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Improving Cardiac Rehabilitation Session Attendance

Using the Self-Regulatory Model and Motivational

Interviewing: A Randomised Controlled Trial

AND CLINICAL RESEARCH PORTFOLIO

VOLUME I

(VOLUME II bound separately)

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MA (Hons.)

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CHAPTER 1: SYSTEMATIC LITERATURE REVIEW

Medical, Psychological and Sociodemographic Factors Associated With Adherence to Cardiac Rehabilitation Programmes: A Systematic Review.

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Abstract

Background: Cardiac Rehabilitation programmes have been shown to reduce mortality and morbidity rates among coronary heart disease patients, but adherence to these classes has been found to be poor.

Objectives: This review aims to summarise and integrate research findings investigating the possible variables that influence patient adherence to cardiac rehabilitation programmes. It also aims to address the methodological failings of past reviews conducted in this area.

Methods: Several databases were searched for studies published between 1990 and 2009. Studies examining cardiac rehabilitation programme adherence or completion, using data based on participants' actual recorded attendance were included.

Results: Eighteen studies were identified that met inclusion criteria. Low mood, participants' age and certain cardiac risk factors were found to be associated with poor adherence to cardiac rehabilitation. A good understanding of the consequences of heart disease and other psychological variables were found to be associated with good adherence. Results were relatively inconsistent across studies due to differences in methods used.

Conclusions: Certain risk factors for poor adherence to cardiac rehabilitation should be assessed and monitored by health professionals in an attempt to improve overall adherence. Studies in future should address the methodological difficulties present in previous research. Recommendations are made for standardising methods in future research. The application of psychological models in the context of cardiac rehabilitation is discussed.

KEYWORDS: Cardiac Rehabilitation; Adherence; Systematic Review

It is estimated that 3.4 million people in the UK have Coronary Heart Disease (CHD) that has resulted in either angina or a heart attack (1). These potentially fatal problems become more common with increasing age, with 1 in 3 men and 1 in 4 women over 75 years living with CHD (1). Cardiac rehabilitation (CR) programmes provide secondary prevention of cardiovascular disease through long-term provision of medical evaluation, exercise, education and counselling (2). Such programmes are widely recommended for individuals who suffer from CHD (3) as they have been shown to reduce mortality rates among those who attend by 20-25% (4). Despite these recognised benefits, attendance rates at CR are relatively poor. Beswick et al. (2) stated that between 14-43% of CHD patients attend CR classes. In addition, Sharp & Freeman (5) recently found that only 31% of patients eligible for rehabilitation went on to be adherent to the programme offered. This implies that even among those individuals who do engage with CR initially, many will fail to complete the prescribed programme of classes. Research has shown that the greatest health benefits of these programmes are associated with ongoing adherence to CR through 12 weeks of exercise or longer (6).

Research has approached the problem of poor CR attendance and adherence from a variety of different perspectives over the last two decades. Demographic, practical, socio-economic, medical and psychological factors have all been investigated as potentially important variables in explaining CR patients' health behaviours (7). Research investigating medical and demographic factors has consistently illustrated that gender (8,9) and physician recommendation (10) have a significant impact upon referral to CR and ongoing adherence. Certain comorbid diagnoses and particular kinds of cardiac problem have also been less definitively associated with referral and initial engagement (11,12). Practical factors such as current medical illness, transportation difficulties and inconvenient timing have also been shown to impact upon patients' engagement with such programmes (13).

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Recent investigations of cognitive factors associated with CR engagement and adherence have found that patients' beliefs about their illness (14,15), beliefs about CR (16), feelings of self-efficacy (17), mood and coping style (18) are all potentially important variables. Studies exploring these factors have recently applied psychological models such as the Self-Regulatory Model (SRM) (19) and the Theory of Planned Behaviour (TPB) (20) to explain these findings. The SRM proposes that people with physical illness form cognitive representations about their symptoms and treatment based upon their interpretation of information provided by past 'lay' experiences, their social environment and their current experiences. These representations subsequently influence which coping strategies and health behaviours individuals choose to pursue. There are five dimensions of illness representation described in this model: identity, cause, timeline, consequences and controllability/curability (21). Alternatively, the TPB suggests that the most important influence on an individual's behaviour is behavioural intention i.e., what they intend to do (22). According to this model, behavioural intention is influenced by an individual's attitudes towards performing the behaviour, perceived social norms around the behaviour and perceived control over the behaviour (20). These models are of some importance as they promote an understanding of CHD patients' health behaviours by both identifying variables that can predict CR attendance and adherence, and by offering an explanation of the underlying processes involved.

A number of authors have conducted reviews of this diverse area of literature over the last decade in an attempt to integrate findings. Jackson et al. (23) conducted a recent systematic review that examined the factors associated with CR referral, participation and post-discharge behavioural change. They concluded that physician endorsement was the principle predictor of referral and patient participation in CR, but also found that no single factor was predictive across all three CR stages. This finding suggests that particular variables are likely to be of most relevance to certain stages of CR. Results such as these add a great deal to our understanding of CR health behaviours; however, reviews of

this area to date have suffered from a variety of methodological weaknesses. These include a lack of systematic criteria for selecting review articles, the inclusion of studies with unclear or unreliable outcome measures, and the exclusion of certain important areas of the literature. For example, to the best of the author's knowledge, all reviews of this area to date have included studies reliant upon self-report data of CR adherence. While one study has recently investigated the reliability of self-report data for CR attendance (24), this remains largely untested and may therefore have increased bias and error within past reviews (25).

The present review seeks to further clarify the impact that psychological, medical and sociodemographic factors have upon certain CHD patients' ongoing adherence or non-adherence to CR. Improved understanding of CR adherence is of particular importance as it could allow programme participation to be maximised, patient outcomes to be improved and subsequent health costs to be reduced. Focusing the review on CR adherence alone also allows potentially confounding variables relevant to different stages of CR to be excluded. The effectiveness of psychological models in explaining CR adherence will also be discussed within this review. In addition, methodological limitations of the included studies will be highlighted and recommendations for future research will be made. The majority of studies in this field have recruited patients who have either suffered a Myocardial Infarction (MI), received a Coronary Artery Bypass Graft (CABG), an Angioplasty or are suffering from Angina. Conclusions will therefore be drawn about CR adherence among these particular CHD populations.

Methods:

Search Strategy:

Using the search term 'cardiac rehabilitation', CINAHL, EMBASE, PsycINFO, Medline and Google Scholar were searched for relevant articles. Cardiac rehabilitation is an

internationally recognised term and has been used as a search term in previous reviews (7,23). The search was limited to articles published between 1990 and January 2009. The titles and abstracts of the search results were reviewed and articles not relevant to the primary research question were excluded. The references of several review articles (7,15,23) located through the search process were then examined in order to identify further relevant studies and improve the sensitivity of the search.

Inclusion/Exclusion Criteria:

All articles were examined using the following criteria. Those not meeting these criteria were excluded:

1. Published in a peer-reviewed journal between 1990 and January 2009

2. Applied quantitative methods

3. Study examined CR programme adherence or completion, using data based on participants' actual recorded attendance

4. Comparisons made between adherence group and non-adherence group

5. CR programme under investigation conformed to the definition provided by Beswick et al. (2)

6. Study assessed associations between CR adherence and medical, sociodemographic or psychological factors, using established, validated measures where possible

8. Study examined data from original research.

Quality Rating & Data Collection:

The remaining studies were quality rated by the investigator using a methods rating sheet based upon existing checklists created by SIGN (26) and the Cochrane Collaboration (27). As the studies were not methodologically homogenous, the rating system was modified for the purpose of this review (see Appendix 2.1). The rating system required each cross-sectional study to be rated on five domains; rationale, sample, assessment,

confounding variables and statistical analysis. Randomised Controlled Trials (RCTs) were rated on three domains; rationale, sample and statistical analysis. Cross-sectional studies could receive a maximum score of 19 and RCTs could receive a maximum score of 23. Total scores were converted into a percentage and studies were categorised as poor quality (<50%), moderate quality (50-75%) or good quality (>75%). Any studies rated as being of 'poor' quality were excluded from the review. A random sample of six studies was independently rated by a second researcher and there was complete agreement between raters on overall quality categorisation i.e. poor, moderate or good. Any minor discrepancies in rating were discussed in order to reach consensus. The characteristics and results of the remaining studies were then collected and, where possible, effect sizes were calculated using established formulae (28). Effect sizes were categorised as small, medium or large based upon generally accepted criteria (29).

Results

The search yielded 1,167 studies. Figure 1 illustrates how many studies were excluded and at what stage. See Appendix 2.2 for a list of studies excluded following full text review. Eighteen studies were found to be eligible for inclusion in the present review.

Insert Figure 1 Here

In total, these studies had 8,842 participants with a mean age of 60. Sixty seven percent of participants were males. In all 11 studies that recorded participant ethnicity, the majority of patients were white. See Table 1 for a summary of study characteristics and participant demographics.

Insert Table 1 Here

Different definitions of adherence were employed across studies. Thirteen of the studies recorded the percentage of patients who completed CR, with a mean completion rate of 58%, and a range between 34% and 80%. Three studies recorded the mean number of sessions attended as a percentage (22,30,31). Across these three studies the mean percentage of sessions attended was 79%, ranging from 75% to 86%. One study recorded the percentage of patients who attended more than half of the available classes, which was found to be 66% (32). One study did not report the rate of observed CR adherence at all (33).

The variables examined across these 18 studies can be divided into the following categories; sociodemographic, medical and psychological. Table 2 provides a summary of those factors that were investigated, their association with CR adherence and, where available (or calculable from the data provided), the effect sizes.

Insert Table 2 Here

Sociodemographic Factors:

Seventeen of the studies included in this review examined the association between age and CR adherence. Six studies found age to be significantly associated with adherence (31,34-38), although the direction of this relationship was not consistent across studies. Younger age and older age were both found to be associated with poor CR adherence, while older age was also found to be associated with good CR adherence. Where it was possible to calculate effect sizes from these studies, results yielded small to medium effects. One study found patients younger than 65 and older than 75 to have poorer adherence rates (36). Of the 14 studies that examined the effect of gender on CR adherence, 5 found a significant effect, with 3 suggesting that women are less likely to adhere to CR than men (14,22,35). The effect sizes of all three of these studies were small. Two studies suggested that women are more likely to adhere to CR than men

(37,39). One study also found an interaction between age and gender, with older women reportedly more likely to be adherent to CR than younger women (34). This study was of moderate quality. Ethnicity was not consistently examined across the majority of studies in this review and only one found ethnic minority status, specifically South Asian ethnicity (40), to predict poor CR adherence.

Employment was examined by nine studies, although differing aspects of employment were measured. Two studies found some types of jobs e.g. white collar, to be associated with CR adherence (31,37), while employment itself was associated with poor adherence in another study (39). Higher deprivation scores were also found to be associated with poor CR adherence by one study which was of good quality (41).

Medical Factors:

The impact of certain diagnoses on CR adherence was investigated by 10 studies, 4 of which found an effect. Two of the four studies found an association between poor adherence and non-CABG/MI diagnoses (35,37), one found a history of angioplasty (42), and one found a diagnosis of MI to be associated with poor CR adherence (14). The good quality studies that investigated this association were however, consistent in their suggestion that CABG patients are more likely to be adherent to CR than other diagnostic groups.

Smoking, obesity, hypertension, family history, physical activity, stress and overall 'risk stratification' were all investigated as potentially important variables. Being an active smoker was found to be associated with poor CR adherence by 3 of 10 studies (31,34,39), while high BMI was associated with poor adherence in 2 of 8 studies (39,43). Small to medium effect sizes were found in studies investigating the impact of increased weight. Hypertension and physical activity were not found to be associated with adherence to CR in the six studies that assessed these factors. Risk stratification was

assessed by only two studies in this review, but both found high risk stratification to be associated with poor CR adherence (37,39). None of the studies in this review assessed the impact of physician endorsement or other iatrogenic factors on CR adherence.

Psychological Factors:

Depression was assessed by five studies in this review and all five found it to be related to CR adherence (14,32,38,42,43). Four of these studies found greater depression scores, as measured by the Beck Depression Inventory (BDI) or Hospital Anxiety and Depression Scale (HADS), to predict poor adherence (14,38,42,43). These findings had small to medium effect sizes and one of the studies found this relationship only among females (14). Three studies investigated anxiety using the HADS (14,32,42), but only one found anxiety scores to be associated with adherence (32). In this case, lower anxiety scores were associated with poor CR adherence.

Illness perceptions were assessed by two studies in this review (14,32), both of which used the Illness Perceptions Questionnaire (IPQ) and found some association between patient scores and adherence. The IPQ is based upon the five dimensions of the SRM described earlier in this review. Higher perceived Consequences scores were associated with improved adherence in both studies, with medium to large effect sizes found. Identity, Treatment Control and Personal Control scores were also found to be associated with adherence, but not consistently across both studies. Effect sizes for these variables were small. Health beliefs based on other psychological models were also assessed. One study investigated beliefs consistent with the Health Belief Model (31), while another investigated the TPB (22). The only component of either of these models found to predict CR adherence was patient beliefs about Severity of Disease Threat within the Health Belief Model (31). Greater perceived severity of threat was associated with reduced adherence to CR.

