Scoping exercise to identify areas for research, evaluation and audit in relation to the practice and delivery of cardiac rehabilitation

Final report, December 2011

Authors:
Bernadette Sewell
Paul Smith
Ceri Phillips
Martin Lane

College of Human and Health Sciences
Swansea University

In cooperation with Mid & South West Wales Cardiac Network
Contents

Executive summary ......................................................................................................................................... 7

1. Introduction ............................................................................................................................................. 10
   1.1. Structure and aims of the scoping exercise ..................................................................................... 10

2. Stage 1 – scoping review to identify areas for research, evaluation and audit in relation to the practice and delivery of CR ............................................................. 12
   2.1. Literature search strategy .................................................................................................................. 12
   2.2. What is cardiac rehabilitation? ......................................................................................................... 12
   2.3. Benefits of cardiac rehabilitation ..................................................................................................... 13
   2.4. Problems and guidelines .................................................................................................................. 14
   2.5. Barriers to patient uptake and continuation ..................................................................................... 15
      2.5.1. Barriers to Phase 3 attendance .................................................................................................. 15
      2.5.2. Barriers to Phase 4 attendance .................................................................................................. 17
      2.5.3. Premature patient drop-out from CR ....................................................................................... 17
      2.5.4. Patients beliefs and their influence on attendance and adherence ........................................ 18
      2.5.5. Under-represented groups ........................................................................................................ 19
         2.5.5.1. Elderly patients .................................................................................................................. 20
         2.5.5.2. Women .............................................................................................................................. 20
         2.5.5.3. Non-English speaking ethnic minorities ....................................................................... 21
         2.5.5.4. Local under-representation due to lack of provision ..................................................... 22
   2.6. Promotion of CR uptake and adherence ........................................................................................... 22
   2.7. Alternative provision of CR ............................................................................................................. 23
      2.7.1. Home based CR ...................................................................................................................... 23
      2.7.2. Community based CR ............................................................................................................ 24
   2.8. The four phases of CR ...................................................................................................................... 24
      2.8.1. Phase 1 (in-patient stage) ........................................................................................................ 25
2.8.1.1. Identification of CR patients ............................................. 25
2.8.1.2. Referral of CR patients ...................................................... 25
2.8.1.3. Delivery of Phase 1 CR ...................................................... 26
2.8.1.4. Patient needs in Phase 1 ..................................................... 26
2.8.2. Phase 2 (Post-discharge stage) ............................................. 27
  2.8.2.1. Patient needs and service delivery in Phase 2 .................. 27
2.8.3. Phase 3 (Structured programme stage) ................................ 28
  2.8.3.1. Delivery of Phase 3 CR .................................................... 28
  2.8.3.2. Delivery of exercise sessions ........................................... 29
  2.8.3.3. Delivery of educational sessions ..................................... 29
  2.8.3.4. Delivery of psycho-social support ................................... 30
  2.8.3.5. Group sessions vs one-on-one sessions ......................... 31
  2.8.3.6. Patient needs in Phase 3 ................................................ 31
2.8.4. Phase 4 (Life-long maintenance stage) ................................. 32
  2.8.4.1. Delivery of Phase 4 CR .................................................. 32
  2.8.4.2. Patient needs in Phase 4 ................................................. 32
  2.8.4.3. Patient fast-tracking to Phase 4 ..................................... 33
2.9. Cost-effectiveness of CR ....................................................... 33
2.10. Cardiac rehabilitation for patients with different diagnoses .... 34
2.11. Programme staffing ............................................................. 35
2.12. Cardiac rehabilitation in Wales ............................................. 36
2.13. Conclusions ......................................................................... 38

3. Stage 2 – Recommendations for further research ....................... 40

3.1. Introduction ............................................................................ 40
3.2. Recommendations for further research .................................. 41
  3.2.1. Health economic evaluation of CR ..................................... 41
    3.2.1.1. Cost-effectiveness/cost consequences analysis ................ 41
    3.2.1.2. Cost-utility analysis .................................................... 42
    3.2.1.3. Long-term costs ......................................................... 42
  3.2.2. Research into different components of CR ......................... 42
    3.2.2.1. The benefits of nutritional counselling ......................... 42
    3.2.2.2. The benefits of psychological counselling ..................... 43
  3.2.3. Research into the improvement of patient uptake ............... 43
    3.2.3.1. Research into patients’ preferences ............................ 44

3
3.2.3.2. Research into patients’ lack of interest 44
3.2.3.3. Research into the “special needs” of women 44
3.2.3.4. Research into CR for excluded patients 45
3.2.4. Research into changes in service provision 46
   3.2.4.1. Research into patient identification and referral 46
   3.2.4.2. Research into the influence of cardiologist and GP recommendation 46
   3.2.4.3. Research into the use of the internet for home-based CR 47
3.2.5. Research into Phase 1 and 2 of CR 48
   3.2.5.1. Research into patient information during Phase 1 48
   3.2.5.2. Research into patient motivation during Phase 2 49

4. **Stage 3 – Prioritisation exercise** ................................................................. 51
   4.1. Introduction 51
   4.2. Methodology 51
   4.3. Results of prioritisation exercise 52
   4.4. Conclusions of the prioritisation exercise 54

5. **Stage 4 - Drafts for research proposals for the six prioritised projects** ................................................................. 55
   5.1. Introduction 55
   5.2. **Cost-effectiveness of cardiac rehabilitation services in Mid and South West Wales** 56
      5.2.1. Introduction 56
      5.2.2. Cost-effectiveness and cost-consequences analyses 57
         5.2.2.1. Aims and objectives 57
         5.2.2.2. Study design and methods 58
         5.2.2.3. Use of resources 59
         5.2.2.4. Methods of analysis 60
         5.2.2.5. Expected outcomes 61
         5.2.2.6. Impact and dissemination 62
         5.2.2.7. Proposed project timetable 62
      5.2.3. Cost-utility analysis 63
         5.2.3.1. Aims and objectives 63
         5.2.3.2. Study design and methods 63
### Scoping exercise to identify areas for research, evaluation and audit in relation to the practice and delivery of cardiac rehabilitation (CR): Final report

December 2011

<table>
<thead>
<tr>
<th>Page</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.2.3.3.</td>
<td>Use of resources</td>
</tr>
<tr>
<td>5.2.3.4.</td>
<td>Methods of analysis</td>
</tr>
<tr>
<td>5.2.3.5.</td>
<td>Expected outcomes</td>
</tr>
<tr>
<td>5.2.3.6.</td>
<td>Impact and dissemination</td>
</tr>
<tr>
<td>5.2.3.7.</td>
<td>Proposed project timetable</td>
</tr>
<tr>
<td>65</td>
<td></td>
</tr>
<tr>
<td>66</td>
<td></td>
</tr>
<tr>
<td>66</td>
<td></td>
</tr>
<tr>
<td>67</td>
<td></td>
</tr>
<tr>
<td>68</td>
<td></td>
</tr>
</tbody>
</table>

5.3. **The influence of GP and cardiologist recommendation on participation and adherence rates of Phase 3 cardiac rehabilitation**

<table>
<thead>
<tr>
<th>Page</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.3.1.</td>
<td>Introduction</td>
</tr>
<tr>
<td>5.3.2.</td>
<td>Aims and objectives</td>
</tr>
<tr>
<td>5.3.3.</td>
<td>Study design and methods</td>
</tr>
<tr>
<td>5.3.4.</td>
<td>Use of resources</td>
</tr>
<tr>
<td>5.3.5.</td>
<td>Methods of analysis</td>
</tr>
<tr>
<td>5.3.6.</td>
<td>Expected outcomes</td>
</tr>
<tr>
<td>5.3.7.</td>
<td>Impact and dissemination</td>
</tr>
<tr>
<td>5.3.8.</td>
<td>Proposed project timetable</td>
</tr>
<tr>
<td>69</td>
<td></td>
</tr>
<tr>
<td>69</td>
<td></td>
</tr>
<tr>
<td>70</td>
<td></td>
</tr>
<tr>
<td>71</td>
<td></td>
</tr>
<tr>
<td>77</td>
<td></td>
</tr>
<tr>
<td>80</td>
<td></td>
</tr>
<tr>
<td>82</td>
<td></td>
</tr>
<tr>
<td>83</td>
<td></td>
</tr>
</tbody>
</table>

5.4. **Patient identification and referral to cardiac rehabilitation in Mid and South West Wales: suitability, efficacy and areas of improvement**

<table>
<thead>
<tr>
<th>Page</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.4.1.</td>
<td>Introduction</td>
</tr>
<tr>
<td>5.4.2.</td>
<td>Aims and objectives</td>
</tr>
<tr>
<td>5.4.3.</td>
<td>Study design and methods</td>
</tr>
<tr>
<td>5.4.4.</td>
<td>Use of resources</td>
</tr>
<tr>
<td>5.4.5.</td>
<td>Methods of analysis</td>
</tr>
<tr>
<td>5.4.6.</td>
<td>Expected outcomes</td>
</tr>
<tr>
<td>5.4.7.</td>
<td>Impact and dissemination</td>
</tr>
<tr>
<td>5.4.8.</td>
<td>Proposed project timetable</td>
</tr>
<tr>
<td>84</td>
<td></td>
</tr>
<tr>
<td>84</td>
<td></td>
</tr>
<tr>
<td>85</td>
<td></td>
</tr>
<tr>
<td>87</td>
<td></td>
</tr>
<tr>
<td>88</td>
<td></td>
</tr>
<tr>
<td>89</td>
<td></td>
</tr>
<tr>
<td>90</td>
<td></td>
</tr>
</tbody>
</table>

5.5. **Patient information during Phase 1 cardiac rehabilitation: availability, suitability, retention and influence on Phase 3 participation**

<table>
<thead>
<tr>
<th>Page</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5.1.</td>
<td>Introduction</td>
</tr>
<tr>
<td>5.5.2.</td>
<td>Aims and objectives</td>
</tr>
<tr>
<td>5.5.3.</td>
<td>Study design and methods</td>
</tr>
<tr>
<td>5.5.4.</td>
<td>Use of resources</td>
</tr>
<tr>
<td>5.5.5.</td>
<td>Methods of analysis</td>
</tr>
<tr>
<td>5.5.6.</td>
<td>Expected outcomes</td>
</tr>
<tr>
<td>5.5.7.</td>
<td>Impact and dissemination</td>
</tr>
<tr>
<td>5.5.8.</td>
<td>Proposed project timetable</td>
</tr>
<tr>
<td>91</td>
<td></td>
</tr>
<tr>
<td>92</td>
<td></td>
</tr>
<tr>
<td>93</td>
<td></td>
</tr>
<tr>
<td>99</td>
<td></td>
</tr>
<tr>
<td>100</td>
<td></td>
</tr>
<tr>
<td>102</td>
<td></td>
</tr>
<tr>
<td>104</td>
<td></td>
</tr>
<tr>
<td>105</td>
<td></td>
</tr>
</tbody>
</table>
5.6. Promoting participation in Phase 3 cardiac rehabilitation through increased patient contact, support and information during Phase 2

5.6.1. Introduction

5.6.2. Intervention development and pilot testing
   5.6.2.1. Aims and objectives
   5.6.2.2. Study design and method
   5.6.2.3. Use of resources
   5.6.2.4. Method of analysis
   5.6.2.5. Expected outcomes
   5.6.2.6. Impact and dissemination
   5.6.2.7. Proposed project timetable

5.6.3. Main trial
   5.6.3.1. Aims and objectives
   5.6.3.2. Study design and method
   5.6.3.3. Use of resources
   5.6.3.4. Method of analysis
   5.6.3.5. Expected outcomes
   5.6.3.6. Impact and dissemination
   5.6.3.7. Proposed project timetable

6. Discussion and future directions

7. References

8. Appendix
Executive summary

The present scoping exercise was commissioned by the Mid and South West Wales Cardiac Network and undertaken by Swansea University.

Background

Coronary heart disease is a major health problem in the United Kingdom and other developed countries. More than 260,000 people suffer a heart attack and around 150,000 people surviving an acute myocardial infarction every year in the UK alone. Ageing of the population and increasing survival rates after cardiac events may explain the increase in hospitalisations and the high healthcare resource use for these patients. However, many cardiovascular risk factors are modifiable by encouraging healthier lifestyles and exercise.

Cardiac rehabilitation has been shown to reduce the risk of coronary heart disease and prevent future cardiac events and has been associated with a 13% reduction in overall mortality and a 26% reduction in cardiac mortality. It has also been found to be cost-effective and to offer good value for money.

Despite the proven and well-documented benefits of CR, service provision and quality of service vary widely across the UK and funding is low and short-term. Even though the National Service Framework for Coronary Heart Disease and the Cardiac Disease National Service Framework for Wales set explicit standards for (CR) in the United Kingdom with the goal of provision of cardiac rehabilitation to > 85% of patients that are discharged from hospital with a primary diagnosis of acute myocardial infarction or after coronary revascularisation, around 70% of MI patients are thought to still not receive cardiac rehabilitation. Furthermore, patient uptake is low which, together with an often inefficient referral and patient identification system, results in the fact that only between 22 and 36% of eligible patients are referred to and actually attend cardiac rehabilitation in England and Wales.

It is therefore of importance to identify, research and address areas of CR where changes may result in more efficient service provision and better patient uptake.

Aims of the scoping exercise

The aims of the scoping exercise are:

a) To create an overview of the literature, research and knowledge available in the field and to provide a reference base for future work.

b) To identify areas where further research could benefit the practice and delivery of CR
Scoping exercise to identify areas for research, evaluation and audit in relation to the practice and delivery of cardiac rehabilitation (CR): Final report

December 2011

c) To develop and provide a choice of relevant recommendations and short descriptions of potential areas of research to enable members of the Mid and South West Wales Cardiac Network to make informed decisions about the directions in which future research should progress.
d) To identify the six recommendations members of the Cardiac Network regard as most important.
e) To develop research proposals for all 6 prioritised research projects
f) To disseminate and report results at the end of April 2011 (interim report) and the end of December 2011 (final report).

Methods
In order to achieve the aims of the scoping exercise a thorough review of the existing literature was performed that formed a knowledge and information base for the remaining project. The literature review helped to identify areas where further research may be important and beneficial and research recommendations were developed that focussed on the practical issues CR services face in daily routine (e.g. costs and lack of funding, service provision, patient preferences, patient information and motivation). These research recommendations were then distributed to members of the Cardiac Network together with a prioritisation questionnaire. They scored and ranked the recommendations according to perceived importance and applicability. These scores were then evaluated to identify six prioritised projects for which research proposals were developed.

Results and discussion
In the first part of the scoping exercise, a literature review was compiled that includes about 98 papers on various aspects of CR between 1995 and 2011. This literature helped to identify five general categories (and 14 individual research projects) in need of further research attention comprising of health economic evaluation of CR (cost effectiveness/cost-consequences analysis, cost-utility analysis of CR services), research into different components of CR (impact of nutritional and psychological counselling on short- and long-term outcomes), research into the improvement of patient uptake (patient preferences, patients’ lack of interest in CR, “special needs” of women attending CR and CR for excluded
patient groups), research into changes in service provision (patient identification and referral, the influence of cardiologist and GP referral on uptake and the use of the internet for home-based CR programmes) as well as research into Phase 1 and 2 (patient information during Phase 1 and patient motivation during Phase 2).

The prioritisation exercise identified six projects that were clearly prioritised by the respondents (n = 9). These projects are:

1. Cost-effectiveness/cost-consequences analysis of CR services in Mid and South West Wales
2. Research into the influence of cardiologist and GP recommendation on patient participation in Phase 3 cardiac rehabilitation
3. Research into suitability and efficacy of patient identification and referral to CR
4. Cost-utility analysis of CR services in Mid and South West Wales
5. Research into availability and suitability of patient information during Phase 1, information retention and influence on Phase 3 participation
6. Research into the influence of enhanced patient motivation, support and information during Phase 2 on Phase 3 participation and patient and carer anxiety and quality of life

Research proposals for these six projects were developed in the second part of the scoping exercise from May to December 2011. It is hoped that these proposals will be translated into trials and studies that will enable the Cardiac Network to make informed decisions about service changes that may significantly improve service provision and patient attendance and satisfaction as well as impact positively on service funding.
1. Introduction

Coronary heart disease is a major health problem in the United Kingdom and other developed countries with more than 260,000 people suffering a heart attack and around 150,000 people surviving an acute myocardial infarction every year in the UK alone (Dalal and Evans, 2003, Beswick et al., 2004, Dalal et al., 2007). Ageing of the population and increasing survival rates after cardiac events may explain the increase in hospitalisations and the high healthcare resource use for these patients (Paquet et al., 2005). However, many cardiovascular risk factors are modifiable by encouraging healthier lifestyles and exercise (Paquet et al., 2005). Cardiac rehabilitation has been shown to reduce the risk of coronary heart disease and prevent future cardiac events (O'Driscoll et al., 2007) and has been associated with a 13 % reduction in overall mortality and a 26 % reduction in cardiac mortality (Cooper et al., 2007).

Despite the proven and well documented benefits of CR, service provision and quality of service vary widely across the UK and funding is low and short-term. The National Service Framework for Coronary Heart Disease (DoH, 2000) and the Cardiac Disease National Service Framework for Wales (WAG, 2001, WAG, 2009) set explicit standards for (CR) in the United Kingdom in general and Wales in particular with the goal of provision of cardiac rehabilitation to > 85 % of patients that are discharged from hospital with a primary diagnosis of acute myocardial infarction or after coronary revascularisation (Beswick et al., 2004, Dalal and Evans, 2003). However, around 70 % of MI patients are thought to still not receive cardiac rehabilitation (Bethell et al., 2008). Furthermore, patient uptake is low which, together with an often inefficient referral and patient identification system, results in the fact that only between 22 and 36 % of eligible patients are referred to and actually attend cardiac rehabilitation in England and Wales (Beswick et al., 2004).

It is therefore of importance to identify, research and address areas of CR where changes may result in more efficient service provision and better patient uptake.

1.1. Structure and aims of the scoping exercise

The scoping exercise has been divided into 5 stages:

- Stage 1 – scoping literature review
- Stage 2 – recommendations for further research
- Stage 3 – prioritisation of research recommendations
- Stage 4 – development of research proposals
- Stage 5 – dissemination of results (interim and final report)

Stages 1 to 3 will be discussed in this interim report. Stages 4 and 5 will be expected to be reported at the end of October 2011.

During Stage 1, a thorough literature review has been conducted to include most of the publications on CR benefits and provision, patient uptake and uptake barriers as well as cost effectiveness and problems. The aim of this stage was to create an overview of the literature, research and knowledge available in the field and to provide a reference base for future work.

In Stage 2, the scoping review of Stage 1 was used to identify areas where further research could benefit the practice and delivery of CR and research recommendations were developed. The aim of this stage was to provide a choice of relevant recommendations and short descriptions of potential areas of research to enable members of the Cardiac Network to make informed decisions about the directions in which future research should progress.

These members of the Cardiac Network were asked in Stage 3 to complete a prioritisation questionnaire in order to establish a ranking of the importance that practitioners, nurses, consultants etc. put towards different research recommendations. The aim of Stage 3 was to identify the six recommendations members of the Cardiac Network regarded as most important. This will allow the development of research proposals in Stage 4 that will offer the most benefit to the provision of CR in practice.
2. Stage 1 – scoping review to identify areas for research, evaluation and audit in relation to the practice and delivery of CR

2.1. Literature search strategy
Electronic databases (Pubmed/Medline, The Cochrane Library) as well as archives and current issues of the most important journals in the field (BMJ, Heart, European Journal of Cardiovascular Nursing, etc) and the homepage of the Department of Health were searched for English language publications that either reported original data on different aspects of CR or reviewed the available literature. No date cut-offs were applied. Various subsets of keywords and MeSH headings were used including “cardiac rehabilitation”, “patient uptake”, “cost effectiveness”, “costs”, “phase”, “referral” and “benefits”. In order to identify additional publications, bibliographies of all papers included in the scoping review were hand searched. The scoping review aims to give a comprehensive overview of the literature in the field and includes 55 publications between 1995 and 2011. Main focus has thereby been given to publications after 2000. Studies with grave methodological flaws and publications from countries with very dissimilar CR programmes compared to the UK were excluded from the review.

2.2. What is cardiac rehabilitation?
Cardiac rehabilitation is a structured programme of care that helps eligible patients to recover from their cardiac event quickly and to improve their physical, mental and social functioning (Knapton et al., 2009). The programme should consist of a multifaceted and multidisciplinary approach to reduce cardiovascular risk, encourage healthy behaviour and compliance, reduce disability and promote an active lifestyle (Balady et al., 2000). In the UK, cardiac rehabilitation is divided into 4 phases including the in-hospital phase, the early post-discharge, the later post discharge and the long term follow up (Thompson et al., 1996). The 4 phases are designed to prevent dependency, disability and hospital readmissions by offering exercise, education and psycho-social support to patient with coronary heart disease (O’Driscoll et al., 2007, Beswick et al., 2004) and should be seamless in taking patients from finding out about their disease to lasting lifestyle changes (Knapton et al., 2009). As core
components of cardiac rehabilitation, patient assessment, nutritional counselling, lipid, hypertension, diabetes and weight management, smoking cessation, psychosocial support, physical activity counselling and exercise training are of particular importance (Balady et al., 2000, Wenger, 2008, Piepoli et al., 2010, Balady et al., 2007). Expected outcomes of cardiac rehabilitation include improved clinical stability and symptom control, reduced cardiovascular risk, increased adherence to medication and healthy lifestyle changes which all will result in better quality of life and improved prognosis (Piepoli et al., 2010, Balady et al., 2007). Well organised cardiac rehabilitation has been shown to be one of the most beneficial and cost-effective treatments available for patients with cardiovascular disease (Bethell et al., 2009).

2.3. Benefits of cardiac rehabilitation

Well structured cardiac rehabilitation has been proven to reduce mortality and increase cardiac patients’ quality of life (Knapton et al., 2009). Furthermore, attendance and completion of a CR programme improves exercise tolerance, cardiovascular symptoms, blood lipid levels and psychosocial well-being and reduces cigarette smoking, stress, recurrent myocardial infarction and the requirement for revascularisation procedures (Taylor and Kirby, 1997, Wenger, 2008, Bethell et al., 2009). Cardiac rehabilitation therefore improves patients’ physical fitness, decreases coronary risk factors, positively influences psychological health and wellbeing and quality of life and improves prognosis (Bethell et al., 2008).

Regular exercise also decreases heart rate as well as systolic and diastolic blood pressure and improves aerobic capacity (Wenger, 2008). Reductions in unplanned hospital stays and reduced length of stay have been reported together with reduced complications and fewer readmissions (Lane and Smith, 2010). However, no significant improvements in depression scores could be found after cardiac rehabilitation when compared to baseline scores (Jolly et al., 2007).

Patients progressing through the exercise programmes describe a sense of achievement and increasing confidence. Learning about the causes of heart disease and healthier lifestyles also created a feeling of control. They also stated that they were learning to overcome the panic they experienced when they were feeling breathless or suffered from any pains (Jolly et al., 2007).

There is now ample evidence for the clinical effectiveness and the benefits of CR as well as of its cost-effectiveness which is why its implementation should be a key priority (Bethell et al., 2008).
2.4. **Problems and guidelines**

In the UK, cardiac rehabilitation services were initiated and developed by dedicated and enthusiastic local staff by their own volition (Thompson et al., 1997, Bethell et al., 2006). For this reason, cardiac rehabilitation centres are not centrally organised and funding sources are diverse which makes service provision and quality of service very variable across the country. Short-term approaches to funding also mean that strategic planning and development of cardiac rehabilitation services is impeded and innovation and planning for the future of services is often not possible (Lane and Smith, 2010). Around 70% of MI patients are thought to still not receive cardiac rehabilitation and funding changes in recent years are further threatening provision of CR (Bethell *et al.*, 2008). Also, some patients do not receive all 4 phases and experience an incomplete rehabilitation (Knapton *et al.*, 2009).

In March 2000, the National Service Framework for Coronary Heart Disease set explicit standards for the provision of cardiac rehabilitation (CR) in the United Kingdom (DoH, 2000). Furthermore, the National Service Framework published service and provision standards explicitly for Wales in 2001 (WAG, 2009, WAG, 2001). According to these standards all people admitted to hospital that are suffering from coronary heart disease should be invited to participate in a multidisciplinary programme of cardiac rehabilitation and secondary prevention with the aim to reduce risk of subsequent cardiac problems and to promote patients’ return to a fully functional, normal lifestyle. The cardiac rehabilitation programme should include patient assessments, advice and education as to the causes of illness and strategies to ensure the best possible health in the future, exercise as well as appropriate and effective management of medication and involvement of informal carers. Effective and successful provision of cardiac rehabilitation will require primary care teams and trusts to implement systems and protocols for the identification, assessment and management of CR patients, the delivery of advice, sessions and treatment and the assessment of the quality of care (DoH, 2000, Knapton *et al.*, 2009). The goal is to provide cardiac rehabilitation to > 85% of patients that are discharged from hospital with a primary diagnosis of acute myocardial infarction or after coronary revascularisation (Beswick *et al.*, 2004, Dalal and Evans, 2003). Once this target is reached, programmes should also include patients with heart failure, angina and other conditions (Bethell *et al.*, 2008).

Despite these steps and the fact that provision of cardiac rehabilitation has been steadily increasing in recent years (Bethell *et al.*, 2006), the provision, management, organisation and practice of cardiac rehabilitation is still subject to considerable variation and many trusts and hospitals are currently not able to meet the NSF targets and objectives (O’Driscoll *et al.*, 2009).
Delays in referral to CR services following hospital discharge, problems of transition between phases, variations in services due to a lack of clinical guidelines and inflexible services are regularly encountered (Lane and Smith, 2010). According to hospital discharge statistics, only between 22 and 36% of eligible patients are referred to and actually attend cardiac rehabilitation in England and Wales (Beswick et al., 2004). This is caused by a lack of resources (O’Driscoll et al., 2007, Bethell et al., 2006) with suggestions that CR programmes, on average, might need about 5 times the current funding to achieve goals (Bethell et al., 2008). Moreover, only 54% of centres actually hold a budget (Bethell et al., 2006). Low levels of provision, referral and invitation (Beswick et al., 2004) and a failure to deliver CR as a vital part of the patient’s treatment with automatic referral instead of it being an optional extra also reduce attendance (Knapton et al., 2009, Bethell et al., 2009). Furthermore, patient uptake of CR has been and remains low with only about 18 to 38% of patients eligible for CR attending the programme in 2007/08 and no increases were found compared to past years (Knapton et al., 2009, Beswick et al., 2004). Of the patients not taking part in CR about a third was “too ill”, “having further investigations” or was “physically incapacitated” whereas another third was “not interested” which is worrying considering the benefit these patients could gain from cardiac rehabilitation and that it is a potentially lifesaving intervention. Also, according to a survey by the Healthcare Commission, many cardiac patients recently discharged from hospital stated that they were unaware that CR was available (Knapton et al., 2009).

2.5. Barriers to patient uptake and continuation

Studies conducted to investigate the barriers that prevent patients from attending a cardiac rehabilitation programme mainly concentrate on Phase 3 and 4 attendance as these are perceived as the core and most important components of CR. Phase 1 participation is mainly dependent upon the identification of patients eligible for CR. Also Phase 2 participation is mainly service related as no active participation or motivation from the patient is required.

