24%); previous diagnosis of polyps (28%); previous diagnosis of cancer (6.7%); symptoms, such as rectal bleeding or anaemia (6.7%) and one patient had a stricture. Concerning employment status, the subjects described themselves as employed or self-employed (60%); retired (25%); students (3%) and unemployed or taking care of the home (12%). Those who were employed, classed themselves as professional/managerial (38.7%); clerical or shopwork (17.3%); skilled manual (2.7%); skilled technical (1.3%) and unskilled manual (1.3%). Forty three percent had previous relaxation, or similar, experience.

6.2.2 Materials

Materials used consisted of the relaxation tapes described in Chapter 4, an 'information sheet-consent form', a letter to the patient and the following: i) Questionnaire, Mood Scales and Check List, which comprised of instructions\(^1\) to patients informing them when to listen to the tape and when to fill in the following anxiety measures: the State-Trait Anxiety Inventory (Spielberger, Gorsuch and Lushene, 1970) and Mood Scales 1 - 4 (two item VAS: asking patients 'to what extent they felt anxious' and 'to what extent they felt calm'); ii) Mood Scale 5; iii) the Endoscopy Questionnaire comprising of pulse recordings, duration of the procedure, amount of sedation and analgesia required and the endoscopists' assessment of the difficulty, and patients' tolerance, of the colonoscopy examination; and iv) the Post-Colonoscopy Questionnaire (Salmon, Shah, Berg and Williams, 1994) with the STAI-state, Mood Scale 6, a modified\(^2\) version of the Health Opinion Survey (Krantz, Baum and Wideman, 1980) and added items regarding previous experience of colonoscopy and relaxation, and questions regarding patients' compliance in listening to the tape, their ability to relax and demographic information and any benefits or drawbacks of taking part in the study.

\(^1\) Instructions to patients were piloted on six patients at the endoscopy unit with explanations that the instructions would be sent out to patients for them to complete in their own homes.

\(^2\) In order to reduce the demand on the patients three items in each subscale of the original scale are repeated in the negative. One of each of the repeated items was removed resulting in four items remaining in the Information subscale and six items in the Involvment subscale. For example, Statement 1, "I usually don't ask the doctor or nurse many questions about what they are doing during a medical exam", was omitted and it's opposite, Statement 8, "I ask the doctor and nurse lots of questions about the procedures during a medical exam", was retained.
The information sheet-consent form, letter and questionnaires are included in Appendix B. The transcripts of the relaxation procedures can be found in Appendix A.

6.2.3 Procedure

Patients were invited to take part in the study when they received their appointment date for a colonoscopy examination. Those who agreed to take part were sent a letter and the Questionnaire, Mood Scales and Check List. Subjects in the 'relaxation alone' group and 'relaxation with control' group also received the appropriate tape. Subjects were instructed to fill in the questionnaire and, if appropriate, listen to the tape on four separate occasions in the week leading up to their colonoscopy to coincide with the instructions they received for bowel preparation. Using random number tables subjects were allocated to one of the three groups, which were balanced for numbers of new and returning patients.

On the day of their colonoscopy examination patients were asked to fill in Mood Scale 5 on arrival at the endoscopy unit. For the majority of cases (76%) the colonoscopy examination was commenced with anti-spasmodic mediation only or with no medication whatsoever, as intended. However, due to a variety of reasons the remainder commenced their examination with half or full dose of medication, consisting of 25mg or 50mg of pethidine and 2.5mg or 5mg of midazolam (Hypnovel), respectively. Additional medication of sedation and/or analgesia was administered as required. The two endoscopists, involved in the study, and the nurses, who were present during the examination, were unaware to which of the three groups each patient was allocated. Observational (patients' tolerance of the examination) and physiological (heart rate and dose of analgesia and sedation) measures were taken by the endoscopist and nurse\(^3\) during, or immediately following the examination (Endoscopy Questionnaire\(^4\)). Further questionnaires (the Post-Colonoscopy Questionnaire) were administered to the patients afterwards, once they had left the recovery area. On completion of the questionnaires patients were asked for comments and thanked for taking part.

\(^3\) A record of which nurses were present during the colonoscopy examination was not kept as they were involved in the recording of 'objective' measures, i.e., time of the commencement of the examination, physiological recording and doses of medication given to the patient.

\(^4\) The issue of inter-rater reliability is an important one and has been addressed in Section 5.2.
6.2.4 Statistical analysis

The data were screened and the relationship between Mood Scale and the state component of the STAI was checked using Pearson product-moment correlation coefficients. Multiple analysis of variance (MANOVA), Kruskal-Wallis and Chi-square tests were used to check that groups did not significantly differ in demographic and examination variables. The Mood Scale items were combined to provide a single score (i.e. the calm item was reversed and then the mean of the two items was calculated).

Hierarchical multiple regression analysis was used to explore which variables, including group contrasts, predicted the outcome measure. One contrast compared the non-intervention control group with the two relaxation groups together and the other compared the two relaxation groups.

A mixed-design multivariate analysis of covariance (MANCOVA) was conducted to test for changes in anxiety in the week leading up to the colonoscopy examination and for differences between the three treatment groups during this period. Mann-Whitney tests were used to investigate whether there were differences between the two relaxation groups in terms of how often patients listened to the tapes and how often they were able to relax. Finally, Kruskal-Wallis one-way analysis of variance by ranks was used to explore whether spontaneous use of a relaxation procedure by patients immediately before or during colonoscopy was associated with their group membership. Follow-up comparisons to the Kruskal-Wallis tests were made using the standard procedure (Siegal and Catellan, 1988).

6.3 Results

Prior to analysis, all variables were examined through various SPSS for Windows programs for accuracy of data entry and missing values. The variables were examined separately for the 24 subjects in the 'relaxation alone' group, the 29 subjects in the 'relaxation plus control' group and the 22 subjects in the non-intervention control group. Two subjects in the control group failed to return their pre-colonoscopy anxiety measures and so have missing data on the Mood Scale items and STAI measures recorded before their arrival at the endoscopy unit. Thirteen subjects
did not listen to the tapes as frequently as instructed or were not able to relax on at least 'some' of the four occasions. They remained in the analysis in accordance with the 'intention to treat' principle (Newell, 1992).

6.3.1 Comparison of anxiety measures

Table 6.1 shows the correlation coefficients between the VAS and STAI state anxiety taken one week before the colonoscopy (Time 1), $r(71) = 0.685$, and immediately after it (Time 2), $r(73) = 0.734$. As expected both are significantly correlated, $p < 0.001$. In addition, the two STAI-state measures, taken on different occasions, correlated with each other, $r(71) = 0.446$, $p < 0.001$, whereas the Mood Scales did not, $r(73) = 0.134$, ns.

<table>
<thead>
<tr>
<th></th>
<th>Time 1a</th>
<th></th>
<th>Time 2b</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>STAI - State</td>
<td>Mood Scale</td>
<td>STAI - State</td>
</tr>
<tr>
<td>Time 1</td>
<td>Mood Scale</td>
<td>0.685**</td>
<td></td>
</tr>
<tr>
<td>Time 2</td>
<td>STAI - State</td>
<td>0.446**</td>
<td>0.264*</td>
</tr>
<tr>
<td></td>
<td>Mood Scale</td>
<td>0.125</td>
<td>0.134</td>
</tr>
</tbody>
</table>

* $p < 0.05$  ** $p < 0.001$

6.3.2 Background variables

Treatment groups were not significantly different in terms of age, number of previous colonoscopy examinations, trait anxiety, state anxiety - STAI and state anxiety - VAS, Wilks' Lambda $= 0.771$, exact $F(10,132)^a = 1.83$, ns, sex, $\chi^2(2) = 4.31$, ns, indication, $\chi^2(4) = 4.69$.

---

$^a$ Wilks' (1935) formula to calculate the exact test for three groups is provided by Marriott (1974) and for a particular value of Wilks' $\lambda$ the equivalent $F$ is $(N-1)-q-1/q \cdot (1-\sqrt{\lambda})/\sqrt{\lambda}$ with $2q$ and $2((N-1)-q-1)$ degrees of freedom, where $q$ refers to the number of dependent variables and $N$ is the number of subjects.
ns, previous relaxation experience, Kruskal-Wallis test, $\chi^2(2) = 5.61$, ns, marital status, $\chi^2(2) = 4.11$, ns, whether employed, $\chi^2(2) = 1.67$, ns, and social status, Kruskal-Wallis test, $\chi^2(2) = 0.19$, ns, which endoscopist carried out the examination, $\chi^2(2) = 1.33$, ns, and the type of

Table 6.2: Means and standard deviations or frequencies of background variables for each group

<table>
<thead>
<tr>
<th></th>
<th>Control group</th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean</td>
<td>sd</td>
<td>mean</td>
</tr>
<tr>
<td>Age</td>
<td>50.95</td>
<td>16.41</td>
<td>59.21</td>
</tr>
<tr>
<td>Previous colonoscopy</td>
<td>1.41</td>
<td>1.33</td>
<td>3.38</td>
</tr>
<tr>
<td>examinations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>40.5</td>
<td>10.10</td>
<td>35.17</td>
</tr>
<tr>
<td>State anxiety-STAI</td>
<td>39.45</td>
<td>10.46</td>
<td>31.17</td>
</tr>
<tr>
<td>State anxiety-VAS</td>
<td>31.33</td>
<td>27.26</td>
<td>24.81</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>0</td>
<td>0</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>II</td>
<td>0</td>
<td>2 (15%)</td>
<td>0</td>
</tr>
<tr>
<td>III</td>
<td>5 (33%)</td>
<td>3 (23%)</td>
<td>5 (28%)</td>
</tr>
<tr>
<td>IV</td>
<td>1 (7%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>V</td>
<td>9 (60%)</td>
<td>8 (62%)</td>
<td>12 (67%)</td>
</tr>
<tr>
<td>Previous relaxation</td>
<td>0</td>
<td>13 (65%)</td>
<td>11 (38%)</td>
</tr>
<tr>
<td>1</td>
<td>4 (20%)</td>
<td>3 (13%)</td>
<td>14 (48%)</td>
</tr>
<tr>
<td>2</td>
<td>3 (15%)</td>
<td>2 (8%)</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>3+</td>
<td>0</td>
<td>1 (4%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Pre-medication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil</td>
<td>4 (%)</td>
<td>4 (%)</td>
<td>4 (%)</td>
</tr>
<tr>
<td>Anti-spasmodic</td>
<td>15 (%)</td>
<td>15 (%)</td>
<td>15 (%)</td>
</tr>
<tr>
<td>½ dose sedation</td>
<td>2 (%)</td>
<td>4 (%)</td>
<td>9 (%)</td>
</tr>
<tr>
<td>Full dose sedation</td>
<td>1 (%)</td>
<td>1 (%)</td>
<td>1 (%)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>9 (41%)</td>
<td>17 (71%)</td>
<td>15 (52%)</td>
</tr>
<tr>
<td>female</td>
<td>13 (59%)</td>
<td>7 (29%)</td>
<td>14 (48%)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>single</td>
<td>9 (41%)</td>
<td>4 (17%)</td>
<td>6 (21%)</td>
</tr>
<tr>
<td>married</td>
<td>13 (59%)</td>
<td>20 (83%)</td>
<td>23 (79%)</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>employed</td>
<td>15 (68%)</td>
<td>12 (50%)</td>
<td>18 (62%)</td>
</tr>
<tr>
<td>not employed</td>
<td>7 (32%)</td>
<td>12 (50%)</td>
<td>11 (38%)</td>
</tr>
<tr>
<td>Indication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>screening</td>
<td>10 (50%)</td>
<td>5 (25%)</td>
<td>10 (34.5%)</td>
</tr>
<tr>
<td>cancer</td>
<td>3 (15%)</td>
<td>5 (25%)</td>
<td>10 (34.5%)</td>
</tr>
<tr>
<td>Crohn's disease</td>
<td>7 (35%)</td>
<td>10 (50%)</td>
<td>9 (31%)</td>
</tr>
<tr>
<td>Endoscopist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#1</td>
<td>18 (82%)</td>
<td>20 (83%)</td>
<td>24 (83%)</td>
</tr>
<tr>
<td>#2</td>
<td>4 (18%)</td>
<td>4 (17%)</td>
<td>5 (17%)</td>
</tr>
</tbody>
</table>
premedication administered beforehand, Kruskal-Wallis test, \( \chi^2(2) = 2.36, \text{ns.} \) Table 6.2 gives the means and standard deviations or frequencies of the background variables for each of the three groups.

### 6.3.3 Experience of colonoscopy

In order to address whether subjects differed in their experience of colonoscopy and at the same time control for individual differences and differences in medication received, hierarchical multiple regression analysis was conducted. Variables yielding significant first-order Pearson correlations with the outcome variable and other important background variables were entered at the first step and consisted of: age, sex, state anxiety at Time 1, the initial amount of analgesia received, the number of previous colonoscopy examinations, the duration of the examination and heart rate before commencement of the examination. Other, similar variables were not included because they were highly correlated with the variables already included in the equation. Excluded variables consisted of the amount of sedation (which correlated with the amount of analgesia, \( r(73) = 0.86, p < 0.01 \)) and the anxiety measures: Mood Scales 2-5 and trait anxiety (all of which correlated with State anxiety 1, correlations ranged from 0.46 to 0.85). State anxiety at Time 1 was selected, over the other anxiety measures, because of the almost significant difference between the three groups as shown with MANOVA.

Contrast 1, comparing the control group with both relaxation groups was then entered (Step 2) followed by the final contrast, Contrast 2, comparing the two relaxation groups (Step 3). \textit{A priori} contrasts consisted of the following coefficients: Control group = -2, 'Relaxation alone' = 1, and 'Relaxation plus control' = 1 for Contrast 1; and Control group = 0, 'Relaxation alone' = 1, and 'Relaxation plus control' = -1 for Contrast 2. Table 6.3 displays the unstandardized regression coefficients \( (b) \), the standardized regression coefficients \( (\beta) \) and the \( t \) score after entry of 9 predictor variables. \( R \) was significantly different from zero at the end of each step.

After Step 1, with demographic, anxiety, previous experience, medication and physiological
variables in the equation, $R^2 = 0.39$, $F(7,67) = 6.17$, $p < 0.001$. The following variables were significantly related to the experience of colonoscopy: age and the amount of initial analgesia received. After Step 2, with Contrast 1 added to the prediction of the experience of colonoscopy to age, sex, anxiety, previous experience, amount of analgesia and heart rate, $R^2 = 0.46$, $F(8,66) = 6.99$, $p < 0.001$. The addition of Contrast 1 to the equation resulted in an increase in $R^2 = 0.46$ (adjusted $R^2 = 0.39$), $F(1,66) = 8.13$, $p < 0.001$ (difference between Step 1 and Step 2), indicating that when differences in age and the amount of initial medication were controlled for there was a difference between the control group and the two relaxation groups. After Step 3, with all predictor variables in the equation, $R^2 = 0.68$, $F(9,65) = 6.35$, $p < 0.001$, accounting for 39.4% of the variance. The addition of Contrast 2 did not significantly improve $R^2$, $F(1,65) = 1.14$, ns (difference between Step 2 and Step 3). Thus, a negative experience of colonoscopy was associated with younger patients, a higher dose of initial analgesia and membership of the control group.

Table 6.3: Regression of demographic variables and contrasts on experience of colonoscopy

<table>
<thead>
<tr>
<th>Variables</th>
<th>$b$</th>
<th>$\beta$</th>
<th>$t$†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-0.019</td>
<td>-0.28</td>
<td>-2.562*</td>
</tr>
<tr>
<td>Sex</td>
<td>0.198</td>
<td>0.09</td>
<td>0.961</td>
</tr>
<tr>
<td>State anxiety before intervention</td>
<td>0.013</td>
<td>0.14</td>
<td>1.361</td>
</tr>
<tr>
<td>Initial analgesia</td>
<td>0.010</td>
<td>0.22</td>
<td>2.089*</td>
</tr>
<tr>
<td>No. of previous examinations</td>
<td>-0.014</td>
<td>-0.04</td>
<td>-0.439</td>
</tr>
<tr>
<td>Duration of colonoscopy</td>
<td>0.019</td>
<td>0.20</td>
<td>1.913</td>
</tr>
<tr>
<td>Heart rate before colonoscopy</td>
<td>0.007</td>
<td>0.13</td>
<td>1.227</td>
</tr>
</tbody>
</table>

Step 1                                     
Step 2 Contrast 1 | -0.206 | -0.28 | -2.850**  
Step 3 Contrast 2 | -0.125 | -0.11 | -1.066  

* $p < 0.05$ ** $p < 0.005$
† Step 1 simultaneously takes all variables in Step 1 into account; Step 2 takes all variables in Steps 1 and 2 into account; and Step 3 takes all variables in Steps 1, 2 and 3 into account.
6.3.4 Anxiety prior to colonoscopy

A mixed design MANCOVA was performed on Mood Scale 2 (4 days before colonoscopy), Mood Scale 3, Mood Scale 4 and Mood Scale 5 (immediately before colonoscopy). Between-subjects effects showed a significant group difference, $F(2,69) = 5.10, \ p < 0.01$. After adjustment by the covariate, Mood Scale 1\(^5\), Wilks' criterion indicated a significant change in anxiety, Wilks' Lambda = 0.77, Approximate $F(3,68) = 6.68, \ p < 0.001$, but not an interaction, $F(2,136) = 0.80, \text{ ns.}$ Figure 6.1 shows the levels of anxiety for the patients in the three treatment groups, during the week before their colonoscopy examination.

**Figure 6.1: Anxiety levels in the week before, immediately before and following colonoscopy**

Error bars represent 95% confidence intervals

\(^5\) Although, Mood Scale 1 did not significantly differ between the three groups, it is used as a covariate due to slight variation between the groups.
There was no difference in how often patients listened to the tapes, Mann Whitney $U(53) = 314$, $ns$, nor how often patients were able to relax, $U(53) = 316$, $ns$, between the two relaxation groups.

6.3.5 Use of relaxation before and during colonoscopy

Forty nine percent of all patients attempted to use a relaxation procedure immediately before, and 37% during, their colonoscopy examination. Differences were found between groups on whether they attempted to use relaxation immediately before, Kruskal-Wallis test, $\chi^2(2) = 8.55$, $p < 0.01$, and almost a difference during, $\chi^2(2) = 6.17$, $p = 0.046$, their colonoscopy examination ($\alpha$ level adjusted for the number of statistical tests and set at 0.025). Comparisons relating to the use of relaxation immediately before colonoscopy show that there was a difference between the control group and the 'relaxation alone' group, and almost a difference between the control and the 'relaxation plus control', but not between the two relaxation groups. Table 6.4 shows the number of patients who used relaxation immediately before colonoscopy in each of the three groups and the mean ranks. Eighty percent of patients who used a relaxation procedure immediately before or during their examination reported that they had used the one they learnt from this study. Of these 59% had undergone previous relaxation or similar training.

<table>
<thead>
<tr>
<th>Use of relaxation</th>
<th>Control group</th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>17 (77%)</td>
<td>10 (42%)</td>
<td>11 (38%)</td>
</tr>
<tr>
<td>A little</td>
<td>3 (14%)</td>
<td>5 (21%)</td>
<td>10 (34%)</td>
</tr>
<tr>
<td>Yes</td>
<td>2 (9%)</td>
<td>9 (37%)</td>
<td>8 (28%)</td>
</tr>
<tr>
<td><strong>Mean Rank</strong></td>
<td><strong>27.55</strong></td>
<td><strong>42.77</strong></td>
<td><strong>41.98</strong></td>
</tr>
</tbody>
</table>

Table 6.4: Numbers of patients who used relaxation immediately before their colonoscopy examination
Following their examination patients, who listened to a tape, were asked how helpful they found the tapes. A Mann Whitney test indicated no difference between the two groups, $U(51) = 296.5$, *ns*. Patients' responses to this question are presented in Table 6.5, together with the mean ranks.

Table 6.5: Patients’ responses to how helpful they found the tapes

<table>
<thead>
<tr>
<th>Helpfulness of the tapes</th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>3 (13%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>A little</td>
<td>4 (16%)</td>
<td>4 (15%)</td>
</tr>
<tr>
<td>Moderately</td>
<td>7 (29%)</td>
<td>10 (37%)</td>
</tr>
<tr>
<td>Very much</td>
<td>7 (29%)</td>
<td>9 (33%)</td>
</tr>
<tr>
<td>Extremely</td>
<td>3 (13%)</td>
<td>3 (11%)</td>
</tr>
<tr>
<td><strong>Mean rank</strong></td>
<td><strong>24.85</strong></td>
<td><strong>27.02</strong></td>
</tr>
</tbody>
</table>

Eighty two percent of all patients reported that their participation in the study helped them, whereas 15% reported that it made no difference. There were no differences between the groups, Kruskal Wallis test, $\chi^2(2) = 4.92$, *ns*. Three out of four patients who reported that their participation in the study 'made things a little worse' were in the control group, one of these failed to return the home-based anxiety measures. The fourth patient, in the 'relaxation plus control' group, reported listening to the tape only once.

6.3.6 Health Opinion Survey

Measures of patients' preferences for information and involvement in health care were taken after their experience of colonoscopy and thus may have been influenced by their participation in the study or by the colonoscopy itself. The means and standard deviations
of these two measures are presented in Table 6.6. The three groups were not significantly
different in their desire for information and desire for involvement in their medical care,
Wilks' Lambda = 0.92, exact $F(4,140) = 1.46$, ns.

Table 6.6: Means and standard deviations of
health belief measures for each group

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean</td>
<td>sd</td>
<td>mean</td>
</tr>
<tr>
<td>Desire for information*</td>
<td>1.73</td>
<td>1.20</td>
<td>1.85</td>
</tr>
<tr>
<td>Desire for involvement**</td>
<td>3.37</td>
<td>1.30</td>
<td>3.25</td>
</tr>
</tbody>
</table>

* possible range of scores = 0 - 4
** possible range of scores = 0 - 6

6.4 Discussion

As expected the two measures of state anxiety were highly correlated, indicating that the
VAS state anxiety can be classed as a reliable measure. These correlation coefficients are in
line with findings in previous research (e.g., Bond et al., 1995). The STAI state anxiety was
correlated on the two occasions to a similar extent to previously reported test-retest
reliabilities (Spielberger, 1983). In contrast, the Mood Scales were not correlated on two
occasions. These results are not easy to interpret due to the low coefficients associated with
test-retest reliability of state measures (Kellner and Uhlenhuth, 1991; Spielberger, 1983). The
next step in exploring the reliability of the Mood Scales would be to compare both measures
when subjects are anxious, such as immediately before a medical examination. Bond et al.
(1995) reported larger coefficients when subjects were highly anxious.

Despite the intention to have an anti-spasmodic as the only initial medication some patients
also received sedation and analgesia before commencement of colonoscopy. Some of the
reasons for this include previous technically difficult examinations for particular patients,
preferences of the individual endoscopists or patients' requests for sedation or analgesia. As a result of this variation in the initial dose of medication a comparison was possible and this initial dose was, in fact, one of the significant predictors of the experience of colonoscopy. Thus, a negative experience of colonoscopy was associated with younger patients, a higher initial dose of analgesia and membership of the control group. Conversely, older patients who underwent a colonoscopy examination with just an anti-spasmodic or no medication and had listened to one of the relaxation tapes were likely to have a much more positive experience of colonoscopy. Thus, the results suggest that relaxation, together with greater age, may actually reduce the amount of medication required for a satisfactory colonoscopy.

Patients in the relaxation groups overall had a better experience of their colonoscopy examination than those in the control group, even after accounting for differences in anxiety levels before the interventions, sex, age, number of previous colonoscopy examinations, analgesia administered, heart rates and duration of the examination. This provides some indication of the importance of the contribution of the patients' state of relaxation to their colonoscopy experience. The two relaxation groups did not differ from each other in patients' overall experience of colonoscopy.

The data also revealed that anxiety levels changed significantly in the week before a colonoscopy examination and that group membership had an effect on the levels of anxiety. Figure 6.1 shows that, the differences in anxiety levels between the three groups became more marked over the days with those in the control group remaining consistently higher than those in the relaxation groups. The trend towards increased levels of anxiety over days for those patients in the control group is similar to that described by Johnston (1980). That is, patients' levels of anxiety are highest on the day before the medical procedure, with the increase in anxiety commencing several days before this. A difference between the two relaxation groups can also be seen in Figure 6.1, in that the 'relaxation plus control' group show an increase in anxiety similar to that seen in the control group in the week before colonoscopy. In contrast, the levels of anxiety in the 'relaxation alone' group do not rise until the day before colonoscopy. A possible explanation for the difference in the effects of the two relaxation tapes on levels of anxiety may be that the wording of the 'relaxation plus control' tape may have in some way reminded patients about their impending colonoscopy.
If so, this may have reduced the effectiveness of the pre-examination relaxation procedure for those listening to the 'relaxation plus control' tape compared to those listening to the 'relaxation alone' tape, despite the lack of difference between the two relaxation groups in terms of their frequency in listening to the tapes and their ability to relax.

Patients in this study were not explicitly advised to practice a relaxation procedure either immediately before or during their colonoscopy examination. This is likely to be the reason for the low levels of implementation of relaxation procedures reported immediately before and during colonoscopy, which may in turn explain the lack of a significant difference between the relaxation groups in terms of the outcome measure. One way of addressing this question would be to introduce specific instructions to use the relaxation procedures during colonoscopy in a home-based intervention similar to the one reported here. Alternatively, the relaxation intervention could be introduced immediately before the colonoscopy on the day of the examination. Even without an explicit instruction to use the relaxation procedure during colonoscopy, a relaxation procedure administered immediately before the examination may produce differences in outcome measures. Under these conditions whether or not patients spontaneously used the relaxation procedures during colonoscopy, is also likely to have lasting effects on outcome measures.

Patients' preferences for health care did not differ significantly between groups, despite the measure being taken after the psychological preparation and colonoscopy examination. It is unclear whether this measure is sensitive to changes in patients' health opinions, or whether such opinions do in fact change as a result of relaxation interventions. An additional measure of coping style could be used in further studies to test for interaction effects, i.e., whether the psychological preparation patients receive has an effect on their experience of colonoscopy depending on their preferred coping style.

Although, the intervention conducted in this study was implemented with some success, i.e. patients appear to have complied sufficiently with the instructions and gained benefit from the relaxation tapes both before and during colonoscopy, the cost effectiveness of such a procedure needs to be considered. In particular, costs of administration and of tapes lost or
not returned need to be taken into account. Furthermore, listening to the tapes at home, especially the 'relaxation plus control' tape, may act as an unpleasant reminder of the forthcoming colonoscopy examination and so patients may fail to comply in terms of the intended frequency of self-exposure to the intervention in the days before their examination. To avoid some of these costs and limitations a second study was planned where patients were recruited on the day of colonoscopy and given one of two relaxation procedures to listen to whilst waiting for their colonoscopy examination. This study is described in the next chapter. Administering the relaxation tapes immediately prior to the colonoscopy allows a further investigation of possible differences in the effectiveness of the 'relaxation alone' and the 'relaxation plus control' tapes when the levels of pre-examination utilization of the tapes is high. In addition, the comparison of the STAI and VAS measures of state anxiety can be further explored in a study of this sort in the context of two very different levels of anxiety, immediately before and after a colonoscopy examination.
Chapter overview

This chapter explores a number of methodological issues, in particular perceived control scales and coping style. Then the second study, which extends the previous study by giving patients a psychological intervention immediately before their colonoscopy examination, is described.

7.1 Background

Fear of loss of control appears to be an important factor in perioperative anxiety and other stressful situations and, conversely, a feeling of being in control has been associated with an increased tolerance for pain and discomfort (Egan, 1990; Thompson, 1981). As noted in Chapter 1, control over a stressor reduces its negative effects on the individual. In particular, an increase in participation and the availability of choice often lead to increases in perceived control, and individuals may believe that they can alter or affect outcomes (Averill, 1973; Seligman, 1975). However, studies also suggest that there are not always direct beneficial effects of providing control (Averill, 1973; Mills and Krantz, 1979). This is also supported by research indicating that individuals perform better in stressful situations where there is congruence between their expectations for control and the actual control they have in that particular situation (e.g., Houston, 1972; Shipley et al., 1979).

The Multiple Health Locus of Control scale (MHLC; Wallston, Wallston and DeVellis, 1978) has been widely used to characterise an individual's beliefs about control over health outcomes (Anderson, DeVellis, Sharpe and Marcoux, 1994). The MHLC has three components relating to patients' beliefs of control: 'Internal' - where the individual claims to take control over his or her health; 'Chance' - where the individual believes that chance or fate plays a big part in influencing his or her health; and 'Powerful Others' - referring to the belief that medical staff or others looking after the needs of the individual are responsible for his or her health. There are also other locus of control scales which have been used in health care settings. One of the first was the Health Locus of Control scale (HLC; Wallston, Wallston, Wallston, and DeVellis, 1978).
Kaplan and Maides, 1976), which has one dimension only, internal/external locus of control, and reflects the original general locus of control scale (Rotter, 1966). Lau and Ware's (1981) Health Specific Locus of Control is another widely used general health locus of control scale and has four factors: Chance Health Outcomes, General Health Threat, Self Control and Provider Control over health. Furnham and Steele (1993) provide a critical review of all the different types of locus of control scales including general, children's and work-related, as well as the variety of health related locus of control questionnaires.

There has been some debate over the best ways to construct and score locus of control scales. Kellner and Uhlenhuth (1991) have suggested that the optimal number of response options for self-rating scales in general is between two and four, provided that the scale has several items. They argue that by reducing the range of response options for each item decreases errors. McCallum, Keith and Wiebe (1988) have shown that the use of two levels of response (agree or disagree) with the Multidimensional Health Locus of Control scale produced comparable results to the standard six-level format, ranging from 1 (strongly disagree) to 6 (strongly agree). A format with more than two levels of response choice per item requires a two stage response, first, the subjects have to decide whether they agree or disagree with the item in question, and secondly, the extent to which they agree or disagree with it. The two-level response format has also been shown to be effective in the classification of subjects into groups (McCallum et al., 1988) and was used in the present study.

The Health Opinion Survey (HOS; Krantz, Baum and Wideman, 1980) has a behavioural and an information sub-scale and claims to measure attitudes or preferences in relation to health care. The MHLC, in contrast, assesses beliefs or expectancies. In addition, the MHLC items focus on health as an outcome, while the HOS concentrates on the health-care delivery process (Krantz et al., 1980; Wallston, Smith, King, Forsberg, Wallston and Nagy, 1983). However, despite the apparently separate aims of the two scales Wallston et al. (1983) looked at the relationship between the MHLC and HOS they found an overlap, especially with the 'Powerful Others' component of the HLC and the 'Behavioural' sub-scale of the HOS. This negative correlation has also been reported by others (e.g., Dinning and Cramptom, 1989; Robson-Whelen and Storandz, 1992) and can be explained by the
assumption that the more individuals believe their health is controlled by powerful others the less likely they are to prefer, or to desire, active behavioural involvement in their own medical care. The reason that Krantz et al. (1980) found little overlap between their HOS measure and the earlier, unidimensional HLC, is most likely because the 'Powerful Others' component of the MHLC scale was absent from the original HLC scale.

The two main scales that measure coping style are the Repression-Sensitization Scale (Byrne, 1961) and the Miller Behavioural Style Scale (MBSS; Miller, 1987). The Repression-Sensitization scale separates individuals on the basis of their coping styles as 'repressors' or 'sensitizers'. Repressors superficially appear non-anxious and deal with impending stress by repression or denial. Sensitizers, in contrast, are overtly anxious and alert to threatening cues and tend to seek information about a stressor as a means of preparing themselves for it. The MBSS divides individuals in a similar way: into 'monitors' or 'blunters'. Monitors may be classed as high or low, depending whether they seek or avoid information, respectively. Blunters seek distractions when dealing with a threatening situation. Again blunters may be high or low, depending on the extent of distraction sought. Further discussion on coping styles can be found in Schultheis, Peterson and Selby (1987).

The Social Desirability scale (Crowne and Marlow, 1960) is widely used in questionnaire studies to identify subjects who respond to questions in a 'socially desirable' way or with the intention of pleasing the investigator. Furnham (1986) reports that recent evidence suggests that social desirability is a trait rather than a state characteristic, in response to a specific situation. Like other scales there have been a number of attempts to reduce the number of items on the scale (e.g., Strahan and Gerbasi, 1972). The Social Desirability scale has also been used to address some problems associated with the Repression-Sensitization scale and to identify those who repress anxiety (Fox, 1992). An important limitation of the Repression-Sensitization scale is that it has been found to correlate highly with trait anxiety measures (Watson and Clark, 1984) and so does not distinguish between repression and anxiety. Furthermore, anxiety and Repression-Sensitization scales cannot identify those patients who are truly low in anxiety as distinct from those who are repressing their anxiety (Fox, 1992). Trait anxiety measures and the social desirability scale have been used to make this distinction: 'truly low anxious' patients score low on both the anxiety and social desirability
scales, whereas 'repressors' report low trait anxiety but tend to score high on the social desirability scale (Fox, O'Boyle, Lennon, and Keeling, 1989; Weinberger, Schwartz and Davidson, 1979). Two other groups can also be identified, those who score high on trait anxiety and low on social desirability have been classified as 'sensitizers' and those who score high on both scales have been classified as 'non-specific defenders' (Fox, O'Boyle and Lennon, 1987). Therefore the Social Desirability Scale was used in this study.

The study described in Chapter 6 was one where patients were given a home-based relaxation procedure. However, as already noted, the cost-effectiveness of such a procedure could be questioned. In particular, there are relatively high administration costs, and the expense of tapes lost or not returned, as well as the failure of some patients to use the tapes effectively without direct supervision need to be taken into account. Other studies have shown effective use of a single session of relaxation on patients undergoing UGI endoscopy (Gatusso et al., 1992; Wilson et al., 1982) or day-case surgery (Markland and Hardy, 1993). Furthermore, Fourie and Nell (1990) found that a brief 10 minute intervention was more effective in reducing patient stress prior to a gastroscopy examination than a detailed intervention consisting of information and coping mechanisms lasting 40 minutes. Therefore, it seems possible that a single relaxation session immediately prior to the endoscopy procedure might be enough to produce a difference between the relaxation and control groups.

In addition to reducing administrative and running costs a further advantage of conducting a study where the intervention is supervised on the premises of the hospital, is that the investigator can ensure that subjects do in fact listen to the tapes, and is also able to assess their immediate effects. It was predicted that the relaxation procedure would have beneficial effects during the colonoscopy examinations as well as in the immediate waiting period.

As in the previous study the two relaxation procedures were 'relaxation alone' and 'relaxation plus control' as described in Chapter 4. An attention control group was also included for comparison to control for the fact that patients were taken into a separate room and given a tape to listen to. Outcome measures were as before, with the additional measure of the attending nurses' assessment of patients' tolerance of the examination as well as measures of
Multiple Health Locus of Control and Social Desirability mentioned above. In view of the
difficulties of ensuring a consistent regime of initial medication encountered in the previous
study, it was decided that the routine pre-medication for the present study should consist of
half the normal dose of analgesia and sedation, with or without an anti-spasmodic, depending
on the preferences of the endoscopist conducting the examination. This was chosen as it was
considered to be in accordance with the expectations of patients and the preferred practices
of doctors, and so it was expected that a greater level of compliance would be achieved.

The aims of this study were: i) to compare the relaxation procedures with an attention control
group as well as a non-intervention control group; ii) to compare two types of relaxation
procedures, with and without control instructions; and iii) to test whether a single session of
relaxation is as effective as the repetitive relaxation practice programme used in the previous
study.

7.2 Methods

7.2.1 Subjects

Of 100 eligible patients 92 consented to take part in the study. Patients were excluded from
this study if their previous examination was technically difficult or if they had undergone
surgery to have part of their bowel resected. Four patients were dropped from the study
because there was no time to carry out the intervention before their colonoscopy
examination. Patients' ages ranged from 23 to 80 years with a mean of 50. Forty one (47%)
patients were male and 53 (62%) had previous experience of colonoscopy. Reasons for
colonoscopy were as follows: family history of cancer (23%); family history of polyps (8%);
diagnosed ulcerative colitis or Crohn's disease (32%); previous diagnosis of polyps (24%);
previous diagnosis of cancer (6%); symptoms, such as rectal bleeding or anaemia (5%); and
two patients had a stricture (2%). Concerning employment status, the subjects described
themselves as employed or self-employed (65%); retired (26%); students (1%) and
unemployed or taking care of the home (8%). Subjects were asked to classify their current
or last employment if presently retired or unemployed. Eight (9%) subjects failed to complete
this question, some because they were not previously employed. Those who were or had been employed classed their current or previous status as professional/managerial (48%); skilled technical (10%); clerical or shopwork (28%); skilled manual (6%) and unskilled manual (9%). Fifty three percent had previous relaxation, or similar, experience.

7.2.2 Materials

Materials used consisted of a Sony WM-D6C cassette-player with headphones, the relaxation tapes described in Chapter 4, a recording of a mythical narrative, "The dream of the emperor Maxen" (Delaney, 1989), used for the attention control group, an information sheet, a consent form and the following questionnaires:

**Questionnaire 1** comprised of the original STAI-trait (Spielberger, Gorsuch and Lushene, 1970), the short form STAI-state (Marteau and Bekker, 1992) and further state anxiety measures in the form of visual analogue scales (VAS) - Mood Scale;

**Questionnaire 2** consisted of the short form STAI-state, Mood Scale and additional VAS items asking patients (who had listened to a tape) how effective the tapes were in helping them to feel 'relaxed', 'in control', 'confident' and 'more able to cope';

**Endoscopy Questionnaire** comprised of pulse recordings, duration of the procedure, amount of sedation and analgesia required, the endoscopists' assessment of the technical difficulty, and patients' tolerance, of the colonoscopy examination and the nurses' assessment of the patients' tolerance of the examination;

**Post-Colonoscopy Questionnaire** consisted of i) the short form STAI-state and Mood Scale; ii) the Post-colonoscopy Questionnaire of Salmon, Shah, Berg and Williams (1994), which has three components of patients' experience of colonoscopy: emotional distress, physical discomfort and satisfaction; iii) the Health Opinion Survey (Krantz et al., 1980), which has two components: desire for information and involvement in medical care; iv) a Health Locus of Control questionnaire (Wallston, Wallston and DeVellis, 1978), which is comprised of three components: powerful others, internal locus of control and chance; v) a shortened version of the Social Desirability Scale (Strahan and Gerbasi, 1972) which measures the extent to which subjects truthfully respond to questions, claiming to identify those who respond in a socially desirable manner, and; vi) additional questions regarding
previous experience of colonoscopy, similar medical procedures and relaxation, demographic information, how helpful they found what they heard on the tape, how effective the tapes were in helping them to feel 'relaxed', 'in control', 'confident' and 'more able to cope' during the colonoscopy and any benefits or drawbacks of taking part in the study.