Certain aspects of patients' personality, such as neuroticism and optimism, may also be associated with adherence to CR programmes. These factors were investigated by two studies in this review which were found to be of good quality (43,44), although they used different measures of personality. Results were therefore not consistent across these studies, as illustrated by the small to large effect sizes found. Patient self-efficacy was also found to predict CR adherence by one study (30), as was the type of coping strategy employed by patients (32). Coping strategy was found to have a medium to large effect size.

Discussion

The results of this review suggest that the majority of patients attending CR either complete the programme or attend more than half of the prescribed classes. These rates of adherence and completion are somewhat higher than those reported by previous research (5,45). Nevertheless, these results indicate that around 40% of CHD patients who initially attend CR do not complete the programme, and demonstrate that a diverse range of variables may influence this behaviour.

The association of patient age with CR adherence was investigated by almost all of the studies in this review. Findings from a mixture of both good and moderate quality articles suggest that younger CHD patients may be more likely to drop out of CR before completion. Results relating to older adults suggest that increased age may result in poor CR adherence for some and good adherence for others. Previous research suggests that older patients may perceive themselves as being less in control of their illness and therefore less likely to participate in CR programmes (46). However, older patients have been found by other authors to be more likely to comply with physician recommended behaviour changes (47), suggesting that the impact of increased age upon CR adherence is complex. Evidence suggests that younger patients may adhere to fewer CR classes as

they are more often affected by practicalities such as the need to return to work (38). They may also see CR as less of a necessity (16).

Sex differences were also found to be relevant to CR adherence in this review, with women found to have poorer participation rates than men in three studies. Effect sizes were small however, and these findings were contradicted by two studies that found women to have better adherence than men. Research has previously concluded that female gender is a significant predictor of early CR drop-out (14,35). The results of the current review suggest that such conclusions should be approached with caution as some programmes appear to succeed in retaining female participants, while others do not.

Medical factors found to be associated with CR adherence in this review include diagnosis, BMI, smoking status and cardiac risk stratification. Findings suggest that patients who have had CABG surgery appear to be more likely to adhere to CR classes than patients with other diagnoses, such as MI or Angina. Turner et al. (42) suggest that those patients who have undergone surgery as a result of their heart disease may feel their illness is more serious or threatening, therefore increasing CABG patients CR adherence. Active smokers and those with high BMI ratings appear to be less likely to adhere to CR, as do those with high or medium risk stratification. These findings suggest that patients who may be in most need of the interventions offered at CR are the least likely to adhere to such programmes. This may be related to patients' beliefs about their own suitability for CR (16) or a lack of self-efficacy among high risk patients (9).

The results of the present review suggest that illness perceptions such as these, along with other psychological variables, do have an impact upon CR adherence. Interestingly, effect sizes calculated from studies in this review appear to show psychological variables to have larger effects than sociodemographic or medical variables. Two such studies assessed illness perceptions using the IPQ, both were found to be of good quality and

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both found greater scores on the Consequences scale to be associated with increased CR adherence (14,32). These findings, which had large effect sizes, suggest that CHD patients who experience their illness as being serious or as having greater consequences are more likely to adhere to CR classes. While it is difficult to generalise from these limited findings, the association of CR adherence with these types of illness perceptions is consistent with meta-analysis findings reported by French et al. (15). These authors, and both studies that used the IPQ in the present review, also suggest that patients' beliefs about control over their illness and treatment are relevant to CR attendance and adherence. French et al. (15) concluded that greater perceived personal and treatment control are associated with improved attendance at CR. The direction of this relationship was not consistent in the present review and effect sizes relating to illness/treatment control were found to be small.

Other psychological factors, such as depression, also appear to influence CR adherence. The association of higher scores on measures of depression with poor CR adherence was the most consistent finding of this review, with effect sizes varying between small and medium. This is corroborated by other research that has reliably shown patients with depression to be less likely to adhere to recommended lifestyle changes than non-depressed patients (48). Barriers to completing CR among depressed patients may include feelings of hopelessness, a lack of self-efficacy, reduced resilience in response to adversity and an increased perception of symptoms as debilitating (38). Studies investigating personality have also shown that sub-scales of the State-Trait Anxiety Inventory (STAI), and the California Personality Inventory (CPI), may be associated with poor CR participation (43,44). These two studies were both found to be of good quality and, in the case of Hershberger et al. (44), to have a large effect size. Other studies in this review have found that self-efficacy (30) and coping style (32) may also be important variables in CR adherence. Given the importance of patients' mood in determining adherence to CR, the possible relationship between personality dimensions, coping style,

self-efficacy, illness perceptions and depressive symptoms could usefully be explored by future research.

Psychological Models & CR Adherence:

Psychological models have been used by relatively few studies in this review to explain CHD patient health behaviours. Two studies used the SRM, one study used the TPB and one study used the Health Belief Model. Aspects of the SRM, as measured by the IPQ, have been proven to be associated with CR adherence behaviours by studies within this review. These relationships have also been assessed by a number of studies not included in this review (15,46,49). The evidence therefore suggests that certain illness related cognitions may be valid predictors of CHD patient health behaviours. The original model of Leventhal et al. (19) proposed that such cognitive illness representations act in parallel with emotional illness representations that also affect individuals' coping strategies, emotional outcomes and subsequent illness outcomes (21). Investigations of the SRM in the context of CR adherence have not, as yet, integrated these parallel pathways. Further exploration of the relationship between patients' emotional and cognitive representations of illness and subsequent coping strategies is therefore likely to be a useful area of future research. This is of particular relevance to depressed CHD patients who are likely to have cognitive biases about themselves, the world and the future (50) that may influence illness outcomes and engagement in treatment. The Health Belief Model and TPB have received less attention than the SRM in the context of CR attendance and adherence. The one RCT included in this review was based upon the TPB, however, and the intervention used by these authors was found to successfully increase initial CR attendance (22). In this study, no differences were found between the intervention and control groups in rates of ongoing CR adherence, suggesting that patients' intention to attend CR may play an important role in the early decision to go to CR but not in the decision to continue attending. This further underlines the fact that some variables are predictive of patient involvement in certain stages of CR, but that no

single factor comprehensively predicts patient participation from referral to programme completion.

Clinical Implications:

Overall, studies of CR adherence in this review suggest that patients are more likely to continue to attend CR if they feel that their illness has serious consequences, but also feel confident about their ability to respond and take control of their treatment and their illness. It seems likely that patients who are oriented in this way are necessarily more likely to use problem-focused coping strategies and be less prone to depressive patterns of thinking, although this assumption requires further research evidence. Ironically, those patients who are at high risk of experiencing further cardiac events are less likely to adhere to CR. Sociodemographic variables, such as age, gender and deprivation are also likely to have an impact upon CR adherence, but the effect of these factors may be particular to each programme. Health professionals working within cardiac rehabilitation departments should therefore be particularly vigilant to the needs of patients who are most likely to become non-adherent i.e. those with high risk of cardiac relapse, low mood, low levels of confidence and a lack of understanding of the consequences of their illness. Interventions aimed at changing these variables may have some success in improving later programme adherence rates. CR departments may also wish to consider how best to adapt their programmes in order to facilitate the participation of patient populations local to their service, specifically targeting both sexes, different age groups and patients from deprived areas.

Recommendations for Future Research:

The studies within the present review include a range of important methodological weaknesses and complications. Research in future should attempt to address these issues in various ways, including the following:

1. Defining Adherence - As previously mentioned, the definition of CR adherence varied across studies in this review, potentially confounding attempts to generalise findings. As noted by Casey et al. (38), there is currently no standardised definition of CR adherence or programme completion. Methods used in this review included reporting the percentage of patients who completed CR, the mean percentage of classes attended, and the percentage of patients who attended more than 50% of classes. Authors in future may consider including relatively comprehensive and transparent data in order to make findings more easily comparable. For example, the following data may be communicated in future studies; mean number of sessions attended, number of patients who dropped out before half-way (non-adherent patients), number who made it beyond half-way but did not complete (adherent patients), number who completed the programme (completing patients), reasons for dropping out if available.

In addition to standardising the methods used for recording patient adherence data, a wider debate should also be encouraged in order to consider the validity of adherence to this field as a whole. Research and clinical guidelines suggest that attending a full programme of CR classes will result in improved physical and psychosocial health outcomes (3,6). However, Scottish guidelines for CR also state that the "incorporation of regular, sustained exercise into an individual's lifestyle is likely to be more important than the frequency or length of formal exercise training" (p.12) (3). The incorporation of such activity into patients' lifestyle will likely take less time for some than it will for others. It therefore follows that for some individuals it would not be necessary to complete the full CR programme in order to receive the same health benefits. Research in future should attempt to record the onset of such sustained exercise in order to assess whether adherence should be considered in terms of lifestyle change rather than the number of classes attended.

2. Selecting Appropriate Variables and Measures - A notable omission from the results of this review is the impact of iatrogenic, or programme specific factors on CR adherence. Jackson et al. (23) found physician endorsement to be the strongest predictor of ongoing CR participation, but none of the studies in this review assessed the effect of this variable. It is also likely that support from local cardiologists, referral pathway, programme accessibility (45) and other programme specific variables may have an effect on participation in CR. The relative impact of these factors should be assessed by future research.

Another difficulty with the findings of this review stems from the use of different measures by authors to assess the same variable. This is particularly relevant when considering studies that attempt to measure the impact of psychological variables upon CR adherence. Two different measures were used to assess depression across five studies in this review. While the scales used in these studies are well validated and reliable, neither the BDI nor the HADS provides a definitive diagnosis of depression. There may also be some overlap between the physical symptoms of depression and the symptoms of CHD, particularly when considering the BDI (38).

3. Methodology - RCTs are now generally accepted as one of the most effective experimental methods used to assess the efficacy of interventions and to identify salient relationships between variables (51). However, only one RCT met inclusion criteria for this review (22) and, to the best of the author's knowledge, there is only one other RCT within this field that was excluded (49). Cross-sectional methods were used by the other 17 studies in this review, which assess the relationship between CR adherence and different variables at one point in time. Due to the fact that one-off observations are made in these studies, definitive causal inferences are difficult to make (52). Results must therefore be interpreted with caution. RCT methods may be applied by future studies in the assessment of interventions designed to increase CR adherence. Potential targets for

such interventions may include patients' low mood, illness perceptions around the consequences of CHD and treatment control, high risk behaviours and self-efficacy.

4. Representative Samples - A majority of studies in the present review either did not record ethnicity or recruited an entirely white sample. Some ethnic minority groups have been found to be particularly vulnerable to CHD (53), suggesting that investigations of participation in CR among these groups should be of some importance. Since these populations are not adequately represented in this review it is not possible to comment on the impact ethnicity may have on CR adherence. It should also be noted that only one third of the participants in this review were women. Approximately 40% of CHD patients are female in the UK (1), suggesting that women are slightly under-represented in this area of research. This is particularly relevant in light of suggestions that they have lower rates of adherence.

Limitations of the Present Review:

The various definitions of adherence used, in addition to the other methodological considerations outlined above, suggest that the conclusions of this review should be deemed as tentative. Research using more widely agreed definitions and controlled methods would likely allow more definitive statements to be made regarding the causes of CR non-adherence in future.

This review also has a deliberately limited focus, assessing the factors that influence CR adherence rather than referral to CR or initial attendance. As such, a number of studies by leading authors in the field were excluded from this review. While this is justified by the evidence that different variables impact upon CR participation at different stages, this nevertheless makes the results of this review less easy to generalise. Low rates of referral and poor initial participation at CR remain significant problems (2). Research

must therefore continue to focus on improving our understanding of these stages of CR in addition to the variables that influence ongoing adherence.

The inclusion of studies with small sample sizes and potentially small effect sizes is also a limitation of this review. Including studies with small samples may lead to results that are not representative of the CHD population as a whole. Including findings with small effect sizes, on the other hand, risks the possibility of confounding statistical significance with clinical meaningfulness. Due to variations in reporting and methods used, it was unfortunately not possible to calculate the effect sizes for all variables examined within this review. Standardisation of the methods used by authors to investigate and report CR adherence would allow systematic reviews and meta-analyses to be more easily conducted in future.