2.5.1. Barriers to Phase 3 attendance

The identification of barriers and patients that are likely to not attend CR is crucial in order to enable the application of targeted interventions that will increase uptake amongst these patients (Cooper et al., 2002). Barriers to patient uptake and adherence are often divided in three groups of factors comprising patient factors, service factors and professional factors (Beswick et al., 2004).
Patient related factors include lack of interest and motivation and a reluctance to change lifestyles together with a dislike of classes or groups and hospital settings as well as depression (Beswick et al., 2004, Dalal et al., 2007). Furthermore, conflicting work commitments and the fear of loss of earnings have been identified as patient factors that reduce CR attendance. It has thereby been shown that patients who spent fewer years in education and those who earn less money or are unemployed are less likely to attend CR (Cooper et al., 2002). A rural residential location, domestic commitments and a lack of family support have also been associated with poor uptake and attendance of cardiac rehabilitation (Cooper et al., 2002). Furthermore, patients often state that they do not want to dwell on their cardiac problems or do not want to be reminded of their cardiac event which suggest some degree of avoidance or denial (Farley et al., 2003). Service related factors include convenience and accessibility of the cardiac rehabilitation programme. Transport issues appear to be one of the most common reasons why people do not attend cardiac rehabilitation (O'Driscoll et al., 2007). Especially travelling in winter and by night as well as problems with car parking were perceived as major barriers to attendance by patients (Paquet et al., 2005). Also, lack of communication, exclusion criteria, lack of physician recommendation and lack of services have been identified as important service related barriers (Jolly et al., 2007). Especially, inadequate service provision has been identified as a major barrier to participation in cardiac rehabilitation (Jolly et al., 2007). In particular, long waiting times, an inevitable consequence of limited CR service capacity, are an important barrier for the uptake of cardiac rehabilitation and patients perceive that waiting and the uncertainty associated with it impact upon their quality of life (Tod et al., 2002). In 2007/08, waiting times were significant with more than 3 weeks between MI and rehabilitation starting, more than a month for angioplasty patients and up to 8 weeks for CABG patients. However, waiting times have been reduced every year since 2003/04 (Knapton et al., 2009). Long waiting times are only partly due to insufficient capacity of centres as a national survey found that about 16 % of CR centres reported spare capacity (Beswick et al., 2004).

Patient knowledge, understanding and attitude towards CR, low referral rate or a disfunctional referral process and prejudice are summarised as professional factors (Beswick et al., 2004). For example, 60 % of patients who had suffered a cardiac event claimed that they were not invited to take part in cardiac rehabilitation (Bethell et al., 2009). Also, patients’ experience with the NHS can influence their attendance of cardiac rehabilitation (Jolly et al., 2007). For patients whose first language is not English, the often inadequate use of interpreters can cause a major language and communication related
barrier (O’Driscoll et al., 2007). Furthermore, staff morale has been suggested to influence patients decision whether or not to attend cardiac rehabilitation (O’Driscoll et al., 2007). None of the above reasons for non-attendance, however, could be identified as the major factor. Instead, patients’ reason for non-attendance and early drop-out are manifold and highly individual whereas women usually give more reasons than men and understand the resumption of domestic task as a form of exercise (Jolly et al., 2007, Farley et al., 2003).

2.5.2. Barriers to Phase 4 attendance

Attendance of Phase 4 has been estimated of being around 30 % (Robinson et al., 2009). A qualitative study of three focus groups of CR patients found that three months after a cardiac event, many patients were reluctant to change their lifestyles and wanted to return to their routine before the cardiac event. This was the result of patients believing that they had already done everything necessary (e.g. stopped smoking) and that they had good habits that did not need to be changed. Also, patients were not convinced that their usual habits posed a risk to their health and wellbeing and many thought that due to their physical condition exercise was not a feasible option (Paquet et al., 2005). Often the need to modify habits and lifestyles was conceived as external pressure instead of a personal objective (Paquet et al., 2005). Furthermore, as their recovery progressed, many patients found that they returned to life before the cardiac event which made it increasingly difficult to find time for exercise due to other commitments (Jolly et al., 2007).

2.5.3. Premature patient drop-out from cardiac rehabilitation

Drop-out rates from exercise programmes have been found to be as high as 20 % within the first 3 months, 50 % at 6 months and up to 87 % after 1 year (Jolly et al., 2007). Even greater drop-out rates have been found in patients who show symptoms of depression (Beswick et al., 2004) and for high-intensity exercise programmes (Jolly et al., 2007). Re-hospitalisation, a deterioration in health, common illness such as influenza or colds and referral to a nursing home have been associated with reduced participation in cardiac rehabilitation and premature drop-out. Also, lack of interest and illness perception played an important role in people’s decision to not attend or continue CR (Beswick et al., 2004, Kerins et al., 2010). Additionally, 34 % of patients gave reasons that could have been avoided by managing CR services more efficiently. These reasons included transport problems, carer responsibilities, return to work, holidays and other appointments, administration failure and dissatisfaction with the course as well as attendance of alternative courses (Beswick et al., 2004).
Also, patients who were disappointed with the rate of their recovery were found to believe that a change in lifestyle and cardiac rehabilitation in general was a pointless exercise which led to early drop-out from CR (Wiles and Kinmonth, 2001).

2.5.4. Patient beliefs and their influence on attendance and adherence

Patients’ beliefs about their treatment and their illness as well as the level of perceived control influence their decision whether or not to attend cardiac rehabilitation. These beliefs are shaped by past experiences, opinions of friends and other people, attitude of health professionals and the media (Cooper et al., 2002). Research has shown that patient beliefs about a treatment they are receiving and their perceptions of cause and severity of their illness as well as coping strategies and feeling of control will have a strong influence on their adherence to the treatment (Jolly et al., 2007). Attendance and adherence is thereby higher the stronger patients believe in the necessity of the treatment and the fewer concerns they have about harmful effects (Cooper et al., 2007).

In detail, four factors have been identified that influence patient beliefs about a certain treatment. These include the value of the treatment (i.e. the benefit of the treatment in controlling cardiac disease), concerns about the treatment (i.e. anxiety and worries about the treatment), decision satisfaction (i.e. satisfaction with and suitability of the treatment) and cure (i.e. the ability of the treatment to remove the disease) (Hirani et al., 2008). Patients attending and completing CR perceived it as necessary and believed in the treatment. They also experienced more personal control and better understanding of their illness (Cooper et al., 2007) and the content and benefits of cardiac rehabilitation programmes (Jolly et al., 2007). Furthermore, a general lack of knowledge about the content of cardiac rehabilitation programmes leads to patients assuming that CR was exercise-only and only appropriate for younger, more active people (Cooper et al., 2007). On the other hand, younger patients attending CR thought that exercise session were predominately used by older people and that they did not feel comfortable with this (Jolly et al., 2007).

Another factor influencing attendance of CR, apart from perceptions about the treatment, is the sum of perceptions of patients regarding their illness, which is usually described as the illness schema (French et al., 2006, Hirani and Newman, 2005). The illness schema can be divided in five different components which include patients’ beliefs about the causes of their illness, the symptoms patients associate with the illness (i.e. its identity), consequences of the illness, beliefs about the time line of the illness (acute, chronic or cyclical) as well as ways to control or cure the illness. People with more positive illness identity, consequences and control or cure perceptions are hypothesised to be more likely to attend cardiac
rehabilitation (French et al., 2006). Indeed, it has been found, that patients who thought that CR was unnecessary or inappropriate and were thus not attending cardiac rehabilitation were found to be more likely to believe that their condition requires rest and would not allow them to exert themselves. These patients also perceived themselves as relatively helpless in preventing the progress of their disease, felt stressed and were embarrassed to exercise in groups (Jolly et al., 2007). They also exhibited a lack of understanding of the role of physical activity and lifestyle changes in recovery and a lack of awareness as well as misconceptions about the contents of CR. Furthermore, these patients believed that stress and worry was the primary cause of their heart condition (Tod et al., 2002, French et al., 2006). Also, a strong belief in the genetic factor as a non-modifiable risk led to a resigned attitude in patients which reduced attendance in patients with a family history of cardiac disease (Paquet et al., 2005, Hirani and Newman, 2005). People who did not attend CR were also less likely to believe that their heart attack was connected to their lifestyle (Cooper et al., 2002). In contrast, especially patients who strongly believed that their condition was controllable and curable and understood that it could be associated with serious consequences were significantly more likely to attend cardiac rehabilitation (French et al., 2006).

2.5.5. Under-represented groups
According to the NACR, the majority of patients taking part in cardiac rehabilitation in 2007/08 were white British males aged between 61 and 70 who had recently been hospitalised because of uncomplicated myocardial infarction or for revascularisation. Women, the elderly, people from ethnic minorities and disabled people have often been found to be referred to and attend CR in fewer numbers than would be expected (Knapton et al., 2009, Thompson et al., 1996, Beswick et al., 2004) although these patient groups could benefit greatly from cardiac rehabilitation (Beswick et al., 2004). Also, it has been suggested that these patients are also often excluded from trials due to age, gender, co-morbidities and language barriers and patients’ ethnic backgrounds are rarely reported (Beswick et al., 2004). Furthermore, frail and confused patients and patients with more severe cardiac illness and psychiatric conditions are normally considered ineligible for cardiac rehabilitation (Beswick et al., 2004).
2.5.5.1. Elderly patients

In the elderly, needs may differ from younger patients as the preservation of mobility, self-sufficiency, functional independence, prevention and treatment of anxiety and depression as well as mental function is the most important goal of cardiac rehabilitation (Beswick et al., 2004, Wenger, 2008, Piepoli et al., 2010). Multifactorial cardiac rehabilitation has been found to result in a significant reduction of coronary risk factors in the elderly (Wenger, 2008) and achievement of most benefits of CR (e.g. increased exercise and functional capacity, improvement in healthy behaviour and quality of life, modification of risk factors, smoking cessation) have been documented for the elderly regardless of their clinical status and co-morbidities (Piepoli et al., 2010). However, invitation to and attendance of CR is lower in older patients which can cause a lack of information and insufficient advice about cardiac risk reduction for this patient group (Beswick et al., 2004). It is therefore important that physicians strongly encourage elderly patients to attend CR and the associated exercise sessions (Wenger, 2008).

Slower paced exercise sessions of lower intensity and less detailed educational sessions may be appropriate in the provision of CR to the elderly (Beswick et al., 2004) and could enable the patient to return to a similar lifestyle as before the cardiac event (Piepoli et al., 2010). However, many elderly patients would not attend CR if it disrupts their daily routine (Tod et al., 2002).

2.5.5.2. Women

Women presenting with cardiovascular disease are usually older and more likely to suffer from co-morbidities (e.g. hypertension, diabetes, hypercholesterolemia or obesity) than man (Beswick et al., 2004, Piepoli et al., 2010). They also have been observed to have significantly lower health status scores, lower exercise capacity and reduced functional capacity (Mayou et al., 2005). Furthermore their health-related quality of life scores are often lower and they are more likely to be diagnosed with depression (Piepoli et al., 2010). All of this is reflected in a lower referral rate for this patient group as women or more likely to be considered unsuitable for CR (Chauhan et al., 2010a). However, as women's functional capacity at entry into cardiac rehabilitation is often less favourable compared to men, they are likely to attain similar or even greater benefit from CR (Wenger, 2008). For example, it has been shown that women attained similar improvements in their physical fitness profiles and quality of life scores suggesting that CR is as effective a treatment for women as it is for men (O'Farrell et al., 2000). However, in addition to lower referral rates, women may also be
reluctant to participate in predominantly male exercise groups and less motivated to do strenuous exercise (Beswick et al., 2004). Especially women who live alone have been found to be sixteen times less likely to attend CR when compared to married women or women in a relationship (Farley et al., 2003). Women also often mention childcare, housework and family responsibilities as reasons for non-attendance (Tod et al., 2002).

2.5.5.3. Non-English-speaking ethnic minorities

In the United Kingdom, ethnic minority groups, especially those originating from the Indian subcontinent, have been observed to present with higher risk and increased prevalence of cardiovascular disease compared to the general population (Chauhan et al., 2010b, Chauhan et al., 2010a). Ethnicity of patients attending CR is rarely recorded and the diversity within clinical studies is often not sufficient to address the influence of ethnicity on attendance of cardiac rehabilitation (Cooper et al., 2002). There is therefore little data available on the uptake, attendance, completion and outcomes of CR for ethnic minority patients (Chauhan et al., 2010a).

However, participation of non-English-speaking ethnic minority patients has been observed to be considerably lower than of English-speaking patients (Beswick et al., 2004). Barriers restricting access for these patients are complex and non-attendance has been associated with poor access, inadequate translational and interpreting services and a lack of translated written information (Beswick et al., 2004). Also, religion, stereotyping and lack of cultural competency can decrease attendance for these patient groups. Especially, mixed gender classes caused a major problem for many women (Chauhan et al., 2010b). Moreover, non-attendance of ethnic minority patients has been observed to be more likely due to health problems and cardiac patients from an ethnic minority are often younger than white patients (Jolly et al., 2007). A lot of patients also described negative experiences with the NHS during their admission or during cardiac rehabilitation as the main reason for non-attendance or early drop-out. These negative experiences are often caused by an inability to communicate with the patient during their acute admission which can lead to delays in diagnosis and a feeling of being left alone (Chauhan et al., 2010b). In fact, it was suggested that rates of referral and invitation was similar in areas with high proportions of ethnic minorities compared to other areas but patient attendance was lower (Beswick et al., 2004). The translation of educational and information materials and presentation of sessions in a way appropriate for these patients may increase participation (Beswick et al., 2004).
Considering the higher risk of cardiac disease in these patients, it appears of particular importance that they are provided with equal access to CR programmes (Jolly et al., 2007).

2.5.5.4. **Local under-representation due to lack of provision**

It appears that service provision of cardiac rehabilitation is variable across the UK with higher levels of eligible patients referred to CR in England and Wales compared to Northern Ireland (Beswick et al., 2004).

Also, the NACR for the period between April 2007 and March 2008 suggested that a “postcode lottery” still exist in both the provision and quality of cardiac rehabilitation with level of staffing and the opportunity to attend varying widely between different areas (Knapton et al., 2009). Moreover, patients living in areas of high social deprivation have been found to have lower uptake of CR (Beswick et al., 2004).

2.6. **Promotion of CR uptake and adherence**

Non-attendance of cardiac rehabilitation (i.e. not attending on the first day of the programme after initially enrolling) and non-completion of programmes results in poorer patient health, increased waiting times and waste of resources (Kerins et al., 2010). Cardiac rehabilitation services that promote CR uptake and adherence do so by follow-up calls, free transport, home visits and personal invitations (Beswick et al., 2004). Physician’s referral and especially referral by a cardiologist has been observed to increase uptake of CR (Beswick et al., 2004). Also, motivational letters and phone calls as well as visits and coordination of care by trained liaison nurses and trained lay volunteers during Phase 2 have been shown to improve uptake of CR (Beswick et al., 2004, Davies et al., 2010). Various studies investigated the promotion of CR attendance through different interventions. These interventions included formal written or oral patient commitment, spouse and family involvement, educational interventions, strategies to aid self-management and psychological interventions. Also, motivational interviews and goal setting have been used to motivate CR adherence (Bethell et al., 2009). These interventions have been shown to significantly increase patient attendance (Davies et al., 2010). However, some studies found no or non-significant changes in the level of attendance (Beswick et al., 2004).

It has been recommended that cardiac rehabilitation services would need to be modified in order to promote uptake and attendance of female patients. Gender-specific approaches to CR could include provision of childcare and home-help, specific counselling and the provision of women-only educational and exercise sessions (Beswick et al., 2004).
Especially, women without a partner should be targeted to ensure uptake of CR as this patient group has been found to be particularly likely to not attend (Farley et al., 2003). Also, the provision of sessions at times suitable for patients may improve adherence (Beswick et al., 2004). The knowledge and enthusiasm of the patient’s physician have been identified as an important factor that can improve uptake of CR during the referral process. It is therefore crucial to provide adequate education to physicians and providers about the benefits of CR in order to assist them in conveying the importance of cardiac rehabilitation to the patient (Beswick et al., 2004).

2.7. Alternative provision of cardiac rehabilitation

Cardiac rehabilitation has traditionally been provided on an outpatient basis and is thus hospital based (Dalal and Evans, 2003, Taylor et al., 2010). In order to provide a more patient friendly service, the importance of tailoring cardiac rehabilitation service provision to the local context has been emphasised.

2.7.1. Home based cardiac rehabilitation

A survey showed that 47% of eligible patients would prefer home based rehabilitation programmes with patients over 60 years of age, women and employed patients who perceive time constraints more likely to choose home-based CR (Jolly et al., 2007, Dalal and Evans, 2003, Taylor et al., 2010, Thompson, 2002). Patients who chose home-based programmes mentioned travel distance to the hospital and parking problems as the main barriers to take up a hospital-based programme whereas patients who preferred hospital CR over home-based programmes did so because they appreciated the peer support and the discipline as the main reasons for their choice (Jolly et al., 2007, Dalal and Evans, 2003). The Heart Manual is a home based programme which offers an alternative to hospital based CR for patients who prefer home settings or are unwilling or unable to attend group sessions or sessions in a hospital setting (Bethell et al., 2008). It is designed to support the patient for the first 6 weeks after an cardiac event and includes education, a home-based exercise programme and relaxation tapes together with a stress management programme. It can also be supplied with accompanying tapes in ethnic minority languages for non-English speaking patients (Jolly et al., 2007, Jolly et al., 2003). Cardiac rehabilitation following the Heart Manual allows patients to self-regulate the frequency and nature of their rehabilitation
sessions and may improve uptake and adherence to CR (Taylor et al., 2007, Taylor et al., 2010). It was suggested that around 20% of cardiac rehabilitation programmes are currently home-based and no significant differences have been found in the short-term or long-term outcomes of home-based CR when compared to centre-based cardiac rehabilitation programmes. In fact, patients in the home-based programmes reported more physical activity after two years than hospital-based patients (Dalal et al., 2007, Jolly et al., 2007).

Patients following the Heart Manual generally found it useful and felt that it answered most of their questions. Furthermore, they thought that exercises were well planned and helped them to build up their confidence (Jolly et al., 2007). However, some patients were worried about exercising on their own and showed reluctance to push themselves due to health concerns (Jolly et al., 2007). Home-based patients were indeed found to have a slightly higher rate of adverse events (e.g. myocardial infarction and death) and revascularisation procedures in some studies but this difference was not significant and the total proportion of patients with adverse events was generally low (Jolly et al., 2007, Taylor et al., 2007). Furthermore, other studies could not confirm increased rates of adverse events (Dalal et al., 2007). However, this method to provide CR may not be suitable for patients with more severe disease and those with low interest and lack of motivation (Beswick et al., 2004).

In recent years, the use of the internet has been advocated as a mode of delivery for home-based CR in order to deliver interactive cardiac rehabilitation tailored to the patient’s needs where peer support can be provided through disease-specific chat rooms (Thompson, 2002).

2.7.2. Community based cardiac rehabilitation

Another alternative approach to hospital based cardiac rehabilitation is to use facilities in the community to provide a similar service to the hospital outpatient programme. This service is often run by a community CR team and is suitable for low risk patients (Jolly et al., 2007). This mode of provision would have the same benefits but may reduce factors that are often associated with reduced attendance such as transport issues and access difficulties (Beswick et al., 2004).

2.8. The four phases of cardiac rehabilitation

In the UK, cardiac rehabilitation is divided into 4 phases including the in-hospital phase, the early post-discharge, the later post discharge and the long term follow up (Thompson et al., 1996).
2.8.1. Phase 1 (In-patient stage)

Phase 1 cardiac rehabilitation encompasses the period the patient spends in hospital immediately after the acute cardiac event (Bethell et al., 2008). The Phase 1 cardiac rehabilitation programme starts when the medical condition of the patient is stable (Bethell et al., 2009). It concerns the individual level of each patient and comprises counselling, a simple programme of education about the patient’s disease and their likely recovery as well as psychological support. Furthermore, ideally, physical, psychological and social needs of each patient should be assessed and the patient is given advice and encouragement for light exercise for Phase 2 (Beswick et al., 2004, Jolly et al., 2007).

2.8.1.1. Identification of CR patients

It has been shown that daily printouts of cardiac enzyme data from a hospital’s database of clinical chemistry results checked by a dedicated cardiac liaison nurse and assessment of patients before discharge by the cardiac nurse were successful in identifying potential CR patients (Dalal and Evans, 2003). However, the collection of names and recording of clinical summaries of eligible patients was found to not be complete in all hospitals (Beswick et al., 2004).

2.8.1.2. Referral of CR patients

According to a survey, in 2002, 35 % of patients discharged from hospital after a cardiac event attended cardiac rehabilitation which equalled 55 % of the patients referred or invited to CR (Beswick et al., 2004). This means that less than 65 % of eligible patients were referred to cardiac rehabilitation.

In the majority of CR services, referral guidelines or criteria are not documented (Smith, 2008). Patient information is often not passed on across healthcare settings and communication between community and hospital CR services is poor. It has therefore been suggested that streamlining and automation of the referral process is of particular importance in order to improve referral rates (Thompson, 2002). Additional resources would be required in order to improve referral processes through information technology and networking (Tod et al., 2002). A recent study conducted in the United States found an increase of the referral rates of cardiac patients to cardiac rehabilitation from 38 % to 90 % and an increase of patient enrolment to CR of 98 % by adding a mandatory reminder to standard electronic cardiovascular admission sets (Patel et al., 2011). Hospital admission of the patient could not be completed unless eligibility of the patient for CR was assessed. In
case the patient was eligible, details of the patient were automatically transferred to cardiac rehabilitation services who could then play an active role in referral, recruitment and promotion of the service. Healthcare professionals play an important role in the recruitment of patient to cardiac rehabilitation whereas their contribution highly depends on education, compliance with guidelines and coordination of services. It was suggested that cardiologists may be more likely to refer patients to cardiac rehabilitation than primary care physicians (Beswick et al., 2004). In fact, in a recent study, about 5% of eligible patients were recommended not to attend CR by their GP (Beswick et al., 2004).

2.8.1.3. Delivery of Phase 1 cardiac rehabilitation

Novel, intimidating and often painful experiences accompany a patient’s hospitalisation phase. Together with unpredictable hospital routine, unfamiliar noises, procedures and equipment as well as a lack of control over their own lives and actions, these are a source of anxiety and may challenge a patient’s senses and their coping mechanisms (Thomas, 1995). It has therefore been suggested that the first components of cardiac rehabilitation should be started as soon as possible after the cardiac event. Especially for uncomplicated events and procedures, risk factor management and physical activity counselling can be started the next day and light exercise should be commenced within a few days (Piepoli et al., 2010). In addition, psychological support and discussions about the patient’s health status and the medical procedures are necessary to address anxiety and help the patient regain a feeling of control (Thomas, 1995). However, in reality, the restricted resources available for many cardiac rehabilitation programmes have been found to cause limitations of the time that staff spend with each individual patient. Especially in Phase 1 this can lead to an overload of information for the patient as too much is being conveyed in a short period of time (O’Driscoll et al., 2007).

2.8.1.4. Patient needs in Phase 1

It has been found, that patients whose condition does not make sense to them and who thus do not understand the nature of heart disease and the underlying chronic processes are less likely to see the relevance of behavioural changes aimed for during cardiac rehabilitation and will therefore be less likely to attend CR (French et al., 2006). In Phase 1, it is therefore of major importance for the patient to get an explanation and understand what has happened to them and the implications of their cardiac disease or event. This information should be conveyed positively and sympathetically and in terms all patients will be able to understand.
Scoping exercise to identify areas for research, evaluation and audit in relation to the practice and delivery of cardiac rehabilitation (CR): Final report

December 2011

(Thompson et al., 1996). In fact, it has been found that immediately after a cardiac event patients thought they needed help in accepting their condition and knowing their limits rather than receiving information about modifying their habits and lifestyles (Paquet et al., 2005). Also, it has been suggested that the interventional cardiologist should explain measures to reduce risk and emphasise that failure to do so may result in further cardiovascular complications (Piepoli et al., 2010). It is therefore of importance to explain the nature of cardiovascular disease in a comprehensive and easily understandable way as research suggest that if the disease is described as chronic many patients believe they have no control over the progression and are therefore less likely to attend CR whereas if the condition is described as acute, people may believe that they will be “back to normal” within a few weeks independent of CR (Wiles and Kinmonth, 2001).

2.8.2. Phase 2 (Post-discharge stage)

Phase 2 of the cardiac rehabilitation programme covers the convalescent period at home between the patient’s discharge from hospital and the start of the supervised outpatient programme of Phase 3 (Bethell et al., 2008, Bethell et al., 2009). The patient is encouraged to take up light exercise guided by educational materials or self-help programmes and supervised during home visits and telephone contact (Beswick et al., 2004, Jolly et al., 2007).

2.8.2.1. Patient needs and service delivery in Phase 2

Particularly the early post-discharge period is a time when patients feel anxious, isolated and insecure. In order to reduce psychological distress, regular support and reassurance through home visits and telephone contact should be provided as soon as possible after discharge (Lane and Smith, 2010, Tod et al., 2002). It has been suggested that after discharge from hospital less general information should be given but instead patients should be instructed about specific activities (Thompson et al., 1996). Also, patients thought that better information for family members and care givers may help to avoid the problem of over-protectiveness (Paquet et al., 2005).

A patient’s decision whether to attend cardiac rehabilitation has been found to be a two-stage process. The first decision to attend is made in hospital and is based on the perceived relevance of CR which is why sufficient information is crucial in Phase 1. However, once patients are discharged from hospital, they start to prioritise and conceptualise and will choose whether to attend CR on the basis of whether they consider it more important than
their daily routine or work and family commitments (Hagan et al., 2007). In fact, at this decision stage, patients will undertake their own individual cost-benefit analysis of cardiac rehabilitation (Hirani and Newman, 2005). Continued motivation and support as well as information about the importance and the benefits of CR are therefore crucial in this phase in order to persuade patients of the high priority of CR. Indeed, a recent Canadian study found an increase of CR participation of 162% when patients were given an early intervention of information, support and motivation immediately after hospital discharge (Parker et al., 2011).

Patient beliefs have been found to influence people’s attendance of cardiac rehabilitation (see Chapter 2.5.4.). It thus appears reasonable that if these beliefs were to be altered towards more patient control and more positive perceptions of their illness during the recuperation period of Phase 2, before patients commence their formal Phase 3 CR programme, uptake and attendance may be increased (French et al., 2006). Furthermore, detailed information and a comprehensive introduction of CR content, purpose, options of individualisation and benefits in Phase 2 may improve Phase 3 attendance as “not interested” and “not for me” have been observed to be among the most common reasons mentioned for non-attendance of cardiac rehabilitation (Kerins et al., 2010).

2.8.3. Phase 3 (Structured programme stage)
Phase 3 is often regarded as the core of cardiac rehabilitation and most quantitative and qualitative studies investigating cardiac rehabilitation to date have focused on this stage of CR (Bethell et al., 2008). Phase 3 cardiac rehabilitation is delivered in an outpatient setting and typically includes hospital or community based exercise sessions, educational sessions, risk factor monitoring and treatment, stress management and relaxation training. It is usually delivered by a multidisciplinary team of nurses, physiotherapists, pharmacists, therapists, psychologists and social workers (Bethell et al., 2008). This phase usually starts within 4 weeks after myocardial infarction and 6 weeks after heart surgery and can last between 6 weeks and 6 months depending on the needs of the patient (Bethell et al., 2008) and the local provision of CR.

2.8.3.1. Delivery of Phase 3 cardiac rehabilitation
A combination of exercise, psychological and educational interventions has been found to be the most effective form of cardiac rehabilitation. However, the most effective combination, frequency, duration and mode of delivery of different components of CR is uncertain (Beswick et al., 2004, Thompson, 2002). It has been suggested that the integration of
rehabilitation services with secondary prevention clinics in primary care and thus the cooperation of primary and secondary care allows national service framework goals and targets to be achieved (Dalal and Evans, 2003, Bethell et al., 2008).

2.8.3.2. Delivery of exercise sessions
Exercise has always been a central component of cardiac rehabilitation as it helps to restore patients’ confidence in their bodies and their abilities, increases their general well-being and improves their level of physical activity. Furthermore, it will help to improve cardiac risk factors and therefore contribute to secondary prevention (Thompson et al., 1996). Patients who exercise have been found to recover quicker, visit their GP or a hospital fewer times and are more likely to return to work after a cardiac event (Thompson et al., 1996). The total time of exercise during CR is about twice as much as the time for health education and four times as much as time spent on psychological interventions (Beswick et al., 2004).

It has been suggested that, for maximum benefit, exercise programmes should be menu based and thus tailored to each patient’s individual needs and specific requirements (O’Driscoll et al., 2007, Bethell et al., 2008). Also, the wrong intensity and irrelevant exercises could lead to early drop-out of patients from the programme if the exercise appears too easy or too hard for them (O’Driscoll et al., 2007, Kerins et al., 2010).

The National Service Framework for Coronary Heart Disease in England set a target of 3 exercise sessions a week of which two should be supervised (Jolly et al., 2007). Patients perceived one session per week as optimal (Paquet et al., 2005). However, there are concerns that patients may have sufficient exercise once a week during sessions but may not exercise sufficiently on other days (Jolly et al., 2007).

The content of exercise sessions varies in different hospitals but may mainly include walking, fixed cycling, circuit training and rowing (Jolly et al., 2007).