The transcript of the attention control tape, all questionnaires and forms used in this study are included in Appendix C.

7.2.3 Procedure

This study was commenced at St Mark's Hospital, City Road and continued at Northwick Park Hospital, Harrow, once St Mark's had moved there in July 1995. Once patients had been seen by a nurse and had put on a hospital gown, they were invited to take part in the study if there was then enough time to conduct the intervention before they would be called for their colonoscopy examination. Patients were randomly allocated to treatment groups using random number tables to ensure that there was no systematic bias. However, it is possible that patients who arrived early for their appointment or those who followed a particularly difficult case were more likely to be recruited into the study. Patients were given the information sheet and consent form. Further explanation regarding the study was also provided, if requested. Once patients gave their consent to take part in the study, they filled in Questionnaire 1. Those allocated to one of the intervention, or attention control, groups were led to a room, where they would not be disturbed, to listen to the audio tape. Once the intervention was complete, subjects filled in Questionnaire 2 and waited to be called in for their examination. Waiting times varied from one minute to 68 minutes.

For the majority of cases (76%) the colonoscopy examination was commenced, as proposed, with half-dose medication. Three patients refused any form of sedation, two patients were given more than the standard medication and the remainder received the usual dose of 50mg of pethidine, 5mg of midazolam (Hypnovel) and 20mg of hyoscine-N-butyl bromide (Buscopan). Additional medication of sedation and/or analgesia were administered as required. The four endoscopists and nine nurses, who completed the questionnaires in this study, were unaware as to which of the four groups each patient was allocated.
Observational and physiological measures were taken by the endoscopist and nurse during, or immediately following the examination (Endoscopy Questionnaire). Further questionnaires (Post-Colonoscopy Questionnaire) were administered to the patients afterwards, once they had left the recovery area and were dressed. On completion of the questionnaires patients were asked for any comments and thanked for taking part.

7.2.4 Statistical analysis

The relationship between Mood Scale and the state component of the STAI was checked using Pearson product-moment correlation coefficients. Principal components factor analysis was carried out on all the anxiety measures. Data were screened and multiple analysis of variance (MANOVA), Kruskal-Wallis and Chi-square tests were used to check that the four groups did not significantly differ in background variables.

Analysis of covariance (ANCOVA) was used to test the immediate effects of the tapes on anxiety levels and MANOVA was used to test for differences in the effectiveness of the tapes. Hierarchical multiple regression analysis was used to explore which variables, including group contrasts predicted the outcome measures. Contrast 1 compared the non-intervention control group with the three tape groups together, Contrast 2 compared the attention control group with the two relaxation groups together and Contrast 3 compared the two relaxation interventions. To test for interaction effects multiplicative terms were also included in the regression equation (Cohen and Cohen, 1983).

Whether self-initiated implementation of relaxation during the examination was associated with particular interventions was tested with a Chi-square test. Kruskal-Wallis one-way analysis of variance by ranks was used to test whether participation in this study and perceived helpfulness of the tapes (both before and during the colonoscopy) were associated with the interventions. Follow-up comparisons to the Kruskal-Wallis tests were made using the standard procedure (Siegal and Catellan, 1988). Finally, MANOVA was used to investigate differences in health and social desirability beliefs and a Pearson product-moment correlation coefficient was used to check the association between Powerful Others health locus of control and the desire for involvement in medical care.

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1 The issue of inter-rater reliability is an important one and has been addressed in Section 5.2.
7.3 Results

Prior to analysis, all variables were examined through various SPSS for Windows programs for accuracy of data entry and missing values. The variables were examined separately for the 23 subjects in the 'relaxation alone' intervention, the 21 subjects in the 'relaxation plus coping' group the 20 subjects in the attention control group and the 24 subjects in the non-intervention control group. Despite missing data for some of the subjects, (3 failed to return the Post-Colonoscopy Questionnaire, 2 patients, allocated to the control group, were called in to their examination before filling in the state anxiety measures at Time 2, and the Endoscopy Questionnaire for one patient was misplaced) all cases were left in the analysis.

7.3.1 Anxiety measures

Table 7.1 shows the correlation coefficients between the VAS and STAI state anxiety taken before the psychological intervention (Time 1), \( r(86) = 0.813 \), immediately after the intervention (Time 2), \( r(84) = 0.782 \), and after the colonoscopy examination (Time 3), \( r(83) = 0.700 \). Both measures were significantly correlated on each of the three occasions, all \( p < 0.001 \).

<table>
<thead>
<tr>
<th></th>
<th>STAI - state</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mood Scale - VAS</td>
<td>Time 1(^a)</td>
</tr>
<tr>
<td>Time 1</td>
<td>0.813**</td>
</tr>
<tr>
<td>Time 2</td>
<td>0.702**</td>
</tr>
<tr>
<td>Time 3</td>
<td>0.174</td>
</tr>
</tbody>
</table>

\(* p < 0.05 \quad ** p < 0.001\)
\(^a n = 88 \quad ^b n = 86 \quad ^c n = 85\)

As the two anxiety measures were highly correlated, a factor analysis on the eight items was conducted and a single factor accounted for 56% of the variance. Combining the measures
resulted in a single score with an alpha coefficient of 0.88. The factor loadings are listed in Table 7.2. The raw variables were combined and the factor score coefficients were used to calculate the corresponding anxiety measures taken on each of the three occasions. These newly created 'overall anxiety' measures were used for the rest of the analyses.

Table 7.2: Factor analysis loadings and alpha coefficients on the anxiety items

<table>
<thead>
<tr>
<th>Item</th>
<th>Factor loadings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spielberger (Short-form)</td>
<td></td>
</tr>
<tr>
<td>I feel calm</td>
<td>-0.82</td>
</tr>
<tr>
<td>I feel tense</td>
<td>0.78</td>
</tr>
<tr>
<td>I feel upset</td>
<td>0.49</td>
</tr>
<tr>
<td>I am relaxed</td>
<td>-0.78</td>
</tr>
<tr>
<td>I am content</td>
<td>-0.67</td>
</tr>
<tr>
<td>I am worried</td>
<td>0.72</td>
</tr>
<tr>
<td>VAS</td>
<td></td>
</tr>
<tr>
<td>To what extent do you feel calm?</td>
<td>-0.88</td>
</tr>
<tr>
<td>To what extent do you feel anxious?</td>
<td>0.78</td>
</tr>
</tbody>
</table>

7.3.2 Background variables

Treatment groups were not significantly different in terms of the following background variables: age, previous number of colonoscopy examinations, trait anxiety, state anxiety at Time 1, time spent waiting for the examination and the type of premedication administered beforehand, Wilks' Lambda = 0.81, approximate F(21,202) = 0.71, ns, sex, \( \chi^2(3) = 0.73, ns \), indication, \( \chi^2(6) = 1.37, ns \), previous relaxation experience, Kruskal-Wallis test, \( \chi^2(3) = 7.28, ns \), marital status, \( \chi^2(3) = 0.72, ns \), whether employed, \( \chi^2(3) = 2.36, ns \), and social status, Kruskal-Wallis test, \( \chi^2(3) = 3.26, ns \), and which endoscopist carried out the examination \( \chi^2(9) = 7.49, ns \). Table 7.3 gives the means and standard deviations or frequencies of the background variables for each of the four groups.
Table 7.3: Means and standard deviations or frequencies of background variables for each of the four groups

<table>
<thead>
<tr>
<th></th>
<th>Control group</th>
<th>Attention control</th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean  sd</td>
<td>mean  sd</td>
<td>mean  sd</td>
<td>mean  sd</td>
</tr>
<tr>
<td>Age</td>
<td>50.7 15.8</td>
<td>46.8 14.26</td>
<td>50.5 14.5</td>
<td>52.1 13.5</td>
</tr>
<tr>
<td>Previous colonoscopy examinations</td>
<td>2.61 2.37</td>
<td>1.9 3.11</td>
<td>1.86 2.26</td>
<td>1.24 2.02</td>
</tr>
<tr>
<td>Waiting time</td>
<td>24.4 18</td>
<td>23.6 17.82</td>
<td>17.7 12.3</td>
<td>26.2 20.7</td>
</tr>
<tr>
<td>Pre-medication</td>
<td>1.54 0.88</td>
<td>1.6 0.88</td>
<td>1.78 1.13</td>
<td>1.55 0.89</td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>40 8.44</td>
<td>36 8.02</td>
<td>39.1 8.59</td>
<td>39 9.5</td>
</tr>
<tr>
<td>State anxiety</td>
<td>18.2 9.58</td>
<td>16.2 9.32</td>
<td>17.8 8.91</td>
<td>18.8 10.8</td>
</tr>
<tr>
<td>Social desirability</td>
<td>16.7 1.86</td>
<td>17.5 1.96</td>
<td>16.8 2.2</td>
<td>16.9 1.65</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Attention control</th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12 (50%)</td>
<td>10 (50%)</td>
<td>9 (39%)</td>
<td>10 (48%)</td>
</tr>
<tr>
<td>Female</td>
<td>12 (50%)</td>
<td>10 (50%)</td>
<td>14 (61%)</td>
<td>11 (52%)</td>
</tr>
<tr>
<td>Indication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crohn's disease</td>
<td>9 (38%)</td>
<td>6 (30%)</td>
<td>6 (26%)</td>
<td>8 (38%)</td>
</tr>
<tr>
<td>Screening</td>
<td>7 (29%)</td>
<td>8 (40%)</td>
<td>7 (30%)</td>
<td>5 (24%)</td>
</tr>
<tr>
<td>Cancer</td>
<td>7 (29%)</td>
<td>6 (30%)</td>
<td>6 (26%)</td>
<td>7 (33%)</td>
</tr>
<tr>
<td>Symptoms*</td>
<td>1 (4%)</td>
<td>0</td>
<td>2 (9%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Stricture*</td>
<td>0</td>
<td>0</td>
<td>2 (9%)</td>
<td>0</td>
</tr>
<tr>
<td>Previous relaxation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>16 (70%)</td>
<td>12 (60%)</td>
<td>6 (29%)</td>
<td>6 (29%)</td>
</tr>
<tr>
<td>1</td>
<td>3 (13%)</td>
<td>4 (20%)</td>
<td>10 (48%)</td>
<td>12 (57%)</td>
</tr>
<tr>
<td>2</td>
<td>4 (17%)</td>
<td>2 (10%)</td>
<td>2 (9%)</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>3+</td>
<td>0</td>
<td>2 (10%)</td>
<td>3 (14%)</td>
<td>0</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>7 (30%)</td>
<td>8 (42%)</td>
<td>8 (38%)</td>
<td>7 (33%)</td>
</tr>
<tr>
<td>Married</td>
<td>16 (70%)</td>
<td>11 (58%)</td>
<td>13 (62%)</td>
<td>14 (67%)</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>15 (65%)</td>
<td>15 (75%)</td>
<td>14 (67%)</td>
<td>11 (52%)</td>
</tr>
<tr>
<td>Not employed</td>
<td>8 (35%)</td>
<td>5 (25%)</td>
<td>7 (33%)</td>
<td>10 (48%)</td>
</tr>
<tr>
<td>Social status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>3 (14%)</td>
<td>2 (11%)</td>
<td>1 (5%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>II</td>
<td>3 (14%)</td>
<td>1 (5%)</td>
<td>1 (5%)</td>
<td>0</td>
</tr>
<tr>
<td>III</td>
<td>6 (27%)</td>
<td>6 (32%)</td>
<td>5 (26%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>IV</td>
<td>2 (9%)</td>
<td>1 (5%)</td>
<td>1 (5%)</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>V</td>
<td>8 (36%)</td>
<td>9 (47%)</td>
<td>11 (58%)</td>
<td>10 (50%)</td>
</tr>
<tr>
<td>Endoscopist</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#1</td>
<td>14 (58%)</td>
<td>12 (60%)</td>
<td>11 (48%)</td>
<td>9 (43%)</td>
</tr>
<tr>
<td>#2</td>
<td>5 (21%)</td>
<td>2 (10%)</td>
<td>2 (8%)</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>#3</td>
<td>3 (13%)</td>
<td>3 (15%)</td>
<td>5 (22%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>#4</td>
<td>2 (8%)</td>
<td>3 (15%)</td>
<td>5 (22%)</td>
<td>7 (33%)</td>
</tr>
</tbody>
</table>

* due to low frequencies these categories were not included in the Chi-square analyses
7.3.3 Immediate effects of the interventions

Between-group ANCOVA carried out to test the effectiveness of the tapes on anxiety levels, with the baseline anxiety level (Time 1) as the covariate, showed a group effect, $F(3,83) = 4.97, p < 0.005$. Figure 7.1 illustrates the mean scores of the overall state anxiety measures at Time 1 and Time 2. *A priori* contrasts consisted of the following coefficients: Control group = 3, Attention control = -1, 'Relaxation alone' = -1, and 'Relaxation plus control' = -1 for Contrast 1; Control group = 0, Attention control = 2, 'Relaxation alone' = -1, and 'Relaxation plus control' = -1 for Contrast 2; and Control group = 0, Attention control = 0, 'Relaxation alone' = 1, and 'Relaxation plus control' = -1 for Contrast 3. Planned contrasts on the difference between the overall anxiety scores at Times 1 and 2 indicate a difference between the non-intervention control group and the three intervention groups combined, $t(82) = -3.22, p < 0.005$, but not between the attention control group and both relaxation groups, $t(82) = -1.00, ns$, nor between the two relaxation groups, $t(82) = -0.56, ns$.

**Figure 7.1: Mean overall anxiety scores taken before (Time 1) and after (Time 2) the intervention**

Error bars represent 95% confidence intervals.
A between-group MANOVA was carried out to test for differences between perceived effectiveness of the tapes in helping subjects to feel 'relaxed', 'in control', 'confident' and 'more able to cope'. Only subjects who listened to a tape were included in this analysis, N = 64. Figure 7.2 shows the mean scores for the three intervention groups to be towards the upper end of the possible range of responses (0-100). Multivariate tests failed to show a significant difference between the items, Wilks' Lambda = 0.86, exact $F(8,114) = 1.12$, ns. Despite the lack of significance it is, nevertheless, worth noting that the trend on all four measures was the same, with the lowest scores in the attention control group and the highest scores in the 'relaxation plus control' group.

**Figure 7.2: Mean scores of items concerning the effectiveness of the interventions**

Error bars represent 95% confidence intervals

---

7.3.4 Experience of colonoscopy

In order to address whether subjects differed in their experience of colonoscopy and at the
same time control for individual differences and differences in medication received, hierarchical multiple regression analysis was conducted. Variables yielding significant first-order Pearson correlations with the outcome variable and other important variables were entered at the first step and consisted of: age, sex, state anxiety at Time 1, social desirability, and the total amount of analgesia received, time taken to reach the caecum and whether patients attempted to use a relaxation procedure during their colonoscopy. Other, similar variables were also correlated with the outcome measure and were not included because they were highly correlated with the variables already included in the equation. Excluded variables consisted of state anxiety at Time 2, amount of additional analgesia, total sedation and amount of additional sedation received. How effective patients thought the use of a relaxation procedure during the examination was also correlated with total experience but was not included in the equation as only 35 (40%) subjects reported using relaxation during their colonoscopy examination and therefore the remaining 60% were not able to respond to this item.

Trait anxiety and social desirability were entered at Step 2 and the three contrasts were entered at Step 3. Contrast 1 compared the control group with the attention control and both relaxation groups, Contrast 2 compared the attention control group with the two relaxation groups and Contrast 3 compared the 'relaxation alone' group with the 'relaxation plus control' group. The coefficients reported in Section 7.3.3 were used for these a priori contrasts. To provide a measure of coping style, the interaction of 'trait anxiety by social desirability' was entered at Step 4. Next, each 'Contrast' was multiplied by 'Social desirability' and then by 'Trait anxiety', producing 6 two-way interaction variables. These were entered at Step 5. Finally, to test for an interaction between group membership and coping style, Contrasts 1, 2 and 3 were each multiplied by the previously multiplied variable of 'Trait anxiety by Social desirability' and these three-way interactions were entered at Step 6. Table 7.4 displays the unstandardized regression coefficients (b), the standardized regression coefficients (β) and the t scores after entry of 21 background, personality, contrast and interaction variables. R was significantly different from zero at the end of each step.

An interesting question is whether each step adds a significant contribution to the equation after the variables in the previous step have been accounted for. The following paragraphs give a detailed account of such contributions following each step.
### Table 7.4: Regression of demographic and examination variables, contrasts and interactions on experience of colonoscopy

<table>
<thead>
<tr>
<th>Variables</th>
<th>$b$</th>
<th>$\beta$</th>
<th>$t^\dagger$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.008</td>
<td>0.11</td>
<td>1.14</td>
</tr>
<tr>
<td>Sex</td>
<td>0.214</td>
<td>0.11</td>
<td>1.15</td>
</tr>
<tr>
<td>Step 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>State anxiety (Time 1)</td>
<td>-0.031</td>
<td>-0.30</td>
<td>-3.07**</td>
</tr>
<tr>
<td>Total analgesia</td>
<td>-0.022</td>
<td>-0.40</td>
<td>-4.34**</td>
</tr>
<tr>
<td>Time taken to reach the caecum</td>
<td>-0.021</td>
<td>-0.24</td>
<td>-2.60*</td>
</tr>
<tr>
<td>Whether relaxation was used during colonoscopy</td>
<td>0.007</td>
<td>0.01</td>
<td>0.14</td>
</tr>
<tr>
<td>Step 2*‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>0.022</td>
<td>0.19</td>
<td>1.72</td>
</tr>
<tr>
<td>Social desirability</td>
<td>0.037</td>
<td>0.14</td>
<td>1.36</td>
</tr>
<tr>
<td>Step 3*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contrast 1</td>
<td>-0.022</td>
<td>-0.039</td>
<td>-0.42</td>
</tr>
<tr>
<td>Contrast 2</td>
<td>0.089</td>
<td>0.11</td>
<td>1.10</td>
</tr>
<tr>
<td>Contrast 3</td>
<td>-0.159</td>
<td>-0.11</td>
<td>-1.23</td>
</tr>
<tr>
<td>Step 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety x Social desirability</td>
<td>0.001</td>
<td>0.03</td>
<td>0.06</td>
</tr>
<tr>
<td>Contrast 1 x Social desirability</td>
<td>0.004</td>
<td>0.01</td>
<td>0.04</td>
</tr>
<tr>
<td>Contrast 2 x Social desirability</td>
<td>0.013</td>
<td>0.22</td>
<td>0.63</td>
</tr>
<tr>
<td>Step 5**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contrast 3 x Social desirability</td>
<td>0.034</td>
<td>0.33</td>
<td>1.21</td>
</tr>
<tr>
<td>Contrast 1 x Trait anxiety</td>
<td>0.001</td>
<td>0.08</td>
<td>0.17</td>
</tr>
<tr>
<td>Contrast 2 x Trait anxiety</td>
<td>-0.010</td>
<td>-0.46</td>
<td>-0.95</td>
</tr>
<tr>
<td>Contrast 3 x Trait anxiety</td>
<td>0.035</td>
<td>1.00</td>
<td>2.24*</td>
</tr>
<tr>
<td>Step 6**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contrast 1 x Trait anxiety x Social desirability</td>
<td>0.003</td>
<td>3.21</td>
<td>1.82</td>
</tr>
<tr>
<td>Contrast 2 x Trait anxiety x Social desirability</td>
<td>0.003</td>
<td>2.22</td>
<td>1.53</td>
</tr>
<tr>
<td>Contrast 3 x Trait anxiety x Social desirability</td>
<td>-0.001</td>
<td>-0.50</td>
<td>-0.29</td>
</tr>
</tbody>
</table>

* $p < 0.05$   ** $p < 0.005$

$^\dagger$ Step 1 simultaneously takes all variables in Step 1 into account; Step 2 takes all variables in Steps 1 and 2 into account; Step 3 takes all variables in Steps 1, 2 and 3 into account; Step 4 takes all variables in Steps 1, 2, 3, and 4 into account; Step 5 takes all variables in Steps 1, 2, 3, 4, and 5 into account; and Step 6 takes all variables in Steps 1, 2, 3, 4, 5, and 6 into account.

$^\ddagger$ Where p values are included for a Step indicates the probability of a significant difference in $F$ value between the variables in that Step and the previous one.

After Step 1, with demographic and examination variables in the equation, $R^2 = 0.33$, $F(6,81) = 6.79$, $p < 0.0001$. State anxiety at Time 1, total analgesia and the time taken to reach the caecum were significantly related to patients' experience of colonoscopy. After Step 2, with
trait anxiety and social desirability added to the prediction of experience of colonoscopy to age, sex, total analgesia, time taken to reach the caecum, state anxiety at Time 1 and whether patients used relaxation during colonoscopy, $R^2 = 0.36, F(8,79) = 5.67, p < 0.0001$. The addition of these two personality variables to the equation resulted in an increase in $R^2, F(2,79) = 3.78, p < 0.05$ (difference between Step 1 and Step 2), indicating that when demographic and examination variables were controlled for these two variables added to the prediction of patients' experience of colonoscopy, although neither variable was significantly related to patients' experience of colonoscopy. After Step 3, with all three contrasts added to demographic, examination and personality variables, $R^2 = 0.38, F(11,76) = 4.37, p < 0.0001$. The addition of the three contrast variables to the equation resulted in an increase in $R^2, F(3,76) = 2.81, p < 0.05$ (difference between Step 2 and Step 3), indicating that when demographic, examination and personality variables were controlled for the contrast variables added to the prediction of patients' experience of colonoscopy. However, none of the contrasts was significantly related to patients' experience of colonoscopy.

After Step 4, with coping style (Trait anxiety x Social desirability) added to background, personality and group contrasts, $R^2 = 0.39, F(12,75) = 3.96, p < 0.0005$. The addition of coping style did not significantly improve $R^2, F(1,75) = 0.004, ns$ (difference between Step 3 and Step 4). After Step 5, with group contrasts and personality interactions added to demographic, examination, personality variables, contrasts and coping style, $R^2 = 0.44, F(18,69) = 3.07, p < 0.0005$. The addition of the 6 two-way interaction variables to the equation resulted in a significant increase in $R^2, F(6,69) = 7.10, p < 0.001$ (difference between Step 4 and Step 5), indicating that when background variables, group contrasts and coping style were controlled for the 'Contrasts by Trait anxiety' and 'Contrasts by Social desirability' interactions added to the prediction of patients' experience. 'Contrast 3 by Trait anxiety' interaction was significantly related to patients' experience of colonoscopy, indicating that there was a difference between the two relaxation groups, in terms of their trait anxiety. After Step 6 with all predictor, contrast and interaction variables in the equation, $R^2 = 0.48, F(21,66) = 2.95, p < 0.0005$, accounting for 32% of the variance. The addition of the three-way interaction between group and coping style significantly improved $R^2, F(3,66) = 5.10, p < 0.005$ (difference between Step 5 and Step 6).

To summarise, a positive experience of colonoscopy was associated with a low score of anxiety at Time 1, a low dose of total analgesia and a shorter procedure as measured by the
time taken to reach the caecum. Furthermore, the interaction of patients' trait anxiety score and allocation to either the 'relaxation plus control' group or to the 'relaxation alone' group was related to their experience of colonoscopy. Steps 2, 3, and 6 made a significant contribution to the equation despite the individual variables within these steps not being significantly associated with patients' experiences of colonoscopy.

The significant contribution of Step 3 indicates that there was a difference between the four groups. However, because the individual contrast variables were not significantly related to the outcome, these differences were not identified in the way the contrasts were set out. Patients' mean experiences of colonoscopy are illustrated in Figure 7.3. (The adjusted means were very similar to the raw means plotted below). To further explore possible group differences, post-hoc analyses were carried out. All possible comparisons were entered into the multiple regression equation at Step 3, after entry of the background and personality variables. The results indicate that the most significant contrast was the one which compared the attention control group with the 'relaxation alone' group, $t(80) = -1.513, p = 0.13$.

![Figure 7.3: Mean scores of patients' experiences of colonoscopy for each group](image)

Error bars represent 95% confidence intervals

* *a higher score represents a 'better' experience of colonoscopy*
In order to interpret the effect of 'Trait anxiety x Contrast 3' interaction found in Step 5, the corresponding regression lines and standard errors of the means were calculated and the scatter plots of the two relaxation groups were examined. These are presented in Figures 7.4 and 7.5.

**Figure 7.4: Scatter plot and regression lines of trait anxiety and patients' experience of colonoscopy for the 'relaxation alone' group**

![Figure 7.4](image)

**Figure 7.5: Scatter plot and regression lines of trait anxiety and patients' experience of colonoscopy for the 'relaxation plus control' group**

![Figure 7.5](image)
Figure 7.6 illustrates the interaction between these two groups without the raw scores. The reader's attention is directed to those scoring between 20 and 38 on trait anxiety. The two groups are significantly different within this range of trait anxiety as 38 is the point where the standard errors intersect. For patients who scored above 39 there is no difference between the groups. For simplicity these calculations were carried out without taking into account all the background variables. Figure 7.7 illustrates the interaction after adjusting for the background variables and is very similar to Figure 7.6. Thus, the point at which there are significant differences between the two relaxation groups is at the lower trait anxiety score of 36.

Figure 7.6: Interaction between trait anxiety and the contrast between the two relaxation groups on patients' experience of colonoscopy

The shaded areas indicate ±1 standard error of the predicted values

* a higher score represents a 'better' experience of colonoscopy
Figure 7.7: Interaction between trait anxiety and the contrast between the two relaxation groups on adjusted patients' experience of colonoscopy

The shaded areas indicate ±1 standard error of the predicted values

7.3.5 Use of relaxation

Thirty five (40%) of all patients reported using a relaxation procedure during their colonoscopy examination. Whether patients used relaxation was related to which group they were allocated, $\chi^2(3) = 15.06, p < 0.002$. Table 7.5 shows the number of patients who used relaxation in each of the four groups. Of those patients who used a relaxation procedure during their colonoscopy examination there was no difference between groups, on how effective they thought using such a procedure was, $F(3,28) = 0.53, ns$. Patients who listened to one of the relaxation tapes were asked two questions regarding whether they used a relaxation procedure during colonoscopy and whether it was the one used in this
study. Of those who reported using a relaxation procedure and responded to both questions (n = 25) 50% of patients in the 'relaxation alone' group and 73% of patients in the 'relaxation plus control' group said that they had used the relaxation procedure provided in this study.

When asked whether participating in the study helped them 75% of all patients reported that it did and the remaining 25% indicated that participation made no difference to their experience of colonoscopy. No patient reported that participating in the study made things worse for them. The corresponding numbers for each group are also shown in Table 7.5. There was no difference between the groups regarding their views on their participation in the study, Kruskal Wallis test, $\chi^2(3) = 4.50, ns$.

Table 7.5: Number of patients who used relaxation during their colonoscopy examination and responses to taking part in the study in each group

<table>
<thead>
<tr>
<th>Patients who used relaxation during colonoscopy</th>
<th>Control</th>
<th>Attention control</th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study helped a great deal</td>
<td>4 (17%)</td>
<td>6 (30%)</td>
<td>10 (48%)</td>
<td>15 (71%)</td>
</tr>
<tr>
<td>Study helped a little</td>
<td>6 (26%)</td>
<td>5 (25%)</td>
<td>8 (38%)</td>
<td>8 (38%)</td>
</tr>
<tr>
<td>Study made no difference</td>
<td>7 (30%)</td>
<td>10 (50%)</td>
<td>10 (48%)</td>
<td>10 (48%)</td>
</tr>
<tr>
<td></td>
<td>10 (43%)</td>
<td>5 (25%)</td>
<td>3 (14%)</td>
<td>3 (14%)</td>
</tr>
</tbody>
</table>

Following their examination patients, who listened to a tape, were asked how helpful the tapes were before and during their examination. Kruskal-Wallis tests indicated an almost significant difference between the three tape groups before, $\chi^2(2) = 6.80, p = 0.03$, and during colonoscopy, $\chi^2(2) = 6.28, p = 0.04$ (α level adjusted for the number of statistical tests and set at 0.025). The patients' responses to these two items are presented in Tables 7.6 and 7.7, together with the medians and mean ranks.
Table 7.6: Patients' responses to how helpful the tapes were before colonoscopy

<table>
<thead>
<tr>
<th>Helpfulness of the tapes</th>
<th>Attention control</th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - Not at all</td>
<td>6 (30%)</td>
<td>2 (10%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>1 - A little</td>
<td>4 (20%)</td>
<td>1 (5%)</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>2 - Moderately</td>
<td>5 (25%)</td>
<td>7 (33%)</td>
<td>4 (19%)</td>
</tr>
<tr>
<td>3 - Very much</td>
<td>4 (20%)</td>
<td>7 (33%)</td>
<td>11 (52%)</td>
</tr>
<tr>
<td>4 - Extremely</td>
<td>1 (5%)</td>
<td>4 (19%)</td>
<td>1 (5%)</td>
</tr>
</tbody>
</table>

*Median* 1 3 3  
*Mean rank* 23.25 36.55 34.31

Table 7.7: Patients' responses to how helpful the tapes were during colonoscopy

<table>
<thead>
<tr>
<th>Helpfulness of the tapes</th>
<th>Attention control</th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - Not at all</td>
<td>12 (70%)</td>
<td>9 (47%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>1 - A little</td>
<td>3 (18%)</td>
<td>3 (16%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>2 - Moderately</td>
<td>2 (12%)</td>
<td>3 (16%)</td>
<td>8 (40%)</td>
</tr>
<tr>
<td>3 - Very much</td>
<td>0</td>
<td>3 (16%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>4 - Extremely</td>
<td>0</td>
<td>1 (5%)</td>
<td>0</td>
</tr>
</tbody>
</table>

*Median* 0 1 1  
*Mean rank* 21 30.34 33.13

7.3.6 Health beliefs

As measures of health locus of control, the health opinion survey and social desirability were taken after the psychological intervention and colonoscopy examination, it is possible that, with the exception of social desirability, these views were influenced by the patients' experiences of colonoscopy and taking part in the study. The means and standard deviations
of these measures are displayed in Table 7.8. The four groups were not significantly different in their desire for information, involvement in their medical care and the three components on the Health Locus of Control Scale, Wilks’ Lambda = 0.83, Approximate $F(15,205) = 0.97$, $ns$.

Table 7.8: Means and standard deviations of health belief measures and social desirability for each group

<table>
<thead>
<tr>
<th></th>
<th>Control group</th>
<th>Attention control</th>
<th>Relaxation alone</th>
<th>Relaxation plus control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean</td>
<td>sd</td>
<td>mean</td>
<td>sd</td>
</tr>
<tr>
<td>Internal HLC</td>
<td>9.65</td>
<td>1.61</td>
<td>10.20</td>
<td>1.11</td>
</tr>
<tr>
<td>Powerful others HLC</td>
<td>9.17</td>
<td>1.50</td>
<td>8.30</td>
<td>1.59</td>
</tr>
<tr>
<td>Chance HLC</td>
<td>8.43</td>
<td>1.56</td>
<td>8.60</td>
<td>1.43</td>
</tr>
<tr>
<td>Desire for information</td>
<td>2.09</td>
<td>1.20</td>
<td>2.33</td>
<td>1.28</td>
</tr>
<tr>
<td>Desire for involvement</td>
<td>1.57</td>
<td>1.47</td>
<td>2.78</td>
<td>1.85</td>
</tr>
</tbody>
</table>

In line with previous findings a significant negative correlation was found between Powerful Others health locus of control and patients' desire for involvement in their own medical care, $r(81) = -0.392$, $p < 0.001$.

### 7.4 Discussion

As expected, the two types of state anxiety measures, STAI-state and the visual analogue Mood Scale, were highly correlated and provide support to the finding in the previous study, described in Chapter 6, that visual analogue measures of state anxiety can be regarded as a reliable measure. Unlike the previous study, both measures were administered when subjects were at their most anxious, before any intervention on the day of their colonoscopy examination and immediately following the intervention in addition to a measure of state
anxiety taken after the medical procedure. In confirmation that state anxiety VAS do in fact measure anxiety in a way comparable to the STAI-state, factor analysis yielded loadings on one factor, all of which were above 0.47. The combined scores produced a good alpha reliability coefficient.

Results indicated a significant difference between the groups in anxiety levels following the intervention. However, the tapes did not differ in their effectiveness in reducing anxiety in the three groups which listened to a tape. Thus, subjects listening to the mythical narrative also reported it to be effective in helping them to feel 'relaxed', 'in control', 'confident' and 'more able to cope'. Thus, it appears that an attention control condition in the form of distraction may help to reduce anxiety and increase a feeling of relaxation, control, confidence and ability to cope for patients waiting to undergo a colonoscopy. In contrast, Markland and Hardy (1993) did not find a reduction in pre-operative anxiety with their attention control procedure (a description of the history of the hospital). Of course whether any effects of the attention control procedures are observed may depend on the type of material used. Unfortunately, two studies which used relaxation with UGI endoscopy patients failed to include an attention control condition (Gatusso et al., 1992; Wilson et al., 1982).

A positive experience of colonoscopy was associated with a low anxiety score at Time 1, a lower dose of total analgesia received and a shorter duration of the colonoscopy examination. Thus, patients who have a lower level of anxiety on arrival at the endoscopy unit, receiving what was probably their optimum level of analgesia and having a quicker procedure (at least to reach the caecum) resulted in a good overall experience of colonoscopy. Conversely, patients who were more anxious at Time 1, received more total analgesia, possibly as a result of being more anxious during the examination, and had a longer procedure was associated with a poorer experience of colonoscopy. Despite these possible links which suggest a plausible explanation for differences in the experience of colonoscopy, anxiety score at Time 1 was not correlated with the total amount of analgesia received, although both were correlated with the outcome measure of overall experience of colonoscopy (which also included observational measures of the patients' tolerance by the endoscopist and attending nurse). This suggests that the total amount of analgesia administered to the patient was not
a direct result of the staff perceiving the patients as being anxious or in pain, although further measures of assessments by staff may be necessary to evaluate this.

Although the two sets of variables in Step 2 (Trait anxiety and Social desirability) and Step 3 (Contrasts 1, 2 and 3) were not significantly related to patients experience of colonoscopy individually, in combination they contributed to its prediction by being significantly different from the previous step. Thus, trait anxiety and social desirability almost reached significance on their own, but together were stronger in their contribution to the predicted outcome. The combined effect of the contrasts indicated that there may be a difference between the four groups, but this was not identified in the manner in which the a priori contrasts were constructed. However, post-hoc comparisons also failed to reveal a significant difference between the four groups. A graphical representation of the means of the outcome measure of each group, illustrated in Figure 7.3 helped to identify where the differences could be. Coping style (the 'Trait anxiety by Social desirability' interaction) also had no effect on patients' experience. That is, whether patients were repressors, truly low anxious, sensitizers or non-specific defenders had no bearing on their experience of colonoscopy. Thus, there were no main effects for group membership nor coping style in this study.

Of the six interactions in Step 5 only the 'Contrast 3 by Trait anxiety' interaction was significantly associated with the outcome measure, indicating that there was a difference between patients in the two relaxation groups, when their trait anxiety was taken into account. Thus, patients who scored low on trait anxiety were more likely to benefit from the 'relaxation plus control' tape compared with the 'relaxation alone' tape in their experience of colonoscopy. The slope in Figure 7.5 also suggests that the more anxious a patient was the less effective the 'relaxation plus control' tape in relation to his or her experience of colonoscopy. Thus, it appears that the less anxious a patient was the more able they were to make use of the 'relaxation plus control' tape to improve their experience of colonoscopy. This can be related to the stress and coping literature, where perceived stress, reflected in the anxiety measure, is related to the individual's available resources to cope with the stressor (Lazarus and Folkman, 1984; McGrath, 1970; Menaghan, 1983). Figure 7.4 indicates that the lower the patients' scores on trait anxiety the less effective the 'relaxation alone' tape in relation to their experience of colonoscopy. Figure 7.7 reveals that the difference between
the two relaxation group lies in those patients who scored between 20 and 36 on the Speilberger-Trait scale. Thus, low anxious patients benefitted from the ‘relaxation plus control’ tape, whereas there was no significant difference as a consequence of group membership for high anxious patients in terms of their colonoscopy experience.

The three Contrasts by Coping style interactions also contributed to patients' experience, despite no individual interaction being significantly associated with the outcome. Thus, there was no relationship between coping style and to which of the four groups patients were allocated as identified by the contrasts set out in the analyses, i.e. comparing the non-intervention control group with the three tape groups, the attention control with the two relaxation groups and finally, the two relaxation groups. This outcome is not consistent with the literature, in which interaction effects have been reported. The congruence theory, for example, predicts that those who repress their anxiety would benefit more from distraction, in the form of an attention control or a relaxation procedure (Gattuso et al., 1992), whereas those who are categorised as sensitizers would benefit from a coping enhancement with relaxation procedure (Gattuso et al., 1992). Sensitizers have also been found to benefit from the provision of information (Shipley et al., 1978, 1979; Wilson et al., 1982) and the addition of an information group in a future study may assist in clarifying this issue.

Despite initial success of the interventions in manipulating anxiety, group membership appears to have had no main effect on the experience of colonoscopy. This lack of difference, in contrast to the previous study, may be explained by the inclusion of an attention control group, thereby identifying the component responsible for the relaxation effect. However, even post-hoc analyses failed to identify a difference between any of the relaxation groups and the non-intervention control group. Listening to a narrative on tape, possibly as a result of distraction, was not significantly different in its effects from listening to a relaxation procedure. Markland and Hardy (1993) found both relaxation and attention control procedures equally effective in reducing the dose required for the maintenance of anaesthesia in surgical patients. Another explanation for the failure to find an effect of relaxation during the examination may be the lack of practice of the relaxation procedures in the present study. It is possible that for some medical procedures, where the patient is given conscious sedation and required to co-operate by changing position, a single session of relaxation is not enough
to show beneficial effects during the medical examination. It is worth recalling two studies, described in Chapter 2, where a single session of relaxation given to patients undergoing UGI endoscopy had a beneficial effect during the examination compared with a non-intervention control group in one study (Wilson et al., 1982). The second study failed to report beneficial effects of a relaxation alone procedure, but did report favourable effects of relaxation with self-efficacy enhancement compared with the remaining three groups (Gatusso et al., 1992).

Attempts to standardise initial medication were not totally successful and, in fact, the percentage of patients receiving the proposed dose was identical to those in the previous study. It appears that even with the usual medication procedure or doses, there would still be a few patients who refuse sedation or patients who would require more than the usual dose, such as those undergoing a colonoscopy for dilatation of a stricture. This needs to be taken into account in future studies. An alternative may be not to adjust the standard initial dose, but instead to use any dose variation as a covariate. Furthermore, a medical procedure where it is usual to give additional doses, depending on patients’ responses to the procedure, may be ‘easier’ to investigate, in that compliance to a different protocol is required.

The ‘relaxation plus control’ and, to a lesser extent, the ‘relaxation alone’ interventions were effective in encouraging patients to use the relaxation procedure during their colonoscopy examination. Low implementation of the relaxation procedures during colonoscopy may explain the lack of an overall difference between the four groups in their experience of colonoscopy. The percentage of patients who used relaxation in this study is comparable to that of the previous study (reported in Chapter 6), with a higher percentage of those in the ‘relaxation plus control’ group, and to a lesser extent those in the ‘relaxation alone’ group than patients in the control groups, as indicated in Table 7.5. It appears that the assumption that relaxation effects would have a lasting impact for those not deliberately using a relaxation procedure during colonoscopy were not upheld. This may be partly explained by the time some patients spent waiting to be called in for their examination, with the mean waiting time being longer than 20 minutes. Other studies, where patients are not conscious throughout the medical or surgical procedure, have found an effect of both attention control and relaxation groups (e.g., Markland and Hardy, 1993). Thus, a single session of a relaxation procedure may be more suited to a different type of medical or surgical procedure than the one used in
the present study.

Perceived control, as measured by Health Locus of Control scales, and patients' desire for information or involvement in their medical care did not appear to be affected by the interventions. There are a number of studies which have used Locus of Control scales as outcome measures (e.g., Wallston and Wallston, 1982) which implies that locus of control may be transitory rather than a trait characteristic and that such scales may be used to measure differences in attitude change. In line with previous findings a significant negative correlation was found between Powerful Others health locus of control and patients' desire for involvement in their own medical care (Dinning and Crampton, 1989; Wallston et al., 1983).

To summarise, there were immediate beneficial effects of listening to any of the tapes used in this study, regardless of content, in reducing anxiety compared with not listening to a tape. Regarding perceived effectiveness of the tapes, there were no differences between the three tape groups in helping the patients to feel 'relaxed', 'confident', 'in control' and 'more able to cope'. Patients' experience of colonoscopy was influenced by state anxiety at Time 1, the total amount of analgesia received and time taken to reach the caecum. Furthermore, there was a significant difference in colonoscopy experience between the two relaxation groups for those who reported a low score on trait anxiety (a group by trait anxiety interaction). It appears from the study described in this chapter and the one reported in Chapter 6 that for colonoscopy a home-based relaxation intervention is more effective than one carried out in a single session at the hospital on the day of the examination. Furthermore, both studies failed to show an overall difference between the two relaxation groups despite the inclusion of measures which refer to the experience as well as physiological measures. The second study also failed to show a difference between the relaxation groups and the two control groups, although an interaction between the two relaxation groups was found. As mentioned above, there is also a need to include more observational measures regarding patients' tolerance and behaviour during medical procedures. In addition, the expected interaction effects of coping style by group were not found, although the inclusion of an information group in a future study might help to demonstrate this interaction.
There are two major options for the progression of this research project: i) to continue exploring the nature of the difference between the two relaxation procedures in patients undergoing colonoscopy or ii) to test the already demonstrated effects of relaxation on a different patient population. The second of these was chosen and the next chapter reports interviews with patients undergoing two different endoscopy procedures.
Chapter overview

The objectives of conscious sedation for medical procedures, such as colonoscopy, are outlined in Chapter 4 and this chapter first of all explores possible explanations for differences in patient responses to benzodiazepine sedation. This is followed by an account of two preliminary studies. The first of these concerns interviews conducted with patients undergoing either upper gastrointestinal (UGI) endoscopy or endoscopic retrograde cholangiopancreatography (ERCP) in order to select a patient group for the next main study (Study 3). The second of these preliminary studies consists of an attempt to modify and validate the Post-Colonoscopy Questionnaire (Salmon et al., 1994), so that it can be applied to the chosen patient sample.

8.1 Responses to benzodiazepine sedation

Reaction to a drug is the result of a number of factors, such as the drug itself, the context in which the drug is administered, the expectations of the patient, the patient's emotional state and personality factors (Janke, Debus and Lange, 1979). The dose of the medication administered is another important factor of which the standard criterion is body weight. This is the case for all drugs, particularly anaesthetics. However, Claridge (1971) found that classification of individuals by psychophysiological measures into "nervous types" was more highly correlated with the amount of anaesthetic required for sedation than was body weight. Trait anxiety is an important modifier of the response to anxiolytic medication and for patients with high anxiety benzodiazepines reduce state anxiety (Janke, Debus and Lange, 1979). In contrast, patients who have low trait anxiety have shown a paradoxical increase in anxiety when some types of benzodiazepines are administered (e.g., Clyde, 1981; Parrott and Kentridge, 1982), particularly when doses are low (Barrett and DiMasio, 1966; Janke, Debus and Lange, 1979).

One explanation to account for differences in responses to benzodiazepine sedation is taken
from neuropsychology. Gray (1982) provides an account of the Behavioural Inhibition System (BIS) to explain individual differences in anxiety. The BIS receives inputs which warn the organism of novel and threatening stimuli. This in turn leads to increased arousal and attention, inhibition of ongoing behaviour and autonomic activation. Individuals with high trait-anxiety would have a system which responds to a relatively large number of stimuli as threatening or anxiety provoking in comparison to individuals with low trait-anxiety. Gray (1982) proposes that benzodiazepines act by reducing the activity of the BIS. A number of authors (e.g., Fox, 1992; Parrott and Kentridge, 1982) have suggested that the BIS operates differently in individuals whose trait anxiety is usually low compared with those who have high trait-anxiety and that this explains why there are differences in individual responses to benzodiazepines. Highly anxious individuals show a greater response to a stressor compared to those low in anxiety and by reducing the activity of the BIS their state anxiety is reduced. In low anxious individuals, where the processing of the BIS is adequate, benzodiazepines impair the workings of the BIS by affecting the individual's performance on some tasks (Parrott and Kentridge, 1982) and consequently increasing anxiety. This effect was found even when individuals had no tasks to perform (Barrett and DiMasio, 1966; Parrott and Kentridge, 1982). One explanation of this increase in anxiety is the accompanying feeling of loss of control (Janke et al., 1979; Fox, 1992; Parrott and Kentridge, 1982). This 'loss of control' explanation is similar to that used by Heide and Borkovec (1983) to account for relaxation-induced anxiety as described in Chapter 1.

An alternative explanation uses the understanding of repressive coping style, particularly when anxiety is repressed. Benzodiazepines can disinhibit behaviours that have been suppressed (e.g., Carlton, Siegel, Murphree and Cook, 1981), especially when administered in low doses. Fox (1992) argues that anxiety would then become disinhibited and this explains the paradoxical induction of anxiety in patients who are usually low in anxiety. Of course this explanation applies to patients who repress their anxiety and may not apply to those individuals who Fox (1992) and others have labelled as "truly low anxious". One study found that a benzodiazepine altered the state anxiety of repressors only slightly in comparison with the anxiety levels of sensitisers and patients with normal levels of trait anxiety (Ulsamer, Doenicke, Ott and Suttmann, 1983). However, this study did not distinguish between truly low anxious individuals and repressors, and so this theory has yet to be formally tested. No other studies which test the effects of benzodiazepines on coping style have been found.
8.2 Preliminary study 3: Interviews with patients undergoing UGI endoscopy and ERCP

8.2.1 Background

The typical procedure for a UGI endoscopy at the Middlesex Hospital involves patients receiving their appointments 2-4 weeks beforehand, with instructions to fast for 6 hours immediately before their planned endoscopy examination and to arrange transport home with an adult escort. Patients generally attend the endoscopy unit for UGI endoscopy as day cases, although in-patients are also referred to the endoscopy unit. Once in the endoscopy unit, patients are provided with the legally required information so that informed consent can be obtained. They are also given a choice of whether they will receive intravenous sedation or a local anaesthetic throat spray only and can decide immediately or think about their options until they are called for their examination. As mentioned in Chapter 3, patients who receive only a throat spray generally spend less time waiting in the recovery area, thus reducing the cost to the patient and the hospital.

Patients undergoing an ERCP are generally admitted to the hospital the day before, or the morning of, their scheduled appointment for ERCP and typically stay in hospital for approximately three days. Their hospital stay depends on whether further investigations or treatment are required. Patients from other hospitals in the South East also attend the endoscopy unit at the Middlesex Hospital for ERCP, as day cases. These patients are escorted by an additional nurse and are seen at the Middlesex Hospital for a variety of reasons, such as an absence of ERCP facilities at their own hospital or following previous failure of, or difficulty with, the ERCP procedure.

In contrast to UGI endoscopy patients, patients undergoing an ERCP at the Middlesex Hospital are generally more heavily sedated because the procedure is longer, complex and more uncomfortable. Also x-rays are taken during the ERCP procedure and this, plus the fine movements required of the physician conducting the procedure, mean that it is extremely important for the patient to keep still. Patients are given an initial dose of a benzodiazepine, an analgesic and an anti-spasmodic, with additional doses of any combination of these
depending on the duration of the procedure and the patient's tolerance of it. Prophylactic oxygen is administered to the elderly patients and to those who are ill. Oxygen is also given to those with an oxygen saturation level of less than 90%. Prophylactic antibiotics are given to those who undergo therapeutic treatment during their ERCP procedure.

The aims of interviewing two patient groups, those undergoing UGI endoscopy and those undergoing ERCP, were: i) to select a new group of patients in which to investigate the effectiveness of the relaxation intervention and ii) to assess the face validity of two possible interventions: a relaxation procedure and the provision of information.

8.2.2 Methods

Subjects

Eleven patients undergoing UGI endoscopy and 10 patients undergoing ERCP were interviewed. All patients who were approached agreed to be interviewed. Eleven subjects were male and 11 patients had previous experience of UGI endoscopy (5) or ERCP (6). Four patients attended the endoscopy unit as day cases from other hospitals for ERCP.

Procedure

Consecutive patients were approached in the endoscopy unit following UGI endoscopy or ERCP and asked to participate in an interview 'to help with a study aimed at reducing patients' concern about an Upper Gastrointestinal Endoscopy (or ERCP)'. Patients were asked about the following themes: the type of sedation they received and their experiences, including how they felt before, during and after the examinations. Patients were also asked about their understanding or expectations of the medical procedure. Finally, patients were given a description of possible psychological interventions and asked for their comments. The structure of the interviews is laid out in the results section. Interviews with patients who had just experienced UGI endoscopy were carried out in a separate room. Those who had undergone an ERCP as day cases were interviewed in the recovery area, whereas those who
had an ERCP as an in-patient were returned to their ward before being fully alert and where interviewed there. Due to the higher doses of sedation received by patients who had undergone an ERCP, these patients were interviewed several hours after the procedure or, for those who were in-patients, the following day. The interviews lasted between ten and thirty minutes. The responses of 12 patients were recorded on audiotape after patients gave their verbal consent. Only one patient refused to have her responses recorded on audiotape. Content analysis was used to analyse the data, where categories for all themes in the results section, except for *Descriptions of ERCP experience*, were exclusive and exhaustive. The numbers and percentages of how patients responded and were categorised are presented in the results section. Additional patients' comments are also given.

8.2.3 Results

*UGI endoscopy*

**Sedation.** Seven (64%) patients received intravenous sedation for UGI endoscopy and two of these thought that the amount of sedation was just right, whereas one said that he would have referred more sedation. The remaining four (36%) patients had undergone this procedure with only a throat spray and were satisfied with this. Of those who received sedation five (71%) had no recollection of the procedure, whereas two (29%) patients were aware of the endoscopy tube in their throat or stomach.

Two (29%) patients of the seven who had received intravenous sedation said that they preferred to be sedated for future endoscopy procedures and would not consider only a throat spray. One (25%) of the patients who received a throat spray said that he may consider having an sedative injection on the next occasion, despite saying that he was satisfied with the throat spray on this occasion. The remaining eight (73%) of the eleven patients did not comment on future endoscopy examinations.

**Patients' descriptions of the procedure.** When asked how they would describe the procedure responses included: 'not painful' (1 patient, 9%), 'fairly uncomfortable, but not painful' (2 patients, 18%), 'unpleasant, but not sore' (1 patient, 9%) and 'uncomfortable' (1
patient, 9%) regardless of whether sedation was received. Only one (9%) patient described the procedure as 'painful', this patient also expressed a preference for more sedation. Three (27%) patients said that they were aware of the tube in their throat before the sedation took effect. Two (18%) patients has no recollection of endoscopy. No other procedural descriptions were given.

Patients' thoughts or feelings before or during the procedure. Seven (64%) patients undergoing a UGI endoscopy mentioned feeling 'nervous' or 'worried' about the procedure. Of these seven, three patients were worried about vomiting or gagging, and one added that he was worried that he "might push the camera up or something". Four of the seven patients said that they were anxious before the procedure. One of these four compared it to waiting at the dentist and another added that she had a "fear of not swallowing the tube"; a third who was anxious before the procedure was concerned that she would have no choice regarding sedation, as she preferred not to be sedated. [expressed fear of swallowing the tube.] A further patient (9%) said that although he "felt panicky when the tube was being put down, it got better and better and I wasn't worried at all". One (9%) patient was aware of the endoscopy tube, but was not bothered by it and another (9%) said that he felt as if he was choking when the tube was in his throat, but added that he was not worried. Only one (9%) patient, who had no recollection of the procedure, claimed not to be worried beforehand.

Patients' understanding of UGI endoscopy. Five (62.5%) out of eight patients who were asked about the information they received said that they were satisfied with it. One (12.5%) patient stated that the letter informing patients about the procedure indicated that the duration was 20 minutes, but in fact the procedure only lasted 2 or 3 minutes and another (12.5%) suggested that people should be explicitly informed that it wasn't a large camera which was to be pushed into the stomach. One (12.5%) patient received no explanation before but would have liked some. Three patients were asked how others might be prepared for an UGI endoscopy. One stated, "...you cannot really prepare someone for what's going to happen." Another patient suggested providing an information leaflet for those who want to read it, especially if they are having the procedure for the first time and the third said, "knowing that everyone is helpful and nice is a great help."

Patients' thoughts or feelings following UGI endoscopy. Three (27%) patients were 'glad'
or 'relieved' that the procedure was over. A further three (27%) reported feeling 'drowsy' or 'drunk' immediately after the procedure and the rest said (46%) that they were 'fine'. On the whole patients were pleased with the staff, describing them as 'helpful' (4 patients, 36%), 'competent' (1 patient, 9%), 'pleasant' (1 patient, 9%), 'nice' (3 patients, 27%), 'great' (1 patient, 9%) or 'efficient and understanding' (1 patient, 9%).

**Relaxation as psychological preparation.** When the eleven patients were asked for their views about the use of a relaxation procedure four (36%) thought that it would help, although one of these wanted to confirm whether a painkiller would also be given; two (18%) said that a relaxation tape may act as distraction or a form of personal interaction and that it would be beneficial especially if patients had to wait for their medical procedure; three (27%) said that a relaxation tape would help those who are tense, although one of these said that she preferred sedation; and one (9%) patient thought that it was up to each person to relax in their own way and suggested that it would help if the waiting area was much quieter, although he added that the busy unit had provided him with distractions which he found helpful. One (9%) patient did not answer the question, but rather talked about other medical problems.

**ERCP**

**Sedation.** All patients received relatively high doses of sedation and consequently their recollection of the experience of ERCP was minimal.

**Descriptions of ERCP experience.** When the ten ERCP patients were asked what they could describe about their experience four (40%) said that they had no recollection and the remainder described at least one of the following events\(^1\): entering the room (2 patients), being instructed to adopt the particular position for the procedure (1 patient), the insertion of a mouth-piece (2 patients), oxygen being administered (1 patient) and, for three patients, the endoscopy tube being put in.

**Patients' thoughts or feelings before or during the procedure.** When asked about their

\(^{1}\) i.e. these responses are not exclusive.
thoughts and feelings before the procedure three (30%) described themselves as feeling 'apprehensive', one (10%) as 'a little anxious' and another (10%) as 'worried beforehand'; one (10%) said that she didn't like the thought of coming in to have this procedure; another (10%) said that she did not have good thoughts before, because of a previous 'bad experience' and two (20%) said that they were not worried on this occasion, one of these added that he had been anxious before previous procedures. One (10%) patient who was extremely tired after the procedure asked for the interview to be brief and therefore was not asked this question. No patient described any thoughts or feelings experienced during the procedure, probably due to the higher dose of sedation and its amnesic properties.

Patients' understanding of ERCP. Four (40%) patients appeared to be satisfied with the explanations they received. Another (10%) patient said that a number of things were explained to him, and although he didn't hear a lot of what was said he was satisfied with amount of information he received. Two (20%) patients said they were happy with the information, although when shown the ERCP leaflet (supplied by Keymed: "Having an ERCP - a guide to the test") one said that she would have liked to have seen it before and the other, who was attending as a day case, said, "I don't worry, I've had it done now. They explained everything to me at my own hospital." One (10%) patient wasn't sure that the provision of information would help her because she had previous experience of ERCP and had received the corresponding leaflet in the past. Another (10%) said that he trusted the doctors to do their best. Finally, one (10%) patient said that everyone explained it all so that he knew what to expect.

Patients' thoughts or feelings following ERCP. Five patients were asked about their thoughts/feelings after ERCP. Two (40%) were anxious to be informed of the outcome of the procedure or treatment. One (20%) patient who had been told the results of his ERCP was very happy with the results and two (40%) patients said that they were pleased that it was over. Four patients commented on the staff, all of which were favourable descriptions including 'helpful', 'competent' and 'very nice'.

Relaxation as psychological preparation. Nine patients were asked whether a relaxation tape would help them or other patients to prepare for an ERCP. Two (22%) responded that a relaxation tape would help others, especially those undergoing the procedure for the first
time or if they are particularly anxious. Four (44%) patients said that a relaxation tape was a good idea, one in particular thought that some kind of distraction would be beneficial. Another (11%) thought that relaxation was a good idea, but wasn't particularly interested in listening to a tape. One (11%) patient wasn't sure about such tapes and added that she didn't want to criticise staff in any way. Finally, one (11%) patient replied that she didn't worry.

8.2.4 Discussion

**UGI endoscopy**

Patients who received intravenous sedation tended to have little recollection of the procedure compared to patients undergoing colonoscopy (see Chapter 3 for descriptions of experiences of colonoscopy patients). This is probably due to the higher sedative and analgesic doses given to UGI endoscopy patients. This difference in medication dosages is partly because patients are required to change position during colonoscopy, whereas they are required to remain still during UGI endoscopy, and also because patients may find UGI endoscopy more stressful than colonoscopy. With one or two exceptions, patients' comments about their satisfaction with the sedation they received and whether they would consider just throat spray in future reflected their choice of sedation or throat spray on this occasion. This suggests that the form of sedation they chose met with their expectations. These findings reflect those of recent studies on patient satisfaction with sedation and throat spray (Martin, Arlett and Holdstock, 1996; Tan and Freeman, 1996).

Despite specific and general anxieties about UGI endoscopy, patients did not particularly mention the outcome of the procedure as a concern. This may be due to the nature of the procedure itself where patients are initially concerned with their performance (i.e., fear of gagging), the discomfort involved or the indication. Unfortunately, the indication for this procedure for this sample of patients was not recorded and so the seriousness of their condition cannot be evaluated.

The majority of patients considered themselves well enough informed about the procedure and satisfied with the information they received. This could be due to the fact that patients
were interviewed immediately after they had undergone the procedure, a time when they may be feeling relieved that the examination is over and not inclined to consider seriously their thoughts or feelings on the matter. In addition, some patients may not be aware of what information is available. Some procedures take longer than others especially if patients are given sedation which may affect their performance or tolerance of the examination, causing them to gag or possibly even push the staff away. Misconceptions were present, particularly concerning the equipment, indicating that further information is required.

Following the procedure some patients referred to the after-effects of the sedation, but on the whole they appeared to be pleased that it was over and were satisfied with the staff during their stay in the endoscopy unit.

Not all patients welcomed the idea of a relaxation procedure especially when they thought that this might prevent them from having the usual sedation. Some patients thought that a form of distraction was needed during the waiting period, although not all thought that relaxation could provide this.

**ERCP**

Not one patient interviewed had any recollection of their ERCP experience from the time the sedation started to take effect, reflecting the higher dose received. These findings, for both UGI endoscopy and ERCP, of the failure to recall procedures are in line with previous research on medical and surgical procedures which use benzodiazepines, such as dental surgery (Milgrom, Weinstein, Beirne and Fiset, 1993) and UGI endoscopy (Johnson and Leventhal, 1974; Webberley and Cuschieri, 1982). Despite the higher level of sedation for ERCP, patients were apprehensive before their ERCP, although for one patient this was due to a previous negative experience.

Patients were generally satisfied with the descriptions of the procedure they had received, although two patients were eager to be informed of the outcome of their procedure. As with UGI endoscopy patients this may reflect the timing of the interviews. However, when shown a leaflet one patient said that she would have liked to have seen it before ERCP and in
general patients agreed that the provision of additional information could be useful. This supports the earlier speculation in relation to the UGI endoscopy interviews that patients may be satisfied with information received, until they discover that there is additional information which may help them. Exceptions to the view that the provision of further information would be beneficial include those patients who had already seen the corresponding leaflet and those who stated that they trust the doctors to do their best or that they didn't want to criticise the staff. Trusting the doctors and at the same time not wanting further information may be because receiving more information places the patient in a position of being able to criticise the doctors or staff. Some patients may feel grateful for the tests and treatment they receive and don't particularly want to be involved in criticising those responsible, although this is clearly not a universal feeling as the recent increase in the number of malpractice suits testifies (Alfidi, 1971).

On the whole, patients agreed that a relaxation procedure could be useful, though not necessarily for themselves. Those undergoing the procedure for the first time or who were particularly anxious were considered to be those who would benefit most.

**Conclusion**

It appears that patients undergoing ERCP would be more willing to accept the usefulness of either a relaxation procedure or the provision of information compared with those undergoing an UGI endoscopy. Other factors which point to those undergoing ERCP as being more suitable for further study are as follows: patients undergoing ERCP already have an incremental system of sedation received in the form of additional doses which can be used as an indication of patients' tolerance of the procedure. For effective management of the unit a quick turn over of patients is required and all patients are encouraged to vacate the unit as soon as possible. ERCP in-patients are transferred back to their ward soon after their procedure whilst day case ERCP patients are transferred back to their own hospital when ambulance transport arrives. Awaiting transport can take some time, generally between one and five hours. Therefore, ERCP patients are likely to be available for follow-up questionnaires, after their procedure, either on the wards or whilst waiting for transport.
In contrast, patients undergoing UGI endoscopy consist of a mixture of sedated and non-sedated procedures, thus reducing those eligible for study. There appears to be an optimal dose of sedation for patients to tolerate UGI endoscopy and it may not be feasible to start with a lower dose, using additional doses for a measure of tolerance. For study purposes those opting for throat spray rather than sedation would be preferable. However, it is difficult to estimate the throughput of patients willing to undergo the procedure without sedation. Furthermore, at the time of these interviews one endoscopist, who worked in the unit, occasionally used hypnosis skills to instruct the patients undergoing UGI endoscopy to relax, which would confound a study investigating these patients and as a result such patients would also have to be excluded from the proposed psychological investigation. Thus, the opportunity for recruiting patients undergoing ERCP is much greater than recruiting those undergoing UGI endoscopy. In addition UGI endoscopy patients are discharged home with an adult escort as soon as it is safe to do so, which reduces their availability for follow-up questionnaires compared to ERCP patients.

For these reasons it was decided to use ERCP patients as subjects for the next main study (Study 3) and to introduce interventions based on both relaxation and the provision of information in order to make comparisons between groups and preferred coping style. In preparation for Study 3 the next section reports an attempt to modify and validate the Post-Colonoscopy Questionnaire, to provide a measure of patients' experience of ERCP.

8.3 Preliminary study 4: Assessment of patients' experience of ERCP

8.3.1 Background

As already noted outcome measures used to assess endoscopy examinations have included behavioural assessment (Shipley et al., 1978, 1979; Wilson et al., 1982) and self-report measures of the experience (Salmon et al., 1994). For more complex procedures where patients are heavily sedated or receive a general anaesthetic outcome measures include the duration of hospital stay, the type and amount of analgesic medication and type and number of complications (Johnston, 1984). Unlike planned surgical cases, patients undergoing ERCP
may undergo additional investigative procedures and so outcome measures specific to recovery from ERCP, such as duration of hospital stay and related complications would not be feasible. In addition, the inclusion of patients from other hospitals in the proposed study, would create difficulty in collecting information relating to hospital stay, and to complications in particular.

There appears to be no specific measure of surgical experience, except for assessments of patients' satisfaction (Meredith, Emberton and Devlin, 1993). However, the extent to which this is a valid measure of patients' actual experience of surgery is unclear. As noted, the questionnaire devised by Salmon et al. (1994) identified additional aspects of colonoscopy experience to that explained by 'satisfaction'. Therefore, a similar questionnaire measure may be suitable to use for the proposed main study to test the psychological interventions on patients undergoing ERCP.

The aim of this preliminary study was to establish the suitability of using such a questionnaire for patients following ERCP. In addition, an attempt was made to identify possible additional items to Salmon et al.'s (1994) Post-Colonoscopy Questionnaire as the first step in creating and validating a Post-ERCP Questionnaire to use as an outcome measure of patients' experience.

8.3.2 Methods

Subjects

Twelve patients were interviewed following ERCP. Interviewing was stopped after 12 patients because it became apparent that as they were so heavily sedated during the procedure no additional information would be forthcoming. Eight patients were male and six had had ERCP before this occasion. Seven patients were day cases from other hospitals and were interviewed on the same day as their ERCP procedure. Of the five patients who were in-patients, three were interviewed the following day. No patient refused to be interviewed.
**Materials**

The Salmon et al. (1994) Post-Colonoscopy Questionnaire was modified to apply to patients undergoing ERCP, where any reference to colonoscopy was replaced with ERCP. Apart from these changes to the headers no modifications were made to the specific items. A seven-point scales was used as in the original Salmon et al. questionnaire as patients appeared to require assistance with VAS. The modified version is included in Appendix D.

**Procedure**

Patients were first asked to describe their experience of ERCP and then to fill in the questionnaire. Patients were also asked for their comments regarding the questionnaire, in particular the appropriateness of the wording of items. Responses were recorded on paper by the interviewer. Content analysis was carried out on the data. The results have been separated into two parts: i) spontaneous comments or descriptions of ERCP and ii) patients' responses to the Post-ERCP Questionnaire. Patients' descriptions of ERCP have been further separated into three themes: how they felt beforehand, comments about their ERCP experience and comments about the staff. Categories were exclusive and exhaustive for all themes. Responses to the Post-ERCP Questionnaire are reported in terms of i) the items which were omitted, with and without comments, ii) completed items to which patients added comments and iii) additional final comments.

8.3.3 Results

**Descriptions of ERCP**

Initial responses to the request for patients to describe their experiences were as follows. Three (25%) patients failed to give a description of, or comment on, their experience until they filled in the questionnaire, which were related to the items. The remaining nine (75%) patients varied in their response, six expressed how they felt beforehand, 7 gave comments about their ERCP experience and 5 described how they found the staff.
How patients felt before. Two patients said that they felt anxious and a further two said that they were nervous or apprehensive before their first ERCP (for both of these patients this was their fifth procedure). One patient was frightened when told of the risks and dangers of undergoing an ERCP and one of the in-patients found waiting for two hours in the endoscopy unit 'unnerving'.

Description of ERCP experience. One patient said that he fell asleep before the real work began; another described feeling 'woosey'; and a third said that he was not aware of the tube in his throat. A fourth patient had no recollection of the procedure saying that she was asleep, as she had asked for extra sedation (because she had gagged during a previous UGI endoscopy). This patient also complained of a sore throat at the time of the interview, which was conducted the day following the procedure. A fifth patient described lying on the endoscopy table, recalled the insertion of a mouth piece and a nasal cannula for oxygen, but didn't remember anything else about the procedure. This patient added that he is always pleased when he is due for an ERCP procedure, because "...it relieves my symptoms and I feel much better." A sixth patient described going in at 4 pm and waking at 6 pm; and not knowing anything else about the procedure. This patient also added that he had undergone this medical procedure before and so he knew what to expect. One other patient simply said that he "lay [in the appropriate position] as requested", when asked about his experience of ERCP.

Descriptions of the staff. All comments regarding the staff were favourable and included the following. One patient said that it was a 'very good performance' and that the staff were very capable. Another patient thought that is was 'all efficient' and 'well run, although she had to wait' for her ERCP procedure. A third patient thought it was, 'very good' and 'done thoughtfully'; a fourth described the staff as 'helpful' and finally one patient described being 'put at ease by the staff,' who were 'very friendly and nice'.

Post-ERCP Questionnaire

Only two (17%) patients completed all the items on the questionnaire and one (8%) patient omitted the following two items without comments: Confused/Not confused and Puzzled/Not
puzzled. The remainder commented on most of the items they didn't complete. Four (33%) patients thought that at least one of the following four items were not applicable to their experience of ERCP: Dignified/Undignified, In control/Helpless, Afraid of making a "fool of myself"/Not afraid of making a "fool of myself", and I'd have preferred to have been more awake/I'd have preferred to have been less awake. For the latter item, eight (67%) patients thought that the amount of sedation they received was 'just right'.

Five patients (42%) omitted the item, It went as expected/Not as I expected, and four (33%) gave the following comments to this item: i) one patient 'couldn't remember', ii) another patient 'didn't feel a thing' and iii) two patients said that they didn't know what to expect. Two patients omitted the item, It was a good experience/It was a bad experience. One patient changed the item to: 'It was an experience that I have had before', and the other patient thought that it should be reworded to ask patients whether they have learnt anything from this experience. Another patient said that as he 'fell asleep' before the real work began he wasn't able to answer the item, Pleased with how it went/Displeased at how it went.

Additional comments on items which were completed include the following: two (17%) patients were Worried at first, and one of these added that he was also Agitated, but again only at first. For items regarding physical discomfort, Soreness/No soreness and Comfortable /Uncomfortable, three patients added that they had sore throats (which for one patient occurred the following day), one patient complained of feeling sore in her side and back, and another patient found the position she was required to lie in, putting her left arm behind while lying on her left side, uncomfortable. For items referring to satisfaction, one patient added that he was satisfied with the results and another indicated that she was satisfied if she didn't have to return for a repeat procedure. This patient also found the staff very attentive. The item, Worried about what they would find/Not worried about what they would find, produced conflicting responses: one patient added, "Not now" and another responded, "Yes, I'm still waiting for the results."

When asked if there was anything else that patients could add to the questionnaire regarding their experience of ERCP, ten (83%) didn't make any additions and two (17%) patients said, "The questionnaire pretty much covers everything."
8.3.4 Discussion

Initial reports of the patients' experience of ERCP is comparable with the previous interviews reported in Section 8.2.3 with little recollection of the procedure itself. Other studies have shown similar findings, but with conscious sedation. For example, Johnson and Leventhal (1974) abandoned interviews with patients regarding their experience of UGI endoscopy, when they also failed to have any recollection of their experiences, due to the amnesic effects of the medication. Webberley and Cuschieri (1982) also reported that those patients who were sedated failed to have any, or had only partial, recollection of their gastroscopy examination in contrast with those not sedated. The amount of sedation received may help to explain why some of the subjects in the present study were unable to comment on their experience, until prompted by the questionnaire which they were then able to complete, albeit not fully. It may also be that some patients completed the questionnaire in terms of their overall experience and not just that in the endoscopy room. As before patients described their thoughts and feelings before the procedure and some were able to provide a description of the sequence of events before sedation took effect. Overall, patients comments about the staff, or their overall experience, were favourable and could be interpreted as an indication of satisfaction. Anxieties of patients undergoing ERCP seemed to be restricted to the period prior to ERCP, although at the time of the interview one patient was also worried about the findings. Any emotional distress which may have been experienced during the procedure would not have been recalled due to the amnesic effects of the sedation received. When giving descriptions of the procedure, the majority of patients referred to physical events or the unaccustomed position they were required to adopt.

When completing the questionnaire, some patients had difficulty replying to some of the items. Items referring to dignity and fear of "making a fool of myself" were specifically related to the embarrassment some patients feel when undergoing a colonoscopy examination. As patients are relatively more sedated during ERCP, and do not expect it to be a particularly embarrassing procedure, some patients felt that these items were not applicable to their experience of ERCP. Similarly, the relevance of the item referring to wanting to be more or less awake was not clear to the majority of patients, who thought that the amount of sedation they received was just right. This response together with the lack of recollection indicates that patients were not aware of the events of the procedure and may not want to be. Furthermore, only one patient
indicated that he'd have preferred to have been more awake indicating that the remainder (who said that the sedation was just right, omitted the item or indicated that they would have preferred to have been less awake) indicated that the majority were satisfied with not knowing what was going on. Thus, this item could also be seen as being applicable only to patients who receive conscious sedation, who may be sensitive to variation in sedation doses.

Items referring to confusion, the procedure progressing as expected and being pleased or displeased with how it went were most probably answered in two ways: either in relation to the overall experience which incorporated a period of amnesia due to the effects of sedation, which the patients did not explicitly acknowledge, or the actual ERCP procedure, in which patients were not consciously aware of what was going on and so indicated that they were not able to answer such questions.

In summary, when patients were asked to describe their experiences, some could not give a description and at best only a brief account of the events before the sedation started to take effect and yet, surprisingly, all patients filled in the majority of the questionnaire. Of course patients may have been responding to the aspects of their experience in terms of what they remembered and incorporated this into their whole experience, which consisted of preparation for the procedure and after-care, as well as the actual experience spent in the procedure room. One explanation may be similar to that found with the 'blind-sight' phenomenon where subjects who have cortical blindness have demonstrated the ability to make visual discriminations even though they have no experience of seeing (Weiskrantz, 1996). An alternative interpretation is that patients may actually be processing information whilst sedated (Millar, 1987). However, it is not within the scope of this thesis to explore this hypothesis. As it is difficult to ascertain what patients were actually responding to when completing the questionnaire it was decided not to use this questionnaire as an outcome measure. Similar decisions have been made by other researchers who interviewed patients following UGI endoscopy but then found that they could not use the interview data due to the amnesic effects of the sedation (Johnson and Leventhal, 1974; Webberley and Cuschieri, 1982). Instead of using self-report measures of patients' experience of ERCP observational measures were used in addition to those measures reported in Chapters 5-7. These extra measures are reported in the next chapter.
9 Study 3: Psychological Preparation for ERCP

Chapter overview

This chapter considers various theoretical and methodological issues, in particular the connection between the provision of information and perceived control. A brief review of studies regarding the provision of information for patients undergoing medical and surgical procedures in relation to coping style, not previously described in this thesis, is included. This is followed by a description of observational measures used to assess patients' adjustment or responses to medical procedures. Finally, the third study, which differs from the previous studies by comparing the provision of information with a relaxation intervention, as well as control groups, immediately before a different medical procedure, endoscopic retrograde cholangiopancreatography (ERCP), is described.

9.1 Background

Information has been considered an aspect of cognitive control because it may increase an individual's ability to prepare for aversive events (Averill, 1973; Breemharr and van den Borne, 1991; Seligman, 1975). In this way, information can promote feelings of control (Thompson, 1981) which subsequently result in a reduction in perceived threat. However, Ludwick-Rosenthal and Neufeld (1993) found that desire for information was not associated with desire for control. The types of control in medical settings identified by various researchers include: behavioural control, such as swallowing during UGI endoscopy; cognitive control in the form of distractions, focusing on the positive aspects or providing patients with an option of various treatments (Breemharr and van den Borne, 1991; Thompson, 1981); and retrospective control, which is when the individual reflects about the causes of a past event (Thompson, 1981). Providing patients with a choice of treatment has also been labelled by some as decisional control (Averill, 1973).

Breemharr and van den Borne (1991) provide a useful account of the types of coping in relation to perceived control. They claim that perceived control over events is important
because it helps to reduce stress, particularly in the hospital setting, where control is generally low. They acknowledge that there are high and low control situations and that this, as well as patients' coping style, needs to be taken into account when planning psychological interventions. They recommend the following for the four combinations: i) for monitors in potentially high control situations provide information, behavioural instructions and choices in order to enhance perceived control; ii) for monitors in low control situations encourage emotion-focused coping; iii) for blunters in potentially high control situations avoid providing detailed information or choices and where the patient's contribution is crucial explain why this is important and reassure the patients that they do have the abilities to carry out their contribution; and iv) for blunters in low control situations provide assistance with emotion-focused strategies and increase patients' confidence in the staff.

Due to the relatively high dose of sedation given to patients undergoing ERCP, there is very little that the patient can do to contribute to the procedure and thus it can be considered as a low control situation. Therefore, in keeping with Breemharr and van den Borne's guidelines the 'relaxation alone' procedure was used in this study in preference to the 'relaxation plus control' procedure used in the earlier studies reported in Chapters 6 and 7.

A review of psychological intervention studies on the simpler GI endoscopy procedures, UGI endoscopy and colonoscopy, was presented in Chapter 2. The next section looks at the provision of information for patients undergoing different and more complex procedures, such as cardiac catheterization, as very few studies which consider patient or psychological aspects of ERCP have been found. It is important to note the distinction between i) providing information as part of the legal requirement for informed consent for medical and surgical procedures and ii) the provision of information as psychological preparation. Papers have been published which explore both issues (e.g., Alfidi, 1971; Edwards, 1990; Kent, 1994; Williams, 1993)

As already outlined there are two types of information which can be provided to the patient: procedural information and sensory information. In a meta-analysis Suls and Wan (1989) have shown that a combination of the two is most effective in terms of outcome measures. However, in a meta-analysis of both published and un-published studies Johnston and Vögele (1993) found that procedural information together with behavioural instructions was most
effective in improving post-operative recovery. Endoscopy studies already described in Chapter 2 indicate that sensitizers benefit most from additional information (Wilson et al., 1982) and information in the form of modeling (Shipley et al., 1978, 1979) compared with repressors. Before looking at studies which have investigated the effects of different levels or types of information and coping styles in response to other medical procedures, it is worth considering the medium in which this information is presented.

The different modes of delivery of information have been investigated and include i) written information, with or without illustrations (e.g., Edwards, 1990; Marteau, Kidd, Cuddeford and Walker, 1996), ii) oral information, often pre-recorded on audio-cassette in order to standardize the delivery of interventions (e.g., Ludwick-Rosenthal and Neufeld, 1993) and iii) video information, including modeling interventions (Shipley et al., 1978; 1979) or as a ‘preview’ before obtaining consent for a medical procedure (Agre, Kurtz and Krauss, 1994). The most effective method of providing information is a combination of both written and oral information (Edwards, 1990; Kerrigan, Thevasagayam, Woods, McWelch, Thomas, Shorthouse and Dennison, 1993). Davis, Maguire, Haraphongse and Schaumberger (1994a) showed that information in the form of a video was better than that on a leaflet, as reflected by their own measure of behavioural adjustment, for patients undergoing cardiac catheterization. However, it is not clear how similar the contents of the two types of presentation were. In addition, the opportunity and cost involved in providing patients with the place and time to view video information are important considerations, especially when patients are attending endoscopy units as day cases from other hospitals. In the present study it was decided to provide information in the form of an audio tape so that the mode of delivery would be as similar as possible to that used for the relaxation intervention.

Regarding different levels of information Marteau, Kidd, Cuddeford and Walker (1996) compared the effects of two information booklets on patients undergoing a colposcopy examination. The booklets were produced with the intention to reduce anxiety associated with the outcome of the procedure. Subjects were allocated to one of four groups, who received one of the following interventions: i) the standard appointment letter, ii) the letter and a simple booklet, iii) the letter and a more complex booklet or iv) the letter and both booklets. Results indicated that a simple booklet of procedural information and behavioural instructions was more effective in reducing anxiety than a more detailed booklet containing information about
the aetiology of cervical abnormalities, details of treatment procedures and their likely outcomes. Furthermore, Marteau et al. (1996) found no association between amount of knowledge and anxiety levels in any of the four groups. Unfortunately, this study was not able to identify the active aspects of the simple information intervention in reducing anxiety.

In an earlier study with patients undergoing colposcopy, Millar and Mangan (1983) investigated the effects of high and low levels of information on patients' levels of arousal. Their findings support those of Marteau et al. (1996), that a low level of information was more effective in reducing arousal than a high level of information. Main effects were also found by Millar and Mangan (1983) for coping style, with blunter indicating less subjective arousal and less behavioural arousal than monitors. Interaction effects emerged with the psychophysiological measures: blunter showed less arousal with low information and monitors showed less arousal with high information.

Ludwick-Rosenthal and Neufeld (1993) also investigated high or low levels of information as preparation, but for a different medial procedure, cardiac catheterization. In contrast to the above studies, they found beneficial effects for those in the high information group, which resulted in the reporting of more positive self-statements and taking less time to undergo the procedure than those in the low information group. In addition, Ludwick-Rosenthal and Neufeld (1993) looked at patients' desire for information and the type of coping (problem-focused or emotion-focused) adopted by patients during the medical procedure. When desire for information and information levels were matched there was less behavioural anxiety during catheterization. Patients' coping disposition alone did not affect their adjustment during catheterization, as assessed by the attending nurse.

Davis, Maguire, Haraphongse and Schaumberger (1994a) also looked at the effects of coping style and the provision of information on patients' anxiety during a cardiac catheterization procedure. Patients were randomly assigned to receive one of three information interventions: i) videotaped procedural modeling information, ii) videotaped procedural and sensory modeling information, and iii) a booklet on procedural and sensory information. Davis et al. (1994a) also found a main effect with information; subjects who received the videotaped modeling information demonstrated greater behavioural adjustment than those who received the information booklet. The findings of this study differs from the others described in that at
first it appears that the effect is due to the mode of delivery of information. However, subjects who received the information booklet were provided with details about the purpose of cardiac catheterization and diagrams in addition to procedural and sensory information. Thus, it is unclear whether the amount of information or the delivery of information was the more effective in benefitting the patients. Davis et al. did not find a main effect of coping style on any of the anxiety measures, which is supported by the findings of Ludwick-Rosenthal and Neufeld (1993), but contradicts those of Millar and Mangan (1983).

In a separate publication of the same study Davis et al. (1994b) reported an interaction between subjects' coping style and the type of information received. Monitors who watched the procedural and sensory modeling video and blunters who watched the procedural modeling video reported significant reductions in state anxiety immediately afterwards and this reduction was maintained until immediately before the cardiac catheterization procedure. In contrast, monitors and blunters who received the other information preparations reported a significant increase, or a nonsignificant change, in state anxiety immediately following the intervention. After the cardiac catheterization, both monitors and blunters in each of the treatment groups reported a significant decrease in state anxiety. Davis et al. (1994b) also report sex differences in state anxiety, with female patients reporting significantly higher state anxiety levels than their male counterparts before any intervention. They also reported that the state anxiety levels of males in each of the three groups were different.

It is difficult to compare the effects of information interventions between studies and between different medical procedures. Some researchers suggest that adverse effects may occur if additional information is given to patients who do not want it (e.g., Andrew, 1970; Shipley et al., 1978, 1979). However, in a review of the literature on communication, compliance and patient satisfaction Ley (1982) failed to find evidence that provision of additional information leads to adverse reactions by patients. Furthermore, a study carried out by Williams (1993) with surgical patients suggests that anxiety was related to the level of satisfaction with the amount of information provided and not the level of knowledge per se. None of the studies which looked at coping style described above have included a non-intervention control group making it difficult to assess whether providing information to repressors was in fact harmful. Therefore, the present study looked at the effects of the provision of additional information on both repressors and sensitizers in terms of their adjustment to the procedure compared
with patients who were not provided with additional information. A question about patients’ satisfaction with the amount of information they received was also included.

Due to the type and amount of sedation received patients were not able to recall their ERCP experiences and hence it was not possible to obtain an assessment of their thoughts or feelings regarding their ERCP procedure (see Preliminary studies 3 and 4, reported in Chapter 8). Therefore, additional measures were necessary to assess patients' responses to ERCP. Items used in other studies which assessed patients' behavioural responses to gastroscopy, such as gagging and arm movements (Wilson, Moore, Randolph and Hanson, 1982) and other sorts of responses to a different medical procedure, cardiac catheterization (Kendall, Williams, Pechacek, Graham, Shisslak and Herzoff, 1979), were used. Items from the latter study assessed patients' adjustment to the procedure and consisted of 5 items regarding the exhibition of signs of anxiety, unnecessary movement, whether they asked questions and their general co-operation. A sixth item 'Did the patient adjust to the procedure?' was not used as four endoscopists and nurses had difficulty interpreting it during the pilot phase of the study. Three of these behavioural items (a, b and e) were reversed and then all were combined to give a total score: one from the endoscopist's assessment and another from the nurse's assessment (see Appendix E, page 275 and 276). These two measures were used in conjunction with the other observational measures regarding patients' tolerance and technical difficulty of ERCP used in Study 2.

The information tape used in the present study was prepared with the assistance of the consultant physician at the endoscopy unit at the Middlesex Hospital. It was based on the leaflet entitled, "Having an ERCP - a guide to the test" supplied by Keymed. Additional information about the potential risks of the procedure and information about the endoscopy unit at the Middlesex Hospital was included in order to extend the duration of the intervention so that it was comparable to that of the relaxation procedure. This also takes into account the view that information is more effectively understood when oral and written information is combined (Edwards, 1990; Kerrigan et al., 1993). The transcript of the information tape is included in Appendix E.

The two psychological interventions used in the present study were a relaxation procedure and
the provision of information. The relaxation procedure chosen was the basic, 'relaxation alone' tape because the research carried out so far indicates that this was more effective in reducing anxiety than the 'relaxation plus control' tape in Study 1. Furthermore, the 'control' additions made reference to patients having some control over the situation, such as being required to move during the (colonoscopy) examination, whereas for ERCP patients are required to remain still, and as mentioned above, this is also in line with Breemharr and van den Borne's (1991) recommendations. By providing patients with cognitive control in the form of information it is expected that their response to the medical procedure will be less threatening compared to patients who are not given such information. As in Study 2 an attention control group was included for comparison, to control for the fact that patients were given a tape to listen to. Outcome measures consisted of patients' tolerance of the examination and the technical difficulty of the procedure and additional items relating to specific behaviours mentioned above. These measures were completed by both the doctor and attending nurse. In view of the seriousness and technical difficulty of ERCP the initial dose of medication was not altered in this study.

The aims of the study were i) to compare two psychological interventions for patients undergoing ERCP with two control groups: non-intervention control and attention control and ii) to test for an interaction effect involving group membership and coping style.

### 9.2 Methods

#### 9.2.1 Subjects

Of 129 eligible patients 99 consented to take part in the study. Subjects were not required to give a reason for refusing to take part (see Consent form, Appendix E). Those who offered a reason said that they were too tired, were not well enough, didn't have their reading glasses or 'just wanted to get it [ERCP] over and done with'. Five patients were dropped from the study because there was no time to carry out the intervention before their ERCP procedure and a further three decided to discontinue because they felt too tired to take part. Of the 91 patients who completed the study, ages ranged from 17 to 86 years with a mean of 56. Forty
seven (52%) patients were male, 52 (57%) were in-patients and 52 (57%) had previous experience of ERCP. Reasons for ERCP were categorised into three groups: investigation for biliary disease (28%), pancreatic disease (24%) or biliary tract disease (48%). Concerning employment status, the subjects described themselves as employed or self-employed (44%); retired (45%); student (1%) and unemployed or taking care of the home (10%). Subjects were asked to classify their current or previous employment if retired or unemployed. Three subjects failed to complete this question. Those who were or had been employed classed their current or previous status as professional/managerial (50%); skilled technical (5%); clerical or shopwork (26%); skilled manual (11%) and unskilled manual (8%). Forty two percent had previous relaxation, or similar, experience.

9.2.2 Materials

Materials used consisted of a Sony WM-D6C cassette-player with headphones, the 'relaxation alone' tape described in Chapter 4, the recording of a mythical narrative (transcript enclosed in Appendix C), a recording of the information tape described above, the Keymed "Having an ERCP - a guide to the test" leaflet, a study information sheet, a consent form and the following questionnaires:

Questionnaire 1 comprised of the original STAI-trait (Spielberger, Gorsuch and Lushene, 1970), the short form STAI-state (Marteau and Bekker, 1992), state anxiety visual analogue scales (VAS) - Mood Scale (with a minor adjustment\(^1\)), the Health Opinion Survey (Krantz et al., 1980), a shortened version of the Social Desirability Scale (Strahan and Gerbasi, 1972) and added items regarding previous experience of ERCP, similar medical procedures and demographic information;

Questionnaire 2 consisted of the short form STAI-state, Mood Scale and additional VAS items asking patients (who had listened to a tape) how effective the tapes were in helping them to feel 'relaxed', 'more informed', 'more able to cope' and 'in control';

Endoscopy Questionnaire, of which there were two versions, one for the endoscopist and the other for the attending nurse. The endoscopist assessed the technical difficulty and the

[^1]: Extra words were added to the mood scale items in order to reduce the occurrence of patients rejecting the word 'anxious' to describe their mood state.
patients' tolerance of ERCP - using VAS and additional items taken from other studies, regarding specific behavioural responses (Wilson et al., 1982) and adjustment to the procedure (Kendall et al., 1979). The endoscopist also recorded the indication for ERCP and additional procedures, e.g., sphincterotomy or balloon trawl, which were carried out on this occasion. The nurse's version comprised of pre- and post-ERCP pulse recordings and oxygen saturation levels, duration of the procedure, amount of sedation, analgesia and any other medication required, and assessment of the patients' tolerance of, and adjustment to, the procedure; and the

Post-ERCP Questionnaire comprising of the short form STAI-state, Mood Scale, the Health Locus of Control questionnaire (Wallston, Wallston and DeVellis, 1978), previous relaxation or similar experience, whether they used a relaxation procedure whilst waiting for their ERCP (regardless to which group they were allocated), how helpful was what they heard on the tape, whether they would have preferred more or less information and whether taking part in the study helped them. An additional item regarding the time and date the questionnaire was added, as the majority of patients completed this questionnaire away from the endoscopy unit when they had recovered from the effects of sedation.

The materials used for this study are included in Appendix E.

9.2.3 Procedure

Patients were invited to take part in the study if there was enough time to conduct the intervention before they would be called for their ERCP. Due to the busy nature of the endoscopy unit, in-patients were initially seen on the wards, and those who consented to take part were brought round to the endoscopy unit so that there was enough time to conduct the study. Patients attending as day-cases from other hospitals were approached in the unit. Patients were given the information sheet and consent form. After consent to take part in the study was obtained, patients filled in Questionnaire 1. On completion of Questionnaire 1, patients were asked by the investigator to give a description of their understanding of the forthcoming ERCP procedure and the number of key words were recorded. Examples of key words included 'endoscopy tube' or 'X-ray' and the total number of key words mentioned formed a knowledge of ERCP score. Subjects were randomly allocated to one of the four
groups. For subjects in one of the intervention or the attention control groups, the screens were drawn round their individual waiting/recovery areas so that they would not be disturbed or distracted while they listened to the audio tape. Subjects in the non-intervention control group were left to sit for approximately the same duration as the intervention groups. Subjects in the information group were also given the leaflet to look through once they had listened to the tape, as that tape lasted only 10 minutes, compared with the 13 minutes duration of the relaxation tape and 12 minutes - of the attention control tape. Once the intervention was complete, subjects filled in Questionnaire 2 and were asked if there was anything they wanted to add to their earlier description of ERCP. Once any additions were recorded, those who had listened to a tape were instructed to, "use what you have learnt from the tape whilst you are waiting for the procedure." Waiting times varied from one minute to 287 minutes.

The three physicians and twelve nurses, who completed the questionnaires in this study, were unaware to which of the four groups each patient was allocated. Observational and physiological measures were taken by the endoscopist and nurse during, or immediately following the examination (Endoscopy Questionnaires) and the Post-ERCP Questionnaire was administered to the patients afterwards, once they were alert enough to fill in the questionnaires. Twelve patients who attended the department from other hospitals were not alert enough to fill in this final questionnaire before the ambulance arrived for their return journey. On these occasions the questionnaire, a stamped-addressed-envelope and a letter of instruction were given to the escort nurse to give to the patient when fully alert. Seven (58%) of these patients returned their Post-ERCP Questionnaires. Soon after their ERCP procedure in-patients were collected by ward staff who were given a brief description of the study and the relevant questionnaire for the patient to fill in when able to do so. Three (6%) in-patients failed to complete the Post-ERCP Questionnaire. On collection of the questionnaires patients were asked for any comments and thanked for taking part.

9.2.4 Statistical analysis

The relationship between Mood Scale and the state component of the STAI was checked using Pearson product-moment correlation coefficients. Principal components factor analysis

2 The issue of inter-rater reliability is an important one and has been addressed in Section 5.2.
was carried out on all the anxiety measures. Data were screened and multiple analysis of variance (MANOVA), Kruskal-Wallis and Chi-square tests were used to check that the four groups did not significantly differ in background variables.

Analysis of covariance (ANCOVA) was used to test the immediate effects of the tapes on anxiety levels and knowledge of ERCP, and MANOVA was used to test for differences in the perceived effectiveness of the tapes. Pearson product-moment correlation coefficients and principal components factor analysis were used to explore the relationship between the observational measures. Hierarchical multiple regression analysis was used to test which variables, including group contrasts predicted the outcome measures. Contrast 1 compared the non-intervention control group with the three tape groups together, Contrast 2 compared the attention control group with the information and relaxation groups together and Contrast 3 compared the information and relaxation groups. Interactions of contrasts by personality variables were also included in the regression equation (Cohen and Cohen, 1983).

A Chi-square test was used to investigate differences in whether or not patients were satisfied with the amount of information received before their ERCP procedure. Whether perceived helpfulness of the tapes, attempts to relax before their ERCP and participation in this study were associated with the interventions were tested using Kruskal-Wallis one-way analysis of variance by ranks. Follow-up comparisons to the Kruskal-Wallis tests were made using the standard procedure (Siegal and Catellan, 1988). Finally, MANOVA was used to assess group differences in Health Locus of Control beliefs.

### 9.3 Results

Prior to analysis, all variables were examined through various SPSS for Windows programs for accuracy of data entry and missing values. The variables were examined separately for the 22 subjects in the relaxation group, the 22 subjects in the information group the 23 subjects in the attention control group and the 24 subjects in the non-intervention control group. Despite missing data for some of the subjects (8 patients failed to return the Post-ERCP Questionnaire, two patients, allocated to the control group, were called in to their ERCP
before completing Questionnaire 2) and one patient who listened to the relaxation tape in the morning but then had her ERCP postponed to the afternoon all cases remained in the analysis. The variable 'similarity to previous relaxation' was not used in this analysis as few subjects (12) both listened to the relaxation procedure and had previous relaxation experience. Furthermore, 23% of patients failed to complete the question concerning whether they attempted to relax whilst waiting for their ERCP and so this variable was not included in the multiple regression analysis.

9.3.1 Anxiety measures

Table 9.1 shows the correlation coefficients between the VAS and STAI state anxiety taken before the psychological interventions (Time 1), $r(89) = 0.78$, immediately after the interventions (Time 2), $r(87) = 0.80$, and after ERCP (Time 3), $r(81) = 0.49$. As expected both measures are significantly correlated on each of the three occasions, $p < 0.001$.

<table>
<thead>
<tr>
<th>Mood Scale - VAS</th>
<th>STAI - state</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time 1$^a$</td>
</tr>
<tr>
<td>Time 1</td>
<td>0.78*</td>
</tr>
<tr>
<td>Time 2</td>
<td>0.74*</td>
</tr>
<tr>
<td>Time 3</td>
<td>0.15</td>
</tr>
</tbody>
</table>

* $p < 0.001$  $^a n = 91$  $^b n = 89$  $^c n = 83$

As the two anxiety measures were highly correlated, a factor analysis on the eight items was conducted and a single factor accounted for 52.4% of the variance. Combining the measures resulted in a single score with an alpha coefficient of 0.87. The factor loadings are listed in Table 9.2. The raw variables were combined and the factor score coefficients were used to calculate the corresponding anxiety measures taken on each of the three occasions. These newly created 'overall anxiety' measures were used for the rest of the analyses.
Table 9.2: Factor analysis loadings and alpha coefficients on the anxiety items

<table>
<thead>
<tr>
<th>Item</th>
<th>Factor loadings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spielberger (Short-form)</td>
<td></td>
</tr>
<tr>
<td>I feel calm</td>
<td>-0.83</td>
</tr>
<tr>
<td>I feel tense</td>
<td>0.74</td>
</tr>
<tr>
<td>I feel upset</td>
<td>0.49</td>
</tr>
<tr>
<td>I am relaxed</td>
<td>-0.76</td>
</tr>
<tr>
<td>I am content</td>
<td>-0.67</td>
</tr>
<tr>
<td>I am worried</td>
<td>0.68</td>
</tr>
<tr>
<td>VAS</td>
<td></td>
</tr>
<tr>
<td>To what extent do you feel calm or relaxed?</td>
<td>-0.84</td>
</tr>
<tr>
<td>To what extent do you feel tense or worried?</td>
<td>0.72</td>
</tr>
</tbody>
</table>

9.3.2 Background variables

Treatment groups were not significantly different in terms of the following background variables: age, number of previous ERCP procedures, trait anxiety, state anxiety at Time 1, knowledge of ERCP at Time 1, time spent waiting for the procedure, the amount of initial medication, desire for involvement and desire for information and social desirability, Wilks' Lambda = 0.745, approximate F(30,214) = 0.756, ns, sex, χ²(3) = 2.67, ns, indication, χ²(6) = 1.40, ns, previous relaxation experience, Kruskal-Wallis test, χ²(3) = 3.62, ns, marital status, χ²(3) = 1.11, ns, whether employed, χ²(3) = 2.05, ns, social status, Kruskal-Wallis test, χ²(3) = 2.26, ns, whether previously seen the 'Having an ERCP' booklet, χ²(3) = 0.08, ns, whether the patient was attending as a day-case patient or an in-patient, χ²(3) = 2.59, ns, and which endoscopist carried out the examination, χ²(6) = 7.48, ns. The means and standard deviations or frequencies of the background variables for each of the four groups are presented in Table 9.3.
### Table 9.3: Means and standard deviations of background variables for each group

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Attention control</th>
<th>Information</th>
<th>Relaxation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean</td>
<td>sd</td>
<td>mean</td>
<td>sd</td>
</tr>
<tr>
<td>Age</td>
<td>56.4</td>
<td>18.9</td>
<td>54.39</td>
<td>16.2</td>
</tr>
<tr>
<td>Previous ERCP exams</td>
<td>1.92</td>
<td>2.65</td>
<td>1</td>
<td>1.28</td>
</tr>
<tr>
<td>Waiting time</td>
<td>29.4</td>
<td>25.8</td>
<td>43.83</td>
<td>28.7</td>
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<tr>
<td>Initial medication</td>
<td>7.29</td>
<td>2.01</td>
<td>7.65</td>
<td>2.14</td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>36.9</td>
<td>10.3</td>
<td>35.39</td>
<td>9.45</td>
</tr>
<tr>
<td>State anxiety</td>
<td>14.6</td>
<td>9.56</td>
<td>17.79</td>
<td>10.7</td>
</tr>
<tr>
<td>Knowledge of ERCP</td>
<td>9.55</td>
<td>3.7</td>
<td>8.91</td>
<td>3.3</td>
</tr>
<tr>
<td>Desire for information</td>
<td>2.37</td>
<td>1.17</td>
<td>1.78</td>
<td>1.04</td>
</tr>
<tr>
<td>Desire for involvement</td>
<td>2.35</td>
<td>1.59</td>
<td>2.46</td>
<td>1.27</td>
</tr>
<tr>
<td>Social desirability</td>
<td>14.5</td>
<td>3.5</td>
<td>14.35</td>
<td>3.75</td>
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</table>

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Attention control</th>
<th>Information</th>
<th>Relaxation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male</td>
<td>Female</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>15(62.5%)</td>
<td>9 (39%)</td>
<td>12 (55%)</td>
<td>11 (50%)</td>
</tr>
<tr>
<td></td>
<td>9 (37.5%)</td>
<td>14 (61%)</td>
<td>10 (45%)</td>
<td>11 (50%)</td>
</tr>
<tr>
<td>Indication</td>
<td>Biliary disease</td>
<td>7 (29%)</td>
<td>5 (22%)</td>
<td>5 (23%)</td>
</tr>
<tr>
<td></td>
<td>Pancreatic disease</td>
<td>11 (46%)</td>
<td>13 (56%)</td>
<td>10 (45%)</td>
</tr>
<tr>
<td></td>
<td>Biliary tract disease</td>
<td>6 (25%)</td>
<td>5 (22%)</td>
<td>7 (32%)</td>
</tr>
<tr>
<td>Previous relaxation</td>
<td>0</td>
<td>1</td>
<td>2+</td>
<td></td>
</tr>
<tr>
<td></td>
<td>15 (68%)</td>
<td>2 (9%)</td>
<td>5 (23%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9 (45%)</td>
<td>4 (20%)</td>
<td>7 (35%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12 (60%)</td>
<td>6 (30%)</td>
<td>2 (10%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 (40%)</td>
<td>8 (40%)</td>
<td>4 (20%)</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td>Single</td>
<td>Married</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 (33%)</td>
<td>16 (67%)</td>
<td>14 (61%)</td>
<td>16 (73%)</td>
</tr>
<tr>
<td></td>
<td>9 (39%)</td>
<td>14 (61%)</td>
<td>16 (73%)</td>
<td>13 (59%)</td>
</tr>
<tr>
<td>Employment status</td>
<td>Employed</td>
<td>Not employed</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>9 (37.5%)</td>
<td>15 (62.5%)</td>
<td>10 (43%)</td>
<td>13 (59%)</td>
</tr>
<tr>
<td></td>
<td>13 (57%)</td>
<td>10 (43%)</td>
<td>13 (59%)</td>
<td>13 (59%)</td>
</tr>
<tr>
<td>Social status</td>
<td>I</td>
<td>II</td>
<td>III</td>
<td>IV</td>
</tr>
<tr>
<td></td>
<td>3 (13%)</td>
<td>2 (9%)</td>
<td>4 (17%)</td>
<td>2 (9.5%)</td>
</tr>
<tr>
<td></td>
<td>4 (17%)</td>
<td>6 (26%)</td>
<td>6 (28.5%)</td>
<td>7 (33%)</td>
</tr>
<tr>
<td></td>
<td>2 (9%)</td>
<td>1 (4%)</td>
<td>0</td>
<td>1 (5%)</td>
</tr>
<tr>
<td></td>
<td>12 (52%)</td>
<td>10 (44%)</td>
<td>13 (62%)</td>
<td>9 (43%)</td>
</tr>
<tr>
<td>Endoscopist #1</td>
<td>6 (25%)</td>
<td>3 (13%)</td>
<td>3 (14%)</td>
<td>3 (14%)</td>
</tr>
<tr>
<td></td>
<td>8 (33%)</td>
<td>12 (52%)</td>
<td>11 (50%)</td>
<td>5 (23%)</td>
</tr>
<tr>
<td></td>
<td>10 (42%)</td>
<td>8 (35%)</td>
<td>8 (36%)</td>
<td>14 (63%)</td>
</tr>
<tr>
<td>Seen Booklet</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 (43%)</td>
<td>13 (57%)</td>
<td>9 (45%)</td>
<td>7 (47%)</td>
</tr>
<tr>
<td></td>
<td>8 (42%)</td>
<td>11 (58%)</td>
<td>11 (55%)</td>
<td>8 (53%)</td>
</tr>
<tr>
<td>Patient</td>
<td>In-patient</td>
<td>Day case</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>17 (71%)</td>
<td>12 (52%)</td>
<td>12 (55%)</td>
<td>11 (50%)</td>
</tr>
<tr>
<td></td>
<td>7 (29%)</td>
<td>11 (48%)</td>
<td>10 (45%)</td>
<td>11 (50%)</td>
</tr>
</tbody>
</table>
9.3.3 Immediate effects of the interventions

Between-group ANCOVA carried out to test the effectiveness of the tapes on anxiety levels, with the baseline anxiety level (Time 1) as the covariate, showed an almost significant difference between the groups, $F(3,84) = 2.59, p = 0.058$. Figure 9.1 shows the mean scores of the state anxiety measure at Time 1 and Time 2. *A priori* contrasts consisted of the following coefficients: Control group = -3, Attention control = 1, Information = 1, and Relaxation = 1 for Contrast 1; Control group = 0, Attention control = -2, Information = 1, and Relaxation = 1 for Contrast 2; and Control group = 0, Attention control = 0, Information = 1, and Relaxation = -1 for Contrast 3. Planned contrasts on the difference between the overall anxiety scores at Times 1 and 2 indicate a difference between the non-intervention control group and the three intervention groups combined, $t(85) = 2.66, p < 0.01$, but not between the attention control group and both relaxation and information groups, $t(85) = 0.472, ns$, nor between the relaxation and information groups, $t(85) = -0.632, ns$.

**Figure 9.1: Mean overall anxiety scores taken before (Time 1) and after (Time 2) the intervention**

Error bars represent 95% confidence intervals
Between-group analysis of covariance carried out to test the effectiveness of the tapes on knowledge of ERCP, with the baseline knowledge level (Time 1) as the covariate, showed a significant difference between the groups, $F(3,82) = 15.29, p < 0.001$. Figure 9.2 illustrates the mean scores of the ERCP knowledge measures at Time 1 and Time 2 and shows the largest improvement in knowledge of ERCP in the information group. A priori contrasts consisted of the following coefficients: Control group = -3, Attention control = 1, Information = 1, and Relaxation = 1 for Contrast 1, as previously; Control group = 0, Attention control = -1, Information = 2, and Relaxation = -1 for Contrast 2, comparing the information group with the other two tape groups; and Control group = 0, Attention control = -1, Information = 0 and Relaxation = 1 for Contrast 3, comparing the remaining two groups. Planned contrasts on the difference between the knowledge scores at Time 1 and Time 2 indicate a difference between the non-intervention control group and the three intervention groups combined, $t(83) = 2.821, p < 0.01$, a difference between the information group and the relaxation and attention control groups, $t(83) = 6.249, p < 0.001$, but not a difference between the attention control group and the relaxation group, $t(83) = 0.219, ns.$

**Figure 9.2: Mean ERCP knowledge scores taken before (Time 1) and after (Time 2) the intervention**

Error bars represent 95% confidence intervals
A between-group MANOVA was carried out to test for differences between perceived effectiveness of the tapes in helping subjects to feel 'relaxed', 'more informed', 'more able to cope' and 'in control'. Only subjects who listened to a tape were included in this analysis, N = 67. Figure 9.3 illustrates the mean scores for the three intervention groups. Multivariate tests showed a significant difference between the three tape groups, Wilks' Lambda = 0.573, approximate $F(8,122) = 4.89$, $p < 0.001$. Univariate $F$ indicated significant differences between three of the four items: 'more informed', $F(2,64) = 17.49$, $p < 0.001$, 'more able to cope', $F(2,64) = 7.22$, $p < 0.002$ and 'in control', $F(2,64) = 4.27$, $p < 0.02$. Univariate, a priori contrasts consisted of the following coefficients: Attention control = -2, Information = 1, and Relaxation = 1 for Contrast 1; and Attention control = 0, Information = 1, and Relaxation = -1 for Contrast 2 and indicated a difference between all groups for the 'more informed' item, $t(64) = 4.34$, $p < 0.001$ (Contrast 1) and $t(64) = 4.02$, $p < 0.001$ (Contrast 2); a difference between all groups for the 'more able to cope' item, $t(64) = 2.51$, $p < 0.02$ (Contrast 1) and

Figure 9.3: Mean scores of items on the effectiveness of the interventions

Error bars represent 95% confidence intervals
\( t(64) = 2.86, p < 0.01 \) (Contrast 2); and a difference between the attention control and the two intervention groups for the 'in control' item, \( t(64) = 2.28, p < 0.05 \). The graph and the direction of the \( t \) values indicate that for the significant differences the information group scored highest and the attention control group the lowest on these measures.

9.3.4 Patients' response to ERCP

The correlations of the observational measures are displayed in Table 9.4 and indicate that, apart from the moderate associations of technical difficulty with the endoscopist's assessment of tolerance and adjustment, the majority of associations were strong. Principal components factor analysis was conducted to check whether these measures were related in this sample. One factor was extracted accounting for 64.7% of the variance. The alpha reliability coefficient for the combined score was 0.85. Eigen-values for each item are as follows: 3.24, 0.84, 0.48, 0.24 and 0.19, and suggest that one major factor exists. The factor loadings are also shown in Table 9.4. Thus, a high score on overall response to ERCP indicated poor patient tolerance, poor patient adjustment and great technical difficulty.

| Table 9.4: Correlations and factor loadings of the behavioural measures$^8$ |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
|                             | Tolerance$^a$ | Adjustment | Factor loading |
|                             | Endoscopist | Nurse | Endoscopist | Nurse | Endoscopist | Nurse |
| Technical Difficulty        | -0.32*      | -0.37** | 0.23†      | 0.35*      | 0.49 |
| Tolerance$^a$               | -           | 0.69** | -0.77**    | -0.62**    | -0.89 |
| Endoscopist                 | -           | -      | -0.64**    | -0.79**    | -0.87 |
| Nurse                       | -           | -      | -           | 0.61**     | 0.86 |
| Adjustment                  | 0.61**     | 0.84   |             |             |     |

$^a$ reverse score $^g n = 91$

† \( p < 0.05 \)  * \( p < 0.01 \)  ** \( p < 0.001 \)
In order to address whether subjects differed in their response to ERCP and at the same time control for individual and procedural differences, hierarchical multiple regression analysis was conducted. Variables yielding significant first-order Pearson correlations with the outcome variable and other important variables were entered at the first step and consisted of: age, sex, whether patients attended as in-patients or daycases, initial medication, additional sedation received, total procedures carried out on this occasion, pre-ERCP oxygen saturation level and time spent waiting for the procedure since completing Questionnaire 2. (Other, similar variables were also correlated with these and were not included because they were highly correlated with the variables already included in the equation. Excluded variables consisted of the amount of additional analgesia, total analgesia, total sedation and duration of the ERCP procedure.) Two other variables: perceived effectiveness of the tapes in helping subjects to feel 'relaxed' and 'in control' also correlated with the outcome measure, but was not included in this analysis, as only patients who listened to a tape were required to complete these questions.

Trait anxiety and social desirability were entered at Step 2 and the three contrasts were entered at Step 3. Contrast 1 compared the control group with the attention control, information and relaxation groups, Contrast 2 compared the attention control group with the information and relaxation groups and Contrast 3 compared the information group with the relaxation group. The coefficients reported in Section 9.3.3, comparing the anxiety measures were used for these a priori contrasts. To provide a measure of coping style, the interaction of 'trait anxiety by social desirability' was entered at Step 4. Next, each 'Contrast' was multiplied by 'Social desirability' and then by 'Trait anxiety', producing 6 two-way interaction variables. These were entered at Step 5. Finally, to test for an interaction between group membership and coping style, Contrasts 1, 2 and 3 were multiplied by the previously multiplied variable of 'Trait anxiety by Social desirability' and this three-way interaction variable was entered at Step 6. Table 9.5 displays the unstandardized regression coefficients (b), the standardized regression coefficients (β) and the t scores after entry of 22 background, personality, contrast and interaction variables. R was significantly different from zero at the end of each step.

Whether each step adds a significant contribution to the equation after the variables in the previous step have been accounted for is reported in the next two paragraphs, where a
A detailed account of such contributions following each step is provided.

### Table 9.5: Regression of background variables and contrasts on patients' response to ERCP

<table>
<thead>
<tr>
<th>Variables</th>
<th>$b$</th>
<th>$\beta$</th>
<th>$t$†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-0.009</td>
<td>-0.15</td>
<td>-1.26</td>
</tr>
<tr>
<td>Sex</td>
<td>0.063</td>
<td>0.03</td>
<td>0.36</td>
</tr>
<tr>
<td>Whether in-patient or day-case</td>
<td>-0.143</td>
<td>-0.07</td>
<td>-0.81</td>
</tr>
<tr>
<td>Total procedures</td>
<td>0.029</td>
<td>0.07</td>
<td>0.37</td>
</tr>
<tr>
<td>Initial medication</td>
<td>-0.054</td>
<td>-0.11</td>
<td>-1.03</td>
</tr>
<tr>
<td>Additional sedation</td>
<td>0.207</td>
<td>0.57</td>
<td>6.34**</td>
</tr>
<tr>
<td>Pre-ERCP oxygen saturation</td>
<td>-0.125</td>
<td>-0.23</td>
<td>-2.64*</td>
</tr>
<tr>
<td>Waiting time</td>
<td>-0.001</td>
<td>-0.04</td>
<td>-0.48</td>
</tr>
<tr>
<td>Step 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>0.004</td>
<td>0.04</td>
<td>0.43</td>
</tr>
<tr>
<td>Social desirability</td>
<td>0.058</td>
<td>0.21</td>
<td>2.21*</td>
</tr>
<tr>
<td>Step 2†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>0.031</td>
<td>0.06</td>
<td>0.65</td>
</tr>
<tr>
<td>Social desirability</td>
<td>-0.117</td>
<td>-0.14</td>
<td>-1.65</td>
</tr>
<tr>
<td>Contrast 3</td>
<td>0.130</td>
<td>0.09</td>
<td>1.06</td>
</tr>
<tr>
<td>Step 3*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trait anxiety x Social desirability</td>
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<td>-0.67</td>
<td>-1.35</td>
</tr>
<tr>
<td>Step 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contrast 1 x Social desirability</td>
<td>0.025</td>
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</tr>
<tr>
<td>Contrast 2 x Social desirability</td>
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<td>-0.20</td>
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<tr>
<td>Contrast 3 x Social desirability</td>
<td>-0.034</td>
<td>-0.36</td>
<td>-0.98</td>
</tr>
<tr>
<td>Contrast 1 x Trait anxiety</td>
<td>0.004</td>
<td>0.25</td>
<td>0.69</td>
</tr>
<tr>
<td>Contrast 2 x Trait anxiety</td>
<td>-0.004</td>
<td>-0.20</td>
<td>-0.54</td>
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<tr>
<td>Contrast 3 x Trait anxiety</td>
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<td>0.46</td>
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<tr>
<td>Step 5**</td>
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<td></td>
</tr>
<tr>
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<td>-0.66</td>
<td>-0.41</td>
</tr>
<tr>
<td>Contrast 2 x Trait anxiety x Social desirability</td>
<td>0.003</td>
<td>2.19</td>
<td>1.19</td>
</tr>
<tr>
<td>Contrast 3 x Trait anxiety x Social desirability</td>
<td>0.002</td>
<td>0.67</td>
<td>0.38</td>
</tr>
</tbody>
</table>

* $p < 0.05$  ** $p < 0.005$

† Step 1 simultaneously takes all variables in Step 1 into account; Step 2 takes all variables in Steps 1 and 2 into account; Step 3 takes all variables in Steps 1, 2 and 3 into account; Step 4 takes all variables in Steps 1, 2, 3, and 4 into account; Step 5 takes all variables in Steps 1, 2, 3, 4, and 5 into account; and Step 6 takes all variables in Steps 1, 2, 3, 4, 5, and 6 into account.

‡ Where $p$ values are included for a Step indicates the probability of a significant difference in $F$ value between the variables in that Step and the previous one.
After Step 1, with demographic and procedural variables in the equation, $R^2 = 0.43$, $F(8,81) = 7.54$, $p < 0.0001$. Additional sedation and pre-ERCP oxygen saturation were significantly related to patients' response to ERCP. After Step 2, with trait anxiety and social desirability added to the prediction of response to ERCP to age, sex, total procedures, pre-ERCP oxygen saturation, whether the subject was an in-patient or a day-case, initial medication and additional sedation, $R^2 = 0.46$, $F(10,79) = 6.74$, $p < 0.0001$. The addition of these two personality variables to the equation resulted in an increase in $R^2$, $F(2,79) = 4.90$, $p < 0.01$ (difference between Step 1 and Step 2), indicating that when demographic and examination variables were controlled for these two variables added to the prediction of patients' response to ERCP, with social desirability being significantly related to the outcome measure. After Step 3, with all three contrasts added to demographic, examination and personality variables, $R^2 = 0.49$, $F(13,76) = 5.58$, $p < 0.0001$. The addition of the three contrast variables to the equation resulted in an increase in $R^2$, $F(3,76) = 4.14$, $p < 0.01$ (difference between Step 2 and Step 3), indicating that when demographic, examination and personality variables were controlled for the contrast variables added to the prediction of patients' response to ERCP. However, none of the contrasts was significantly related to patients' response to ERCP.

After Step 4, with coping style (Trait anxiety x Social desirability) added to background, personality and group contrasts, $R^2 = 0.50$, $F(14,75) = 5.37$, $p < 0.0001$. The addition of coping style did not significantly improve $R^2$, $F(1,75) = 1.82$, ns (difference between Step 3 and Step 4). After Step 5, with group and personality interactions added to demographic, examination, personality variables, contrasts and coping style, $R^2 = 0.54$, $F(20,69) = 4.05$, $p < 0.0001$. The addition of the 6 two-way interaction variables to the equation resulted in a significant increase in $R^2$, $F(6,69) = 5.98$, $p < 0.001$ (difference between Step 4 and Step 5), indicating that when demographic, examination, personality, group and coping style variables were controlled for the interaction variables added to the prediction of patients' response to ERCP. However, none of the interaction variables was significantly related to patients' response to ERCP. After Step 6 with all predictor, contrast and interaction variables in the equation, $R^2 = 0.55$, $F(23,66) = 3.54$, $p < 0.0001$, accounting for 39.6% of the variance. The addition of the three-way interaction between group and coping style did not significantly improve $R^2$, $F(3,66) = 1.73$, ns (difference between Step 5 and Step 6).
To summarise, these analyses suggest that patients assessed as having a poor response to ERCP were also more likely to have had additional sedation, a lower pre-ERCP oxygen saturation level and score higher on the social desirability scale. Together the variables in Step 3 made a significant contribution to the equation indicating that there was a difference between the four groups. As no individual contrast was significantly associated with the outcome measure indicates that any difference was not identified in the way the contrasts were set out. Patients' unadjusted mean responses to ERCP and responses adjusted after taking background variables into account are illustrated in Figure 9.4.

**Figure 9.4: Patients' original and adjusted mean responses to ERCP for each group**

Error bars represent 95% confidence intervals

![Graph showing mean responses to ERCP for each group](image)

* High score represents a poor response to ERCP

To further explore possible group differences, post-hoc analyses were carried out. All possible comparisons were entered into the multiple regression equation at Step 3, after entry of the background and personality variables. The results indicate that the most significant
contrast was the one which compared the attention control group with the relaxation group, \( t(80) = -1.69, p = 0.096. \)

### 9.3.5 Information, relaxation and participation in the study

After their ERCP procedure patients were asked about their preferences for information, whether they used a relaxation procedure and whether participation in the study helped them (not all patients completed these questions). Table 9.6 shows the numbers of patients and their preferences for information in each of the four groups. Only one patient, in the information group, expressed a preference for less information. For the purpose of Chi-square the patient who reported a preference for less information was not included in the analysis. More patients in the control group reported a preference for additional information than in any of the intervention groups, \( \chi^2(3) = 9.65, p < 0.025, \) with the majority expressing satisfaction with the amount of information they received.

**Table 9.6: Patients' preferences for information in each group**

<table>
<thead>
<tr>
<th>Amount of Information received</th>
<th>Control</th>
<th>Attention control</th>
<th>Information</th>
<th>Relaxation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Would have preferred <strong>less</strong></td>
<td>0</td>
<td>0</td>
<td>1 (5%)</td>
<td>0</td>
</tr>
<tr>
<td>Amount received was just right</td>
<td>10 (53%)</td>
<td>15 (83%)</td>
<td>17 (85%)</td>
<td>14 (88%)</td>
</tr>
<tr>
<td>Would have preferred <strong>more</strong></td>
<td>9 (47%)</td>
<td>3 (17%)</td>
<td>2 (10%)</td>
<td>2 (12%)</td>
</tr>
</tbody>
</table>

A significant difference was found between the three tape groups in reference to whether they found the tape helpful, Kruskal-Wallis test, \( \chi^2(2) = 7.44, p < 0.025. \) Table 9.7 shows patients' responses to the helpfulness of the tapes, along with the mean ranks. Comparisons relating to the perceived helpfulness of the tapes show that there was a difference between the attention control group and the information group, but not between the attention control and the relaxation, nor between the information and relaxation groups. Thus, patients in the information group rated the tapes more favourably than those in the attention control group.
Table 9.7: Responses to perceived helpfulness of the tapes

<table>
<thead>
<tr>
<th>Helpfulness of Tape</th>
<th>Attention control</th>
<th>Information</th>
<th>Relaxation</th>
</tr>
</thead>
<tbody>
<tr>
<td>'Not at all'</td>
<td>6 (30%)</td>
<td>2 (10%)</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>'A little'</td>
<td>4 (20%)</td>
<td>3 (14%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>'Moderately'</td>
<td>6 (30%)</td>
<td>3 (14%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>'Very much'</td>
<td>3 (15%)</td>
<td>7 (33%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>'Extremely'</td>
<td>1 (5%)</td>
<td>6 (29%)</td>
<td>3 (15%)</td>
</tr>
<tr>
<td><strong>Mean rank</strong></td>
<td><strong>24.65</strong></td>
<td><strong>39.02</strong></td>
<td><strong>28.92</strong></td>
</tr>
</tbody>
</table>

A significant difference was found between groups in whether patients attempted to relax whilst waiting for their ERCP, Kruskal Wallis test, $\chi^2(3) = 9.31$, $p < 0.05$. Further comparisons indicated that only the relaxation and the information groups were significantly different, with more patients in the relaxation group attempting to relax to a greater extent compared with those in the information group. Table 9.8 shows patients' use of relaxation before ERCP, along with the mean ranks for each group. Of those in the relaxation group who used a relaxation procedure before ERCP, 77% used the one provided in this study. One patient used a mixture of a previously learned relaxation procedure and the one used here.

Table 9.8: Patients' use of relaxation before ERCP for each group

<table>
<thead>
<tr>
<th>Attempts to relax</th>
<th>Control</th>
<th>Attention control</th>
<th>Information</th>
<th>Relaxation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>7 (37%)</td>
<td>8 (44%)</td>
<td>10 (67%)</td>
<td>4 (22%)</td>
</tr>
<tr>
<td>A little</td>
<td>4 (21%)</td>
<td>5 (28%)</td>
<td>2 (13%)</td>
<td>2 (11%)</td>
</tr>
<tr>
<td>Quite a lot</td>
<td>5 (26%)</td>
<td>5 (28%)</td>
<td>2 (13%)</td>
<td>8 (45%)</td>
</tr>
<tr>
<td>Very much so</td>
<td>3 (16%)</td>
<td>0</td>
<td>1 (7%)</td>
<td>4 (22%)</td>
</tr>
<tr>
<td><strong>Mean rank</strong></td>
<td><strong>37.42</strong></td>
<td><strong>31.25</strong></td>
<td><strong>26.23</strong></td>
<td><strong>45.44</strong></td>
</tr>
</tbody>
</table>

When asked whether participating in the study helped them, 72% of patients reported that
it did and the remaining 28% indicated that participation made no difference to their experience of ERCP. No patient reported that participating in the study made things worse for them. The corresponding numbers for each group are shown in Table 9.9. No difference was found between the four groups in relation to whether they found participating in the study helpful, Kruskal-Wallis test, $\chi^2(3) = 1.73$, ns.

### Table 9.9: Responses to taking part in the study for each group

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Attention control</th>
<th>Information</th>
<th>Relaxation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study helped a great deal</td>
<td>9 (41%)</td>
<td>5 (25%)</td>
<td>10 (50%)</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>Study helped a little</td>
<td>7 (32%)</td>
<td>8 (40%)</td>
<td>4 (20%)</td>
<td>9 (45%)</td>
</tr>
<tr>
<td>Study made no difference</td>
<td>6 (27%)</td>
<td>7 (35%)</td>
<td>6 (30%)</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>Mean rank</td>
<td>40.39</td>
<td>47.05</td>
<td>38.40</td>
<td>40.28</td>
</tr>
</tbody>
</table>

9.3.6 Health beliefs

As perceived control measures were taken after the psychological intervention and ERCP, these views may have been influenced by the patients' experiences of taking part in the study. The means and standard deviations of these measures are presented in Table 9.10. The four groups were similar in the three components on the Health Locus of Control Scale, Wilks' Lambda = 0.868, Approx. $F(9,188) = 1.25$, ns.

### Table 9.10: Means and standard deviations of health belief measures for each group

<table>
<thead>
<tr>
<th></th>
<th>Control group</th>
<th>Attention control</th>
<th>Information</th>
<th>Relaxation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean</td>
<td>sd</td>
<td>mean</td>
<td>sd</td>
</tr>
<tr>
<td>Internal HLC</td>
<td>8.55</td>
<td>2.84</td>
<td>7.38</td>
<td>3.47</td>
</tr>
<tr>
<td>Powerful others HLC</td>
<td>7.27</td>
<td>3.73</td>
<td>5.86</td>
<td>3.31</td>
</tr>
<tr>
<td>Chance HLC</td>
<td>6.09</td>
<td>2.84</td>
<td>5.95</td>
<td>3.85</td>
</tr>
</tbody>
</table>

174
A significant negative correlation was found between Powerful Others health locus of control and patients' desire for involvement in their own medical care, \( r(81) = -0.38, p < 0.001 \).

### 9.4 Discussion

Despite minor changes to the Mood Scale items, factor analysis yielded loadings on one factor, all of which were above 0.49. A good alpha reliability coefficient was produced by the combined scores. This measure was highly correlated with the STAI-state measure and provide further support to the findings of Studies 1 and 2, that the state anxiety visual analogue measures can be regarded as a reliable measure.

Multivariate analysis indicated a borderline difference between the groups on levels of anxiety before and after the psychological intervention. Furthermore, the tapes did not differ in their effectiveness in reducing anxiety in the three groups which listened to a tape. However, univariate analyses showed a significant difference between the control group and the three tape groups in anxiety levels immediately following the intervention. Thus, it appears that just listening to a tape, regardless of whether it is composed of a narrative or information about the impending medical procedure, seems to be as effective as listening to a relaxation tape on reducing self-reported anxiety levels. As expected, the information intervention had a significant effect on patients' knowledge of ERCP.

When patients, who listened to a tape, were asked to rate the immediate effects of the tapes, there were significant differences between three of the four items, helping subjects to feel: 'more informed', 'more able to cope', and 'in control'. Patients in the information group indicated that they felt 'more informed' and 'more able to cope' compared with those in the relaxation group, who in turn indicated that they felt 'more informed' and 'more able to cope' compared with those in the attention control group. Patients in both the information group and the relaxation group considered the tapes helped them feel 'in control' compared with the attention control group. Thus, not only were there differences between the attention control group and both psychological intervention tapes together, but also between the two
interventions for the 'more informed' and the 'more able to cope' items. There was no difference between the relaxation and information groups in patients' perceptions for the 'in control' item. It is possible that patients, whichever of the two intervention tapes they listened to interpreted the message as providing them with either informational control or behavioural control, despite the fact that they were not explicitly required to contribute to their ERCP procedure. Furthermore, patients may have perceived their 'contribution' as taking the form of being as relaxed as possible prior to ERCP.

A lack of a difference in perceived relaxation effects of the tapes between the groups indicates that patients listening to the mythical narrative or information about ERCP also reported it to be effective in helping them to feel relaxed, as reflected in patients' anxiety levels outlined above. Unfortunately, it is not possible to compare the 'actual' state of relaxation objectively using self-report measures. Studies have previously used psychophysiological measures, such as pulse rate and EMG, to make objective assessments of the effectiveness of relaxation and other interventions on anxiety levels (Gattuso et al., 1992). Baum, Grunberg and Singer (1982) provide details of these and other physiological measures of stress, which can also be used for measuring immediate effects of relaxation.

Patients assessed as having a poor response to ERCP were more likely to have a higher dose of additional sedation, have a lower pre-ERCP oxygen saturation level and score highly on the social desirability scale. Conversely, those assessed as responding well to ERCP, had less additional sedation, a higher pre-ERCP oxygen saturation level and a lower score of social desirability. It is probable that it was the staff's assessment of the patient's response which led to the administration of additional sedation despite patients' response to ERCP being the outcome measure and additional sedation - one of the predictor variables. For example, if a patient was judged as responding poorly to ERCP, then more sedation may have been given, whereas when a patient was responding in a favourable way, then it was probably assumed that the patient was sufficiently sedated and that further sedation was not required. It is not within the scope of this thesis to comment on the association of pre-ERCP oxygen saturation levels with patients' response. Regarding the association of ERCP response with social desirability, it could be that patients acting in a socially desirable way, possibly by hiding, or inhibiting, their anxiety and fear, did in fact display, or disinhibit, their fears once the initial
sedation was received (see Chapter 8; Fox, 1992).

Although individually Contrasts 1, 2 and 3 were not significantly related to patients' response to ERCP, in combination they contributed to its prediction by being significantly different from the previous step. This indicated that there may be a difference between the four groups, but this was not identified in the way the a priori contrasts were composed. Post-hoc comparisons also failed to reveal a significant difference between the four groups, although there was almost a significant difference between the attention control group and the relaxation group. Patients' coping style (the 'Trait anxiety by Social desirability' interaction) also had no effect on their response to the procedure. In other words, whether patients were repressors, truly low anxious, sensitisers or non-specific defenders had no bearing on their response to ERCP. To summarise so far, there were no significant main effects for group membership nor coping style in this study, although post-hoc tests suggest that those in the relaxation group had a marginally better response than those in the attention control group.

None of the six interactions in Step 5 was significantly associated with the outcome measure, response to ERCP, although in combination they added to its predication. Again, it is possible that the contrasts were not set up in the optimal way to test for this. Two of the interactions, 'Contrast 1 x Social desirability' and 'Contrast 3 x Trait anxiety' had $t$ values of greater than 1, and these two together probably contributed to the overall significance of Step 5. The final step which consisted of the three Contrasts by Coping style interactions failed to contribute to patients' response to ERCP. Thus, the expectations that sensitizers would benefit from the provision of information and repressors - from a relaxation procedure were not met. Possible explanations for this are discussed below.

Despite the initial effects of the interventions, group membership had no main effect on patients' response to ERCP. Furthermore, contrary to expectations, no interaction effect between group membership and coping style was found. This lack of difference, as in the previous colonoscopy study (Study 2), and lack of interaction may again be explained by the lack of opportunity to practice the relaxation procedure. Similarly, studies which have provided patients with information, have given them the time and opportunity to ask questions and this may be required for optimal effect (Kerrigan et al., 1993; Ridgeway and
Mathews, 1982). It seems that even for ERCP, where the patient is relatively more heavily sedated, a single session of relaxation or the provision of information immediately before the procedure was not enough to show the effects of such interventions. It is possible that patients were not given enough information to affect their response to ERCP. It could be that more information was required to satisfy the needs of the sensitizers (Miller and Mangan, 1983). Furthermore, patients had the opportunity to ask questions when they were consented and if this took place after the intervention and after the assessment of their knowledge of ERCP, then any potential effects as a result of the provision of information would have been confounded. The lack of a 'group by coping style' interaction also suggests that repressors were not harmed by the provision of information, nor sensitizers by the lack of it.

A greater number of patients in the non-intervention control group, indicated that they would have preferred more information before their ERCP compared with those in the other groups, who listened to a tape. This suggests that even providing patients with a relaxation or distraction procedure seemed to be enough to satisfy their information needs. However, it is possible that patients are not aware of the information available, which, had they received it, might have further improved their satisfaction. Only one patient who listened to the information tape, expressed a preference for less information. Furthermore, in contrast to the interviews concerning the appropriateness of the provision of information reported in Chapter 8, a few patients said that they particularly welcomed the additional information. One patient, when told that he was allocated to the provision of information group, expressed reservations about listening to that particular tape. However, after listening to it he said that he liked it and was reassured by it. One reason for not wanting to be exposed to additional information may be fear of the implications of that information, especially discovering the risks involved with the particular medical procedure. The information tape used in this study provided some information about the endoscopy unit, in addition to details of ERCP, and in this sense may be considered as providing reassurance. This may explain the lack of an interaction effect. In low control situations Breemharr and van den Borne (1991) recommend increasing confidence in the staff's ability for repressors. Thus, on reassessment of the contents of the information intervention (see Appendix E), it appears that messages which satisfied the needs of both repressors and sensitizers were inadvertently included, thereby preventing the identification of a difference between the two coping styles.
There was a significant difference between the groups who listened to a tape, in their perceived helpfulness of the corresponding tape, with those in the information group rating the tape more favourably compared with those in the attention control group. However, this group difference was not upheld when patients were asked about their participation in the study as a whole, with the majority of patients indicating that the study helped them. No patients reported that they were hindered by the study. One explanation for the lack of group difference may be that patients misinterpreted the question and answered it in terms of the benefit of the study to research in general. Alternatively, patients who did not feel that their participation specifically benefited them, may have either responded with social desirability - answering in a way they thought the investigator may have expected them to or, to avoid a state of cognitive dissonance - that having invested time and energy in the study, they didn't like to admit that they had not received any benefit at all (Festinger, 1957). Another possibility is that patients might have felt relieved that the medical procedure was over and this may have been reflected in their responses.

Despite some subjects failing to respond to the item which asked 'whether they relaxed or attempted to relax whilst waiting for their ERCP', there was a difference between the information and relaxation groups, as might be expected. Some patients may routinely try to relax whilst waiting for medical procedures and this may explain the attempts to relax by those in the control and the attention control groups. Alternatively, it may be that patients who listened to the information tape, felt reassured about the impending procedure and thus may not have felt the need to deliberately relax.

Perceived control, as measured by the MHLC scale, was similar in the four groups and, therefore, assumed to be unaffected by the interventions. This was also found in the previous study. However, as these measures were only taken on one occasion, after the intervention and medical procedure and not prior to a psychological intervention, it is not possible to ascertain whether perceived control was in fact influenced by their experiences in these patients. Future studies could test this by taking the measure on more than one occasion. A significant negative correlation was found between Powerful Others health locus of control and patients' desire for involvement in their own medical care. This is in line with previous findings (Dinning and Crampton, 1989; Wallston et al., 1983) including those of Study 2.
In summary, immediate beneficial effects of the interventions on levels of anxiety were found in each group which listened to a tape, and not in the non-intervention control group. Only those in the information group showed an increase in their knowledge of ERCP. Patients in the information group rated that tape in being more effective in helping them to feel 'more informed' and 'more able to cope' than those in the relaxation group, who in turn perceived their tape in being more effective than those in the attention control group. There was no difference between the two intervention groups in patients' perceptions of the tapes helping them feel more 'in control', although both intervention tapes helped patients to feel more 'in control' compared with the attention control tape. Predictors of patients' response to ERCP included additional sedation, pre-oxygen saturation levels and social desirability. No group by coping style interaction was found. One of the reasons for this may be the contents of the information tape as well as the fact that patients only listened to the tapes on one occasion, immediately before their medical procedure. Future studies could incorporate a measure of effects of information over time (Ludwick-Rosenthal and Neufeld, 1993), in particular, the extent that information is understood and remembered during the pre-procedural period. Despite findings by Elfant et al., (1995) that the timing of informed consent does not affect how much information is retained, it is also important that patients are given time to assimilate the information received (Kerrigan et al., 1993; Ridgeway and Mathews, 1982) and the opportunity to ask questions. Another possibility is the provision of more elaborate information, such as modeling or cognitive-behavioural interventions with this patient population. The type of information, particularly where details of the procedure or about the skills of the staff involved are provided, should be paid particular attention.
10 General Discussion

Chapter overview

This final chapter commences with a discussion of general themes which are common to two or more of the studies already described. This is followed by an outline of the contribution that the work included in this thesis makes to the research literature. Finally, there is a description of how the individual studies and the research project as a whole might have been carried out differently, with suggestions for future research in this field.

10.1 Common themes emerging from the studies reported in this thesis

10.1.1 Patients' experiences of GI endoscopy and their attitudes to psychological preparation

The first of the preliminary studies showed how the experience of colonoscopy can vary between individuals. Patients also described how their experience of colonoscopy at the time of the interview differed from that of previous examinations. These differences in colonoscopy experiences were reflected in patients' descriptions, reported in Preliminary study 1. In an attempt to ascertain the best psychological preparation for a colonoscopy examination patients were also asked about the information they had received. The majority were satisfied with the amount of information provided by the endoscopy unit, which consisted solely of instructions concerning the administration of the bowel preparation, whereas, accounts of the colonoscopy procedure itself were obtained from a number of different sources.

Similarly, the majority of patients undergoing UGI endoscopy and ERCP considered themselves well enough informed about the procedure and satisfied with the information they received (Preliminary study 3). As with the colonoscopy interviews this could be due to the timing of the interview, especially as patients generally express relief once their medical
procedure is over (e.g., Salmon et al., 1994) and were satisfied with the staff during their stay in the endoscopy unit. As already mentioned patients may not be aware of what information is available and there seems to be a general fear of becoming aware of the medical details concerning particular procedures which patients had recently experienced. As a consequence some patients do not want to be informed of the details of the particular medical procedure concerned, although it is unlikely that all patients interviewed would hold this view or adopt this approach to stressful medical procedures. Future studies could test this by taking measures of coping styles and patients' attitudes to their involvement in their own medical care when asking about the provision of additional information. In the interviews carried out with patients who had undergone ERCP some patients stated that they trusted the doctors to do their best or that they didn't want to criticise the staff. Breemharr and van den Borne (1991) in fact recommend, amongst other things, increasing the patients' confidence in the staff for patients who use a 'blunting' or 'repressing' strategy for coping with stress in low control situations, such as ERCP procedures. Thus, it seems that some patients adopt attitudes that would help their particular coping style.

In contrast to the interview data, patients in Study 3 who were not given any form of intervention reported that they would have preferred more information before their ERCP compared with those in the other groups, who listened to a tape. Only one patient who listened to the information tape, expressed a preference for less information, although some patients who had previously undergone ERCP said that they particularly welcomed the additional information.

Analyses carried out in Studies 1 and 2 indicate that the dose of analgesia reflected the type of experience patients had, with a higher dose being associated with a poorer experience. Study 1 also identified age and group membership as further predictors of colonoscopy experience, with older patients and those who underwent one of the psychological interventions having had a more successful colonoscopy examination. Study 2, in comparison, revealed that a low anxiety state before any psychological intervention and a shorter procedure was associated with a good examination, as indicated by both self-report and observational measures.
Like patients undergoing colonoscopy, lower doses of sedation were associated with better responses to the procedure for the patients undergoing ERCP. Unlike the colonoscopy studies, however, the outcome measure used for this study was completely based on behavioural observations, reflecting the staff’s assessment of patients’ responses which imply that the response was judged to be better when the dose required to maintain sedation was lower. Therefore, as mentioned in Chapter 9, it is not surprising to note the association between the staffs' assessment of patients' response to the procedure and the amount of sedation received. In addition to sedation dose, patients’ pre-ERCP oxygen saturation was related to their response to the procedure, where patients with lower oxygen saturations had a poor response to ERCP. Social desirability was also associated with patients' response to ERCP, but not with patients' experience of colonoscopy as indicated in Study 2 where this measure was also taken. Patients with higher scores on the Social desirability scale tended to also have a poor response to ERCP. As discussed in Chapter 9 this may be due to the differences in alertness of patients in both types of endoscopy studies and differences in the types of outcome measures used. Future research is necessary to test this speculation as this measure was not included in the first colonoscopy study.

10.1.2 Efficacy of the psychological interventions

When the effectiveness of the relaxation tapes was first tested in Preliminary study 2, there was a favourable response for both relaxation procedures (see Chapter 4). Study 1, where patients recorded their levels of anxiety in the week prior to their colonoscopy examination, showed a favourable effect of the ‘relaxation alone’ procedure on the reduction of anxiety (see Figure 6.1). The ‘relaxation plus control’ procedure also appeared to have an effect on the anxiety trend compared to the control group, albeit to a lesser extent than the ‘relaxation alone’ tape. Listening to any of the relaxation procedures in Study 2 was immediately effective in reducing anxiety levels in patients about to undergo colonoscopy, but this was not significantly different from the effects of the attention control procedure, a mythical narrative. A similar effect was found in patients waiting to undergo an ERCP procedure, where all of the tapes used in Study 3 (relaxation, attention control and information) were effective in reducing anxiety compared with a non-intervention control group. In Studies 2
and 3 it appears that just listening to a tape, regardless of whether it is composed of a narrative or information about the impending medical procedure, seems to be as effective as listening to a relaxation tape in reducing anxiety levels. This was the case for patients waiting to undergo either ERCP or colonoscopy. As mentioned in Section 7.4 the material used for attention control groups would probably influence their effectiveness in reducing anxiety.

Manipulation checks are important and their absence has been criticised in other intervention studies (see Chapter 2; Ludwick-Rosenthal and Neufeld, 1988). It was not enough to test the effects of relaxation on anxiety levels, as the other interventions (information and attention control) were as effective as the relaxation procedures in reducing state anxiety. Manipulation checks in the form of items seeking to establish the immediate effects of the interventions were carried out. The items were as follows: 'How effective were the tapes in helping you to feel 'relaxed', 'confident', 'more able to cope' and 'in control'? In Study 3, the 'confident' item was replaced with 'more informed'. As this could not be done immediately after the intervention in Study 1, patients were given a choice of responses when asked how often they listened to the tape and how often they were able to relax, once their examination was over.

The two relaxation groups in Study 1 did not differ in how often they listened to the tapes, nor their ability to relax. However, it is not clear whether patients attempted to relax without listening to the tapes as this information was not sought. This could be rectified in future studies which incorporate home-based interventions. There is a potential problem with patients who already use some form of relaxation. It was probably not enough to ask about the number of experiences of different relaxation-type procedures subjects have attempted, as this is no indication of the amount of practice in any one type of procedure. What is important is to know how much they practice their particular procedure and what benefits they receive, as this coping strategy is likely to influence the effectiveness of interventions introduced in studies like the ones conducted in this thesis.

There was no distinction in Study 2 between the tape groups ('relaxation alone', 'relaxation plus control' and attention control) in how effective the interventions were in helping patients to feel 'in control' and 'more able to cope'. In Study 3, in contrast, the attention control tape
was not as effective as the relaxation tape and the information tape in helping patients to feel 'in control' and 'more able to cope'. There were no differences in Study 3 between the relaxation and information groups in the 'control' item. Thus, the relaxation procedure was as effective as the information tape in helping patients to feel 'in control'. These differences between Study 2 and Study 3 in the 'control' and the 'more able to cope' item may reflect the type of endoscopy procedure patients were about to undergo or whether patients attended the endoscopy unit as an in-patient or as a day-case, either of which may in fact indicate their state of health. In addition, there were no differences between the tape groups in Study 2 in how effective the interventions were in helping patients to feel 'confident'. All patients in this study were day cases. As this item was not included in Study 3 comparisons cannot be made.

As well as manipulation checks carried out to test the effects of relaxation, information was also assessed in Study 3. The item 'more informed' was used as part of this assessment, though it was not specified what patients would feel more informed about. There were differences between all three tape groups, with those in the information groups indicating that they felt better 'informed' than those in the relaxation group and both intervention tapes were assessed as providing more information than the attention control tape. Analyses also revealed differences between the relaxation and information groups in perceived ability to cope, which may reflect the difference in the information received. Information checks were more closely assessed with questions where patients' knowledge of ERCP was measured. Further manipulations checks regarding the self-initiated practice of relaxation - before or during endoscopy - are discussed in Section 10.1.5.

It is worth noting in this context that the conditions when running the experiments were not ideal. Every effort was taken to ensure that the patients were not disturbed when listening to one of the tapes. Unfortunately, there were occasions when the surrounding noise levels were particularly high. Although this is considered a nuisance it does add to the ecological validity of the interventions, in that it reflects the situation in the 'real' world. A study which was conducted in ideal circumstances may not be readily applied to 'unfavourable' circumstances, resulting in different outcomes. Findings from Preliminary study 2 indicated that patients' awareness of, or disturbance by, noise was not associated with their state of relaxation. However, awareness of noise was related to their strength of imagery
and perceived effectiveness of the tape. Unfortunately, comparisons cannot be made for the effects of noise on either the attention control tape or the provision of information tape.

10.1.3 Group differences during GI endoscopy

Beneficial effects of relaxation on GI endoscopy procedures emerged in Study 1, but not in Studies 2 or 3. Thus it appears that in order for group membership to make a difference in patients' experience of colonoscopy or patients' response to ERCP a single session of relaxation was not enough and repetitive exposure to a relaxation procedure or other psychological intervention may be required. Future studies could formally compare groups of patients, some of which listen to a relaxation tape on only one occasion with a group who listen to a relaxation tape on a number of occasions. The assumption that the effects of relaxation would have a lasting impact for those not deliberately using it during colonoscopy or immediately before ERCP was not upheld. This may be explained by the amount of time patients spent waiting for their respective medical procedures (the mean waiting time was approximately 20 minutes in Study 2 and 40 minutes in Study 3).

The finding that the main effects of intervention were significant in Study 1 but not in Studies 2 and 3 may also indicate that the effects of sedation are more powerful than psychological interventions when the latter are carried out on only one occasion. The question of sedation raises a further possible explanation for the difference in that patients in the first study had less sedation overall compared with those in the second study. The mean total sedation in Study 1 was 1.32mgs of midazolam, compared with 2.31mgs in Study 2. Although an explanation along these lines appears plausible, it is in contrast to other studies where a single session of relaxation was effective as reflected in intra-operative outcome measures for patients undergoing day-case surgery, where the level of sedation was even greater than that of patients undergoing ERCP (Markland and Hardy, 1993).

Following the validation of the relaxation tapes in Preliminary study 2 it was hoped that differences in their effects would be identified when other measures relating to the endoscopy itself were used. This was not the case in Study 1. However, an interaction was found in
Study 2, where patients with low scores on trait anxiety had a 'better' experience of colonoscopy when they listened to the 'relaxation plus control' procedure than those who listened to the 'relaxation alone' procedure. Those scoring moderate or high trait anxiety showed no difference in experience of colonoscopy in relation to which relaxation tape they listened to. On this evidence, patients scoring low on trait anxiety appear to be more able to utilize the 'control' message to improve their experience of colonoscopy. This could be explained in terms of an individual's available resources to cope with a stressor (Lazarus and Folkman, 1984; McGrath, 1970; Menaghan, 1983). Thus, there is some evidence of a difference between the two relaxation procedures for those with low trait anxiety, but further research would be necessary to examine the presence of any other differences.

The multiple regression analysis used in both Study 2 and Study 3, suggested that there was a difference between the groups, although not in the way that the contrasts were set up. However, even post-hoc tests failed to reveal where this difference was. This is a common finding in studies of this sort and relates to statistical power. Some conservative post-hoc tests, such as the Scheffé test, sometimes also fail to reveal differences when the overall \( F \) in an analysis of variance indicates a significant difference between groups. One explanation is that due to the number of tests used, the alpha level should have been set lower, in which case there would have been no significant differences between the groups.

Coping style (the 'Trait Anxiety by Social Desirability' interaction) had no effect on patients' experience of colonoscopy (Study 2) nor on patients' response to ERCP (Study 3). One would not necessarily expect there to be a significant main effects difference between patients with different coping styles. Contrary to expectations, however, no interaction effects were found in Studies 2 or 3. Factors which might account for the lack of an interaction effect in Study 3, as discussed in Chapter 9, include the lack of opportunity to practice relaxation or to discuss the information received and the amount or level of information provided. In the case of the provision of information it might be questioned whether it was enough for the needs of sensitizers or alternatively whether its provision was reassuring for repressors, thus potentially satisfying the needs of both. An important additional fact is that patients had the opportunity to ask questions when they gave their consent for ERCP. If this took place after the intervention and after the assessment of their knowledge of ERCP, then any potential
effects as a result of the provision of information would have been confounded. Finally, it could be that the differences between the two relaxation tapes used in Study 2 was not large enough, specifically the coping enhancement, to result in a significant group by coping style interaction, like the one found by Gattuso et al. (1992).

10.1.4 Health care preferences and perceived control

As might be expected, there were no group differences in Health Opinion Survey (HOS) scores when the measure was used prior to any psychological intervention in Study 3. Similarly, patients' preferences for health care did not differ significantly between groups in Study 1, though in this case the measures were taken after the psychological preparation and the colonoscopy examination. It is not clear from the literature whether such preferences are sensitive to changes in patients' health opinions, or whether such opinions do in fact change as a result of brief psychological interventions, such as relaxation. The results of Study 2, however, suggest that health care opinions may be influenced by patients' experiences. In that study, with the measure being taken following the intervention, the desire for involvement in medical care was significantly different in the four groups. The patients who listened to a tape scored slightly higher than those in the non-intervention control group. It appears that having an active role in their preparation, such as listening to a tape, may influence patients' reports concerning their desire for greater involvement in their medical care.

In Studies 2 and 3 perceived control, as measured by the Multi-dimensional Health Locus of Control scale following the respective medical procedures, was similar in the four groups and, therefore, is assumed to have been unaffected by the interventions. However, it is important to note that these measures were not taken prior to any psychological intervention and so it is possible that perceived control may have differed between the groups at the start of the studies. It would be expected that due to random allocation the groups would not be significantly different before any intervention. However, inspection of the background variables in Study 1 revealed differences in state anxiety levels and previous number of colonoscopy examinations. Previous studies have used Locus of Control scales as outcome
measures (e.g., Wallston and Wallston, 1982) indicating they may be used to detect changes in perceived control.

Both these measures were only taken on one occasion, generally after the intervention and medical procedure and, apart from the HOS in Study 3, not prior to any psychological intervention. Therefore it is not possible to determine the extent that subjects' experiences can influence perceived control. Future studies could ensure that these measures are either taken prior to any intervention or, to test any changes in health opinions and perceived control, the measures would have to be taken on more than one occasion - before and after the psychological intervention and following the medical procedure.

A significant negative correlation was found between Powerful Others health locus of control and patients' desire for involvement in their own medical care in Studies 2 and 3. This is in line with previous findings (Dinning and Cramptom, 1989; Robson-Whelen and Storandz, 1992; Wallston et al., 1983) which support that notion that these two sub-scales are measuring a similar construct. Wallston et al. (1983) note that the degree of overlap between the two scales in their studies was not totally accounted for and they make a distinction between the locus of control scales as measuring expectancies concerning health, an outcome, and the HOS as measuring attitudes or preferences with respect to aspects of health care delivery, a process.

10.1.5 Self-implementation of relaxation

In Studies 1 and 2 there were low levels of implementation of the relaxation procedures during the colonoscopy examinations. Patients were not explicitly advised to relax which may explain both this low level of implementation and the lack of group differences in the second colonoscopy study. More patients in the relaxation group in Study 3 attempted to relax whilst waiting for ERCP, than the patients in the equivalent groups in both colonoscopy studies. However, due to the nature of the medical examinations there are problems in making comparisons between the studies regarding the actual numbers of those who used relaxation in this way. For Study 1 patients could spontaneously choose to relax on two
occasions: whilst waiting for their colonoscopy or during it. For both Study 2 and Study 3 some patients would not have had time to practice relaxing before being called in for their respective medical procedures. Furthermore, in Study 3, with the patients being so heavily sedated, any attempts to relax during ERCP would be taken over by the effects of the medication.

Another explanation for the low levels of implementation is in the nature of the medical examinations. Patients are required to change position during the colonoscopy examination when requested to do so by the physician. They are encouraged to observe the monitor screen which displays their own colon. Furthermore, the physician may explain aspects of the examination and encourage the patient to ask questions. These distractions, along with the effects of any sedation, would undoubtedly make any attempts to relax very difficult. As already mentioned, patients undergoing ERCP were so heavily sedated that they were unable to, or didn't need to, attempt to deliberately relax.

The percentage of patients who used relaxation during colonoscopy in Study 2 is comparable to that of Study 1. A higher percentage of patients in the 'relaxation plus control' group, and to a lesser extent those in the 'relaxation alone' group reported that they used relaxation compared with patients in the control groups. In Study 1 more patients attempted to relax immediately before colonoscopy than during the examination. Again the explanation for the reduction in the numbers relaxing during colonoscopy may be the distractions outlined above. In Study 3 there was a difference between the information and relaxation groups in whether they relaxed whilst waiting for their ERCP procedure. As discussed in Chapter 9, patients in the information groups may have been reassured about ERCP and didn't feel the need to relax, whereas those in the control groups may automatically seek to relax whilst waiting for medical procedures. Alternatively, patients may have in fact precisely followed the instructions given to them following the interventions, where they were instructed to 'use whatever they had learnt from the tape whilst waiting for their ERCP procedure'.

O'Halloran and Altmaier (1995) recommend that not only should manipulation checks be used to ensure that patients use the interventions used, but also that interventions implemented are the ones learnt in the study and not patients' own preparations. Information
regarding past experience of relaxation or similar procedures was sought and the percentage of patients who used the relaxation procedures introduced to them in the relevant studies reported in this thesis are as follows: 80% of patients in Study 1, 64% of patients in Study 2 and 77% of patients in Study 3.

10.1.6 Helpfulness of the tapes and participation in the studies

Patients who had listened to one of the tapes were asked how helpful they found it. There was no difference in perceived helpfulness between the two relaxation tapes in Study 1 and Study 2. However, in the latter study there was almost a significant difference between the attention control group and relaxation groups when examining the medians and mean ranks in Tables 7.6 and 7.7. In Study 3 there was a significant group difference, with those in the information group rating the tape more favourably compared with those in the attention control group. The remaining comparisons were not significantly different. Thus, overall patients found the relaxation and the information tapes more helpful than the attention control tape, as expected. Any differences between the relaxation and information tapes in Study 3 were not significant nor were any differences between the relaxation tape and the attention control tape. Thus compared with the attention control tape the relaxation tapes were perceived as more helpful by patients undergoing colonoscopy, whereas those undergoing ERCP found the information tape more helpful. This could be formally tested in a study which included both types of patients and two or more different tapes.

There were no differences between groups in all three studies in patients' perceptions regarding their participation. This was the case even where there was a difference between groups in their perceptions of the usefulness of the psychological interventions, in Studies 2 and 3. Of course those who were allocated to the non-intervention control group were not included for the usefulness of tapes assessment. Only in Study 1 did any patients indicate that the study had unfavourable effects. Extensive participation was required of these patients compared with those of Studies 2 and 3. This extra effort might account for these few patients being prepared to report the unfavourable effects of taking part in this study. On the whole the majority of patients indicated that they benefitted from the respective studies. As
mentioned in Chapter 9 patients may have misunderstood the question and answered it in terms of the benefit of the study to research in general. Alternatively, patients may have either responded in the way they thought the investigator expected them to or to avoid a state of cognitive dissonance (Festinger, 1957). Another possibility is that patients might have felt relieved that the medical procedure was over and this may have been reflected in their responses. Of course the reasons may include a combination of some or all of these alternatives.

10.1.7 Anxiety, observational and outcome measures

The results from all three studies provide strong support for the notion that the visual analogue anxiety mood scales reported in this thesis do in fact measure state anxiety comparable to that measured by the STAI, both the long and the short versions. Concurrent validity was upheld even when slight modifications to the items were made in Study 3. In line with other studies (e.g., Bond et al., 1995) correlations on the whole were stronger when anxiety was high. This is especially apparent in Study 3, where the measures taken at Time 3, following ERCP, were weaker than when taken at Time 1 or Time 2. Contrary to this general finding are the coefficients in Study 1, where the associations between the two anxiety measures were moderate, even though both measures were taken on occasions when patients were not expected to be anxious - a week prior to their colonoscopy examination and following it.

With each study the number of observational items and assessors completing the items was increased, commencing with just the endoscopist carrying out the procedure assessing the patients in Study 1. In Study 2 the attending nurse was added in order to test the concordance of assessment and additional measures previously used by others (Kendall et al., 1979; Wilson et al., 1982) were included in Study 3. One criticism of some of the items used in these studies is they have not been formally validated although the visual analogue scales seeking an assessment of patients tolerance and technical difficulty of colonoscopy has been used by other researchers (Saunders et al., 1994). Another criticism of the methodology in this thesis is the lack of measurement of inter-rater reliability of the observational measures.
Some studies which have included observational assessments have checked inter-rater reliability between two raters (e.g., Gattuso et al., 1992; Wilson et al., 1982), although not all have (e.g., Levy et al., 1989). Furthermore, some studies report that an observer was trained to carry out such assessments but fail to provide specific details (Johnson et al., 1973). When observational measures were taken in Studies 2 and 3 a record was also made of which nurse completed the assessment in order to compare individual raters. However, due to the nature of the management of the respective units, the turnover of nurses to the different areas within the endoscopy unit was frequent and not one nurse recorded the behavioural measures for more than 10% of the time.

It is important to note that although comparison between studies are made there are fundamental differences which need to be considered. In particular, the outcome measures used for the main multiple regression analyses. Where possible the type of measure used has been identified, but often comparisons are made between patients' experiences of colonoscopy (Studies 1 and 2) and patients' responses to ERCP (Study 3). The former have both self-report measures and observational measures which make up the overall experience score, whereas the latter only have the observational measures.

10.2 Contribution of the present studies to the research literature

In preparation for the experimental work an extensive literature search was carried out and, as well as forming the introductory chapters to this thesis, the material gathered together has been published as a review paper (Woloshynowycz et al., 1996). The work carried out in this thesis has provided an indication of patients' levels of anxiety in the week leading to colonoscopy, where measures were taken prospectively. These data support Johnston's (1980) speculation concerning patients' anxiety levels prior to surgical procedures and suggest that the same may be the case for this particular medical procedure. Study 1 showed that it is possible to delay the increasing trend in anxiety in the week leading to a colonoscopy examination by using relaxation procedures. This has important implications not only for those working with GI patients but also patients waiting to undergo other medical or surgical
procedures. Future studies could attempt to replicate this finding with this and other patient populations.

To date no studies which seek to explore both psychological and physiological factors which relate to patients' experience of colonoscopy have been found. Only one other study has sought to identify the different aspects of patients' experience of colonoscopy (Salmon et al., 1994), but without identifying which intra-examination aspects relate to the experience. The questionnaire devised by Salmon et al. (1994) was included in the outcome measures used in Studies 1 and 2. Pervious intervention studies have either used only self-report anxiety as outcome measures (e.g., Lanius et al., 1990) or, where the three recommended types of outcome measures have been used, the studies are restricted to UGI endoscopy (Gattuso et al., 1992; Levy et al., 1989; Wilson et al., 1982) or to sigmoidoscopy (Kaplan et al., 1982). Psychological aspects of ERCP have not been studied in this way before and except for the area of informed consent (Newton et al., 1994) and patient controlled analgesia (Jowell et al., 1996), no studies have been found which have investigated any psychological aspects of ERCP. As with colonoscopy, factors identifying patients' response to ERCP have been examined in the present studies.

It is a matter of some concern that previous studies with colonoscopy and UGI endoscopy patients have failed to use attention control groups (e.g., Gatusso et al., 1992; Wilson et al., 1982). This is particularly true as two of the three studies described here have shown that such control groups can be as effective as psychological interventions in reducing anxiety and increasing perceptions of relaxation. However, the attention control procedures were not as effective in influencing perceptions of coping ability as a result of the interventions.

Finally the data collected on patients' perceptions of their involvement in such studies and their opinions on the usefulness of interventions as well as of participating in a study as a whole should be helpful in planning future studies.
10.3 Shortcomings of the present studies and suggestions for future research

Some possibilities for future research have already been mentioned in this chapter. Suggestions as to how the studies reported in this thesis might have been conducted differently and the implications for future work are outlined in the following paragraphs.

A shortcoming of the first study is that it did not include an attention control group. There is, however, a problem in selecting the material to use for this purpose. Poetry, prose or music could have been used, although no one of these is likely to suit everyone, especially as the participants were required to listen to the tape on numerous occasions. However, the same might be said of a relaxation tape. Not everyone would be expected to assess any one intervention favourably.

A measure of self-efficacy could have been added, although when a question relating to this was put to patients in the second preliminary study some replied that they would not know how effective the tape would be during their colonoscopy examination until they had experienced it. Others were more confident regarding the effects of relaxation during the preparation for colonoscopy in their own home rather than during the colonoscopy itself. As mentioned in Chapter 4, this may reflect views on the responsibility for health care, particularly in relation to medical screening procedures where patients do not have symptoms.

Ideally, in future studies more patients would be recruited in order to compare those who are having the medical procedure for the first time with those who have had the procedure previously. This would also help to identify any group differences, especially when the effects of the interventions are small. The Ways of Coping Questionnaire (Folkman and Lazarus, 1985) could also be used to identify which type of coping patients generally used, whether emotion-focused or problem-focused.

Other factors which may have influenced potential differences in the effects of the tapes on outcome measures include the extent of patient preference for participation in their own
medical care. Patients vary in their desire to be involved in their medical care as well as varying in their coping styles (e.g., Wilson et al., 1982). Unfortunately, for both colonoscopy studies, which included the two relaxation procedures, the Health Opinion Survey was taken after the interventions and indeed following the medical procedure and therefore, it is difficult to test this speculation in this series of studies. Thus, various personality and perception measures could be taken prior to any interventions and additionally following the medical procedure to test for changes, as outlined in Section 10.1.4.

The interventions could have been made more explicit to patients and perhaps they could have been advised that the desired effect was that less sedation would be needed for a successful examination, although care is required not to disclose the expected effects to patients. There is a risk of priming, as well as the uncontrolled effects of suggestibility and social desirability. Patients may perceive themselves as not being able to relax, some may not want to help, others may try their hardest to be a good subject or respond in a way that they think that the investigator wants them to.

Confirmatory Factor Analysis could be used to establish the factor structure of the outcome measures used in Studies 1 and 2. This analysis is now in progress and is being prepared for submission for publication in a psychometric journal in collaboration with a colleague who acted as statistical advisor for the studies described in this thesis. In future studies Structural Equation Modelling could be used to test the interesting question of whether patients' tolerance of a medical procedure affects its duration, or whether the duration of the procedure has an influence on patients' tolerance. Measures of patients' tolerance or pain levels and an indication of how far the endoscopist is progressing into the gastrointestinal tract would need to be taken at regular intervals, such as every 5 or 10 minutes. Similarly, the relationship between the amount of sedation administered to patients undergoing ERCP, or other procedures, and the observations of their responses to it could also be formally explored.

These studies were conducted in an attempt to expand and improve on existing research and they in turn need to be improved on in the ways suggested above. Assessing or evaluating previous research is difficult, taking into account different methodological considerations and
the diverse measures, including outcome measures, that have been used. Such difficulty has been widely acknowledged by review authors (e.g., Anderson and Masur, 1983; Ludwick-Rosenthal and Neufeld, 1988; O'Halloran and Altmaier, 1995). Whilst recognising that it is extremely difficult to address all of the flaws or shortcomings in previous research or in our own studies, as researchers we should strive to do so.
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APPENDIX A - Materials for Preliminary study 2

* Transcript of the 'Relaxation Alone' tape

* Transcript of the 'Relaxation Plus Control' tape
  Additions to the 'Relaxation Alone' tape are in italics.

* Post-Relaxation Tape Questionnaire*
  This is one version of the questionnaire which contains the extra question referring to the gaps in the main part of the tape, which was given to patients who received the 'relaxation alone' tape and is shown here in italics.

* Questionnaires are reduced to 70% for binding purposes
Transcript of the 'Relaxation Alone' tape

Sitting or lying as comfortably as you can, take a deep breath and relax as you breathe out. Let your body sink down into a more relaxed position. You may find that it helps to close your eyes. Breathe gently and slowly, using the base of your lungs so that your abdomen, your tummy, is the part that is gently moving. Continue to relax more and more with each breath... on your own for a few moments...

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PAUSE 25 SECONDS
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... now,... I would like you to pay attention to your legs. You may feel the muscles of your legs becoming less and less tense ... supported by the surface beneath you... allowing the tension to drain away. The muscles of your legs ... loose, and easy and relaxed. Warm and comfortable... calm and relaxed. Tension just draining away... more and more relaxed, Breathing gently and slowly. You may notice the warmth of the surface beneath you spreading into the muscles of your legs... helping them to feel comfortable, easy and relaxed. Your legs, supported, safely and easily ... the tension draining away ... helping you to relax more and more deeply. Breathing slowly and gently. And as you breathe out feel yourself sinking down deeper into relaxation. Deeper and more relaxed. Calm, comfortable and relaxed. Continue to relax on your own for a few moments...

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PAUSE 25 SECONDS
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... And now,... The muscles of your legs, ... warm, comfortable and relaxed and the feeling of relaxation spreading into the muscles of your back. The muscles of your back becoming comfortable, relaxed ... the tension draining away as you breathe gently and slowly and deeply. More and more relaxed. Tension draining away... calm, comfortable and relaxed. The muscles of your back ... loose, and easy and relaxed. Letting the tension go, allowing a safe, warm, comfortable feeling to grow. More and more relaxed. Breathing slowly and gently. And as you breathe out ... sinking down deeper and deeper into relaxation. Deeper and more relaxed... calm, comfortable and relaxed. Continue to relax on your own for a few moments...
And now... feeling the warmth of the surface, supporting your legs and back, helping to make the muscles relaxed and comfortable and letting this warm, comfortable feeling spread to your neck and your shoulders. Breathing gently and slowly... feeling calm and relaxed. Tension in your shoulders and neck draining away with each breath. More and more relaxed. More and more comfortable. Your shoulders and neck... safely supported... the tension draining away, allowing a feeling of comfort, warmth and relaxation. More and more relaxed. Breathing slowly and gently. And as you breathe out feeling yourself sinking down deeper into relaxation. Deeper and more relaxed. Continue to relax on your own for a few moments...

PAUSE 25 SECONDS

... And now,... The muscles of your neck and shoulders, ... warm, comfortable and relaxed and the feeling of relaxation spreading into your arms. Your arms, comfortably supported, becoming relaxed... the tension draining away as you breathe gently and slowly and deeply. More and more relaxed. Tension draining away. Letting the tension go... allowing a more relaxed, warm comfortable feeling to grow. More and more relaxed. The muscles of your arms becoming loose and easy and relaxed. Breathing slowly and gently. And as you breathe out feeling yourself sinking down deeper and deeper into relaxation. Deeper and more relaxed. Calm, comfortable and relaxed. Continue to relax on your own for a few moments...

PAUSE 25 SECONDS

... And now,... The muscles of your arms, neck and shoulders, ... warm, comfortable and relaxed and the feeling of relaxation spreading into the muscles of your face... allowing your expression to soften... a nice, easy, relaxed expression. Your face, becoming comfortable, relaxed... the tension draining away as you breathe gently and slowly and deeply. More and more relaxed. Feeling tension draining away. Letting the tension go...
the muscles of your face becoming loose, easy and relaxed. More and more relaxed. Breathing slowly and gently. And as you breathe out feeling yourself sinking down deeper and deeper into the surface supporting you and deeper into relaxation. Deeper and more relaxed. Continue to relax on your own for a few moments...

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PAUSE 25 SECONDS
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Now I would like you to think of a place where you feel comfortable or relaxed. A holiday spot... a beach,... a garden perhaps, or somewhere else. It can be a real place that you know or an imagined place... or a mixture of the two. Begin to imagine... as clearly as you can, the sights, sounds and smells and all of the other feelings and sensations that are associated with being in that special place. Seeing the colours, textures and any movements ... clearer and clearer. Becoming as aware as you can of the sounds and the smells that make this special place unique. Using any or all of these sensations to allow yourself to become part of this special place... Just take a little time now to enjoy being in your special place.

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PAUSE 80 SECONDS
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... And now,... Just leave the special place if you haven't already done so, but bring with you all the good, positive and relaxing feelings.

In a moment I will count slowly from 3 to 1 and on 1 I want you to open your eyes... feeling good... completely normal... still pleasantly relaxed.
3... getting lighter and lighter... 2 getting more alert, lighter still... feeling good... feeling relaxed... and 1 ... wide awake and alert and calm.
Transcript of the 'Relaxation Plus Control' tape

Sitting or lying as comfortably as you can, take some well deserved time for yourself away from other thoughts and pressures. Take a deep breath and relax as you breathe out. Let your body sink down into a more relaxed position. You may find that it helps to close your eyes. Breathe gently and slowly, using the base of your lungs so that your abdomen, your tummy, is the part that is gently moving. Knowing that as we become calmer in our minds, our bodies know automatically how to relax and work how they should... Continue to relax more and more with each breath.

I would like you to pay attention to your legs. You may feel the muscles of your legs becoming less and less tense ... supported by the surface beneath you... allowing the tension to drain away. The muscles of your legs ... loose, and easy and relaxed. Warm and comfortable... calm and relaxed. Tension just draining away... more and more relaxed, more and more confident and in control. Breathing gently and slowly. You may notice the warmth of the surface beneath you spreading into the muscles of your legs... helping them to feel comfortable, easy and relaxed. Your legs, supported, safely and easily ... the tension draining away ... helping you to relax more and more deeply. Breathing slowly and gently. And as you breathe out feel yourself sinking down deeper into relaxation. Deeper and more relaxed. Calm, comfortable and relaxed. Knowing that if you needed, or wanted, to move you could do so without affecting whatever level of relaxation you have reached, easily and without effort.

The muscles of your legs, ... warm, comfortable and relaxed and the feeling of relaxation spreading into the muscles of your back. The muscles of your back becoming comfortable, relaxed ... the tension draining away as you breathe gently and slowly and deeply. More and more relaxed. Tension draining away... calm, comfortable and relaxed. The muscles of your back ... loose, and easy and relaxed. Letting the tension go, allowing a safe, warm, comfortable feeling to grow. More and more relaxed. Breathing slowly and gently. And as you breathe out ... sinking down deeper and deeper into relaxation. Deeper and more relaxed... calm, comfortable and relaxed. Feeling pleased and comfortable about the way in which you can help yourself by simply letting go, ... relaxing calmly.

And now,... feeling the warmth of the surface, supporting your legs and back, helping to make the muscles relaxed and comfortable and letting this warm, comfortable feeling
spread to your neck and shoulders. Breathing gently and slowly ... feeling calm and relaxed. Tension in your shoulders and neck draining away with each breath. More and more relaxed. More and more comfortable. Your shoulders and neck ... safely supported ... the tension draining away, allowing a feeling of comfort, warmth and relaxation. More and more relaxed. Breathing slowly and gently. And as you breathe out feeling yourself sinking down deeper and deeper into relaxation. Deeper and more relaxed. *Just letting your body relax and do all the things it needs to, automatically, without concerning yourself with how or why.*

The muscles of your neck and shoulders, ... warm, comfortable and relaxed and now the feeling of relaxation spreading into your arms. Your arms, comfortably supported, becoming relaxed ... the tension draining away as you breathe gently and slowly and deeply. More and more relaxed. Tension draining away. Letting the tension go ... allowing a more relaxed, warm comfortable feeling to grow. More and more relaxed. The muscles of your arms becoming loose and easy and relaxed. Breathing slowly and gently. And as you breathe out feeling yourself sinking down deeper into relaxation. Deeper and more relaxed... calm, comfortable and relaxed. *Remembering that if you needed, or wanted, to move you could do so without affecting whatever level of relaxation you have reached.*

The muscles of your arms, neck and shoulders, ... warm, comfortable and relaxed and the feeling of relaxation spreading into the muscles of your face... allowing your expression to soften... a nice, easy, relaxed expression. Your face, becoming comfortable, relaxed ... the tension draining away as you breathe gently and slowly and deeply. More and more relaxed. Feeling tension draining away. Letting the tension go ... the muscles of your face becoming loose, easy and relaxed. *The rest of your body responding easily and automatically.* More and more relaxed. Breathing slowly and gently. And as you breathe out feeling yourself sinking down deeper and deeper into the surface supporting you and deeper into relaxation. Deeper and more relaxed. *Calm, comfortable and in control.*

Now I would like you to think of a place where you feel comfortable or relaxed. A holiday spot... a beach,... a garden perhaps, or somewhere else. It can be a real place that you know or an imagined place... or a mixture of the two. Begin to imagine... as clearly as you can, the sights, sounds and smells and all of the other feelings and sensations that are associated with being in that special place. Seeing the colours, textures and any movements ... clearer and clearer. Becoming as aware as you can of the sounds
and the smells that make this special place unique. Using any or all of these sensations to allow yourself to become part of this special place... Just take a little time now to enjoy being in your special place.

-------------------
PAUSE 1 MINUTE
-------------------

...And now, staying in your special place... knowing that when you would like to relax or need to be calm you can bring back all these feeling by just thinking about this special place. Choose a feature, thought or feeling which will symbolise the place for you... and you can use that symbol, just by thinking about it or bringing it to mind, to bring back feelings of comfort, relaxation, calm and control whenever you need them. When you have these feelings, relaxing in your special place, you know that it will be simple to move comfortably and easy into a new position, to move a leg or arm without effort, just as you do quite automatically when you are asleep... without having to think about it. Like a cat moving its limbs lazily as it snoozes in the warmth of the sun or in front of an open fire.

Just leave the special place if you haven't already done so, but bring with you all the good, positive and relaxing feelings. Feeling good about the fact that spending some time for yourself relaxing and practising entering a calm, confident state is a positive way of helping yourself and of developing resources which will also help others when they help you.

In a moment I will count slowly from 3 to 1 and on 1 I want you to open your eyes... feeling good... completely normal... still pleasantly relaxed.

3... getting lighter and lighter... 2 getting more alert, lighter still... feeling good... feeling relaxed... and 1... wide awake and alert and calm, ready to face the rest of the day, rest of the week and the future.
POST-RELAXATION TAPE QUESTIONNAIRE

Here are some statements which people have used to describe how they feel. For each item, please place a tick on the scale which best describes how you feel right now.

e.g. If you feel extremely sleepy, you might tick the scale like this:
I feel sleepy

Totally  ✓  ✓  ✓  ✓  ✓  ✓  ✓  Not at all

If you do not feel sleepy, but quite awake, you might tick it thus:
I feel sleepy

Totally  _  _  _  _  _  _  ✓  Not at all

To what extent do the following describe how you feel now:

I feel calm

Totally  _  _  _  _  _  _  _  Not at all

I feel relaxed

Totally  _  _  _  _  _  _  _  Not at all

I feel comfortable

Totally  _  _  _  _  _  _  _  Not at all

I feel in control

Totally  _  _  _  _  _  _  _  Not at all

I feel confident

Totally  _  _  _  _  _  _  _  Not at all

I feel positive

Totally  _  _  _  _  _  _  _  Not at all

I feel safe

Totally  _  _  _  _  _  _  _  Not at all

I feel warm

Totally  _  _  _  _  _  _  _  Not at all

I feel content

Totally  _  _  _  _  _  _  _  Not at all

I feel pleased

Totally  _  _  _  _  _  _  _  Not at all

I feel unconcerned

Totally  _  _  _  _  _  _  _  Not at all

I feel supported

Totally  _  _  _  _  _  _  _  Not at all

I feel alert

Totally  _  _  _  _  _  _  _  Not at all

I feel peaceful

Totally  _  _  _  _  _  _  _  Not at all
<table>
<thead>
<tr>
<th>Question</th>
<th>Totally</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Not at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel able to move easily</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel good</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel pleasant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel secure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel at ease</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel rested</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel able to move effortlessly</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

**HERE ARE SOME QUESTIONS ABOUT THE RELAXATION TAPE.**

How effective was the tape in making you feel relaxed?  
Totally   |   |   |   |   |   |   | Not at all

What do you think of the gaps during the main part of the relaxation procedure?  
Are they helpful?  
If not, why not?

When you were asked to imagine your special place how similar was the experience to that of really being there?  
(Please circle 0, 1, 2, 3 or 4, which best describes your experience.)

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>not at all the same</td>
</tr>
<tr>
<td>1</td>
<td>a little the same</td>
</tr>
<tr>
<td>2</td>
<td>between a little and much the same</td>
</tr>
<tr>
<td>3</td>
<td>much the same</td>
</tr>
<tr>
<td>4</td>
<td>almost exactly the same</td>
</tr>
</tbody>
</table>

Were you given enough time in the special place?  
Y / N  
If not, would you have preferred more or less?

Do you think that such a relaxation procedure would help you to prepare for an investigation such as a colonoscopy?  
Y / N

Do you think that relaxation skills learnt from such a procedure would help you during a colonoscopy?  
Y / N

Feel free to add any other comments.
APPENDIX B - Materials for Study 1

❖ Transcript of the 'Relaxation Alone' tape - see Appendix A
❖ Transcript of the 'Relaxation Plus Control' tape - see Appendix A
❖ Patient Consent Form/Information Sheet*
❖ Letter to Patient*
  For patients in the control group, references to the tape were omitted.
❖ UCL/St Mark's Hospital Questionnaire, Mood Scales and Check List**
  For patients in the control group, references to the tape were omitted.
❖ Mood Scale 5
❖ Endoscopy Questionnaire*
❖ Post Colonoscopy Questionnaire*
  For patients in the control group, references to the tape were omitted.

* Forms and questionnaires are reduced to 70% for binding requirements
** The original UCL/St. Mark's Hospital Questionnaire, Mood Scales and Check List was A4 size folded into an A5 sized leaflet.
You are invited to take part in a study to be carried out by St Mark's Hospital and University College London. This study is designed to look at ways of reducing the concern and anxiety experienced by some patients preparing to undergo colonoscopy or similar procedures and to make the procedure itself as comfortable and successful as possible.

If you agree to take part you will be asked to fill in a couple of questionnaires: one in the week before the colonoscopy and the other after the colonoscopy. The questionnaires will ask you about how you feel and about your experience of colonoscopy. In addition, on some days you will be asked to fill in a simple mood scale (taking one minute to complete). You may also be asked to listen to a tape (which would be sent to your home).

All the information you give will be treated as strictly confidential.

The results of this study will be used to help patients whose medical treatment involves colonoscopy and other similar procedures.

If anything is not clear and you wish to discuss this study please contact:-

Maria on 071 387 7050 extension 5948

I have read the above information and I understand:

(a) What the study involves
(b) That refusal to participate will not affect my treatment in any way
(c) That I may withdraw at any time.

I therefore agree to take part in this study.

Signature: - ................................................................. Date: .................................

Your full name and address (in capitals): ........................................................................................................
........................................................................................................................................................................
........................................................................................................................................................................
........................................................................................................................................................................
........................................................................................................................................................................

(Postcode if known) ........................................

Please complete both copies of this form and send one of them in the envelope provided to:-

Ms M. Woloshynowych, Department of Psychology, Philips House, University College London, Gower Street, London, WC1E 6BT.

Thank you for your assistance.
Dear

Thank you for agreeing to take part in this study.

Please find enclosed one relaxation tape with instructions, a questionnaire, mood scales and checklist.

It is important that the mood scales are not filled in immediately after listening to the tape. Please listen to the tape at least as often as indicated on the checklist, more often if possible.

Please bring the tape and questionnaire with you when attending the hospital for your colonoscopy examination.

Just to remind you, there will be a further mood scale just before the examination and a questionnaire for you to fill in afterwards.

I look forward to meeting you and hearing your views.

Yours sincerely,

Maria Woloshynowycz,
Clinical Researcher,
UCL/St. Marks hospital
UCL/St. MARK'S HOSPITAL QUESTIONNAIRE,
MOOD SCALES AND CHECK LIST

Check list

Please fill in mood scales at the same time of day on the days requested and not immediately after listening to the tape.

1 week before colonoscopy
☐ fill in questionnaire and mood scale 1
☐ listen to tape

4 days before
☐ stop any iron or other tablets with constipating side effects
☐ fill in mood scale 2
☐ listen to tape

2 days before
☐ commence low fibre diet
☐ fill in mood scale 3
☐ listen to tape

1 day before
☐ clear fluids only; commence laxatives/preparation
☐ fill in mood scale 4
☐ listen to tape

Day of Colonoscopy
☐ return tape and questionnaire to St. Marks
☐ fill in mood scale and questionnaire at St. Marks
**I week before Colonoscopy Questionnaire**

Please answer all 40 questions.

DIRECTIONS (questions 1-20): A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

<table>
<thead>
<tr>
<th>Almost never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel pleasant.</td>
<td>2. I tire quickly.</td>
<td>3. I feel like crying.</td>
<td>4. I wish I could be as happy as others seem to be.</td>
</tr>
<tr>
<td>5. I am losing out on things because I can't make up my mind soon enough.</td>
<td>6. I feel rested.</td>
<td>7. I am 'cool, calm and collected'.</td>
<td>8. I feel that difficulties are piling up so that I cannot overcome them.</td>
</tr>
<tr>
<td>9. I worry too much over something that really doesn't matter.</td>
<td>10. I am happy.</td>
<td>11. I am inclined to take things hard.</td>
<td>12. I lack self-confidence.</td>
</tr>
<tr>
<td>13. I feel secure.</td>
<td>14. I try to avoid facing a crisis or difficulty.</td>
<td>15. I feel blue.</td>
<td>16. I am content.</td>
</tr>
<tr>
<td>17. Some unimportant thought runs through my mind and bothers me.</td>
<td>18. I take disappointments so keenly that I can't put them out of my mind.</td>
<td>19. I am a steady person.</td>
<td>20. I get in a state of tension or turmoil as I think over my recent concerns and interests.</td>
</tr>
</tbody>
</table>

(continued on opposite page)
DIRECTIONS (questions 21-40): A few more statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Somewhat</th>
<th>Moderately so</th>
<th>Very much so</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. I feel calm</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. I feel secure</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23. I feel tense</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24. I feel regretful</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25. I feel at ease</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26. I feel upset</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27. I am presently worrying over possible misfortunes</td>
<td>1 2 3 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28. I feel rested</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>29. I feel anxious</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30. I feel comfortable</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31. I feel self-confident</td>
<td>1 2 3 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32. I feel nervous</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>33. I feel jittery</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34. I feel 'highly strung'</td>
<td>1 2 3 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35. I am relaxed</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36. I am content</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37. I am worried</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>38. I feel over-excited and 'rattled'</td>
<td>1 2 3 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39. I feel joyful</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40. I feel pleasant</td>
<td></td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As this next part is a different type of question, here is an example:

**Mood scale example**

Please mark the scale to show how you feel right now.

If the scale was about tiredness and you felt extremely tired (but not totally), you might mark the scale like this:

**To what extent do you feel tired?**

Not at all tired [ ] [ ] [ ] [ ] Totally tired

Now please turn over to complete Mood scale 1 only.
Mood Scale 1: 1 week before colonoscopy
Please mark both scales to show how you feel right now.
To what extent do you feel calm?
Not at all _______________________________ Totally calm
Not at all anxious ___________________________ Totally anxious

Mood Scale 2
4 days before colonoscopy
Please mark both scales to show how you feel right now.
To what extent do you feel calm?
Not at all _______________________________ Totally calm
Not at all anxious ___________________________ Totally anxious

Mood Scale 3
2 days before colonoscopy
Please mark both scales to show how you feel right now.
To what extent do you feel calm?
Not at all _______________________________ Totally calm
Not at all anxious ___________________________ Totally anxious

Mood Scale 4
1 day before colonoscopy
Please mark both scales to show how you feel right now.
To what extent do you feel calm?
Not at all _______________________________ Totally calm
Not at all anxious ___________________________ Totally anxious
Mood Scale 5
Please mark both scales to show how you feel right now.

To what extent do you feel calm?
Not at all __________________________________________________  Totally calm

To what extent do you feel anxious?
Not at all __________________________________________________  Totally anxious
Endoscopy Questionnaire

Patient’s Name ................................................................. Indication ...........................................

Type of premedication given ..............................................

Time procedure started .............................................

<table>
<thead>
<tr>
<th>TIME (5 min intervals)</th>
<th>Heart rate</th>
<th>Analgesia</th>
<th>Sedation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Before colonoscopy)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(End of colonoscopy)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please indicate the difficulty of the procedure?

Very easy _____________________________ Very difficult

Please indicate how well the patient tolerated the procedure?

Poorly tolerated _____________________________ Well tolerated

Time procedure ended ..................

Time patient left recovery area .............

Endoscopist ......................
**POST-COLONOSCOPY QUESTIONNAIRE**

All the answers you give are confidential, and will help our future research into Colonoscopy.

**DIRECTIONS:** A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

<table>
<thead>
<tr>
<th>Number</th>
<th>Statement</th>
<th>Not at all</th>
<th>Somewhat</th>
<th>Moderately so</th>
<th>Very much so</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I feel calm</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>I feel secure</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>I feel tense</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>I feel regretful</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>I feel at ease</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>I feel upset</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7</td>
<td>I am presently worrying over possible misfortunes</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8</td>
<td>I feel rested</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9</td>
<td>I feel anxious</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10</td>
<td>I feel comfortable</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>11</td>
<td>I feel self-confident</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>12</td>
<td>I feel nervous</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>13</td>
<td>I feel jittery</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>14</td>
<td>I feel 'highly strung’</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>15</td>
<td>I am relaxed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>16</td>
<td>I am content</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>17</td>
<td>I am worried</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>18</td>
<td>I feel over-excited and 'rattled'</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>19</td>
<td>I feel joyful</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>20</td>
<td>I feel pleasant</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

**Mood Scale 6**

Please mark both scales to show how you felt then.

- **To what extent do you feel calm?**
  - Not at all ____________________________ Totally calm
  - Not at all ____________________________ Totally anxious

**Colonoscopy Experience**

This part of the questionnaire is for you to tell us how you felt about the last colonoscopy you had.

**Example**

For each item, place a mark on the scale to describe your experience.

- If you felt extremely sleepy, you might mark the scale like this:
  - Sleepy _______ Awake

- If you felt quite awake, you might mark it thus:
  - Sleepy _______ Awake
For each item, place a mark on the scale to describe your experience.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Interested</td>
<td>Uninterested</td>
<td></td>
</tr>
<tr>
<td>Confused</td>
<td>Not confused</td>
<td></td>
</tr>
<tr>
<td>Worried</td>
<td>Calm</td>
<td></td>
</tr>
<tr>
<td>Dignified</td>
<td>Undignified</td>
<td></td>
</tr>
<tr>
<td>In control</td>
<td>Helpless</td>
<td></td>
</tr>
<tr>
<td>Staff were warm</td>
<td>Staff were cool</td>
<td></td>
</tr>
<tr>
<td>Comfortable</td>
<td>Uncomfortable</td>
<td></td>
</tr>
<tr>
<td>Satisfied</td>
<td>Dissatisfied</td>
<td></td>
</tr>
<tr>
<td>Relieved when it was over</td>
<td>Not relieved</td>
<td></td>
</tr>
<tr>
<td>Agitated</td>
<td>Calm</td>
<td></td>
</tr>
<tr>
<td>Staff were interested in me</td>
<td>Staff weren’t interested in me</td>
<td></td>
</tr>
<tr>
<td>Pleased with how it went</td>
<td>Displeased with how it went</td>
<td></td>
</tr>
<tr>
<td>Confident in the staff</td>
<td>Not confident in the staff</td>
<td></td>
</tr>
<tr>
<td>Soreness</td>
<td>No soreness</td>
<td></td>
</tr>
<tr>
<td>It went as expected</td>
<td>Not as I expected</td>
<td></td>
</tr>
<tr>
<td>Staff were informative</td>
<td>Staff were uninformative</td>
<td></td>
</tr>
<tr>
<td>Weary afterwards</td>
<td>Not weary afterwards</td>
<td></td>
</tr>
<tr>
<td>Afraid of making a “fool of myself”</td>
<td>Not afraid of making a “fool of myself”</td>
<td></td>
</tr>
<tr>
<td>Frightened</td>
<td>Not frightened</td>
<td></td>
</tr>
<tr>
<td>I understood what was happening</td>
<td>Did not understand what was happening</td>
<td></td>
</tr>
<tr>
<td>Not Painful</td>
<td>Painful</td>
<td></td>
</tr>
<tr>
<td>I’d have preferred to have been more awake</td>
<td>I’d have preferred to have been less awake</td>
<td></td>
</tr>
<tr>
<td>Puzzled</td>
<td>Not puzzled</td>
<td></td>
</tr>
<tr>
<td>Worried about what they would find</td>
<td>Not worried about what they would find</td>
<td></td>
</tr>
</tbody>
</table>
Health Opinions

Please tick the box to show whether you agree or disagree with each statement.

Except for serious illness, it’s generally better to take care of your own health than to seek professional help.

Clinics and hospitals are good places to go for help since it’s best for medical experts to take responsibility for health care.

I’d rather be given many choices about what’s best for my health than to have the doctor make the decision for me.

Learning how to cure some of your own illness without contacting a doctor is a good idea.

I usually ask the doctor or nurse lots of questions about the procedures during a medical exam.

It is better to rely less on doctors and more on your own common sense when it comes to caring for your body.

It is better to trust the doctor or nurse in charge of a medical procedure than to question what they are doing.

Recovery is usually quicker under the care of a doctor or nurse than when patients take care of themselves.

I usually wait for the doctor or nurse to tell me the results of a medical exam rather than asking them immediately.

It’s almost always better to seek professional help than to try to treat yourself.

You and this study

Have you ever had a colonoscopy before? YES/NO

If YES, how many times before? ............

What is your age? .........

Please tick one of the following...

□ Single (or divorced or widowed)
□ Married (or living with a partner)

Please tick one of the following that best describes your employment.

□ Employed  □ Self-employed  □ Housewife/husband
□ Unemployed  □ Retired  □ Student

If you do have a job, tick the one of the following that best describes it.

□ unskilled manual
□ skilled manual
□ shopwork/clerical/officework
□ skilled technical
□ professional/managerial

Were you able to listen to the tape?

□ More than the minimum suggested
□ Same as the minimum suggested
□ Sometimes
□ Only once
□ Not at all
Were you able to relax? □ Yes, every time □ Sometimes □ Only once □ Not at all

Please tick the type of relaxation, or similar, instruction you have received in the past?
□ None □ meditation □ yoga □ ante natal classes □ aromatherapy □ stress management □ other (please specify) .................................................................

If you have used a relaxation procedure in the past, how similar was it to the tape used in this study?
Not at all similar ____________________________________________ Almost the same

Did you use any relaxation skills you have acquired to relax:
1) immediately before the colonoscopy? yes/ a little/ no
2) during the colonoscopy? yes/ a little/ no

If you answered yes or a little, was the relaxation skill you used the one you learned from the St. Mark’s tapes? Yes/No

How helpful were the St. Mark’s tapes? Not at all/A little/Moderately/Very much/Extremely

In connection with your experience of colonoscopy do you think your participation in this study has:
(please circle 1 of the following)
helped a great deal □ helped a little □ made no □ made things □ made things
helped a little □ made no □ made things □ made things □ made things

made no □ made things □ made things □ made things □ made things

Please feel free to add any other comments.

THANK YOU VERY MUCH FOR YOUR HELP
APPENDIX C - Materials for Study 2

* Transcript of the 'Relaxation Alone' tape - see Appendix A

* Transcript of the 'Relaxation Plus Control' tape - see Appendix A

* Transcript of the attention control tape

* Information sheet*

* Consent form*

* Questionnaire 1

* Questionnaire 2
  For patients in the control group, references to the tape were omitted.

* Endoscopy Questionnaire*
  The nurses's assessment of patient's tolerance was backed, to prevent comparisons with the endoscopist's assessment.

* Post Colonoscopy Questionnaire*
  For patients in the two control groups, references to comparisons with the relaxation procedure was omitted; and for patients in the non-intervention control group references to the tape were also omitted.

* Forms and questionnaires are reduced to 70% for binding requirements
The Dream of The Emperor Maxen

In the days of ancient Rome the Emperor Maxen, a man of wisdom and tolerance, had an extraordinary experience.

One morning, announcing that he wanted to hunt, he and a bunch of companions rode to the Tiber valley north of Rome. Rarely has a hunting-party had such illustrious membership - no fewer than thirty-two crowned heads, all client-kings, tenants of his empire, all offering the most explicit allegiance to Maxen. From such glorious groupings around him Maxen took his real pleasure (much more, it has to be said, than from the actual hunting).

The day, as it does along the Tiber, grew very hot and sleepy and the emperor's attendants arranged a shelter around him. They did this by hanging all the party's shields on their spears until they formed a kind of tented roof, and they pillowed him with an imperial gold shield. Honoured and protected, he slept well, and then came the beginning of the strange experience - because Maxen had a dream, a colourful, journey dream.

He dreamt that he left the space where they had all now gathered and travelled to the far end of the valley where a high mountain rose, the highest on earth, its tip as high as the blue sky itself. When he climbed this mountain, a wide and beautiful plain lay beyond. Several broad shining rivers flowed down the mountain across this plain to the sea, and he joined the widest of these, travelling downstream until he came to the river's huge mouth. Within this bay stood a city, protected by a great castle, distinguished by many multi-coloured towers. Beneath the castle walls, riding at anchor on the water, Maxen saw the biggest fleet he had ever encountered or even heard of, with a flagship so magnificent that the planks on deck alternated from gold to silver and the gangplank had been made from the ivory of walrus tusks. In his dream Maxen was himself walking along that ivory plank, and when he had embarked the mariners hoisted sail; the ship sailed out of the harbour across oceans to an island that, he felt, must be the most exquisite and lush anywhere.

He traversed this island on whose furthermore side stood insurmountably tall and jagged peaks and then came another island, where in another wide bay stood another great castle. Maxen entered this gigantic building, walking into the high hall of the keep.

He looked slowly all around him in amazement. The roof of this hall had been made of gold, the walls inset with jewels, the doors gold too, and golden couches beside silver
tables. On one such seat two young golden-haired boys played a board game; they wore
clothes made of jet-black satin and brocade, thin headbands of gold studded with shining
gemstones and brilliant leather shoes strapped to their feet with bars of pure gold.

At the foot of a pillar nearby Maxen saw an ancient man with copious white hair. He
sat on a large ivory chair on which had been carved in gold the twinned figure of eagles.
Wearing gold armlets and rings as well as a thick gold torc round his neck, the old man
seemed most distinguished by virtue of his bearing as well as his dress. He sat carving pieces
for the same type of board game that the young boys were playing.

Across the room from the elderly man Maxen saw a girl, sitting in a gold chair, and
her beauty dazzled him like the sun. She wore a bodice of white silk with gold brooches, a
gold brocade cloak fastened by a gem-encrusted brooch; her hair stayed in place under a
band of gold studded with rubies and she wore a wide, deep belt of gold. She greeted Maxen,
embraced him and drew him down to sit beside her, her arms wound around his neck.

But at this moment, as Emperor Maxen slept amid his hunting-party in the Tiber
valley, the heat of the afternoon made the animals moan restlessly, and the wind made the
shields rattle and clang where they hung high on the spears. The emperor woke up.

After that dream Emperor Maxen never had an easy moment; he could not get that
girl out of his mind. He grew listless, withdrew from occasions he had previously enjoyed
tremendously, indulged no longer, for example, in wine or music. He gave his courtiers the
impression that he wished to sleep all the time - true, too, because then he could dream
uninterruptedly of this woman in the hall, with the boys in the black brocade and the white-
haired man on the ivory throne with the carved eagles.

Eventually on of his most senior officials approached the emperor.

'Sir, your kings are most upset,' he said. 'They are even turning against you.'

'But why?' asked the listless Maxen.

'Because you show no leadership, you give them no imperial tasks to carry out, they
feel they have lost their emperor, they can neither speak to you nor hear from you.'

'Call all the wise men of Rome, and I will tell them the truth of what afflicts me.'

Maxen stood before them with something like his old verve and told them of his
dream, and of how the girl in it had captured not just his heart but his soul too. Then he
asked for the benefit of their collective wisdom. Having conferred they advised him that he
should send messengers to all three parts of the world for three years, who would surely
bring back news of this woman.

To begin with, this failed, and after a year Maxen fell into deeper despair. Then one
of his most senior kings suggested he take up the beginnings of the journey himself and sure
enough Maxen found the place on a river-bank where his dream journey had begun. His best
messengers were summoned once more, their robes folded in special ways to guarantee them
safe passage - by arranging their caps and sleeves they made it clear that they were
messengers and therefore not to be molested. Step for step, river for river, island for island,
they traced Maxen's dream journey.

A day came when, near Mount Snowdon, with the island of Anglesey visible in the
distance, they found the girl. She was just as Maxen had described her - simple and glorious
to behold, in the golden hall near the boys in the black satin and brocade, seated across from
the white-haired man on the ivory throne.

They knelt and addressed her as 'Empress of Rome', a greeting which irritated and
then intrigued her. To her queries they replied by telling her that the Emperor of Rome had
dreamed of her existence and sent them to bring her his love and his invitation to return with
them. She, though beguiled, instructed them to tell their master that he should come and
make these offers himself. They left, without even halting for refreshments, and helter-
skelter rode back the way they had come.

Maxen having prepared just in case they had found her, left immediately with them.
He brought his armies too, and they conquered all before them, including Britain. At each
stage of the journey he confirmed, from the detailed of his dream, the rightness of the
messengers' direction. Arriving within sight of the final destination in Wales, he knew they
had well and truly found the place of which he had dreamed.

In a state of almost unendurable excitement Maxen entered the golden hall. He
shivered to see them all once more, his dream-people, this time in real life. Walking with his
full emperor's grace to the place where the girl sat, he raised her to her feet, embraced her
and greeting her as Empress of Rome. She accepted him.

And so to bed. In the morning, pleased that his dream had found a virgin for him, he
made her an offer of any dowry she wished. She chose Britain as a gift to her father, claimed
three large islands for herself in her capacity as Empress Helen and three fortresses to be
built for her - at Arvon, Carmarthen and Caerlion. Maxen granted all these gifts with
pleasure.

In the company of his wife, and in the enjoyment again of all the pleasures of life he
held dear, hunting and music and wine, Maxen stayed seven years in Helen's land. By doing
so he ran the risk of forfeiting his empire; the Romans had allowed a tradition to evolve
whereby any emperor, no matter how distinguished or godlike, who stayed abroad for seven
years for any reason, even on a campaign for the empire, must relinquish the Purple. Thus,
Maxen received a message telling him that his throne had been usurped, and to stay away
from Rome.

Riled, he set out to return, and en route conquered part of Gaul, but his siege of Rome proved ineffectual in terms of taking the city. His wife, however, came up with the strength he needed; she had brought with her, led by her brothers, a band of devoted soldiers, men who would have risked anything, undertaken any task for her.

The brothers and their officers, all experienced soldiers, analysed Maxen's strategy at the walls of Rome. They agreed that cunning might prove more effective than the hitherto fruitless frontal attacks. So they measured the height of the walls in several places and then, out of sight of the garrison of Rome, set carpenters to work making scores of scaling ladders.

The informal rules of engagement permitted both emperors a two-hour break each early afternoon to eat and rest. The contingent led by Helen's brothers decided to take advantage of this, so they fed their soldiers more copiously in the morning. When the break came, with the soldiers inside the walls resting, up went the scaling ladders and the attackers had captured the killed the usurping emperor almost before he knew what had happened. It took three days to subdue the rest of the garrison, and only when the entire city had been completely taken did they allow Maxen to enter in triumph, his empress, Helen, beside him.

And so ends the tale of the Emperor Maxen and his dream.
You are invited to take part in a study being carried out by St Mark's Hospital and University College London.

This study is designed to look at ways of reducing the concern and anxiety experienced by some patients about to undergo colonoscopy or similar procedures and to make the procedure itself as comfortable and successful as possible.

If you agree to take part you will be asked to fill in some questionnaires, before and after your colonoscopy.

The questionnaires will ask you about how you feel and about your experience of colonoscopy.

You may also be asked to listen to a tape before your colonoscopy procedure.

All the information you give will be treated as strictly confidential.

The results of this study will be used to help patients whose medical treatment involves colonoscopy and other similar procedures.

Your participation in this study will not delay your colonoscopy examination.

Refusal to take part will not affect your treatment in any way and you may withdraw at any time without giving a reason for doing so.

If you wish to discuss this study further you may contact:

Ms. Maria Woloshynowycz on 0171 387 7050 x5934

or (in confidence, on any issue)

the Secretary of the Ethical Committee on 0181 869 2688
HARROW HEALTH AUTHORITY

RESEARCH PROJECT CONSENT FORM

TITLE OF PROJECT: Psychological preparation for colonoscopy

ETHICAL COMMITTEE (E.C.) NO: 2068 PRINCIPAL INVESTIGATOR: Ms Maria Woloshynowych

PART A - TO BE COMPLETED BY INVESTIGATOR

I confirm that I have explained this study both orally and in writing to the patient who I am satisfied is now in a position to make an informed decision about participation.

I have/have not [delete as necessary] completed the attached checklist.

Signature Date
Name in block letters (INVESTIGATOR)

PART B - TO BE COMPLETED BY PATIENT

I have been given and read the Patient Information Sheet.
I have had the opportunity to ask questions and discuss this study.
I have received and understood the answers to all my questions.
I do not need further information about the study.
I have spoken to the person named in Part A of this form.
I understand that I am free to refuse to take part in the study or to withdraw from it:
* at any time
* without having to give a reason for withdrawing and
* without affecting my medical care.
I therefore agree to take part in this study.

Signature Date
Name in block letters (PATIENT)

PART C - TO BE COMPLETED BY REGISTERED NURSE OF RELEVANT GRADE

I was present while this study was explained by the investigator to the patient who was given the opportunity to ask any questions (s)he wished.

Signature Date
Name in block letters (NURSE)

NOTES FOR STAFF:
• THIS FORM SHOULD BE USED ONLY IN STUDIES INVOLVING PATIENTS AND NOT HEALTHY VOLUNTEERS
• ALL PARTS OF THIS FORM MUST BE COMPLETED
• ON COMPLETION, THIS FORM (ORIGINAL) MUST BE INSERTED INTO THE PATIENT'S CASE NOTES AND A COPY HANDED TO THE PATIENT TO KEEP
CONSENT CHECKLIST FOR INVESTIGATORS

Prepared by Harrow Health Authority Ethical Committee in order to assist compliance with Good Clinical Practice in the European Community issued by the Committee of Proprietary Medicinal Products, 1990 and Reports of the Royal College of Physicians, 1990, 1986 and Department of Health Circulars HC (90) 22 and HSG (91)3.

Questions marked with an asterisk are relevant to research in patients only.

TITLE OF PROJECT: Psychological Preparation for Colonoscopy
ETHICAL COMMITTEE (EC) NO: 2068
SUBJECT’S NAME:
NAME OF INVESTIGATOR OBTAINING CONSENT: DATE:

1. Have you given the Information Sheet to the subject? Yes/No
   Did this make clear, inter alia:
   2.1 that this is a research project? Yes/No
   2.2 that participation is voluntary? Yes/No
   2.3 the aims of the project? Yes/No
   2.4 the likely duration of the subject’s involvement? Yes/No
   2.5 the expected benefits to the subject* and/or others? Yes/No
   2.6 the nature of the drug or device being tested, if any? Yes/No
   2.7 that the subject may instead receive a reference treatment or placebo? Yes/No
   2.8 what alternative standard medical therapy is available? Yes/No
   2.9 what risks, inconvenience, discomfort or distress may reasonably be anticipated for the subject? Yes/No
   2.10 that a refusal to participate may be given without reasons and * will not affect the care which will be given to the subject? Yes/No
   2.11 that the subject may withdraw at any time without giving reasons and *will not affect the care which will be given to the subject? Yes/No
   2.12 that personal information may be scrutinised during audit competent authorities and properly authorised people, but this will be treated as strictly confidential and will not be made publicly available? Yes/No
   2.13 what compensation arrangements are available? Yes/No
   2.14 whom to contact in an emergency and how? Yes/No

2. Has the subject given authorisation to approach his/her GP and for permission for GP to disclose medical information? Yes/No

3. Is or has the subject been involved in any other research studies? Yes/No

4. Is or has the subject recently been taking any other medicines or preparations? Yes/No

5. Have you allowed the subject sufficient time to consider the matter on his/her own, discuss with others, or ask you questions? Yes/No

6. In your opinion, has the subject understood and consented to take part? Yes/No

7. If you answered “No” or not answered any of the above questions, record why.

8. Has the subject signed and dated the consent form? Yes/No
   (This is essential for non-therapeutic research)

9. If not, has the consent form been signed and dated by some other independent person (usually a senior nurse) recording that the subject has understood and given consent? Yes/No

10. For a minor procedure in therapeutic research (e.g. taking blood), has consent been documented? Yes/No

11. If the subject is not capable of giving consent:
   11.1 has the Ethical Committee agreed to this research in principle? Yes/No
   11.2 are you of the opinion that this subject’s participation will promote the welfare and interest of the subject? Yes/No
   11.3 has signed, dated consent been obtained from any legal representative of the subject? Yes/No

12. * If the subject’s signed consent nor witnessed oral consent has been obtained, explain why

13. * If neither the subject’s signed consent nor witnessed oral consent has been obtained, explain why
Questionnaire 1

Please answer all questions.

DIRECTIONS (questions 1-20): A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

<table>
<thead>
<tr>
<th>Statement</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel pleasant</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2. I tire quickly</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3. I feel like crying</td>
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<td></td>
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<tr>
<td>4. I wish I could be as happy as others seem to be</td>
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<td></td>
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<tr>
<td>5. I am losing out on things because I can't make up my mind soon enough</td>
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<tr>
<td>6. I feel rested</td>
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<tr>
<td>7. I am 'cool, calm and collected'</td>
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<td></td>
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<tr>
<td>8. I feel that difficulties are piling up so that I cannot overcome them</td>
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<td></td>
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<tr>
<td>9. I worry too much over something that really doesn't matter</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>10. I am happy</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>11. I am inclined to take things hard</td>
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<td></td>
<td></td>
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<tr>
<td>12. I lack self-confidence</td>
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<tr>
<td>13. I feel secure</td>
<td></td>
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<tr>
<td>14. I try to avoid facing a crisis or difficulty</td>
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<td>15. I feel blue</td>
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<td></td>
<td></td>
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<tr>
<td>16. I am content</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>17. Some unimportant thought runs through my mind and bothers me</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>18. I take disappointments so keenly that I can't put them out of my mind</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. I am a steady person</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>20. I get in a state of tension or turmoil as I think over my recent concerns and interests</td>
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<td></td>
<td></td>
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</tbody>
</table>

(continued on opposite page)
DIRECTIONS (questions 21-26): A few more statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Somewhat</th>
<th>Moderately so</th>
<th>Very much so</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

21. I feel calm ........................................ 1 2 3 4
22. I feel tense ......................................... 1 2 3 4
23. I feel upset ......................................... 1 2 3 4
24. I am relaxed .......................................... 1 2 3 4
25. I am content .......................................... 1 2 3 4
26. I am worried .......................................... 1 2 3 4

As this next part is a different type of question, here is an example:

Mood scale example
Please mark the scale to show how you feel right now.

If the scale was about tiredness and you felt extremely tired (but not totally), you might mark the scale like this:

To what extent do you feel tired?
Not at all ______________________ √________ Totally
tired

Mood Scale
Please mark both scales to show how you feel right now.

To what extent do you feel calm?
Not at all ___________________________ Totally
calm
To what extent do you feel anxious?
Not at all ___________________________ Totally
anxious
QUESTIONNAIRE 2

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

Not at all Somewhat Moderately so Very much so
1 2 3 4

1. I feel calm ............................................. 1 2 3 4
2. I feel tense ............................................ 1 2 3 4
3. I feel upset ........................................... 1 2 3 4
4. I am relaxed .......................................... 1 2 3 4
5. I am content ......................................... 1 2 3 4
6. I am worried ........................................... 1 2 3 4

Mood Scale

Please mark both scales to show how you feel right now.

To what extent do you feel calm?
Not at all ________________________________ Totally calm

To what extent do you feel anxious?
Not at all ________________________________ Totally anxious

How effective was the tape in helping you feel:

Relaxed
Not at all ________________________________ Totally

In control
Not at all ________________________________ Totally

Confident
Not at all ________________________________ Totally

More able to cope
Not at all ________________________________ Totally
Endoscopy Questionnaire

Patient's Name .................................................... Indication ....................... 
Type of premedication given .............................................. 
Pulse before procedure .................................................... 

Time procedure started ................................. 

<table>
<thead>
<tr>
<th>TIME (5 min intervals)</th>
<th>Heart rate</th>
<th>Analgesia</th>
<th>Sedation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(End of colonoscopy)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Time caecum reached .................
Time procedure ended .........................

Please indicate the difficulty of the procedure?
Very easy ................................................... Very difficult

Please indicate how well the patient tolerated the procedure?
Poorly tolerated ................................................. Well tolerated

Endoscopist ..........................
Please indicate how well the patient tolerated the procedure?

Poorly tolerated ________________________________  Well tolerated

Nurse ........................................
POST-COLONOSCOPY QUESTIONNAIRE

All the answers you give are confidential, and will help our future research into Colonoscopy.

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

<table>
<thead>
<tr>
<th>1</th>
<th>Not at all</th>
<th>2</th>
<th>Somewhat</th>
<th>3</th>
<th>Moderately so</th>
<th>4</th>
<th>Very much so</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel calm</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I feel tense</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I feel relaxed</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. I am content</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. I am worried</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mood Scale  Please mark both scales to show how you feel right now.

To what extent do you feel calm?

Not at all __________________________________________________Totally calm

To what extent do you feel anxious?

Not at all ____________________anxious

Colonoscopy Experience  This part of the questionnaire is for you to tell us how you felt about the colonoscopy you have just had.

Example

For each item, place a mark on the scale to describe your experience.

If you felt extremely sleepy, you might mark the scale like this:
Sleepy  Awake

If you felt quite awake, you might mark it thus:
Sleepy   Awake

For each item, place a mark on the scale to describe your experience.

Interested  Uninterested

Confused  Not confused

Worried  Calm

Dignified  Undignified

In control  Helpless

Staff were warm  Staff were cool

Comfortable  Uncomfortable

Satisfied  Dissatisfied
For each item, place a mark on the scale to describe your experience.

<table>
<thead>
<tr>
<th>Item</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relieved when it was over</td>
<td></td>
</tr>
<tr>
<td>Agitated</td>
<td></td>
</tr>
<tr>
<td>Staff were interested in me</td>
<td></td>
</tr>
<tr>
<td>Pleased with how it went</td>
<td></td>
</tr>
<tr>
<td>Confident in the staff</td>
<td></td>
</tr>
<tr>
<td>Soreness</td>
<td></td>
</tr>
<tr>
<td>It went as expected</td>
<td></td>
</tr>
<tr>
<td>Staff were informative</td>
<td></td>
</tr>
<tr>
<td>Weary afterwards</td>
<td></td>
</tr>
<tr>
<td>Afraid of making a &quot;fool of myself&quot;</td>
<td></td>
</tr>
<tr>
<td>Frightened</td>
<td></td>
</tr>
<tr>
<td>I understood what was happening</td>
<td></td>
</tr>
<tr>
<td>Not Painful</td>
<td></td>
</tr>
<tr>
<td>I'd have preferred to have been more awake</td>
<td></td>
</tr>
<tr>
<td>Puzzled</td>
<td></td>
</tr>
<tr>
<td>Worried about what they would find</td>
<td></td>
</tr>
<tr>
<td>It was a good experience</td>
<td></td>
</tr>
</tbody>
</table>

Health Opinions  These questions generally refer to routine aspects of medical care. Place a tick (√) if you Agree or a cross (ₓ) if you Disagree with each statement.

... 1. Except for serious illness, it's generally better to take care of your own health than to seek professional help.

... 2. Clinics and hospitals are good places to go for help since it's best for medical experts to take responsibility for health care.

... 3. I'd rather be given many choices about what's best for my health than to have the doctor make the decision for me.

... 4. Learning how to cure some of your own illness without contacting a doctor is a good idea.

... 5. I usually ask the doctor or nurse lots of questions about the procedures during a medical exam.

... 6. It is better to rely less on doctors and more on your own common sense when it comes to caring for your body.

... 7. It is better to trust the doctor or nurse in charge of a medical procedure than to question what they are doing.

... 8. Recovery is usually quicker under the care of a doctor or nurse than when patients take care of themselves.

... 9. I usually wait for the doctor or nurse to tell me the results of a medical exam rather than asking them immediately.

... 10. It's almost always better to seek professional help than to try to treat yourself.
11. If I get sick, it is my own behaviour which determines how soon I get well again.
12. No matter what I do, if I am going to get sick, I will get sick.
13. Having regular contact with my doctor is the best way for me to avoid illness.
14. Most things that affect my health happen to me by accident.
15. Whenever I don’t feel well, I should consult a medically trained professional.
16. I am in control of my health.
17. My family has a lot to do with my becoming sick or staying healthy.
18. When I get sick I am to blame.
19. Luck plays a big part in determining how soon I will recover from an illness.
20. Health professionals control my health.
21. My good health is largely a matter of good fortune.
22. The main thing which affects my health is what I myself do.
23. If I take care of myself, I can avoid illness.
24. When I recover from an illness, it’s usually because other people (e.g. doctors, nurses, family, friends) have been taking good care of me.
25. No matter what I do, I’m likely to get sick.
26. If its meant to be, I will stay healthy.
27. If I take the right actions, I can stay healthy.
28. Regarding my health, I can only do what my doctor tell me to do.

General Opinions
1. I never hesitate to go out of my way to help someone in trouble.
2. I have never intensely disliked anyone.
3. I sometimes feel resentful when I don’t get my way.
4. There have been times when I felt like rebelling against people in authority even though I knew they were right.
5. I remember ‘playing sick’ to get out of something.
6. When I don’t know something I don’t mind admitting it.
7. I am always courteous, even to people who are disagreeable.
8. I would never think of letting someone else be punished for my wrong doings.
9. There have been times when I was quite jealous of the good fortune of others.
10. I am sometimes irritated by people who ask favours of me.

You and this study
Please fill in the table below to indicate whether you have ever had a colonoscopy, or similar procedure, before?

<table>
<thead>
<tr>
<th>MEDICAL PROCEDURE</th>
<th>YES OR NO</th>
<th>NUMBER OF TIMES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colonoscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sigmoidoscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barium enema</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What is your age? ........

Please tick one of the following... □ Single (or divorced or widowed) □ Married (or living with a partner)

Please tick one of the following that best describes your employment.
□ Employed □ Self-employed □ Housewife/husband
□ Unemployed □ Retired □ Student

Tick the one of the following that best describes your present or most recent job.
□ unskilled manual
□ skilled manual
□ shopwork/clerical/officework
□ skilled technical
□ professional/managerial
Please tick the type of relaxation, or similar, instruction have you received in the past?

□ None       □ relaxation classes       □ yoga
□ ante natal classes       □ aromatherapy       □ stress
management
□ meditation       □ other (please specify)……………………………………..

If you have used a relaxation procedure in the past, how similar was it to the tape used in this study?
Not at all similar .................................................................................. Almost the same

How helpful was what you heard on the tape
(please circle)
1) immediately before the colonoscopy? Not at all/A little/Moderately/Very much/Extremely
2) during the colonoscopy? Not at all/A little/Moderately/Very much/Extremely

During your colonoscopy, how effective was the tape in helping you to feel:

Relaxed
Not at all .......................................................... Totally

In control
Not at all .......................................................... Totally

Confident
Not at all .......................................................... Totally

More able to cope
Not at all .......................................................... Totally

During the colonoscopy examination were you using the relaxation procedure you heard on the tape? Yes/No
If you answered No, were you using a relaxation procedure other than that on the tape? Yes/No
If you answered Yes to either of the above, how effective was the procedure you used?
Not at all .......................................................... Totally effective

In connection with your experience of colonoscopy do you think your participation in this study has:
(please circle 1 of the following)

helped a great deal       helped a little       made no difference       made things a little worse       made things much worse

Please feel free to add any other comments.

THANK YOU VERY MUCH FOR YOUR HELP
APPENDIX D  - Materials for Preliminary study 4

❖ Post-ERCP Questionnaire*
POST-ERCP QUESTIONNAIRE

This questionnaire is for you to tell us how you feel about the ERCP procedure you have just had. All the answers you give are confidential, and will help our future research into ERCP.

For each item, please place a tick on the scale which best describes your experience.

e.g. If you felt extremely sleepy, you might tick the scale like this:

<table>
<thead>
<tr>
<th>Sleepy</th>
<th>Awake</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you felt quite awake, you might tick it thus:

<table>
<thead>
<tr>
<th>Sleepy</th>
<th>Awake</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>√</td>
</tr>
</tbody>
</table>

Interested – Uninterested
Confused – Not confused
Worried – Calm
Dignified – Undignified
In control – Helpless
Staff were warm – Staff were cool
Comfortable – Uncomfortable
Satisfied – Dissatisfied
Relieved when it was over – Not relieved
Agitated – Calm
Staff were interested in me – Staff weren't interested in me
<table>
<thead>
<tr>
<th></th>
<th>Pleased with how it went</th>
<th>Displeased at how it went</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confident in the Staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soreness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It went as expected</td>
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</tr>
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</tr>
<tr>
<td>Afraid of making a “fool of myself”</td>
<td></td>
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<tr>
<td>Frightened</td>
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</tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>It was a good experience</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

THANK YOU VERY MUCH FOR YOUR HELP
APPENDIX E - Materials for Study 3

* Transcript of the information tape

* 'Having an ERCP' leaflet - see inside back cover

* Transcript of the relaxation tape

* Transcript of the attention control tape - see Appendix C

* Patient Information Sheet*

* Patient Consent form*

* Questionnaire 1*
   This questionnaire was backed.

* Questionnaire 2
   For patients in the control group, references to the tape were omitted.

* Endoscopy Questionnaire* - Endoscopist's version

* Endoscopy Questionnaire* - Nurse's version

* Post ERCP Questionnaire*
   For patients in the two control and information groups, references to comparisons with the relaxation procedure was omitted; and for patients in the non-intervention control group references to the tape were omitted.
   This questionnaire was backed

* Forms and questionnaires are reduced to 70% for binding requirements
Transcript of the Information Tape

Receiving information on specific medical procedures can help us form accurate expectations of what these procedures involve. Fear of the unknown may cause unnecessary worry. It is hoped that this tape will provide you with a comprehensive guide to Endoscopic Retrograde Cholangio-Pancreatography or ERCP, as it is usually called.

This information tape has been prepared after talking to patients who have had the procedure. It may not answer all your questions, so if you have any worries please don't hesitate to ask. The staff who are doing the test will be available to answer any queries.

By listening to this tape it is hoped that you will understand: firstly, what is involved in ERCP and other related procedures; then, why ERCP is carried out and finally, what to expect immediately before, during and after this medical procedure, as well as any potential problems.

The GI Unit at the Middlesex Hospital has long been recognised as a major centre for endoscopic procedures, that is procedures in which the digestive system can be examined using a tube known as an endoscope. The endoscope is a long flexible tube (thinner than your little finger) with a bright light at the end. The GI Unit has been at the forefront of developing new and different ways of investigating and treating disorders of the digestive system using an endoscope under sedation. This avoids the need for major surgery which used to be the only way of dealing with such disorders. Patients are referred to the unit from a wide area around London and the South of England for these procedures, particularly for ERCP.

ERCP is a procedure which allows the doctor to take detailed X-rays of parts of the body such as bile duct or pancreas. You will be given some sedation before the doctor passes the endoscope through your mouth, into the stomach and round into the beginning of the small intestine, the duodenum. By looking down the endoscope, the doctor can find the opening where the bile duct and pancreatic duct empty into the duodenum. A smaller tube is passed down the endoscope into this opening, through which dye is injected into the ducts, allowing X-ray pictures to be taken.

You may have this procedure performed to take X-rays only, to aid in the diagnosis and management of your problem.
If the X-rays show a gallstone, usually trapped beyond the narrow opening of the bile duct, the doctor will enlarge this opening. This is gently done with an electrically heated wire (or diathermy) which you will not feel. Any stones will be collected and removed or left to pass into the intestine.

If the X-rays show a blockage in the bile duct the doctor may place a short plastic tube, a stent, inside the duct itself to help the bile drain into the intestine in the normal way. This is to relieve the jaundice which you may have developed and the itching from which you may be suffering. You will not be aware of the presence of the stent which will remain in place permanently. Occasionally it may be necessary to replace the stent some months later if it becomes blocked.

If you have therapy performed at the time of ERCP, such as gall stones removed or a stent inserted, you will receive antibiotics for 24 hours, usually by intravenous injection via a cannula in the arm. **It is essential you tell the nursing or medical staff of any known allergies before the procedure.** It is also important to tell the nursing staff if you have had previous endoscopies that have been unpleasant. Allowances can usually be made for this and more sedation given if necessary. **It is essential for women of childbearing age to let nursing or medical staff know if there is any chance they might be pregnant as X-rays are used.**

The following is what you should expect to happen before, during and after your ERCP. Shortly after listening to this tape the procedure will be explained, once again by a doctor who will ask you to sign a consent form. This is to ensure that you understand the test and its implications. If you have any worries or questions at this stage don't be afraid to ask. The staff will want you to be as relaxed as possible for the test and will not mind answering your queries.

A hospital gown is usually worn for the procedure. It will also be necessary for you to remove any false teeth or contact lenses. Jewellery or metal objects should also be removed because they interfere with X-rays and the diathermy instrument. Your possessions will be kept safely until after the examination.

Once inside the examination room you will be made comfortable on an X-ray table, resting on your left side. X-ray equipment will be beside the table and the room will be darkened. A nurse will stay with you throughout the procedure. The staff will be wearing X-ray
protective aprons because of their repeated exposure to X-rays. The amount of X-rays you receive will be strictly controlled for your safety.

Some doctors spray a local anaesthetic on the back of your throat to help numb the area and prevent gagging. You will be given an injection to make you feel sleepy and relaxed. Most patients have little or no memory of the test being done.

To keep your mouth slightly open, a plastic mouthpiece will be gently placed between your teeth. When the doctor passes the endoscope into your stomach it will not cause you any pain. Nor will it interfere with your breathing.

The test usually takes up to thirty minutes. When the dye is put into the ducts it may cause some discomfort but most people feel nothing. X-ray pictures are taken during the procedure and sometimes after removal of the endoscope (which is quick and easy).

If you have had a stent inserted you will not be aware of its presence at all.

After the test you will be taken back to the ward or left in the unit to rest. The nurses will check your pulse and blood pressure regularly. You will not be able to have anything to eat or drink for a few hours. When you do start to eat you should keep to simple meals for a day or two. Very occasionally it is necessary to keep patients on a drip for one or two days and avoid food altogether.

For the first day you may feel soreness at the back of the throat and also some bloating if air has remained in your stomach. It is important for you to tell the staff if you have any pain, fever or sickness in the days following the procedure.

The effects of the test and the sedation should have worn off by the next day when most patients are able to resume normal activities.

The average length of stay in hospital is between 1 to 3 days, but it may be much longer if several procedures are necessary or if problems arise.

This endoscopic treatment for bile stones and blockages has been developed and is recommended to you because it is simpler and safer than surgery. However, you should realise that it is not always completely successful and complications related to both the
underlying disease and the technical aspects of the procedure can sometimes occur. These complications are found in only a small proportion of patients, less than 5%. These complications, such as infection, bleeding and pain from pancreatitis, are usually mild and only take 24 hours to settle. Very occasionally these complications are serious and may need surgery to correct, but this happens only very rarely... in less than 1 in 1000 patients.

Please discuss these aspects and any other questions you may have, with the team who will be carrying out the procedure.

By now you will understand that an ERCP allows the doctor to take detailed X-rays of the bile or pancreatic ducts to establish the cause of any blockage and that procedures may also be carried out, at the same time, in order to treat such blockages.

You will be seen by a doctor who will obtain consent from you and will give you the opportunity to ask questions. Once in the endoscopy room you will lie on your left side, oxygen and sedation will be given to you, and a mouth-piece inserted before the procedure commences. The sedation will keep you sleepy and comfortable during the procedure but you might have a slight awareness of what is going on around you. Once it is all over, you will be taken back to the ward or left in the unit to rest. You are advised to let the staff know of any discomfort, pains or other symptoms which you may become aware of in the days following your ERCP.
Transcript of the Relaxation Tape (Study 3)

Learning to become relaxed in our bodies and calm in our minds can help us in many ways. In particular, it can help us to face unfamiliar and stressful situations, to cope with them well and feel in control. When we are mentally relaxed our bodies function and respond automatically and easily without interference from unwanted thoughts. Although we may not be aware of it, most of us have tension in various parts of our bodies; Learning to be calm and relaxed can be a very positive contribution to the preparation for a medical investigation, such as ERCP.

Although you may feel very relaxed whilst listening to this tape, you will be able to respond to any emergency should one arise.

Let any everyday thoughts drift to the back of your mind.

Sitting or lying as comfortably as you can, take some well deserved time for yourself away from other thoughts and pressures. Take a deep breath and relax as you breathe out. Let your body sink down into a more relaxed position. You may find that it helps to close your eyes. Breathe gently and slowly, using the base of your lungs so that your abdomen, your tummy, is the part that is gently moving. Knowing that as we become calmer in our minds, our bodies know automatically how to relax and work how they should... Continue to relax more and more with each breath.

I would like you to pay attention to your legs. You may feel the muscles of your legs becoming less and less tense ... supported by the surface beneath you... allowing any tension to drain away. The muscles of your legs ... loose, and easy and relaxed. Warm and comfortable... calm and relaxed. Tension just draining away... more and more relaxed, more and more confident and in control. Breathing gently and slowly. You may notice the warmth of the surface beneath you spreading into the muscles of your legs... helping them to feel comfortable, easy and relaxed. Your legs, supported, safely and easily ... the tension draining away ... helping you to relax more and more deeply. Breathing slowly and gently. And as you breathe out feel yourself sinking down deeper into relaxation. Deeper and more relaxed. Calm, comfortable and relaxed.

The muscles of your legs, ... warm, comfortable and relaxed and the feeling of relaxation spreading into the muscles of your back. The muscles of your back becoming comfortable,
relaxed ... any tension draining away as you breathe gently and slowly and deeply. More and more relaxed. Tension draining away... calm, comfortable and relaxed. The muscles of your back ... loose, and easy and relaxed. Letting the tension go, allowing a safe, warm, comfortable feeling to grow. More and more relaxed. Breathing slowly and gently. And as you breathe out... sinking down deeper and deeper into relaxation. More and more relaxed... calm, comfortable and relaxed. Feeling pleased and comfortable about the way in which you can help yourself by simply letting go, ... relaxing calmly.

And now,... feeling the warmth of the surface, supporting your legs and back, helping to make the muscles relaxed and comfortable and letting this warm, comfortable feeling spread to your neck and shoulders. Breathing gently and slowly ... feeling calm and relaxed. Tension in your shoulders and neck draining away with each breath. More and more relaxed. more and more comfortable. Your shoulders and neck ... safely supported ... the tension draining away, allowing a feeling of comfort, warmth and relaxation. More and more relaxed. Breathing slowly and gently. And as you breathe out feeling yourself sinking down deeper and deeper into relaxation. More and more relaxed. Just letting your body relax and do all the things it needs to, automatically, without concerning yourself with how or why.

The muscles of your neck and shoulders, ... warm, comfortable and relaxed and now the feeling of relaxation spreading into your arms. Your arms, comfortably supported, becoming relaxed ... the tension draining away as you breathe gently and slowly and deeply. More and more relaxed. Any tension draining away. Letting the tension go ... allowing a more relaxed, warm comfortable feeling to grow. More and more relaxed. The muscles of your arms becoming loose and easy and relaxed. Breathing slowly and gently. And as you breathe out feeling yourself sinking down deeper into relaxation. Deeper and more relaxed... calm, comfortable and relaxed.

The muscles of your arms, neck and shoulders, ... warm, comfortable and relaxed and the feeling of relaxation spreading into the muscles of your face... allowing your expression to soften... a nice, easy, relaxed expression. Your face, becoming comfortable, relaxed ... the tension draining away as you breathe gently and slowly and deeply. More and more relaxed. Feeling tension draining away. Letting the tension go ... the muscles of your face becoming loose, easy and relaxed. The rest of your body responding easily and automatically. More and more relaxed. Breathing slowly and gently. And as you breathe out feeling yourself sinking down deeper and deeper into the surface supporting you and deeper into relaxation. Deeper and more relaxed. Calm, comfortable and in control.
Now I would like you to think of a place where you feel comfortable or relaxed. A holiday spot... a beach,... a garden perhaps, or somewhere else. It can be a real place that you know or an imagined place... or a mixture of the two. Begin to imagine... as clearly as you can, the sights, sounds and smells and all of the other feelings and sensations that are associated with being in that special place. Seeing the colours, textures and any movements... clearer and clearer. Becoming as aware as you can of the sounds and the smells that make this special place unique. Using any or all of these sensations to allow yourself to become part of this special place... Just take a little time now to enjoy being in your special place.

------------------------
PAUSE 1 MINUTE
------------------------

....And now, staying in your special place...knowing that when you would like to relax or need to be calm you can bring back all these feeling by just thinking about this special place. Choose a word, a thought or a feeling which will symbolise the place for you... and you can use that symbol, just by thinking about it or bringing it to mind, to bring back feelings of comfort, calm and relaxation whenever you need them.

Just leave the special place if you haven't already done so, but bring with you all the good, positive and relaxing feelings. Feeling good about the fact that spending some time for yourself relaxing and practising entering a calm, confident state is a positive way of helping yourself and of developing resources which will also help others when they help you.

Remembering that just by thinking about the symbol you can back feelings of comfort, calm and relaxation whenever you need them.

In a moment I will count slowly from 3 to 1 and on 1 I want you to open your eyes... feeling good... completely normal... still pleasantly relaxed. 3... getting lighter and lighter... 2 getting more alert, lighter still... feeling good... feeling relaxed... and 1... wide awake and alert and calm, ready to face the rest of the day, rest of the week and the future.
Consultant: Dr A Hatfield

Investigators: Ms M Woloshynowych
Dr DA Oakley

Title of project: Psychological preparation for ERCP

You are invited to take part in a study being carried out by Middlesex Hospital and University College London.

This study is designed to look at ways of reducing the concern and anxiety experienced by some patients about to undergo ERCP (endoscopic retrograde cholangio-pancreatography) or similar procedures and to make the procedure itself as comfortable and successful as possible.

If you agree to take part you will be asked to fill in some questionnaires, before and after your ERCP. The questionnaires will ask you about how you feel and about your views on health and illness.

You may also be asked to listen to a tape before your ERCP procedure.

All the information you give will be treated as strictly confidential.

The results of this study will be used to help patients whose medical treatment involves ERCP and other similar procedures.

You do not have to take part in this study if you do not want to. If you decide to take part you may withdraw at any time without having to give a reason. Your decision to take part or not will not affect your care and management in any way.

If you wish to discuss this study further you may contact:

Ms. Maria Woloshynowych on 0171 387 7050 Ext. 5934

or Department of Psychology
University College London
Gower Street
LONDON WC1E 6BT

All proposals for research using human subjects are reviewed by an ethics committee before they can proceed. This proposal was reviewed by Joint UCL/UCLH Committees on the Ethics of Human Research: Committee Alpha.
PATIENT CONSENT FORM

TITLE OF STUDY: Psychological preparation for ERCP

INVESTIGATOR: Maria Woloshynowych

TO BE COMPLETED BY PATIENT

I have been given and read the Patient Information Sheet.
I have had the opportunity to ask questions and discuss this study.
I have received satisfactory answers to all my questions.
I have received enough information about this study.
I understand that I am free to withdraw from this study
* at any time
* without giving a reason for withdrawing
* without affecting my future medical care.

I therefore agree to take part in this study.

Signed ............................................. Date ...................................

Name in block letters ..............................................................

Investigator: .................................................................
QUESTIONNAIRE 1 All the answers you give are confidential, and will help our future approach and practice in ERCP.

Please answer all questions.
DIRECTIONS (questions 1-20): Place a tick (√) if you Agree or a cross (x) if you Disagree with each statement. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe what you generally think. The health questions generally refer to routine aspects of medical care.

Health Opinions
... 1. Except for serious illness, it's generally better to take care of your own health than to seek professional help.
... 2. Clinics and hospitals are good places to go for help since it's best for medical experts to take responsibility for health care.
... 3. I’d rather be given many choices about what’s best for my health than to have the doctor make the decision for me.
... 4. Learning how to cure some of your own illness without contacting a doctor is a good idea.
... 5. I usually ask the doctor or nurse lots of questions about the procedures during a medical exam.
... 6. It is better to rely less on doctors and more on your own common sense when it comes to caring for your body.
... 7. It is better to trust the doctor or nurse in charge of a medical procedure than to question what they are doing.
... 8. Recovery is usually quicker under the care of a doctor or nurse than when patients take care of themselves.
... 9. I usually wait for the doctor or nurse to tell me the results of a medical exam rather than asking them immediately.
... 10. It's almost always better to seek professional help than to try to treat yourself.

General Opinions
... 11. I never hesitate to go out of my way to help someone in trouble.
... 12. I have never intensely disliked anyone.
... 13. I sometimes feel resentful when I don't get my way.
... 14. There have been times when I felt like rebelling against people in authority even though I knew they were right.
... 15. I remember 'playing sick' to get out of something.
... 16. When I don’t know something I don’t mind admitting it.
... 17. I am always courteous, even to people who are disagreeable.
... 18. I would never think of letting someone else be punished for my wrong doings.
... 19. There have been times when I was quite jealous of the good fortune of others.
... 20. I am sometimes irritated by people who ask favours of me.

Personal details
Have you ever had an ERCP or similar procedure before?

<table>
<thead>
<tr>
<th>MEDICAL PROCEDURE</th>
<th>YES OR NO</th>
<th>NUMBER OF TIMES</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERCP</td>
<td>.................................</td>
<td>.................................</td>
</tr>
<tr>
<td>Gastroscopy/OGD</td>
<td>.................................</td>
<td>.................................</td>
</tr>
<tr>
<td>Barium meal</td>
<td>.................................</td>
<td>.................................</td>
</tr>
</tbody>
</table>

What is your age? .........

Please tick one of the following... □ Single (or divorced or widowed)
□ Married (or living with a partner)

Please tick one of the following that best describes your employment.
□ Employed □ Self-employed □ Housewife/husband
□ Unemployed □ Retired □ Student

Tick the one of the following that best describes your present or most recent job.
□ unskilled manual
□ skilled manual
□ shopwork/clerical/officework
□ skilled technical
□ professional/managerial
QUESTIONNAIRE 1  All the answers you give are confidential, and will help our future approach and practice in ERCP.

Please answer all questions.

DIRECTIONS (questions 1-20): A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

| Mood Scale Example |  |  |  |  |
|--------------------| 1 | 2 | 3 | 4 |
| 1. I feel pleasant | 1 | 2 | 3 | 4 |
| 2. I tire quickly | 1 | 2 | 3 | 4 |
| 3. I feel like crying | 1 | 2 | 3 | 4 |
| 4. I wish I could be as happy as others seem to be | 1 | 2 | 3 | 4 |
| 5. I am losing out on things because I can't make up my mind soon enough | 1 | 2 | 3 | 4 |
| 6. I feel rested | 1 | 2 | 3 | 4 |
| 7. I am 'cool, calm and collected' | 1 | 2 | 3 | 4 |
| 8. I feel that difficulties are piling up so that I cannot overcome them | 1 | 2 | 3 | 4 |
| 9. I worry too much over something that really doesn't matter | 1 | 2 | 3 | 4 |
| 10. I am happy | 1 | 2 | 3 | 4 |
| 11. I am inclined to take things hard | 1 | 2 | 3 | 4 |
| 12. I lack self-confidence | 1 | 2 | 3 | 4 |
| 13. I feel secure | 1 | 2 | 3 | 4 |
| 14. I try to avoid facing a crisis or difficulty | 1 | 2 | 3 | 4 |
| 15. I feel blue | 1 | 2 | 3 | 4 |
| 16. I am content | 1 | 2 | 3 | 4 |
| 17. Some unimportant thought runs through my mind and bothers me | 1 | 2 | 3 | 4 |
| 18. I take disappointments so keenly that I can't put them out of my mind | 1 | 2 | 3 | 4 |
| 19. I am a steady person | 1 | 2 | 3 | 4 |
| 20. I get in a state of tension or turmoil as I think over my recent concerns and interests | 1 | 2 | 3 | 4 |

DIRECTIONS (questions 21-26): A few more statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

| Mood Scale Example |  |  |  |  |
|--------------------| 1 | 2 | 3 | 4 |
| 21. I feel calm | 1 | 2 | 3 | 4 |
| 22. I feel tense | 1 | 2 | 3 | 4 |
| 23. I feel upset | 1 | 2 | 3 | 4 |
| 24. I am relaxed | 1 | 2 | 3 | 4 |
| 25. I am content | 1 | 2 | 3 | 4 |
| 26. I am worried | 1 | 2 | 3 | 4 |

As this next part is a different type of question, here is an example:

**Mood Scale example**

Please mark the scale to show how you feel right now.

If the scale was about tiredness and you felt extremely tired (but not totally), you might mark the scale like this:

To what extent do you feel tired?

Not at all

Mood Scale

Please mark both scales to show how you feel right now.

To what extent do you feel calm or relaxed?

Not at all

To what extent do you feel anxious, tense or worried?

Not at all
QUESTIONNAIRE 2

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is **at this moment**. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Somewhat</th>
<th>Moderately so</th>
<th>Very much so</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>1. I feel calm ...........................................</td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I feel tense ............................................</td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I feel upset ...........................................</td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. I am relaxed ...........................................</td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. I am content ...........................................</td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. I am worried ............................................</td>
<td>1 2 3 4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mood Scale

Please mark both scales to show **how you feel right now**.

To what extent do you feel calm or relaxed?
Not at all _________________________________________ Totally

To what extent do you feel anxious, tense or worried?
Not at all _________________________________________ Totally

How effective was the tape in helping you feel:

**Relaxed**
Not at all _________________________________________ Totally

**More informed**
Not at all _________________________________________ Totally

**More able to cope**
Not at all _________________________________________ Totally

**In control**
Not at all _________________________________________ Totally
Endoscopy Questionnaire

Patient’s Name ......................................................  Indication  ......................................................

Procedure ERCP Sphincterotomy

........................................................................
........................................................................

Please indicate the difficulty of the procedure? (To be filled in by Endoscopist carrying out the procedure)

Very easy ........................................................................ Very difficult

Please indicate how well the patient tolerated the procedure?

Poorly tolerated ................................................................... Well tolerated

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Did the patient follow instructions in general?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>b) Was the patient generally co-operative?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>c) Did the patient exhibit signs of anxiety or tension? e.g. verbalisations of fear, behaviour signs of clenching fists, sweating, shaking</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>d) Did the patient move round unnecessarily?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>e) Did the patient ask relevant questions about the procedure beforehand?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

How many times did the patient gag during insertion? □ not at all □ once or twice □ more than twice

How many times did the patient move his/her arms during ERCP? □ not at all □ once or twice □ more than twice

Endoscopist ......................................................
Endoscopy Questionnaire

Patient's Name .......................................................................................

Before procedure  Pulse ............................................... O₂ Sat. ....................... 

Time procedure started ...........................................................  

<table>
<thead>
<tr>
<th>Time given</th>
<th>Pethidine</th>
<th>Midazolam</th>
<th>Buscopan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other drugs

Throat spray? Yes/No 

Time procedure ended  Lowest O₂ Sat.  

Please indicate how well the patient tolerated the procedure?

Poorly tolerated  ................................................................. Well tolerated

a) Did the patient follow instructions in general?  Not at all  1  2  3  4  Yes
b) Was the patient generally co-operative?  1  2  3  4
c) Did the patient exhibit signs of anxiety or tension?
   e.g. verbalisations of fear, behaviour signs of clenching fists, sweating, shaking  1  2  3  4
d) Did the patient move round unnecessarily?  1  2  3  4
e) Did the patient ask relevant questions about the procedure beforehand?  1  2  3  4

How many times did the patient gag during insertion?  □ not at all
□ once or twice
□ more than twice

How many times did the patient move his/her arms during ERCP?  □ not at all
□ once or twice
□ more than twice

Nurse .................................

Post ERCP  Pulse  ......................  O₂ Sat.  ..................

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POST-ERCP QUESTIONNAIRE

All the answers you give are confidential, and will help our future approach and practice in ERCP.

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Somewhat</th>
<th>Moderately so</th>
<th>Very much so</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

1. I feel calm ............................................. 1 2 3 4
2. I feel tense ............................................... 1 2 3 4
3. I feel upset .............................................. 1 2 3 4
4. I am relaxed .............................................. 1 2 3 4
5. I am content ............................................... 1 2 3 4
6. I am worried ............................................... 1 2 3 4

Mood Scale
Please mark both scales to show how you feel right now.

To what extent do you feel calm or relaxed?
Not at all __________________________________________Totally

To what extent do you feel anxious, tense or worried?
Not at all __________________________________________Totally

Health Opinions

DIRECTIONS (questions 1-18): As before, these questions generally refer to routine aspects of medical care. Please tick the box to show whether you agree or disagree with each statement. There are no right or wrong answers. Do not spend too much time on any one statement.

<table>
<thead>
<tr>
<th>Agree</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. If I get sick, it is my own behaviour which determines how soon I get well again</td>
<td></td>
</tr>
<tr>
<td>2. No matter what I do, if I am going to get sick, I will get sick</td>
<td></td>
</tr>
<tr>
<td>3. Having regular contact with my doctor is the best way for me to avoid illness</td>
<td></td>
</tr>
<tr>
<td>4. Most things that affect my health happen to me by accident</td>
<td></td>
</tr>
<tr>
<td>5. Whenever I don't feel well, I should consult a medically trained professional</td>
<td></td>
</tr>
<tr>
<td>6. I am in control of my health</td>
<td></td>
</tr>
<tr>
<td>7. My family has a lot to do with my becoming sick or staying healthy</td>
<td></td>
</tr>
<tr>
<td>8. When I get sick I am to blame</td>
<td></td>
</tr>
<tr>
<td>9. Luck plays a big part in determining how soon I will recover from an illness</td>
<td></td>
</tr>
<tr>
<td>10. Health professionals control my health</td>
<td></td>
</tr>
<tr>
<td>11. My good health is largely a matter of good fortune</td>
<td></td>
</tr>
<tr>
<td>12. The main thing which affects my health is what I myself do</td>
<td></td>
</tr>
<tr>
<td>13. If I take care of myself, I can avoid illness</td>
<td></td>
</tr>
<tr>
<td>14. When I recover from an illness, it's usually because other people (e.g. doctors, nurses, family, friends) have been taking good care of me</td>
<td></td>
</tr>
</tbody>
</table>

(please turn over)
15. No matter what I do, I’m likely to get sick □  □
16. If it’s meant to be, I will stay healthy □  □
17. If I take the right actions, I can stay healthy □  □
18. Regarding my health, I can only do what my doctor tells me to do □  □

You and this study
1. Please tick the type of relaxation, or similar, instruction have you received in the past?
   □  None □  relaxation classes □  yoga
   □  antenatal classes □  aromatherapy □  stress management
   □  meditation □  other (please specify)............................................

2. If you have used a relaxation procedure in the past, how similar was it to the tape used in this study?
   Not at all similar .................................................................................. Almost the same

3. Whilst waiting for your ERCP procedure were you using, or trying to use, a relaxation procedure?
   (please circle 1 of the following)
   Not at all  A little  Quite a lot  Very much so

4. If so, was it the one you heard on the tape?  Yes / No

5. In connection with your experience of ERCP how helpful was what you heard on the tape?
   (please circle 1 of the following)
   Not at all  A little  Moderately  Very much  Extremely

6. Before your ERCP procedure, would you have preferred more or less information about what
   was going to happen?  (please tick 1 of the following)
   □  I would have preferred more information
   □  The amount of information I received was about right
   □  I would have preferred less information

7. In connection with your experience of ERCP do you think your participation in this study as a whole:
   (please circle 1 of the following)
   helped you helped you made no made things made things a great deal a little difference a little worse much worse for you for you

8. I completed this questionnaire at (time)............... on (date)...................

9. Please feel free to add any other comments.

THANK YOU VERY MUCH FOR YOUR HELP
Going Home

If you are having an ERCP without any additional treatment it is likely that you will be allowed home after the test, but it is **essential that someone comes to collect you**. Once home, it is important to rest quietly for the remainder of the day. Sedation lasts longer than you think.

You should not:
- drive a car
- operate machinery
- drink alcohol

The effects of the test and sedation should have worn off by the next day when most patients are able to resume normal activities.

If you are required to stay in hospital, the average length of stay is between 1-3 days, but it may be much longer if several procedures are necessary or if problems arise.

What are the Risks and Complications?

Fortunately, these procedures are very safe - this is why they are used instead of surgery. Problems do sometimes occur, however, but these can be explained if you wish by your doctor or hospital staff. If you have any problems after ERCP which you feel may be related to the test, please inform your doctor or hospital staff at once. An operation may be necessary to treat a complication, but this is very rare. Again, please do not hesitate to discuss possible complications or risks with hospital staff before ERCP.

Written by Alison Hadley; formerly of the Middlesex Hospital, in collaboration with the Department of Gastroenterology at the Middlesex Hospital, and revised in collaboration with Dr. Derrick F. Martin, Consultant Radiologist, at the Department of Radiology, University Hospital of South Manchester.

Published as a service to medicine by

KeyMed

suppliers of

OLYMPUS

endoscopy equipment in the UK and Ireland
As a result of tests, you have been advised to have an ERCP (Endoscopic Retrograde Cholangio-Pancreatography). This test allows the examination of the pancreas and bile ducts. This leaflet has been prepared after talking to patients who have had the procedure. The doctors and nurses you meet in hospital will also explain the procedure, but if you have any further questions, please do not hesitate to ask them.

**Before the test**

To allow a clear view, the stomach and duodenum must be empty. You will therefore be asked not to have anything to eat or drink for at least six hours before the procedure. When you come to the department, the procedure will be explained and a doctor will ask you to sign a consent form. This is to ensure you understand the test and its implications. Please tell the nurse or doctor if you have had any previous endoscopic examinations, or reactions to drugs or allergies. In some situations, antibiotics are given by injection before the procedure. If you have any worries or questions at this stage don’t be afraid to ask. The staff will want you to be as relaxed as possible for the test and will not mind answering your queries.

You may be asked to take off your shirt or jumper and to put on a hospital gown. It will also be necessary for you to remove any false teeth or contact lenses. Jewellery or metal objects should also be removed because they interfere with X-rays and a special instrument called a diathermy. They will be kept safely until after the examination.

**What is an ERCP?**

ERCP is a procedure which allows the doctor to take detailed X-rays of the bile duct and/or pancreas. You will lie on an X-ray table and the doctor who is to perform the test will explain briefly what will happen. Your throat will be numbed with a special spray. A fine soft tube will be placed into one nostril to give you a little oxygen to breathe during the test. You will be given an injection into your drip which will make you very sleepy. Once you are sleepy, an endoscope (a long, thin flexible tube with a bright light at one end) will be passed through your mouth, down into your stomach and the upper part of the small intestine (the duodenum). X-ray dye will be injected down the endoscope so that the pancreas and bile ducts may be seen on X-ray films. If everything is normal, the endoscope is then removed and the test is complete. The dye is passed out of your body harmlessly.

If the X-rays show a gallstone, the doctor will enlarge the opening of the bile duct. This is done with an electrically heated wire (diathermy) which you will not feel. Any stones will be collected into a tiny basket or left to pass into the intestine.

If a narrowing is found, bile can be drained by leaving a short plastic tube (endoprosthesis) in the bile duct. You will not be aware of the presence of the tube which will remain in place permanently. Occasionally it may be necessary to replace the tube some months later if it becomes blocked.

**After the test**

When you return to the ward, you will feel sleepy. The nurses will advise you when you can eat and drink. You will be told the results of the test and what treatment has been given. You should be allowed to leave the next day. You may be given an envelope with a report of what has happened to you during your stay in hospital. This should be given to your family doctor as soon as possible after you return home. You may read what is written in this report, but it contains only medical details which you will have already been told.
Important psychological aspects of endoscopy include physical discomfort, emotional distress and patient satisfaction. Anxiety associated with endoscopy reflects concerns regarding the examination itself, as well as its outcome. Sedation or analgesia, or both, are often given to overcome discomfort and distress, but place the patient at risk of drug side-effects. There has, therefore, been much debate concerning the need for sedation or analgesia in endoscopy. When asked about their preferences, the majority of patients continue to request some kind of sedation. Research into alternatives to traditional benzodiazepine and opiate intravenous medication has explored the use of nitrous oxide and oxygen inhalation, acupuncture, and hypnosis. Psychological techniques can be used to assist patients in coping with the stress of endoscopy by providing a variety of strategies that redress the balance between perceived threat and the ability to cope with it. This review assesses the effectiveness of psychological interventions, including the provision of information, relaxation, cognitive-behavioural approaches and modeling, and takes account of the differences between patients in their preferred coping style.

**The Experience of Endoscopy**

In an audit of the experiences of patients following an upper gastrointestinal endoscopy, 25% reported the experience as unpleasant (5). Fox et al. (6) gathered physiological, observational, and self-report measurements from 60 patients undergoing a sigmoidoscopy or a left-sided colonoscopy without medication. Overall, they concluded that the examinations were highly unpleasant and painful experiences for the majority of patients.

Patients report two sources of anxiety: the examination itself and its findings (7). Of 98 patients about to undergo a gastroscopy or a colonoscopy examination, 67% stated that they felt anxious, with half reporting intense anxiety (8). Sixty percent of these patients had previously experienced an endoscopy. Explanations given by the patients as to the cause of their anxiety included: unpleasant previous experiences of endoscopy (24%), alarm over what they had heard about such procedures (22%), and concern about what the procedure might reveal (24%). Patients having a colonoscopy for diagnostic reasons, because of symptoms such as bleeding, report more worry than those referred for cancer prevention screening or for follow-up after cancer surgery (9). The experience of the endoscopist may also affect the anxiety of patients, with those examined by the most experienced endoscopist appearing to be less worried (9).

As a result of such anticipatory anxiety, patients may want sedation to reduce the unpleasantness of the forthcoming experience. Requests for sedation depend on whether the patient is interviewed before or after the procedure, whether sedation was used during the examination, and the type of examination (5,6,8). The relevant figures vary from 11%, who requested additional sedation for upper gastrointestinal endoscopy (5); to 63% for both upper and lower gastrointestinal endoscopy (8); to 74.6% of patients requesting sedation, who had just experienced a sigmoidoscopy or left-sided colonoscopy without medication (6). The latter study also looked at the endoscopists’ perception of patients’ need for sedation; the endoscopists reported that sedation was indicated in only 28% of cases. Like endoscopists,
nurses also underestimated the distress and pain reported by the patients, although in general the nurses' assessments were closer to those of the patients.

When offered a choice of a general anaesthetic, light intravenous sedation, hypnosis, or acupuncture for upper gastrointestinal endoscopy, 4% of patients refused any sort of sedation (10). Approximately one-third of patients (both first-time and returning) opted for a general anaesthetic; 53% of first-time and 36% of returning endoscopy patients chose light intravenous sedation; and 18% of each type of patient expressed no preference for the type of sedation. No patient specifically chose hypnosis or acupuncture.

Salmon et al. acknowledged the recent trend towards a consumer-orientated approach in health care by including patient satisfaction as part of their overall assessment of the experience of endoscopy (9). A questionnaire, based on patients' descriptions of colonoscopy, revealed three independent aspects: satisfaction with the experience, emotional distress relating to the procedure, and the physical discomfort experienced during it. Satisfaction and physical discomfort were not related to which endoscopist carried out the procedure. Women reported more physical discomfort than men, but no sex differences where found in relation to satisfaction or worry. Another study also reported no differences in relation to age, sex, or social class in patients' attitudes to endoscopy or their initial concerns about their illness (5).

Studies indicate that sedation in colonoscopy is associated with a higher percentage of complete examinations (11) and that patients receiving sedation tolerate endoscopy better than those not receiving sedation for upper gastrointestinal endoscopy (the use of a local anaesthetic spray did not effect patients' tolerance) (5). Patients' own recommendations of ways to reduce the distress associated with endoscopy include: more detailed information about the procedure (21%); a calm, relaxed atmosphere (19%); or the presence of a relative during the procedure (7%) (8). Thus, as the authors suggested, greater effort should be made to reduce patients' fears and worries. Salmon et al. (9) showed that attempting to reduce discomfort by giving medication with amnesic qualities did not necessarily result in a more satisfactory experience for the patient. They concluded that patient satisfaction was most related to a caring approach on the part of the staff involved, minimizing embarrassment and humanizing the event. Nonetheless, some argue that medication should be given to all patients (12).

Psychological Interventions

Psychological interventions have been attempted in order to manipulate individual cognitive (thought) and behavioural (action) processes in various settings to reduce the distress and discomfort associated with medical procedures or symptoms of illnesses (19). Such attempts at "stress management" include a variety of behavioural and cognitive-behavioural interventions.

Providing Information

Access to reliable information enables the patient to form more accurate cognitive expectations about the procedure (20), and so may increase his or her sense of control and ability to cope (21). Two types of information may be given: procedural information (explaining the sequence of events that will occur during the medical procedure) and sensory information (describing the types of sensations likely to be experienced).

It has not been easy to demonstrate the anticipated beneficial effects of providing information in endoscopy settings. Lanius et al. (22), for example, provided half the patients undergoing gastroscopy or colonoscopy with information booklets, but found no changes in anxiety levels. Similarly, Agre et al. (23) compared live versus videotaped consent information for colonoscopy, and although patients in the information groups had significantly better knowledge scores, anxiety was not influenced by an increased understanding of the risks and benefits of colonoscopy. Both of these studies used the patients' own rating of anxiety. Levy et al. (24) took ratings by the endoscopist as well as the patients' own ratings into account, but again found no effect of information with either measure.

Wilson et al. (25), however, as part of a larger study, did find a beneficial effect of information provision in upper gastrointestinal endoscopy. They reported that, compared with the control group, patients receiving information exhibited less distress during insertion of the tube, showed smaller increases in heart rate, reported the procedure as being less uncomfortable than expected, said that they...
would be less frightened in future, and were more positive about receiving information concerning other hospital procedures.

Irrespective of its effectiveness, patients vary in their desire for additional information. One study revealed that 94% of first-time patients were aware of the reason for their investigation, 38% said they would like an information booklet, and 18% reported that they would like to see a video of the procedure (10). Of those having a repeat endoscopy, 25% and 18% said they would have liked access to a booklet and video, respectively. Even though the percentage requesting additional information was relatively low, the authors recommended that all patients should be offered an information booklet (10).

Cognitive-Behavioural Strategies

Cognitive-behavioural techniques for stress reduction are intended to alter thoughts and evaluations surrounding the noxious event (26). Examples of techniques that have been used include distraction, attention focusing, the use of positive self-statements (sometimes in an effort to enhance perceived control) and multiple-strategy packages such as “stress inoculation” (27). Stress inoculation entails three stages: first, the establishment of a conceptual framework for understanding stress reactions; second, an introduction to a variety of coping techniques; and third, a rehearsal of strategies in real or imagined situations.

On the basis of the small amount of information available, cognitive-behavioural interventions do appear to have some beneficial effects for endoscopy patients. Subjects in self-instruction training groups undergoing sigmoidoscopy rated themselves as less anxious, moved less often during the examination, and produced fewer pain utterances than those in a control group (28). In another study, patients who had experienced relaxation plus coping strategies reported greater confidence in their ability to cope and less distress before and during gastroscopy (29). Overall, those who received relaxation training rated themselves as less anxious than patients who did not receive such training (28). Physiological measures of frontal-lobe electromyography and pulse rate were significantly reduced in two groups undergoing relaxation compared with a group receiving information (29).

Modeling

The therapeutic use of modeling is based on the assumption that the patient can learn how to cope successfully during a distressing medical procedure after exposure to another individual (“a model”) who is coping well in the same situation. Modeling is rarely used as the sole strategy, and approaches featuring modeling often include aspects of the other interventions, such as providing information and coping strategies. Two studies have used modeling as an intervention in an endoscopy setting.

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Individual Differences

Individuals differ in the ways in which they attempt to cope with stressful situations. One important distinction, for which there are established psychological tests (32,33), is between a) “sensitizers” or “monitors” (those who are overtly anxious and alert to threatening cues, and tend to seek information about a stressor as a means of preparing themselves for it) and b) “repressors” or “blunters” (those who superficially appear non-anxious, and deal with impending stress by repression, denial, or distraction).

Studies indicate that sensitizers or monitors benefit from additional information (25), including modeling (30,31) and specific psychological preparation in the form of coping strategies (29). The beneficial effects were seen in measures of gagging (29), as a lower increase in heart rate (30,31) and by patients being rated as less anxious by the physician and nurse during and after endoscopy (30).

Individuals who are categorized as repressors or blunters, on the other hand, cope better with no intervention (control group) or relaxation than if they receive information (29); those who score high in emotional control and avoidance benefit more from pre-endoscopy relaxation, showing lower distress during the examination (25). In the modeling studies, increased viewing of the model produced greater increases in heart rate, indicating an increased stress response, in repressors (30,31).

In the psychological literature, there are two models that attempt to explain how different interventions help individuals. The “congruency” model proposes that psychological preparation would be more effective if it was compatible with the patient’s coping style. On this model, patients who use avoidant approaches, for example, may not benefit from, or may even be harmed by, information (30,31,34). The alternative model, the “compensation” model, adopts the view that preparatory procedures should compensate for any deficiencies in a patient’s coping style (25). The studies presented here tend to support the congruency model.

Conclusions

The wider use of psychological interventions aimed primarily at reducing anxiety and discomfort should be complementary to analgesic and sedative procedures, with the
prospect of reducing medication dosage levels and improving the quality of the patient’s experience. Investigation of the effectiveness of psychological approaches in endoscopy is only just beginning, but some conclusions can be drawn from the work reviewed here.

Research on the effects of providing patients with additional information about gastrointestinal endoscopy has not produced a clear outcome. Two studies that used the patients’ own rating of anxiety (22, 23), and one that also included ratings by others (24), failed to show a reduction in anxiety following the provision of information. One study that used physiological measures in addition to patients’ and observers’ reports, however, did show beneficial information effects (25).

There are no studies using relaxation alone as an intervention, and it is difficult to draw specific conclusions about its contribution to gastrointestinal endoscopy. Overall, however, findings from larger studies indicate that relaxation does have a beneficial effect, leading, for example, to less distress during insertion of the endoscope, lower heart rate increases, and a significant elevation in mood after endoscopy (25). Not surprisingly, perhaps, relaxation appears to be most effective for those patients with high levels of fear, as well as those high in emotional control, and patients who have undergone a relaxation procedure rate themselves as less anxious compared to those not receiving a relaxation procedure (28, 35).

Effects of relaxation appear to be enhanced when they form part of a cognitive-behavioural programme, e.g. relaxation with coping strategies. Patients undergoing such an intervention reported greater confidence in their ability to cope, and less distress before and during endoscopy, than did patients who received relaxation only, procedural information, or no psychological preparation (29). Both relaxation groups, however, showed reduced physiological measures of anxiety. Interestingly, the study by Kaplan et al. (28) failed to show an interactional effect of relaxation and instructional training; both interventions benefited the patients independently.

Beneficial effects have also been reported regarding the use of viewing a human “model”, who is coping well with the procedure, to improve the patient’s endoscopy experience (30, 31). It is not clear, however, whether this is due to patients having another opportunity to receive information, or whether the specific action of viewing the model made the difference.

An important issue in our review is that of matching psychological interventions to individual coping styles. One question is whether an intervention should aim to complement the patient’s existing coping style (the congruency model), or whether it should seek to address deficiencies (the compensation model). In general, the congruency model has been supported. Overtly anxious patients (“sensitizers” or “monitors”) appear to benefit more from receiving preparatory information in the form of coping instructions (29) or via a modeling procedure (30), whereas those who actively suppress their anxiety (“repressors” or “blunters”) did less well when preparatory information was given to them (29, 30), but benefited from relaxation training, which might be viewed as a form of distraction (29).

Clearly, psychological preparation for endoscopy patients should be tailored to their own individual coping style, and not offered as a blanket provision. Even the simple act of providing an information leaflet, for example, may help some patients to cope, but increase the anxiety of others. Future research into the effectiveness of psychological preparation for endoscopy should take this into account.

It is also of practical interest that, in comparison with first-time patients, patients with previous experience of endoscopy did not differ in their expressed need for psychological preparation, such as the provision of information (10), or in the outcome of other psychological interventions (29–31).

Although psychological interventions should be tailored to the individual needs and coping styles of the patient, cost-effective ways of delivering them will need to be devised. Psychological preparations, such as relaxation, distraction, etc., may be provided in the form of audio tapes for patients to listen to whilst waiting for their examination, or which could even be mailed to them for use during the week leading up to their examination.

With endoscopy procedures, an important contribution to patient satisfaction is the development of a positive and caring environment in which the examination is to be carried out (9). This can be introduced without great cost. Some practical steps that are currently being taken in our endoscopy unit to improve patient satisfaction include the following: patients are informed of any delays; patients are taken to a separate room where they are admitted, the procedure is explained, and they are given the opportunity to ask questions; wherever possible, an additional nurse stays with every anxious patient before the procedure; during the examination, the endoscopist talks patients through the examination and warns them of potentially painful moments just before they occur. Prior to colonoscopy, patients are asked whether or not they wish to view the endoscopy screen during the examination. If they do, every attempt is made to explain what is seen on the monitor as the procedure progresses. This approach is also applicable to many patients undergoing gastroscopy, providing that an extra monitor is available and can be placed so that the patient can see what is going on. During all endoscopic examinations, reassurance is provided to the patient by both the endoscopist and the nurse, and an opportunity to ask further questions is also given. Overall, in our experience patients report that being treated as a whole person and not just as a subject for investigation makes a major contribution to a satisfactory procedure.
References


Introduction

Not very long ago, the suggestion that virtual reality imaging might play a role in clinical medicine would have been dismissed as futuristic nonsense. However, a combination of two factors has led to the rapid development and introduction of virtual reality imaging. The first of these factors has been the burgeoning use of virtual reality technology in industry. This has paralleled the rapid progress in computer technology, which has permitted unprecedented developments in diagnostic imaging, particularly in the fields of spiral computed tomography (CT) and magnetic resonance imaging (MRI). The current published data on virtual reality imaging relate primarily to CT-based virtual endoscopic imaging of the bronchial tree and colon. Although virtual reality imaging is undoubtedly in its infancy, it shows enormous potential for providing simulated endoscopic views of other hollow organs.

This article will introduce virtual reality imaging, detailing the general principles and technical aspects of producing virtual endoscopic images, particularly in relation to CT. We outline the various techniques available for producing such images, and review the current status of developments with reference to the current literature. We highlight the potential clinical advantages of this technique, particularly in connection with CT-based virtual colonoscopy, and describe its current clinical and technical limitations. We address specific research issues that need to be further developed by workers in this field, and review the cost implications and potential issues of professional territory and competence. Finally, we look at what the future might hold for this exciting imaging modality, address the need for a common terminology, and stress the importance of adequate data sharing.

Definitions

Virtual reality should no longer be regarded as a modern technological gimmick that is only of interest to computer buffs; virtual reality is an evolving technology that will undoubtedly revolutionize medical education, diagnostic imaging, and minimally invasive therapy. Virtual reality could be defined as the sense of place and being that exists in "cyberspace". Cyberspace is a virtual environment occupied by one or more human beings, but created and maintained by computers. Whatever the strict definitions, virtual reality is the next step in the evolution of human–computer interfaces, and it allows the individual to interact visually with a computer-generated environment. Graham (1) has suggested that the term "virtual reality" should be replaced, at least in relation to its perceptual content, by the term "interactive visualization". Such visualization relates to a display of data in a manner that will provide the required information to the viewer. The key to obtaining such information from data lies in two areas. The first is the way in which the data is presented, and the second is the level of interaction the viewer is allowed to have with the data. The rapid development of high-technology digital imaging modalities such as spiral CT, and the rapid scans now available with MRI, allow three-dimensional representation of a "volume" of tissue. Coupled with this representation, there has been the development of sophisticated computer technology that allows such images to be displayed on a computer terminal, as if they were being viewed by the endoscopist. This allows a considerable degree of interactivity between the operator and the "virtual" environment. This type of virtual endoscopic imaging, which was only first carried out in 1994 (2), has now developed to a point at which there are already preliminary reports in the literature documenting early experiences with this new technique.