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Figure 1:

TITLE: FLOW CHART OF REVIEW PROCESS & STUDY INCLUSION/EXCLUSION
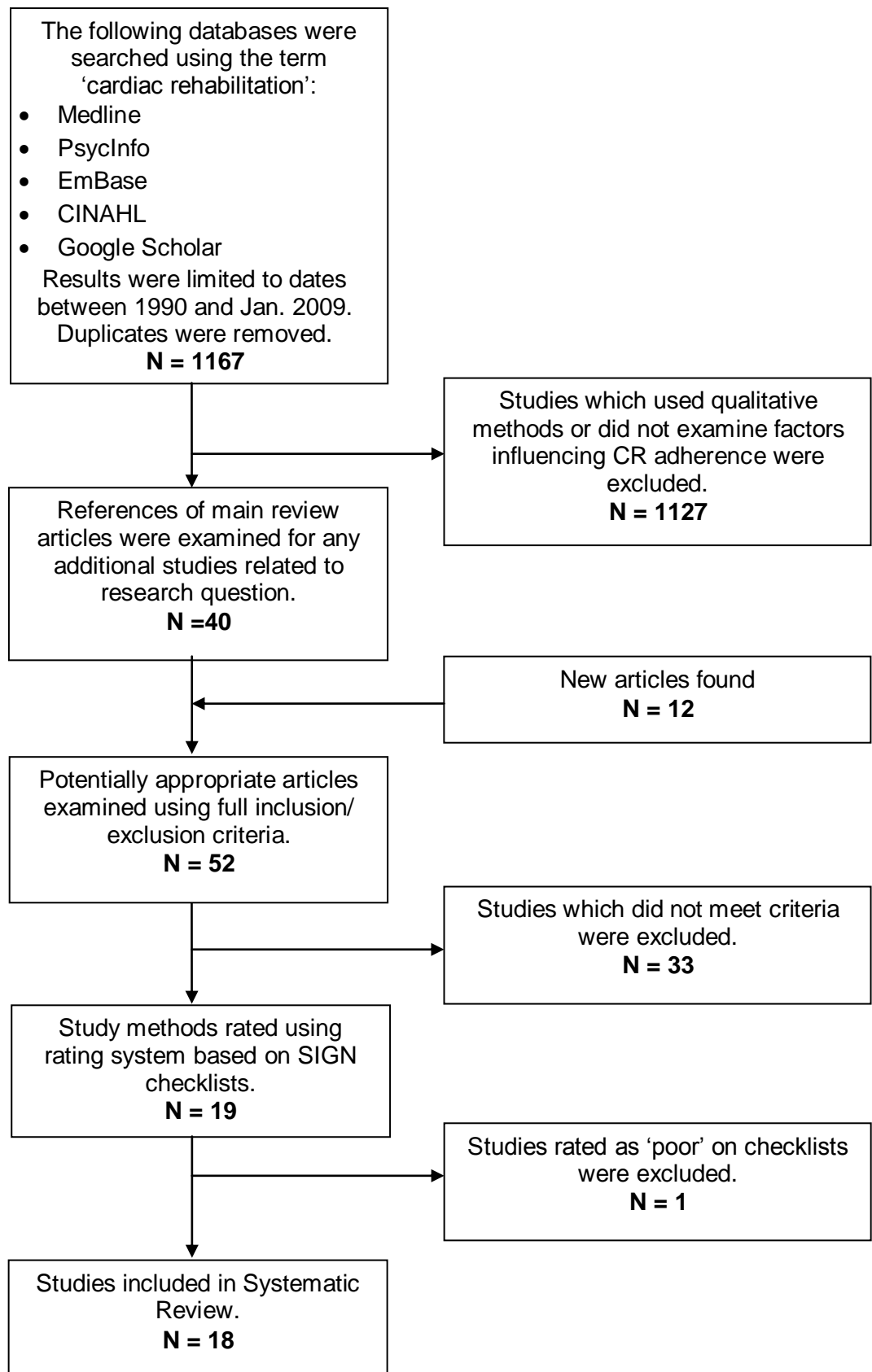
Table 1:
TITLE: REVIEWED ARTICLES: STUDY QUALITY, PARTICIPANT NUMBERS, DEMOGRAPHIC DATA & DIAGNOSES

Authors	Quality Rating (%)	N	Sex (Male, Female)	Mean Age (Standard Deviation)	Ethnicity	Diagnoses*
Oldridge & Streiner (31)	Moderate (68%)	120	100%, 0%	55	-	MI, Bypass, Angina
Cannistra et al (34)	Moderate (63%)	225	77%, 23%	55 (SD 10)	78% White	>4 diagnoses
Oldridge et al (35)	Good (84%)	492	68%, 32%	58	-	CABG, MI, Other
Cannistra et al (54)	Moderate (63%)	82	0%, 100%	56 (SD 11)	57% White, 43% Black	>4 diagnoses
Pell et al (41)	Good (84%)	1120	59%, 41%	Median=66	-	MI
Hershberger et al (44)	Good (84%)	49	100%, 0%	62.4 (SD 9.6)	-	>4 diagnoses
Wyer et al (22)	Good (83%)	87	88%, 12%	63	100% White	-
Jones et al (33)	Good (79%)	30	0%, 100%	64	83% White, 10% Black, 3% Asian, 3% Hispanic	>4 diagnoses
Glazer et al (43)	Good (95%)	46	74%, 26%	58 (SD 10.2)	74% White, 22% Black, 2% Hispanic	>4 diagnoses
Turner et al (42)	Moderate (68%)	1902	80%, 20%	61 (SD 10.2)	-	>4 diagnoses
Sanderson et al (39)	Moderate (68%)	526	65%, 35%	60 (SD 12)	69% White, 31% Non-White	Ischemic HD
Whitmarsh et al (32)	Good (95%)	93	76%, 24%	63.9 (SD 11.5)	100% White	MI
Doolan-Noble et al (36)	Moderate (57%)	916	65%, 35%	-	84% White, 9.9% Maori, 2.5% Asian, 3.3% Pac.Isl.	MI, Unstable Angina
Yohannes et al (14)	Good (95%)	189	68%, 32%	60	-	MI, CABG
Banerjee et al (40)	Good (89%)	1200	75%, 25%	58	82% White; 18% South Asian	MI, CABG
Sarrafzadegan et al (37)	Good (95%)	1115	77%, 23%	55	-	>4 diagnoses
Casey et al (38)	Good (84%)	600	70%, 30%	66 (SD 12)	94% White	>4 diagnoses
Millen & Bray (30)	Good (84%)	50	62%, 38%	62 (SD 12.5)	88% White, 2% Native Indian, 2% Hispanic	MI, Angio, Angina

*MI=Myocardial Infarction; CABG=Coronary Artery Bypass Graft; Angio=Angioplasty; HD=Heart Disease

Table 2:
TITLE: VARIABLES ASSESSED & THEIR ASSOCIATION WITH CR ADHERENCE

Variable	Total number of studies	CR adherence related to... (measures used)	Number of Studies found variable related to poor CR adherence (Effect Sizes)†	Number of Studies found variable related to good CR adherence (Effect Sizes)†
Sociodemographic				
Age	17	Younger Age	3 (d=0.19)	0
		Older Age	2 (d=0.44)	2 (d=0.47)
Sex	14	Female	3 (d=0.34, r=0.19, r^2=0.03)	2
Employment	9	Being Employed	1	0
		Certain jobs	1	0
		White Collar work	0	1
Ethnicity	8	South Asian Ethnicity	1	0
Marital Status	7	No relationship	-	-
Education	6	No relationship	-	-
Deprivation	4	Greater deprivation	1	0
Distance	2	No relationship	-	-
Social Support	1	No relationship	-	-
Medical				
Diagnosis	10	MI	1	0
		Angio	1	0
		CABG	0	1
		Non-CABG/MI	2	0
Smoking	10	Active smoking status	3	0
Exercise Capacity	9	Poor exercise capacity	1	0
Obesity/Weight	8	High BMI	3	0
Hypertension	6	No relationship	-	-
Diabetes	5	Diabetic diagnosis	0	1
Medication	2	No relationship	-	-
Family History	2	Family history among males	1	0
Physical Activity	2	No relationship	-	-
Individual Differences	2	Greater height	1	0
Risk Stratification	2	High risk stratification	2	0
Comorbidities	2	No relationship	-	-
Days in Hospital	1	More days in hospital	0	1
Stress	1	Home Stress	1	0
Insurance	1	Non-private health insurance	1	0
Psychological				
Depression	5	Higher depression scores (HADS & BDI)*	4 (d=0.37-0.61)	1 (d=0.61)
Anxiety	3	Higher anxiety scores (HADS)*	0	1
Illness perceptions	2	Higher Consequences scores (IPQ)*	0	2 (d=0.77-0.82)
		Higher Identity scores (IPQ)*	0	1
		Lower Treatment Control scores (IPQ)*	1 (r^2=0.07)	0
		Higher Personal Control scores (IPQ)*	1 (r^2=0.02)	0
		Higher Control scores (IPQ)*	0	1 (d=0.31)
Personality	2	Lower Socialisation score (CPI)*	1 (d=1.17)	0

		Lower Good Impression score (CPI)*	1 (*d*=1.03)	0
		Lower neuroticism & higher Optimism scores (STAI, LOT)*	0	1 (*d*=0.22, *d*=0.19)
Health beliefs	2	Lower perceived severity of disease threat (SCQ)*	0	1
Quality of Life	2	No relationship	-	-
Self-efficacy	1	Higher barrier self-efficacy scores (Barrier SE Scale)*	0	1 (*r*=0.41)
Locus of Control	1	No relationship	-	-
Coping	1	Higher Emotion & Problem focused coping scores (COPE)*	0	1 (*d*=0.54, *d*=0.79)

*BDI=Beck Depression Inventory; HADS=Hospital Anxiety and Depression Scale; IPQ=Illness Perception Questionnaire; CPI=California Personality Inventory; STAI=State-Trait Anxiety Inventory; LOT=Life Orientation Test; SCQ=Standardised Compliance Questionnaire; COPE=Coping Orientation to Problems Experienced Scale

† It was not possible to determine effect size for all variables. Type of effect size calculated varied depending upon data available within articles. *d*=Cohen's *d*; *r*=Pearson's *r*; *r*²=Pearson's *r* squared

CHAPTER 2: MAJOR RESEARCH PROJECT

Improving Cardiac Rehabilitation Session Attendance Using the Self-Regulatory Model and Motivational Interviewing: A Randomised Controlled Trial

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Prepared in accordance with the requirements for submission to *British Journal of Cardiology* (see Appendix 1)

Abstract

Objective: This study aimed to investigate the effectiveness of a theory-based, one-session intervention in enhancing cardiac rehabilitation (CR) adherence among patients attending their first class. The intervention session was structured to elicit and change patients' illness perceptions, and to enhance motivation.

Design: Randomised, controlled trial.

*Participants***:** Patients attending for their first Phase III CR class were recruited.

Outcome Measures: The primary outcome measure was the number of rehabilitation exercise sessions attended, providing data on participant adherence to the programme. The Illness Perception Questionnaire-Revised was used as a secondary outcome measure. Sociodemographic data and information on coping style and mood were also collected.

Results: Patients in the intervention group were found to attend significantly more CR classes than the control group ($p < .05$). Illness perceptions were not found to be different between groups at three-month follow up. Sociodemographic, medical and psychological variables were not found to be associated with CR adherence, although high levels of anxiety and depression were reported among participants.

Conclusions: Rates of initial CR attendance and ongoing adherence were relatively high among all participants. Improved adherence among the intervention group suggests that brief psychological intervention sessions may be useful within a CR setting. However, the lack of change in illness perceptions following intervention suggests that more research is necessary in order to understand the present findings. Other recommendations for future research are also discussed.

KEYWORDS: Randomised Controlled Trial; Cardiac Rehabilitation; Adherence

It is estimated that there are approximately 2.5 million people aged 35 or over with Coronary Heart Disease (CHD) in the UK (1). These patients are significantly more vulnerable to premature death, stroke and other health problems, and are estimated to cost the economy £30.7 billion per year in health care and lost productivity (1). Cardiac Rehabilitation (CR) programmes typically offer patients with CHD a long-term programme of medical evaluation, exercise, education and counselling (2). Such programmes have been found to reduce mortality rates, cardiovascular morbidity and cardiac risk factors among patients who have had a myocardial infarction (MI) (3). Despite the recommendations of national guidelines that acknowledge the benefits of CR and detail best practice (4,5), research suggests that the use of such services is poor (2,6). Attendance rates in the UK have been found to vary between 14%-43% following MI (2). A recent audit of CR services within a general hospital in Glasgow also revealed that only 31% of those eligible for rehabilitation participation were considered to be adherent to the programme (7).

A broad range of variables have been associated with adherence to CR. These include sociodemographic factors such as gender, age and socioeconomic status, systemic factors such as physician recommendation (8), and psychological factors (9) such as those proposed in the Self-Regulatory Model (SRM) of Leventhal et al. (10). The SRM suggests that people with physical illness form cognitive and emotional representations about their symptoms and treatment based upon their interpretation of information available to them. This information may be provided by past experiences, by their social environment or by their current experiences. Individual's cognitive and emotional representations are then hypothesised to influence their choice of coping strategies and health behaviours. Leventhal et al. (10) describe five dimensions of illness representation in the SRM: identity, cause, timeline, consequences, and controllability/curability (11). Recent research has focused on the relationship between these dimensions and CR attendance and adherence (6,12,13).

Studies examining the predictive relationship of the five SRM dimensions have found beliefs about illness consequences and control/cure to be strongly correlated with CR attendance and ongoing adherence (6). Patients who perceive the consequences of their illness to be serious appear to be more likely to adhere to CR programmes than those who do not (9,14). While the relationship between perceived control/cure and CR adherence is less definitive, patients who believe themselves to be in control of their illness and treatment appear to be more likely to attend CR than those with low perceived control (12,13). Such findings suggest that an intervention aimed at altering cardiac patients' illness beliefs, specifically those associated with perceived consequences or controllability/curability, could facilitate increased adherence to a CR programme.

Interventions designed to modify illness perceptions and enhance CR adherence have had some success (15,16). Petrie et al. (15) in particular showed that illness perceptions could be changed using a brief psychological intervention that resulted in both an earlier return to work and a slight improvement in attendance at CR. Whilst studies of this kind have had various methodological limitations, they nevertheless indicate that interventions aimed at changing illness perceptions can have an impact on CR health behaviours.

Fostering health behaviour change is often approached using a motivational interviewing style (17). A recent review by Dunn et al. (18) found strong evidence for the use of motivational interviewing as a method to enhance treatment engagement among substance abusing populations. Recent investigations of interventions aimed at motivating individuals to engage with services for substance abuse suggest that brief sessions (i.e., 15-40 minutes) can be as successful as longer interventions (19). It has been postulated that interventions of this nature might be applicable to CR (20).