2.8.3.3. Delivery of educational sessions
It is important to consider learning needs of patients when providing educational sessions as what the healthcare professional considers vital for the patient’s recovery is not always what the patient considers important (Fridlund, 2002). A qualitative analysis of the delivery of CR in an NHS hospital showed that a lot of the staff were not adequately trained to deliver educational sessions which resulted in vague, non-interactive presentations and contradicting or inaccurate advice given by different speakers (O’Driscoll et al., 2007). Poor education techniques and inconsistent information can result in patients questioning the
quality of the information received which may influence their decision to take up or continue with cardiac rehabilitation (O’Driscoll et al., 2007). The format of information sharing has been shown to influence how much knowledge patients retain and can thus affect patients’ recovery (O’Driscoll et al., 2007). Interactive group sessions where patients are actively involved in problem-solving have been shown to result in a greater sense of power and control over their condition, reduce anxiety and increase the likelihood of patients implementing lifestyle changes which may be associated with a feeling of personal loss. However, these sessions will need especially trained staff which would impact on the CR budget (Thomas, 1995).

Cooperation and coordination between staff is crucial to avoid conflicting advice (Thompson et al., 1996). Insufficient organisation has also been cited as a problem associated with CR educational sessions (Jolly et al., 2007).

### 2.8.3.4. Delivery of psycho-social support

The NSF-CHD recommends that all CR teams should include a psychologist (DoH, 2000) and Standard 6 of the Cardiac Disease National Service Framework for Wales states that CR teams should have staff with skills and competences in psychological support (WAG, 2009). However, many CR teams still do not include a psychologist. In extreme cases, patients are referred to a psychologist but many CHD patients have been found to suffer from anxiety and depression which can cause a major barrier to recovery (O’Driscoll et al., 2007) and can substantially increase the use of healthcare resources (Mayou, 1996). The third NACR found that while 17% of cardiac patients were borderline or clinically depressed and 28% suffered from anxiety, only 3% were recorded as having received psychological help or counselling (Knapton et al., 2009). Patients exhibiting symptoms of depression have been found to be more likely to not complete cardiac rehabilitation (Swardfager et al., 2011) and mortality is 4 times higher in this patient group compared with non-depressed patients which is why these patients require enhanced support and psychotherapeutic attention (Wenger, 2008, Farley et al., 2003).

Patients thought that support groups may help them to manage stress and would also give them a feeling that they have a socially meaningful function by helping others at the same time (Paquet et al., 2005).
2.8.3.5. **Group sessions versus one-on-one sessions**

Evidence suggest that, in order to encourage better uptake of cardiac rehabilitation, group sessions as well as one-on-one sessions should be provided as patient preferences vary. Some patients advocate group sessions due to the companionship. Patients attending focus and discussion group meetings appreciated the support and the sense of security it gave them and the communication with other people who had experienced a cardiac event (Paquet et al., 2005). Furthermore, sessions that included other cardiac patients as well as members of the family/spouses were considered helpful as especially caregivers were thought to be in need of support (Paquet et al., 2005).

Other patients, however, found group sessions socially stressful and thought that they lacked privacy and that they would not fit in (Tod et al., 2002). Individual one-on-one sessions were preferred by people with hearing disabilities, patients who had returned to work and when “delicate” matters were discussed (Paquet et al., 2005).

2.8.3.6. **Patient needs in Phase 3**

Early after hospital discharge, patients’ motivation to change their lives is highest and their need for support and guidance is greatest due to the anxiety and fear they experience after a life-threatening event (Fridlund, 2002, Paquet et al., 2005). This means that early provision and invitation and thus a reduction of waiting times may increase uptake of CR (Beswick et al., 2004). Currently Phase 3 programmes start about 6 weeks after the cardiac event due to waiting lists and the insistence in some centres that patients complete symptom limited exercise tests which may not be necessary. This 6 week delay period was suggested to result in support that is too late to help overcome the anxiety and uncertainty and to take advantage of the initial motivation (Thompson, 2002). The more time passes after the cardiac event the more encouragement and support the patient will require in order to maintain long-term lifestyle changes. Nurses can play a major role in providing this support by acting as educators, coaches and supervisors for patients throughout their cardiac rehabilitation experience (Fridlund, 2002). Also, “back-end loading” has been suggested which means that more contacts with the CR team occur later on in the programme to counteract decreasing motivational levels of the patients and relapse to old behavioural patterns (Reid et al., 2005). Tailoring of the programme to patients’ needs could also help to overcome barriers of attendance.
2.8.4. Phase 4 (Life-long maintenance stage)

Phase 4 of cardiac rehabilitation encompasses the entire long term future of the patient in which the patient continues the healthy living habits that were encouraged during Phase 1 to 3.

2.8.4.1. Delivery of Phase 4 cardiac rehabilitation

Once patients reach Phase 4 of cardiac rehabilitation they are considered stable enough to continue exercise in a community setting (Woolf-May and Bird, 2005). Phase 4 cardiac rehabilitation exercise sessions are often provided in fitness centres in the community by trained fitness instructors under the “Fit for life” scheme (Woolf-May and Bird, 2005, Bethell et al., 2009). Maintenance of healthy behaviour through continued exercise and adherence to lifestyle changes can thereby be mediated through a cardiac support group (Beswick et al., 2004). During this phase, usually the primary care team will monitor the patient’s clinical condition, risk factors and medication on a regular basis (Bethell et al., 2008).

2.8.4.2. Patient needs in Phase 4

Patients who attended Phase 3 cardiac rehabilitation in a hospital setting reported that they did appreciate the provision of Phase 4 community sessions. Furthermore, where this was not provided, many patients found that some kind of programme should exist as they seemed to feel reluctant to exercise outside the controlled environment (Jolly et al., 2007). It has been shown that, 2 years after cardiac rehabilitation, patients’ health-related quality of life was significantly higher than before they commenced CR. However, HRQL scores dropped significantly when compared to scores directly after Phase 3 cardiac rehabilitation (Höfer et al., 2009, Höfer et al., 2006). This means, that after Phase 3, patients still appear to require some kind of reinforcement in order to maintain a healthy lifestyle since research has shown that, after initial improvement during CR, blood pressure and BMI tend to increase after completion of the cardiac rehabilitation programme (Reid et al., 2005). Also, patients’ exercise levels during Phase 4 are usually not high enough to enhance aerobic fitness (Woolf-May and Bird, 2005). This motivational reinforcement can be provided through a Phase 4 programme, telephone support or through primary or secondary care (Jolly et al., 2007). However, in a recent study providing regular telephone support to Phase 4 patients to encourage exercise maintenance only small effects could be found and 6 months after Phase 3 completion participants did not exercise significantly more (measured in minutes of physical activity) compared to the control group (Pinto et al., 2011).
2.8.4.3. **Patient fast-tracking to Phase 4**

Fast tracking of CR patients from Phase 2 directly to a Phase 4 community based programme supervised by an exercise instructor was found to be feasible and effective and to achieve similar results in improving physical and mental wellbeing when compared to the conventional hospital based Phase 3 outpatient programme. Low risk cardiac rehabilitation patients who were fast-tracked directly to a community based Phase 4 programme have been shown to have significantly higher continued attendance of exercise classes compared to normal CR participants at 6 months follow-up which might suggest that fast-tracking can bring continued long term benefit (Robinson *et al.*, 2009). It was therefore suggested that the transition from hospital classes to unfamiliar community classes poses another barrier for uptake of Phase 4 long-term exercise which can be avoided by fast-tracking low risk patients directly to Phase 4 (Robinson *et al.*, 2009).

2.9. **Cost effectiveness of cardiac rehabilitation**

The limited budget available to healthcare in general means that cardiac rehabilitation does not only have to be clinically effective but also cost-effectiveness needs to achieved in order to be able to compete for scarce resources (Hall *et al.*, 2002). In 2007/08, the median cost for cardiac rehabilitation in England, Wales and Northern Ireland was £ 567.00 per patient completing all four phases. Cardiac rehabilitation has been found to be highly cost-effective due to reduced readmissions and hospital stays, decreased length of stay and reduced subsequent need of percutaneous coronary interventions when costs associated with CR delivery and the use of cardiac specific healthcare resources were considered (Papadakis *et al.*, 2008, Lane and Smith, 2010, Lee *et al.*, 2007, Yu *et al.*, 2004). Other studies found non-significant, small improvements in patient’s quality of life and supported the provision of CR due to the low cost (Briffa *et al.*, 2005). One study, however, could not confirm cost-savings and improvements in quality of life and suggested that CR was therefore unnecessary for low risk patients and should be directed to higher risk patients instead (Hall *et al.*, 2002). CR costs often only include an NHS perspective and comprise staff costs, overheads, building capital and equipment costs. However, cost varies significantly between different programmes according to format of delivery and staffing level and values between £ 185 and £ 567 have been reported (Beswick *et al.*, 2004, Knapton *et al.*, 2009, Taylor *et al.*, 2007, Lane and Smith, 2010, Bethell *et al.*, 2006, Bethell *et al.*, 2009). This may be due to differences in intensity of programme, staff involvement, purchase of equipment and costs of
hiring facilities (Taylor and Kirby, 1997, Beswick et al., 2004). Staffing thereby represents up to 80% of total direct costs with nursing cost (60 to 70%) and physiotherapy costs (14 to 23%) making up the most important share of staffing costs (Beswick et al., 2004). Also different cost-effectiveness values have been found when programmes were delivered to different patient groups. For example, it has been shown that standard cardiac rehabilitation is more cost-effective when provided to men compared with provision to women (Papadakis et al., 2008).

The incremental cost-effectiveness ratio (ICER) of cardiac rehabilitation after myocardial infarction has been estimated to be around £ 7860 per QALY for men and £ 8360 per QALY for women (Bethell et al., 2008). Also, CR programmes have been found to exhibit economies of scale with a reduction of cost per patient when output increases. However, the extension of CR services will require additional resources (Beswick et al., 2004). It has been proposed that an investment in the early prevention of cardiac disease through cost-effective cardiac rehabilitation is a better way to achieve greater health in the population than investment in cost-ineffective invasive procedures such as stenting for angina pectoris (Bethell et al., 2008).

Costing studies of home-based rehabilitation programmes normally include staff costs, cost of home visits, nurses’ travel cost and the cost of the Heart Manual as well as cost of staff training (Jolly et al., 2007). Some studies could not detect a statistically significant difference in cost between the two types of programme provision (Taylor et al., 2010). Others found that home-based programmes were about 25% more costly than hospital-based CR (Jolly et al., 2007) or reported that cost were significantly lower in the home-based programmes due to reduced personnel costs (Taylor et al., 2007, Lee et al., 2007).

Most studies investigating the cost of cardiac rehabilitation do not include patients’ out of pocket cost which may include travel costs or costs for special clothing. Even though these cost will not affect provision and organisation of CR programmes, they can influence patient attendance if they are considered too high (Beswick et al., 2004).

2.10. Cardiac rehabilitation for patients with different diagnoses

Evidence suggests that in addition to patients with myocardial infarction, patients who have undergone revascularisation or who suffered from angina pectoris or coronary artery disease as well as heart failure patients can also benefit from cardiac rehabilitation (Beswick et al., 2004).
However, the NACR 2007/08 found that a considerable number of CR programmes excluded patients with certain heart problems such as heart failure, pacemakers, implanted cardiac defibrillators or angina (Knapton et al., 2009). The complexity of the medical condition of heart failure patients poses a considerable barrier to the referral of these patients to cardiac rehabilitation (Beswick et al., 2004). Especially patients that have undergone percutaneous transluminal coronary angioplasty (PTCA) are less likely to be referred to cardiac rehabilitation as a consequence of the short hospital stay and thus limited time for recruitment associated with this type of revascularisation. Only 6 to 10 % of PTCA patients were found to attend cardiac rehabilitation in 1997 compared to 14 to 23 % of myocardial infarction and 33 to 56 % of CABG patients (Beswick et al., 2004) and 14 % of cardiac rehabilitation services did not offer CR to angioplasty patients in 2006 (Jolly et al., 2007). Despite a lack of referral, the exercise training during CR has been shown to prevent re-occurrence of cardiovascular disease after percutaneous coronary interventions which will improve patient prognosis in the long-term and affect a reduction in healthcare costs (Dendale et al., 2008).

Patients suffering from angina pectoris will still benefit from cardiac rehabilitation. However, as many of these patients are not admitted to hospital the possibility of referral from general practice with active involvement of practice nurses may be of particular value for these patients (Beswick et al., 2004).

It was found that more than 23 % of cardiac patients were not eligible for cardiac rehabilitation mainly due to age and co-morbidities such as chronic medical disorders, e.g. chronic obstructive pulmonary disease, arthritis, back problems or alcohol dependency (Beswick et al., 2004, Dalal and Evans, 2003). However, these patients may still benefit from some aspects of CR and providing them with customised information packages may improve patients’ modifiable risk factors (Dalal and Evans, 2003).

2.11. Programme staffing

Due to the multifaceted nature of cardiac rehabilitation, a wide range of knowledge and skills is required which is typically provided by a range of healthcare professionals (Thompson, 2002). Ideally, CR programmes should be a meeting point for a multidisciplinary team comprising of nurses, physiotherapists, dieticians, pharmacists, clinical psychologists and administrators (Bethell et al., 2009), led and coordinated by a cardiologist or a dedicated rehabilitation professional in order to promote health behavioural changes, increase quality of life and reduce further cardiovascular events (Piepoli et al., 2010). The third National Audit
Scoping exercise to identify areas for research, evaluation and audit in relation to the practice and delivery of cardiac rehabilitation (CR): Final report

December 2011

of Cardiac rehabilitation found improvements in the range of professions available to patients during CR. In particular, more dieticians, pharmacists, psychologists and occupational therapist were involved. However, none of the audited programmes were staffed to the level recommended by the Scottish Intercollegiate Guideline Network (SIGN) (Knapton et al., 2009) which leads to gaps and inequalities of provision of CR (Lane and Smith, 2010) and an overwhelming workload for existing staff (Tod et al., 2002). Also, due to resource limitations, a professional may be part of the CR team but can only borrow time for cardiac rehabilitation due to other work commitments which results in them not having the time to deal with patients’ individual needs (Knapton et al., 2009, Bethell et al., 2008). Insufficient staffing levels can lead to patients being inadequately prepared for discharge, delay in patient referral, cancellation of home visits and Phase 3 classes and reduced service quality which in turn will increase patient anxiety and reduce satisfaction and adherence to and uptake of cardiac rehabilitation programmes (Smith, 2008). Also, a lack of staff training and dedication was found to deter patients from cardiac rehabilitation as they felt they didn’t receive enough information, felt abandoned, isolated and vulnerable and were not understood or listened to (Kerins et al., 2010, Tod et al., 2002). Members of staff were thereby found to be aware of the limitations associated with CR programmes (Tod et al., 2002). A breakdown in communication between colleagues and different healthcare professionals involved in cardiac rehabilitation can lead to tension and uncertainty and result in demoralisation and staff undermining each other (O’Driscoll et al., 2007). This was considered a problem by patients (Paquet et al., 2005). Especially physicians and cardiologist have been found to play a very minor part in cardiac rehabilitation programmes and many services do not have a designated lead consultant cardiologist or GP with a special interest in cardiac rehabilitation (Lane and Smith, 2010, Lewin et al., 1998).

2.12. Cardiac rehabilitation in Wales

Standard 6 of the Cardiac Disease National Service Framework for Wales from June 2009 states that every patient with established coronary heart disease should be offered an appropriate evidence-based cardiac rehabilitation plan and has the high quality, multidisciplinary cardiac rehabilitation support they need to achieve this plan. Cardiac rehabilitation should therefore be an integral part of the treatment of patients with coronary heart disease and should be individualised to the needs of each patient (WAG, 2009). In order to achieve this standard, the importance of information provision to the patient,
patients’ competence in self-care, provision of care based on best practice and continuous professional development of staff as well as clinical audit has been emphasised (WAG, 2009).

All patients admitted to hospital in Wales with acute coronary syndrome, myocardial infarction or revascularisation, surgery or implantation as well as patients suffering from angina, heart failure or congenital heart disease should be referred to the cardiac rehabilitation team. In Phase 1, the patients’ rehabilitation requirements should be assessed and the CR team and patients should agree on an individualised initial exercise and mobilisation programme. Upon hospital discharge, the patients should be referred to a local rehabilitation service and given a hand held record card (WAG, 2009).

During Phase 2, patients should be contacted by their cardiac rehabilitation team within 7 days of discharge from hospital to arrange an appointment for further assessment. On this occasion, the patient should also be encouraged to attend the structured Phase 3 rehabilitation programme (WAG, 2009).

The Phase 3 rehabilitation programme should be tailored to each individual patient’s needs and should normally include health education, supervised exercise sessions or home exercise as well as psychological support. Also, the patients should be referred to other services (e.g. dietetic or smoking cessation programmes) when required (WAG, 2009).

At the beginning of Phase 4, the patients should be offered the opportunity to continue the CR programme in a community setting and risk factors should be monitored regularly by the primary care team (WAG, 2009).

Coronary heart disease mortality as well as deprivation is higher in Wales than in many other areas across the UK. In order to provide CR as an integral part of care for cardiac patients in Wales and to allow strategic development of services, for several years now, the Welsh Assembly Government has provided a £ 2 million ring-fenced funding within Local Health Board discretionary allocations and in 2007/08, 24 cardiac rehabilitation centres were recorded in Wales (Knapton et al., 2009). Cardiac rehabilitation practitioners work closely with Assembly Government schemes such as the National Exercise Referral Scheme in order to provide a seamless, patient friendly, high-quality and efficient service to cardiac patients (Lane and Smith, 2010). However, despite these efforts and its effectiveness and cost-effectiveness, cardiac rehabilitation is still not provided to a minimum standard in Mid and South West Wales and the National Audit of Cardiac Rehabilitation found that only 30 % of patients with heart disease take up CR in these regions. An estimated total of £ 630,000 would be needed in order to address gaps and inequities of CR service provision in Mid and South West Wales (Lane and Smith, 2010).
2.13. Conclusions

The success of cardiac rehabilitation depends on the delivery of high quality services, new and innovative techniques, evidence-based interventions and the production of proven outcomes. In order to achieve this, national standards and audits as well as accreditation and comparison of centres and programmes are crucial and coordinated, collaborative and systematic provision of implementation, monitoring and evaluation is required (Thompson, 2002). Data from qualitative studies in NHS hospitals suggest that cardiac rehabilitation programmes would need to be restructured in order to meet NSF targets and increase patient attendance (O'Driscoll et al., 2007). Tailoring programmes to individuals’ needs, clear and uniform referral processes, good communication between different elements within the NHS structure, provision of Phase 4 programmes in the community, high-quality services and well trained staff will be vital to improve CR services and attendance (Lane and Smith, 2010). This will mean increased investment and improved planning and structuring of services in order to increase communication between the different healthcare professionals involved in the programme as well as between NHS and local authority staff and to remove existing barriers for accessing cardiac rehabilitation (O'Driscoll et al., 2007, Lane and Smith, 2010). The cost implications of increasing provision and restructuring programmes will need to be assessed (Beswick et al., 2004).

Also, interventions for improving uptake and adherence have to be assessed. Especially issues of patient motivation and the perceived relevance of cardiac rehabilitation will have to be addressed in order to increase patient uptake of cardiac rehabilitation (Beswick et al., 2004). Furthermore, the barriers preventing patients, and especially patients from under-represented groups, to attend cardiac rehabilitation will have to be studied further and addressed in order to accommodate all groups of patients equally (Knapton et al., 2009, Thompson, 2002). Especially, the provision of same gender classes and home-based rehabilitation programmes have been suggested to increase attendance amongst under-represented groups such as of ethnic minority patients and women (Chauhan et al., 2010b, Lane and Smith, 2010).

Three major questions have been identified that summarise the issue of improving uptake of cardiac rehabilitation. These include the improvement of patient referral, improvement of patient attendance and adherence as well as maintenance of lifestyle changes and compliance of CR professionals to guidelines and good practice (Beswick et al., 2004).
Another important factor that appears to determine whether people attend CR is patient perception of illness. However, appropriately powered intervention studies will be needed in order to investigate whether an alteration of illness perceptions during Phase 2 cardiac rehabilitation will have a significant effect on attendance (French et al., 2006). Further work is also needed in order to understand in which areas patients lack knowledge about their heart condition and about cardiac rehabilitation (French et al., 2006).

Studies of the cost-effectiveness of cardiac rehabilitation have often been inconclusive and contradictory and many methodologies have been found to have limitations. An urgent need therefore exists to comprehensively investigate cost-effectiveness (Lee et al., 2007) and to include cardiac rehabilitation in tariffs for the management of coronary heart disease (Bethell et al., 2009).

The aim of the literature review conducted during Stage 1 of this scoping exercise was to provide a thorough knowledge base that can inform any further work. This aim has been achieved as the literature review has not only given an overview of publications and information on CR to date but has also identified many areas in cardiac rehabilitation where further research and assessment and subsequently changes to service provision and evaluation could result in improvements for patients, attendance and staff and help to maximise the benefits from the funds available.
3. **Stage 2 - Recommendations for further research**

3.1. **Introduction**

In Stage I of the Scoping Exercise undertaken by Swansea University in cooperation with the Mid and South West Wales Cardiac Network a review of the available literature in the field of cardiac rehabilitation was undertaken in order to determine the information available and to summarise the research conducted to date. Stage 2 of the Scoping Exercise is building on the information gathered previously and will develop recommendations for further research. Since Phase 3 of the CR programme is often regarded as the core of cardiac rehabilitation, it is not surprising that most quantitative and qualitative studies investigating cardiac rehabilitation to date have focused on this stage of CR (e.g. Thompson et al., 1996; Thompson, 2002; Farley et al., 2003; Jolly et al., 2003; Beswick et al. 2004; Paquet et al., 2005; Dalal et al., 2007; O'Driscoll et al., 2007; Jolly et al., 2007; Taylor et al., 2007; Taylor et al., 2010). In particular, this research has been concentrating on exercise during Phase 3 of CR as it has always been a central component of cardiac rehabilitation and it helps to restore patients’ confidence in their bodies and their abilities, increases their general well-being and improves their level of physical activity. Furthermore, it will help to improve cardiac risk factors and therefore contribute to secondary prevention (Thompson et al., 1996).

Another intensely researched area appears to be the reasons for non-attending of patients and the barriers that decrease uptake and adherence (e.g. Cooper et al., 2002; Tod et al., 2002; Farley et al., 2003; Cooper et al., 2007; Hagan et al., 2007; Davies et al., 2010; Kerrins et al., 2010). However, none of the investigated reasons for non-attendance could be identified as a major factor. Instead, patients’ reasons for non-attendance and early drop-out were found to be manifold and highly individual (Jolly et al., 2007, Farley et al., 2003). Also, research focused on comparisons of the costs and benefits of home-based CR versus centre-based cardiac rehabilitation (e.g. Jolly et al., 2003; Dalal et al., 2007; Jolly et al., 2007; Taylor et al., 2007; Taylor et al., 2010).

However, other stages and aspects of CR have not been investigated sufficiently and further research will be necessary in order to improve CR services and outcomes by increasing attendance as well as adherence.
3.2. **Recommendations for further research**

It is crucial that certain areas of cardiac rehabilitation are further investigated in order to gather evidence that can be used to implement changes that may improve service provision. The aim of the recommendations summarised in this chapter is to provide a choice of research projects that would considerably add to the knowledge base about CR and may be used for making informed decisions about beneficial changes to the CR services in Mid and South West Wales. The following recommendations will then be prioritised by members of the Mid and South West Wales Cardiac Network including cardiac nurses, practitioners and cardiologists to ensure that research proposals are developed that will maximise the practical use and meaning of the research undertaken in the future.

3.2.1. **Health economic evaluation of CR**

The limited budget available to healthcare in general means that cardiac rehabilitation does not only have to be clinically effective but also cost-effectiveness needs to be achieved in order to be able to compete for scarce resources (Hall *et al.*, 2002). Several studies of the cost-effectiveness of cardiac rehabilitation have been conducted to date (e.g. Hall *et al.*, 2002; Beswick *et al.*, 2004; Briffa *et al.*, 2005; Denda *et al.*, 2008; Papadakis *et al.*, 2008) but they have often been inconclusive and contradictory and many methodologies have been found to have limitations. An urgent need therefore exists to comprehensively investigate cost-effectiveness (Lee *et al.*, 2007) and to include cardiac rehabilitation in tariffs for the management of coronary heart disease (Bethell *et al.*, 2009). Furthermore, costs of healthcare can vary between countries, regions and even hospitals and results may not always be meaningful or accurate when transferred to other settings.

3.2.1.1. **Cost-effectiveness/cost-consequences analysis**

Since the clinical effectiveness is sufficiently and widely established and documented, data (e.g. number of admissions, length of stay, re-admissions etc.) from National statistics and hospital records can be used to estimate resource use of cardiac patients both attending and not attending CR in South Wales. These data can also help to establish outcomes in order to inform a cost-effectiveness analysis and ICER calculations. Unit costs for resources used can be derived from literature and hospital accounts.
3.2.1.2. **Cost-utility analysis**
This would require patient involvement as utility scores need to be derived from patient questionnaires for CR patients and non-attending patients at the time of hospital discharge (baseline), at completion of CR (and the equivalent time for non-attenders) and after 6 months (times may be subject to further discussion). Utility scores are then converted into QALYs and cost per QALY values can be calculated.

3.2.1.3. **Long-term costs**
Due to cost implications, patient costs and patient follow-up questionnaires can only be collected for a limited period of time. Economic models populated by the data generated in the health economic short-term analysis can be used to generate long-term forecasts of future healthcare costs for patients with and without CR.

3.2.2. **Research into different components of CR**

The exercise component of Phase 3 cardiac rehabilitation has been extensively researched and described. However, other important components (e.g. nutrition and diet, psychological treatment and support etc.) have not experienced the same scientific interest.

3.2.2.1. **The benefits of nutritional counselling**
Several studies have shown that, even though CR has a positive effect on patients’ exercise tolerance, cardiovascular symptoms, blood lipid levels and psychosocial well-being (Taylor and Kirby, 1997, Wenger, 2008, Bethell et al., 2009), there is often no significant change in patients’ BMI. Furthermore, after initial improvement during CR, blood pressure and BMI were found to increase after completion of the cardiac rehabilitation programme (Reid et al., 2005). For this reason it seems important to investigate the benefits of nutritional counselling during CR in order to achieve long-lasting changes in patients’ eating behaviour and therefore help to decrease prevalence of recurrent cardiac illness. Ideally, a randomised controlled trial could investigate the clinical effectiveness of a newly revised nutritional counselling schedule with increased dietician involvement against the existing programme. Outcomes could include lifestyle change (patient questionnaire), short-term and long-term
blood pressure and BMI as well as patient QoL compared in both groups. This study could also include a cost-effectiveness arm if required.

3.2.2.2. **The benefits of psychological counselling**

The third NACR found that while 17 % of cardiac patients were borderline or clinically depressed and 28 % suffered from anxiety, only 3 % were recorded as having received psychological help or counselling (Knapton et al., 2009). Patients exhibiting symptoms of depression have been found to be 5 times more likely to not complete cardiac rehabilitation and mortality is 4 times higher in this patient group compared with non-depressed patients which is why these patients require enhanced support and psychotherapeutic attention (Wenger, 2008, Farley et al., 2003). Furthermore, patients often mention a reluctance/fear to change lifestyles as a reason for not attending CR (Beswick et al., 2004, Dalal et al., 2007) or state that they do not want to dwell on their cardiac problems or do not want to be reminded of their cardiac event which suggest some degree of avoidance or denial (Farley et al., 2003). The evidence suggests that most patients would benefit from counselling sessions as an integral part of CR in order to overcome anxiety, depression and fears, all of which have a negative effect on attendance and consequently health outcomes. A randomised controlled trial could investigate the differences in outcomes between an intervention group of patients receiving psycho-social support as integral part of CR and the control group of patients attending existing CR programmes. Outcomes could include attendance and adherence to CR, patients' QoL and anxiety scores. This study could also include a cost-effectiveness arm if required.

3.2.3. **Research into the improvement of patient uptake**

Significant research efforts have been dedicated towards the question what reasons patients might have for not attending CR (see Chapter 2.5). Considerably less information is available about how interventions could improve patient uptake and thus increase health benefits and outcomes. Patient uptake of CR has been and remains low with only about 18 to 38 % of patients eligible for CR attending the programme in 2007/08 and no increases were found compared to past years (Knapton et al., 2009, Beswick et al., 2004). For this reason a main objective of CR networks and programmes should be to increase patient uptake and reduce as many barriers to attendance as possible. However, considerably more research into the effects of different interventions will be necessary in order to achieve this.
3.2.3.1. **Research into patients’ preferences**

It is well known that factors such as waiting times, accessibility, parking, information and awareness, quality of CR and time and intensity of classes and sessions reduce the rate of patients who will take up a CR programme. However, little is known about how patients prioritise and which thresholds exist (i.e. how long a waiting time is too much for the patient or how long a way would they travel to attend). The knowledge about patient preferences and prioritising could help to improve CR service provision and uptake by allowing service providers to determine and adapt the most important barriers for the patients. This study could either be done as a qualitative patient questionnaire study (open end and closed end questions possible; e.g. how far would you travel to attend CR 3 times a week?) with possible focus groups if necessary or as a Discrete Choice Experiment.

3.2.3.2. **Research into patients’ lack of interest**

According to a recent audit, about a third of the patients not taking part in CR stated to be “too ill”, “having further investigations” or was “physically incapacitated” whereas another third was “not interested” which is worrying considering the benefit these patients could gain from cardiac rehabilitation and that it is a potentially lifesaving intervention (Knaptom et al., 2009). This means that more than 20% of eligible patients have no interest in CR or cannot see any benefit in attending. The reasons for this are unknown and may include lack of knowledge and information, lack of recommendation from GPs and cardiologists and lack of information. It appears important that the reasons for this lack of interest are investigated in order to be able to address potential issues and thus increase CR uptake. This study could be done as a questionnaire, telephone interview and possibly focus group study recruiting patients that have been invited to CR but chose not to take part.

3.2.3.3. **Research into the “special needs” of women**

Women have often been found to attend CR in fewer numbers than men (Knaptom et al., 2009, Thompson et al., 1996, Beswick et al., 2004) although they could also benefit greatly from cardiac rehabilitation (Beswick et al., 2004). Women often mention childcare, housework and family responsibilities as reasons for non-attendance (Tod et al., 2002). Furthermore, women may also be reluctant to participate in predominantly male exercise groups and are often less motivated to do strenuous exercise (Beswick et al., 2004). An
especially designed CR programme for women (e.g. including morning sessions while children are in school, women-only exercise sessions or offering child care) may affect the numbers of women participating in CR positively. A study could develop a “women’s CR programme” by conducting interviews with or sending out questionnaires to women eligible to CR to investigate their priorities and preferences (also by reviewing literature of already existing measure for the improvement of women participation). This CR programme could then be tested in a controlled trial with women of the intervention group being offered and taking part in the newly designed CR programme whereas control group participants would be offered standard CR. Outcome measures could include numbers of women participating in CR as well as QoL and changes in physical parameters such as blood pressure before and after CR compared for both groups. This study could also include a cost-effectiveness arm if required.

3.2.3.4. Research into CR for excluded patients

According to the NACR, the majority of patients taking part in cardiac rehabilitation in 2007/08 were white British males aged between 61 and 70 who had recently been hospitalised because of uncomplicated myocardial infarction or for revascularisation. Women, the elderly, people from ethnic minorities and disabled people have often been found to be referred to and attend CR in fewer numbers than would be expected (Knapton et al., 2009, Thompson et al., 1996, Beswick et al., 2004). Also, frail people and patients with co-morbidities and other heart conditions (e.g. heart failure, angina) have often been found to be excluded from cardiac rehabilitation (Knapton et al. 2009). It has been shown that these patients could gain considerable benefit from CR even though the desired outcomes may vary from “standard” CR patients. For example, in the elderly, needs may differ from younger patients as the preservation of mobility, self-sufficiency, functional independence, prevention and treatment of anxiety and depression as well as mental function is the most important goal of cardiac rehabilitation (Beswick et al., 2004, Wenger, 2008, Piepoli et al., 2010). Especially designed CR programmes could be developed for any of the excluded groups and modified services could be trialled following the short outline in the section above (women’s CR). Also the possibility of in-patient CR for the elderly, frail patients or patients with co-morbidities could be explored. Cost-effectiveness analyses could be included in any study exploring the benefit and implications for CR uptake and adherence of especially designed CR programmes for “excluded” groups.
3.2.4. Research into changes in service provision

3.2.4.1. Research into patient identification and referral

According to a survey, in 2002, 35% of patients discharged from hospital after a cardiac event attended cardiac rehabilitation which equalled 55% of the patients referred or invited to CR (Beswick et al., 2004). This means that less than 65% of eligible patients were referred to cardiac rehabilitation. Also, 60% of patients who had suffered a cardiac event claimed that they were not aware that they were invited to take part in cardiac rehabilitation (Bethell et al., 2009). In the majority of CR services, referral guidelines or criteria are not documented (Smith, 2008). Patient information is often not passed on across healthcare settings and communication between community and hospital CR services is poor. It has therefore been suggested that streamlining and automation of the referral process is of particular importance in order to improve referral rates (Thompson, 2002). A literature review based study could investigate options for referral and identification of CR patients by comparison of systems that are in place in other countries. This could generate ideas and knowledge that could help develop systems for Wales that improve patient identification and increase referral rate and could lead to the development of guidelines and criteria as well as audit and evaluation procedures that could standardise patient identification and referral across Wales.

3.2.4.2. Research into the influence of cardiologist and GP recommendation

Research has shown that encouragement by patients’ cardiologist or GP to attend CR greatly increases uptake of CR (Knapton et al., 2009). In particular, the knowledge and enthusiasm of the patient’s physician have been identified as an important factor that can improve uptake of CR during the referral process. Healthcare professionals thus play an important role in the recruitment of patients to cardiac rehabilitation whereas their contribution highly depends on education, compliance with guidelines and coordination of services. It was suggested that cardiologist may be more likely to refer patients to cardiac rehabilitation than primary care physicians (Beswick et al., 2004). In fact, in a recent study, about 5% of eligible patients were recommended not to attend CR by their GP (Beswick et al., 2004). It is therefore crucial to provide adequate education to physicians and providers about the benefits of CR in order to assist them in conveying the importance of cardiac rehabilitation to the patient (Beswick et al., 2004). Unfortunately, especially physicians and
cardiologist have been found to play a very minor part in cardiac rehabilitation programmes and many services do not have a designated lead consultant cardiologist or GP with a special interest in cardiac rehabilitation (Lane and Smith, 2010, Lewin et al., 1998). A study could therefore investigate the effect of active involvement of GPs in CR and active encouragement to patients to attend on uptake rates of CR. Courses could be offered to participating GPs to increase their knowledge about CR and active recommendations for attendance would be encouraged. The trial could involve intervention surgeries or GPs and control services where no education is given and no further encouragement of patients other than common practice is provided. Outcome measures could include patient uptake of CR, patient anxiety scores and patient satisfaction. This study could also include a cost-effectiveness arm.

3.2.4.3. Research into the use of the internet for home-based CR

Almost half of cardiac patients stated that they would prefer home based rehabilitation programmes with patients over 60 years of age, women and employed patients who perceive time constraints more likely to choose home-based CR (Jolly et al., 2007, Dalal and Evans, 2003, Taylor et al., 2010, Thompson, 2002). However, some patients were worried about exercising on their own and showed reluctance to push themselves due to health concerns and fear of adverse events. Also, lack of motivation to exercise alone and without support was mentioned as a reason for non-adherence (Jolly et al., 2007). In recent years, the use of the internet has been advocated as a mode of delivery for home-based CR in order to deliver interactive cardiac rehabilitation tailored to the patient’s needs where peer support can be provided through disease-specific chat rooms (Thompson, 2002). A study could attempt to develop an internet-based CR programme potentially including an e-learning course to convey information about illness and the effect of lifestyle changes, chat rooms for moral support and to counteract patients’ feelings of isolation, an “Ask your doctor” page for health and CR related questions if patients are concerned about their wellbeing or require further information, a “Frequently asked questions” section and exercise tutorials. Initially, interviews with patients could determine patient preferences and needs which would then enable website development potentially together with other NHS departments and universities working on similar approaches. Once the website is online, patient uptake and participation as well as patient satisfaction and QoL could be recorded for the internet-based CR compared with conventional home-based CR and hospital-based CR. This study would
require a longer time scale for website development and could include a cost-effectiveness arm.

3.2.5. Research into Phase 1 and 2 of CR

Most research to date focussed on Phase 3 as the main component of CR. However, once patients enter into Phase 3 they have already made their decision whether they want to take part in CR or not. A main problem of CR programmes is the poor uptake as according to hospital discharge statistics, only between 22 and 36 % of eligible patients actually attend cardiac rehabilitation in England and Wales (Beswick et al., 2004). More emphasis should therefore be placed on Phase 1 and 2 as these are the stages of CR when patients will decide whether they think CR is important enough to sacrifice time and effort.

3.2.5.1. Research into patient information during Phase 1

Novel, intimidating and often painful experiences accompany a patient’s hospitalisation phase. Together with unpredictable hospital routine, unfamiliar noises, procedures and equipment as well as a lack of control over their own lives and actions, these are a source of anxiety and may challenge a patient's senses and their coping mechanisms (Thomas, 1995). This means that patients are likely to retain only a little percentage of information that they receive in hospital as the whole experience can be overwhelming. Furthermore, the restricted resources available for many cardiac rehabilitation programmes have been found to cause limitations of the time that staff spends with each individual patient. Especially in Phase 1 this can lead to an overload of information for the patient as too much is being conveyed in a short period of time (O’Driscoll et al., 2007). The patient will therefore prioritise and will most likely only retain information concerning their condition as it has been found that immediately after a cardiac event patients thought they needed help in accepting their condition and knowing their limits rather than receiving information about modifying their habits and lifestyles (Paquet et al., 2005). It is therefore conceivable that information regarding Phase 3 and the benefits of participation in CR may not be remembered to a sufficient degree after hospital discharge to encourage uptake. If this is the case, nurse and doctor time spent in hospital informing patients about CR may be a waste of time and resources and this information may better be conveyed in Phase 2 of the CR programme. A questionnaire or interview study could therefore investigate how much and what particular
information patients retain once they are discharged from hospital to determine the amount and content of information that should be conveyed as a priority while patients are in hospital.

3.2.5.2. Research into patient motivation during Phase 2

After hospital discharge, during Phase 2, patients are normally contacted by their cardiac rehabilitation team within 7 days of discharge from hospital to arrange an appointment for further assessment. On this occasion, the patient is encouraged to attend the structured Phase 3 rehabilitation programme (WAG, 2009). The patient is encouraged to take up light exercise guided by educational materials during this convalescent period (Beswick et al., 2004, Jolly et al., 2007). This is the only contact and information the patient will receive during Phase 2. Phase 2, however, is the time when patients will decide upon participation in CR and a considerable chance of patient recruitment is missed by keeping patient contact and information in this stage to a minimum. Attendance and adherence has been shown to be higher in patients who believe in the necessity of the treatment and have fewer concerns about harmful effects (Cooper et al., 2007). In detail, four factors have been identified that influence patient beliefs about a certain treatment. These include the value of the treatment (i.e. the benefit of the treatment in controlling cardiac disease), concerns about the treatment (i.e. anxiety and worries about the treatment), decision satisfaction (i.e. satisfaction with and suitability of the treatment) and cure (i.e. the ability of the treatment to remove the disease) (Hirani et al., 2008). Phase 2 is the optimal time to “shape” patients' beliefs by giving them information about the importance of CR, alleviate concerns and inform about illness and possible consequences of non-attendance. Also, the content of Phase 3 should be addressed as many patients do not participate in Phase 3 as they believe it is an exercise-only programme. It thus appears reasonable that if these beliefs were to be altered towards more patient control and more positive perceptions of their illness during the recuperation period of Phase 2, before patients commence their formal Phase 3 CR programme, uptake and attendance may be increased (French et al., 2006). Furthermore, detailed information and a comprehensive introduction of CR content, purpose, options of individualisation and benefits in Phase 2 may improve Phase 3 attendance as “not interested” and “not for me” have been observed to be the most common reasons mentioned for non-attendance of cardiac rehabilitation (Kerins et al., 2010). Visits and coordination of care by trained liaison nurses and trained lay volunteers during Phase 2 have indeed been shown to improve uptake of CR (Beswick et al., 2004, Davies et al., 2010).
Early after hospital discharge, patients’ motivation to change their lives is highest and their need for support and guidance is greatest due to the anxiety and fear they experience after a life-threatening event (Fridlund, 2002, Paquet et al., 2005). However, an average waiting time of 6 to 8 weeks before commencement of Phase 3 means that this important stage is missed. Appropriately powered intervention studies will be needed to investigate whether an alteration of illness perceptions and a concentration of information and advice during Phase 2 cardiac rehabilitation will have a significant effect on attendance (French et al., 2006). This study could investigate the change in patient uptake of Phase 3 CR after a newly designed Phase 2 containing motivational support and information compared to conventional Phase 2 programmes. Outcome measures could include patient uptake of Phase 3 compared for both groups, patient satisfaction and QoL. This study could include a cost-effectiveness arm.
4. Stage 3 – Prioritisation exercise

4.1. Introduction
The overall aim of the present scoping exercise is to identify areas of research and propose research studies that, once completed, will add important evidence which could be of considerable benefit in the adaptation and modification of CR programmes and services in order to achieve improvements and increase effectiveness. In order to achieve this aim, it is crucial that the recommended research is strongly associated to the day to day practice of cardiac rehabilitation and that results will eventually be applicable to important practical areas and issues of CR.

It was therefore important to undertake a prioritisation exercise by asking health care professionals involved in the Mid and South West Wales Cardiac Network who deal with the reality of cardiac rehabilitation on a daily basis to share their opinions of the proposed research studies and to evaluate the importance they place on each study recommended in Chapter 3.

4.2. Methodology
A prioritisation questionnaire was specifically designed by the South Wales Cardiac Network (see Appendix). This questionnaire contains the titles of the recommended research projects and the 5 overall groups they are divided into and asks participants to score the main 5 groups as well as the projects within each group according to their priorities and their opinions of the importance of each topic and proposed project. Topics and projects were scored from 1 to 4 with 1 being highest priority and 4 being lowest priority. Participants were also asked to give a rational for their choices or to comment. Every member of the South Wales Cardiac Network who filled in the questionnaire was asked to read the research recommendations (see Chapter 3.2) prior to completion of the questionnaire and to return the questionnaire by a given deadline.

After the deadline, scores of all received questionnaires were recorded in MS Excel 2010 for overall prioritisation of the 5 categories and prioritisation of all 14 recommended research projects. Scores where then converted into points (score 1 = 4 points; score 2 = 3 points; score 3 = 2 points; score 4 = 1point) and the sum of all points for each topic and each project were calculated. Topics and projects were then scored from highest to lowest number of points received.
4.3. Results of prioritisation exercise

The prioritisation questionnaire was returned by nine members of the South Wales Cardiac Network including nurses and cardiologists from all areas of South Wales.

Table 1 shows how the respondents scored the research categories/topics.

<table>
<thead>
<tr>
<th>Respondent</th>
<th>Prioritisation scores</th>
<th>Conversion into points</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>9</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

According to the overall prioritisation scores of the general topics (Table 1), respondents thought that research into changes in the service provision of CR and health economic evaluations were most important, followed by research into patient information needs in Phase 1 and 2 of CR.

Rationales and comments for this choice included:

“I have chosen ‘Research into changes in service provision’ as first choice as it would be an important and worthwhile area of study possibly leading to timely, appropriate interventions by cardiologists and other medical doctors which could be easily incorporated into regular practice”
“Evidence for the cost benefit of CR is vital in the current climate. A study showing how CR reduces hospital re-admission rates would certainly make managers more interested in the service.”

“Clearly identifying what information should be given at Phase 1 and 2 would help standardise care and ensure that time is not wasted giving patients information that they don’t want or retain.”

“Research into different components of CR’ and ‘Research into improvement of patient uptake’: there is research into these elements of CR already.”

Table 2 illustrates the prioritisation of the individual research projects (converted into points) of all nine respondents.

<table>
<thead>
<tr>
<th>Respondents</th>
<th>a</th>
<th>b</th>
<th>c</th>
<th>d</th>
<th>e</th>
<th>f</th>
<th>g</th>
<th>h</th>
<th>i</th>
<th>j</th>
<th>k</th>
<th>l</th>
<th>m</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>3</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>9</td>
<td>3</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Points</th>
<th>38</th>
<th>27</th>
<th>25</th>
<th>24</th>
<th>25</th>
<th>23</th>
<th>15</th>
<th>18</th>
<th>30</th>
<th>31</th>
<th>18</th>
<th>27</th>
<th>27</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Rank</td>
<td>1</td>
<td>4</td>
<td>7</td>
<td>10</td>
<td>7</td>
<td>11</td>
<td>14</td>
<td>12</td>
<td>3</td>
<td>2</td>
<td>12</td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>
As apparent from the prioritisation point scores of all 14 proposed research projects, the projects respondents put most importance on are the cost effectiveness/cost consequences analysis, research into patient identification and referral and into the influence of cardiologist and GP recommendation of CR as well as cost-utility analysis. Also, research into patient information in Phase 1 and patient motivation in Phase 2 was prioritised. In contrast, respondents considered research into women’s participation and excluded patients as well as the development and testing of internet based CR as least important.

4.4. Conclusions of the prioritisation exercise
The prioritisation exercise identified 6 projects that were clearly prioritised by the respondents. These projects are:

1. Cost-effectiveness/cost-consequences analysis of CR services in Mid and South West Wales
2. Research into the influence of cardiologist and GP recommendation on patient participation in Phase 3 cardiac rehabilitation
3. Research into suitability and efficacy of patient identification and referral to CR
4. Cost-utility analysis of CR services in Mid and South West Wales
5. Research into availability and suitability of patient information during Phase1, information retention and influence on Phase 3 participation
6. Research into the influence of enhanced patient motivation, support and information during Phase 2 on Phase 3 participation and patient and carer anxiety and quality of life
5. Stage 4 - Drafts for research proposals for the 6 prioritised projects

5.1. Introduction
As discussed in chapter 1.1, the scoping exercise has been divided into 5 stages comprising the scoping literature review (Stage 1), recommendations for further research (Stage 2), prioritisation of research recommendations (Stage 3), development of research proposals (Stage 4) and dissemination of results (Stage 5). Stages 1 to 3 have been reported in the previous chapters. The following chapter will address Stage 4 by developing research proposals for the 6 projects prioritised during Stage 3. Every proposal is designed to be a draft for submission to a funding body and is therefore developed as a stand-alone piece. Due to this fact, information and certain passages of the literature review will be repeated in one or more proposals to allow potential funders to understand the background as well as the need and impact of the proposed study.

Research proposals for the following prioritised studies (see Chapter 4) are presented and described in the following chapter:

1. Cost-effectiveness/cost-consequences analysis of CR services in Mid and South West Wales (chapter 5.2.2)
2. Research into the influence of cardiologist and GP recommendation on patient participation in Phase 3 cardiac rehabilitation (chapter 5.3)
3. Research into suitability and efficacy of patient identification and referral to CR (chapter 5.4)
4. Cost-utility analysis of CR services in Mid and South West Wales (chapter 5.2.3)
5. Research into availability and suitability of patient information during Phase 1, information retention and influence on Phase 3 participation (chapter 5.5)
6. Research into the influence of enhanced patient motivation, support and information during Phase 2 on Phase 3 participation and patient and carer anxiety and quality of life (chapter 5.6)
5.2. Cost-effectiveness of cardiac rehabilitation services in Mid and South West Wales

5.2.1. Introduction

Like all healthcare interventions and programmes, cardiac rehabilitation (CR) is faced with limited budgets and recent budget cuts put pressure on programmes to not only prove that they are clinically effective but also that they are cost-effective in order to be able to compete for scarce resources (Hall et al., 2002). Several studies of the cost-effectiveness of cardiac rehabilitation have been conducted to date (e.g. Hall et al., 2002; Beswick et al., 2004; Briffa et al., 2005; Dendale et al., 2008; Papadakis et al., 2008) but they have often been inconclusive and contradictory and many of the methodologies employed have been found to have limitations. For example, cardiac rehabilitation has been found to be highly cost-effective by several studies (Fidan et al., 2007, Papadakis et al., 2008, Lane and Smith, 2010, Lee et al., 2007, Yu et al., 2004, Bennett et al., 2009) while other studies found only non-significant, small improvements in patient’s quality of life but supported the provision of CR due to the low cost (Briffa et al., 2005). One study, however, could not confirm cost-savings and improvements in quality of life and suggested that CR was therefore unnecessary for low risk patients and should be directed to higher risk patients instead (Hall et al., 2002).

Furthermore, cost has been found to vary significantly between different programmes according to format of delivery (home-based versus centre-based CR) and staffing level and programme costs between £185 and £567 per patient have been reported (Beswick et al., 2004, Knapton et al., 2009, Taylor et al., 2007, Lane and Smith, 2010, Bethell et al., 2006, Bethell et al., 2009). Also different cost-effectiveness values have been found when programmes were delivered to different patient groups (Papadakis et al., 2008).

Furthermore, costs of healthcare can vary between countries, regions and even hospitals and results may not always be meaningful or accurate when transferred to other settings. An urgent need therefore exists to comprehensively investigate cost-effectiveness of CR (Lee et al., 2007) and to include cardiac rehabilitation in tariffs for the management of coronary heart disease (Bethell et al., 2009).
5.2.2. Cost effectiveness and cost consequences analyses

The investment in CR for coronary patients has been shown to have several benefits including reduced mortality and increased cardiac patients’ quality of life (Knapton et al., 2009). Furthermore, attendance and completion of a CR programme improves exercise tolerance, cardiovascular symptoms, blood lipid levels and psychosocial well-being and reduces cigarette smoking, stress, recurrent myocardial infarction and the requirement for revascularisation procedures (Taylor and Kirby, 1997, Wenger, 2008, Bethell et al., 2009). Cardiac rehabilitation therefore improves patients’ physical fitness, decreases coronary risk factors, positively influences psychological health and wellbeing and quality of life and improves prognosis (Bethell et al., 2008). Regular exercise also decreases heart rate as well as systolic and diastolic blood pressure and improves aerobic capacity (Wenger, 2008). Reductions in unplanned hospital stays and reduced length of stay have been reported together with reduced complications and fewer readmissions (Lane and Smith, 2010). All of these benefits of CR have to be weighed up against the cost of CR and potential adverse events in order to establish whether CR offers cost-effective prevention of cardiac events.

5.2.2.1. Aims and objectives

The aim of the study is to investigate the cost-effectiveness of cardiac rehabilitation in South Wales.

Specific objectives are as follows:

- To assess the cost per patient of CR provision in the CR centres of the Mid and South West Wales Cardiac Network
- To assess healthcare resource use of cardiac patients attending CR between the cardiac event the end of follow-up or death
- To assess healthcare resource use of cardiac patients not attending CR between the cardiac event the end of follow-up or death
- To assess health outcomes of cardiac patients attending CR between the cardiac event the end of follow-up or death
- To assess health outcomes of cardiac patients not attending CR between the cardiac event the end of follow-up or death
- To assign costs to all resources used for CR and non-CR patients
- To compare costs and health outcomes of patients attending and those not attending CR
5.2.2.2. Study design and method

The proposed study is an observational study from a healthcare perspective using retrospective cardiac patient data from the last 6 years to examine and compare healthcare resource use, health outcomes and mortality of cardiac patient in South Wales who attend and do not attend CR, respectively. The study will be run over 2 years and will follow up retrospective patient data from the initial cardiac event (myocardial infarction, CABG or revascularisation) for 24 months or until death. Furthermore, running costs of CR centres of the Mid and South West Wales Network will be collected to calculated cost per patient.

a. Cardiac rehabilitation cost per patient

In order to assess the cost of CR per patient (invited, started and completed), a micro-costing exercise will be undertaken including scrutiny of financial records of consenting CR centres and structured interviews managers and key staff. Resource use and cost of running each centre will be determined by including staff resources (staff number and time, source of funding and skill mix), training, consumables, overheads and capital as well as other costs.

b. Collection of retrospective patient data

Retrospective cardiac patient data will be collected using the SAIL and CVRG-C databases which contain detailed information of healthcare resource use and outcomes for cardiac patients. Additionally, national statistics, PEDW and hospital records (where possible) will be searched. Data collected will include hospital admissions, length of stay, inpatient procedures, outpatient appointments, GP visits, A&E visits and readmissions as well as blood pressure values, cholesterol levels and BMI (if possible). Also, mortality rates will be recorded. All outcome parameters (blood pressure, cholesterol, BMI, death) will be collected at baseline (hospital discharge after initial cardiac event or procedure), after 6 months, at 12 months and at 24 months. Resource use will be added up for the whole 2 year follow-up period or until death. Unit costs will be allocated to resource use using published literature, routine data sources and NHS reference costs.

Eligibility for participation

Every CR centre of the Mid & South West Wales Network consenting to scrutiny of financial records and the interview process is eligible for participation.
Cardiac patients admitted to hospitals in South Wales for myocardial infarction, CABG or revascularisation within the last 6 years whose data is available in the SAIL and CVRG-C databases (anonymised) are eligible to be added to the evaluation.

**Ethical approval**
Ethical approval will be sought from the National Research Ethics Service (NRES). R&D approval will be sought from the appropriate NHS Health Boards in the Mid and South West Wales area.
The study does not require patient interaction or contact. However, confidential financial and patient information needs to be searched.

### 5.2.2.3. Use of resources

**Staff:** a principal investigator (Grade 8; 0.5 FTE over 24 months) will take responsibility for the day to day running of the study, organise and conduct financial searches and interviews, oversee the data extraction from the patient databases and perform data analysis and reporting.

A researcher (Grade 6/7, 0.5 FTE over 24 months) will conduct patient data extraction from the databases and assist with data analysis and reporting.

A senior health economist (Professorial, 0.04 FTE over 24 months) will provide advice and support throughout the project and supervise data collection, health economic analysis and reporting.

Additionally, interviewees may have to be reimbursed for their time.

**Travel:** The coordination of the interviews in several CR centres in Mid and South West Wales will require the principal investigator/researcher to travel to and from the different interview locations on a regular basis.

**Consumables:** This includes printing of interview schedules as well as consent and information forms. Also, participant feedback about the study results will be provided to those CR centres who request it.

**Other costs:** Other costs will include charges for SAIL and CVRG-C database access and dissemination costs (e.g. conference fees).
5.2.2.4. Method of analysis

a. Cardiac rehabilitation cost per patient

All resources used will be tabulated in Microsoft Excel and costs will be attached to each resource. For each CR centre, running cost per year and cost per patient invited, cost per patient starting and cost per patient completing CR will be calculated using Excel. Also, the mean cost (including standard deviation and 95% confidence intervals) of CR per year and cost per patient invited, cost per patient starting and cost per patient completing CR in South Wales will be calculated from results of all CR centres.

b. Analysis of retrospective patient data

Cardiac patients for whom healthcare resource use and outcome data have been collected will be divided in 2 groups comprising patients who were invited and attended CR (intervention) and patients who were invited but did not attend CR (control). Costs will be attached to all resources used and cost of treatment for each patient will be calculated in Microsoft Excel. Mean costs (standard deviation and 95% confidence interval) will be calculated for both groups (CR and no CR) and independent-samples t-tests (if data is continuous, normally distributed) or non-parametric Wilcoxon signed-rank test (in case of non-normal distribution) will be applied to compare proportions and means of healthcare cost with 0.05 as the level of statistical significance and a 95% confidence interval around point estimates.

Mean outcome figures will be calculated for each group and for each follow-up point within groups and will compared using independent-samples t-tests (if data is continuous, normally distributed) or non-parametric Wilcoxon signed-rank test (in case of non-normal distribution) with 0.05 as the level of statistical significance and a 95% confidence interval around point estimates both between groups as well as within groups for all follow-up points. Descriptive analyses will be used to describe participating patients in terms of age, gender, nature of cardiac event/procedure and co-morbidities. Sub-group analyses will explore the effect of co-morbidities, nature of cardiac event/procedure, age and gender on the results. All quantitative data analysis will be done using SPSS.

A cost-consequences analysis table will be compiled to visually compare costs and consequences (outcomes) of CR. Additionally, incremental cost-effectiveness ratios (ICERs) will be calculated in a cost-effectiveness analysis to establish cost per life saved as well as cost per blood pressure, cholesterol and BMI improvement.
A series of univariate sensitivity analysis will address any uncertainty attached to certain parameters (e.g. the use of mean costs etc.) and examine sensitivity of the results of the economic evaluation to assumptions made. A probabilistic sensitivity analysis will be undertaken to determine the probability that CR can be regarded as a cost-effective intervention relative to accepted thresholds for society’s willingness-to-pay for specific health outcomes.