The present study sought to investigate the effectiveness of a brief intervention aimed at altering individuals' illness perceptions and increasing the number of CR sessions attended. The intervention was informed by the SRM and applied using a motivational interviewing style. This study represents a novel application of the SRM model that has practical implications for the delivery of brief, theoretically-driven psychological interventions in cardiac settings.

Experimental Hypotheses:

A single session intervention based on the SRM will have the following effects when administered to cardiac patients attending their first CR session:

- The number of CR exercise classes attended will be greater among the treatment group than the control group.

- Participants in the treatment group will view their illness as having greater consequences and see it, and their treatment, as being more controllable than those in the control group.

MATERIALS & METHODS

Ethics approval was received by the South Glasgow and Clyde Research Ethics Committee in October 2008 (see Appendix 3.1 for approval letters).

Participants:

All patients entering into Phase III of the cardiac rehabilitation service at three Greater Glasgow & Clyde hospitals were considered for recruitment. CR across all general hospitals in Glasgow consists of a 10-week, 20-session programme of exercise, medical monitoring, educational talks and evaluation for dietetic and clinical psychology input.

Inclusion/Exclusion Criteria:

Patient consent was required from all participants. Patients were required to have an ability to read, write and speak fluently in English. Participants were only considered if they were eligible for the CR exercise and education programme and were attending for their first class. Participants needed to be over 18, to have no hearing impairment requiring the use of an interpreter, and to have no severe cognitive impairments.

Recruitment:

Participants were recruited from the Southern General Hospital (SGH), Stobhill Hospital (SH) and Victoria Infirmary (VI), Glasgow, between November 2008 and May 2009. A study information sheet was made available to all patients attending assessment clinics prior to their participation in the CR exercise programme. This information sheet advised patients who were interested in the study to speak to the investigator prior to, or following their first CR class. New patients at CR classes were then reminded about the study by CR nurses and were directed to speak to the investigator if they wished to discuss the study further. Following a discussion of the study with the investigator, participants' consent was obtained. Follow-up questionnaires were posted to participants between February and July 2009.

Measures:

Sociodemographic & Medical Measures - Information on participant age, gender, ethnicity, postcode (for Scottish Index of Multiple Deprivation (SIMD) classification (21)), distance from CR programme (calculated using www.maps.google.co.uk), marital status, education, employment status, medical diagnosis and intensity of CR class was collected following completion of the study consent form.

Psychological Measures - Coping strategy and mood have been found to effect initial CR attendance and ongoing adherence (9,14). The following scales were administered to measure these variables:

- The Brief Coping Orientation to Problems Experienced (Brief-COPE) scale is adapted from the COPE and assesses several responses relevant to adaptive and maladaptive coping. It comprises 14 subscales, including denial, active coping and behavioural disengagement, which have demonstrated internal reliability (α=.5-.82) and validity (22).

- The Hospital Anxiety & Depression Scale (HADS) (23) is a 14-item questionnaire designed to measure psychological distress in medical out-patient populations. While the HADS is not diagnostic, a score exceeding eight on either the anxiety or depression sub-scale is indicative of a possible clinical affective disorder (24). HADS subscales have been found to be a valid and reliable (Anxiety, α=.83; Depression, α=.82) measure of depression and anxiety, both generally and specifically among cardiac patients (24,25).

Primary Outcome Measure - Number of CR sessions attended was the main measure of adherence. CR attendance was measured as a continuous variable. For descriptive purposes, patients were also categorised based upon the number of classes attended. Whilst there is no convention for categorising those who are adherent vs. non-adherent, a similar approach to that of Whitmarsh et al. (14) was used in this study (i.e., non-adherent = ≤50% sessions attended, adherent = >50% sessions attended, completer = completed entire programme (10 weeks)).

Secondary Outcome Measure - The Illness Perception Questionnaire-Revised (IPQ-R) is based on the dimensions of the SRM. It comprises eight subscales and 38 items measuring attributions of illness. There are no cut-off scores for any subscales of the IPQ-R. The IPQ-R has demonstrated good test-retest reliability (α=.46-.88), and

discriminant and predictive validity in a range of patient populations, including chronic and acute pain, rheumatoid arthritis, multiple sclerosis, and MI patients (26).

Design/Procedures:

This study used a between-subjects randomised, controlled trial design. Participants were randomly allocated to the intervention group or the control group using a randomisation sequence created by a computerised random sequence generator (www.randomizer.org). Each participant's allocation was concealed within a numbered envelope by a member of the research team not actively involved in recruitment. The investigator opened this envelope only after consent had been obtained and was therefore blind to each participant's allocation during recruitment.

The intervention group received one session following the completion of their first CR class, approximately 60 minutes in duration. At the beginning of this session, participants were asked to complete the IPQ-R, Brief-COPE and the HADS. All sessions were structured to include a series of stages, each designed to focus on certain dimensions of the SRM. These stages included the following:

1) Establish rapport, set agenda and seek input from patient (Treatment Control).

2) Brief discussion about heart conditions and symptoms commonly occurring during recovery (Consequences, Illness Control).

3) Brief discussion about what cardiac rehabilitation classes involve and why they are important (Consequences, Treatment Control)

4) Explore current beliefs about the cause of their heart disease and their readiness for change using a 'readiness ruler' (Consequences, Illness/Treatment Control).

5) Create dissonance and encourage the development of a plan to engage with CR, including personal, achievable goals. This will vary depending upon the individual's level of readiness for change (Treatment Control).

6)   Review action plan and summarise session.

This structure was followed in all intervention sessions in an attempt to ensure integrity of treatment. The investigator used a standard session structure as a prompt to maintain consistency between sessions (Appendix 3.2). Discussion within the session was tailored according to the patient's willingness to make changes to their health behaviours. Figure 1 charts the possible courses taken during the intervention session depending upon the participant's readiness for change (see Appendix 3.3 for 'Readiness Ruler'). This is based upon a brief motivational intervention described by Berg-Smith et al. (27). The FRAMES acronym (Feedback, Responsibility for change, Advice-giving, Menu of options, Empathic style, Self-efficacy) recommended for brief motivational interviewing interventions (28) was used during this session, although the 'Advice-giving' component was not utilised in order to more closely reflect the collaborative spirit of this intervention style. Towards the end of the session, patients were encouraged to note down their own goals and plans for their future health behaviours if they felt it was appropriate (see Appendix 3.4).

Insert Figure 1.

The control group received treatment as usual. They were asked to complete the IPQ-R, Brief-COPE, and HADS at the time of recruitment.

Three-months following consent, the IPQ-R was posted to all participants for follow-up. CR attendance data was collected by the investigator from individual's medical records approximately 10-weeks after consent. In cases where the patient was known to have dropped out of CR for a given reason, this information was also recorded.

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Sample Size:

Wyer et al. (29) conducted a letter-based intervention aimed at increasing CR attendance that had a large effect size (r=0.72). Whitmarsh et al. (14) found significant differences in illness perceptions and coping strategies between attendees and poor/non-attendees of CR. These differences translate into large effect sizes (Consequences, d=0.77, Identity, d=0.81; Problem focused coping, d=0.77). Yohannes et al. (9) found illness perceptions to account for 19% of the variance in CR adherence (r^2=0.19). This is a medium to large effect size. Brief interventions using motivational interviewing have consistently found medium effect sizes e.g. d = 0.5 - 0.7 (18,19).

These findings presented a mixed picture of the likely effect size for the present study. No intervention studies have yet focused on dimensions of the SRM or motivational interviewing as a means to increase CR adherence. In addition, it is also important to consider the clinical application of the present intervention. If its effect is not robust enough to be visible in a relatively small sample of patients then it is unlikely that it will warrant the time and energy of busy health professionals in future.

Taking these factors into account it was therefore assumed that the present study would have an effect size of 0.8 with a significance level of alpha = .05. Using GPower v3.0.8 (30), a sample size of 42 was determined to be appropriate, with treatment and control groups each consisting of 21 randomly allocated patients.

Data Analysis:

All data analyses were conducted using SPSS v.15. Descriptive statistics were used to summarise the psychological and sociodemographic characteristics of the participants. Treatment and control group differences in demographic and clinical characteristics were examined using t-tests and, when parametric assumptions were not met, Mann-Whitney tests. An alpha level of .05 was used for all statistical tests. Assumptions were not met

for χ^2 tests to be carried out on categorical data as expected frequencies were less than five for some cells within contingency tables. CR adherence data was assessed for skewness, kurtosis and homogeneity of variance and was found to be significantly skewed (z=2.03). In order to transform the data, number of CR sessions missed was examined instead of number of sessions attended (i.e., (20-N) instead of N). Adherence data were then transformed using the square root function, yielding a data set with a normal distribution. Data were graphed using scatterplots and Pearson's or Spearman's correlation coefficients were used to assess whether significant correlations existed between CR attendance and other demographic, medical and psychological variables. Correlational analyses were conducted across groups and for the control and treatment groups separately. Treatment-control group differences in CR attendance were examined using a one-tailed t-test as the hypothesis predicted the direction of effect. This analysis was performed with all CR attendance data and with a data set excluding participants whose non-adherence to CR was either anticipated or unavoidable e.g. due to return to work or ill health. IPQ-R sub-scale scores at baseline and three-month follow up were compared between groups using t-tests. The intention to treat (ITT) principle (31) was considered during analyses.

RESULTS

Figure 2 summarises participant flow through each stage of the study. Ninety four patients were scheduled to begin CR classes on recruitment days. Seventy eight referrals were male patients and 16 were female patients. Of the 94 patients referred, 67 attended their first CR class, 49 agreed to discuss the study, 13 did not wish to discuss the study, and 5 did not meet inclusion criteria. Of the five excluded individuals, two did not speak English and three were not physically fit enough to start CR that day. Upon discussion of the study, 18 patients declined participation. The most common reason for non-

participation was insufficient time to stay behind after the CR class. Thirty one participants consented to take part in the study and were randomised. Eighteen participants were randomised into the intervention group, and 13 into the control group. ITT analysis was ultimately not required as all participants who were randomised to the intervention group completed the session.

Insert Figure 2 Here

Six of the 31 participants were female and the mean age of all participants was 61.7 years of age (SD=9.9). Clinical, demographic and psychological characteristics of the intervention and control groups are summarised in Tables 1 and 2. No significant differences were found between intervention and control groups in age (t(29)=.532, p=.599), education (u=114.5, p=.917), distance from hospital (u=93, p=.336), deprivation (u=98, p=.859), anxiety (t(29)=.905, p=.373), depression (u=82, p=.153) or any sub-scale of the IPQ-R or Brief-COPE at baseline.

Overall, 11 of the 31 participants (31%) had HADS anxiety scores equal to or greater than the cut-off score of eight. Seven participants (23%) had depression scores equal to or greater than the HADS cut-off. There were no apparent differences between participants recruited across hospital sites except in HADS anxiety and depression scores. The mean HADS anxiety score at the SGH was 11, at SH it was 6, and at VI it was 5. The mean HADS depression score at the SGH was 9, at SH it was 2, and at VI it was 4. These differences were not formally analysed due to the small numbers of participants recruited from SH and SGH.

Insert Table 1 & 2 Here

Adherence:

Adherence data were collected for 25 of the 31 participants who took part in the study. CR data for six participants were not available as these individuals were still actively attending the programme at thesis submission. CR adherence data were available for 14 intervention participants and 11 control participants.

The mean number of sessions attended across groups was 15.6 (SD=5.6). Among the intervention group, the mean number of sessions attended was 17.0 (SD=5.1). For the control group, the mean was 13.7 (SD=6.0). Ten of the 14 intervention participants were considered 'completers', 1 was 'adherent' (attended >50% of classes) and 3 were 'non-adherent' (attended ≤50% of classes). Three of the 11 control participants were 'completers', 6 were 'adherent' and 2 were 'non-adherent'. Reasons for non-completion were obtained for four patients; two control and two intervention participants. Three of these individuals stopped attending CR as they had to return to work and one had a leg injury.

Following square root transformation, CR attendance data met assumptions for parametric data analysis. Scatterplots and correlational analyses did not reveal significant linear correlations between CR attendance and any other recorded psychological, medical or sociodemographic variables (data not shown). On average, participants in the intervention group attended more CR classes (M=.92, SD=1.5) than participants in the control group (M=2.03, SD=1.5). This difference was statistically significant (t(23)=-1.796, p=.043, 95%CI=-2.4–.17) and represented a medium effect size (r=.35). Repeating this analysis while excluding data from the four participants who returned to work or were injured did not substantively change these results. The intervention group were still found to attend more CR classes (M=.58, SD=1.3) than the control group (M=1.87, SD=1.7) and this difference was also found to be significant (t(19)=1.814, p=.032, 95%CI=-2.7 – .08).

Pearson's χ^2 analysis could not be used to compare CR attendance among male and female participants due to the small number of women who took part in the study. CR attendance data was available for four women by the time of submission. The mean number of sessions attended by these women (M=9.8, SD=7.9) was lower than for men (M=16.9, SD=4.5).

Illness Perceptions:

Follow-up questionnaires were returned by 20 of the 31 participants (65%). See Table 3 for a summary of IPQ-R scores at baseline and three-month follow-up. There were no significant differences in IPQ-R scores between control and intervention participants at three-month follow-up. The most common primary perceived cause of illness among both groups at baseline was heredity, followed by stress/overwork and smoking. At three-month follow-up, heredity and ageing were the most common perceived causes among the control group, while heredity and stress/overwork were the most common perceived causes among the intervention group. These results may have been skewed by some patients' failure to return the follow-up questionnaire.