5.2.2.5. Expected outcomes

- **Cost of CR**
  Searching of financial record of CR centres of the Mid & South West Wales Cardiac Network as well as interviews with managers and key staff will allow the detailed calculation of the cost of cardiac rehabilitation in South Wales. Outcomes of this stage of the project will include cost of CR per centre per year, mean cost of CR in South Wales and cost of CR per patients.

- **Difference of healthcare resource use and cost of cardiac patients attending and those not attending CR**
  Collection of healthcare resource use data and costs for patients in both groups will allow comparison of costs to the NHS for patients attending and patients not attending CR.

- **Difference in health outcomes and mortality of cardiac patients attending and those not attending CR**
  Collection of patient outcome data (including mortality) for patients in both groups will allow comparison of health outcomes for patients attending and patients not attending CR and will allow tracking of changes in outcomes for patients over the follow-up period.

- **Cost-effectiveness of CR**
  The analysis of healthcare resources/costs against the outcomes achieved will allow the calculation of ICERs which will give an indication of the cost-effectiveness of CR in South Wales.
5.2.2.6. Impact and dissemination

Positive results regarding the cost-effectiveness of CR and the potential for the healthcare system to save money may encourage investment in CR services in South Wales which could enable expansion of the program, improvements to the service and better planning of service delivery. This could ultimately increase health and wellbeing of cardiac patients and increase patient quality of life while reducing their healthcare resource use.

Possible publications may include:
- The cost of cardiac rehabilitation in South Wales
- Cost-effectiveness of cardiac rehabilitation in South Wales
- The effects of cardiac rehabilitation on health outcomes and mortality of cardiac patients in South Wales

5.2.2.7. Proposed project timetable

Months 1 - 3:
Post funding decision develop detailed study protocols, develop interview schedules and apply for SAIL and CVRG-C database access. Recruit staff and obtain ethical and R&D approvals.

Months 3 - 12:
Individual interviews with CR centre managers and key staff, scrutiny of CR centre financial information.

Months 6 – 18
Data collection of healthcare resource use and outcomes of cardiac patients from the SAIL and CVRG-C databases.

Months 12-19
Costing of healthcare resources used by cardiac patients.

Months 20 – 24
Data cleaning, analysis, health economic evaluation and report preparation/publication
5.2.3. Cost utility analysis
The cost-utility analysis can be run alongside the cost-effectiveness analysis. In this way, cost of CR could be used as calculated from scrutiny of financial records of CR centres and interviews with CR centre staff and managers as described in chapter 5.2.2. Utility scores will need to be derived from literature and through patient questionnaires.

5.2.3.1. Aims and objectives
The aim of the study is to investigate the cost per QALY gained through cardiac rehabilitation in South Wales.

Specific objectives are as follows:
- To review the literature for quality of life scores/gains of cardiac rehabilitation
- To assess the quality of life of cardiac patients attending CR at hospital discharge and 6 and 12 months after hospital discharge
- To assess the quality of life of cardiac patients not attending CR at hospital discharge and 6 and 12 months after discharge
- To calculate QALYs for both groups (CR and no CR) at all data collection points (discharge, 6 and 12 months)
- To compare QALY changes of patients attending and those not attending CR both between and within groups

5.2.3.2. Study design and method
The proposed project will include a systematic literature review and a questionnaire study. The project will be run over 24 months in the catchment area of the CR centres of the Mid and South West Wales Network.

a. Systematic review of literature
This stage of the study will address objective 1 and will encompass following sub-objectives:
- Developing a search strategy
- Reviewing UK and international literature as well as government documents and statistics dealing with quality of life scores of cardiac
patients, QALY changes from hospital discharge to end of follow-up and QALY/QoL differences between cardiac patients attending and those not attending CR

Electronic databases (Pubmed, Medline (Ovid), The Cochrane Library, Embase) as well as archives and current issues of the most important journals in the field (BMJ, Heart, European Journal of Cardiovascular Nursing, etc) and the homepage of the Department of Health will be searched for English language publications that either report original data on cardiac patient quality of life and QALYs or review the available literature. No date cut-offs will be applied in the initial search. A search strategy will be developed which will include various subsets of keywords and MeSH headings including “cardiac rehabilitation”, “quality of life”, “QALY”, “rehabilitation service”, and others. Abstracts of all identified publications will be scanned for suitability according to the agreed inclusion/exclusion criteria. Included publications will be obtained. In order to identify additional publications, bibliographies of all papers included in the scoping review will be hand searched. All publications included in the final review will undergo detailed data extraction to inform the cost-utility analysis.

b. Patient questionnaire study
Cardiac patients eligible for CR will be identified through the CR network and contacted after hospital discharge with the invitation of taking part in the questionnaire study. After informed consent has been given, patients will receive a copy of the SF-12 and EQ-5D questionnaires in the post together with a prepaid envelope in order to collect baseline data. Patients will not be randomised as it will be their own decision whether they wish to attend CR or not. Patients will be sent a further set of QoL questionnaires at 6 and 12 months after hospital discharge together with a short questionnaire asking about whether they attended and/or completed CR and how satisfied they were with it at the 6 month follow-up point. Patients who have not responded to the questionnaires after 2 weeks will be sent reminders. Patients who have not responded after 4 weeks will be phoned to remind them.

Eligibility for participation
Every cardiac patient identified by the Mid & South West Wales Cardiac Network as eligible for cardiac rehabilitation who speaks English well enough to answer the questionnaires and does not suffer from severe physical or mental illness will be included in the study.
Ethical approval

Ethical approval will be sought from the National Research Ethics Service (NRES). R&D approval will be sought from the appropriate NHS Health Boards. As the intervention will not include an exercise component, the risks to patients are minimal. All interactions with patients will be delivered by appropriately trained research staff.

5.2.3.3. Use of resources

**Staff:** a principal investigator (Grade 8; 0.3 FTE over 24 months) will take responsibility for the day to day running of the study, oversee patient recruitment and questionnaire distribution and perform data analysis and reporting.

A researcher (Grade 6/7, 0.5 FTE over 24 months) will be responsible for patient recruitment through liaison with the Cardiac Network, sending of information packs, obtaining informed consent and sending/phonning reminders to participants as well as assist with data analysis and reporting.

A senior health economist (Professorial, 0.04 FTE over 24 months) will provide advice and support throughout the project and supervise data collection, health economic analysis and reporting.

**Travel:** The coordination of patient recruitment and data collection in the catchment areas of CR centres in Mid and South West Wales will require the principal investigator/researcher to travel to and from the different CR centres on a regular basis.

**Consumables:** This includes printing of the questionnaires as well as consent and information forms. Also, participant feedback about the study results will be provided to those patients who request it.

**Other costs:** Other costs will include fees for SF-12 license and dissemination costs (e.g. conference fees).
5.2.3.4. Method of analysis

a. Systematic review of literature
Publications that are included in the systematic review will be analysed separately and relevant data will be extracted according to standard guidelines.

b. Questionnaire study
Health related quality of life scores at baseline and both follow-up points for all patients will be converted into QALYs using SPSS. Patients will then be divided into 2 groups (CR and no CR) according to their answers provided to the CR attendance questionnaire at follow-up 1 (6 months). Mean QALY scores (plus standard deviation and 95 % confidence interval) for both groups will be calculated and compared using independent-samples t-tests (if data is continuous, normally distributed) or non-parametric Wilcoxon signed-rank test (in case of non-normal distribution) with 0.05 as the level of statistical significance and a 95 % confidence interval around point estimates. All quantitative data analysis will be done using SPSS.

Mean QALY difference between the patients attending and those not attending CR and cost of CR (derived from analysis described in chapter 5.2.2) will be used to do a cost-utility analysis and calculated cost/QALY of CR. A series of univariate sensitivity analysis as well as probabilistic sensitivity analysis will address any uncertainty attached to certain parameters (e.g. the use of mean costs etc.), examine sensitivity of the results of the economic evaluation to assumptions made and determine the probability that CR can be regarded as a cost-effective intervention relative to accepted thresholds for society’s willingness-to-pay for specific health outcomes.

5.2.3.5. Expected outcomes

• Health related quality of life of cardiac patients attending and not attending CR
Main outcome of the questionnaire study will be a measure of the quality of life a cardiac patients who attend and do not attend CR, respectively between hospital discharge and 12 months follow-up.
• **Difference in quality of life of cardiac patients attending and those not attending CR**
  Comparison of the quality of life scores of cardiac patients who attended and those who did not attend CR will allow the assessment of the effect of CR on patients’ quality of life.

• **Cost per QALY of CR**
  The results of the cost-utility analysis will allow the calculation of the cost of CR per quality adjusted life year gained.

### 5.2.3.6. Impact and dissemination
Positive results regarding the cost-utility of CR and the potential of being cost-effective considering the NICE threshold of £20,000/QALY may encourage investment in CR services in South Wales which could enable expansion of the program, improvements to the service and better planning of service delivery. This could ultimately increase health and wellbeing of cardiac patients and increase patient quality of life while reducing their healthcare resource use.

Possible publications may include:

- Cost-utility analysis of cardiac rehabilitation in South Wales
- The effects of cardiac rehabilitation on quality of life of cardiac patients in South Wales
5.2.4. Proposed project timetable

Months 1 - 3:
Post funding decision develop detailed study protocols, obtain SF-12 license and develop CR participation questionnaire. Recruit staff and obtain ethical and R&D approvals.

Months 4 - 9:
Patient recruitment and baseline questionnaires (SF-12 and EQ-5D). Postal reminder after 2 weeks without response, phone reminder after 4 weeks of no response.

Months 10 – 15
Follow up 1 at 6 months (SF-12, EQ-5D and CR participation). Postal reminder after 2 weeks without response, phone reminder after 4 weeks of no response.

Months 16 - 21
Follow-up 2 at 12 months (SF-12 and EQ-5D). Postal reminder after 2 weeks without response, phone reminder after 4 weeks of no response.

Months 20 – 24
Data cleaning, analysis, cost-utility analysis and report preparation/publication
5.3. The influence of GP and cardiologist recommendation on participation and adherence rates of Phase 3 cardiac rehabilitation

5.3.1. Introduction
In the early 1990s, it was suggested that the general practitioner could be an effective educator in the prevention of coronary heart disease and that one-on-one consultations with a GP are an effective and cost-effective method of patient health education (Calnan and Williams, 1993, Calnan, 1995). Furthermore, more recent research has shown that encouragement by patients’ cardiologist or GP to attend CR greatly increased uptake of Phase 3 CR (Knapton et al., 2009). Phase 3 (structured exercise and information) participation plays a crucial role in the reduction of recurrent cardiac events in patients with cardiovascular disorders by decreasing risk factors such as high blood pressure, high cholesterol level, obesity and smoking. This will ultimately lead to reduced health care resource use, increased vitality and independence (especially in older patients) and improved quality of life. However, only 35% of cardiac patients participated in Phase 3 CR in Wales in 2008/09 (NACR, 2010). Studies have shown that patient information and encouragement during the early stage of CR can significantly increase Phase 3 participation as well as improve clinical outcomes and quality of life (Beswick et al., 2004, Davies et al., 2010). In particular, the knowledge and enthusiasm of the patient’s physician have been identified as an important factor that can improve uptake of CR during the referral process. Healthcare professionals thus play an important role in the recruitment of patients to cardiac rehabilitation whereas their contribution highly depends on their education, knowledge and training, compliance with guidelines and coordination of services. Thus, it was suggested that cardiologist may be more likely to refer patients to cardiac rehabilitation than primary care physicians (Beswick et al., 2004). In fact, in a recent study, about 5% of eligible patients were recommended not to attend CR by their GP (Beswick et al., 2004). It is therefore crucial to provide adequate education and information about the benefits of CR to physicians and providers in order to assist them in conveying the importance of cardiac rehabilitation to the patient (Beswick et al., 2004). Unfortunately, especially physicians and cardiologists have been found to play a very minor part in CR programmes and many services do not have a designated lead consultant cardiologist or GP with a special interest in cardiac rehabilitation (Lane and Smith, 2010, Lewin et al., 1998). Moreover, the key interventions for the provision of cardiac rehabilitation in Wales do not mention the general practitioner as integral part of the CR process (WAG, 2009) even though the integration of
CR across primary and secondary care has been advocated and failure to do so has been associated with a detrimental effect on patient care (Cleland et al., 2011, Dalal et al., 2011). It is therefore of major importance to actively involve general practitioners in the process of patient information and encouragement in order to increase patient uptake of Phase 3 CR and ultimately improve patients clinical outcomes, quality of life and anxiety scores.

5.3.2. Aims and objectives

Phase 3 CR is a structured programme consisting of exercise and information sessions and is often regarded as the core of cardiac rehabilitation. Non-attendance of Phase 3 cardiac rehabilitation (i.e. not attending on the first day of the programme after initially enrolling) and non-completion of programmes results in poorer patient health, increased waiting times and waste of resources (Kerins et al., 2010). When patients are discharged from hospital, they start to prioritise and conceptualise and will choose whether to attend CR on the basis of whether they consider it more important than their daily routine or work and family commitments (Hagan et al., 2007). Attendance and adherence is thereby higher the stronger patients believe in the necessity of the treatment and the fewer concerns they have about harmful effects (Cooper et al., 2007). Also, patients who strongly believe that their condition is controllable and curable and understand that it may be associated with serious consequences are significantly more likely to attend cardiac rehabilitation (French et al., 2006). Information, encouragement and a clear recommendation of a patient’s GP or cardiologist to attend cardiac rehabilitation could therefore significantly increase patient uptake of Phase 3 CR. However, it was found that the involvement of GPs in preventative care depends on their knowledge and training in the subject area. Furthermore, patient compliance with the recommendations is associated with patient satisfaction and confidence in the advice and thus with the practitioner’s communication skills and the ability to convey relevant information in a way the patient can understand and relate to (Calnan and Williams, 1993).

The aim of the proposed study is to investigate the effect of active involvement of GPs in patient information about the importance on CR and active encouragement of patients to attend on uptake rates of Phase 3 CR, patient quality of life, anxiety and patient satisfaction.

Specific objectives are as follows:

1. To assess GP information and training needs regarding cardiac rehabilitation in order to be able to actively recommend participation to cardiac patients
2. To assess health professionals' opinions on the information patients may need to encourage their participation in Phase 3 CR
3. To assess patients’ information needs after a cardiac event and the support they would expect from their GP
4. To develop a GP training and information program that will enable them to confidently and actively encourage Phase 3 CR participation
5. To provide GPs with the training and information they require to actively encourage their patients’ participation in CR
6. To investigate the effect of GP recommendation on patient participation in Phase 3 CR
7. To investigate the effect of GP recommendation and information on patient anxiety, quality of life and patient satisfaction with and opinion of CR
8. To assess the cost-effectiveness of GP training that will enable them to actively recommend CR to their patients

5.3.3. Study design and method
The proposed study will run over 3 years and comprise 3 separate stages including information needs assessment and intervention development, pilot testing and amendment of intervention (if necessary) and the main trial which will be testing the GP training and information intervention in routine care against standard information given to cardiac patients by control GP practices.

a. Information and training needs assessment and intervention development:
This stage of the study will address objectives 1 to 4 and will encompass following sub-objectives:

- Exploring the knowledge and training/information needs of GPs regarding CR
- Exploring GPs, CR nurses and cardiologists opinions of patient information needs to encourage Phase 3 participation
- Exploring the quality and quantity of information and support patients need after a cardiac event to encourage them to participate in Phase 3 CR
• Inviting suggestions for improving patient experience and uptake of Phase 3
• Gathering information on health professionals’ opinions on feasibility and acceptability of possible GP training and information sessions
• Assessing standard information and support given to patients by their GPs after a cardiac event
• Develop most appropriate and acceptable training and information intervention according to results of data gathering and exploration exercise

The intervention development stage will commence with a 6-month qualitative exploratory study using individual semi-structured interviews with GPs, health professionals involved in CR, cardiologists and patients in Mid and South West Wales. This will assist in the formulation and design of an intervention that will address GPs training needs, seems feasible in the context of routine primary care and is acceptable to both patients and health professionals.

General practitioners from several surgeries in the Mid and South West Wales area (n=15) will be interviewed in order to assess their information and training needs.

Open-ended questions on following topics will be included in the interviews:

• Description of current standard CR information giving on a daily basis to cardiac patients by GPs (including topics covered, length and number of sessions etc.)
• Views on the standard of GP education regarding CR and main knowledge gaps
• Opinion of what training and information would be required in order to be able to confidently and actively recommend CR to cardiac patients
• Views on patient needs after a cardiac event and how current service delivery addresses those needs
• Views on how information delivery could be improved in regards to patient quality of life, anxiety and participation in Phase 3
• Views on the value of the planned intervention
• Views on the acceptability and feasibility of the intervention in the context of day-to-day running of the surgery in a routine primary care environment, budget and staffing
Suggestions of most important topics that should be covered as part of the GP training and information sessions

Any other comments, things they may wish to add

Demographic data

Views on the interview process

Different health professionals involved with routine cardiac rehabilitation (n=10) will be interviewed in order to assess information needs of patients after a cardiac event.

Open-ended questions on following topics will be included in the interviews:

- Views on patient needs after a cardiac event and how current service delivery addresses those needs
- Views on how information delivery could be improved in regards to patient quality of life, anxiety and participation in Phase 3
- Opinions and experiences on why patients chose not to participate in Phase 3
- Views on the value of the planned intervention
- Suggestions of most important topics to be covered as part of GP patient information in order to encourage patients to participate in Phase 3 CR
- Any other comments, things they may wish to add
- Demographic data
- Views on the interview process

Furthermore, eligible patients (cardiac patients discharged from hospital who attended at least on follow-up appointment with their GP without severe illness and severe mental health problems who consent to participating; n = 15) will be invited to take part in the evaluation of information needs by a study nurse. Patients who give permission will be interviewed to assess patient information needs in primary care as well as their understanding and prioritisation of CR.

Open-ended questions on following topics will be included in the interviews:

- Explanation of the purpose of the study and the interview
- Assessment of the patient’s cardiac knowledge and information needs
- Assessment of support needs (e.g. to deal with anxiety, isolation etc.)
- Satisfaction with the information and support received from their GP
- Opinion on the recommendation received from their GP
b. Pilot testing:

Once a suitable intervention has been designed and approved by the members of the advisory group, it will be tested on 30 cardiac patients in 2 GP surgeries in South Wales. Consenting GPs will receive the intervention developed in conjunction with GPs, CR professionals and patients (e.g. information materials or training sessions provided to GPs). They will then advise 30 cardiac patients who consent to taking part in the pilot study according to their knowledge and views of CR after receiving the intervention information. GPs will then be interviewed to assess their opinion on the usefulness of the intervention as well as feasibility within their routine practice and feedback from patients.

After participating cardiac patients have received information from their GPs they will be interviewed as described in stage 1 (Information and training needs assessment and intervention development) to assess their satisfaction with the information provided, their views and opinions of the intervention, what priority they assign to CR and the probability of them taking part in Phase 3 CR. GPs and patients will also have the opportunity to suggest improvements and point out areas where they felt amendments could be made.

At the end of stage one, the intervention information will be amended (if necessary) based on the results of the pilot study and qualitative feedback of the participants.

c. Main trial:

The main trial will be run over a total of 18 months (3 month planning, 10 month recruitment, 5 months analysis). The intervention that was developed and pilot tested in the first two stages of the trial will be tested in GP surgeries in South Wales in a multi-centre randomised,
controlled trial. GPs will be sent a trial information pack and will have the chance to ask questions. Consenting GPs will be randomised into 2 groups on a 1:1 basis of which one will receive the information intervention aimed at providing them with the knowledge and confidence they need to actively recommend CR to their cardiac patients whereas the control group will not receive any further information. English speaking cardiac patients eligible for GP follow-up after hospital discharge with no severe illness, co-morbidities or mental illness will be invited by the practice nurse to take part in the main trial. Patients will receive an information leaflet and the practice nurse will explain the study and answer questions. After informed consent has been given, baseline data (including demographics, anxiety scores and level of cardiac knowledge) is collected and the patient is then treated and advised by their GP. Whether the patient is in the intervention or control group will depend on the randomisation state of their GP practice. The intervention group will receive advice from a GP who participated in the intervention information designed in stage 1 of the trial. The nature of this intervention (quantity and quality of the received information) cannot be specified as it will depend on the stage 1 results and the input of the advisory group. The control group will receive standard information from their GP. After their first GP appointment, the first set of follow-up data is collected (F1) by the study nurse including information on patient anxiety and cardiac knowledge. A second set of follow-up data (F2) is recorded 8 weeks after the first GP appointment (Phase 3 CR should have begun for the patient at this point) and a further data-set (F3) will be collected 20 weeks after hospital discharge to gain information on whether patients completed Phase 3 CR. Questionnaires of follow-up 2 and 3 will be sent to patients' homes. Freepost envelopes will be provided and reminders will be sent if response is not received within 2 weeks. Also telephone reminders will be used to improve response rates.

Data collected and measures used will include:

**Baseline only**
- Baseline questionnaire asking for demographics (gender, age, education, occupation), co-morbidities (e.g. diabetes) and nature of the cardiac event or diagnosis (e.g. MI, PCI, CABG, angina, heart failure)

**Baseline and follow-up**
- Patient anxiety and depression scores using the Hospital Anxiety and Depression Scale HADS
- Investigator developed questionnaire testing patients' knowledge of core information about cardiac disease, cardiac rehabilitation, medication and lifestyle changes as well as other topics if identified as important during stage 1

**Follow-up only**

- Patient satisfaction questionnaire investigating satisfaction of participants with information received from their GP (F1)
- Patient uptake of Phase 3 cardiac rehabilitation (started/not started; F2)
- Patient participation in Phase 3 (number of sessions attended and reasons for attending/not attending) and completion (completed/not completed, reasons for non-completion; F3)
- Priority of cardiac rehabilitation (adapted Likert scale and visual analogue scale) and reasons for choice of priority score (all follow-up points)
- Patient healthcare resource use questionnaire
- GP satisfaction questionnaire (F3)

**Sample size calculation**

Patient uptake of CR has been in the range of 18 and 38 % of patients eligible for CR between 2007 and 2009 with no significant increases compared to past years (Beswick et al., 2004, NACR, 2010). Considering this range of 20 % for patient participation and basing power calculations on a power of 80 %, probability of a type I error of 0.05 and probability of a type II error of 0.20, 392 patients per group (684 in total) will need to be recruited. Drop-out rates from exercise-based CR programmes have been found to be as high as 20 % within the first 3 months (Jolly et al., 2007). Even though a lower drop-out rate can be assumed for non-exercise based programmes, a final completion rate of 80 % is anticipated (accounting for loss to follow-up through drop-out/withdrawal, death and leaving the geographical area without a forwarding address) which means that 940 patients need to be recruited for the study to detect a significant difference in Phase 3 participation. Each CR centre of the Mid & South West Wales Cardiac Network registers on average 10 patients per week for Phase 2 cardiac rehabilitation (personal communication). In a ten month (40 week) recruitment period, 30 patients will need to be recruited every week (accounting for drop-outs and withdrawals). It is assumed that 15 to 20 GPs would need to be recruited to achieve the required patient sample size within the given timescale.
**Trial setting**

GPs will be recruited from the catchment area of the CR centres of the Mid and South West Wales Cardiac Network.

**Blinding**

In order to minimise bias, data analysts and patient participants will be blinded to GP (and thus patient) allocation. Due to the nature of the study, however, it is not possible to blind GPs as they will know whether the intervention is provided to them.

**Eligibility for participation**

Every GP in the catchment area of the CR centres of the Mid and South West Wales Cardiac Network who has contact with 2 or more cardiac patients per week is eligible to take part in the study. Every cardiac patient consulting a participating GP will be eligible for the trial. Age and co-morbidities which are often a cause for exclusion from research trials (Beswick et al., 2004) will not be considered reasons for exclusion as it is important to receive data as close to real-life scenario as possible for the trial to be able to provide information of the effectiveness of the intervention as a potential part of routine CR. Patients will be excluded if they decline consent or their English is not sufficient to complete the questionnaires. Also, severely ill or mentally ill patients will be excluded.

**Ethical approval**

Ethical approval will be sought from the National Research Ethics Service (NRES). R&D approval will be sought from the appropriate NHS Health Boards once the trial hospitals have been chosen.

As the intervention will not include an exercise component, the risks to patients are minimal. All information sessions and advice will be given to GPs by appropriately trained and experienced staff of the Mid & South West Wales Cardiac. All interactions with patients will be delivered by the participating GPs.

**5.3.4. Use of resources**

**Staff:** a principal investigator (Grade 8; 0.3 FTE over 3 years) will take responsibility for the day to day running of the trial, organise cooperation with the CR centres and GPs and perform data analysis and reporting.
A researcher (Grade 6/7, 0.5 FTE over 3 years) will conduct interviews, administer questionnaires, organise reminders and assist in cooperation with CR centres, GPs and data analysis and reporting.

Additionally, practice and study nurses (Band 6/7; 0.3 FTE over 18 months) will need to oversee patient recruitment in the recruited GP practices.

GP training time will need to be reimbursed to GPs and the time of CR health professionals and cardiac nurses providing the intervention information will need to be accounted for.

**Travel:** The coordination of the intervention in several GP practices will require the principal investigator/researcher and study nurse to travel to and from the different surgeries on a regular basis. Further travel expenses will arise from travel reimbursements of the study nurses and the advisory group.

**Consumables:** This includes printing of the questionnaires, consent and information forms, license fees for the questionnaires and postage as well as free-post for consent, questionnaires and reminders. Also, participant feedback about the study results will be provided to those participants who request it.

**Catering:** Meetings of the advisory group will incur room hire (if not possible to do in CR centres) and will require catering (e.g. tea, coffee, buffet lunch).

**Other costs:** Other costs will include randomisation, trial registration, and dissemination costs (e.g. conference fees).

### 5.3.5. Method of analysis

**Intervention development:** Interviews with GPs, health professionals and patients will be audio-taped with consent of the participants and transcribed verbatim. Qualitative data derived from the interviews will be coded and analysed to produce readable narrative descriptions using the software NVivo 8. Major themes, categories and illustrative examples in regards to GP and patient needs and preferences and professional opinion and expertise will be extracted through content analysis.

Together with the input and directions of the advisory group this will allow the design of an appropriate and useful intervention that improves GP knowledge of CR and gives them the
confidence to actively encourage patient participation in Phase 3 CR, decreases patient anxiety levels and can be is feasible and acceptable in routine practice of a busy GP surgery.

**Pilot testing:** Data from the pilot trial will primarily be analysed in regards to intervention acceptability, practicability and feasibility. The main objective is to test the intervention information material (too little/too much, too complicated, not understandable etc.) and the content of the training sessions and to establish how acceptable it is to GPs and patients. The pilot study will therefore help in the maximisation of user-friendliness of the intervention to ensure improved GP knowledge and recommendation and thus improved patient satisfaction and increased response rate and compliance throughout the main trial. Qualitative data derived from GP and patient feedback will be coded and analysed to produce readable narrative descriptions using the software NVivo 8. Major themes, categories and illustrative examples in regards to patient opinions and views will be extracted through content analysis.

If weaknesses of the intervention are detected, they will be amended before start of the main trial.

**Main trial:**
Data will be analysed applying an intention to treat analysis. Subjects who withdraw from the study at any point will be followed up for endpoints and missing information will be handled by the application of sensitivity analyses. Reasons for non-participation and withdrawal will be documented and recorded and participation rates will provide a measure of acceptability of the intervention to GPs and patients. The quantitative analyses will compare GP and patient satisfaction scores, patient participation in and completion of Phase 3 CR and patient anxiety levels between the intervention and control group and between baseline and follow-up data both within and between groups. Independent-samples t-tests will be used for continuous, normally distributed parameters (non-parametric Wilcoxon signed-rank test for non-normal distributions) and Chi-square tests for categorical data will be applied to compare proportions and means of targeted parameters with 0.05 as the level of statistical significance and a 95 % confidence interval around point estimates.

Descriptive analyses will be used to describe participating patients in terms of age, gender, nature of cardiac event/procedure and co-morbidities. Sub-group analyses will explore the effect of co-morbidities, nature of cardiac event/procedure, age and gender on the trial results.
All quantitative data analysis will be done using SPSS.