Insert Table 3 Here

DISCUSSION

This study assessed the impact of a single exposure psychological intervention upon CHD patient adherence to CR programmes. The findings suggest that this intervention had a positive impact upon patients' adherence to CR. Participants who received the treatment session attended more classes on average than the control group. The intervention was designed to target participants' illness perceptions relating to the consequences of CHD and their ability to control the illness and its treatment. However, the results do not

support the hypothesis that IPQ-R scores would differ between the intervention and control groups at three-month follow-up as no differences were found. This suggests that, while the intervention had a significant effect upon patients' CR adherence behaviour, it did not have the predicted effect upon participants' perception of their illness consequences or personal/treatment control. Although it is possible that this study lacked the statistical power to detect such differences in IPQ-R scores at follow-up, the intervention appears to have influenced CR behaviour through means other than the modification of illness beliefs.

The findings from the present investigation are in contrast to the study conducted by Petrie et al. (15), in which MI patients' illness beliefs were successfully modified following a brief three-session intervention. These authors recruited 65 participants, potentially providing greater statistical power than in the present study, and administered their intervention while participants were still in-patients. It is possible that, following discharge and commencement of rehabilitation, individuals' illness beliefs are more firmly established and perhaps more resistant to change. It is also possible that a single session is not sufficient to facilitate such changes in illness beliefs, despite the evidence for brief interventions in addictions populations (19). In the present study, participants' scores on IPQ-R 'Control' and 'Consequences' scales were also relatively high at baseline and at follow up. High perceived consequences and control scores have been associated with improved CR adherence by previous studies (9,14). This sample may therefore have had misconceptions about CHD and perceptions of poor control addressed prior to starting CR, thus reducing the potential impact of this intervention on illness beliefs.

The intervention applied in the present study was based on the SRM as a model of CR health behaviour. However, other models may serve to explain the present findings. For example, the Theory of Planned Behaviour (TPB) suggests that an individual's intention to engage in a given behaviour is pivotal in influencing their actual choice of behaviour (32).

This theory suggests that behavioural intention is influenced by an individual's attitudes towards performing the behaviour, perceived social norms around the behaviour and perceived control over the behaviour. It is feasible that the intervention in the present study may have helped to consolidate participants' behavioural intention to attend CR through the active discussion of attitudes about attending and social norms. It is also possible that patient's behavioural intentions may have been facilitated by the development of an 'implementation intention' (33). This was originally described by Gollwitzer (34), who proposed the existence of a post-decision phase in which plans, or implementation intentions are formed about when and where a given behaviour may be enacted. The formation of these plans has been shown to increase the likelihood that health behaviours will be carried out (33). The present intervention may have encouraged the development of an implementation intention through goal setting and the discussion of explicit action plans to achieve these goals. Finally, the Transtheoretical, or Stages of Change Model (35) suggests that readiness to make cognitive and behavioural change progresses through a series of stages from 'pre-contemplation' to 'maintenance'. Participants who received the intervention session may have been encouraged to progress from the 'action' to the 'maintenance' stage through the use of a motivational interviewing style. This involved the use of a supportive, client-centred therapeutic approach, in which empathic reflection, praise and feedback were utilised to increase motivation. Future research may therefore seek to assess the 'active ingredient' of the present intervention to determine which, if any of these models are of most relevance.

While no statistically significant differences were found between the control and intervention groups at baseline, more intervention participants reported being single, divorced or widowed than control participants. As a result, these individuals may have had less social support than the control group. Social support has been associated with improved CR attendance in previous research (36). The intervention group was also more likely to be retired and to have experienced a MI. Employment status and diagnosis

have also been implicated in CR attendance behaviours (9,37,38). Despite these possibilities, this study did not provide evidence to support previous findings that have shown psychological, medical and sociodemographic variables to be associated with participation in CR. Preliminary results suggest that female gender may have been associated with poor CR adherence. Unfortunately the small sample size in this study limits our ability to draw definitive conclusions.

Clinical Implications:

Overall, initial CR attendance and ongoing adherence rates recorded in this study were higher than expected from previous research, both within Glasgow (7) and elsewhere in the UK (39). Seventy one percent of referred patients attended for their first class, and 52% completed the prescribed programme. Although this is a relatively small and highly selective sample, it can be concluded from these results that at least some Glasgow CR programmes may be successfully retaining patients in CR classes at rates above the national average. The relative success of these programmes may be attributed to a variety of variables not fully assessed within this study, such as referral pathway, support from local cardiologists (39), and adherence to national guidelines, amongst many others.

Despite the high rate of programme completion and adherence among all participants, intervention recipients were still found to attend more CR classes on average than those in the control group. This implies that the intervention session, or elements of it, could potentially be applied within CR programmes in order to further improve participant adherence. The intervention used in this study differs from the typical procedures of CR as it allows patients the opportunity to tell their story, to discuss their perceptions and opinions about their illness, and to develop health related goals in a format that is not prescriptive. The application of a motivational interviewing style is also a novel component of this intervention that has not been previously tested in a CR setting. While many of the elements of this intervention are undoubtedly applied by some CR health

professionals at present, these findings highlight the potential value of a dedicated session in which CR patient's self-efficacy and motivation are targeted. Such sessions could be administered by most members of a multidisciplinary team.

The results of this study also further corroborate evidence that CHD patients are particularly vulnerable to experiencing anxiety and depression during their recovery. Almost a third of the sample reported high anxiety and a quarter of the sample reported high depression, as measured by the HADS. Screening measures such as this should be used within CR programmes to assess individuals for affective disorders and signpost them to appropriate services, as recommended by national guidelines (5).

Only 17% of the CHD patients referred to CR during this study were women, suggesting that there are considerably lower numbers of women referred to CR than men in Glasgow at present. Estimations suggest that approximately 40% of CHD patients are women in the UK (1). Ethnic minority patients were entirely unrepresented in the present study, with all participants describing themselves as white. Criteria used in recruiting for this study, which excluded non-English speakers, may have contributed to this lack of diversity. Other types of rehabilitation available within Glasgow, such as home-based programmes, may also be preferred by some ethnic minority groups due to a variety of cultural factors, such as the use of Western music and mixed sex classes. Prevalence of heart attack and angina has been estimated to be twice as high among South Asian men in the UK (40), and at least one study has shown adherence rates to be poor among this population (41). This illustrates the pressing need for research into the rates of CR referral and uptake among ethnic minority groups, and the development and application of intervention strategies for these populations. These considerations suggest that the sample recruited into the present study may not be representative of the wider CHD patient population, although it may represent an accurate sample of the patients accessing CR exercise classes in Glasgow at present.

Limitations:

This study has a number of limitations, the first of which is a small sample size that prevented some planned analyses from being performed. Participant numbers were lower than had been anticipated due to time constraints and low referral rates. Conclusions must therefore be considered as tentative and any generalisations should be treated with caution.

The failure to observe the hypothesised changes in illness perceptions in the intervention group also limits the value of the present study. While various theoretical models have been discussed that may explain the present findings, these results do not allow the confirmation or rebuttal of any of these possibilities.

The majority of participants in this study were recruited from one site (VI), which may have led to a biased sample. The VI generally appeared to have higher numbers of CHD patients referred into their CR programme than the other two hospitals, suggesting that iatrogenic and programme factors, such as physician recommendation, may have varied between sites. Participant selection in this study could therefore have been biased towards the recruitment of individuals who may already have been motivated to attend CR. In addition, those patients who are most ambivalent about CR may not have been captured within this sample as they are potentially less likely to volunteer for research.

The time available for conducting this study was limited and it was only possible to recruit participants on one or two days per week. As a result, the majority of participants were recruited from either moderate or high intensity classes that occurred on recruitment days across the three sites. Only one participant was recruited from a low intensity class. Patients with the lowest levels of physical fitness were therefore largely unrepresented in

the present sample. This may further limit our ability to generalise the findings of this study.

Finally, the principle investigator was responsible for both recruitment and the provision of intervention sessions to participants. This dual role may have been a confounding factor as control participants still had a 10-15 minute conversation with the investigator in the process of giving consent and completing questionnaires. Unfortunately, due to the limited resources available, it was not possible to avoid this potential confound.

Future Research:

The results of this study suggest that brief interventions aimed at increasing CR attendance and adherence are worthy of further research. Replication of this study with a larger sample would potentially yield more definitive answers about the utility of the SRM in such interventions. The use of additional outcome measures to assess possible changes in motivation, behavioural intention and implementation intention may also be informative. In addition, the application of this type of intervention strategy at an earlier phase of CR may be investigated as a means by which to improve initial programme attendance. More research should also be encouraged to better understand and facilitate CR participation among women and ethnic minority groups.

Conclusions:

Evidence shows that CHD patients can benefit greatly from attending CR programmes as part of their recovery. Encouragingly, this study illustrates that some CR programmes are succeeding in initiating and retaining comparatively high numbers of patients into their Phase III classes. Results also showed that patients who received a brief intervention as part of this study went on to attend more CR classes than control participants. Although the expected changes in illness perceptions did not occur among the intervention group, this study suggests that brief psychological interventions may hold promise within the

context of CR. This study had a small sample size and future research in this area is necessary to further consolidate these findings and to clarify the theoretical foundation of the intervention session.

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Figure 1. *Flow Chart of Intervention Session Content.*

```
                    ┌─────────────────────────┐
                    │    Establish Rapport     │
                    └─────────────────────────┘
                                │
                                ▼
```

Agenda Setting:
"Here's what I thought we might do in the time we have today..."
- Discuss heart conditions
- Discuss what you think of your illness
- Discuss change, goals etc.

"Is there anything else you want to discuss or want to do?"
- Accommodate any suggested discussion points in session plan.

Cardiac Education:
Discuss the causes of cardiac problems, expected duration of recovery, normal symptoms experienced during recovery.

Elicit participant response to information: *"What do you make of all this information?"*

Cardiac Rehabilitation Education:
Discuss the programme that they are recommended to attend and elicit perceptions of treatment:
"What do you think of attending for these sessions?"
"Do you think this programme is going to help you to recover?"

Assess Current Illness Beliefs:
"What do you think caused your illness?"
"Why is that?"
"Are their alternatives?"
"Do you plan on making any changes in your life as a result?"

Assess Readiness for Change:
Show 'Readiness Ruler' and have them rate their readiness.

"Tell me more about the number you chose..."

Tailor Intervention Approach

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Not Ready	**Unsure**	**Ready**
Respectfully acknowledge their decision i.e. *"You're the best judge of what's right for you."*	Explore ambivalence about change.	Identify change options.
Key Questions: • *"Why did you give yourself a 3 not a 1?"* • *"What would you need to be different for you to consider making changes?"* • *"How could you get from a _ to a _ on this ruler?"*	Key Questions: • *"What are some of the good things about making a change?"* • *"What is the cost of not changing?"* • *"What would your partner/friends think if you didn't change at all?"*	Key Questions: • *"What do you think needs to change?"* • *"What are your ideas for making change?"* • *Which options make the most sense to you?"*
Goal Setting: Elicit realistic short-term goals i.e. *"Can we set some goals for your health over the next few months?"* Discuss any dissonance between goals and readiness for change? Aim to model problem-focused strategies.	Look into the future: *"I can see why you're unsure about change. Let's imagine for a moment that you did decide to change. What would be different? Why would you want to do this?"*	Goal Setting: Elicit realistic short-term goals i.e. *"Can we set some goals for your health over the next few months?"* Aim to model problem-focused strategies.
Develop an action plan if appropriate.	Goal Setting: Elicit realistic short-term goals i.e. *"Can we set some goals for your health over the next few months?"* Discuss any dissonance between goals and readiness for change? Aim to model problem-focused strategies.	Discuss potential obstacles to achieving goals. Develop an action plan.
	Develop an action plan if appropriate.	

Close Session:
Review action plan if there is one.