5.3.6. Expected outcomes

Intervention development: The main outcome of this stage of the project will be the development of an intervention to increase GP knowledge about CR and as a consequence encourage GPs to actively recommend CR to cardiac patients presenting to their surgery.

Pilot testing: The intervention developed in the first stage of the project will be pilot tested to ensure that it is accepted by GPs and patients and is understandable. Expected outcome of this pilot study is GP and patient feedback on intervention and questionnaire which will allow alterations if necessary. Also, the pilot study will allow an estimation of recruitment rates for the main trial.

Main trial:
Primary outcomes:

- **Patient CR knowledge**
  It was found that information provision and retention was directly related to uptake of cardiac rehabilitation in female cardiac patients (Rushford et al., 2007). Patients whose condition does not make sense to them and who thus do not understand the nature of heart disease and the underlying chronic processes are less likely to see the relevance of behavioural changes aimed for during cardiac rehabilitation and will therefore be less likely to attend CR (French et al., 2006). The new intervention information is aimed at improving patient information by providing GPs with the means and knowledge to convey information regarding CR.
  By assessing recall scores of the intervention patient group compared to the routine control group at baseline and all follow-up points, differences in recall and information retention can be detected.

- **Participation and completion rates of Phase 3 cardiac rehabilitation:**
  Standard 6 of the Cardiac Disease National Service Framework for Wales states that every patient with coronary heart disease should be offered an appropriate, evidence-based cardiac rehabilitation (WAG, 2009). The identified key interventions are service-related including patient identification and referral,
patient review and assessment, patient information and encouragement to participate in CR and achieve lifestyle changes (WAG, 2009). Phase 3 (structured exercise and information) participation plays a crucial role in the reduction of recurrent cardiac events in patients with cardiovascular disorders by decreasing risk factors such as high blood pressure, high cholesterol level, obesity and smoking. This will ultimately lead to reduced health care resource use, increased vitality and independence (especially in older patients) and improved quality of life. However, only 35% of cardiac patients participated in Phase 3 CR in Wales in 2008/09 (NACR, 2010). Studies have shown that patient information and encouragement during the early stage of CR can significantly increase Phase 3 participation as well as improve clinical and quality of life outcomes (Beswick et al., 2004, Davies et al., 2010). It is therefore of particular importance to modify service delivery and introduce interventions on primary care level that will engage patients to participate in Phase 3 and make the appropriate lifestyle changes in order to address Standard 6.

By assessing the change in Phase 3 participation and completion after the proposed GP information intervention compared to routine information using a specifically designed questionnaire at follow-up points 2 and 3, the impact of the intervention in relation to Standard 6 will be measured.

Secondary outcomes

- **Patient anxiety**

After a life-threatening experience and unfamiliar surrounding during their hospital stay following a cardiac event, patients experience a high level of anxiety and a significant reduction in health-related quality of life. Advice, information and Phase 3 exercise programmes have been shown to considerably improve anxiety levels and QoL (Thompson et al., 1996, Paquet et al., 2005). Also, patients experience anxiety directly related to CR as they are unsure as to what to expect. Results and scores from HADS questionnaires at baseline and all follow up points will allow comparison of patients receiving the intervention to control patients which will give an indication of the effectiveness of the intervention in regards to patient anxiety.
• **Patient satisfaction with GP information**
  In order to compare satisfaction of patients with the information they received from their GPs during intervention compared to routine information, data from the patient satisfaction questionnaire completed at follow-up point 1 will be analysed.

5.3.7. **Impact and dissemination**
Encouraging results from the trial regarding patient recall and satisfaction, effectiveness in increasing Phase 3 uptake and effect on patient anxiety could result in the introduction of the provision of GP training sessions and information materials in Mid and South West Wales that may enhance CR effectiveness through increased uptake as well as patient wellbeing.
Possible publications may include:

- A qualitative study of patient information needs from their primary care practitioner after cardiac events
- A descriptive analysis of the development of an intervention to improve patient information retention and anxiety as well as patient uptake of Phase 3 cardiac rehabilitation by offering tailored information provided by their GP
- Outcomes and results of a new intervention targeted to increase patient recall, satisfaction and uptake of Phase 3 CR by providing more information in the primary care setting
- A randomised study of the effect of tailored GP information and training on information recall, patient anxiety and satisfaction as well as Phase 3 participation and completion
5.3.8. Proposed project timetable

Months 1 - 3:
Post funding decision develop detailed study protocols, develop interview schedules as well as patient needs and baseline questionnaire, recall questionnaire, Phase 3 participation and satisfaction questionnaires, obtain licenses for HADS. Recruit staff and obtain ethical and R&D approvals.

Months 3 - 9:
Individual interviews of consenting GPs, patients and healthcare professionals in order to establish GP information needs, patient needs and health professionals opinions on an appropriate intervention

Months 6 – 12
Design and development of intervention in cooperation with advisory group

Months 13 - 16
Main trial organisation, recruitment of GPs, staff and GP training and provision of information materials

Months 17 – 25
Randomisation of GP practices, patient recruitment, consent and baseline data collection. Collection of follow up data (F1)

Months 19 - 27
Collection of follow-up data for F2 8 weeks after GP appointment.

Months 22 - 30
Collection of follow up data for F3 20 weeks after GP appointment.

Months 30 – 36
Data cleaning, analysis and report preparation/publication
5.4. Patient identification and referral to cardiac rehabilitation in Mid and South West Wales: suitability, efficacy and areas of improvement

5.4.1. Introduction

According to a survey, in 2002, 35% of patients discharged from hospital after a cardiac event attended cardiac rehabilitation which equalled 55% of the patients referred or invited to CR (Beswick et al., 2004). This means that less than 65% of eligible patients were referred to cardiac rehabilitation.

In the majority of CR services, referral guidelines or criteria are not documented (Smith, 2008). Patient information is often not passed on across healthcare settings and communication between community and hospital CR services is poor. This results in many eligible patients being missed and therefore not invited to attend CR. It has therefore been suggested that streamlining and automation of the referral process is of particular importance in order to improve referral rates (Thompson, 2002). In fact, adding a new mandatory reminder for cardiac rehabilitation to standardised electronic cardiovascular admission order sets with an automated direct referral to CR services increased the percentage of referred cardiac patients from 34% to 90% in the U.S. (Patel et al., 2011). In the UK, it has been shown that daily printouts of cardiac enzyme data from a hospital’s database of clinical chemistry results checked by a dedicated cardiac liaison nurse and assessment of patients before discharge by the cardiac nurse were successful in identifying potential CR patients (Dalal and Evans, 2003). However, the collection of names and recording of clinical summaries of eligible patients was found to not be complete in all hospitals (Beswick et al., 2004) and additional resources would be required in order to improve referral processes through information technology and networking (Tod et al., 2002).

In order to improve identification and referral of cardiac patients to CR, it is necessary to first provide an inventory of established processes which can be used as a stepping stone for changes and improvements in order to ensure that as many cardiac patients as possible are invited to take part in CR.

5.4.2. Aims and objectives

The overall aim of the proposed study is the review of the identification and referral processes that are in place in Wales and other countries in order to generate ideas and knowledge that could help develop systems for Wales that improve patient identification and
increase referral rate. This could lead to the development of guidelines and criteria as well as audit and evaluation procedures that could standardise patient identification and referral across Wales.

Specific objectives are as follows:

- To review patient identification and referral systems in Wales and other countries
- To assess the identification and referral processes in place within the Mid and South West Wales Cardiac Network
- To assess healthcare professionals’, managers’ and CR professionals’ opinions of the in situ identification and referral systems
- To investigate efficacy and suitability of the in situ identification and referral systems
- To identify areas of improvement of the identification and referral systems
- To suggest alternative identification and referral systems for consideration to the Mid and South West Wales Cardiac Network

5.4.3. Study design and method

The proposed study is a scoping exercise that will run over 18 months and comprise 3 separate stages including a systematic review of the literature, an interview stage and a recommendation development stage.

a. Systematic review of the literature and other data sources:

This stage of the study will address objective 1 and will encompass following sub-objectives:

- Developing a search strategy
- Reviewing UK and international literature dealing with identification and referral systems for cardiac rehabilitation and other rehabilitation services in the UK and other countries
- Assessing UK statistics, hospital data and literature to get a picture of current identification and referral processes and rates

Electronic databases (Pubmed, Medline (Ovid), The Cochrane Library, Embase) as well as archives and current issues of the most important journals in the field (BMJ, Heart, European Journal of Cardiovascular Nursing, etc) and the homepage of the Department of Health will be searched for English language publications that either report original data on identification
and referral systems to rehabilitation services or review the available literature. No date cut-offs will be applied in the initial search. A search strategy will be developed which will include various subsets of keywords and MeSH headings including “cardiac rehabilitation”, “identification”, “referral”, “rehabilitation service”, and others. Abstracts of all identified publications will be scanned for suitability according to the agreed inclusion/exclusion criteria. Included publications will be obtained. In order to identify additional publications, bibliographies of all papers included in the scoping review will be hand searched. All publications included in the final review will undergo detailed data extraction to inform the recommendations at the end of the scoping exercise.

Government, Department of Health and NHS and trust statistical data will be searched in order to extract current patient identification and referral rates within the UK.

b. Interview stage

Different health professionals involved with routine cardiac rehabilitation or cardiac inpatient care, as well as managers and stakeholders of CR services and hospitals (n=40) will be invited to take part in the interview study. Consenting individuals will be interviewed in order to assess opinions on the efficacy, quality and shortcomings of the identification and referral systems in place.

Open-ended questions on following topics will be included in the interviews:

- Description of the identification and referral systems of cardiac patients to CR that are in place in their centre/hospital
- Views on the efficacy and quality of the identification and referral systems in place in their centre/hospital
- Opinions and experiences on the shortcomings of identification and referral systems
- Estimate of how many cardiac patients are missed and not invited to CR due to the identification and referral system in place in their centre/hospital
- Suggestions on how to improve identification and referral systems in their centre/hospital
- Any other comments, things they may wish to add
- Demographic data
- Views on the interview process
c. Recommendation development

After data collection is complete, a 6-month data analysis and recommendation development stage will begin. During this stage, an advisory group consisting of healthcare professionals, managers and stakeholders will offer feedback and assistance throughout the development process to ensure all recommendations of possible alterations and re-design of identification and referral processes are acceptable and will be feasible in routine care.

Trial setting

The systematic review will be conducted at Swansea University. All interviews will take place in the catchment area of the CR centres of the Mid and South West Wales Cardiac Network.

Ethical approval

Ethical approval will be sought from the National Research Ethics Service (NRES). R&D approval will be sought from the appropriate NHS Health Boards where individuals participate in interviews. Interviews will only be conducted with individuals who give their informed consent.

5.4.4. Use of resources

Staff: a principal investigator (Grade 8; 0.3 FTE over 18 months) will take responsibility for the day to day running of the scoping exercise, organise and conduct interviews, oversee the systematic review and perform data analysis and reporting.

A researcher (Grade 6/7, 0.5 FTE over 18 months) will conduct interviews, perform the systematic review and assist with data analysis and reporting.

Additionally, interviewees and members of the advisory group may have to be reimbursed for their time.

Travel: The coordination of the interviews in several hospitals/centres in Mid and South West Wales will require the principal investigator/researcher to travel to and from the different interview locations on a regular basis. Further travel expenses will arise from travel reimbursements of members of the advisory group.
Consumables: This includes printing of included papers, consent and information forms and charges for publications not available online or in Swansea University library (interlibrary loans). Also, participant feedback about the study results will be provided to those participants who request it.

Catering: Meetings of the advisory group will incur room hire (if not possible to do in CR centres) and will require catering (e.g. tea, coffee, buffet lunch).

Other costs: Other costs will include dissemination costs (e.g. conference fees).

5.4.5. Method of analysis

Systematic review:
Publications that are included in the systematic review will be analysed separately and relevant data will be extracted according to standard guidelines. Descriptions of all available and included identification and referral systems will be provided and compared to the UK system. Benefits and shortcomings as well as costs (where available) will be detailed for each referral system.

Interview stage:
Interviews with health professionals, managers and stakeholders will be audio-taped with consent of the participants and transcribed verbatim. Qualitative data derived from the interviews will be coded and analysed to produce readable narrative descriptions using the software NVivo 8. Major themes, categories and illustrative examples in regards to patient identification and referral to cardiac rehabilitation will be extracted through content analysis. Together with the input and directions of the advisory group this will allow the design of recommendations for appropriate and useful alterations to the identification and referral process that are thought to improve referral rates and ultimately patient participation in CR and can be feasible and acceptable in routine practice of a busy cardiac unit.

Recommendation development:
Results of the analyses of the systematic review and the interview stage will then allow the development of recommendations for the alteration and improvement of identification and referral processes of cardiac patients to CR in South Wales.
5.4.6. Expected outcomes

Systematic review: The expected outcomes from the systematic review will include data, information and descriptions of different identification and referral systems all over the world for cardiac rehabilitation and other comparable rehabilitation services. A summary table will compare benefits, referral rates, disadvantages and costs of all reviewed systems with the current UK referral system.

Interview stage: The interview stage is expected to provide better insight into the identification and referral system as employed in South Wales and will provide opinions and recommendations for improvement from individuals who are involved in the day-to-day running of referral processes and hospital/service management.

Recommendation development:
The outcome of the recommendation development stage will be several recommendations and suggestions of how to re-design and improve cardiac patient identification and CR referral processes and rates based on the results from the systematic review, the interview stage and the input of the advisory group.

5.4.7. Impact and dissemination
Suitable, acceptable and feasible recommendations for the improvement of cardiac patient identification and CR referral processes in South Wales may encourage more research to be conducted in this thus far rather neglected field and could ultimately lead to a re-design of patient identification and referral processes as well as a standardisation of these processes across South Wales. This could result in improved patient referral to CR, increased uptake of CR and ultimately in increased wellbeing of cardiac patients.

Possible publications may include:
- A systematic review of patient identification and rehabilitation referral systems in the UK and other countries
- A qualitative study investigating health professionals’, managers’ and stakeholders’ opinions of the current cardiac patient identification and CR referral processes in South Wales
• Recommendations and suggestions to improve cardiac patient identification and CR referral processes in South Wales and the UK

5.4.8. Proposed project timetable

Months 1 - 3:
Post funding decision, develop detailed study protocols, develop interview schedules as well as identification and referral systems questionnaire and literature search strategy. Recruit staff and obtain ethical and R&D approvals.

Months 2 - 8:
Conduct systematic literature review of identification and referral processes and systems within the UK and in other countries. Use statistics, published information and hospital/trust data to assess current referral rates of cardiac patients to CR.

Months 6 - 12
Conduct interviews with health professionals, managers and stakeholders.

Months 12-15
Data entry, cleaning and data analysis.

Months 15-18
Develop and write up recommendations for referral system improvements. Write up final report.
5.5. Patient information during Phase 1 cardiac rehabilitation: availability, suitability, retention and influence on Phase 3 participation

5.5.1. Introduction

Phase 1 cardiac rehabilitation encompasses the period the patient spends in hospital immediately after the acute cardiac event (Bethell et al., 2008). The Phase 1 cardiac rehabilitation programme starts when the medical condition of the patient is stable (Bethell et al., 2009). It concerns the individual level of each patient and comprises counselling, a simple programme of education about the patient’s disease and their likely recovery as well as psychological support. Furthermore, ideally, physical, psychological and social needs of each patient should be assessed and the patient is given advice and encouragement for light exercise for Phase 2 (Beswick et al., 2004, Jolly et al., 2007). However, in reality, the restricted resources available for many cardiac rehabilitation programmes have been found to cause limitations of the time that staff spend with each individual patient. Especially in Phase 1 this can lead to an overload of information for the patient as too much is being conveyed in a short period of time (O’Driscoll et al., 2007). Furthermore, novel, intimidating and often painful experiences that accompany a patient’s hospitalisation phase together with unpredictable hospital routine, unfamiliar noises, procedures and equipment as well as a lack of control over their own lives and actions are a source of anxiety and may challenge a patient’s senses and their coping mechanisms (Thomas, 1995). This information overload and coping problems can further decrease information retention and recall of patients which has been shown to generally be poor (Astley et al., 2008, Kandula et al., 2011, Patel et al., 2008). This will result in a lack of knowledge in cardiac patients about their condition, cardiac rehabilitation and other treatment options. It has been found, that patients whose condition does not make sense to them and who thus do not understand the nature of heart disease and the underlying chronic processes are less likely to see the relevance of behavioural changes aimed for during cardiac rehabilitation and will therefore be less likely to attend CR (French et al., 2006). In fact, according to a survey, in 2002, only 55 % of the patients referred or invited to CR actually attended Phase 3 cardiac rehabilitation (Beswick et al., 2004).

In Phase 1, it is therefore of major importance for the patient to get an explanation and understand what has happened to them and the implications of their cardiac disease or event. This information should be conveyed positively and sympathetically and in terms all patients will be able to understand (Thompson et al., 1996). In fact, it has been found that
immediately after a cardiac event patients thought they needed help in accepting their condition and knowing their limits rather than receiving information about modifying their habits and lifestyles (Paquet et al., 2005). Also, it has been suggested that the interventional cardiologist should explain measures to reduce risk and emphasise that failure to do so may result in further cardiovascular complications (Piepoli et al., 2010). It is therefore of importance to explain the nature of cardiovascular disease in a comprehensive and easily understandable way as research suggests that if the disease is described as chronic many patients believe they have no control over the progression and are therefore less likely to attend CR whereas if the condition is described as acute, people may believe that they will be “back to normal” within a few weeks independent of CR (Wiles and Kinmonth, 2001).

In order to decrease patient anxiety and increase CR participation, it therefore appears important to assess patient information retention and recall and, if necessary, to redesign and generalise information given to the patients in Phase 1 with the aim to increase recall and CR participation.

### 5.5.2. Aims and objectives

Phase 3 CR is a structured programme consisting of exercise and information sessions and is often regarded as the core of cardiac rehabilitation. Most quantitative and qualitative studies investigating cardiac rehabilitation to date have focused on this stage of CR (Bethell et al., 2008). Non-attendance of Phase 3 cardiac rehabilitation (i.e. not attending on the first day of the programme after initially enrolling) and non-completion of programmes results in poorer patient health, increased waiting times and waste of resources (Kerins et al., 2010). A patient’s decision whether to attend cardiac rehabilitation has been found to be a two-stage process. The first decision to attend is made in hospital and is based on the perceived relevance of CR which is why sufficient information as well as information retention and recall are crucial in Phase 1. However, once patients are discharged from hospital, they start to prioritise and conceptualise and will choose whether to attend CR on the basis of whether they consider it more important than their daily routine or work and family commitments (Hagan et al., 2007). In fact, at this decision stage, patients will undertake their own individual cost-benefit analysis of cardiac rehabilitation (Hirani and Newman, 2005).

Attendance and adherence is thereby higher the stronger patients believe in the necessity of the treatment and the less concerns they have about harmful effects (Cooper et al., 2007). Also, patients who strongly believed that their condition was controllable and curable and
understood that it could be associated with serious consequences were found to be significantly more likely to attend cardiac rehabilitation (French et al., 2006). In fact, it was found that information provision and retention was directly related to uptake of cardiac rehabilitation in female cardiac patients (Rushford et al., 2007). It therefore seems crucial that cardiac patients retain as much information as possible from their Phase 1 CR experience to be able to prioritise CR over their daily routine.

The general aim of the proposed study is to assess information retention of cardiac patients after Phase 1 CR, test information recall and design and test tailored information to increase retention with the goal to ultimately increase Phase 3 CR participation.

Specific objectives are as follows:

1. To assess patient information needs during Phase 1 cardiac rehabilitation
2. To assess health professionals’ opinions on patient information needs during Phase 1 CR
3. To investigate the quality, quantity and generalisability of information given to patients during Phase 1 CR in different hospitals in Mid and South West Wales
4. To investigate the quality, quantity and generalisability of information given to patients during Phase 1 CR by different health professionals in Mid and South West Wales
5. To design a generalised information layout aimed at the improvement of patient recall
6. To pilot test the generalised information on a small number of patients
7. To test the suitability, feasibility and acceptability of the generalised information in improving patient recall and participation in Phase 3 CR in routine care in hospitals in Mid and South West Wales in comparison to standard Phase 1 CR.

5.5.3. Study design and method

The proposed study will run over 3 years and comprise 3 separate stages including information needs assessment and intervention development, pilot testing and amendment of intervention (if necessary) and the main trial which will be testing the information intervention in routine care against standard information given to cardiac patients during Phase 1 CR.
a. **Information needs assessment and intervention development:**

This stage of the study will address objectives 1 to 5 and will encompass following sub-objectives:

- Exploring patients’ information and support needs during Phase 1
- Exploring patients’ experiences during CR (with focus on Phase 1)
- Exploring the degree of priority patients attribute to cardiac rehabilitation after standard Phase 1 CR
- Inviting suggestions for improving patient experience and uptake of Phase 3
- Gathering information on health professionals’ opinions on patient needs during Phase 1
- Gathering information on health professionals’ opinions on possible changes to Phase 1 CR delivery to improve efficiency, uptake and patient experience
- Assessing standard information and support given to patients during Phase 1 CR in hospitals in Mid and South West Wales
- Assessing standard information and support given by different health professionals during Phase 1 CR in hospitals in Mid and South West Wales
- Assessing generalisability, uniformity, quality and quantity of standard information given to patients during Phase 1 CR in Mid and South West Wales
- Develop most appropriate and acceptable intervention according to results of data gathering and exploration exercise

The intervention development stage will commence with a 6-month qualitative exploratory study using individual semi-structured interviews with hospital staff involved with Phase 1 CR in hospitals in Mid and South West Wales. Different health professionals in several hospitals involved with routine Phase 1 cardiac rehabilitation (n=20) will be interviewed in order to formulate and design a Phase 1 cardiac rehabilitation information intervention that is addressing patient needs, seems feasible in the context of routine hospital care and standard Phase 1 CR and is acceptable to both patients and health professionals. Open-ended questions on following topics will be included in the interviews:
- Description of current standard Phase 1 CR information giving on a daily basis to cardiac patients (including topics covered, length and number of sessions etc.)
- Views on patient needs during Phase 1 and how current service delivery addresses those needs
- Views on how information delivery could be improved in regards to patient quality of life, anxiety and participation in Phase 3
- Opinions and experiences on why patients chose not to participate in Phase 3
- Views on the value of the planned intervention
- Views on the acceptability and feasibility of the intervention in the context of day-to-day running of Phase 1 CR in a routine hospital care environment, budget and staffing
- Suggestions of most important topics to be covered as part of Phase 1 CR
- Any other comments, things they may wish to add
- Demographic data
- Views on the interview process

Furthermore, eligible patients (stable cardiac inpatients who have just received Phase 1 CR without severe illness and severe mental health problems who consent to participating; n = 30) will be invited to take part in the evaluation of information needs by a study nurse. Patients who give permission will be given a questionnaire designed to assess patient information needs and patients’ Phase 1 CR experience as well as their understanding and prioritisation of CR.
Questionnaires will include:
- Explanation of the purpose of the study and the questionnaire
- Assessment of the patient’s cardiac knowledge and information needs
- Assessment of support needs (e.g. to deal with anxiety, isolation etc.)
- Views on delivery of Phase 1 CR
- Opinion on the value of the Phase 1 CR service
- Preferences in service provision and thresholds (e.g. amount of information received, timing of information etc.)
- Priority the patient puts on Phase 3 CR based on the information received during Phase 1
Scoping exercise to identify areas for research, evaluation and audit in relation to the practice and delivery of cardiac rehabilitation (CR): Final report  December 2011

- Estimated probability that patient will participate in Phase 3 CR based on the information received during Phase 1
- Any other comments, things they may wish to add
- Demographic data

After data collection is complete, a 6-month data analysis and intervention development stage will begin. During this stage, an advisory group consisting of patients, cardiac specialist nurses, cardiologists and other healthcare professionals involved in Phase 1 CR will offer feedback and assistance throughout the development process to ensure the intervention is acceptable and will be feasible for patients and CR centres.

b. **Pilot testing:**

Once a suitable intervention has been designed and approved by the members of the advisory group, it will be tested on 30 cardiac patients in one hospital in South Wales. Cardiac patients eligible for standard Phase 1 CR who consent to taking part in the pilot study will be given the standardised intervention information instead of routine Phase 1 CR information. After they received the intervention information they will be given the questionnaire described in stage 1 (assessment and intervention development) to assess their knowledge, information recall and satisfaction with the information provided. They will then be interviewed on their views and opinions of the intervention and the questionnaires and will have the opportunity to suggest improvements and point out areas where they felt amendments could be made.

At the end of stage one, the intervention information will be amended (if necessary) based on the results of the pilot study and qualitative feedback of the participants.

c. **Main trial:**

The main trial study will be run over a total of 18 months (3 month planning, 10 month recruitment, 5 months analysis). The intervention that was developed and pilot tested in the first two stages of the trial will be tested in hospitals in South Wales in a multi-centre randomised, controlled trial. English speaking cardiac patients eligible for and stable enough to receive Phase 1 CR with no severe illness, co-morbidities or mental illness will be invited by the study nurse to take part in the main trial. Patients will receive an information leaflet and the study nurse will explain the study and answer questions. After informed consent has been given, baseline data (including demographics, anxiety scores and level of cardiac knowledge) is collected and the patient is then randomised into either the intervention or the
control group based on a 1:1 ratio. The intervention group will receive the intervention information designed in stage 2 of the trial. The nature of this intervention (quantity and quality of the received information) cannot be specified as it will depend on the stage 1 results and the input of the advisory group. The control group will receive standard information during routine Phase 1 CR. At hospital discharge, the first set of follow-up data is collected (F1) by the study nurse including information on patient anxiety and cardiac knowledge. A second set of follow-up data (F2) is recorded 8 weeks after hospital discharge (Phase 3 CR should have begun for the patient at this point) and a further data-set (F3) will be collected 20 weeks after hospital discharge to gain information on whether patients completed Phase 3 CR. Questionnaires of follow-up 2 and 3 will be sent to patients’ homes. Freepost envelopes will be provided and reminders will be sent if response is not received within 2 weeks. Also telephone reminders will be used to improve response rates.

Data collected and measures used will include:

**Baseline only**
- Baseline questionnaire asking for demographics (gender, age, education, occupation), co-morbidities (e.g. diabetes) and nature of the cardiac event or diagnosis (e.g. MI, PCI, CABG, angina, heart failure)

**Baseline and follow-up**
- Patient anxiety and depression scores using the Hospital Anxiety and Depression Scale HADS
- Investigator developed questionnaire testing patients’ knowledge of core information about cardiac disease, cardiac rehabilitation, medication and lifestyle changes as well as other topics if identified as important during stage 1 and 2 (6 questions that will differ between different follow-ups to reduce bias due to repetition learning)

**Follow-up only**
- Patient satisfaction questionnaire investigating satisfaction of participants with Phase 1 CR information received (F1)
- Patient uptake of Phase 3 cardiac rehabilitation (started/not started; F2)
- Patient participation in Phase 3 (number of sessions attended and reasons for attending/not attending) and completion (completed/not completed, reasons for non-completion; F3)
• Priority of cardiac rehabilitation (adapted Likert scale and visual analogue scale) and reasons for choice of priority score (all follow-up points)

Sample size calculation
Patient uptake of CR has been in the range of 18 and 38 % of patients eligible for CR between 2007 and 2009 with no significant increases compared to past years (Beswick et al., 2004, NACR, 2010). Considering this range of 20 % for patient participation and basing power calculations on a power of 80 %, probability of a type I error of 0.05 and probability of a type II error of 0.20, 392 patients per group (684 in total) will need to be recruited. Drop-out rates from exercise-based CR programmes have been found to be as high as 20 % within the first 3 months (Jolly et al., 2007). Even though a lower drop-out rate can be assumed for non-exercise based programmes, a final completion rate of 80 % is anticipated (accounting for loss to follow-up through drop-out/withdrawal, death and leaving the geographical area without a forwarding address) which means that 940 patients need to be recruited for the study to detect a significant difference in Phase 3 participation. A study of similar design studying patient recall in orthodontics at several follow-up points found in a retrospective sample-size calculation that a sample size of 80 participants would have a 94 % power to detect a difference in mean recall scores of 2.4 in a 16 scale recall questionnaire (Patel et al., 2008). It is therefore assumed that a sample size of 940 will be sufficient to detect significant differences in the scores provided by the 6 scale recall questionnaire used in this trial.