Review session: *"Did I get it all?"*

Support self-efficacy & control:
"I applaud your efforts, there are many ways you can prevent this happening again and I know you can make changes in future."
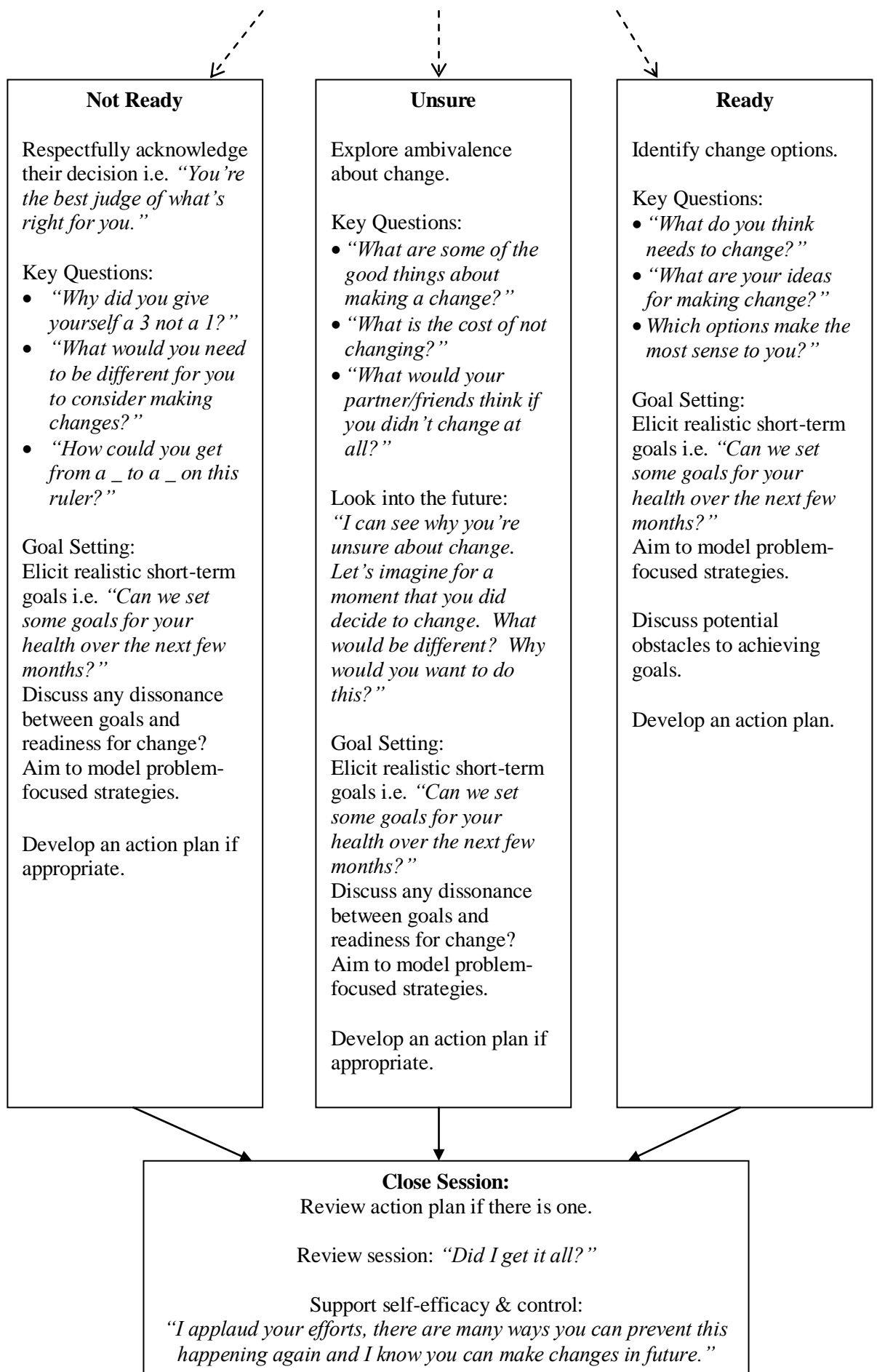
Figure 2. *Participant Flow.*

Table 1. *Clinical & Demographic Characteristics of Sample at Baseline*

	Control (*n*=13)	Intervention (*n*=18)
Gender	11 M, 2 F	14 M, 4 F
Age	61 (10.6)	63 (9.6)
Ethnicity		
Caucasian	13	18
Marital Status		
Single	1	3
Married/Cohabiting	10	9
Divorced/Separated	1	4
Widowed	1	2
Employment Status (%)		
Unemployed- benefits	0	1
Unemployed- no benefits	1	0
Employed Full Time	6	7
Employed Part Time	3	1
Retired	3	9
Years of Education	11.6 (1.8)	12 (2.7)
Diagnoses		
Myocardial Infarction	5	11
Angina	8	6
Angioplasty	8	11
CABG	5	4
Other	0	1
Hospital		
VI	10	11
SGH	2	5
SH	1	2
Class Intensity		
Low	0	1
Medium	5	10
High	8	7
Miles from Hospital	2.8 (1.7)	4.0 (3.2)

Values are means (SD) or numbers of participants. No significant differences were found.
CABG-Coronary Artery Bypass Graft; VI-Victoria Infirmary; SGH-Southern General Hospital
SH-Stobhill Hospital

Table 2. *Psychological Characteristics of Sample at Baseline*

	Control (*n*=13)	Intervention (*n*=18)
Mood (HADS)		
Anxiety	5.9 (4.3)	7.2 (3.8)
Depression	3.5 (3.1)	5.8 (4.7)
Coping (Brief-COPE)		
Self-Distraction	5.3 (1.4)	5.3 (2.4)
Active Coping	6.0 (1.3)	6.0 (2.0)
Denial	3.3 (1.5)	3.4 (1.7)
Substance Use	2.4 (1.2)	3.1 (1.7)
Emotional Support	4.8 (1.7)	4.5 (2.2)
Instrumental Support	5.6 (1.6)	4.2 (2.3)
Behavioural Disengagement	2.4 (1.0)	2.7 (1.2)
Venting	3.4 (1.2)	3.2 (1.7)
Positive Reframing	5.3 (1.4)	5.7 (2.2)
Planning	5.8 (1.5)	5.7 (2.1)
Humour	4.3 (2.1)	4.4 (2.0)
Acceptance	5.8 (1.6)	6.1 (1.8)
Religion	3.2 (1.6)	2.7 (1.2)
Self-Blame	3.6 (1.8)	3.7 (2.1)

Values are means (SD). No significant differences were found.

Table 3. *Mean IPQ-R Scores at Baseline & 3-month Follow-Up*

IPQ-R Sub-Scale	Baseline		3-month Follow Up	
	Control (*n*=13)	Intervention (*n*=17)	Control (*n*=8)	Intervention (*n*=12)
Identity	4.8 (3.5)	3.2 (2.7)	2.4 (2.1)	1.7 (2.1)
Timeline	18.4 (4.3)	18.7 (4.9)	22.0 (3.8)	20.1 (5.3)
Consequences	19.2 (3.7)	17.4 (5.4)	17.3 (5.8)	15.7 (3.4)
Treatment Control	19.1 (2.0)	20.6 (2.5)	18.6 (2.1)	20.8 (3.6)
Personal Control	23.4 (3.4)	24.8 (3.2)	24.0 (1.4)	24.3 (3.2)
Illness Coherence	20.2 (3.5)	20.4 (2.7)	20.0 (3.3)	20.4 (2.4)
Timeline Cyclical	10.2 (3.5)	8.8 (3.5)	11.0 (2.6)	8.5 (3.1)
Emotional Representations	15.5 (3.8)	16.7 (5.2)	16.0 (5.2)	15.0 (5.3)
Cause				
Heredity	4	5	2	3
Stress/Overwork	3	4	0	3
Smoking	1	4	1	1
Diet	1	2	1	2
Lifestyle	0	2	1	0
Alcohol	1	0	1	1
Ageing	1	0	2	1
Chance/Bad Luck	1	0	0	1
Lack of Exercise	1	0	0	0
Diabetes	0	1	0	0

Values are means (SD) or numbers of participants. No significant differences were found.

CHAPTER 3: ADVANCED PRACTICE I – REFLECTIVE CRITICAL ACCOUNT (Abstract Only)

Diversity, cultural bias and clinical practice.

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ABSTRACT

Issues of diversity and cultural sensitivity are particularly important to clinical psychology services due to the wide range of populations seen by clinicians. The governing bodies in psychology have produced ethical guidelines relating to working with diverse populations and the government has made recommendations regarding the inclusion of ethnic minority communities in service development. However, clinical psychology is a largely white profession in the UK and a Eurocentric focus is the norm. This account describes an experience which prompted me to reflect on these issues and the ways in which my own practice and assumptions impact upon clients from different cultural backgrounds from myself. The account is structured using a model of reflection proposed by Boud, Keogh, & Walker (1985). The professional implications of this experience, the process of reflection and future personal developments are also discussed.

CHAPTER 4: ADVANCED PRACTICE II – REFLECTIVE CRITICAL ACCOUNT (Abstract Only)

The challenges of clinical research and consultancy in modern psychology practice.

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ABSTRACT

Clinical psychologists are expected to fulfil various roles within the NHS. As researchers, psychologists are expected to add to the knowledge base of psychological science and, as consultants, pass this knowledge on to other health professionals and shape best practice. These two roles are closely connected and require some of the same high level skills in practice. Communication between clinical psychologists and other health professionals is not always successful however, and this can cause misunderstandings, tension and resistance. This reflective account describes an experience which prompted me to carefully consider how psychologists conduct research and work in Multi-disciplinary Teams. The challenges that face clinical psychologists in these roles are discussed. A formal model of reflection has been used to structure this reflection. Professional implications and directions for future development are also discussed.

LIST OF APPENDICES

Appendix 1: British Journal of Cardiology, Instructions for Authors

The British Journal of Cardiology is pleased to consider original papers, review articles and letters for publication. All material is assumed to be exclusively submitted to BJC unless otherwise stated in writing.

Types of manuscripts

Review articles provide in-depth surveys of recent advances in a field. Suggestions for review
articles should be provided in the form of a one page synopsis or discussed with the editors prior to submission.
Original articles may appear as full length reports (approximately 2,000 words excluding references and figure legends) or short communication (approximately 1,000 words) which report preliminary data from original work.
Letters are encouraged to provide comments on previously published papers or on important or novel aspects of research in the field.
Case reports cannot currently be accepted for publication. The editors will announce in the journal when they are open to the submission of case reports again.

Manuscripts

Original manuscripts should include:

- Title page, full names, position and university/hospital affiliation of each author should be given (Please provide address, telephone number, fax number and email address for corresponding author)
- Abstract (up to 200 words) plus keywords
  (Keywords should be from the Medical subject headings (MeSH) list in Index Medicus where possible)
- Key messages (three or four bullet points to summarise the article for the busy reader)
- Introduction
- Materials and methods
- Results
- Discussion
- References (Vancouver style, see References below)
- Tables
- Figures (see Illustrations, artwork and photographs below)
- Picture of author for sole-authored papers (see Illustrations, artwork and photographs below)
- Acknowledgements
- List all sources of support for research

References

Example of typical reference:

1. Bell GM, Bernstein RK, Laragh JH *et al*. Increased plasma atrial natriuretic factor and reduced plasma renin in patients with poorly controlled diabetes mellitus. *Clin Sci* 1989;**77**:177-82.
2. McMurray J, McDonough T, Morrison CE, Dargie HJ. The growing problem of heart failure in Scottish hospitals. *Br Heart J* 1993;**69**(suppl 1):73-6.

Example of reference for a chapter of a book or irregular data:

1. Edvinsson L, Mackenzie E, McCulloch J (eds). *Cerebral blood flow and metabolism*. New York: Raven Press, 1993:1-683.
2. Reus DJ, Iadecola C. Intrinsic central neural regulation of CBF and metabolism in relation to volume transmission. In: Fuxe K and Agnati LF (eds). *Volume transmission in the brain: novel mechanisms for neural transmission*. New York: Raven Press, 1991;523-38.

Appendix 2.1: Quality Criteria Data Collection Sheets

	QUALITY CRITERIA ASSESSMENT DATA COLLECTION SHEET: CROSS SECTIONAL STUDIES		
Author(s):			
Date:			
Title:			

1. RATIONALE

1.1	The study addresses an appropriate and clearly focused question.	1 Yes 0 No	
1.2	Are the main objectives clearly stated?	1 Yes 0 No	
TOTAL: SECTION 1			/ 2

2. SAMPLE

2.1	The sample is representative of the population being studied.	2 Well covered 1 Adequately addressed 0 Poorly addressed	
2.2	The study indicates how many of the people asked to take part did so.	2 Well covered 1 Adequately addressed 0 Poorly addressed	
2.3	How were the participants recruited?	2 Consecutive referrals 1 Convenience Sample 0 Not stated	
2.4	Are any inclusion/exclusion criteria stated?	1 Yes/Not relevant to study 0 No/not stated	
2.5	Is the sample size stated?	1 Yes 0 No/not stated	
TOTAL: SECTION 2			/ 8

3. ASSESSMENT

3.1	The outcomes are clearly defined.	2 Well covered 1 Adequately addressed 0 Poorly addressed	
3.2	The measures of outcome assessment are reliable and valid, with evidence from other sources cited.	2 Well covered 1 Adequately addressed 0 Poorly addressed	
TOTAL: SECTION 3			/ 4

4. CONFOUNDING FACTORS

4.1	The main potential confounders are identified and taken into account in the design and analysis where appropriate.	2 Well covered 1 Adequately addressed 0 Poorly addressed	
TOTAL: SECTION 4			/ 2

5. STATISTICAL ANALYSIS

5.1	Is the analysis appropriate to the design and type of outcome measure?	1 Yes 0 No/not stated	
5.2	Are the results clearly reported?	1 Yes	

		0	No/not stated
5.3	Have confidence intervals, effect sizes, p-values etc. been provided where appropriate?	1 0	Yes/Not appropriate No/not stated

TOTAL: SECTION 5	/ 3

OVERALL TOTAL: / 19

PERCENTAGE: ___ %

QUALITY RATING: _____   Poor (<50%), Moderate (50-74%), Good (>75%)

DESCRIPTION OF THE STUDY (*Note: The following information is required for evidence tables to facilitate cross-study comparisons. Please complete all sections for which information is available*).

6.1	How many patients are included in this study? *List the number in each group separately*	
6.2	What are the main characteristics of the study population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	
6.3	What environmental or prognostic factor is being investigated in this study?	
6.4	What comparisons are made in the study? *Are comparisons made between presence or absence of an environmental / prognostic factor, or different levels of the factor??*	
6.5	For how long are patients followed-up in the study?	
6.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess the impact of the chosen environmental or prognostic factor.*	
6.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk. Include p values and any confidence intervals that are provided.* **Note**: *Be sure to include any adjustments made for confounding factors, differences in prevalence, etc.*	
6.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	

QUALITY CRITERIA ASSESSMENT DATA COLLECTION SHEET: RCT STUDIES

Author(s):

Date:

Title:

1. RATIONALE

1.1	The study addresses an appropriate and clearly focused question.	1 Yes 0 No
1.2	Are the main objectives clearly stated?	1 Yes 0 No

TOTAL:SECTION 1	/ 2

2. SAMPLE

2.1	The assignment of subjects to treatment groups is randomised	2 Well covered 1 Adequately addressed 0 Poorly addressed
2.2	An adequate concealment method is used	2 Well covered / NA 1 Adequately addressed 0 Poorly addressed
2.3	The treatment and control groups are similar at the start of the trial	2 Well covered 1 Adequately addressed 0 Poorly addressed
2.4	Are any inclusion/exclusion criteria stated?	1 Yes 0 No
2.5	Is the sample size stated?	1 Yes 0 No/not stated
2.6	The only difference between groups is the treatment under investigation	2 Well covered 1 Adequately addressed 0 Poorly addressed
2.7	All relevant outcomes are measured in a standard, valid and reliable way	2 Well covered 1 Adequately addressed 0 Poorly addressed
2.8	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	2 Well covered 1 Adequately addressed 0 Poorly addressed
2.9	Where the study is carried out at more than one site, results are comparable for all sites	2 Well covered 1 Adequately addressed 0 Poorly addressed

TOTAL: SECTION 2	/ 18

3. STATISTICAL ANALYSIS

3.1	Is the analysis appropriate to the design and type of outcome measure?	1 Yes 0 No/not stated
3.2	Are the results clearly reported?	1 Yes 2 No/not stated

3.3	Have confidence intervals, effect sizes, p-values etc. been provided where appropriate?	1 Yes/Not appropriate 0 No/not stated
TOTAL: SECTION 3		**/ 3**

OVERALL TOTAL: / 23

PERCENTAGE: _____ %

QUALITY RATING: _____   Poor (<50%), Moderate (50-74%), Good (>75%)

DESCRIPTION OF THE STUDY (*Note: The following information is required for evidence tables to facilitate cross-study comparisons. Please complete all sections for which information is available*).

4.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	
4.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	
4.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	
4.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	
4.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	
4.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	
4.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	
4.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	

Appendix 2.2: Articles excluded following full-text review & reasons for exclusion

CR Adherence Not Measured

Petrie, K., Broadbent, E., Ellis, C., & Ying, J. Improving recovery following heart attacks by changing illness perceptions: a randomized trial. *Psychological Health* 2005; 20(Suppl 1):212.

Thomas, R.J., Miller, N.H., Lamendola, C., Berra, K., Hedback, B., Durstine, J.L., & Haskell, W. National survey on gender differences in cardiac rehabilitation programs: Patient characteristics and enrolment patterns. *Journal of Cardiopulmonary Rehabilitation* 1996; 16(6):402-412.

Measured Initial Attendance, Not Adherence

Bengt, F. Self-rated health in women after their first myocardial infarction: A 12-month comparison between participation and nonparticipation in a cardiac rehabilitation programme. *Health Care for Women International* 2000; 21:727-738.

Blackburn, G.G., Foody, J.M., Sprecher, D.L., Park, E., Apperson-Hansen, C., & Pashkow, F.J. Cardiac rehabilitation participation patterns in a large, tertiary care center. *Journal of Cardiopulmonary Rehabilitation* 2000; 20(3):189-195.

Cooper, A., Weinman, J., Hankins, M., Jackson, G., & Horne, R. Assessing patients' beliefs about cardiac rehabilitation as a basis for predicting attendance after acute myocardial infarction. *Heart* 2007; 93:53-58.

Farley, R.L., Wade, T.D. & Birchmore, L. Factors influencing attendance at cardiac rehabilitation among coronary heart disease patients. *European Journal of Cardiovascular Nursing 2* 2003: 205-212.

French, D.P., Lewin, R., Watson, N. & Thompson, D.R. Do illness perceptions predict attendance at cardiac rehabilitation and quality of life following myocardial infarction? *Journal of Psychosomatic Research* 2005; 59:315-322.

Harlan III, W.R., Sandler, S.A., Lee, K.L., Lam, L.C., & Mark, D.B. Importance of baseline functional and socioeconomic factors for participation in cardiac rehabilitation. *American Journal of Cardiology* 1995; 76:36-39.

Lane, D., Carroll, D., Ring, C., Beevers, D.G., & Lip, G. Predictors of attendance at cardiac rehabilitation after myocardial infarction. *Journal of Psychosomatic Research* 2001; 51:497-501.

Lieberman, L., Meana, M., & Stewart, D. Cardiac rehabilitation: Gender differences in factors influencing participation. *Journal of Women's Health* 1998; 7(6):717-723.

McGee, H.M. & Horgan, J.H. Cardiac rehabilitation programmes: Are women less likely to attend? *British Medical Journal* 1992; 305:283-284.

Melville, M.R., Packham, C., Brown, N., Weston, C., & Gray, D. Cardiac rehabilitation: Socially deprived patients are less likely to attend but patients ineligible for thrombolysis are less likely to be invited. *Heart* 1999; 82:373-377.

Petrie, K., Cameron, L., Ellis, C., Buick, D., & Weinman, J. Changing illness perceptions after myocardial infarction: An early intervention randomized controlled trial. *Psychosomatic Medicine* 2002; 64:580-586.

Petrie, K., Weinman, J., Sharpe, N., & Buckley, J. Role of patients'view of their illness in predicting return to work and functioning after myocardial infarction: Longitudinal study. *British Medical Journal* 1996; 312:1191-1194.

Quality Rated as Poor

Halm, M., Penque, S., Doll, N., & Beahrs, M. Women and cardiac rehabilitation: Referral and compliance patterns. *Journal of Cardiovascular Nursing* 1999; 13(3):83-92.

Review Article, Not Original Research

Benz Scott, L.A., Ben-Or, K., & Allen, J.K. Why are women missing from outpatient cardiac rehabilitation programs? A review of multilevel factors affecting referral, enrolment, and completion. *Journal of Women's Health* 2002; 11(9):773-790.

Beswick, A.D., Rees, K., Griebsch, I., Taylor, F.C., Burke, M., West, R.R., Victory, J., Brown, J., Taylor, R.S., & Ebrahim, S. Provision, uptake and cost of cardiac rehabilitation programmes: Improving services to under-represented groups. *Health Technology Assessment* 2004; 8(41).

Beswick, A.D., Rees, K., West, R.R., Taylor, F.C., Burke, M., Griebsch, I., Taylor, R.S., Victory, J., Brown, J., & Ebrahim, S. Improving uptake and adherence in cardiac rehabilitation: Literature review. *Journal of Advanced Nursing* 2005; 49(5):538-555.

Cooper, A., Jackson, G., Weinman, J. & Horne, R. Factors associated with cardiac rehabilitation attendance: A systematic review of the literature. *Clinical Rehabilitation* 2002; 16:541-552.

Daly, J., Sindone, A.P., Thompson, D.R., Hancock, K., Chang, E., & Davidson, P. Barriers to participation in and adherence to cardiac rehabilitation programs: A critical literature review. *Progress in Cardiovascular Nursing* 2002; 17:8-17.

French, D.P., Cooper, A., & Weinman, J. Illness perceptions predict attendance at cardiac rehabilitation following acute myocardial infarction: A systematic review with meta-analysis. *Journal of Psychosomatic Research* 2006; 61:757-767.

Grace, S.L., Abbey, S.E., Shnek, Z.M., Irvine, J., Franche, R. & Stewart, D.E. Cardiac rehabilitation I: Review of psychosocial factors. *General Hospital Psychiatry*; 24:121-126.

Jackson, L., Leclerc, J., Erskine, Y., Linden, W. Getting the most out of cardiac rehabilitation: A review of referral and adherence predictors. *Heart* 2005; 91:10-14.

Self-Report Attendance Data Only

Barber, K., Stommel, M., Kroll, J., Holmes-Rovner, M. & McIntosh, B. Cardiac rehabilitation for community-based patients with myocardial infarction: Factors predicting discharge recommendation and participation. *Journal of Clinical Epidemiology* 2001; 54;1025-1030.

Cooper, A., Lloyd, G., Weinman, J., & Jackson, G. Why patients do not attend cardiac rehabilitation: Role of intentions and illness beliefs. *Heart* 1999; 82:234-236.

Grace, S.L., Abbey, S.E., Shnek, Z.M., Irvine, J., Franche, R. & Stewart, D.E. Cardiac rehabilitation II: Referral and participation. *General Hospital Psychiatry* 2002: 24;127-134.

Johnson, J.E., Weinert, C., & Richardon, J.K. Rural residents' use of cardiac rehabilitation programs. *Public Health Nursing* 1998; 15(4):288-296.

Worcester, M.U.C., Murphy, B.M., Mee, V.K., Roberts, S.B., & Goble, A.J. Cardiac rehabilitation programmes: Predictors of non-attendance and drop-out. *European Journal of Cardiovascular Prevention and Rehabilitation* 2004; 11:328-335.

Appendix 3.1: Ethics & R&D Approval Letters

Primary Care Division

NHS
Greater Glasgow and Clyde

Research Ethics
South Glasgow & Clyde REC
R&D Directorate
1st Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Mr Gavin Taylor
Trainee Clinical Psychologist
Glasgow University Section in
Psychological Medicine
Department of Psychological Medicine
Gartnavel Royal Hospital
Academic Centre,
Administration Building
1055 Great Western Road
Glasgow G12 0XH

Date	01 October 2008
Your Ref	
Our Ref	
Direct line	0141 211 2123
Fax	0141 211 2811
E-mail	Liz.Jamieson@ggc.scot.nhs.uk

Dear Mr Taylor

Full title of study:	**Improving Cardiac Rehabilitation Session Attendance Using the Self-Regulatory Model and Motivational Interviewing: A Randomised Controlled Trial**
REC reference number:	**08/S0710/65**

The Research Ethics Committee reviewed the above application at the meeting held on 30 September 2008. Thank you for attending to discuss the study.

Ethical opinion

Members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. This favourable opinion is subject to the following issures being addressed through the Committee Co-ordinator.

1) You state that the site is a Primary Care Site. Please confirm in writing that this is not the case.

2) Please confirm in writing how you wiill define those with a severe cognitive impairment.

3) Research data is normally held for 5 years then destroyed. Please advise whether you intend to comply with this or whether you will hold the data for 10 years.

4) Please advise in writing why you will not see the patient in hospital.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Application		03 September 2008
Investigator CV		03 September 2008
Protocol		14 July 2008
Covering Letter		03 September 2008
Summary/Synopsis	Version 1	
Questionnaire: Validated		
Letter of invitation to participant		
GP/Consultant Information Sheets		
Participant Information Sheet	Version 4	
Participant Consent Form	Version 1	14 August 2008
Supervisor's CV		
Referee's Report		11 June 2008

Membership of the Committee

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

Statement of compliance

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

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

08/S0710/65	Please quote this number on all correspondence

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

Yours sincerely

Liz Jamieson

Liz Jamieson
Interim Committee Co-ordinator on behalf of Mr Gerald F Belton OBE, Chair

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments "After ethical review – guidance for researchers"
Copy to:	Mr Brian Rae, R&D

Primary Care Division

Research & Development Directorate
NHS Greater Glasgow and Clyde
The Tennent Institute
WIG, 38 Church Street
Glasgow
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NHS
Greater Glasgow
and Clyde

Mr Gavin Taylor
Trainee Clinical Psychologist
Glasgow University Section in
Psychological Medicine
Gartnavel Royal Hospital
Department of Psychological Medicine
Academic Centre
1055 Great Western Road
Glasgow, G12 OXH

Date	04 November 2008
Your Ref	
Our Ref	BR/EC/approve
Direct Line	0141 211 8551
Fax	0141 211 2811
Email	Emma.Cuthbertson@ggc.scot.nhs.uk

Dear Mr Taylor

Reference Number: **PN08CP405**
Project Title: **Improving Cardiac Rehabilitation Session Attendance Using the Self Regulatory Model and Motivational Interviewing: A Randomised Controlled Trial**

Thank you for submitting a Research & Development (R&D) Management Approval Application for the above study. I am pleased to inform you that R&D management approval has been granted by NHS Greater Glasgow & Clyde Community & Mental Health Partnership subject to the following requirements:

- You should notify me of any changes to the original submission and send regular, brief, interim reports including recruitment numbers where applicable. **You must also notify me of any changes to the original research staff and send CVs of any new researchers.**

- **Researchers covered by this approval are:- Mr Gavin Taylor**

- Your research must be conducted in accordance with the National Research Governance standards. (see CSO website: www.show.scot.nhs.uk/cso)

- Local Research Governance monitoring requirements are presently being developed. This may involve audit of your research at some time in the future.

- You must comply with any regulations regarding data handling (Data Protection Act).

- A final report, with an abstract which can be disseminated widely within the NHS, should be submitted when the project has been completed.

Do not hesitate to contact the R & D office if you need any assistance.

Thank you again for your co-operation.
Yours sincerely

Brian Rae
Research Manager

Appendix 3.2: Session Structure

1. Set Agenda

"*Here's what I thought we might do in the time we have today...*"
- Discuss heart conditions
- Discuss what you think of your illness
- Discuss change, goals etc.

"Is there anything else you want to discuss or want to do?"
- Accommodate any suggested discussion points in session plan.

2. Heart Conditions

"What's your understanding of how the heart works?"

"What have you been told in the past?"

- The heart as a pump
- What can go wrong and why
- Common symptoms
- Risk factors
- Prevention & treatment

Elicit participant's understanding of this information. Correct misconceptions without using the stance of 'the expert'.

3. Cardiac Rehabilitation

*"CR classes are a type of treatment so that follows on from that we've just been talking about. **What do you think of attending for these classes?**"*

"Who suggested you attend?"

"What do you think is going to happen at these classes over the coming weeks?"

"Do you think this programme is going to help you to recover?"

Correct misconceptions without using the stance of 'the expert'.

Try to instil confidence and congratulate participants on attending the first class.

4. Assess Current Illness Beliefs

*"Now we've just been talking about some of the potential causes of CHD, but **what specifically do you think caused your illness?**"*

"Why is that?"

"Is there anything else that might have contributed to your illness?"

"Do you plan on making any changes in your life as a result?"

5. Assess Readiness for Change

Show 'Readiness Ruler' and have them rate their readiness.

"Tell me more about the number you chose..."

6. Discuss Change

Not Ready	*"Why did you give yourself a 3 not a 1?"*
	"What would you need to be different for you to consider making changes?"
	"What are the disadvantages of not making any changes? And what are the advantages of changing?"
Unsure	*"What are some of the good things about making a change?"*
	"What is the cost of not changing?"
	"I can see why you're unsure about change. Let's imagine for a moment that you did decide to change. What would be different? Why would you want to do this?"
Ready	*"What do you think needs to change? What would be good about making those changes?"*
	"What are your ideas for making change?"

Reinforce any change talk with encouragement and praise.

"Can we set some goals for your health over the next few months?"

Use **Goals & Action** sheet. Select short term goals.

Any dissonance between goals and readiness for change?

 Develop an **action plan** if appropriate. **Have participants write action points** down themselves.

"How confident are you that you can achieve these goals, on a scale from 0-10?"

If not confident, ask questions to positively reframe i.e. "why a 3 and not a 1?"

8. Close Session

Review session and support self-efficacy.

READINESS RULER

ID Number: _____   **Date:**   _____

How ready are you to make changes to your lifestyle as a result of your cardiac condition?

Please circle a number that indicates how ready you feel, from 0 to 10, on the scale below.

Not Ready to Change	**Unsure**	**Ready to Change**

      0   1   2   3   4   5   6   7   8   9   10

GOALS & ACTION PLAN

SHORT TERM GOALS:

LONG TERM GOALS:

ACTION YOU PLAN TO TAKE: **CONFIDENCE (0-10)**

Appendix 3.5: MRP Proposal

MAJOR RESEARCH PROJECT PROPOSAL

Improving Cardiac Rehabilitation Session Attendance Using the Self-Regulatory Model and Motivational Interviewing: A Randomised Controlled Trial

14th July 2008

Word Count:
2,676
(Including references)

ABSTRACT

Objective: The proposed study aims to investigate the effectiveness of a theory-based, one-session intervention in altering illness perceptions among patients initiating cardiac rehabilitation and, as a consequence, enhance adherence to the rehabilitation programme.

Design: Randomised, controlled trial.

Settings: Glasgow Cardiac Rehabilitation Service, Glasgow, UK.

Subjects: The proposed investigation aims to recruit 42 patients eligible to participate in phase three of cardiac rehabilitation at the time of their initial attendance.

Outcome Measures: The primary outcome measure will be the number of rehabilitation exercise sessions attended, which will reflect adherence to the programme. The Illness Perception Questionnaire-Revised will be a secondary outcome measure. Sociodemographic data and information on coping style and mood will also be collected.

Cardiac rehabilitation programmes typically offer patients with coronary heart disease a long-term programme of medical evaluation, exercise, education and counselling[1]. Despite national guidelines[2,3] acknowledging the benefits of Cardiac Rehabilitation (CR) following a variety of cardiac events[4], research suggests that utilisation of such services is poor[5]. Attendance rates in the UK have been found to vary between 14%-43% following Myocardial Infarction (MI)[1]. A recent audit of CR services within a general hospital in Glasgow[6] revealed that only 31% of those eligible for rehabilitation participation were considered to be adherent to the programme.

A broad range of variables have been associated with adherence to CR. These include sociodemographic factors such as gender, age and socioeconomic status, systemic factors such as physician recommendation[7], and psychological factors such as those proposed in Leventhal et al.'s[8] Self-Regulatory Model (SRM)[9]. There are five dimensions of illness representation described in this model: identity, cause, timeline, consequences and controllability/curability. Recent research[5,10,11] has focused on the relationship between these dimensions and CR attendance and adherence.

Studies examining the predictive relationship of the five SRM dimensions have found control/cure to be the most strongly correlated with CR attendance[5]. Patients with high levels of perceived control/cure after MI appear to be more likely to attend CR than those with low levels[10,11]. Whilst other studies in this area have found less definitive evidence of this link, results consistently suggest that illness beliefs are of relevance to CR attendance and adherence[9,12]. For example, Whitmarsh et al.[12] illustrated that the best predictors of non-attendance at CR were a perception of fewer symptoms (identity dimension of SRM), low perceived control (controllability/curability dimension), and the use of maladaptive coping strategies rather than problem-focused strategies. Similarly, Yohannes et al.[9] found illness perceptions about control, among other factors, to predict early drop-out from a CR programme. Such findings suggest that an intervention aimed at altering cardiac

patients' illness beliefs, specifically those associated with aspects of controllability/curability, could facilitate increased adherence to a CR programme[1,13].

Interventions designed to modify illness perceptions and enhance CR adherence have had some previously demonstrated success[14,15]. Whilst these studies had some methodological limitations, they nevertheless indicated that interventions aimed at changing illness perceptions can have an impact on health behaviours.

Fostering health behaviour change is often approached using a motivational interviewing[16] style. A recent review by Dunn et al.[17] found that there is strong evidence for the use of motivational interviewing as a substance abuse intervention method. Recent investigations of interventions aimed at motivating individuals to engage with services for substance abuse suggest that brief sessions (i.e., 15-40 minutes) can be as successful as longer interventions[18]. Hancock et al.[19] discussed the application of motivational interviewing to MI patients in CR, concluding that this is an area worthy of further research.

The proposed study will seek to investigate the effectiveness of a brief intervention (independent variable) aimed at altering individual's illness perceptions and increasing the number of CR sessions attended (dependent variables). The intervention will be informed by the SRM and applied using a motivational interviewing style. The proposed study represents a novel application of the SRM model that, if demonstrated to be effective, may have practical implications for the delivery of brief, theoretically driven psychological interventions in cardiac settings.

Experimental hypotheses:

A single session intervention based on the SRM will have the following effects when administered to cardiac patients attending their first CR session:

- The number of CR exercise classes attended will be greater among the treatment group than the control group.

- Participants in the treatment group will view their illness and their treatment as more controllable than those in the control group.

Participants:

All patients from participating Greater Glasgow & Clyde hospitals who are entering into phase three of the cardiac rehabilitation service will be considered for recruitment.

Inclusion/Exclusion Criteria:

Patient consent will be required. Patients will have an ability to read, write and speak fluently in English. Patients must also be eligible for the CR exercise and education programme and be attending for their first class. Participants must be over 18, have no hearing impairment requiring the use of an interpreter and have no severe cognitive impairment.

Recruitment:

Participants will be recruited from the Southern General Hospital, Stobhill Hospital and Victoria Infirmary, Glasgow. A study information sheet will be made available to all patients attending assessment clinics prior to participation in the CR exercise programme. Any patients expressing an interest in the study will be directed to speak to the investigator at the beginning or the end of their first CR class, at which stage consent will be sought.

Measures:

Psychosociodemographic measures:

Information on participant age, gender, ethnicity, postcode (for SIMD classification[20]), distance from CR programme (calculated using www.maps.google.co.uk), marital status,

education, medical diagnosis, intensity of CR class and employment status will be collected at the time of recruitment prior to randomisation.

As coping strategy and mood have been found to effect CR attendance and adherence[9,12] scales to measure these variables will also be used. The Brief Coping Orientation to Problems Experienced (Brief-COPE) scale is adapted from the COPE and assesses several responses relevant to effective and ineffective coping. It has 14 subscales, including denial, active coping and behavioural disengagement and has been shown to have both reliability and validity[21]. The Hospital Anxiety & Depression Scale (HADS)[22] is a 14-item questionnaire designed to measure psychological distress in medical out-patient populations. The HADS has been found to be a valid and reliable measure of depression and anxiety among cardiac patients[23].

Primary outcome measure:

Number of CR sessions attended will be the main measure of adherence. Whilst there is no convention for categorising those who are adherent vs. non-adherent, a similar approach to that of Whitmarsh et al.[12] will be used in this study i.e. non-adherent = ≤50% sessions attended, adherent = >50% sessions attended, completer = completed entire programme (10 weeks). Where recorded in CR notes, number of classes patients plan to attend at the beginning of the programme will be used to exclude from the analysis those patients who expected to drop out early e.g. due to work obligations.

Secondary outcome measure:

The Illness Perception Questionnaire-Revised (IPQ-R) is based on the dimensions of the SRM. It comprises 4 subscales and 10 items measuring causal attributions of illness. The IPQ-R has demonstrated sound discriminant, known group, and predictive validity in a range of patient populations[24].

<u>Design/Procedures:</u>

The proposed study will use a between-subjects randomised, controlled trial design. Participants will be randomly allocated to the intervention group or the control group using a computerised random sequence generator (www.randomizer.org). The investigator will be blind to the randomisation sequence until consent is obtained, at which point a sealed envelope will be opened containing this information. The intervention group will receive one session, minimum duration 20 minutes, following the completion of their first CR class. At the beginning of this session, participants will be asked to complete the IPQ-R, Brief-COPE and HADS. Discussion within the session will then be tailored according to the patient's willingness to make changes to their health behaviours. All sessions will be structured to include a series of stages, each designed to focus on certain dimensions of the SRM. This structure will be followed in all intervention sessions in an attempt to ensure integrity of treatment. For further details regarding the exact content of this intervention see Appendix 1. The FRAMES style recommended for motivational interviewing interventions[25] will be used during this session.

The control group will receive treatment as usual. They will be asked to complete the IPQ-R, Brief-COPE, and HADS at the time of recruitment.

Three-months following consent, the IPQ-R will be posted to all participants for follow-up, with a request that they complete it and return it in the accompanying postage-paid envelope. In order to monitor all participant's attendance, data collection sheets will be placed in their individual CR records. These will be completed by the study investigator using cardiac rehabilitation attendance records. Patients planned attendance will also be recorded by the investigator, where available, using CR records.

<u>Sample Size:</u>

Wyer et al.'s[15] letter-based intervention aimed at increasing CR attendance had a large effect size (r=0.72). Whitmarsh et al.[12] found significant differences in illness perceptions and coping strategies between attendees and poor/non-attendees of CR. These differences translate into large effect sizes (Identity, d=0.81; Problem focused coping, d=0.77). Yohannes et al.[9] found illness perceptions to account for 19% of the variance in CR adherence (r²=0.19). This is a medium to large effect size. Brief interventions using motivational interviewing have consistently found medium effect sizes e.g. d = .05 - .07[17,18].

These findings present a mixed picture of the likely effect size for the present study. No intervention studies have yet focused on dimensions of the SRM or motivational interviewing as a means to increase CR adherence. It seems possible that the effect of changing illness perceptions combined with a motivational interviewing style may have a large effect size.

In addition to these results, it is also important to consider the clinical application of the present intervention. If its effect is not robust enough to be visible in a relatively small sample of patients then it is unlikely that it will warrant the time and energy of busy health professionals in future.

Taking these factors into account it is therefore reasonable to assume that the present study will have an effect size of 0.8 with a significance level of alpha = 0.05. Using GPower v3.0.8[26], a sample size of 42 was determined to be appropriate; giving treatment and control groups each consisting of 21 randomly allocated patients.

Settings & Equipment:

Space to administer the intervention session should be available within CR settings, although it may not always be possible to book a room.

Data Analysis:

Descriptive statistics will be used to summarise demographic characteristics of the participants. Analysis of covariance (ANCOVA) will be used to test the main and interaction effects. Independent t-tests will be used to assess changes in IPQ-R scores between recruitment and 3-month follow up. All analyses will be conducted according to the intention to treat (ITT) principle[27].

Time Scale:

Approval from cardiac rehabilitation clinical directors, management and nursing staff has been received. Application to NHS Research and Development and a local ethics committee will likely take between two and three months. This would allow recruitment to begin between September and November 2008. Duration of data collection is dependant on the rate of recruitment, but should be completed in order to begin data analysis by May 2008.

Health & Safety:

Participant and researcher safety will not be compromised as a result of the proposed intervention. All local health and safety policies will be followed within each site and CR staff will be made aware of times when sessions are being conducted. If any patient is found to be experiencing significant mental health problems during the study then an appropriate referral will be made to the cardiac psychology service.

Ethical Issues:

It will be imperative not to impose upon patients as they recover from what is a significant life event. The provision of study information sheets will serve to limit unwanted intrusions. All participation is voluntary. Participants will be free to withdraw their consent

at any time. Ethical approval will be sought from either the South Glasgow and Clyde Local REC or the Glasgow Royal Infirmary Local REC. Additional applications may be made to other sites if multi-site recruitment is deemed necessary.

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