Trial setting
In October 2010, the Mid & South West Wales Cardiac Network commissioned Swansea University to conduct a scoping exercise to identify areas for research, evaluation and audit in relation to the practice and delivery of cardiac rehabilitation. After a thorough review of the existing literature on cardiac rehabilitation, this exercise identified 15 areas where further information and thus further research could assist in improving service delivery. The 15 research recommendations were then scored in a prioritisation exercise by professional members of the Cardiac Network and the proposed study was amongst the top six priority studies according to cardiac nurses, cardiologists and other health professionals involved in CR in Mid and South Wales. The 10 CR centres of the Mid & South West Wales Cardiac Network are supporting the study. Two hospital in the Mid and South West Wales area with strong links to the Cardiac Network (i.e. Phase 1 CR provided by cardiac nurses and
members of CR centres) as well as two hospitals where hospital staff provides Phase 1 CR will be chosen and invited to participate in the study.

**Blinding**
In order to minimise bias, data analysts and participants will be blinded to patient allocation. Due to the nature of the study, however, it is not possible to blind members of the CR centres or health professionals as they will know what intervention they are providing.

**Eligibility for participation**
Every patient eligible for Phase 1 cardiac rehabilitation will be eligible for the trial. Age and co-morbidities which are often a cause for exclusion from research trials (Beswick et al., 2004) will not be considered reasons for exclusion as it is important to receive data as close to real-life scenario as possible for the trial to be able to provide information of the effectiveness of the intervention as a potential part of routine CR. Patient will be excluded if they decline consent or their English is not sufficient to complete the questionnaires. Also, severely ill or mentally ill patients will be excluded.

**Ethical approval**
Ethical approval will be sought from the National Research Ethics Service (NRES). R&D approval will be sought from the appropriate NHS Health Boards once the trial hospitals have been chosen.
As the intervention will not include an exercise component, the risks to patients are minimal. All sessions and interactions with patients will be delivered by appropriately trained and experienced staff of the Mid & South West Wales Cardiac Network and health professionals of participating hospitals.

**5.5.4. Use of resources**
**Staff:** a principal investigator (Grade 8; 0.3 FTE over 3 years) will take responsibility for the day to day running of the trial, organise cooperation with the CR centres and hospitals and perform data analysis and reporting.
A researcher (Grade 6/7, 0.5 FTE over 3 years) will conduct interviews, administer questionnaires, organise reminders and assist in cooperation with CR centres, hospitals and data analysis and reporting.
Additionally, study nurses (Band 6/7; 0.3 FTE over 18 months) will need to oversee patient recruitment in the 4 hospitals and training time of health professionals and cardiac nurses providing the intervention information will need to be accounted for.

**Travel**: The coordination of the intervention in the four hospitals will require the principal investigator/researcher to travel to and from the hospitals on a regular basis. Further travel expenses will arise from travel reimbursements of the study nurses.

**Consumables**: This includes printing of the questionnaires, consent and information forms, license fees for the questionnaires and postage as well as free-post for consent, questionnaires and reminders. Also, participant feedback about the study results will be provided to those participants who request it.

**Catering**: Meetings of the advisory group will incur room hire (if not possible to do in CR centres) and will require catering (e.g. tea, coffee, buffet lunch).

**Other costs**: Other costs will include randomisation, trial registration, and dissemination costs (e.g. conference fees).

### 5.5.5. Method of analysis

**Intervention development**: Interviews with health professionals and CR centre staff will be audio-taped with consent of the participants and transcribed verbatim. The number of interviews will be divided equally among different hospitals in Mid & South West Wales. Qualitative data derived from interviews and open-ended patient questionnaire questions will be coded and analysed to produce readable narrative descriptions using the software NVivo 8. Major themes, categories and illustrative examples in regards to patient needs and preferences and professional opinion and expertise will be extracted through content analysis. Together with the input and directions of the advisory group this will allow the design of an appropriate and useful intervention that improves patient participation in Phase 3, QoL and anxiety levels and can be is feasible and acceptable in routine practice of hospital based Phase 1 CR.
Pilot testing: Data from the pilot trial will primarily be analysed in regards to intervention and recall questionnaire acceptability, practicability and feasibility. The main objective is to test the intervention information (too little/too much, too complicated, not understandable etc.) and the investigator-developed questionnaire (too long, confusing questions etc.) and establish how acceptable it is to patients. The pilot study will therefore help in the maximisation of user-friendliness of the intervention and the recall questionnaire to ensure improved patient satisfaction and increased response rate throughout the main trial. Qualitative data derived from patient feedback will be coded and analysed to produce readable narrative descriptions using the software NVivo 8. Major themes, categories and illustrative examples in regards to patient opinions and views will be extracted through content analysis. If weaknesses of the intervention or the questionnaire are detected, they will be amended before start of the main trial.

Main trial:
Data will be analysed applying an intention to treat analysis. Subjects who withdraw from the study at any point will be followed up for endpoints and missing information will be handled by the application of sensitivity analyses. Reasons for non-participation and withdrawal will be documented and recorded and participation rates will provide a measure of acceptability of the intervention to patients. The quantitative analyses will compare recall questionnaire scores, participation in and completion of Phase 3 CR, patient anxiety levels between the intervention and control group and between baseline and follow-up data both within and between groups. Independent-samples t-tests will be used for continuous, normally distributed parameters (non-parametric Wilcoxon signed-rank test for non-normal distributions) and Chi-square tests for categorical data will be applied to compare proportions and means of targeted parameters with 0.05 as the level of statistical significance and a 95 % confidence interval around point estimates. Descriptive analyses will be used to describe participating patients in terms of age, gender, nature of cardiac event/procedure and co-morbidities. Sub-group analyses will explore the effect of co-morbidities, nature of cardiac event/procedure, age and gender on the trial results. All quantitative data analysis will be done using SPSS.
5.5.6. Expected outcomes

**Intervention development:** The main outcome of this stage of the project will be the development of an intervention to reduce patient anxiety and increase information recall and ultimately participation in Phase 3 cardiac rehabilitation by offering optimum information (in quality and quantity) during Phase 1.

**Pilot testing:** The intervention developed in the first stage of the project will be pilot tested to ensure that it is accepted by patients and is understandable. Also, the recall questionnaire will be tested to ensure it can be easily understood, used and completed by patients. Expected outcome of this pilot study is patient feedback on intervention and questionnaire which will allow alterations if necessary. Also, the pilot study will allow an estimation of recruitment rates for the main trial.

**Main trial:**

**Primary outcomes:**

- **Patient information retention and recall**
  It was found that information provision and retention was directly related to uptake of cardiac rehabilitation in female cardiac patients (Rushford et al., 2007). Patients whose condition does not make sense to them and who thus do not understand the nature of heart disease and the underlying chronic processes are less likely to see the relevance of behavioural changes aimed for during cardiac rehabilitation and will therefore be less likely to attend CR (French et al., 2006). The new intervention information is aimed at improving patient recall and ultimately Phase 3 participation. By assessing recall scores of the intervention group compared to the routine control group at baseline and all follow-up points, differences in recall and information retention can be detected.

- **Participation and completion rates of Phase 3 cardiac rehabilitation:**
  Standard 6 of the Cardiac Disease National Service Framework for Wales states that every patient with coronary heart disease should be offered an appropriate, evidence-based cardiac rehabilitation (WAG, 2009). The identified key interventions are service-related including patient identification and referral, patient review and assessment, patient information and encouragement to
participate in CR and achieve lifestyle changes (WAG, 2009). Phase 3 (structured exercise and information) participation plays a crucial role in the reduction of recurrent cardiac events in patients with cardiovascular disorders by decreasing risk factors such as high blood pressure, high cholesterol level, obesity and smoking. This will ultimately lead to reduced health care resource use, increased vitality and independence (especially in older patients) and improved quality of life. However, only 35% of cardiac patients participated in Phase 3 CR in Wales in 2008/09 (NACR, 2010). Studies have shown that patient information and encouragement during the early stage of CR can significantly increase Phase 3 participation as well as improve clinical and quality of life outcomes (Beswick et al., 2004, Davies et al., 2010). It is therefore of particular importance to modify service delivery and introduce interventions during Phase 1 and 2 of cardiac rehabilitation that will engage patients to participate in Phase 3 and make the appropriate lifestyle changes in order to address Standard 6. By assessing the change in Phase 3 participation and completion after the proposed Phase 1 intervention compared to routine information using a specifically designed questionnaire at follow-up points 2 and 3, the impact of the intervention in relation to Standard 6 will be measured.

Secondary outcomes

- **Patient anxiety**
  After a life-threatening experience and unfamiliar surrounding during their hospital stay following a cardiac event, patients experience a high level of anxiety and a significant reduction in health-related quality of life. Advice, information and Phase 3 exercise programmes have been shown to considerably improve anxiety levels and QoL (Thompson et al., 1996, Paquet et al., 2005). Results and scores from HADS questionnaires at baseline and all follow up points will allow comparison of patients receiving the intervention to control patients which will give an indication of the effectiveness of the intervention in regards to patient anxiety.

- **Patient satisfaction with Phase 1 information**
  In order to compare satisfaction of patients with the information they received during intervention compared to routine information, data from the patient satisfaction questionnaire completed at follow-up point 1 will be analysed.
5.5.7. Impact and dissemination

Encouraging results from the trial regarding patient recall and satisfaction, effectiveness in increasing Phase 3 uptake and effect on patient anxiety could result into the re-design and standardisation of Phase 1 cardiac rehabilitation in Mid and South West Wales that may enhance CR effectiveness as well as patient wellbeing.

Possible publications may include:

- A qualitative study of patient information needs during their hospital stay after cardiac events
- A descriptive analysis of the development of an intervention to improve patient information retention and anxiety as well as patient uptake of Phase 3 cardiac rehabilitation by offering tailored information during Phase 1
- Rational and description of a new Phase 1 cardiac rehabilitation intervention targeted to increase patient recall of cardiac information giving in hospital and Phase 3 participation
- Outcomes and results of a new Phase 1 cardiac rehabilitation intervention targeted to increase patient recall of cardiac information giving in hospital and Phase 3 participation
- A randomised study of the effect of tailored patient information during Phase 1 cardiac rehabilitation on information recall, patient anxiety and Phase 3 participation and completion
- Patient satisfaction with patient information during Phase 1 cardiac rehabilitation
5.5.8. Proposed project timetable

Months 1 - 3:
Post funding decision develop detailed study protocols, develop interview schedules as well as patient needs and baseline questionnaire, recall questionnaire, Phase 3 participation and satisfaction questionnaires, obtain licenses for HADS. Recruit staff and hospitals and obtain ethical and R&D approvals.

Months 3 - 9:
Individual staff interviews and recruitment of patients to complete patient needs questionnaires in order to establish patient needs and health professionals opinions on an appropriate intervention

Months 6 – 12
Design and development of intervention in cooperation with advisory group

Months 13 - 16
Main trial organisation, trial establishment in recruited hospital, staff training

Months 17 – 25
6. Patient recruitment, consent and baseline data collection. Randomisation and intervention; Collection of follow up data (F1)

Months 19 - 27
Collection of follow-up data for F2 8 weeks after hospital discharge.

Months 22 - 30
Collection of follow up data for F3 20 weeks after hospital discharge.

Months 30 – 36
Data cleaning, analysis and report preparation/publication
5.6. Promoting participation in Phase 3 cardiac rehabilitation through increased patient contact, support and information during Phase 2: intervention development, pilot testing, acceptability and feasibility testing and evaluation of effectiveness, cost effectiveness and patient and carer quality of life

5.6.1. Introduction

Coronary heart disease is a major health problem in the UK, with 9264 people admitted with myocardial infarction (MI) or for percutaneous coronary interventions (PCI) and coronary artery bypass grafting (CABG) in 2008/09 in Wales alone (NACR, 2010). Cardiac rehabilitation (CR) reduces the risk of coronary heart disease and prevents future cardiac events (O’Driscoll et al., 2007). However, low patient uptake, an often inefficient referral system and a lack of funding resulted in only 3223 (35 %) patients actually attending CR in Wales in 2008/09 (NACR, 2010).

In Wales, patients are contacted by their CR team within 7 days of hospital discharge when the patient is encouraged to attend Phase 3 CR (WAG, 2009). This is the only contact and information the patient receives during Phase 2. Early after hospital discharge patients’ motivation to change their lives is highest and their need for support is greatest due to anxiety they experience after a life-threatening event (Paquet et al., 2005). However, average waiting times of 5 weeks before commencement of Phase 3 means that this important stage is missed. Regular patient contacts, information about illness and importance of CR and alleviation of concerns during Phase 2 could increase uptake of Phase 3, improve quality of life and decrease healthcare use and levels of anxiety. Indeed, a recent Canadian study found an increase of CR participation of 162 % when patients were given an early intervention of information, support and motivation immediately after hospital discharge (Parker et al., 2011). However, the need for further research, especially including multiple sites and patients with co-morbidities, remains.

An appropriately powered intervention study is needed to investigate whether increased information and advice during Phase 2 CR influences Phase 3 attendance and quality of life of patients and carers (French et al., 2006). Results of the pilot study will allow intervention adaptation and will inform a large multi-centre randomised controlled trial conducted within the South Wales Cardiac Network. Positive results from this trial may have immediate effects on CR service delivery in South Wales and will encourage further work to restructure CR programmes in the UK.
The whole study will be divided into an intervention development and pilot and feasibility testing phase of 2 years and a subsequent randomised controlled trial to assess effectiveness of the intervention of 2 years. Up to a certain point, participant numbers, trial duration, costs and staff requirements can be adjusted in order to fit requirements.

5.6.2. Intervention development and pilot testing

5.6.2.1. Aims and objectives
Phase 3 CR is a structured programme consisting of exercise and information sessions and is often regarded as the core of cardiac rehabilitation. Most quantitative and qualitative studies investigating cardiac rehabilitation to date have focused on this stage of CR (Bethell et al., 2008). Non-attendance of Phase 3 cardiac rehabilitation (i.e. not attending on the first day of the programme after initially enrolling) and non-completion of programmes results in poorer patient health, increased waiting times and waste of resources (Kerins et al., 2010). A patient’s decision whether to attend cardiac rehabilitation has been found to be a two-stage process. The first decision to attend is made in hospital and is based on the perceived relevance of CR which is why sufficient information is crucial in Phase 1. However, once patients are discharged from hospital, they start to prioritise and conceptualise and will choose whether to attend CR on the basis of whether they consider it more important than their daily routine or work and family commitments (Hagan et al., 2007). In fact, at this decision stage, patients will undertake their own individual cost-benefit analysis of cardiac rehabilitation (Hirani and Newman, 2005). Attendance and adherence is thereby higher the stronger patients believe in the necessity of the treatment and the less concerns they have about harmful effects (Cooper et al., 2007). Also, patients who strongly believed that their condition was controllable and curable and understood that it could be associated with serious consequences were significantly more likely to attend cardiac rehabilitation (French et al., 2006). Continued motivation and support as well as information about the importance and the benefits of CR during Phase 2 are therefore crucial in order to persuade patients of the high priority of CR. Various studies investigated the promotion of CR attendance through different interventions. These interventions included formal written or oral patient commitment, spouse and family involvement, educational interventions, strategies to aid self-management and psychological interventions. Also, motivational interviews and goal setting have been used to motivate CR adherence (Bethell et al., 2009). Some of these interventions have been shown to significantly increase patient attendance (Davies et al., 2010). However, some studies found no or non-significant changes in the level of attendance.
(Beswick et al., 2004). Also, most interventions were either placed during Phase 3 (e.g. free transport and travel grants, choice of menu options for exercise classes, choice of time, day and venue for exercise and information sessions) or merely invitational in nature during Phase 2 (e.g. follow-up telephone calls, invitation letters). It is crucial to provide patients with the information required for them to be able to prioritise cardiac rehabilitation over other activities and to disperse any fears, anxieties or preconceptions patients may associate with CR attendance during Phase 2 when they make the actual decision whether or not to take part in order to increase patient uptake of Phase 3, reduce anxiety and ultimately increase patient health and quality of life.

The overall aim of the proposed project is therefore to design and pilot test a tailoured intervention to improve patient participation in Phase 3 cardiac rehabilitation as well as health outcomes and patient and carer quality of life by offering appropriate support and information during the waiting time between hospital discharge after a cardiac event and commencement of the structured Phase 3 information and exercise programme on average 5 to 8 weeks later (Phase 2) in South Wales.

**Specific objectives are as follows:**

1. To design an appropriate, acceptable and feasible intervention that will reflect patients' and carers' needs in Phase 2 CR as well as take into account health care professionals' opinions and expertise who are involved in routine cardiac rehabilitation
2. To implement the intervention in a small sample of CR centres in South Wales and to train and engage CR centre staff
3. To test the intervention in clinical practice by assessing feasibility and acceptability to patients and carers
4. To investigate the acceptability and feasibility of the intervention in the context of routine cardiac rehabilitation
5. To gather fundamental data on the potential of the intervention to address following outcomes:
   a. the effectiveness of the intervention in regards of patient uptake of the structured routine Phase 3 exercise and information programme to routine Phase 2 CR
   b. the impact of the intervention on patients in terms of patient anxiety and quality of life
c. the impact of the intervention on patients’ carers/closest family members in terms of carer anxiety and quality of life.

d. the implementation cost and budget impact of the intervention for cardiac rehabilitation centres in South Wales and its relative cost-effectiveness

5.6.2.2. Study design and method

The proposed development and pilot study will be run over a total of two years and will comprise of 3 separate stages.

a. Intervention development:

This stage of the study will address objective 1 and will encompass following sub-objectives:

- Exploring patients’ and carers’ information and support needs during Phase 2
- Exploring patients’ and carer’s experiences during CR (with focus on Phase 2)
- Exploring reasons for giving CR low priority resulting in non-attendance
- Investigating preferences of intervention provision (e.g. home-based, community-based, centre-based, group versus individual information sessions, telephone support versus home visits etc.) and willingness-to-accept
- Inviting suggestions for improving patient experience and uptake of Phase 3
- Gathering information on health professionals’ opinions on patient needs during Phase 2
- Gathering information on health professionals’ opinions on possible changes to CR delivery to improve efficiency, uptake and patient experience
- Develop most appropriate and acceptable intervention according to results of data gathering and exploration exercise

The intervention development stage will commence with a 6-month qualitative exploratory study using individual semi-structured interviews in and around the main cardiac rehabilitation centres in South Wales. Cardiac patients who have just completed CR (n=10)
and patients who are just being discharged from hospital (n=10) after a cardiac event, their carers (n=10) as well as professionals involved with routine cardiac rehabilitation (n=10) will be interviewed in order to formulate and design a Phase 2 cardiac rehabilitation intervention that is addressing patient and carer needs, seems feasible in the context of routine cardiac rehabilitation and is acceptable to both patients and health professionals.

Eligible patients (patients just starting Phase 2 and patients just finished with Phase 3 without severe illness and severe mental health problems who consent to participating) and their partners/carers will be invited to take part in the evaluation by the cardiac nurse during one of the routine appointments/home visits. Patients and carers who give permission will be contacted by the researcher to arrange an appointment for the interview. Interviews will be conducted at a time and place chosen by the patient.

Interviews will be adapted to the participant group (patient before CR, patient after CR, carer). During the interview open-ended prompt questions will cover topics including:

- Explanation of the purpose of the study and the interview
- Assessment of the patient’s cardiac knowledge and information needs
- Assessment of support needs (e.g. to deal with anxiety, isolation etc.)
- Views on service delivery
- Opinion on the value of the service
- Preferences in service provision and thresholds (e.g. number of session they would be willing to attend per given time)
- Any other comments, things they may wish to add
- Demographic data
- Views on the interview process

Healthcare professionals involved with cardiac rehabilitation in the South Wales CR centres will be invited to participate in interviews. This group will include cardiac specialist nurses, cardiologists, exercise instructors, psychologists, dieticians and managers. After consent to participate has been given interviews will be conducted by telephone or at a time and place that suits the participant. Open-ended questions on following topics will be included in the interview:

- Views on patient needs during Phase 2 and how current service delivery addresses those needs
- Views on how service could be improved in regards to patient quality of life, anxiety and participation in Phase 3
- Opinions and experiences on why patients chose not to participate in Phase 3
- Views on the value of the planned intervention
• Views on the acceptability and feasibility of the intervention in the context of day-to-day running of CR centres, budget and staffing
• Suggestions of feasible modes of intervention delivery achievable as part of CR routine services
• Any other comments, things they may wish to add
• Demographic data
• Views on the interview process

After data collection is complete, a 6-month data analysis and intervention development stage will begin. An advisory group consisting of patients, carers, cardiac specialist nurses, cardiologists, CR centre managers and other healthcare professionals involved in CR will offer feedback and assistance throughout the development process to ensure the intervention is acceptable and will be feasible for patients and CR centres.

b. Pilot trial:
During the 5-month pilot trial stage, the intervention will be tested in 2 CR centres in South Wales in a small-scale multi-centre randomised, controlled trial. During the routine visit of cardiac patients within 7 days of hospital discharge, patients will be invited to take part in the study. Patients will receive an information leaflet and the cardiac nurse will explain the study and answer questions. After informed consent has been given, baseline data is collected and the patient is then randomised into either the intervention or the control group based on a 1:1 ratio. The intervention group will receive the intervention designed in stage 1 of the trial for 4 consecutive weeks. The nature of this intervention cannot be specified as it will depend on results of the focus group study. It is, however, anticipated that it may include one or more of the following: information sessions for patients and partners/carers including a multidisciplinary team of cardiac nurses, dieticians and counsellors, additional nurse visits, social gatherings of patients and carers sharing the same experiences, telephone consultations and advice. The control group will receive routine care during Phase 2 CR, i.e. written information, recommendations of light exercise but no further contact with the cardiac team. Six weeks after hospital discharge the first set of follow-up data is collected (F1) including information on whether patients started taking part in Phase 3. A second set of follow-up data (F2) is recorded at 12 weeks (usually the end of structured CR) after hospital discharge.

In order to assist the health economic analysis, this stage will also include collection of data on resource use for intervention implementation in the CR centres, out-of-pocket expenses for patients and health care resources used by patients.
Data collected and measures used will include:

**Baseline only**
- Baseline questionnaire asking for demographics (gender, age, education, occupation), co-morbidities (e.g. diabetes) and nature of the cardiac event or diagnosis (e.g. MI, PCI, CABG, angina, heart failure)

**Baseline and follow-up**
- Patient quality of life measured using the Quality of life after myocardial infarction questionnaire QLMI and the generic EuroQol EQ-5D
- Patient anxiety and depression scores using the Hospital Anxiety and Depression Scale HADS
- Carer quality of life using the Adult Carer Quality of Life questionnaire AC-QoL

**Follow-up only**
- Patient participation in Phase 3 cardiac rehabilitation (started/not started, number of sessions attended and reasons for attending/not attending)
- Patient resource use questionnaire (out-of-pocket expenses, health care use, medication etc.)
- Patient intervention satisfaction and acceptability questionnaire (F1 only)

**Sample size calculation**

In contrast to randomised controlled trials, there are no guidelines or rules concerning the sample size of pilot trials. As a rule of thumb it has been suggested that 10 % of the estimated sample size of the main trial (see chapter 5.6.3.) should be tested (Hertzog, 2008, Thabane et al., 2010). Taking this into account, a sample size of 94 participants (47 per group) should be sufficient in the pilot study to test for the feasibility of the intervention.

**Trial setting**

In October 2010, the Mid & South West Wales Cardiac Network commissioned Swansea University to conduct a scoping exercise to identify areas for research, evaluation and audit in relation to the practice and delivery of cardiac rehabilitation. After a thorough review of the existing literature on cardiac rehabilitation, this exercise identified 15 areas where further information and thus further research could assist in improving service delivery. The 15 research recommendations were then scored in a prioritisation exercise by professional members of the Cardiac Network and the proposed study was amongst the top six priority
studies according to cardiac nurses, cardiologists and other health professionals involved in CR in Mid and South Wales. The 10 CR centres of the Mid & South West Wales Cardiac Network are supporting the study. Two centres will be chosen to participate in the pilot study.

**Randomisation**
Once enrolled in the study, participants will be randomly allocated to either the intervention or the control group. Each patient will be given a progressive number and will be allocated to their group based upon a two-column series (one for each group) of randomly generated numbers without any restriction.

**Blinding**
In order to minimise bias, the researcher and data analyst will be blinded to patient allocation. Due to the nature of the study, however, it is not possible to blind participants or members of the CR centres.

**Eligibility for participation**
Every patient eligible for cardiac rehabilitation and thus visited by the cardiac nurse within 7 days after hospital discharge will be eligible for the trial. Age and co-morbidities which are often a cause for exclusion from research trials (Beswick et al., 2004) will not be considered reasons for exclusion as it is important to receive data as close to real-life scenario as possible for the trial to be able to provide information of the effectiveness of the intervention as a potential part of routine CR. Patient will be excluded if they decline consent or their English is not sufficient to complete the questionnaires.

**Assessment of patient and staff acceptability and feasibility**
Finally, in stage 3 of the study, a 6-month qualitative individual semi-structured interview study will take place in the participating CR centres. Participating cardiac nurses, administration staff and managers (n=10) will be interviewed in order to establish acceptability of intervention by using an open-ended question interview schedule amongst CR staff including following topics

- Clinical experience of using the intervention
- Views on feasibility of intervention in relation to staffing level, time and other resource consumption
• Integration with other centre activities and organisational/administrative issues
• Views on benefits and problems of the intervention
• Understanding of the intervention and opinions on value for patients
• Any other comments, things they may wish to add
• Demographic data
• Views on the interview process

Patient and carer acceptability is assessed during follow-up 1 using a patient satisfaction and acceptability questionnaire including questions on following topics

• Views on value of the intervention in regards to effects on quality of life, anxiety
• Views on acceptability of the intervention including timing (e.g. too much/little time expenditure), opportunity cost
• Views on the degree to which the intervention meets their lifestyle, psychological and social needs
• Views on the effect of intervention on burden of caring
• Any other comments, things they may wish to add
• Demographic data
• Views on the interview process

**Ethical approval**

Ethical approval will be sought from the National Research Ethics Service (NRES). R&D approval will be sought from the appropriate NHS Health Boards once the trial centres have been chosen. As the intervention will not include an exercise component, the risks to patients are minimal. All sessions and interactions with patients will be delivered by appropriately trained and experienced staff of the Mid & South West Wales Cardiac Network. All participants will be given information sheets and will have the chance to ask questions about the study before giving informed consent. It will be made clear to participants that they can withdraw from the study at any time without having to state reasons. Staff members of the CR centres will also be advised that they can withdraw consent at any time. Participants will be given an alphanumeric identifier during analysis and reporting to ensure anonymity. No identifying information will be kept with the data which will be stored and analysed on a secure network drive at Swansea University. All files will be password protected and used only for the purposes of the study solely by the researchers involved in the study.
5.6.2.3. Use of resources

**Staff:** a principal investigator (Grade 7; 0.5 FTE over 2 years) will take responsibility for the day to day running of the trial, conduct interviews, administer questionnaires, organise cooperation with the CR centres and perform data analysis and reporting. Additionally, the in-situ cardiac specialist nurse (Band 6/7; 2 x 0.2 FTE over 10 weeks) of each of the two trial centres will be required to take up certain tasks such as additional home visits, patient recruitment, lead of information sessions etc.

**Travel:** It is important that participants feel comfortable during interviews and the interview process does not cause any disruption to their work or social life. It is thus crucial to give the interview participants the choice of when and where the interview will take place. Therefore resources need to be allocated to travel to and from participants’ houses or workplaces and telephones if participants prefer telephone interviews. Also, the coordination of the intervention in the 2 pilot centres and the organisation of patient information sessions, workshops and social gatherings will require the principal investigator to travel to and from the pilot centres on a regular basis. Further travel expenses will arise from meetings of the advisory group.

**Consumables:** This includes printing of the questionnaires, consent and information forms, license fees for the questionnaires and postage as well as free-post for consent, questionnaires and reminders. Also, participant feedback about the study results will be provided to those participants who request it.

**Catering:** Meetings of the advisory group as well as group sessions for patients and carers will incur room hire (if not possible to do in CR centres) and will require catering (e.g. tea, coffee, buffet lunch).

**Other costs:** Other costs will include randomisation, trial registration, CR centre staff training and dissemination costs (e.g. conference fees).

5.6.2.4. Method of analysis

**Intervention development:** Interviews will be audio-taped with consent of the participants and transcribed verbatim. The number of interviews will be divided equally among the 10 CR
centres of the Mid & South West Wales Cardiac Network. Qualitative data will be coded and analysed to produce readable narrative descriptions using the software NVivo 8. Major themes, categories and illustrative examples in regards to patient needs and preferences and professional opinion and expertise will be extracted through content analysis. Together with the input and directions of the advisory group this will allow the design of an appropriate and useful intervention that improves patient participation in Phase 3, QoL and anxiety levels and can be is feasible and acceptable in routine practice of a CR centres.

**Pilot testing:** Data from the pilot trial will primarily be analysed in regards to intervention and study feasibility. The main objective is to test the intervention and establish how feasible it is in routine practice. The pilot study will therefore test the trial and intervention parameters to ensure the optimal conduct of a large multi-centre trial. The pilot trial mimics the large study to allow the identification of weaknesses and inform the development of a successful study protocol.

Data collected during the pilot trial will be analysed applying an intention to treat analysis. Subjects who withdraw from the study at any point will be followed up for endpoints and missing information will be handled by the application of sensitivity analyses. Reasons for non-participation and withdrawal will be documented and recorded and participation rates will provide a measure of acceptability of the intervention to patients. The quantitative analyses will compare participation in Phase 3 CR, quality of life of patient and carer and anxiety levels between the intervention and control group and between baseline and follow-up data both within and between groups. Due to the small sample size, non-parametric Mann-Whitney U test will be used to analyse continuous data and Chi-square tests will be applied to categorical data. Wilcoxon signed rank test will be used to determine changes in outcomes between and within groups over time. All analyses will be conducted using SPSS with 0.05 as the level of statistical significance and a 95 % confidence interval around point estimates.

Descriptive analyses will be used to describe participating patients in terms of age, gender, nature of cardiac event/procedure and co-morbidities.

**Assessment of patient and staff acceptability and feasibility**

Data analysis will involve qualitative methods for interview data from health professionals and data from satisfaction questionnaires from trial participants. Analysis of this data will allow the assessment of acceptability and feasibility of the intervention.
Economic evaluation

The economic evaluation will be undertaken from a societal perspective and encompass NHS and personal social services and patient perspectives. Health care costs will include general practice contacts, all prescribed medications, hospital in-patient stays and out-patient attendances, contacts with emergency services and readmissions. Intervention costs will reflect necessary staff time as well as overhead costs including new equipment, stationary and capital expenditure. Patient costs will include out-of-pocket expenses (e.g. travel, over the counter medication) and time input into the intervention process. Loss of productivity and work time will be measured for the societal impact of the intervention. Unit costs will be collected from published resources and CR centre finance departments and applied to the resources collected during intervention implementation and through the patient resource use questionnaire. A cost-consequences analysis will compare patient and carer outcomes to implementation and running cost of the intervention. Furthermore, EQ-5D results will be used to perform a cost-utility analysis in order to compare cost of intervention to changes in patients’ quality of life. Cost per QALY will be calculated as part of the cost-utility analysis. Incremental cost-effectiveness and cost-utility ratios will be calculated for all outcomes and cost-effectiveness acceptability curves will be generated. One-way and probabilistic sensitivity analyses will be performed to investigate the uncertainty of results.

5.6.2.5. Expected outcomes

Intervention development: The main outcome of this stage of the project will be the development of an intervention to promote patient well-being and participation in Phase 3 cardiac rehabilitation by offering support and information during Phase 2.

Pilot testing: The intervention developed in the first stage of the project will be pilot tested to ensure that it is accepted by patients and makes sense in the context of routine CR. Also, if the intervention proves acceptable and feasible and the pilot trial promises good results, a large multi-centre randomised controlled trial will establish how useful the intervention could be in routine CR. The pilot trial will therefore also test all parameters, measures and protocols used to ensure the study protocol is sound and to maximise the potential of the main trial to achieve its aims and objectives. In order to establish feasibility of the trial protocol, the following outcomes of the pilot trial will be analysed:
- **Participation rates of Phase 3 cardiac rehabilitation**: Standard 6 of the Cardiac Disease National Service Framework for Wales states that every patient with coronary heart disease should be offered an appropriate, evidence-based cardiac rehabilitation (WAG, 2009). The identified key interventions are service-related including patient identification and referral, patient review and assessment, patient information and encouragement to participate in CR and achieve lifestyle changes (WAG, 2009). Phase 3 (structured exercise and information) participation plays a crucial role in the reduction of recurrent cardiac events in patients with cardiovascular disorders by decreasing risk factors such as high blood pressure, high cholesterol level, obesity and smoking. This will ultimately lead to reduced health care resource use, increased vitality and independence (especially in older patients) and improved quality of life. However, only 35% of cardiac patients participated in Phase 3 CR in Wales in 2008/09 (NACR, 2010). Studies have shown that patient information and encouragement during the early stage of CR can significantly increase Phase 3 participation as well as improve clinical and quality of life outcomes (Davies et al., 2010, Beswick et al., 2004, Bethell et al., 2009). It is therefore of particular importance to modify service delivery and introduce interventions during Phase 1 and 2 of cardiac rehabilitation that will engage patients to participate in Phase 3 and make the appropriate lifestyle changes in order to address Standard 6. By assessing the change in Phase 3 participation after the proposed Phase 2 intervention compared to routine care using a specifically designed questionnaire at all follow-up points the impact of the intervention in relation to Standard 6 will be measured.

- **Patient and carer anxiety and quality of life**: After a life-threatening experience and unfamiliar surrounding during their hospital stay following a cardiac event, patients experience a high level of anxiety and a significant reduction in health-related quality of life. Furthermore, caregivers and informal carers have been found to experience deteriorating mental and physical health as a consequence of caregiver burden (Agren et al., 2010) and their quality of life is poor when compared to the general population (Jaarsma et al., 2010). Advice, information and Phase 3 exercise programmes have been shown to considerably improve anxiety levels and QoL in patients and information and support have been proposed to improve carer QoL and reduce worries. Furthermore, an informed carer will enhance patient
adherence to CR programmes and lifestyle changes (Agren et al., 2010, Moulaert et al., 2011).
Results and scores from HADS, QLMI and EQ-5D questionnaires at baseline and all follow up points will allow comparison of patients receiving the intervention to control patients which will give an indication of the effectiveness of the intervention in regards to patient anxiety and QoL.

- **Cost-effectiveness of the intervention:** Considering budget restrictions in health care in general and lack of funding in cardiac rehabilitation specifically, it is crucial for a new intervention to demonstrate cost-effectiveness to decision makers. Costs will be measured using patient resource questionnaires at all follow-up points and through interviews with staff of CR centres and unit costs from published sources and finance information will be allocated.

- **Contacts with health care and social care:** Date extracted from the patient resource use questionnaire completed at every follow-up point will be used to compare the frequency of contacts with health care (general practice, A&E, in-patients stays, out-patient appointments, community nurse, physiotherapist) and social care (social worker, aids and adaptations, community support services) between intervention and control group. This measure will be reported individually but will also form part of the cost-effectiveness measure.

In addition to the pilot trial outcomes, the following feasibility outcomes will be included (Thabane et al., 2010):

- Standard deviation of the pilot trial outcome measures to allow estimation of main trial sample size
- Establishing data variability
- Determination of recruitment rates, refusal rates, compliance rates and drop-out rates
- Testing of eligibility criteria (sufficient, too loose, to restrictive)
- Testing of randomisation process
- Patient understanding of all study questionnaires
- Time needed to administer and fill in questionnaires
- Suitability of outcome measures and overall study design
- Suitability of follow-up points
• Determining CR centre willingness and capacity
• Challenges to study personnel and centre staff

The pilot trial will be considered a success if
• 94 patients can be recruited from 2 centres within 5 weeks (approximately 10 patients per centre per week)
• At least 70% of eligible patients can be recruited
• Complete follow-up data can be achieved from at least 95% of all recruited participants

According to the results of the pilot trial the main trial will be either considered feasible, feasible with modifications or not feasible.

**Assessment of patient and staff acceptability and feasibility:** Main outcomes of this stage of the project will be the acceptability of the intervention to patients and CR centre staff and the feasibility of the intervention in the context of its effectiveness and its potential for integration into routine CR services.

### 5.6.2.6. Impact and dissemination

It has been suggested that it is unethical to consider running a large phase III type study without having sufficient data or information about feasibility (Thabane et al., 2010). In case the intervention and study protocol prove feasible during the pilot testing, funding for a large multi-centre randomised controlled trial in South Wales will be applied for. If funding can be secured and the effectiveness of the intervention can be clinically proven, the intervention may significantly change service provision of cardiac rehabilitation in South Wales and even in the UK by re-distributing resources from Phase 1 and Phase 3 into Phase 2 in order to alleviate patient anxiety, increase quality of life and improve participation in Phase 3 exercise programmes. It can be assumed that a higher participation rate in CR will increase patient health and well-being and reduce hospital admissions, length of stay and use of health care resources in general.

In case the results of the pilot trial show that the intervention and/or study protocol are not feasible, this information will be conveyed to the research community as a reference in order to save resources on that may otherwise be unnecessarily spent on studies that are not feasible.
**Possible publications:**

a. A qualitative study of patient and carer needs after hospital discharge after cardiac events

b. A descriptive analysis of the development of a multidisciplinary intervention to improve patient quality of life and anxiety as well as patient uptake of Phase 3 cardiac rehabilitation by offering tailored support and information during Phase 2

c. A qualitative study of patients’ and health professionals’ experiences of a new multidisciplinary intervention to improve patient quality of life and anxiety as well as patient uptake of Phase 3 cardiac rehabilitation by offering tailored support and information during Phase 2

d. A multidisciplinary intervention to improve patient quality of life and anxiety as well as patient uptake of Phase 3 cardiac rehabilitation by offering tailored support and information during Phase 2: a pilot study

e. An economic analysis of a new multidisciplinary intervention to improve patient quality of life and anxiety as well as patient uptake of Phase 3 cardiac rehabilitation by offering tailored support and information during Phase 2

### 5.6.2.7. Proposed project timetable

**Months 1 - 3:**
Post funding decision develop detailed study protocols, develop interview schedules as well as patient baseline, resource use, Phase 3 participation and satisfaction questionnaires, obtain licenses for QLMI, HADS, AC-QoL and register for EQ-5D. Recruit centres and obtain ethical and R&D approvals.

**Months 3 - 9:**
Individual patient, carer and staff interviews to establish patient needs and health professionals opinions on an appropriate intervention

**Months 6 – 12**
Design and development of intervention in cooperation with advisory group

**Months 13 - 14**
Training of CR centre staff and set-up of intervention in the recruited CR centres

**Months 14 – 16**
Patient recruitment, consent and baseline data collection. Randomisation and intervention

**Months 15 - 18**
Collection of follow up data for F1 6 weeks after hospital discharge. Collection of data on patient satisfaction with Phase 2 intervention.

Months 17 - 19

Collection of follow up data for F2 12 weeks after hospital discharge.

Months 17 – 20

Interviews with CR centre staff to gather information on perceived value, feasibility and acceptability of intervention as well as realisation in CR routine programmes.

Months 20 – 24

Data cleaning, analysis and report preparation/publication

These rates are based on an average 10 patients being registered in any CR centre per week.

5.6.3. Main trial

5.6.3.1. Aims and objectives

The overall aim of the proposed study is to test a tailored intervention to improve patient participation in Phase 3 cardiac rehabilitation as well as health outcomes and patient and carer quality of life by offering support and information during the waiting time between hospital discharge after a cardiac event and commencement of the structured Phase 3 information and exercise programme on average 5 to 8 weeks later (Phase 2) in South Wales.

Specific objectives are as follows:

1. To compare the effectiveness of the intervention in regards of patient uptake of the structured routine Phase 3 exercise and information programme to routine Phase 2 CR
2. To examine the impact of the intervention on patients in terms of patient anxiety, quality of life and clinical outcomes
3. To examine the impact of the intervention on patients’ carers/closest family members in terms of carer anxiety and quality of life.
4. To establish the implementation cost and budget impact of the intervention for cardiac rehabilitation centres in South Wales and its relative cost-effectiveness
5. To investigate the acceptability and feasibility of the intervention in the context of routine cardiac rehabilitation

5.6.3.2. **Study design and method**

The proposed study will be run over a total of two years. The intervention that was developed and pilot tested in the first stage of the trial will be tested in CR centres in South Wales in a multi-centre randomised, controlled trial. During the routine visit of cardiac patients within 7 days of hospital discharge, patients will be invited to take part in the study. Patients will receive an information leaflet and the cardiac nurse will explain the study and answer questions. After informed consent has been given, baseline data is collected and the patient is then randomised into either the intervention or the control group based on a 1:1 ratio. The intervention group will receive the intervention designed in stage 1 of the trial for 4 consecutive weeks. The nature of this intervention cannot be specified as it will depend on results of the focus group study. It is, however, anticipated that it may include one or more of the following: information sessions for patients and partners/carers including a multidisciplinary team of cardiac nurses, dieticians and counsellors, additional nurse visits, social gatherings of patients and carers sharing the same experiences, telephone consultations and advice. The control group will receive routine care during Phase 2 CR, i.e. written information, recommendations of light exercise but no further contact with the cardiac team. Six weeks after hospital discharge the first set of follow-up data is collected (F1) including information on whether patients started taking part in Phase 3. A second set of follow-up data (F2) is recorded after 12 weeks (usually the end of structured CR) and a further data-set (F3) will be collected 6 months after hospital discharge to gain information on longer-term effects of the intervention.

In order to assist the health economic analysis, this stage will also include collection of data on resource use for intervention implementation in the CR centres, out-of-pocket expenses for patients and health care resources used by patients.

Data collected and measures used will include:

**Baseline only**

- Baseline questionnaire asking for demographics (gender, age, education, occupation), co-morbidities (e.g. diabetes) and nature of the cardiac event or diagnosis (e.g. MI, PCI, CABG, angina, heart failure)
Baseline and follow-up
- Patient quality of life measured using the Quality of life after myocardial infarction questionnaire QLMI and the generic EuroQol EQ-5D
- Patient anxiety and depression scores using the Hospital Anxiety and Depression Scale HADS
- Carer quality of life using the Adult Carer Quality of Life questionnaire AC-QoL
- Patients' blood pressure, body mass index and cholesterol level

Follow-up only
- Patient participation in Phase 3 cardiac rehabilitation (started/not started, number of sessions attended and reasons for attending/not attending)
- Patient resource use questionnaire (out-of-pocket expenses, health care use, medication etc.)

Sample size calculation
Patient uptake of CR has been in the range of 18 and 38 % of patients eligible for CR between 2007 and 2009 with no significant increases compared to past years (Beswick et al., 2004, NACR, 2010). Considering this range of 20 % for patient participation and basing power calculations on a power of 80 %, probability of a type I error of 0.05 and probability of a type II error of 0.20, 392 patients per group (684 in total) will need to be recruited. Drop-out rates from exercise-based CR programmes have been found to be as high as 20 % within the first 3 months (Jolly et al., 2007). Even though a lower drop-out rate can be assumed for non-exercise based programmes, a final completion rate of 80 % is anticipated (accounting for loss to follow-up through drop-out/withdrawal, death and leaving the geographical area without a forwarding address) which means that 940 patients need to be recruited. Of the patients not taking part in CR, about a third stated they were "not interested" (NACR, 2010). It must be assumed that those patients may also have no interest in the Phase 2 intervention. For this reason, 1253 patients may need to be contacted to achieve a recruitment of 940 participants. Each CR centre of the Mid & South West Wales Cardiac Network registers on average 10 patients per week for Phase 2 cardiac rehabilitation (personal communication). In an eight month (32 week) recruitment period, four centres would therefore be needed to recruit the required sample size.
**Trial setting**
In October 2010, the Mid & South West Wales Cardiac Network commissioned Swansea University to conduct a scoping exercise to identify areas for research, evaluation and audit in relation to the practice and delivery of cardiac rehabilitation. After a thorough review of the existing literature on cardiac rehabilitation, this exercise identified 15 areas where further information and thus further research could assist in improving service delivery. The 15 research recommendations were then scored in a prioritisation exercise by professional members of the Cardiac Network and the proposed study was amongst the top six priority studies according to cardiac nurses, cardiologists and other health professionals involved in CR in Mid and South Wales. The 10 CR centres of the Mid & South West Wales Cardiac Network are supporting the study. Four representative centres will be chosen to participate in the study.

**Blinding**
In order to minimise bias, data analysts will be blinded to patient allocation. Due to the nature of the study, however, it is not possible to blind participants or members of the CR centres.

**Eligibility for participation**
Every patient eligible for cardiac rehabilitation and thus visited by the cardiac nurse within 7 days after hospital discharge will be eligible for the trial. Age and co-morbidities which are often a cause for exclusion from research trials (Beswick et al., 2004) will not be considered reasons for exclusion as it is important to receive data as close to real-life scenario as possible for the trial to be able to provide information of the effectiveness of the intervention as a potential part of routine CR. Patient will be excluded if they decline consent or their English is not sufficient to complete the questionnaires.

**Ethical approval**
Ethical approval will be sought from the National Research Ethics Service (NRES). R&D approval will be sought from the appropriate NHS Health Boards once the trial centres have been chosen.
As the intervention will not include an exercise component, the risks to patients are minimal. All sessions and interactions with patients will be delivered by appropriately trained and experienced staff of the Mid & South West Wales Cardiac Network.

5.6.3.3. Use of resources

Staff: a principal investigator (Grade 7; 1.0 FTE over 2 years) will take responsibility for the day to day running of the trial, administer questionnaires, organise cooperation with the CR centres and perform data analysis and reporting. Additionally, the in-situ cardiac specialist nurse (Band 6/7; 2 x 0.2 FTE over 10 months) of each of the four trial centres will be required to take up certain tasks such as additional home visits, patient recruitment, lead of information sessions etc.

Travel: The coordination of the intervention in the four test centres and the organisation of patient information sessions, workshops and social gatherings will require the principal investigator to travel to and from the centres on a regular basis. Further travel expenses will arise from travel reimbursements of the study nurses.

Consumables: This includes printing of the questionnaires, consent and information forms, license fees for the questionnaires and postage as well as free-post for consent, questionnaires and reminders. Also, participant feedback about the study results will be provided to those participants who request it.

Catering: Group sessions for patients and carers will incur room hire (if not possible to do in CR centres) and will require catering (e.g. tea, coffee, buffet lunch).

Other costs: Other costs will include randomisation, trial registration, CR centre staff training and dissemination costs (e.g. conference fees).

5.6.3.4. Method of analysis

Data will be analysed applying an intention to treat analysis. Subjects who withdraw from the study at any point will be followed up for endpoints and missing information will be handled by the application of sensitivity analyses. Reasons for non-participation and withdrawal will be documented and recorded and participation rates will provide a measure of acceptability.
of the intervention to patients. The quantitative analyses will compare participation in Phase 3 CR, clinical parameters, quality of life of patient and carer and anxiety levels between the intervention and control group and between baseline and follow-up data both within and between groups. Independent-samples t-tests will be used for continuous, normally distributed parameters (non-parametric Wilcoxon signed-rank test for non-normal distributions) and Chi-square tests for categorical data will be applied to compare proportions and means of targeted parameters with 0.05 as the level of statistical significance and a 95% confidence interval around point estimates. Descriptive analyses will be used to describe participating patients in terms of age, gender, nature of cardiac event/procedure and co-morbidities. Sub-group analyses will explore the effect of co-morbidities, nature of cardiac event/procedure, age and gender on the trial results. All quantitative data analysis will be done using SPSS.

**Economic evaluation:**
The economic evaluation will be undertaken from a health care/CR centre perspective, societal perspective and a patient perspective. Health care costs will include general practice contacts, all prescribed medications, hospital in-patient stays and out-patient attendances, contacts with emergency services and readmissions. Intervention costs will reflect necessary staff time as well as overhead costs including new equipment, stationary and capital expenditure. Patient costs will include out-of-pocket expenses (e.g. travel, over the counter medication) and time input into the intervention process. Loss of productivity and work time will be measured for the societal impact of the intervention. Unit costs will be collected from published resources and CR centre finance departments and applied to the resources collected during intervention implementation and through the patient resource use questionnaire. A cost-consequences analysis will compare patient and carer outcomes to implementation and running cost of the intervention. Furthermore, EQ-5D results will be used to perform a cost-utility analysis in order to compare cost of intervention to changes in patients' quality of life. Cost per QALY will be calculated as part of the cost-utility analysis. Incremental cost-effectiveness and cost-utility ratios will be calculated for all outcomes and cost-effectiveness acceptability curves will be generated. One-way and probabilistic sensitivity analyses will be performed to investigate the uncertainty of results.
5.6.3.5. Expected outcomes

Primary outcomes:

- **Participation rates of Phase 3 cardiac rehabilitation**: Standard 6 of the Cardiac Disease National Service Framework for Wales states that every patient with coronary heart disease should be offered an appropriate, evidence-based cardiac rehabilitation (WAG, 2009). The identified key interventions are service-related including patient identification and referral, patient review and assessment, patient information and encouragement to participate in CR and achieve lifestyle changes (WAG, 2009). Phase 3 (structured exercise and information) participation plays a crucial role in the reduction of recurrent cardiac events in patients with cardiovascular disorders by decreasing risk factors such as high blood pressure, high cholesterol level, obesity and smoking. This will ultimately lead to reduced health care resource use, increased vitality and independence (especially in older patients) and improved quality of life. However, only 35% of cardiac patients participated in Phase 3 CR in Wales in 2008/09 (NACR, 2010). Studies have shown that patient information and encouragement during the early stage of CR can significantly increase Phase 3 participation as well as improve clinical and quality of life outcomes (Beswick et al., 2004, Davies et al., 2010). It is therefore of particular importance to modify service delivery and introduce interventions during Phase 1 and 2 of cardiac rehabilitation that will engage patients to participate in Phase 3 and make the appropriate lifestyle changes in order to address Standard 6.

By assessing the change in Phase 3 participation after the proposed Phase 2 intervention compared to routine care using a specifically designed questionnaire at all follow-up points the impact of the intervention in relation to Standard 6 will be measured.

- **Patient anxiety and quality of life**

  After a life-threatening experience and unfamiliar surrounding during their hospital stay following a cardiac event, patients experience a high level of anxiety and a significant reduction in health-related quality of life. Advice, information and Phase 3 exercise programmes have been shown to considerably improve anxiety levels and QoL (Thompson et al., 1996, Paquet et al., 2005).
Results and scores from HADS, QLMI and EQ-5D questionnaires at baseline and all follow up points will allow comparison of patients receiving the intervention to control patients which will give an indication of the effectiveness of the intervention in regards to patient anxiety and QoL.

- **Cost-effectiveness of the intervention**
  Considering budget restrictions in health care in general and lack of funding in cardiac rehabilitation specifically, it is crucial for a new intervention to demonstrate cost-effectiveness to decision makers. Costs will be measured using patient resource questionnaires at all follow-up points and through interviews with staff of CR centres and unit costs from published sources and finance information will be allocated (see 5d).

Secondary outcomes

- **Clinical outcomes**
  Clinical outcome measures will include blood pressure, cholesterol level and body mass index. These measures will be taken at baseline and all follow-up points by the cardiac nurse. Outcomes of the intervention group will be compared to outcomes of the control group to establish the clinical impact of the intervention.

- **Contacts with health care and social care**
  Date extracted from the patient resource use questionnaire completed at every follow-up point will be used to compare the frequency of contacts with health care (general practice, A&E, in-patients stays, out-patient appointments) and social care (community nurse, physiotherapist, psychologist etc.) between intervention and control group. This measure will be reported individually but will also form part of the cost-effectiveness measure.

- **Carer quality of life**
  It has been suggested that information, reassurance and support could also benefit carers who often experience a poor quality of life, worries and anxiety and increase Phase 3 participation of patients as carers can play a very important role in enhancing patient motivation (Agren et al., 2010, Moulaert et al., 2011). Results and scores for carer quality of life derived from the Adult Carer Quality of Life questionnaire AC-QoL collected at baseline and all follow up points will allow
comparison of QoL of carers of patients receiving the intervention to carers of control patients which will give an indication of the effectiveness of the intervention in regards to carer anxiety and QoL.

5.6.3.6. **Impact and dissemination**

Encouraging results from the trial regarding patient and carer quality of life, effectiveness in increasing Phase 3 uptake and cost-effectiveness could result into the re-design of Phase 2 cardiac rehabilitation in Mid and South West Wales that may enhance CR effectiveness as well as patient wellbeing.

Possible publications may include:

- Rational and description of a new Phase 2 cardiac rehabilitation intervention targeted to increase patient and carer quality of life and Phase 3 participation
- Outcomes and results of a new Phase 2 cardiac rehabilitation intervention targeted to increase patient and carer quality of life and Phase 3 participation
- The change in patient quality of life and anxiety through early post-discharge information, advice and support.
- The change in carer quality of life through early post-discharge information, advice and support.
- Economic evaluation of a new Phase 2 cardiac rehabilitation intervention targeted to increase patient and carer quality of life and Phase 3 participation

5.6.3.7. **Project timetable**

Months 1 - 3:
Post funding decision develop detailed study protocols, develop patient baseline, resource use, Phase 3 participation and satisfaction questionnaires, obtain licenses for QLMI, HADS, AC-QoL and register for EQ-5D. Recruit centres and obtain ethical and R&D approvals. Staff recruitment.

Months 3 – 6
Training of CR centre staff and set-up of intervention in the recruited CR centres.

Months 6 – 14
Patient recruitment, consent and baseline data collection. Randomisation and intervention.
Months 7 - 15
Collection of follow up data for F1 6 weeks after hospital discharge. Collection of data on patient satisfaction with Phase 2 intervention.

Months 9 - 17
Collection of follow up data for F2 12 weeks after hospital discharge.

Months 12 – 20
Collection of follow up data for F3 6 months after hospital discharge.

Months 20 – 24
Data cleaning, analysis and report preparation/publication

These rates are based on an average 10 patients being registered in any CR centre per week.
6. Discussion and future directions

The presented report discusses Stages 1 to 5 of the scoping exercise commissioned by the Mid and South West Wales Cardiac Network undertaken by Swansea University.

The aims of Stages 1 to 5 were:

- **g)** to create an overview of the literature, research and knowledge available in the field and to provide a reference base for future work (Stage 1).
- **h)** to identify areas where further research could benefit the practice and delivery of CR (Stage 2)
- **i)** to develop and provide a choice of relevant recommendations and short descriptions of potential areas of research to enable members of the Cardiac Network to make informed decisions about the directions in which future research should progress (Stage 3).
- **j)** to identify the six recommendations members of the Cardiac Network regarded as most important (Stage 3).
- **k)** To develop research proposals for all 6 prioritised research projects (Stage 4).
- **l)** To disseminate and report results at the end of April 2011 (interim report) and the end of December 2011 in the final report (Stage 5).

All these aims of Stages 1 to 5 have been achieved and are reported here. A thorough review of the existing literature allowed the identification of areas where further research could improve the knowledge base and subsequently CR services, research recommendations were developed and scored by members of the Cardiac Network and the six recommendations onto which respondents put highest priority were identified.

In Stages 4 and 5, research proposals were developed for all 6 chosen projects. It is hoped that these proposals will be translated into trials and studies that will enable the Cardiac Network to make informed decisions about service changes that may significantly improve service provision and patient attendance and satisfaction as well as impact positively on service funding.
7. References


8. **Appendix**

![CARDIAC REHABILITATION SERVICES IN WALES RECOMMENDATIONS FOR FURTHER RESEARCH
PRIORITISATION OF RECOMMENDATIONS](image)

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Priority By Category</th>
<th>Overall Prioritisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 Health Economic Evaluation of CR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Cost-effectiveness analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Cost-utility analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Long-term costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2 Research into different components of CR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. The benefits of nutritional counselling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. The benefits of psychological counselling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3 Research into the improvement of patient uptake</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Research into patient preferences</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Research into patients’ lack of interest</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Research into the “special needs” of women</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Research into CR for excluded patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.4 Research into changes in service provision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Research into patient identification and referral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Research into the influence of cardiologist and GP recommendation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Research into the use of the internet for home-based CR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 Research into Phase 1 and 2 of CR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Research into patient information during Phase 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Research into patient motivation during Phase 2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please feel free to offer a rationale for your choice of priorities above: