Improving access to and uptake of early pulmonary rehabilitation following hospitalisation for acute exacerbations of COPD

A thesis submitted for the degree of

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Statement of originality

The majority of the studies described in this thesis were performed between 2018 and 2020 during my PhD candidature at Imperial College London. Recruitment to one study began prior to commencing my PhD candidature at Imperial College London. I confirm that the work in it is my own, and I take full responsibility for the analysis and presentation of the data. This thesis was written wholly by me with the guidance of my supervisors: Dr William Man, Dr Matthew Maddocks, Professor Morag Farquhar and Professor Jadwiga Wedzicha.

Dr Claire Nolan (Research Physiotherapist), Ms Suhani Patel (Research Physiologist), Ms Jessica Walsh (Research Physiotherapist), Mr Oliver Polgar (Research Physiotherapist) and Ms Sarah Jones (Research Physiotherapist) helped with the recruitment of participants and / or collection of data for the studies presented in Chapters 3 and 6.

Mrs Lisa Brighton and Dr Joanne Bayly helped review papers and with the qualitative data collection for the studies presented in Chapters 4, 5 and 6.

All sources of information have been referenced within the text. The work in this thesis has not previously been presented for assessment in a higher degree application.

Ruth Emily Barker

9th June 2021

Copyright declaration

Awards arising during this thesis

2018

- **American Thoracic Society Abstract Scholarship**

Awarded for best abstracts submitted to the American Thoracic Society Conference Pulmonary Rehabilitation Assembly.

- **European Respiratory Society Young Scientist Sponsorship**

Awarded to support attendance to European Respiratory Society Congress.

- **Imperial Clinical Academic Training Office Annual Symposium Abstract Award**

Awarded for best abstracts submitted to the Imperial Clinical Academic Training Office Annual Symposium.

- **Royal Brompton and Harefield NHS Foundation Trust Annual Research Showcase Abstract Award**

Awarded for the category 'Greatest patient impact'.

2019

- **American Thoracic Society Abstract Scholarship**

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2020

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Chapter 2

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Chapter 3

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Dedication

To Jon, this simply would not have been possible without you.

Abstract

Background: Substantial benefits are associated with early pulmonary rehabilitation (PR) following severe acute exacerbations of chronic obstructive pulmonary disease (AECOPD) requiring hospitalisation. However, referral for, and uptake of, early PR are poor.

Methods and findings: In a prospective cohort study of 291 hospitalisations for AECOPD, COPD discharge bundles delivered by PR practitioners were associated with increased PR referral (60% vs 12%, p<0.001; adjusted odds ratio [OR]: 14.46, 95% confidence interval [CI]: 5.28 to 39.57) and uptake (40% vs 32%, p=0.001; adjusted OR: 8.60, 95% CI: 2.51 to 29.50) compared with non-PR practitioners.

In a randomised controlled trial with convergent qualitative interviews, a co-designed education video delivered at hospital discharge did not improve post-hospitalisation PR uptake (41% usual care vs. 34% intervention group; p=0.37), referral, or completion. Six of fifteen interviewed participants from the intervention group did not recall receiving the video.

Given the poor uptake of outpatient post-hospitalisation PR, a mixed methods systematic review was conducted to explore the feasibility, acceptability and clinical effectiveness of home-based models of PR in the post-AECOPD setting. Although home-based exercise training appeared to be feasible and acceptable to patients and healthcare professionals (HCPs), there were few trials and data was heterogenous regarding clinical effectiveness.

A model of care integrating home-based exercise training and hospital at home care was co-designed by service users and HCPs. This was tested in a mixed methods feasibility study. The model of care was feasible and acceptable to patients, family carers and HCPs, and was not associated with adverse events, suggesting formal evaluation of clinical efficacy is warranted.

Conclusions: Both referrer and patient factors contribute to poor referral and uptake rates for post-hospitalisation outpatient PR. Home-based PR is feasible and acceptable to patients, carers and HCPs; further research is needed to explore clinical efficacy and cost-effectiveness of post-hospitalisation home-based PR.

Table of contents

Chapter 1: Introduction 38

1.1 CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) 38

1.1.1 Acute exacerbations of COPD (AECOPD) 38

1.1.2 Pulmonary consequences of AECOPD 39

1.1.3 Impact of severe AECOPD on health services 40

1.1.4 Impact of AECOPD on physical activity and function 40

1.1.5 Impact of AECOPD on HRQoL 41

1.1.6 Impact of AECOPD on psychological function 43

1.1.7 Impact of AECOPD on family members and informal carers 43

1.2 PULMONARY REHABILITATION (PR) 44

1.2.1 PR following AECOPD 48

1.2.2 Uptake of PR following AECOPD 50

1.2.3 Improving uptake of PR following AECOPD 54

1.3 HOSPITAL AT HOME (HaH) 57

1.3.1 HaH following AECOPD 59

1.3.2 Implementation of HaH following AECOPD 61

1.4 INTEGRATING PR WITH HAH FOLLOWING AECOPD 62

1.5 OVERALL AIM AND PHASE SPECIFIC OBJECTIVES 65

1.6 HYPOTHESES 65

1.7 PROGRAMME OF WORK 68

1.7.1 Between phase mixed methods designs 70

1.7.2 Within phase mixed methods designs 71

1.7.3 Professional background and lens of researcher 71

1.7.4 Public and patient involvement 72

Chapter 2: Risk factors for non-referral and non-uptake of PR following hospital admission for AECOPD – a cohort study 74

2.1 BACKGROUND 74

2.2 OBJECTIVE 76

2.3 HYPOTHESIS 76

2.4 METHODS 77

2.4.1 Study design 77

2.4.2 Population 78

2.4.3 Study exposure 78

2.4.4 Study reference 78

2.4.5 Study covariates 79

2.4.5.1 Age 80

2.4.5.2 Sex 80

2.4.5.3 Forced expiratory volume in one second (FEV_1) percent predicted 80

2.4.5.4 Smoking history (smoking status) 81

2.4.5.5 Index of multiple deprivation 81

2.4.5.6 DECAF score 82

2.4.5.7 Additional clinically relevant variables 82

2.4.6 Study outcomes 83
2.4.6.1 Primary outcome 83
2.4.6.2 Secondary outcome 83
2.4.7 Sample size 83
2.4.8 Statistical analysis 84
2.5 RESULTS 85
2.5.1 Baseline characteristics 86
2.5.2 PR referral 88
2.5.2.1 Predictors of PR referral 89
2.5.3 PR uptake 91
2.5.3.1 Predictors of PR uptake 91
2.6 DISCUSSION 92
2.6.1 Proposed rationale for study findings 93
2.6.2 Strengths 94
2.6.3 Limitations 94
2.7 CONCLUSION 95
Chapter 3: A randomised controlled trial of a Video Intervention to facilitate RehabiliTation Uptake following hospitalised Exacerbations of COPD (VIRTUE) 96
3.1 BACKGROUND 97
3.2 OBJECTIVE 98
3.3 HYPOTHESIS 98
3.4 METHODS 98

3.4.1 Study design 98

3.4.2 Ethical approval and trial registration 100

3.4.3 Participants 100

3.4.3.1 Trial eligibility criteria 100

3.4.3.2 Qualitative interviews purposive sampling criteria 101

3.4.4 Randomisation procedure 101

3.4.5 Blinding 102

3.4.6 Study interventions 103

3.4.6.1 Video intervention development 104

3.4.7 Study measurements 106

3.4.7.1 Smoking history (smoking status and pack year history) 107

3.4.7.2 Comorbidity burden (Charlson Comorbidity Index) 107

3.4.7.3 Index of multiple deprivation 109

3.4.7.4 Anthropometry (height, weight and body mass index) 109

3.4.7.5 Physical frailty status (four metre gait speed) 110

3.4.7.6 Lung function (spirometry) 111

3.4.7.7 Respiratory disability (MRC dyspnoea scale) 113

3.4.7.8 HRQoL (COPD Assessment Test [CAT]) 113

3.4.8 Study outcomes 116

3.4.8.1 Primary outcome 116

3.4.8.2 Secondary outcomes 116

3.4.8.3 Clinical safety endpoints 117

3.4.8.4 Qualitative outcomes 117
3.4.9 Sample size 119
3.4.9.1 Trial sample size 119
3.4.9.2 Qualitative interviews sample size 119
3.4.10 Data analysis 119
3.4.10.1 Statistical analysis 120
3.4.10.2 Qualitative analysis 121
3.4.10.3 Integrated analysis 121
3.5 QUANTITATIVE RESULTS 121
3.5.1 Baseline characteristics 123
3.5.2 PR uptake rate 125
3.5.3 PR referral, adherence and completion rates 126
3.5.4 Change in Physical Performance and HRQoL 127
3.5.5 Clinical safety 128
3.5.6 Sensitivity analysis 128
3.5.7 Post-hoc analysis 131
3.6 QUALITATIVE RESULTS 133
3.6.1 Perceptions of the method 133
3.6.2 Impact of video perceptions and understanding of PR 135
3.6.3 Proposed strategies to enhance the video intervention 136
3.6.4 Experiences of post-hospitalisation PR 138
3.6.5 Reasons for declining post-hospitalisation PR 140

3.7 DISCUSSION 141

3.7.1 Comparisons to previous studies 141

3.7.2 Strengths 145

3.7.3 Limitations 146

3.8 CONCLUSION 148

Chapter 4: Intervention development Stage 1: Home-based exercise training for patients following hospitalisation for acute exacerbation of COPD – a mixed methods systematic review 149

4.1 BACKGROUND 149

4.2 OBJECTIVE 150

4.2.1 Intervention development objective 150

4.2.2 Systematic review objectives 150

4.3 METHODS 151

4.3.1 Design and registration 151

4.3.2 Types of evidence 151

4.3.3 Participants 152

4.3.4 Interventions 152

4.3.5 Comparators 153

4.3.6 Outcomes 153

4.3.6.1 Feasibility 153

4.3.6.2 Experiences and acceptability 154

4.3.6.3 Clinical effectiveness 154

4.3.7 Search strategy 154

4.3.8 Screening 156
4.3.9 Data extraction, analysis and interpretation 156
4.3.10 Quality assessment process 157
4.4 RESULTS 158
4.4.1 Outline of included papers 158
4.4.2 Quality assessment of included papers 163
4.4.3 Integrated synthesis 164
4.4.4 Feasibility 170
4.4.4.1 Recruitment and retention 170
4.4.4.2 Compliance 171
4.4.5 Experiences and acceptability 171
4.4.6 Clinical effectiveness 173
4.4.6.1 Physical function 173
4.4.6.1.1 Exercise capacity 173
4.4.6.1.2 Strength 174
4.4.6.1.3 Physical activity 174
4.4.6.1.4 Daily function 174
4.4.6.2 HRQoL 175
4.4.6.2.1 Health status 175
4.4.6.2.2 Psychological status 176
4.4.6.3 Health service utilisation 177
4.5 DISCUSSION 177

4.5.1 Comparison to current guidelines 178

4.5.2 Intervention development 178

4.5.3 Methodological considerations 180

4.5.4 Critique of the method 183

4.5.5 Strengths 184

4.5.6 Limitations 185

4.6 CONCLUSION 185

Chapter 5: Intervention development Stage 2: Integrating home-based exercise training with a hospital at home service for patients hospitalised with exacerbations of COPD – an accelerated experience-based co-design project 187

5.1 BACKGROUND 187

5.2 OBJECTIVE 188

5.2.1 Intervention development objective 188

5.2.2 EBCD project objective 189

5.3 METHODS 189

5.3.1 Study design 189

5.3.2 Study setting 191

5.3.3 Participants 191

5.3.4 Topic guides 192

5.3.5 Data analysis 193

5.4 RESULTS 194

5.4.1 Stakeholder events 196

5.4.1.1 Individualisation of the home-based exercise training 197

5.4.1.2 Progression and transition during home-based exercise training and outpatient-based programme 199

5.4.1.3 Continuity between services 201

5.4.1.4 Communication between stakeholders 204

5.4.2 Co-design meetings 206

5.4.3 Model of care developed 208

5.5 DISCUSSION 210

5.5.1 Comparison of co-designed model of care to previous studies 210

5.5.2 Comparison of stakeholder perspectives to previous studies 211

5.5.3 Interactions between stakeholders during project 213

5.5.4 Critique of the method 214

5.5.5 Strengths 215

5.5.6 Limitations 216

5.6 CONCLUSION 216

Chapter 6: Testing the acceptability feasibility of a home-based exercise training intervention alongside a hospital at home service for AECOPD 218

6.1 BACKGROUND 218

6.2 OBJECTIVES 218

6.3 HYPOTHESIS 219

6.4 METHODS 219

6.4.1 Study design 219

6.4.2 Ethical approval and study registration 220

6.4.3 Participants 221

6.4.3.1 Trial eligibility criteria 221

6.4.3.2 Qualitative interviews and focus group purposive sampling criteria 223

6.4.4 Randomisation procedure 224

6.4.5 Blinding 225

6.4.6 Study interventions 225

6.4.7 Study measurements 226

6.4.7.1 Smoking status (smoking history and pack years) 227

6.4.7.2 Index of multiple deprivation 227

6.4.7.3 Comorbidity burden (age-adjusted Charlson Comorbidity Index) 227

6.4.7.4 DECAF score 227

6.4.7.5 Respiratory disability (eMRC dyspnoea scale) 227

6.4.7.6 Ability to complete activities of daily living (ADL) (LCADL scale) 228

6.4.7.7 Accelerometer-measured daily physical activity (ActiGraph wGT3x) 230

6.4.7.8 The Short Physical Performance Battery (SPPB) 230

6.4.7.9 Hand grip strength 231

6.4.7.10 HRQoL (COPD Assessment Test [CAT]) 232

6.4.7.11 Health utility (Euro-QoL 5-dimensions 5-levels [EQ5D5L]) 232

6.4.7.12 Anxiety and depression (HADS) 235

6.4.7.13 Fatigue (mCES-D) 237

6.4.7.14 Six-minute step test (6MST) 237

6.4.7.15 Body composition (bioelectrical impedance analysis) 238
6.4.8 Study outcomes 239
6.4.8.1 Study feasibility outcomes 239
6.4.8.2 Intervention feasibility outcomes 240
6.4.8.3 Clinical outcomes 240
6.4.8.4 Safety outcomes 240
6.4.8.5 Qualitative outcomes 241
6.4.9 Sample size 243
6.4.9.1 Trial sample size 243
6.4.9.2 Qualitative interviews sample size 243
6.4.9.3 Qualitative focus groups sample size 243
6.4.10 Data analysis 244
6.4.10.1 Statistical analysis 244
6.4.10.2 Qualitative analysis 244
6.4.10.3 Integrated analysis 245
6.5 QUANTITATIVE RESULTS 245
6.5.1 Baseline characteristics 246
6.5.2 Study feasibility 250
6.5.3 Intervention feasibility 254
6.5.4 Clinical outcomes 256
6.5.5 Clinical safety 257
6.6 QUALITATIVE RESULTS 259

6.6.1 Between-stakeholder analysis 260

6.6.2 Patient and family carer perspectives 267

6.6.2.1 Experiences of exercise training 269

6.6.2.2 Impact of COPD admission 271

6.6.2.3 Experiences of research processes 272

6.6.2.4 Perceptions of support 274

6.6.2.5 Perceived impact of COPD 276

6.6.2.6 Additional noteworthy perspectives 278

6.6.3 Healthcare professional perspectives 279

6.6.3.1 PR team perspectives 281

6.6.3.1.1 Delivery of usual care 283

6.6.3.1.2 Views of patients' perceptions of outpatient-based PR 283

6.6.3.1.3 Perceptions of intervention 284

6.6.3.1.4 Perceptions of impact on family members or carers 286

6.6.3.1.5 Experiences and perceptions of the study 287

6.6.3.1.6 Additional noteworthy perspectives 289

6.6.3.2 HIRS team perspectives 289

6.6.3.2.1 Delivery of usual care 290

6.6.3.2.2 Perceptions of intervention 291

6.6.3.2.3 Perceptions of integration 293

6.6.3.2.4 Experiences and perceptions of the study 294

6.6.3.3 Researcher perspectives 295

6.6.3.3.1 Individual's role in the study 296
6.6.3.3.2 Communication between researchers 297
6.6.3.3.3 Experiences and perceptions of the study 298
6.6.3.3.4 Learning for future studies 300
6.7 INTEGRATED RESULTS 302
6.8 DISCUSSION 313
6.8.1 Implications of the findings 313
6.8.1.1 Study feasibility 313
6.8.1.2 Intervention feasibility 315
6.8.1.3 Clinical outcomes and safety 316
6.8.1.4 Potential application for a future efficacy trial 318
6.8.2 Adaption to study as result of COVID-19 319
6.8.3 Critique of the method 320
6.8.4 Strengths 322
6.8.5 Limitations 323
6.9 CONCLUSION 324
Chapter 7: Summary and future work 325
7.1 SUMMARY OF FINDINGS 325
7.2 SIGNIFICANCE OF FINDINGS 329
7.3 LIMITATIONS AND FUTURE WORK 331
7.4 CONCLUSION 334

References 335

Appendix 1: Permission to reprint or re-use tables, figures and published data 349

Appendix 2: VIRTUE usual care Pulmonary Rehabilitation leaflet 354

Appendix 3: Clinical decision-making tool from Delphi study 362

Appendix 4: Short Physical Performance Battery Standard Operating Procedure 366

Appendix 5: Six-minute step test Standard Operating Procedure 381

Appendix 6: Mixed methods feasibility study topic guides 384

Appendix 7: Mixed methods feasibility study reflective proforma for qualitative components 400

List of tables

Table 1.1. Examples of differences modes of exercise based upon delivery settings 46

Table 1.2. Pulmonary Rehabilitation education topics recommended by the British Thoracic Society 47

Table 1.3. DECAF score 59

Table 1.4. Results chapters which address each specific objective and their related hypothesis 67

Table 2.1. Characteristics of whole cohort and according to bundle completion status 87

Table 2.2. Characteristics of cohort with bundle completed according to involvement of the hospital practitioner in PR delivery who completed the bundle 88

Table 2.3. PR referral rate, uptake, completion and adherence according to the involvement of the hospital practitioner in PR delivery who completed the bundle 89

Table 2.4. Univariate logistic regression for predictors of PR referral and uptake within 28 days of hospital discharge for those with completed bundles 90

Table 2.5. Multivariate logistic regression for predictors of PR referral and uptake within 28 days of hospital discharge for those with completed bundles 91

Table 3.1. Scoring used to compute age-adjusted Charlson Comorbidity Index 108

Table 3.2. Medical Research Council dyspnoea scale 113

Table 3.3. Baseline characteristics for whole group and according to group allocation 124

Table 3.4. Referral rate, uptake, completion and adherence to early PR for whole group and according to group allocation 125

Table 3.5. Baseline characteristics for all PR-naïve and according to group allocation 129

Table 3.6. Referral rate, uptake, completion and adherence to early PR for all PR-naïve and according to group allocation 130

Table 3.7. Logistic regression for predictors of uptakeof early PR following hospitalisation for an acute exacerbation of COPD 132

Table 3.8. Subgroup analyses for factors associated with reduced PR uptake from logistic multivariate analysis 133

Table 4.1. Search strategy employed in this review 155

Table 4.2. Summary of included papers 160

Table 4.3. Assessment of risk of bias for RCTs and non-RCTs included in this review 163

Table 4.4. Integrated synthesis of outcomes from home-based exercise training for patients hospitalised with AECOPD 165

Table 5.1. Accelerated experience-based co-design project attendees at each stakeholder event and co-design meeting 195

Table 6.1. RCT eligibility criteria 222

Table 6.2. Purposive sampling criteria for qualitative components 224

Table 6.3. Baseline demographics for whole group and according to group allocation 247

Table 6.4. Baseline questionnaire scores for whole group and according to group allocation..... 249

Table 6.5. Baseline physical assessment findings for whole group and according to group allocation 250

Table 6.6. Completion rates of clinical outcome measures at baseline, 4 weeks and 12 weeks for whole group 253

Table 6.7. Home-based exercise training uptake and adherence according to each participant allocated to the intervention group..... 255

Table 6.8. Change in clinical outcome measures between the baseline and 4-week assessment and baseline and 12-week assessment according to group allocation 256

Table 6.9. Safety outcomes (adverse events, readmissions and mortality) according to whole group and group allocation by participants reporting event, event classification and event nature 258

Table 6.10. Qualitative component participants 259

Table 6.11. Between-stakeholder analysis according to specific stakeholder groups 262

Table 6.12. Themes and subthemes from the patient participant interviews 268

Table 6.13. Themes and subthemes from the family carer interviews 268

Table 6.14. Themes and subthemes from the PR team focus group..... 282

Table 6.15. Themes and subthemes from the HIRS team focus group 290

Table 6.16. Themes and subthemes from the researcher interviews 296

Table 6.17. A joint display of the integrated findings according by individual patient participants (and their family carers where appropriate)..... 306

Table 7.1 Completed TIDieR checklist with information from this thesis to describe the intervention developed within this programme of work 328

List of figures

Figure 1.1. Referral, uptake and adherence data to post-exacerbation pulmonary rehabilitation following an admission to hospital over 12 months in a north-west London hospital, UK. 51

Figure 1.2. Reasons for poor referral, uptake and completion rates to post-exacerbation pulmonary rehabilitation 52

Figure 1.3. Proposed benefits of integrating a pulmonary rehabilitation programme within a hospital at home service following hospitalisation for an acute exacerbation of COPD. 63

Figure 1.4. Schema of the programme of work presented within this thesis. 70

Figure 2.1. Example of standardised paperwork which requires completion for the COPD discharge bundle. 76

Figure 2.2. Schema of cohort study design. 79

Figure 2.3. Schema of the flow of patients, including COPD discharge bundle completion according to the three classifications of exposure. 86

Figure 3.1. Schema of VIRTUE trial design. 99

Figure 3.2. Schema of experience-based co-design process to develop the video intervention. 106

Figure 3.3. Equation to calculate pack year history. 107

Figure 3.4. a) Leicester Height Stadiometer (Model 217, Seca, Hamburg, Germany); b) Seca Dual Measurement analogue scales (Model 761 Seca, Hamburg, Germany). 110

Figure 3.5. Set-up and timing during four metre gait speed assessment. 111

Figure 3.6. a) EasyOne diagnostic spirometer; b) Calibration adapter; c) 3-litre calibration syringe. 112

Figure 3.7. COPD Assessment Test questionnaire. 115

Figure 3.8. Topic guide for the qualitative interviews. 118

Figure 3.9. CONSORT diagram for flow of participants in VIRTUE trial. 122

Figure 3.10. Kaplan-Meier curve demonstrating uptake of pulmonary rehabilitation within 28 days of discharge after hospitalisation for an acute exacerbation of COPD according to group allocation. . 126

Figure 4.1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis flow diagram for this review 159

Figure 5.1. Schema of this accelerated experience-based co-design project 190

Figure 5.2. Schematic of the final co-deigned model of care. 209

Figure 6.1. Schema of mixed methods feasibility study design. 220

Figure 6.2. London Chest Activities of Daily Living questionnaire. 229

Figure 6.3. Position for wearing ActiGraph wGT3x. 230

Figure 6.4. Jamar Hand Grip Dynamometer. 231

Figure 6.5. Euro-QoL 5-dimensions 5-levels questionnaire. 234

Figure 6.6. Hospital Anxiety and Depression Scale. 236

Figure 6.7. Modified Centre for Epidemiologic Studies Depression questionnaire. 237

Figure 6.8. Bodystat Quadscan 4000. 239

Figure 6.9. Correct electrode placement using Bodystat Quadscan 4000. 239

Figure 6.10. Study flow diagram. 251

List of abbreviations

Δ	Change
4MGS	Four metre gait speed
6MST	Six-minute step test
ADL	Activities of daily living
AE	Acute exacerbation
AECOPD	Acute exacerbation of chronic obstructive pulmonary disease
BIA	Bioelectrical impedance analysis
BMI	Body mass index
CAT	COPD Assessment Test
CES-D	Center for Epidemiologic Studies Depression
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
CRQ	Chronic Respiratory Disease Questionnaire
CRQ-D	Chronic Respiratory Disease Questionnaire Dyspnoea
DECAF	Dyspnoea, eosinophils, consolidation, acidaemia, atrial fibrillation
EBCD	Experience-based co-design
eMRC	Extended Medical Research Council
EQ5D5L	Euro-QoL 5 Dimensions 5 Levels

et al.	et alia
e.g.	For example
FEV_1	Forced expiratory volume in one second
FVC	Forced vital capacity
HaH	Hospital at home
HADS	Hospital Anxiety and Depression Scale
HCP	Healthcare professional
HET	Home-based exercise training
HIRS	Hillingdon Integrated Respiratory Service
HRQoL	Health-related quality of life
HSU	Health service utilisation
IQR	Interquartile range
ISRCTN	International Standard Randomised Controlled Trial Number
LCADL	London Chest Activities of Daily Living scale
m	Metres
max.	Maximum
mCES-D	Center for Epidemiologic Studies Depression
min.	Minimum
MRC	Medical Research Council
m/s	Metres per second

NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OR	Odds ratio
pH	Potential of hydrogen
PhD	Doctor of Philosophy
PR	Pulmonary Rehabilitation
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	International Prospective Register of Systematic Reviews
RCT	Randomised controlled trial
SD	Standard deviation
SGRQ	St George's Respiratory Questionnaire
SPPB	Short Physical Performance Battery
UK	United Kingdom
VAS	Visual analogue scale
VIRTUE	A randomised controlled trial of a Video Intervention to facilitate RehabiliTation Uptake following hospitalised Exacerbations of COPD

Chapter 1: Introduction

1.1 CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

Chronic obstructive pulmonary disease (COPD) is a "*common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases"* (1). The cardinal features of COPD include dyspnoea, cough, regular sputum production and wheezing (1). There are over 250 million cases of COPD worldwide and it is the third leading cause of death globally, and the burden from the disease is predicted to continue rising (2, 3). Consequently, the direct financial implications of COPD upon healthcare services is significant, estimated to be £2 billion per year in the United Kingdom (UK) alone, with indirect and intangible costs of COPD estimated to be over £60 million and £46 billion respectively (4).

1.1.1 Acute exacerbations of COPD (AECOPD)

Acute exacerbations of COPD (AECOPD) are defined as a *"sustained worsening of the patient's condition from the stable state and beyond normal day-to-day variations that is acute in onset and may warrant additional treatment in a patient with underlying COPD"* (5). The Global initiative for Chronic Obstructive Lung Disease has simplified the classification of exacerbations into three categories (6). Mild exacerbations require treatment with short acting bronchodilators, moderate exacerbations are those which require antibiotic therapy and / or steroids and severe exacerbations result in hospitalisation (or attendance to accident and emergency) (6).

The impacts of acute exacerbations, particularly severe exacerbations that require hospitalisation, are far-reaching. There are significant pulmonary consequences (see section 1.1.2) and severe exacerbations are a major contributor to the financial burden placed by COPD upon healthcare services (see section 1.1.3). For patients, exacerbations lead to deleterious physical, health-related quality of life (HRQoL) and psychological effects (see sections 1.1.4, 1.1.5 and 1.1.6), which often extend to their family members and informal carers (see section 1.1.7).

1.1.2 Pulmonary consequences of AECOPD

Acute exacerbations typically amplify existing symptoms of COPD as a result of acute worsening airway inflammation (6). This airway inflammation leads to worsening dyspnoea (breathlessness) due to expiratory flow limitation, increased air trapping and lung hyperinflation (7) and ventilation-perfusion mismatching (8). Long term damage to the airways can also occur as a result of this acute airway inflammation, including alveolar wall thickening and loss of surface area for gas exchange, escalating the progression of COPD. Respiratory viral infections are the main triggers of COPD exacerbations, although other possible aetiological factors include bacterial infections and environmental factors such as pollution and changes in ambient temperature (6).

Typical treatment for AECOPD include short acting inhaled bronchodilators, systemic corticosteroids and antibiotics (when indicated) to reduce the adverse long-term impact of the exacerbation, and to minimise the risk of future re-exacerbation (6). Non-invasive ventilation should be considered as the first ventilatory option for treating acidotic hypercapnic ventilatory failure (6), and is required for approximately one in ten patients hospitalised with an AECOPD (9). The 2020 National Asthma and Chronic Obstructive Pulmonary Disease Audit Programme COPD clinical outcomes demonstrated the

median length of inpatient stay and inpatient mortality rates in the UK to be four days and approximately 3% respectively (9, 10).

1.1.3 Impact of severe AECOPD on health services

Severe exacerbations (those which require hospitalisation) are one of the commonest causes of emergency hospital admissions, contributing to over one million hospital bed day per annum in the UK (11-13). The more severe the exacerbation, the greater the resources required to successfully treat the exacerbation (14). As a result, severe acute exacerbations place significant pressures upon resources, staffing and bed occupancy for health services.

Despite the exact cost of treating AECOPD being unknown, one estimate suggests 50% of the total cost of treating COPD in the UK is attributable to treating acute exacerbations (15). Treating severe exacerbations is estimated to cost 15 times more than treating a moderate exacerbation (16). Whilst severe acute exacerbations account for only 16% of overall reported exacerbations, they contribute to 90% of the total costs of treating exacerbations (14).

1.1.4 Impact of AECOPD on physical activity and function

There are numerous significant and adverse extra-pulmonary consequences of acute exacerbations on patients. Patients have a significant reduction in their physical activity. Pitta and colleagues, using accelerometers to objectively measure physical activity, showed time during the day spent walking and standing to be limited at day two and day seven of hospitalisation for an acute exacerbation (median [interquartile range «IQR»]): 7% [3% to 18%] and 9% [7% to 21%] respectively) (17). Time spent walking remained 50% lower one month after a hospitalisation for an exacerbation compared

to those with stable COPD (17). Moreover, the authors showed that participants with one or more hospitalisation in the year preceding the study had a lower walking time one month post discharge compared to those with no hospitalisations in the year preceding the study (17).

Unsurprisingly, the negative impact of exacerbations on physical activity extends to a decline in exercise capacity and muscle strength. Cote *et al.* showed walking distance, as measured by the six-minute walk test, was significantly reduced at the time of an acute exacerbation by 72 metres, and recovery to baseline levels was not observed at six months, one year or two years post-exacerbation (18). Similarly, the loss of lower limb muscle function in hospitalised patients with COPD was reported by Spruit and colleagues. They measured quadriceps peak torque at day three, day eight, and 90 days following hospitalisation for an exacerbation (19) and demonstrated a significant reduction in quadriceps peak torque between day three and day eight post-hospitalisation, with incomplete recovery observed 90 days from admission (19).

These objectively measured outcomes are corroborated by patient survey data. 85% of patients reported a noticeable deterioration in their abilities to complete activities of daily living during an AECOPD, with almost 50% of patients stopping all activities (20). Furthermore, 45% of patients report they become bed or chair bound during an exacerbation, and 55% of working patients have to stop work activities (21).

1.1.5 Impact of AECOPD on HRQoL

Aside from physical consequences, severe AECOPD have negative psychosocial impacts for patients. Cohort studies have shown significantly worse HRQoL during an AECOPD, and recovery of HRQoL following hospitalisation for an acute exacerbation (22-24). Mackay *et al.* showed a greater decline in

HRQoL was reported by patients, as measured by the COPD Assessment Test (CAT), who experienced a more persistent heightening of exacerbation-related symptoms (22). Furthermore, the authors demonstrated that "frequent exacerbators" (two or more exacerbations a year) had a worse baseline HRQoL than those who were infrequent exacerbators (22).

These findings were corroborated by studies from Miravitlles and colleagues (24). The authors demonstrated high CAT scores at baseline (at the beginning of an exacerbation), which improved significantly during the post-exacerbation recovery period (mean [standard deviation (SD)] point reduction of 9.9 [5.2]) within four- to six- weeks (24). These improvements occur in patients who experienced both severe and moderate acute exacerbations (24). Although no between group differences were reported, Miravitlles and colleagues indicated that those who experienced a severe exacerbation reported worse HRQoL at baseline than those who were treated in primary care (mean [SD] CAT score at baseline: 22.8 [7.0] versus 20.4 [5.1] respectively) (24).

A study by Kon *et al.* found mean change in CAT scores to be –3·0 (95% confidence interval [CI] –4·4 to –1·6) from day of hospital discharge to 90 days after a hospitalisation for an AECOPD (23). These data suggest HRQoL recovers following hospitalisation for an acute exacerbation, and that CAT is responsive in measuring HRQoL recovery post-hospitalisation (23). These studies therefore demonstrate that: 1) HRQoL worsens during an exacerbation, 2) HRQoL deteriorates during an exacerbation in line with the severity of exacerbation experienced, 3) patients experiencing more frequent exacerbations in the past year have worse HRQoL, and 4) HRQoL recovers following an acute exacerbation (22-24).

1.1.6 Impact of AECOPD on psychological function

Another psychosocial impact of acute exacerbations is upon feelings of anxiety and depression. A study which recruited patients admitted to hospital with an AECOPD reported significant levels of anxiety and depression in over 50% and 40% of patients respectively during an acute exacerbation (25). These finding have been corroborated in other studies. Quint and colleagues (26) demonstrated symptoms of depression were significantly elevated during an acute exacerbation. The authors also showed patients who had three or more exacerbations in the preceding year presented with significantly higher depressive symptoms than those who had less than three exacerbations in that period (26). In relation to anxiety, Gudmundsson *et al.* have shown the presence of anxiety during an exacerbation to be associated with an increased risk of readmission within one year following hospitalisation for an acute exacerbation (hazard ratio [95% CI]: 1.76 [1.16 to 2.68]) (27). Therefore, these findings not only demonstrate a significant proportion of patients present with anxiety and depression during the time of an AECOPD, but also that these symptoms can persist and adversely impact readmission risk following an exacerbation.

1.1.7 Impact of AECOPD on family members and informal carers

Adverse impacts of acute exacerbations on family members or informal carers of those living with COPD are evident. A recent systematic review, which included 15 studies, reported the five key aspects of a family carer's life which are negatively affected as a direct result of caring for someone living with COPD (28). These included physical, emotional, social, relational, and financial and employment impacts (28). These are similar to the issues reported in other reviews which explored informal carer-giver burden in COPD (29).

Within their review, Cruz and colleagues highlighted that acute exacerbations intensify the burden felt by family carers (28). First, family carers were shown to suffer with fatigue and exhaustion due to demands of constant supervision and regular travel to hospital or appointments, which becomes more frequent during acute exacerbations (28). Second, family carers reported stress and anxiety (28), which was attributable to the constant fear and everyday worry felt by the family carer that the person they are supporting with COPD may suffer an acute exacerbation of their symptoms (30). Finally, depressive symptoms in family carers were worse for those who cared for patients with more severe dyspnoea (31, 32). Therefore, the negative burden of AECOPD are likely to be intensified for family members or informal carers who support patients experiencing more severe exacerbations. This is likely due to more severe exacerbations requiring more intensive treatment (and potentially extended inpatient hospital stays), having greater symptom burden (for example, worse dyspnoea) and presenting a greater unpredictability with regards to outcome (for example a greater chance of mortality).

1.2 PULMONARY REHABILITATION (PR)

PR is defined as a *'comprehensive intervention based on a thorough patient assessment followed by patient tailored therapies that include, but are not limited to, exercise training, education, and behaviour change, designed to improve the physical and psychological condition of people with chronic respiratory disease"* (33). In the UK, the traditional delivery model for PR is outpatient-based in hospital or community settings, typically comprising two supervised exercise-training and education sessions per week over six- to 12- weeks (34). Patients attending PR should also be advised to complete further sessions of unsupervised exercise (34) to adhere to standard healthy living advice of 30 minutes of exercise five times per week (35).

The exercise training provided in PR should be individually prescribed for each patient according to the pre-PR assessment outcomes (34). The exercise prescribed is required to take into account type, duration, frequency, intensity, mode and progression (36). Each session should aim to include a minimum of 30 minutes of aerobic exercise, either interval or continuous training, and resistance training should be prescribed to either increase strength or endurance (34). The speed to initially prescribe aerobic training should correspond to 60-80% of peak work rate based on the exercise capacity test, or self-reported 'moderate' to 'somewhat severe' (3-4) perceived level of breathlessness on BORG CR-10 scale if no exercise capacity test is available (37). Strength resistance training should initially be prescribed at 60 to 70% of one repetition maximum or 'moderate' to 'hard' (13-15) intensity on rate of perceived exertion scale if no muscle strength assessment is available (38). Endurance resistance training should initially be prescribed at <50% of 1 repetition maximum or 'light' to 'moderate' (11-13) intensity on rate of perceived exertion scale if no muscle strength assessment is available (38). Resistance training to increase muscle strength should be prescribed in sets of two to four of between eight to 12 repetitions, whereas resistance training to increase muscle endurance should be prescribed in one to two sets of between 15 to 25 repetitions (38).

The mode of exercise delivery may vary depending on whether the PR programme is delivered in a gym-based or community setting. Table 1.1 includes examples of modes of exercise that could be prescribed based upon delivery settings. A recent study comparing PR using specialist (gym-based) or minimal (community-based) exercise equipment demonstrated similar improvements in exercise capacity and HRQoL (39).

Table 1.1. Examples of differences modes of exercise based upon delivery settings

Gym-based programme	Community-based programme
Aerobic	
• Treadmill • Stationary cycle • Cross-trainer • Step-ups	• Free walking (measure distance and time) • Step-ups • Stepper • Marching on the spot
Resistance	
• Machine weights • Free weights • Resistance bands • Body weight	• Free weights • Resistance bands • Body weight

Education is another key component of PR. Previous work on education and self-management interventions in COPD, outside of the PR setting, have shown a reduction in healthcare utilisation and improved quality of life (40, 41).

Expert consensus has recommended that the PR education component should create objectives based on learner needs, formulate a delivery strategy (consisting of content and method of learning) and assessment of learner outcomes (42). As patients and carers have different learning styles and attention spans, the ideal education programme should use a variety of modalities, including group sessions, hands-on demonstrations with visual aids and models, peer-to-peer learning, and case-based learning. There is little data on the essential or mandatory topics for inclusion, nor the minimum duration of a PR education programme. Due to the heterogeneity of study interventions and sometimes inadequate description of the intervention, it is not possible to relate a specific educational model to improved health outcomes. Globally, the recommendations for education topics have been

based on expert opinion, and broadly comparable. Table 1.2 outlines topics suggested by the British Thoracic Society guidelines development group (34).

Table 1.2. Pulmonary Rehabilitation education topics recommended by the British Thoracic Society

Education topics
Anatomy, physiology and pathology in chronic respiratory disease
Medication (including oxygen therapy)
Smoking cessation
Dyspnoea/symptom management
Chest clearance techniques
Energy conservation/pacing
Patient support groups
Nutritional advice
Managing travel
Benefits system and welfare rights
Advance directives
Anxiety management and relaxation
Goal setting and reward
Confidence, self-efficacy and self-management
Identifying and changing beliefs about exercise and health related behaviours
Loving relationships/sexuality
Exacerbation management
The benefits of physical exercise
Opportunities to exercise after PR

A substantial evidence-base exists to support the benefits of PR in patients with stable COPD. The last iteration of the Cochrane review, published in 2015, identified 65 randomised clinical trials involving 3822 participants (43). This review demonstrated that PR relieves dyspnoea and fatigue, and

significantly improves exercise capacity, HRQoL and emotional function (43). From the strength of the evidence, the authors and Cochrane editor group recommended that no further studies were required to demonstrate the efficacy of PR compared with usual care in patients with stable COPD (43).

1.2.1 PR following AECOPD

Trials of PR in the severe AECOPD setting are a more recent phenomenon than in stable COPD for multiple reasons. Post-exacerbation patients are recovering from an acute illness, and there was initial understandable concern that exercise during this period might be harmful (44). In addition, trials in the post-exacerbation setting are notably harder to conduct than in those with stable COPD trials (45). Nonetheless, the updated Cochrane review for post-acute exacerbation PR, published by Puhan and colleagues in 2016, included 20 clinical trials (11 of these were newly added) and 1477 participants (46). All the rehabilitation interventions were primarily conducted in the inpatient or supervised outpatient setting, except for one small study conducted in the home (47).

The review reported post-exacerbation PR to have moderate to large effects on HRQoL, as measured by the St George's Respiratory Disease Questionnaire (SGRQ) total score (mean difference [95% CI]: -7.80 [-12.12 to -3.47]) and SGRQ sub-domains of impact (mean difference [95% CI]: -10.44 [-16.11 to -4.76]) and activity (mean difference [95% CI]: -8.23 [-12.88 to -3.57]) (46). However, the authors reported there to be no effect on the SGRQ sub-domain of symptoms (mean difference [95% CI]: -2.45 --7.33 to 2.45]) (46). In relation to the Chronic Respiratory Disease questionnaire (CRQ), another measure of HRQoL, statistically significant improvements were observed for the dyspnoea (mean difference [95% CI]: 0.97 [0.35 to1.58]), fatigue (mean difference [95% CI]: 0.81 [0.16 to 1.45]) and emotional function (mean difference [95% CI]: 0.94 [0.46 to 1.42]) domains (46). No effect was found in CRQ mastery (mean difference [95% CI]: 0.93 [-0.13 to 1.99]) (46). Along with the reported

improvements in HRQoL, there was a statistically significant improvement in exercise capacity, as measured by the six-minute walk distance (mean improvement [95% CI]: 62 metres [38 to 86]) and the incremental shuttle walk test (mean improvement [95% CI]: 48 metres [-1 to 97]).

With respect to healthcare use, Puhan and colleagues found that readmissions rates were reduced as a result of post-exacerbation PR (odds ratio [OR] [95% CI]: 0.44 [0.21 to 0.91]), although the results were heterogenous (46). The authors suggested this heterogeneity was explained to some extent by the "extensiveness" of the interventions studied. Using guidelines from international societies (33, 34), the authors graded interventions according to the total number, frequency, supervision and content of exercise training sessions, and whether the intervention included a self-management/education programme. The authors reported a trend to a greater reduction in hospital readmissions when comparing more comprehensive with less extensive programmes. Contemporary data from a retrospective analysis of outcomes in Medicare beneficiaries hospitalised with AECOPD demonstrated that attendance at post-exacerbation PR within 90 days was associated with reduced risk of one-year mortality (hazard ratio [95% CI]: 0.63 [0.57 to 0.69]) (48). The authors also explored timing of PR initiation from hospital discharge. They found those who commenced PR within 30 days, between 31 and 60 days and between 61 to 90 days to all be associated with lower risk of one year morality compared to completing PR after 90 days or not completing PR at all (hazard ratio [95% CI]: 0.74 [0.67-0.82]; 0.43 [0.34-0.54] and 0.4 [0.3-0.54] respectively). This data suggests that although the guidance in the UK is to offer PR 'early' within four weeks of hospital discharge (49), commencing a PR programme any time within 90 days of an acute exacerbation may be associated with a reduction in one year mortality risk.

Consequently, PR post-hospitalisation for an AECOPD is recommended in clinical guidelines. The British Thoracic Society PR Guidelines makes a Grade A recommendation that all patients should be

offered post-exacerbation PR at discharge from hospital (34), and that post-exacerbation PR programmes should begin within one month, termed 'early', post-discharge (34). The British Thoracic Society PR guidelines recommend services should record uptake, adherence and completion rates of the programme for this patient group (34), and that routine PR (within three months of the referral being received) should be offered to post-exacerbation patients should they decline 'early' PR (34).

PR post-hospitalisation for an AECOPD is also included within the National Institute for Health and Care Excellence (NICE) COPD Quality Standards as a key priority of post-exacerbation care pathway (49). The NICE Quality Standard makes recommendations that patients hospitalised as a result of an AECOPD should commence a PR programme within four weeks of hospital discharge, and provides information on measuring implementation (49). This Quality Standard mandates that: 1) service providers should have the relevant infrastructure to be able to offer an 'early' post-exacerbation PR programme, 2) that the healthcare professionals involved in care delivery are referring to the programme, and 3) that commissioners are funding these 'early' post-exacerbation PR programmes (49).

1.2.2 Uptake of PR following AECOPD

As a result of this growing evidence-base and recommendations in guidelines, widespread adoption of post-exacerbation PR programmes has been observed in the UK. Data from the 2017 national PR audit in England and Wales showed over 70% of PR services offer a PR programme for patients in the post-acute exacerbation period (50). Data regarding the proportion of services which offered post-exacerbation PR was unavailable on earlier iterations of the national PR audit, indicating the degree of importance recently placed upon adoption of PR for the post-exacerbation population (51). However, uptake of PR (and subsequent completion rates) following hospitalised AECOPD are low.

The national audit of UK PR services shows that post-AECOPD PR programmes constituted less than three percent of total PR caseload in England and Wales despite it being widely offered (50). This is corroborated by data from a systematic audit, conducted in a region where availability of clinical PR services was good. Only 20% of patients were referred for PR following hospitalisation for an AECOPD, with less than 10% of all eligible patients completing a PR programme following hospitalisation (Figure 1.1) (52). Comparatively, in one of the seminal randomised controlled trial (RCT) investigating outpatient-based PR post-hospitalisation for an AECOPD, less than 15% of patients screened declined to take part in the trial, a surrogate for referral to PR, with 76% of the patients allocated to received PR completing the programme (53). This would indicate that real-world implementation is challenging.

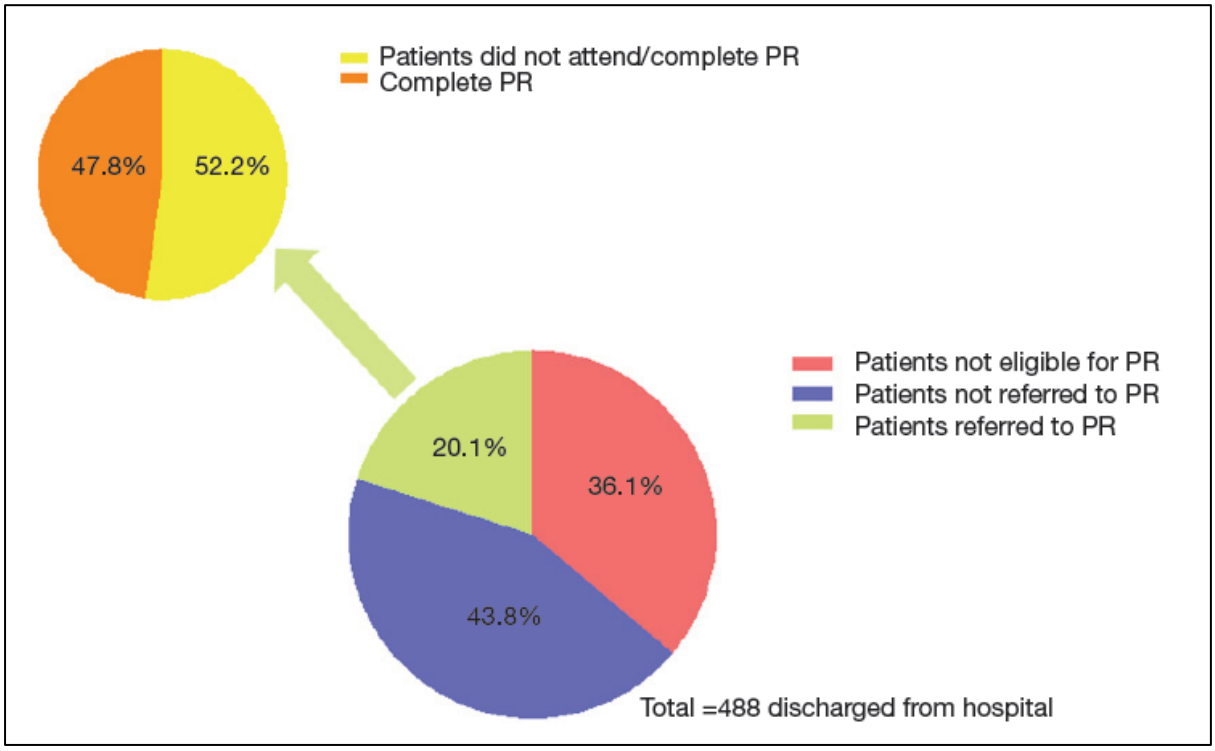

Figure 1.1. Referral, uptake and adherence data to post-exacerbation pulmonary rehabilitation following an admission to hospital over 12 months in a north-west London hospital, UK.
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Abbreviations: PR: pulmonary rehabilitation.

The reasons for poor referral to, uptake and subsequent completion of PR programmes post-hospitalisation are complex and multifactorial. However they can be broadly classified into three areas: barriers related to referrer, patient, or the wider healthcare system (Figure 1.2) (54).

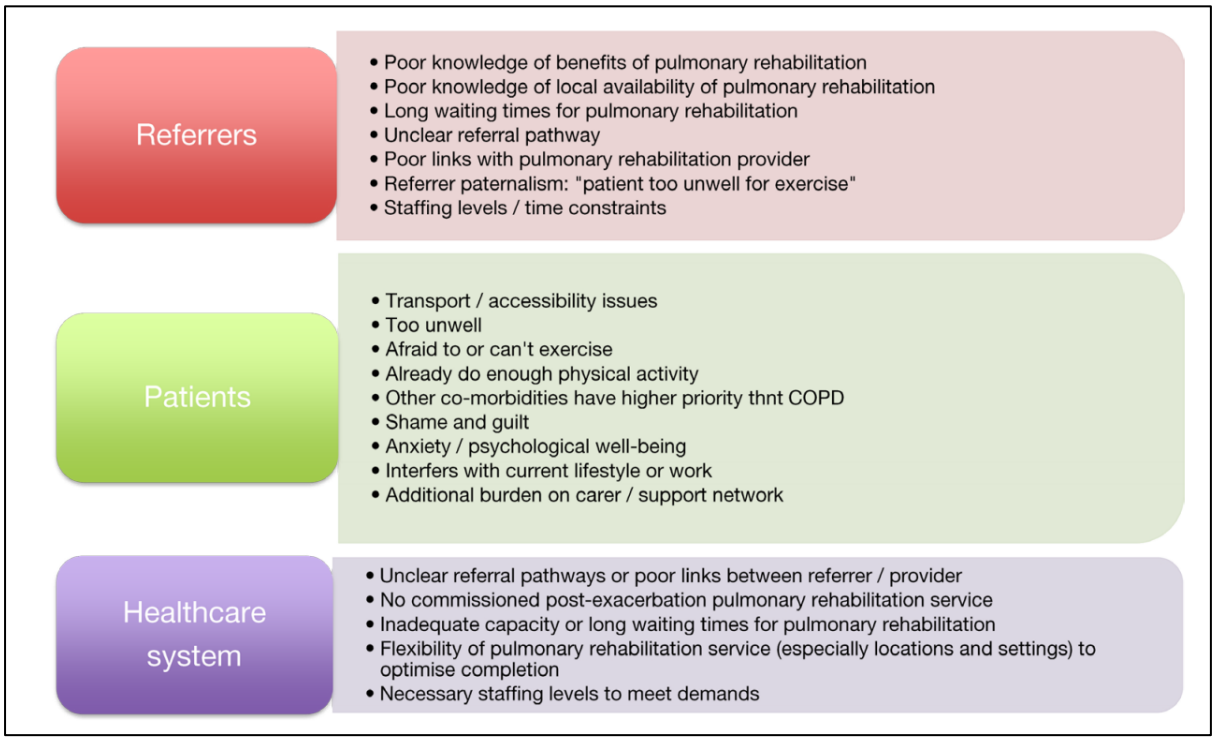


Figure 1.2. Reasons for poor referral, uptake and completion rates to post-exacerbation pulmonary rehabilitation.
Reproduced with permission of the © Journal of Thoracic Disease 2020: doi: 10.21037/jtd.2018.03.18.
Abbreviations: COPD: chronic obstructive pulmonary disease.

Referrer factors include poor healthcare professional knowledge of the benefits of PR, the local availability of clinical services and/or details of referral processes and pathways (55, 56). Inadequate staffing, time constraints, and competing clinical priorities may also affect PR referral rates (55, 56). Patient-related barriers have been highlighted by several studies (25, 55-58). Thorpe, Kumar & Johnston explored the barriers and enablers to physical activity following hospitalisation and found patients to report many barriers to activity post-hospitalisation, but also perceived some enablers (57). For example, comorbidities, feeling unwell, transport, advancing age and past experiences of PR

being too intense were some of the barriers identified, with access to health professionals and exercise equipment, motivation, and improved perceptions of health after partaking in a PR course as enablers to physical activity (57). In a UK-based observational study, Harrison and colleagues recruited 129 patients, and explored the acceptance and uptake of post-hospitalisation PR and identified patient perceptions and beliefs following hospitalisation. This study found patient acceptance of post-hospitalisation PR to be poor across the three distinct 'groups' of patients identified (those 'in control', 'disengaged' and 'distressed') (25). The authors propose that the current method of delivering post-hospitalisation PR is only feasible for a small proportion of patients (25). From the qualitative studies, patients were reluctant to increase their activity early post-AECOPD due to anxiety or fear of breathlessness. They also had concerns regarding transport and accessibility or had conflicting commitments or co-morbidities which resulted in PR not being considered a high priority (55-57). As a result, uptake of post-exacerbation PR programmes in patients with high symptom burden, reduced functional capacity and significant co-morbidities may be challenging (55, 56) even with provision of free door-to-door transport to support attendance (58). In comparison, there are also patients who perceived themselves to be at the other end of the spectrum who feel they are independently completing sufficient exercise and therefore decline PR (25, 55-57).

A previous systematic review (55) and a qualitative study (56) suggested healthcare systems may not have not have the necessary flexibility to adapt the method of delivery of PR programmes for patients post-acute exacerbation (such as the location or setting), the channels for referral being ineffectively established and may have insufficient staffing to meet PR service demands to deliver a programme in a timely fashion (55, 56). This is corroborated in the prospective observational study by Harrison and colleagues, who reported adapting the delivery method of post-hospitalisation PR (and deviating away from the tradition outpatient-based model in the UK) may be required to better facilitate acceptability and feasibility of post-hospitalisation PR (25).

1.2.3 Improving uptake of PR following AECOPD

As highlighted in section 1.2.2, real-world implementation of PR following an AECOPD is challenging. Despite this being a well-reported problem (25, 50, 52), and calls for research to find strategies which address this issue, there are limited clinical trial data on interventions designed to increase uptake of PR following AECOPD to date. Recently, two systematic reviews have synthesised studies that have included interventions designed to enhance referral, uptake and completion of PR for patients with both stable COPD and post-AECOPD (59, 60). Neither review could identify any published RCTs which had referral, uptake or completion of PR post-AECOPD as the primary endpoint (59). Even for patients with stable COPD, only one quasi-experimental controlled study was identified in one review, and this was considered to have a high risk of bias (59, 60). This trial examined the use of a tablet computer as an adjunct to PR as opposed to it being an intervention implemented with the direct intention of improving uptake or completion, and found there to be no significant difference in drop-out rates between the intervention and control groups (p=0.19) (61).

From the data reported in the systematic review by Early *et al.* (60), the majority of the studies took place in primary care, and were mainly observational or before and after studies. The interventions were also predominantly aimed at improving referrals for those with stable disease (for example, education for healthcare professionals (62-66), aide memoires to prompt PR referral (62, 67), financial incentives (68) and service activity monitoring (69)). The two patient-focused interventions included a patient manual delivered in outpatient clinics (70) and individual care planning in a general practice (71). Six studies reported statistically significant findings (60). Increased referral resulted from education for healthcare professionals in general practice (64, 66), monitoring of key performance indicators of services (69) and care quality standards initiated by patients (72); increased uptake was found when patients were provided with evidence behind care being offered (70) and with

individualised care planning between nurses and general practitioners (71). Despite all the studies being considered to have high risk of bias or conflicts of interest, and heterogeneity between studies limiting meta-analysis, the findings suggest interventions aimed at healthcare professionals may increase referral to PR, and that increasing patient education may improve uptake rates (60).

A feasibility study by Milner and colleagues, published since the two systematic reviews, has attempted to improve uptake of outpatient-based PR post-AECOPD by delivering a PR taster session for patients hospitalised with acute exacerbations of COPD (73). However, this intervention was only considered acceptable to six out of 31 patients (19%) studied. Another contemporary study by Williams and colleagues explored patient experiences of attending outpatient-based PR in order to develop strategies for improvement within their own service (74). One of the service improvement strategies the authors implemented included a buddy system to provide patients with reassurance when initially attending PR (74). To date, no evaluation data is available to determine the effectiveness of this buddy system.

Another strategy derived from the service improvement literature included in Early and colleague's systematic review (60) sought to extend 'reach' using COPD discharge bundles. These bundles are a structured aide memoire of evidence-based practices prior to hospital discharge. In the UK, COPD discharge bundles often include assessment and referral for PR (75). Since 2017, provision of the COPD discharge bundle has been incentivised with National Health Service (NHS) England introducing a COPD Best Practice Tariff (financial incentives awarded if a percentage of patients admitted for an AECOPD receive specialist input within 24 hours of admission and receive a COPD discharge bundle prior to discharge). However, COPD discharge bundles are challenging to deliver, with as few as 8% of patients who receive the bundle receiving all five components (76). Issues relating to staff, infrastructure and implementation processes have been cited as barriers to bundle delivery (77).

COPD discharge bundles are potentially delivered by staff who have inadequate education surrounding its core components (which includes offering a referral to PR) or have insufficient understanding of the wider healthcare system processes to allow proficient completion of the bundle components (77). Therefore, it is not clear whether COPD discharge bundles do indeed increase the 'reach' of post-hospitalisation PR in practice. COPD discharge bundles are potentially limited further as they are focussed solely upon improving referral rates at hospital discharge, and it is unknown whether there is any downstream impact (for example upon patient uptake of a PR programme).

As intimated previously, transport and travel are commonly cited barriers to uptake and completion of PR, particularly in the outpatient setting (55, 56). Therefore although proposals such as COPD discharge bundles (67), better education for patients and referrers alike (55, 56, 60), taster sessions (78) and buddy systems (74) for the traditional outpatient-based model have been proposed, altering the setting of delivery may prove advantageous, particularly as previous trials of outpatient PR that have included free door-to-door transport have not observed increased completion rates (58). Delivering rehabilitation in the home-setting is therefore potentially attractive to address the travel and transport issue of 'engagement' with PR post-acute exacerbation.

Interest in PR in the home-setting post AECOPD has grown following the potential of home-based trials in patients with stable COPD which have shown clinically significant benefits similar to supervised outpatient-based PR (79-81). Holland and colleagues, who investigated a telephone supervised eight week PR programme, showed equivalence of the trial intervention compared with a usual face-to-face PR programme in their primary outcome (six-minute walk distance: mean difference [95% CI] favouring home group: 18.6 m [−3.3 m to 40.7 m]) and other secondary outcomes of HRQoL (CRQ-dyspnoea [CRQ-D] domain: mean difference [95% CI] favouring home group: 1.6 points [−0.3 to 3.5]) (79-81). Horton *et al.*, who trialled an online resource supported by two telephone calls a week for

seven weeks, also concluded that a non-statistically significant difference was seen when compared to traditional outpatient-based PR in their primary outcome (CRD-D: mean group difference [95% CI], favouring traditional outpatient-based PR: −0.24 [−0.61 to 0.12]) (80). Bourne and colleagues showed a six week online PR intervention completed between two and five times a week to be non-inferior to a traditional outpatient-based six week PR programme for the co-primary outcomes (six-minute walk distance: mean distance [95% CI] favouring traditional outpatient-based PR: 23.8 m [−4.5 m to 52.2 m]; CAT: mean distance [95% CI] favouring online PR: -1.0 [-0.29 to 0.86]) (79-81). Despite these trials in patients with stable COPD, there remains a paucity of published data on (face-to-face, telephone or online) supervised home-based PR in the post-acute exacerbation setting.

1.3 HOSPITAL AT HOME (HaH)

Given that AECOPD are a major reason for acute medical admissions and a significant contributor to winter bed pressures, there is a clear rationale for interventions and novel models of care that can reduce inpatient burden. One established model of care is hospital at home (HaH) services.

HaH services are defined as *"a subtype of Intermediate Care, encompassing both the active treatment at home by health care professionals of patients (always for a limited period) who may otherwise be admitted to hospital, and early supported discharge schemes following a Hospital Provider Spell"* (82). In the UK, the typical delivery model for HaH services for AECOPD-management are nursing-supervised medical treatments, with the British Thoracic Society recommending a treatment package including provision of antibiotics, steroids, nebulised bronchodilators and oxygen, delivered in the patients' home, supported by regular home visits to monitor treatment response (83).

HaH can include providing admission avoidance (referrals from e.g. general practitioners or Accident and Emergency prior to prevent a hospital admission) or early supported discharged services (referrals from e.g. inpatient wards) (83).

Decisions to provide HaH care require consideration of several factors. Foremost is the medical status of the patient. The British Thoracic Society recommends specific exclusion criteria for HaH care (83): impaired level of consciousness; acute confusion; pH <7.35, if arterial blood gases have been measured; acute changes on chest radiograph; concomitant medical problem requiring inpatient stay; insufficient social support, no telephone, residence geographically removed from hospital; and new hypoxaemia (peripheral capillary oxygen saturation less than 90%) – a contraindication if oxygen cannot be provided at home. Contemporary studies also recommend using risk-stratification scores. One example is the DECAF score (extended Medical Research Council **D**yspnoea score, **E**osinopaenia, **C**onsolidation, **A**cidaemia and atrial **F**ibrillation), initially developed and validated by Steer and colleagues (84). This is calculated by totalling the score for each of five items (see Table 1.3). The lower the overall score (minimum is 0), the lower the risk of 30 day mortality, with the highest achievable overall score being 6 (Table 1.3) (85).

Table 1.3. DECAF score

DECAF score		
Variable	**Criteria**	**Score**
Dyspnoea	Too breathless to leave the house: a) & independent washing and / or dressing; or b) & dependent washing and / or dressing.	 1 2
Eosinopaenia	<0.05 x 10^9/l	1
Consolidation	Present (on radiograph)	1
Acidaemia	pH <7.3	1
Atrial Fibrillation	Present	1

1.3.1 HaH following AECOPD

Multiple systematic reviews and meta-analyses of HaH services post-AECOPD have been conducted in recent years, which all investigated similar outcomes of interest and retrieved similar papers (86-89). Echevarria and colleagues aimed to determine the safety and efficacy of HaH services compared to usual inpatient care (86). The outcomes of interest were six-month mortality and all-cause readmission. There was significant heterogeneity in the HaH service criteria and degree of support provided (a combination of five- and seven- day services providing telephone and / or face-to-face support) within the eight studies included in the review. All eight studies were considered low risk bias for mortality and readmission outcomes. HaH care did not increase the risk of six month mortality (risk ratio [95% CI]: 0.66 [0.40 to 1.09], p=0.10) nor all-cause readmissions (risk ratio [95% confident interval]: 0.84 [0.69 to 1.01], p=0.07) (86). A second review by McCurdy assessed similar safety outcomes (87) and corroborated the conclusions drawn by Echevarria *et al*. However, this review only

considered studies with shorter-term mortality and readmission data (between two and six months) following an acute exacerbation (risk ratio [95% CI]: 0.68 [0.41 to 1.12], p=0.13 and 0.90 [0.70 to 1.16], p=0.41 for mortality and readmission respectively) (87).

Unsurprisingly, given the similarities in the outcomes of interest and papers retrieved, the results regarding readmission and mortality from the two systematic reviews conducted by Echevarria *et al.* and McCurdy are further corroborated by the findings from two Cochrane reviews of HaH services for acute exacerbations of COPD (88, 89). The first Cochrane review, published in 2003, showed there to be a trend towards reduced risk for mortality and readmissions (risk ratios [95% CI]: 0.61 (0.36 to 1.05) and 0.89 (0.72 to 1.12) respectively) associated with HaH care compared to usual inpatient care (88). The latest iteration of the Cochrane review by Jeppesen *et al.* included two new studies and excluded one study which had been included in the initial analysis by Ram and colleagues (89). Of the eight studies included in the updated review, seven were considered to have low risk of bias. However, the trials were found to deliver HaH service models that were notably heterogenous. Despite this, similar conclusions were drawn with regards to mortality in the 2012 Cochrane review, with the newly included studies resulting in additional, moderate quality evidence to suggest that HaH could potentially reduce hospital readmissions compared to usual inpatient care (risk ratio [95% CI]: 0.76 [0.59 to 0.99], p=0.04) (89). Overall, these four systematic reviews have shown that HaH for an AECOPD, as an alternative to inpatient care, reduces hospital bed days through the provision of treatment in patients' homes, with no increase in mortality or emergency readmissions (86-89). However, the optimal model for delivering this type of care has not been firmly established.

From the perspective of the service users (patients and informal unpaid caregivers), HaH services have generally been shown to be acceptable. In one trial, patients found HaH care to be preferable to usual inpatient care, with over 95% of patients who received HaH care reporting HaH to be their preferred

model of care (90) whilst less than 60% of the patients who received inpatient care reported preference for inpatient care (p=0.001) (90). Another study by Utens *et al.* reported similar overall satisfaction for home-based and usual inpatient care to caregivers (mean [SD] of satisfaction score on scale from 0 to 100: 70 [12.7] and 71 [12.5] for home-based and inpatient respectively, p=0.863) (91).

Utens and colleagues measured the informal, unpaid caregiver strain index at discharge, seven days and 90 days post-index exacerbation in patients receiving either usual inpatient care or HaH care for an acute exacerbation (92). No between group differences were found in the caregiver strain index for inpatient versus home-based care when change between baseline and seven days and baseline and 90 days were compared (mean difference [95% CI]: seven days: 0.47, [-0.96 to 1.91]; 90 days: 0.36 [-1.85 to 1.35]) (92). Data reported by Ojoo and colleagues suggested HaH services may even be preferable to inpatient care for caregivers (90). The authors found that over 85% of caregivers of family members with COPD who received HaH care reported preference for this model of care (90), compared with less than 45% of the caregivers of patients receiving inpatient care reporting preference for the inpatient care (p=0.001) (90). These preferences might reflect the need for less travelling for hospital visits, thus reducing carer burden and fatigue (28).

1.3.2 Implementation of HaH following AECOPD

As a result of the emerging evidence-base for its safety as well as stakeholder acceptability, there has been growing national adoption of HaH services. In the 2018 national audit of COPD secondary care, nearly 55% of patients were candidates for HaH services at hospital discharge (93), compared to 40% and 18% of patients in 2014 and 2008 respectively (94). Although there has been growth in its availability, and patients have reported preferences to receiving home-based care (90, 91), patients allocated to receive home-based care also reported feeling less able to recommence their activities of

daily living at the end of their treatment compared with those who receive inpatient care (54.7% versus 30.5% [p=0.018] for home-based care and inpatient care respectively) (91). This could be due to the focus of HaH services for AECOPD-management being medical treatments supported by regular home visits to monitor treatment response (83) without the inclusion of rehabilitation. In comparison, patients who are hospitalised with an AECOPD may be referred for occupational therapy or physiotherapy input regarding functional status, with mobility or exercise programmes provided as an inpatient. A recent systematic review by Torres-Sanchez and colleagues has shown inpatient physiotherapy interventions (including chest physiotherapy and physical exercise programmes) to be effective, potentially improving the functional status of patients (95).

1.4 INTEGRATING PR WITH HAH FOLLOWING AECOPD

As indicated in section 1.3.2, HaH services are increasingly used to deliver medical treatments in patients' home. This has helped safely reduce the burden of AECOPD on hospital beds, and indirectly reduce the burden on family carers. However, it has been noted that these HaH services are primarily nurse-led (83), and are not focused on meeting the rehabilitation needs of patients' post-acute exacerbation, including the provision of routine physiotherapy which they may otherwise receive as an inpatient (95).

As described in section 1.2.2, whilst outpatient post-exacerbation PR is associated with improvements in physical function and HRQoL, the benefits are hampered by low referral, uptake and completion rates. A potential solution is the consideration of home-based PR.

Therefore, combining two evidence-based interventions and integrating a PR programme within a HaH service may result in synergistic benefits (Figure 1.3). It provides a unique opportunity to expand the

scope of HaH by bringing the clinical benefits of PR on the extra-pulmonary manifestations of AECOPD. This may also address the issue of poor referral, uptake and completion rates of traditional outpatient-based PR programmes through provision in a more accessible setting (a patients' home).

Figure 1.3. Proposed benefits of integrating a pulmonary rehabilitation programme within a hospital at home service following hospitalisation for an acute exacerbation of COPD.
Abbreviations: AECOPD: acute exacerbation of chronic obstructive pulmonary disease; HaH: hospital at home; HRQoL: health-related quality of life; PR: pulmonary rehabilitation.

Two studies suggest this may be a feasible proposal. First, a small pilot study explored a home-based PR intervention, trialled alongside a HaH service. Murphy *et al.* provided twice-weekly supervised exercise training for six weeks alongside HaH (home-based, pharmacological management of AECOPD under nurse-supervision) (47). The sessions were up to 40 minutes in length, incorporating aerobic exercise (e.g. step ups) at between 3 and 5 on the Borg breathlessness scale and resistance training using elastic resistance bands. The authors demonstrated improvements in exercise capacity (mean [SD] at baseline to six weeks, p value: incremental shuttle walk test: 198 m [95] to 304 m [136], $p<0.001$; three minute step test: 119 [41] to 163 [26], $p<0.001$) and HRQoL (mean [SD] at baseline to six weeks, p value: SGRQ total score: 70.2 [14.2] to 54.2 [15], $p<0.05$) in the intervention group only

(47). However, this study was underpowered (n=13 per arm), with unreported between-group differences. A second study investigated a geriatric home-based service (which incorporated physical and occupational therapy as well as nursing care) compared with inpatient care (96). Aimonino Ricauda and colleagues showed that this home-based service to be associated with lower hospital readmission rates at six months compared with inpatient care (42% versus 87% respectively, $p<0.001$) (96). Moreover, the authors reported significant differences in HRQoL ($p=0.04$) and depression ($p<0.001$) between the home-based care group and inpatient care group at six months, despite there being no between group difference in these outcomes at baseline between the groups (96). Neither study included any education components, which is a key component within traditional PR.

National and international groups are also calling for closer integration of respiratory services. The NHS Long Term Plan (and the British Thoracic Society (97) in response to the NHS Long Term Plan) require integrated care systems to be implemented by respiratory services in the UK (98). The recent update by European Respiratory Society and American Thoracic Society regarding the management of COPD exacerbations has also stated studies are needed to better define key elements of home-based models of care, including the roles of multidisciplinary team members (99). This provides further rationale that integration of PR within a HaH service has potential as a viable model of care in the future.

Therefore, studies with patients hospitalised with an AECOPD are required to explore the feasibility and acceptability (along with efficacy and cost-effectiveness) of delivering home-based PR in the post-AECOPD setting. This will allow for not only implementation of a potentially more accessible PR service but will also ensure integrated services are optimised prior to widespread implementation.

1.5 OVERALL AIM AND PHASE SPECIFIC OBJECTIVES

Early PR is considered a cornerstone in management of acute exacerbations of COPD. However clinical implementation of post-hospitalisation PR is problematic and there are currently no known interventions which increase referral, uptake or completion of PR in the post-exacerbation population.

Consequently, the primary aim of this programme of work is to examine different ways of improving referral, uptake and completion of PR following hospitalised AECOPD. There will be four main phases within this programme of work, each with specific objectives, to address the primary aim.

The specific objectives are:

1. To identify patient, referrer and hospital admission characteristics associated with non-referral and non-uptake of PR post-hospitalisation for AECOPD;
2. To determine whether a patient co-designed education video delivered alongside the COPD discharge bundle increases referral rate, uptake and completion of PR post-hospitalisation for AECOPD;
3. To develop a home-based exercise training intervention as an adjunct to a standard HaH service; and
4. To determine the acceptability of a home-based exercise training intervention for healthcare staff, patients and carers, and the feasibility of conducting a future efficacy trial.

1.6 HYPOTHESES

The hypotheses which relate to these objectives are outlined below:

A. Delivery of a COPD discharge bundle by a hospital practitioner involved in PR delivery is associated with increased odds of PR referral and uptake, independent of factors associated with the hospital admission and clinical characteristics of patients;
B. Using a patient co-designed education video alongside a COPD discharge bundle will enhance referral rate, uptake and completion of PR post-hospitalisation for AECOPD; and
C. A co-designed home-based exercise training intervention, delivered alongside a HaH service for AECOPD, is both acceptable and feasible to service users and providers.

Table 1.4 shows the results chapters which report the findings for each objective and the related hypothesis.

Table 1.4. Results chapters which address each specific objective and their related hypothesis

Primary thesis aim: **To examine different ways of improving referral, uptake and completion of PR following hospitalised AECOPD**		
Phase specific objective and related hypothesis	**Corresponding results chapter/s**	**Design**
Objective 1: To identify patient, referrer and hospital admission characteristics associated with non-referral and non-uptake of PR post-hospitalisation for AECOPD. **Related hypothesis: A**	**Chapter 2**	A prospective cohort study which included all hospitalised AECOPD to Hillingdon Hospital over one year.
Objective 2: To determine whether a patient co-designed education video delivered alongside the COPD discharge bundle increases referral rate, uptake and completion of PR post-hospitalisation for AECOPD. **Related hypothesis: B**	**Chapter 3**	A mixed methods trial which included a parallel, two-group RCT with embedded qualitative interviews.
Objective 3: To develop a home-based exercise training intervention as an adjunct to a standard HaH service. **Related hypothesis: C**	**Chapter 4**	A mixed methods systematic review which included synthesis of RCTs, non-randomised or quasi-experimental controlled trials, observational papers, case studies and qualitative studies.
	Chapter 5	An accelerated EBCD project which included three stakeholder events followed by two co-design meetings.
Objective 4: To determine the acceptability of a home-based exercise training intervention for healthcare staff, patients and carers, and the feasibility of conducting a future efficacy trial. **Related hypothesis: C**	**Chapter 6**	A mixed methods feasibility trial which included a parallel, two-group RCT with embedded qualitative interviews and focus groups.

1.7 PROGRAMME OF WORK

This programme of work was a multi-phase mixed methods programme. It included a combination and integration of both quantitative and qualitative data collection methods (termed mixed methods), both within and between phases (100). These multiple phases intended on addressing the same overall aim, as well as each phase intending on its own specific objectives (termed multi-phase) (100). This was with the intention of supporting the development (identification of evidence-based and theory), understanding feasibility and piloting (testing procedures, estimating recruitment and retention and determining sample size) prior to evaluation and wider implementation, undertaken in accordance with the Medical Research Council Framework for developing and evaluating complex interventions (101). Methodologically, using mixed methods is a relatively recent concept compared to single method designs (100). Purists believe combining data derived from two fundamentally different modes of investigation (quantitative and qualitative) to be impracticable as the underpinning paradigms and types of data generated are inherently incompatible (102). Nonetheless, others believe undertaking mixed methods research results in a broader, more in-depth, and more comprehensive interrogation of each type of data (103). Given my own ontological and epistemological assumptions are that of a pragmatist, a mixed methods programme of work is both plausible and preferable to a single method of enquiry to allow for richer understandings to be derived and to adequately address the research questions (104).

A schematic of this multi-phased mixed methods programme of work is presented in Figure 1.4. The types of data enquiry used in each phase are included in Figure 1.4. For example, phase one utilises quantitative (abbreviated to ‘quan’) data only, as indicated by the ‘quan’ stated under ‘phase one’;

phase two utilises both quantitative and qualitative (abbreviated to 'qual') data collection methods, as indicated by the 'quan' and 'qual' stated under 'phase two' (102).

In the instance where both quantitative and qualitative data collection methods are used and there is a dominant data collection method, the dominant method for that phase is indicated by presenting it in uppercase, with the ancillary method indicated by presenting it in lowercase (102). For example, in phase two, 'quan' is presented in uppercase (QUAN) and 'qual' in lowercase to present this dominant/ancillary relationship; in phase three, 'quan' and 'qual' are both presented in uppercase as neither method of enquiry was more dominant.

For each phase which includes both qualitative and qualitative data collection methods, the sequence the methods of enquiry are undertaken in is also indicated. Where an arrow (-->) connects the methods of enquiry, the second method of enquiry stated was being undertaken and/or analysed after the first to build upon it; where a plus sign (+) connects the two methods of enquiry, the two methods of enquiry are being collected and/or analysed at the same time (102).

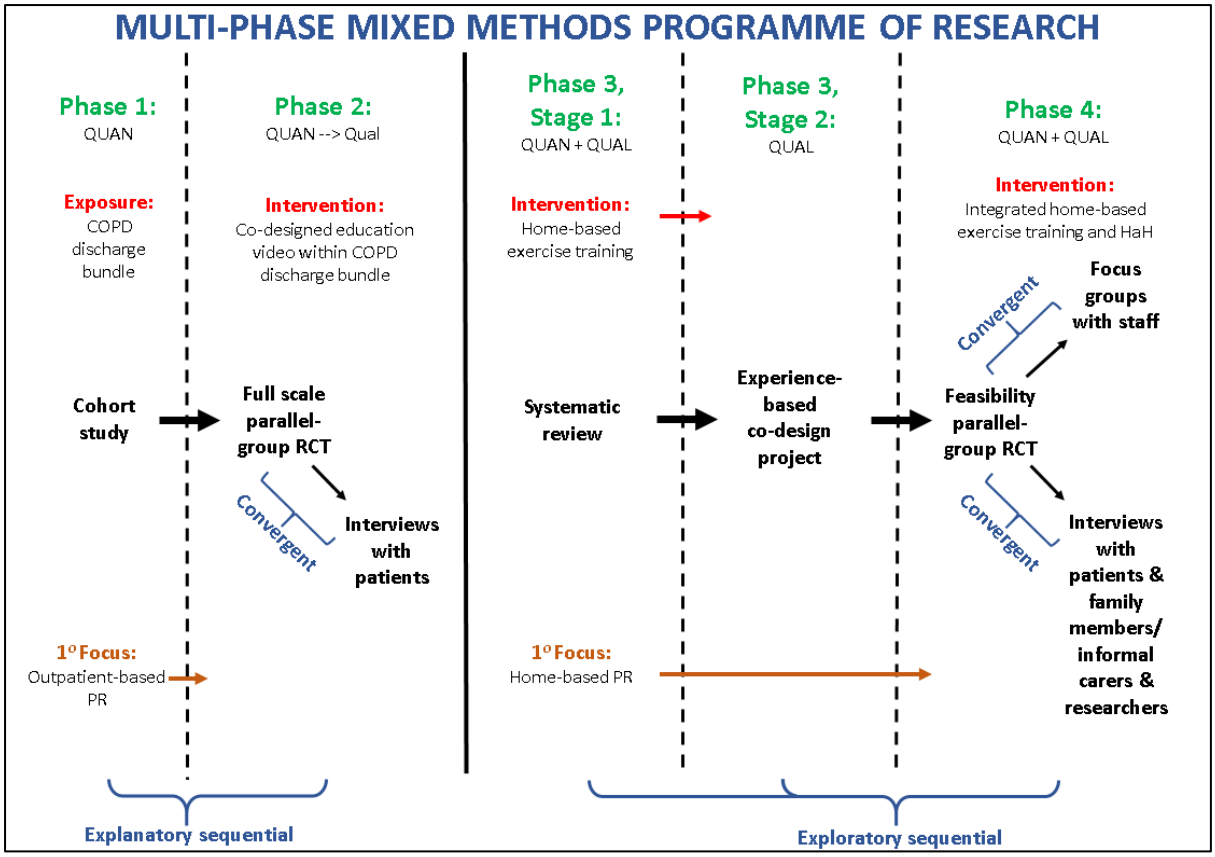


Figure 1.4. Schema of the programme of work presented within this thesis.
Abbreviations: 1^0: primary; COPD: Chronic obstructive pulmonary disease; PR: pulmonary rehabilitation; Qual: qualitative; Quan: quantitative; RCT: randomised controlled trial.

1.7.1 Between phase mixed methods designs

A cohort study was the first of four phases within this multi-phase mixed methods programme of work. 'A randomised controlled trial of a Video Intervention to facilitate RehabiliTation Uptake following hospitalised Exacerbations of COPD', or VIRTUE, was the second phase. Phase one (the cohort study) and phase two (VIRTUE) were explanatory sequential in nature (100) in that the quantitative results from phase one (the cohort study) aided the understanding and interpretation of the mixed methods findings of phase two (VIRTUE); both were focused on traditional outpatient-based PR (100).

The focus from phase three onwards switched to exploring a home-based model as an alternate delivery strategy to traditional outpatient-based PR following hospitalisation for an AECOPD. In comparison to phases one and two, phases three and four were exploratory sequential in nature as the feasibility study undertaken within phase four was founded upon the exploratory, primarily qualitative work synthesised and generated within phase three (100).

1.7.2 Within phase mixed methods designs

For phases two and four, which includes both RCT and qualitative data collection components, the mixed methods design implemented was a convergent design, given the two components of the studies were undertaken and separately analysed prior to the merging of the findings (100). Sections 3.4.10.3 and 6.4.10.3 illustrate the data analysis processes for integration of the data sets in phase two and four respectively.

The same convergent mixed methods design was implemented in stage one of phase three as the extraction of the quantitative and qualitative data from the papers retrieved in the systematic review was undertaken separately prior to merging the data sets (100). Section 4.3.9 illustrates the data extraction and analysis processes for collecting and then integrating the data sets in stage one of phase three.

1.7.3 Professional background and lens of researcher

My professional background is as a highly specialised respiratory physiotherapist, with previous clinical experience working across both acute and community services. I have worked patients

hospitalised with AECOPD, from their arrival into accident and emergency and through their inpatient journey, including leading the physiotherapy team to support critical care outreach teams to set-up, delivery and monitoring of patients requiring non-invasive ventilation and high flow nasal cannula oxygen therapy. These roles also required evidence-based discharge planning and community follow-up to be offered and co-ordinated, and delivery of community COPD clinics.

More recently I have worked alongside a PR service and an integrated respiratory service, which includes the delivery of an outpatient-based PR programme, outpatient-based community clinics for patients with asthma and COPD and HaH (early supported discharge and admission avoidance) care.

Therefore, the lens through which I am approaching this programme of work is one that is wider than purely focusing on the role of PR for patients living with COPD. I have a more holistic approach and bring my understanding of the wider pathway for managing AECOPD to determine how the evidence-based, vital components of this pathway can be better optimised and integrated.

1.7.4 Public and patient involvement

Public and patient involvement (PPI) was central to this programme of work: from inception of this programme of work's overall research question, and within each phase of this programme of work. PPI were involved in, and in many cases led, decision-making. For example, PPI representatives helped determine appropriate study designs, supported the selection of outcomes, reviewed study paperwork, were members of trial steering groups, provided ad hoc advice as required during the programme of work as well as advised on dissemination of the findings (such as with Harefield Breathing Support Group). They were also central to the decision-making process around whether to restart the mixed methods feasibility study (Chapter 6) whereby it was deemed inappropriate to

undermine the intervention development phases of this programme of work to adapt the intervention to comply with temporary COVID-19 restrictions. Further, patients' views were fundamental element of feedback and reflection utilised within this programme of work, partly as a result of stakeholder involvement being a key feature of experience-based co-design projects.

Chapter 2: Risk factors for non-referral and non-uptake of PR following hospital admission for AECOPD – a cohort study

Some of the results from this chapter were published in Thorax on 3rd March 2021 (105). These results are reprinted with permission of Thorax, © Author(s) (or their employer(s)) 2021. Re-use permitted under CC BY-NC. No commercial re-use. Published by British Thoracic Society. Barker RE, Kon SS, Clarke SF, *et al.* COPD discharge bundle and pulmonary rehabilitation referral and uptake following hospitalisation for acute exacerbation of COPD. *Thorax* Published Online First: 02 March 2021. doi: 10.1136/thoraxjnl-2020-215464.

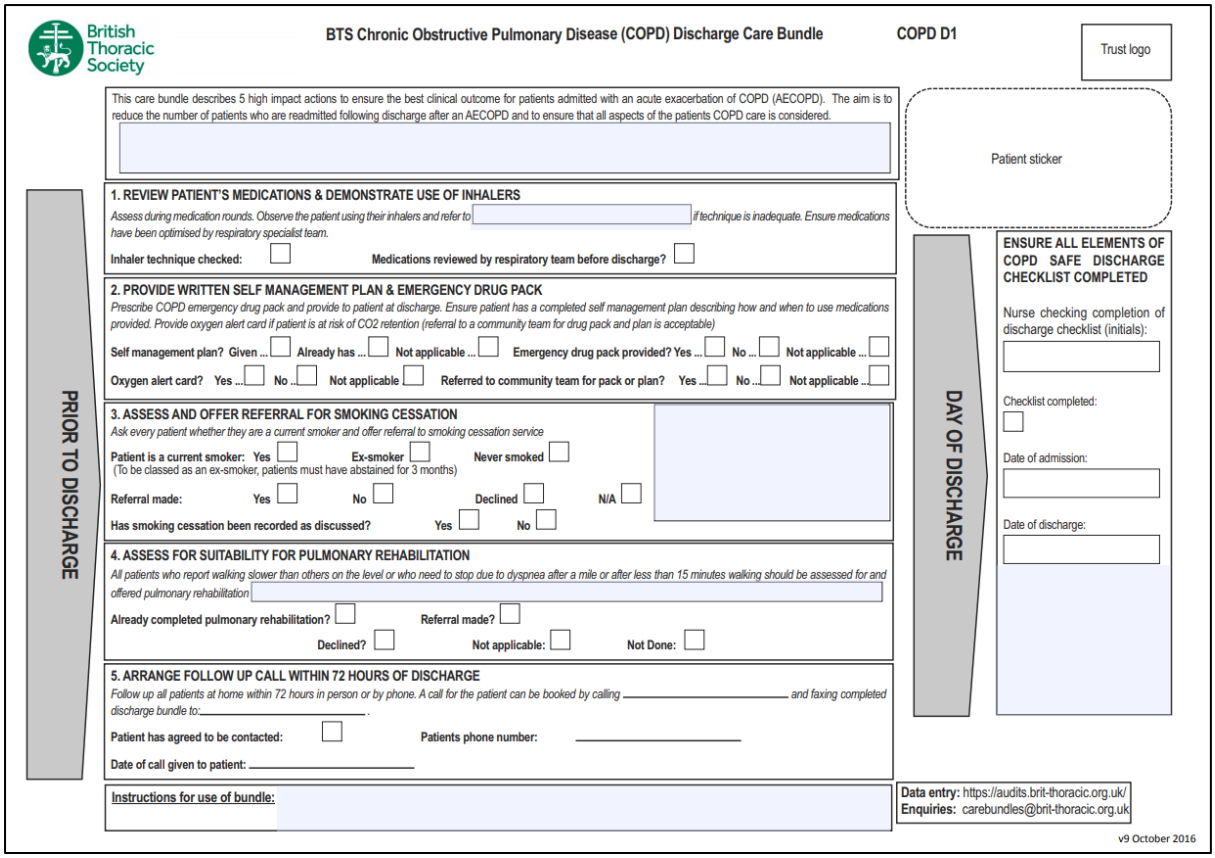
Some of the results from this chapter have previously been reported in a conference abstract, which was presented at the American Thoracic Society International Conference 2020 (106). These results are reprinted with permission of the American Thoracic Society and with permission of the authors, copyright © 2020 American Thoracic Society. All rights reserved.

2.1 BACKGROUND

There is an established evidence-base supporting the benefits of pulmonary rehabilitation (PR) following hospitalisation for acute exacerbations of chronic obstructive pulmonary disease (AECOPD), including improved exercise capacity and health-related quality of life (HRQoL), and reduced readmissions and mortality (46, 48), as illustrated in Chapter 1, section 1.2.1. However, PR referral and uptake rates are low. Previous data have shown that very few eligible patients are referred for post-

hospitalisation PR, with less than 10% completing a programme (see Figure 1.1 in Chapter 1, section 1.2.2) (107). Barriers to referral and uptake are complex and multi-factorial (108).

The COPD discharge bundle is a structured list of evidence-based practices (which includes review of medications and inhaler technique training, provision of a self-management plan, assessments and offering referral for smoking cessation, offering referral to PR and arrangement of post-hospitalisation follow-up) which should be delivered to all patients prior to hospital discharge following admission for an AECOPD to attempt to standardise post-discharge care in the UK (Figure 2.1) (67, 75). Since 2017, provision of the COPD discharge bundle has been incentivised with NHS England introducing a COPD Best Practice Tariff (financial incentives awarded if a percentage of patients admitted for an AECOPD receive specialist input within 24 hours of admission and receive a COPD discharge bundle prior to discharge). PR referral was included within the bundle to facilitate increased referrals to post-hospitalisation PR following AECOPD (67, 75) through increasing the 'reach' of post-hospitalisation PR to a greater number of patients (78). Despite this, the COPD discharge bundle can be hard to implement (76) and its impact remains unclear (109).



British Thoracic Society

BTS Chronic Obstructive Pulmonary Disease (COPD) Discharge Care Bundle COPD D1

Trust logo

This care bundle describes 5 high impact actions to ensure the best clinical outcome for patients admitted with an acute exacerbation of COPD (AECOPD). The aim is to reduce the number of patients who are readmitted following discharge after an AECOPD and to ensure that all aspects of the patients COPD care is considered.

Patient sticker

PRIOR TO DISCHARGE

1. REVIEW PATIENT'S MEDICATIONS & DEMONSTRATE USE OF INHALERS

Assess during medication rounds. Observe the patient using their inhalers and refer to _____ *if technique is inadequate. Ensure medications have been optimised by respiratory specialist team.*

Inhaler technique checked: ☐ Medications reviewed by respiratory team before discharge? ☐

2. PROVIDE WRITTEN SELF MANAGEMENT PLAN & EMERGENCY DRUG PACK

Prescribe COPD emergency drug pack and provide to patient at discharge. Ensure patient has a completed self management plan describing how and when to use medications provided. Provide oxygen alert card if patient is at risk of CO2 retention (referral to a community team for drug pack and plan is acceptable)

Self management plan? Given ... ☐ Already has ... ☐ Not applicable ... ☐ Emergency drug pack provided? Yes ... ☐ No ... ☐ Not applicable ... ☐

Oxygen alert card? Yes ... ☐ No ... ☐ Not applicable ☐ Referred to community team for pack or plan? Yes ... ☐ No ... ☐ Not applicable ... ☐

3. ASSESS AND OFFER REFERRAL FOR SMOKING CESSATION

Ask every patient whether they are a current smoker and offer referral to smoking cessation service

Patient is a current smoker: Yes ☐ Ex-smoker ☐ Never smoked ☐
(To be classed as an ex-smoker, patients must have abstained for 3 months)

Referral made: Yes ☐ No ☐ Declined ☐ N/A ☐

Has smoking cessation been recorded as discussed? Yes ☐ No ☐

4. ASSESS FOR SUITABILITY FOR PULMONARY REHABILITATION

All patients who report walking slower than others on the level or who need to stop due to dyspnea after a mile or after less than 15 minutes walking should be assessed for and offered pulmonary rehabilitation _____

Already completed pulmonary rehabilitation? ☐ Referral made? ☐

Declined? ☐ Not applicable: ☐ Not Done: ☐

5. ARRANGE FOLLOW UP CALL WITHIN 72 HOURS OF DISCHARGE

Follow up all patients at home within 72 hours in person or by phone. A call for the patient can be booked by calling _____ *and faxing completed discharge bundle to:* _____.

Patient has agreed to be contacted: ☐ Patients phone number: _____

Date of call given to patient: _____

DAY OF DISCHARGE

ENSURE ALL ELEMENTS OF COPD SAFE DISCHARGE CHECKLIST COMPLETED

Nurse checking completion of discharge checklist (initials):

Checklist completed: ☐

Date of admission:

Date of discharge:

Instructions for use of bundle:

Data entry: https://audits.brit-thoracic.org.uk/
Enquiries: carebundles@brit-thoracic.org.uk

v9 October 2016

Figure 2.1. Example of standardised paperwork which requires completion for the COPD discharge bundle.

2.2 OBJECTIVE

The objective of this study was to identify patient, referrer and hospital admission characteristics associated with non-referral and non-uptake of PR post-hospitalisation for AECOPD.

2.3 HYPOTHESIS

It was hypothesised that delivery of a COPD discharge bundle by a hospital practitioner involved in PR delivery (termed current PR practitioner) is associated with increased odds of PR referral and uptake, independent of factors associated with the hospital admission and clinical characteristics of patients.

2.4 METHODS

2.4.1 Study design

This was a prospective cohort study which included consecutive hospital episodes for an AECOPD at Hillingdon Hospital, London, UK and was considered service evaluation by the Health Research Authority (Figure 2.2 includes a schematic of the study design). Hillingdon Hospital was selected for specific reasons: 1) the hospital maintains a real-time continuous database of patients admitted with COPD as part of the National COPD secondary care audit and the introduction of the NHS England COPD Best Practice tariff; 2) the hospital has an integrated respiratory team with responsibility for delivering all COPD discharge bundles, and providing specialist respiratory input within 24 hours of admission; and 3) the hospital, and patients in Hillingdon borough, are served by a single PR provider, which facilitates systematic collection of PR outcome data. This is important as the accuracy of outcomes derived from electronic healthcare records can vary (110, 111). Consequently, determining and implementing a systematic and robust process for obtaining the data for this cohort study was important. Patients were followed-up for four weeks after hospital discharge.

All COPD discharge bundles (Figure 2.1 in section 2.1) were delivered by a hospital-based multidisciplinary respiratory team with responsibility for early supported discharge, admission avoidance and community respiratory clinics. Two out of six team members were current PR practitioners, defined as someone also employed to deliver PR (assessments and/or supervision of classes) for a minimum 20% of their job plan. As the researcher I had no involvement in exposure allocation (no randomisation, no influence on care team assignment). The clinical team delivering the bundle were blinded to the study objectives.

2.4.2 Population

All consecutive hospital episodes for patients hospitalised with AECOPD between 1st April 2018 and 31st March 2019 were included. However, patients admitted previously during the study period (and therefore already included in the data collection) and patients who were ineligible for PR were excluded (e.g. those with unstable cardiac conditions, unable to walk five metres).

2.4.3 Study exposure

The exposure of interest was receipt of a COPD discharge bundle from a current PR practitioner.

2.4.4 Study reference

The references of interest were: 1) receipt of a COPD discharge bundle from a hospital practitioner not involved in PR delivery, or 2) did not receive a COPD discharge bundle.

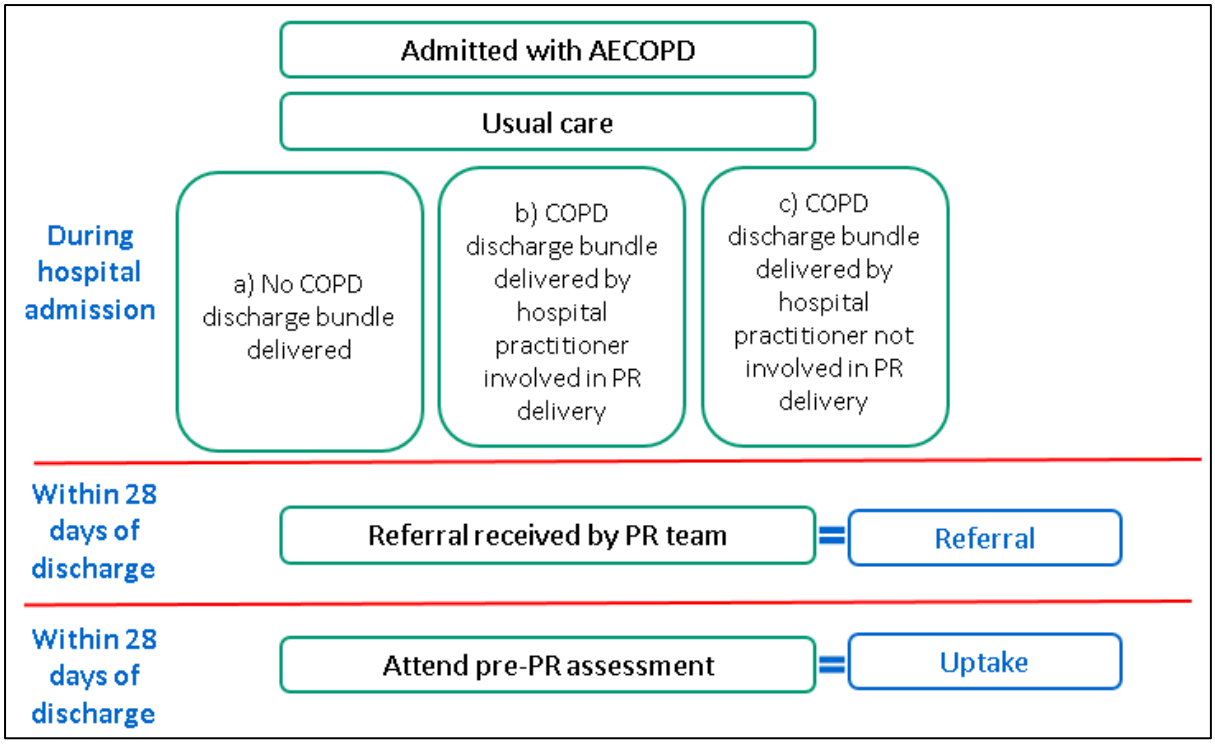


Figure 2.2. Schema of cohort study design.
Abbreviations: AECOPD: acute exacerbation of chronic obstructive pulmonary disease; COPD: chronic obstructive pulmonary disease; PR: pulmonary rehabilitation.

2.4.5 Study covariates

Covariates were selected *a priori* as patient or hospital admission variables which could be potential predictors of non-referral and non-uptake of post-hospitalisation PR. The patient variables included a selection of those previously shown to affect referral, uptake, completion or adherence to PR from previous studies in patients with stable COPD (age (112-114), sex (114), forced expiratory volume in one second [FEV_1] percent predicted (112, 114), smoking history (114, 115), and index of multiple deprivation (115, 116)). Variables which were deemed to be clinically relevant related to the hospital admission were also included (DECAF score (85), length of inpatient stay, review of respiratory specialist within 24 hours of admission, and acute non-invasive or invasive ventilation requirement during hospital admission). More detailed rationale for the selection of each these covariates is included below.

2.4.5.1 Age

Age in years on day of admission was recorded for each hospital episode as multiple studies have shown age to be a predictor of PR adherence and completion. A previous study has shown that age predicts adherence to a PR programme (OR [95% CI]: 64-70 years, 1.99 [1.2 to 3.3]; 71-67 years, 2.57 [1.48 to 4.45] and 77-89 years 1.17 [0.71 to 1.93], with reference as 33-63 years, p=0.0013) (114). In addition, Selzler and colleagues found that those who dropped out from PR were younger than completers (mean [SD]: 63 [13] years versus 69 [10] years respectively, p<0.001). This was corroborated by Boutou *et al.* who demonstrated those who completed PR to be older than non-completers (mean [SD]: 69 [10] years versus 67 [11] years respectively, p=0.013) (112).

2.4.5.2 Sex

Sex (male or female) was recorded for each hospital episode as a previous study has shown that women are more likely to attend PR than men (OR [95% CI], p value: 1.53 [1.05 to 2.25], p=0.0286) (114).

2.4.5.3 Forced expiratory volume in one second (FEV_1) percent predicted

FEV_1 percent predicted was recorded from the most recently completed spirometry available for each hospital episode. Multiple studies have shown more severe airway obstruction, as measured by a lower FEV_1 percent predicted, to be a predictor of non-attendance and non-completion of PR programmes for those with stable COPD (112, 114). Hayton and colleagues showed patients with an FEV_1 percent predicted of >55% to be more than twice as likely to adhere to a PR programme than those with an FEV_1 percent predicted ≤31% (OR [95% CI], p value: 2.2 [1.26 to 3.82], p=0.0426) (114). Another study reported similar findings, with non-completers having a significantly lower baseline

FEV_1 percent predicted than those who completed a PR programme (baseline FEV_1 percent predicted (mean [SD]: 51.9 [20.7] versus 46.6 [17.8] for completers and non-completers respectively, p=0.006) (112).

2.4.5.4 Smoking history (smoking status)

Smoking history was recorded to determine smoking status (never smoker, current smoker, former smoker) for each hospital episode. The leading cause of COPD is smoking tobacco, with an estimated 50% of smokers developing COPD (117). Studies have shown current smoking to be a predictor for declining a referral to PR, with never smokers more likely to consent to PR referral compared with former smokers (OR [95% CI]: 1.38 [1.21 to 1.58] and 0.84 [0.65 to 1.09] for current and never smokers respectively, p<0.0001) (115). Non-attendance to PR is also associated with smoking history. Former smokers were significantly more likely to attend PR (current smokers attendance and former smoker attendance respectively: 56.6% vs. 74.9%), with current smoking also an independent predictor for poor adherence to PR (OR [95% CI]: 7.59 [3.93 to 14.64], p<0.001) (114). Another study corroborated these findings, with the percent of current smokers significantly lower in patients with stable COPD who attended >67% of sessions versus those attending ≤67% of sessions (17.7% vs 56.5% respectively, p<0.001) (118).

2.4.5.5 Index of multiple deprivation

Index of multiple deprivation was calculated (derived from home postcode) for each hospital episode using 'The English Indices of Deprivation 2015' calculator published by the UK government (weblink link: http://imd-by-postcode.opendatacommunities.org/). The seven domains which contributed to the index of multiple deprivation in the 2015 were income, employment, education skills and training, health deprivation and disability, crime, barriers to housing and services, and living environment (119).

Each had individual weightings within the index of 22.5%, 22.5%, 13.55, 13.5%, 9.3%, 9.3% and 9.3% respectively (119).

Studies have shown living with a greater degree of deprivation to be a predictor for declining a referral to PR in stable COPD (OR [95% CI]: 1.36 [1.08 to 1.71], 1.44 [1.15 to 1.79], 1.59 [1.29 to 1.96], 1.81 [1.46 to 2.25] for quintiles two, three, four and five (the most deprived) respectively compared to quintile one (the least deprived), $p<0.0001$) (115). Steiner and colleagues have also shown those with stable COPD who were more deprived to be less likely to complete a PR programme (risk ratio [95% CI]: 0.79 [0.73 to 0.85] comparted to the least deprived group, $p<0.001$) (116).

2.4.5.6 DECAF score

DECAF score was calculated as it is a well-established prognostic marker for hospitalised AECOPD and is a surrogate indicator for admission severity. Section 1.3 provides rationale and method for recording DECAF score.

2.4.5.7 Additional clinically relevant variables

Along with DECAF score, length of inpatient stay and acute non-invasive or invasive ventilation requirement were considered clinically relevant hospital admission variables that are surrogate indicators of admission severity (5). These were deemed relevant as patients who experience more severe exacerbations may be less likely to be referred for or take up PR due to symptom burden (25, 55, 56). The last hospital admission related variable included was review by a respiratory specialist within 24 hours of admission. This was considered important as review by a respiratory specialist was considered to have the potential to indirectly effect the likelihood that a COPD discharge bundle would be completed.

2.4.6 Study outcomes

Data related to study outcomes were collected by a clinical team member who was blinded to the classification of bundle completion.

2.4.6.1 Primary outcome

The primary outcome was the referral to post-hospitalisation PR within 28 days of hospital discharge. PR referral was defined as the percentage of patients where a referral was received by the PR team within 28 days of hospital discharge, with the denominator being total number of patients in each exposure group (49).

2.4.6.2 Secondary outcome

The secondary endpoint was PR uptake within 28 days of hospital discharge, defined as documented attendance at a PR assessment, with the denominator being total number of patients referred to PR at discharge in each exposure group (49).

2.4.7 Sample size

The sample size calculation was based on previous observations that approximately 30% of those receiving a discharge bundle are referred for PR (107). To demonstrate an increase in referral rate to 60% in those who received a discharge bundle from a current PR practitioner, with 80% power at the 5% significance level and assuming an exposure ratio of 1:9 (i.e. 10% of discharges would receive a

bundle from a current PR practitioner) would require a minimum of 220 patients (MedCalc Software, Ostend, Belgium).

For the overall population at hospital discharge, an estimate of the proportion taking up PR was 20% (107). To demonstrate an increase in the proportion of those at hospital discharge taking up PR to 50%, with 80% power at the 5% significance level and assuming an exposure ratio of 1:9 (i.e. 10% of discharges would receive a bundle from a current PR practitioner), would require a minimum of 190 patients (MedCalc Software, Ostend, Belgium).

The minimum data collection period was one year to take into account seasonal variations. However, if the sample size had not been reached by one year, it was planned to extend the data collection period.

2.4.8 Statistical analysis

Outcomes were compared between the two COPD discharge bundle exposure groups who received a COPD discharge bundle using independent T-Test (or Mann-Whitney for non-normally distributed data) or Chi-Squared tests. Normal distribution was determined in SPSS when calculating other descriptive statistics by opting to also calculate skewness and kurtosis (normal distribution has a skewness of 0, with skewness <-1 or >1 = highly skewed data) and kurtosis (normal distribution has a kurtosis of 0, with kurtosis is <– 3 or >3 = excess kurtosis). Associations were investigated using multivariate logistic regression. Adjusted odds ratios (OR) with 95% CIs were estimated with p values ≤0.05 considered significant, with all clinically relevant covariates inputted into the multivariate model using the enter method.

2.5 RESULTS

Of 411 hospital episodes screened, 120 were excluded (24 were due to the patient being ineligible for PR [n=13 unstable cardiac disease; n=9 unable to walk 5 meters independently; n=2 severe locomotor disease precluding moderate intensity exercise] and 96 as it was a readmission of a patient already included in the study) (Figure 2.3). The remaining 291 hospital episodes for an AECOPD were included. 228 (78%) of the 291 hospitalisations received a COPD discharge bundle (Figure 2.3). 25 (11%) of the 228 COPD discharge bundles were completed by a current PR practitioner compared to 203 (89%) who received a COPD discharge from a hospital practitioner not involved in PR delivery (Figure 2.3).

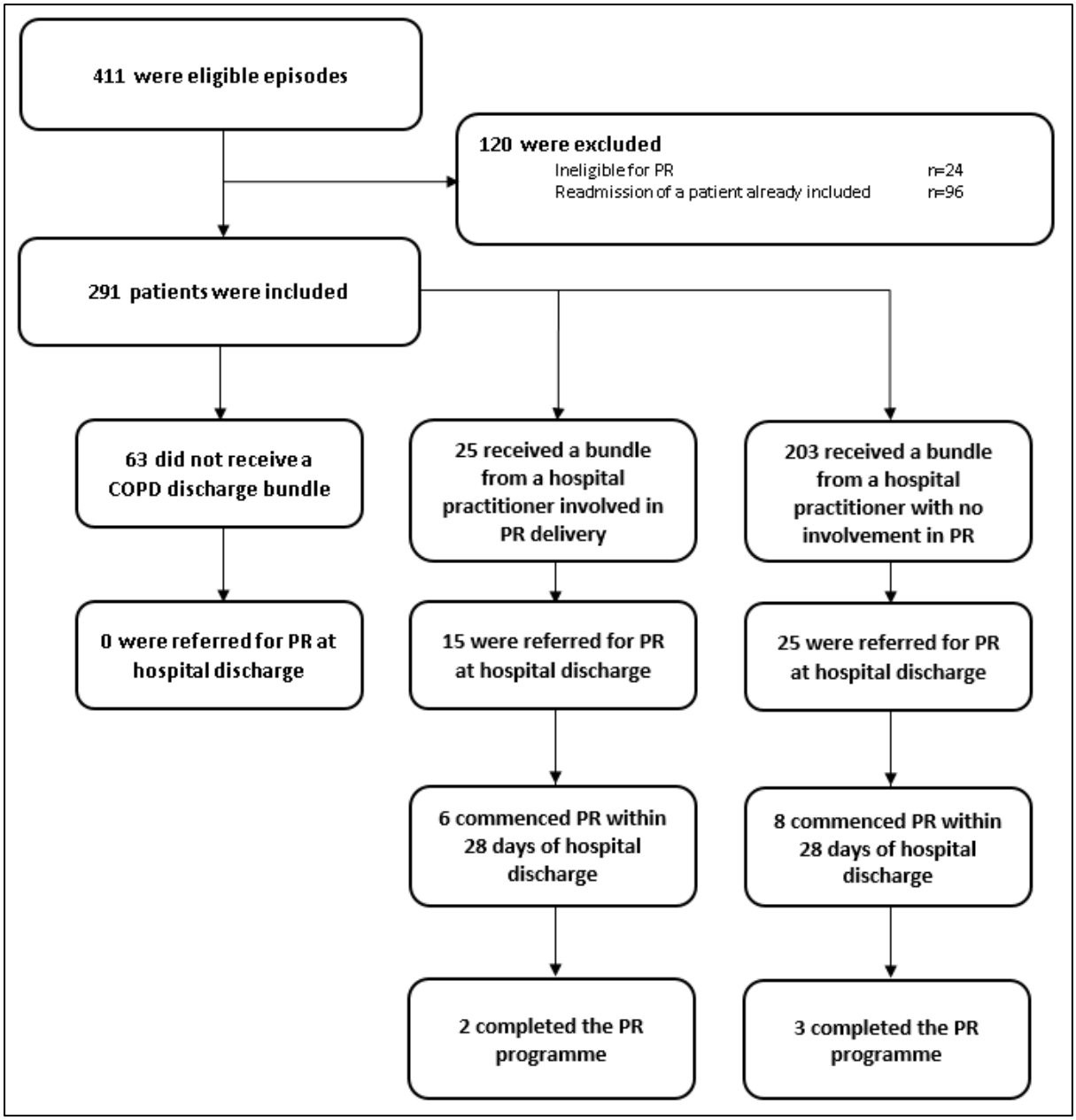


Figure 2.3. Schema of the flow of patients, including COPD discharge bundle completion according to the three classifications of exposure.
Abbreviations: COPD: chronic obstructive pulmonary disease; PR: pulmonary rehabilitation.

2.5.1 Baseline characteristics

The baseline characteristics for all 291 hospital episodes included were n: 145 women, 146 men; %: 33% current smokers; mean age 72 (SD: 9) years, median FEV_1 38 (IQR: 26, 52) percent predicted; median length of stay 3 (IQR: 2, 7) days. Patients who did not receive a COPD discharge bundle had a

longer length of inpatient stay than those who received a COPD discharge bundle (median [IQR]: 4 [2, 9] days vs 3 [1, 6] days respectively, p=0.024) and were less likely to be reviewed by a respiratory specialist within 24 hours of admission than those who received a COPD bundle (70% vs 99% respectively, p=<0.001) (Table 2.1).

Table 2.1. Characteristics of whole cohort and according to bundle completion status

Variable	Whole cohort (n=291)	No bundle completed (n=63)	Bundle completed (n=228)	p value
Age (years)	72 (9)	72 (9)	72 (9)	0.968
Male (n (%))	146 (50)	29 (46)	117 (51)	0.458
FEV_1 % predicted ~	38 (26, 52)	42 (26, 62)	37 (26, 50)	0.228
Smoking status: Never / current / former (n (%))[§]	4 (1) / 95 (33) / 191 (66)	2 (3) / 18 (29) / 42 (67)	2 (1) / 77 (34) / 149 (65)	0.313
Index of multiple deprivation	12404 (8357, 17762)	12930 (8771, 18062)	12212 (7955, 17715)	0.408
DECAF score on admission[+]	1 (1, 2)	1 (1, 1)	1 (1, 2)	0.727
Length of inpatient stay (days)	3 (2, 7)	4 (2, 9)	3 (1, 6)	0.024*
Review of respiratory specialist within 24 hours of admission (n (%))	270 (93)	44 (70)	226 (99)	<0.001*
Non-invasive or invasive ventilation required during admission (n (%))	32 (11)	4 (6)	28 (12)	0.194

Data expressed as mean (SD) or median (25^{th} centile, 75^{th} centile) unless otherwise stated; Independent T-Test (or Mann-Whitney for non-normally distributed data) or Chi-Squared test was used to compare no bundle completion versus bundle completion; p value significance = ≤0.05, indicated by*; ~ = FEV_1 % predicted, n=180; [§] = smoking status, n=290; [+] = DECAF, n=120.
Abbreviations: DECAF: dyspnoea, eosinophils, consolidation, acidaemia, atrial fibrillation; FEV_1: forced expiratory volume in one second.

Baseline demographics according to COPD discharge bundle exposure are shown in Table 2.2. No between group differences were seen in the baseline characteristics of the 228 patients who received a bundle when compared according to the involvement of the hospital practitioner delivering the COPD discharge bundle.

Table 2.2. Characteristics of cohort with bundle completed according to involvement of the hospital practitioner in PR delivery who completed the bundle

Variable	Bundle completed (n=228)	Bundle delivered by hospital practitioner involved in PR delivery (n=25)	Bundle delivered by hospital practitioner not involved in PR delivery (n=203)	p value
Age (years)	72 (9)	72 (11)	72 (9)	0.975
Male (n (%))	117 (51)	12 (48)	105 (52)	0.725
FEV_1 % predicted~	37 (26, 50)	41 (30, 63)	37 (26, 48)	0.131
Smoking status: Never / current / former (n (%))	2 (1) / 77 (34) / 149 (65)	1 (4) / 7 (28) / 17 (68)	1 (1) / 70 (34) / 132 (65)	0.180
Index of multiple deprivation	12212 (7955, 17715)	13025 (11426, 17669)	11492 (7694, 17762)	0.063
DECAF score on admission⁺	1 (1, 2)	1 (0, 2)	1 (1, 2)	0.267
Length of inpatient stay (days)	3 (1, 6)	3 (2, 8)	3 (1, 6)	0.438
Review of respiratory specialist within 24 hours of admission (n (%))	226 (99)	24 (96)	203 (100)	0.116
Non-invasive or invasive ventilation required during admission (n (%))	28 (12)	5 (20)	23 (11)	0.213

Data expressed as mean (SD) or median (25^{th} centile, 75^{th} centile) unless otherwise stated; Independent T-Test (or Mann-Whitney for non-normally distributed data) or Chi-Squared test was used to compare bundle delivered by hospital practitioner involved in PR delivery versus bundle delivered by hospital practitioner not involved in PR delivery; p value significance = ≤0.05; ~ = FEV_1 % predicted, n=150; ⁺ = DECAF, n=117.

Abbreviations: DECAF: dyspnoea, eosinophils, consolidation, acidaemia, atrial fibrillation; FEV_1: forced expiratory volume in one second; PR: pulmonary rehabilitation.

2.5.2 PR referral

Of the 63 hospital episodes where a COPD discharge bundle was not delivered, no patient was referred for PR at discharge from hospital. In comparison, 40 of the 228 receiving the bundle were subsequently referred for PR (18%). A significant between group difference was seen in referral rates of those who received a COPD discharge bundle by a current PR practitioner compared with those delivered by a hospital practitioner not involved in PR delivery (60% versus 12%, p=<0.001) (Table 2.3).

Table 2.3. PR referral rate, uptake, completion and adherence according to the involvement of the hospital practitioner in PR delivery who completed the bundle

Outcome	Bundle delivered by hospital practitioner involved in PR delivery (n=25)	Bundle delivered by hospital practitioner not involved in PR (n=203)	p value
Primary outcome			
Referral to PR received within 28 days of hospital discharge	15/25 (60)	25/203 (12)	<0.001*
Secondary outcome			
Uptake of PR within 28 days of hospital discharge	6/15 (40)	8/25 (32)	<0.001*

Data expressed as n (%); Chi-Squared test was used to compare group; p value significance = ≤0.05, indicated by *.
Abbreviations: PR: pulmonary rehabilitation.

2.5.2.1 Predictors of PR referral

Table 2.4 includes the univariate logistic regression. In adjusted multivariate logistic regression, delivery of COPD discharge bundle delivered by a current PR practitioner was a predictor of increased PR referral (adjusted OR: 14.46, 95% CI: 5.28 to 39.57), with length of inpatient stay also an independent predictor for PR referral (adjusted OR: 0.89, 95% CI: 0.80 to 0.99) (Table 2.5). DECAF score and FEV_1 percent predicted were missing for a proportion of the patients. Therefore, DECAF score and FEV_1 percent predicted were unable to be included in the multivariate logistic regression models for referral to post-hospitalisation PR.

Table 2.4. Univariate logistic regression for predictors of PR referral and uptake within 28 days of hospital discharge for those with completed bundles

Variable	PR referral within 28 day of hospital discharge			PR uptake within 28 days of hospital discharge		
	Univariate			Univariate		
	OR	95% CI	p value	OR	95% CI	p value
Practitioner delivering bundle involved in PR delivery (ref: not involved in PR delivery)	10.68	4.33 to 26.35	<0.001*	7.70	2.42 to 24.22	0.001*
Age (years)	0.98	0.94 to 1.01	0.213	1.00	0.95 to 1.06	0.922
Sex (ref: male)	0.65	0.33 to 1.31	0.228	1.98	0.64 to 6.09	0.236
FEV_1% predicted	1.01	0.99 to 1.04	0.263	1.02	0.99 to 1.05	0.223
Smoking status (ref: current)	0.94	0.46 to 1.92	0.856	1.29	0.39 to 4.27	0.672
Index of multiple deprivation	1.00	1.00 to 1.00	0.305	1.00	1.00 to 1.00	0.110
DECAF score	0.65	0.39 to 1.07	0.090	0.63	0.28 to 1.38	0.244
Non-invasive or invasive ventilation required (ref: no)	1.03	0.37 to 2.88	0.963	1.21	0.26 to 5.70	0.814
Duration of inpatient stay (days)	0.94	0.86 to 1.02	0.139	0.90	0.75 to 1.07	0.233

p value significance = ≤0.05, indicated by *.

Abbreviations: CI: confidence interval; DECAF: dyspnoea, eosinophils, consolidation, acidaemia, atrial fibrillation; FEV_1: forced expiratory volume in one second; OR: odds ratio; PR: pulmonary rehabilitation.

Table 2.5. Multivariate logistic regression for predictors of PR referral and uptake within 28 days of hospital discharge for those with completed bundles

Variable	PR referral within 28 day of hospital discharge			PR uptake within 28 days of hospital discharge		
	Adjusted multivariate			Adjusted multivariate		
	OR	95% CI	p value	OR	95% CI	p value
Practitioner delivering bundle involved in PR delivery (ref: not involved in PR delivery)	14.46	5.28 to 39.57	<0.001*	8.60	2.51 to 29.50	0.001*
Age (years)	0.98	0.94 to 1.02	0.277	0.99	0.99 to 1.05	0.717
Sex (ref: male)	0.56	0.25 to 1.24	0.152	1.83	0.54 to 6.19	0.325
Smoking status (ref: current)	0.87	0.37 to 2.06	0.748	0.93	0.24 to 3.65	0.917
Index of multiple deprivation	1.00	1.00 to 1.00	0.481	1.00	1.00 to 1.00	0.227
Non-invasive or invasive ventilation required (ref: no)	1.31	0.36 to 4.72	0.680	1.53	0.23 to 3.64	0.917
Duration of inpatient stay (days)	0.89	0.80 to 0.99	0.037*	0.88	0.72 to 1.03	0.178

p value significance = ≤0.05, indicated by *; all variables were entered in the model using the enter method.

Abbreviations: CI: confidence interval; OR: odds ratio; PR: pulmonary rehabilitation.

2.5.3 PR uptake

A significant between group difference was seen in uptakes rates of those who received a COPD discharge bundle by a current PR practitioner compared with those completed by a hospital practitioner not involved in PR delivery (Table 2.3).

2.5.3.1 Predictors of PR uptake

Table 2.4 includes the univariate logistic regression. In adjusted multivariate logistic regression, COPD discharge bundle delivered by a current PR practitioner was the only predictor of increased PR uptake

(adjusted OR: 8.60, 95% CI: 2.51 to 29.50) (Table 2.5). DECAF score and FEV_1 percent predicted were missing for a proportion of the patients. Therefore, DECAF score and FEV_1 percent predicted were unable to be included in the multivariate logistic regression models for uptake of post-hospitalisation PR.

2.6 DISCUSSION

In this prospective cohort study, provision of a COPD discharge bundle was an important factor in determining referral and uptake rates for post-hospitalisation PR. No resulting PR referrals or uptake occurred when a COPD discharge bundle was not delivered to the patient. This data supports earlier observations that the introduction of COPD discharge bundles can generate increased referrals for post-hospitalisation PR (120).

A novel aspect of this study examined whether the role of the hospital practitioner delivering the COPD discharge bundle was influential. Intriguingly, this study demonstrated that referral and uptake rates were significantly increased when the practitioner delivering the bundle also had responsibilities and was involved in the delivery of PR. Although this could simply represent referrer bias, it was reassuring to observe that there was also a higher PR uptake rate in those patients referred by current PR practitioners. After taking into account potential confounders including patient demographics and hospital admission factors, the practitioner's current involvement in delivering PR remained an independent predictor for both increased PR referral and uptake.

2.6.1 Proposed rationale for study findings

One explanation for the observations found in this cohort study includes increased referrer knowledge about local referral pathways and processes. Referrer knowledge and attitudes may also influence the patient-referrer interaction, which in turn could shape the patient's understanding and demystify their expectations of PR. Knowledge is frequently identified as a barrier/enabler for PR referral and participation (121). This is consistent with many of the domains which underpin behaviour change proposed by Michie and colleagues (122), highlighting the role of the referrer as a well-informed, skilled credible source being important. The data from this study is hypothesis generating, and an area of further research is to test whether improving referrer knowledge and experience, potentially through formal training or closer integration between hospital services and PR, might increase referral and uptake for post-hospitalisation PR. This is particularly important given the paucity of effective interventions that address this area (123).

The observations from this cohort study also suggest that patients who did not receive a COPD discharge bundle had a longer inpatient stay and were less likely to receive a review from a respiratory specialist within 24 hours. Rationale for this is unknown from the data collected in this cohort study, but it is possible these patients might have complex multimorbidity or were cared for by non-respiratory physicians, such as geriatricians. This cohort study indicates the need for future exploration into the inpatient care pathways for those admitted with an AECOPD who have a prolonged length of inpatient stay to facilitate these patients receiving a COPD discharge bundle (and in turn the opportunity of being offered post-exacerbation PR).

2.6.2 Strengths

This was an adequately powered study, with the required sample size achieved. Hillingdon Hospital maintains a real-time continuous database of patients admitted with COPD as part of the National COPD secondary care audit and the introduction of the NHS England COPD Best Practice tariff. The hospital has an integrated respiratory team with responsibility for delivering all COPD discharge bundles. Patients in Hillingdon borough are served by a single PR provider, which facilitates collection of PR outcome data. These are important as they promote accuracy of data derived from electronic healthcare records, which is known to vary (110, 111), and effectively minimise loss to follow-up, which did not occur in this study, through implementation of a systematic and robust process to obtain data (124). Finally, the patient, referrer and hospital admission covariates selected *a priori* for this cohort study were based upon the potential predictors of PR outcomes from the existing evidence-base as well as variables considered to be clinically relevant.

2.6.3 Limitations

This was a single centre cohort study, without an external cohort to validate the findings. Therefore, these findings may not be generalisable beyond our local population. Moreover, although the *a priori* sample size was met, only a small proportion of bundles were completed by a hospital practitioner who contributed to PR delivery and the wide 95% confidence intervals suggest a degree of uncertainty. Another limitation is that this study utilised routinely collected data as part of service evaluation and audit (80). As a result, it is possible that the findings could be explained by confounding factors not collected in the dataset, with differences in patient knowledge, beliefs and attitudes between the exposure groups potentially relevant (121). This is a generic weakness of cohort studies whereby only association, and not causation, can be shown (80).

Although this was a prospective cohort study, variables recorded in 'real-time' (DECAF scoring and FEV_1 percent predicted) were missing for a proportion of the patients. Therefore, DECAF score and FEV_1 percent predicted were unable to be included in the multivariate logistic regression models for referral and uptake to post-hospitalisation PR, and therefore it is not known whether these two variables are important confounders for the outcomes of interest.

Another variable, review by respiratory specialist within 24 hours of hospital admission, was also not included in any of the multivariate logistic regression models to determine predictors of PR referral and uptake as there was no reference group; all those who received a COPD discharge bundle by a hospital practitioner not involved in PR delivery had a review by a respiratory specialist within 24 hours of hospital admission.

2.7 CONCLUSION

COPD discharge bundle completion is associated with increased referral and uptake rates for post-hospitalisation PR. In particular, COPD discharge bundle delivery by a practitioner delivering PR within their workplan is an independent predictor of PR referral and uptake. Closer integration between clinical services and standardisation of information delivered between hospital and PR practitioners may increase post-hospitalisation PR referral and uptake rates.

The focus of the next chapter is to investigate whether PR uptake and referral rates can be increased through standardisation of the information provided to patients regarding post-hospitalisation PR within the COPD discharge bundle.

Chapter 3: A randomised controlled trial of a Video Intervention to facilitate RehabiliTation Uptake following hospitalised Exacerbations of COPD (VIRTUE)

Some of the results from this chapter were published in the American Journal of Respiratory and Critical Care Medicine on 17th March 2020 (123). These results are reprinted with permission of the American Journal of Respiratory and Critical Care Medicine, copyright © 2020 American Thoracic Society. All rights reserved. Barker *et al*, 2020, Am J Respir Crit Care Med Vol 201, Iss 12, pp 1517–1524. The American Journal of Respiratory and Critical Care Medicine is an official journal of the American Thoracic Society.

Some of the results from this chapter have also previously been reported in a conference abstract, which was presented at the American Thoracic Society International Conference in May 2019 (125). These results are reprinted with permission of the American Thoracic Society and with permission of the authors, copyright © 2020 American Thoracic Society. All rights reserved.

Please note that I was the trial manager for this study prior to starting this PhD, and I recruited the majority of participants before formally starting my PhD. I was not involved in the development of the intervention. The main components that I have conducted during my PhD have been the development of the statistical analysis plan, the completion of recruitment and follow-up for participants, analysis of the data and the interpretation of findings

3.1 BACKGROUND

Pulmonary rehabilitation (PR) following hospitalised acute exacerbations of COPD (AECOPD) improves exercise capacity and health-related quality of life (HRQoL), and reduces readmissions and mortality (46, 48). However, post-hospitalisation PR uptake is low (52) and no randomised trials of interventions to increase uptake in this population have been published (59, 60). Poor referral and uptake rates are partly attributable to poor patient engagement with, or lack of awareness of the benefits of, PR, as well as referrer-related barriers including lack of knowledge of PR or the referral processes (56). Therefore, PR services need to explore novel strategies to better engage patients (78).

As previously discussed, one advocated strategy is the delivery of a COPD discharge bundle during a hospital admission following an AECOPD (126). In the UK, this aide memoir of evidence-based best practice includes the offer of referral to early post-discharge PR following a hospitalization for AECOPD. However, as demonstrated in the previous chapter, despite delivery of the COPD discharge bundle, outcomes such as referral to PR can vary according to practitioner job role. This may be related to referrer knowledge.

The aim of the current study was to investigate whether an intervention delivered alongside the COPD discharge bundle, which not only provides more in-depth information to patients regarding post-exacerbation PR but also allows for standardisation of the information being provided by hospital practitioners, can increase the referral to and uptake of post-hospitalisation PR.

3.2 OBJECTIVE

The objective of a 'Video Intervention to facilitate RehabiliTation Uptake following hospitalised Exacerbations of COPD', or VIRTUE was to determine whether a patient co-designed education video delivered alongside the COPD discharge bundle increases referral rate, uptake and completion of PR post-hospitalisation for AECOPD.

3.3 HYPOTHESIS

It was hypothesised that using a patient co-designed education video alongside a COPD discharge bundle would enhance referral rate, uptake and completion of PR post-hospitalisation for AECOPD.

3.4 METHODS

3.4.1 Study design

VIRTUE was a mixed methods trial which included a parallel, two-group RCT with convergent qualitative interviews for patients recruited to the RCT. Figure 3.1 is a schematic of the trial design.

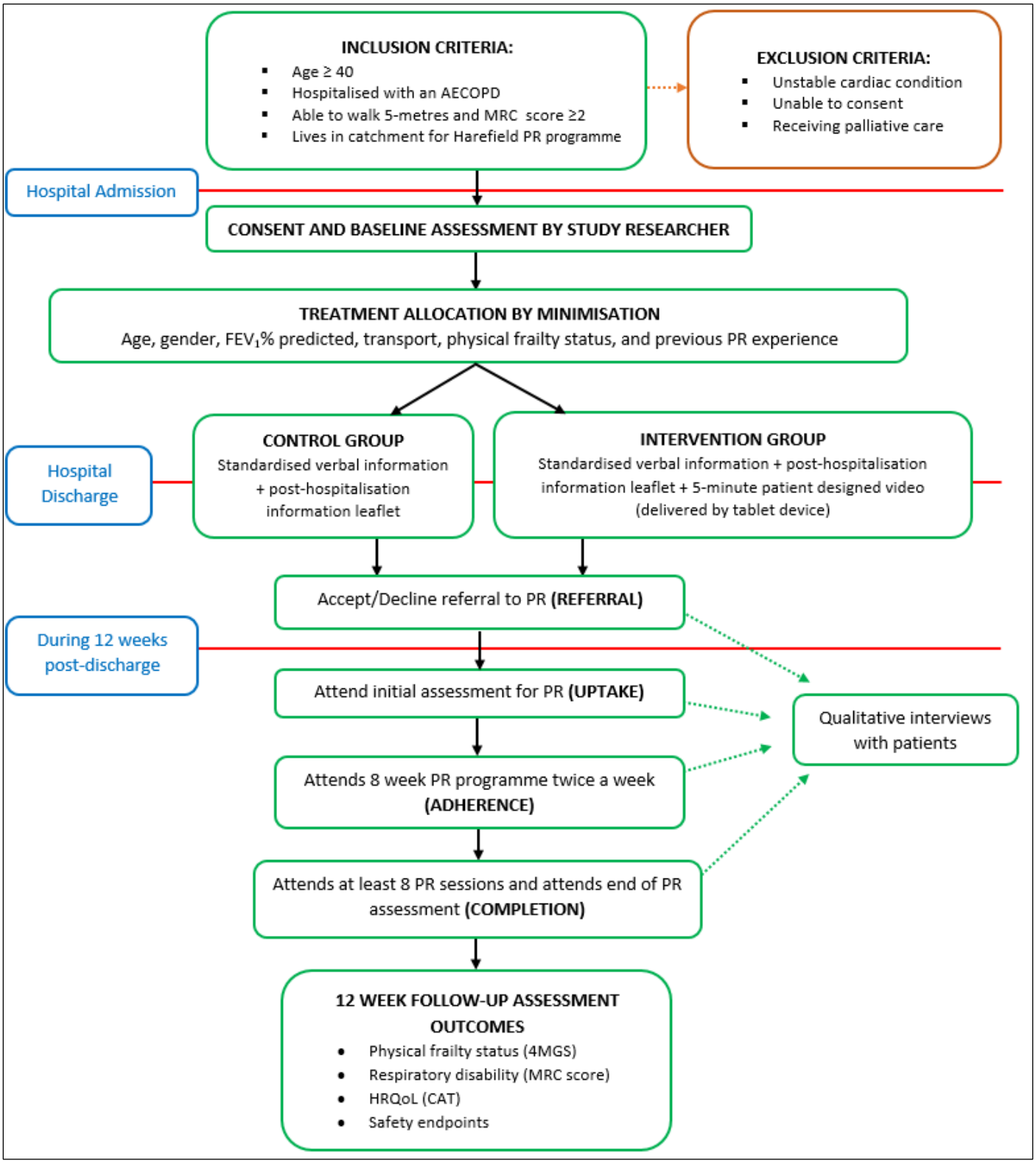


Figure 3.1. Schema of VIRTUE trial design.

Abbreviations: 4MGS: four metre gait speed; AECOPD: acute exacerbation of chronic obstructive pulmonary disease; CAT: COPD Assessment Test; HRQoL: health-related quality of life; MRC: Medical Research Council; PR: pulmonary rehabilitation.

3.4.2 Ethical approval and trial registration

The study was approved by the London – City and East Research Ethics Committee (14/LO/1740). All participants provided written informed consent when recruited to the RCT, and additional written informed consent was received from all participants who participated in the qualitative interviews. VIRTUE was prospectively registered on the International Standard Randomised Controlled Trial Number (ISRCTN) registry (13165073).

3.4.3 Participants

3.4.3.1 Trial eligibility criteria

Recruitment took place at Hillingdon Hospital between February 2015 and May 2018. Eligible participants were aged 40 years or over and hospitalised at Hillingdon Hospital with a primary diagnosis of AECOPD (or primary diagnosis of pneumonia and secondary diagnosis of AECOPD). A diagnosis of COPD was based upon a clinical opinion from a specialist respiratory physician with access to hospital and primary care records including previous spirometry results, to ensure a diagnosis of COPD could be confirmed (127). A conservative age cut-off of ≥40 years of age was included to reduce the likelihood that those with a differential diagnosis of asthma would be recruited (National Institute for Health and Care Excellence guidelines suggest asthma (another common obstructive lung condition) is more prevalent in those under 35 years of age (127)).

Patients were also required to be eligible for post-hospitalisation PR according to local criteria (able to walk 5-metres, with a Medical Research Council [MRC] score ≥2 (34)) and be living within catchment area of Harefield PR programme. This was to ensure those being recruited to the trial were suitable

to be referred for PR at hospital discharge, and the outcome data could be robustly collected from a single database.

Exclusion criteria included other significant co-morbidities that were a contraindication for exercise training (e.g. evidence of acute coronary syndrome or unstable ischaemic heart disease, severe aortic stenosis, uncontrolled cardiac arrythmia) (34), lack of consent due to cognitive dysfunction or poor English, and those receiving palliative care with expectation of death within three months. Experience of PR in the preceding 12 months was initially included as an exclusion criterion. However, this was removed in September 2016 (following approval being obtained from the London – City and East Research Ethics Committee via a substantial amendment) as the group allocation process (minimisation) accounted for past experience of PR (see section 3.4.4).

3.4.3.2 Qualitative interviews purposive sampling criteria

Using purposive sampling, a sub-group of patients allocated to the intervention group were interviewed to capture their perspectives about the education video and research processes. The purposive criteria took into account ages, sex, ethnicity, whether they agreed, or declined a referral for PR, and PR completers and non-completers. This was to ensure the range of perspectives explored were evidence-based (113, 114, 128) and specifically selected participants who achieved different degrees of engagement with the PR (129).

3.4.4 Randomisation procedure

Participants were randomised 1:1 to either control (COPD discharge bundle alone) or intervention (COPD discharge bundle plus patient co-designed education video). The allocation sequence was

computer-generated (Minim) (130), inputted by an independent administrator. Minimisation was used as it is a widely accepted as a method of group allocation to ensure groups are balances according to pre-defined variables (131).

The groups in this study were balanced according to six criteria: 1) age (years: </≥65), 2) sex (male/female), 3) FEV_1 (percent predicted: </≥50), 4) transport availability (independent driver with a car: yes/no), 5) physical frailty status (four metre gait speed [4MGS] metres/second [m/s]: </≥0.6 (132)), and 6) previous PR experience (previously attended PR: yes/no). These six criteria were deemed to be clinically relevant factors which have previously been shown to negatively affect PR service utilisation (age (112, 113), sex (114), FEV_1 percent predicted (112, 114), transport availability (58, 133) and physical frailty (134)). Previous PR experience was considered a factor which was likely to influence uptake of PR.

3.4.5 Blinding

This RCT was assessor- and statistician- blinded. The researcher who conducted the patient screening, recruitment, 12 weeks (approximated as 90 days) post-discharge outcome assessments and data collection for PR service utilisation outcomes (referral, uptake, adherence and completion) was blinded to group allocation. All statistical analysis was undertaken jointly by a researcher and statistician who remained blinded to group allocation until primary statistical analysis was completed. Group allocation was completed by an administrator who liaised with a unblinded researcher who delivered the intervention. This was independent to the blinded researcher completing the tasks stated above.

Once participants were recruited, the independent administrator contacted the external qualitative researcher with participant details relating to group allocation and PR referral status at hospital discharge. The external qualitative researcher requested the further detail required from the independent administrator following the 12 weeks post-discharge outcome assessment to confirm whether patients met the purposive sampling criteria.

3.4.6 Study interventions

All participants received usual care, comprising delivery of a COPD discharge bundle (Figure 2.1 in Chapter 2, section 2.1) (126) from a specialist respiratory allied health professional. This included organising appropriate follow-up post-discharge, smoking cessation advice (and referral) if appropriate, inhaler technique education, written self-management plan, and information about PR (126).

All patients were given standardised verbal information in this trial regarding post-hospitalisation PR: *"PR is a set of personalised classes to help you manage your breathlessness and gradually increase your fitness level. Each class consists of an education and an exercise session and lasts around 2 hours. Classes are held twice a week for eight weeks. Once you have been referred, you will be contacted within 2 weeks to arrange an assessment. During this assessment, a specialist physiotherapist will discuss your goals with you and complete a full lung health check-up. The assessment takes place at Harefield Hospital, but you can choose where you would like to attend your PR programme. For example, in Hayes, Uxbridge, Harefield, Harrow Weald and South Harrow. This is your leaflet which will provide you with more information."*. All participants also received standardised written information regarding post-exacerbation PR (Appendix 2). Participants were offered a referral to the programme, with a referral generated only with patient consent.

The intervention group were provided with the same COPD discharge bundle but also watched a five-minute patient co-designed education video providing additional information about post-exacerbation PR. The video was delivered via handheld tablet device (mini iPad) at the bedside whilst patients were in hospital. The intervention group were provided with a secure internet link and password to allow them or their family members to watch the video once discharged. Since the end of the study, the video has been made available at: https://www.youtube.com/watch?v=jNtNPsC931I

3.4.6.1 Video intervention development

The development of the intervention was conducted before the start of this PhD. An experience-based co-design (EBCD) methodology was used. This is a quality improvement approach that enables key stakeholders, in this instance service users and healthcare professionals, to co-design an information video intervention in partnership (135): these differing participant types were selected and described as 'stakeholders' given that all can either affect, or be affected by, the intervention (136). The EBCD process gathers experiences from service users and healthcare professionals through observations and group discussions, identifying key 'touchpoints' (emotionally significant views) and ensuring a consensus is reached (135).

The EBCD process is outlined below (see Figure 3.2 for a schematic representation of the process):

1. Video-recorded interviews were conducted with patients to understand their experiences of PR after an acute exacerbation of COPD. One of the key issues raised by patients was insufficient information about the components of PR, and the potential benefits for themselves;

2. Clips which illustrated the key perceptions and experiences raised in the interviews (known as 'touchpoints') were subsequently combined and edited to produce a 'touchpoints' video;
3. The edited 'touchpoints' video was then played at three key stakeholder feedback events;
    a. Patients alone (all patients had experienced a hospitalisation for exacerbation of COPD, with some previously undergoing post-hospitalisation PR [this included those who offered but declined to attend, started and dropped out, and those who completed early PR]);
    b. Healthcare professionals alone (from acute care teams involved in the inpatient care of patients with exacerbation of COPD as well as from the PR service); and
    c. Joint patient and healthcare professional event (including a similar heterogenous combination of patients and healthcare professionals from the groups stated above);
4. From these three stakeholder events, the key priority was to develop an education video that would allow real past patients to tell prospective patients about the benefits of PR in a visual manner; and
5. Patient/healthcare professional co-design groups were then formed to develop the intervention, how it would be delivered, and at which point in the patient pathway.

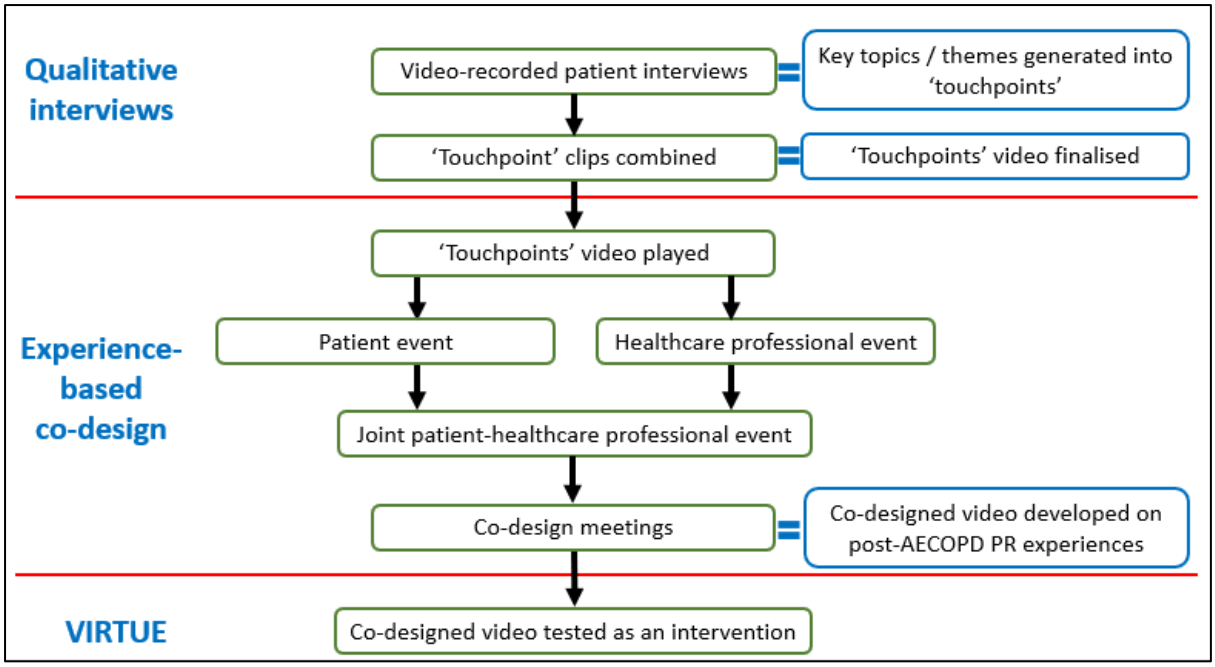


Figure 3.2. Schema of experience-based co-design process to develop the video intervention.
Reprinted with permission of the American Thoracic Society, copyright © 2020 American Thoracic Society. All rights reserved. Barker *et al*, 2020, Am J Respir Crit Care Med Vol 201, Iss 12, pp 1517–1524. The American Journal of Respiratory and Critical Care Medicine is an official journal of the American Thoracic Society.
Abbreviations: AECOPD: acute exacerbation of chronic obstructive pulmonary disease; PR: pulmonary rehabilitation; VIRTUE: A randomised controlled trial of a Video Intervention to facilitate RehabiliTation Uptake following hospitalised Exacerbations of COPD.

3.4.7 Study measurements

Along with a structured history (which included smoking status, Charlson Comorbidity Index and index of multiple deprivation), the following were measured on the day of hospital discharge: anthropometry (height and weight), physical frailty status (4MGS (132)), lung function (spirometry (137)), respiratory disability (MRC dyspnoea score (138)), and disease-specific HRQoL (COPD Assessment Test [CAT] (23)). 4MGS and CAT were re-measured 12 weeks post-discharge. Qualitative interviews were conducted within a week after the end of the 12-week follow-up period.

3.4.7.1 Smoking history (smoking status and pack year history)

Smoking history was recorded at baseline to determine smoking status. Section 2.4.5.4 includes rationale and method for recording smoking history. In relation to smoking, particular note was also taken regarding duration in years and daily volume of tobacco or number of cigarettes smoked (termed pack year history) (139). Figure 3.3 shows how pack year history is calculated (140). For example, the total pack year history for someone who smoked 15 cigarettes a day from the ages of 16 to 35, and then 20 cigarettes a day from the ages 36 to 61 would be: ([15/20]*19)+([20/20]*25)=39.25 years.

$$\left(\frac{\text{number of cigarettes smoked per day}}{20}\right) \text{x number of years smoked}$$

Figure 3.3. Equation to calculate pack year history.

3.4.7.2 Comorbidity burden (Charlson Comorbidity Index)

The Charlson Comorbidity Index was recorded at baseline to determine comorbidity burden, and subsequent risk for patients admitted to hospital (141). A study has shown living with a higher comorbidity burden to be a predictor for lower referral rates to PR in stable COPD (115). The Charlson Comorbidity Index is an index which includes 19 comorbid conditions identified from the International Classification of diseases–9 codes which are assigned to hospital discharges, and weights accordingly according to risk of dying (141). The scores are totalled, with the overall score predictive of 10-year mortality; higher scores are associated with a higher mortality risk. The age-adjusted version of the Charlson Comorbidity Index accounts for the mortality associated with aging, with points added to the overall score. Charlson Comorbidity Index was computed using a calculator in this trial based upon the scoring system presented in Table 3.1.

Table 3.1. Scoring used to compute age-adjusted Charlson Comorbidity Index

Variable	Point scored
Age	-
≥40 years	0
>40-≥50 years	1
>50-≥60 years	2
>60-≥70 years	3
>70-≥80 years	4
>80 years	4
Myocardial infarction	1
Congestive heart failure	1
Peripheral vascular disease	1
Cerebrovascular disease	1
Dementia	1
Chronic obstructive pulmonary disease	1
Rheumatic disease	1
Peptic ulcer disease	1
Mild liver disease	1
Diabetes mellitus without end-organ damage	1
Diabetes mellitus with end-organ damage	2
Hemiplegia	2
Renal disease	2
Any malignancy	2
Lymphoma	2
Leukaemia	2
Moderate liver disease	3
Metastatic solid tumour	6
Acquired immunodeficiency syndrome	6

3.4.7.3 Index of multiple deprivation

Index of multiple deprivation was calculated at baseline using the patients' home postcode. Section 2.4.5.5 includes rationale and method for recording index of multiple deprivation.

3.4.7.4 Anthropometry (height, weight and body mass index)

Height and weight were recorded at baseline to allow calculation of body mass index (BMI), and to support performance of lung function measures (142). BMI has been shown to be associated with worse PR attendance in patients with stable COPD (143). Height was determined to the nearest centimetre using height stadiometer (Model 217, Seca, Hamburg, Germany) intended for mobile use, with the participant in bare feet (Figure 3.4a). Weight was measured in kilograms to one decimal place with the participant lightly dressed using Seca flat digital scales (Model 875 Seca, Hamburg, Germany) intended for mobile use (Figure 3.4b). BMI was calculated by dividing weight (in kilograms) by height (in metres) squared.

Figure 3.4. a) Leicester Height Stadiometer (Model 217, Seca, Hamburg, Germany); b) Seca Dual Measurement analogue scales (Model 761 Seca, Hamburg, Germany).

3.4.7.5 Physical frailty status (four metre gait speed)

The four metre gait speed (4MGS) was recorded to measure physical frailty status at baseline and 12 weeks post discharge. Frailty has been shown to be a predictor of non-completion of PR in patients with stable COPD (134). Frailty, as measured by 4MGS as a surrogate marker of physical frailty, also predicts readmission risk at 90 days for patients admitted to hospital with an AECOPD (132).

Staff were trained to perform the 4MGS assessments according to the local standard operating procedure (Appendix 4), which was based upon the National Institutes of Health Toolbox (144). The test was completed on a flat, unobstructed four metre course delineated with tape with a stopwatch (Unisex Black Sports LCD stopwatch, Argos, UK) used to record the time taken to two decimal places. Participants started stationary, with their toes positioned just touching the start line, with the staff member positioned behind the participant. This was to ensure the patient was not paced by the assessor during the test. Timing commenced from when the heel of the first foot was lifted. Timing ended when the first foot completely crossed the second line, demonstrating four metres had been covered (Figure 3.5).

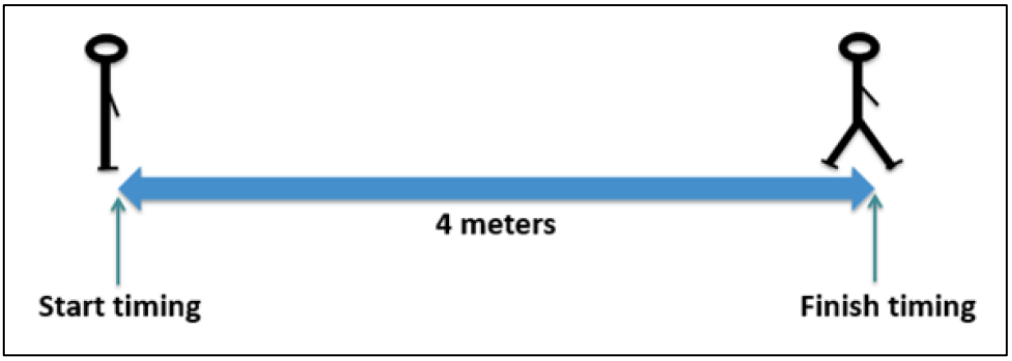


Figure 3.5. Set-up and timing during four metre gait speed assessment.

Gait speed in metres per second (m/s) was calculated by taking the distance walked (i.e. four metres) divided by time taken recorded to cover the distance in seconds to two decimal places. For example, the 4MGS time would be 1.00 m/s if the participant took 4.00 seconds to walk four metres.

3.4.7.6 Lung function (spirometry)

Spirometry was performed according to according to American Thoracic Society / European Respiratory Society guidelines (145) to measure lung function at baseline and 12 weeks post-

discharge. Section 2.4.5.3 includes rationale for performing spirometry. Spirometry was performed using an EasyOne diagnostic spirometer (model 2001, Medixintechnik, Zurich, Switzerland) (Figure 3.6a). Forced vital capacity (FVC) and FEV_1 were measured (absolute and percent predicted values), with FEV_1/FVC ratio calculated. A minimum of three attempts were performed, and repeated until reproducible FVCs were recorded (142). The data from the best of three reproducible attempts was used, with predicted values derived from the equations recommended by the European Respiratory Society (142). The spirometer was calibrated daily using the *ndd* calibration adapter and a 3-litre calibration syringe (*ndd* Medical Technologies, Massachusetts, USA) (Figure 3.6: b and c).

Figure 3.6. a) EasyOne diagnostic spirometer; b) Calibration adapter; c) 3-litre calibration syringe.

3.4.7.7 Respiratory disability (MRC dyspnoea scale)

The MRC dyspnoea score was recorded to measure respiratory disability (137, 138) at baseline. The MRC dyspnoea Scale is a 5-point scale (Table 3.2). No respiratory disability is represented by score 1, whilst worsening degrees of limitation which have increasing impact on function are scored from 2 upwards. Patients with higher MRC dyspnoea scores have been shown to have lower attendance rates to a PR programme in patients with stable COPD (118), and lower PR completion rates (112, 146). There is excellent reproducibility using the MRC dyspnoea scale, with strong correlations with other breathlessness scales and lung function measures (147).

Table 3.2. Medical Research Council dyspnoea scale

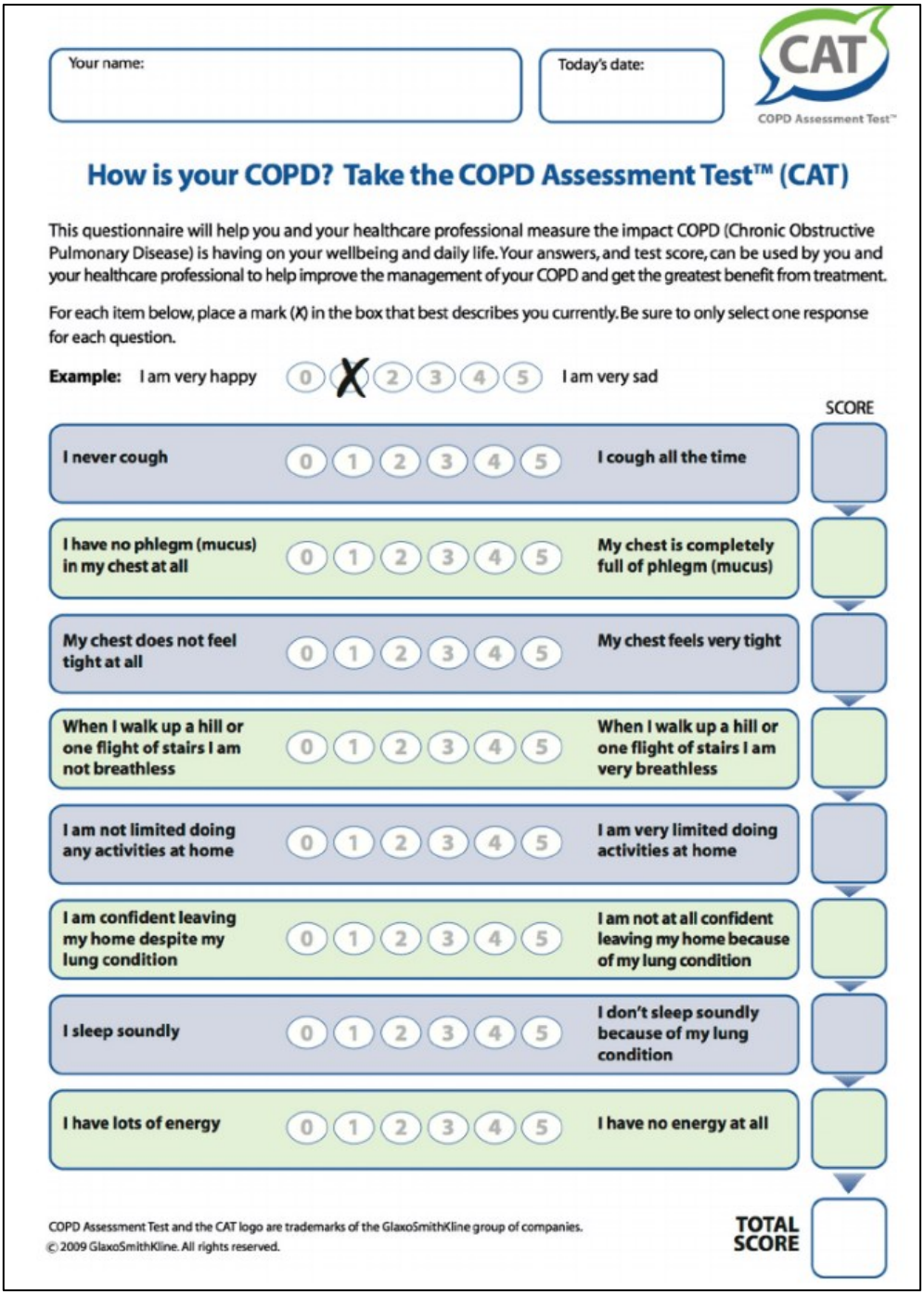
Medical Research Council dyspnoea scale
1. Not troubled by breathlessness except on strenuous exertion. 2. Short of breath when hurrying or walking up a slight hill. 3. Walks slower than contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own pace. 4. Stops for breath after walking about 100ms or after a few minutes on level ground. 5. Too breathless to leave the house, or breathless when dressing or undressing.

3.4.7.8 HRQoL (COPD Assessment Test [CAT])

The CAT was completed at baseline and 12 weeks post-discharge to measure disease-specific HRQoL. The CAT is a short, self-administered questionnaire containing 8 items, scored from 0 to 5, which takes two to three minutes to complete (148). The overall score for the questionnaire is calculated by totalling the score (0 to 5) for each of the eight items (Figure 3.7). The lower the overall score

(minimum is 0), the less impact COPD has on the participants, with the highest achievable overall score being 40. Scores of between 0 and 10, 11 and 20, 21 and 30 and 31 and 40 indicate COPD has a low, medium, high and very high impact on participants respectively (149).

The CAT has been shown to have excellent internal consistency and test-retest reliability, can be used longitudinally to monitor health status (150) and is known to be responsive to both PR (23) and exacerbations (151). Higher scores are seen in patients with frequent exacerbations (22), and a change of two or more units is considered to be the minimum clinically important difference (23). Non-completers of PR have been shown to have significantly higher baseline CAT scores than those who completed a PR programme (112), and CAT score has been shown to be a predictor of non-completion of a PR programme in patients with stable COPD (134).



Your name:

Today's date:

CAT
COPD Assessment Test™

How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy 0 X 2 3 4 5 I am very sad

		SCORE
I never cough	0 1 2 3 4 5	I cough all the time
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	My chest is completely full of phlegm (mucus)
My chest does not feel tight at all	0 1 2 3 4 5	My chest feels very tight
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 5	When I walk up a hill or one flight of stairs I am very breathless
I am not limited doing any activities at home	0 1 2 3 4 5	I am very limited doing activities at home
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	I am not at all confident leaving my home because of my lung condition
I sleep soundly	0 1 2 3 4 5	I don't sleep soundly because of my lung condition
I have lots of energy	0 1 2 3 4 5	I have no energy at all
		TOTAL SCORE

Figure 3.7. COPD Assessment Test questionnaire.

3.4.8 Study outcomes

3.4.8.1 Primary outcome

Outcome data was collected by a researcher blinded to treatment allocation. The primary outcome was percentage uptake of PR within 28 days of hospital discharge. Uptake was defined as documented attendance at a PR assessment, with the denominator being total number of patients in each treatment group. This denominator was selected as a result of the process outlined in the National Institute for Health and Care Excellence Quality Standard to determine the proportion of those patients discharged from hospital commencing a post-exacerbation PR programme within four weeks of hospital discharge (49).

3.4.8.2 Secondary outcomes

Secondary endpoints were:

1. PR referral rate, defined as the percentage of patients where a referral was received by the PR team within 28 days of hospital discharge, with the denominator being total number of patients in each treatment group (49);
2. PR completion rate, defined as percentage of patients attending ≥8 (equivalent to 50% or more) PR sessions and attending end of course assessment (50), with the denominator being patients who had attended a PR assessment;
3. PR adherence, defined as mean number of PR sessions attended per participant attending PR;
4. Change in physical performance (4MGS, a surrogate marker of physical frailty) between the day of discharge and 12 weeks post-discharge; and
5. Change in HRQoL (CAT, a marker of disease-specific health status) between the day of discharge and 12 weeks post-discharge.

3.4.8.3 Clinical safety endpoints

Safety endpoints in the 12-week follow-up period were:

1. Mortality;
2. Hospital readmissions; and
3. Acute hospital bed days.

3.4.8.4 Qualitative outcomes

The interview topic guide (Figure 3.8) explored participants experiences of the verbal and written information received about PR (both positive and negative, how this influenced or impacted their decision to accept or decline referral for PR). They were asked whether the video intervention impacted their perceptions and understanding of PR. Participants were also asked about possible ways of enhancing the effective delivery of the video. In this way, rich data was collected in order to gain insights into compliance with the intervention from a patient's perspective, and how participants made sense of PR in the context of their daily life and during their current acute exacerbation.

Can you please tell me about when you were first approached to take part in this research project?

Prompts: Information given; information sheet; communication skills of staff; consent process.

Tell me about your experiences of doing the research procedures and questionnaires

Prompts: arranging procedures; research assessments and questionnaires; research environment; research staff.

Tell me what you thought about the DVD about post-hospitalisation pulmonary rehabilitation?

Prompts: Content of the DVD; what patients said; the information given; the quality of the filming; what healthcare professionals said; helpfulness in understanding what is involved in post-hospitalisation pulmonary rehabilitation?

Tell me about the way you saw the video? What was it like?

Prompts: Seeing the DVD via iPad

Who talked to you about coming to post-hospitalisation pulmonary rehabilitation? What was this process like for you?

Prompts: Initial thoughts; information given; communication; steps to referral.

If patient came to post-hospitalisation pulmonary rehabilitation:

What was your experience like?

Prompts: Experience of PR pathway: assessment, exercise and education sessions, communication, staff, finishing; best/worst thing

If patient did not come to post-hospitalisation pulmonary rehabilitation:

Tell me why you decided not to attend post-hospitalisation pulmonary rehabilitation?

Thoughts on improvements to the DVD; the pulmonary rehabilitation programme or the way the research project was done?

Thank participant for taking part- Any questions?

Figure 3.8. Topic guide for the qualitative interviews.

3.4.9 Sample size

3.4.9.1 Trial sample size

In a previous audit of the same setting, 68 of 286 eligible patients admitted to Hillingdon Hospital attended an initial PR assessment post-hospitalisation (24% uptake) (52). To demonstrate an increase in the primary outcome measure from 24% in the control group to 45% in the intervention group, 178 patients (89 in each group) were required with 80% power at the 5% significance level (MedCalc Software, Ostend, Belgium). To account for a potential 10% drop-out rate, a total of 200 patients (100 per group) were recruited.

3.4.9.2 Qualitative interviews sample size

Sample size of the qualitative study was based on the predicted minimum number of interviews required to achieve saturation (the point at which gathering fresh data does not generate new theoretical insights related to the research question and objectives) and is based on the concept of Information Power (152). Based on the work of Guest *et al.* (153), saturation of themes is usually reached by the twelfth interview. Therefore 12 qualitative interviews were the minimum required to be completed in this trial.

3.4.10 Data analysis

The initial analysis of the quantitative and qualitative data was undertaken separately, with both a statistical analysis plan (section 3.4.10.1) and a qualitative analysis plan (section 3.4.10.2) outlined below (termed a segregated analysis method (154), which complements the convergent mixed methods design selected for this study (100)). Following initial analysis of the quantitative and

qualitative data separately, the findings were subsequently integrated. Section 3.4.10.3 provides details of the integrated analysis plan.

3.4.10.1 Statistical analysis

Quantitative data analysis was completed by the trial statistician and a blinded researcher using Stata version 14.1 (StataCorp LP, Texas, USA). The statistician and researcher remained blinded to treatment allocations until completion of analysis. The pre-specified primary analysis was by intention to treat. Categorical data were presented as percentages and compared between groups using the Pearson X^2 test. A p value <0.05 was considered statistically significant.

Change in physical performance and HRQoL from hospital discharge to 12 weeks (or 90 days) post-discharge were compared by trial group using independent samples T-Test (two-sided). Missing data were explored and reported according to cause. Missing data were assumed to have occurred completely at random and were handled by a Markov Chain Monte Carlo method (155), using multiple imputations (10 datasets) using simulations from a Bayesian prediction distribution for normal data. Data were assumed to be from a multivariate normal and data augmentation was applied to Bayesian inference with missing data. The data were log transformed for multiple imputation then anti-logged for the analysis. A pre-planned sensitivity analysis considered patients who were naïve to PR at recruitment, as these participants were identified as those that might particularly benefit from the co-designed educational video intervention. Additional post-hoc analysis was completed to determine factors associated with PR uptake and treatment effect in subgroups.

3.4.10.2 Qualitative analysis

The audio-recorded qualitative interviews were anonymised and transcribed verbatim (156). Interview transcripts were analysed thematically using a framework approach through the steps of: 1) data management, 2) descriptive accounts, and 3) explanatory accounts (157). This approach provided a systematic framework to analysis for applied qualitative research (157). Participants' accounts were coded in categories of similar experiences, actions or events and common themes have been derived. NVivo was used to review and code data to aid the identification of topic categories and themes.

3.4.10.3 Integrated analysis

The themes were critically discussed by the research team to check for any inconsistencies in analysis and to link the qualitative to quantitative data, facilitating a broader, mixed methods analysis of the dataset (158).

3.5 QUANTITATIVE RESULTS

Figure 3.9 shows the trial CONSORT flowchart. 200 patients were recruited and 196 were randomised (98 per group). Four participants were not randomised due to being discharged from hospital prior to the baseline assessment being completed. All 196 participants were analysed for the primary outcome, as well as the secondary outcomes relating to PR service utilisation and safety. 42 and 38 were lost to follow-up for the intervention and control group respectively for the secondary outcomes which required face-to-face assessment (physical performance and HRQoL).

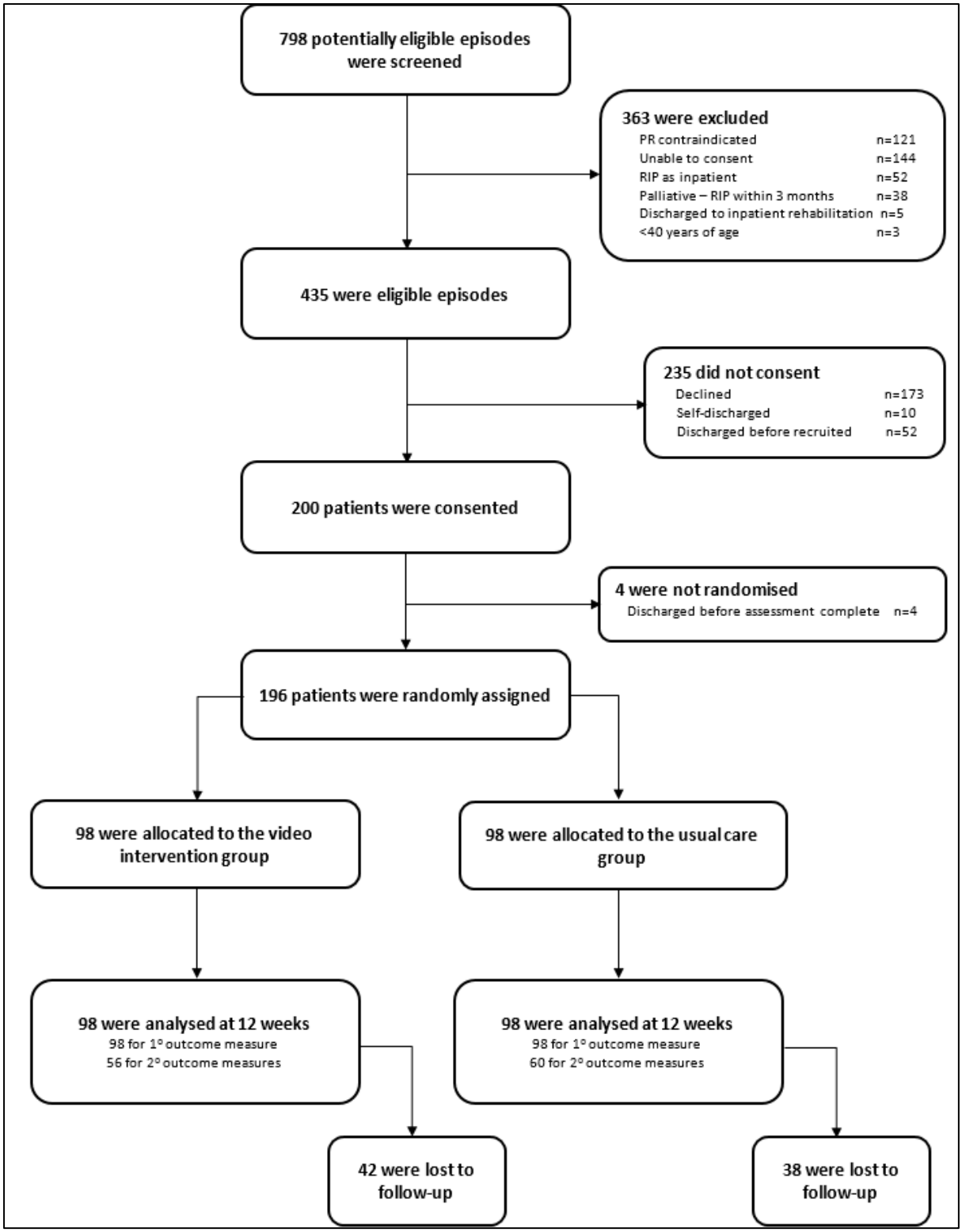


Figure 3.9. CONSORT diagram for flow of participants in VIRTUE trial.

 Barker *et al*, 2020, Am J Respir Crit Care Med Vol 201, Iss 12, pp 1517–1524. The American Journal of Respiratory and Critical Care Medicine is an official journal of the American Thoracic Society.

Abbreviations: 1^0; primary; 2^0: secondary; PR: pulmonary rehabilitation.

3.5.1 Baseline characteristics

The baseline characteristics of the 196 participants randomised are shown in Table 3.3. 49% of the randomised participants were male, with a mean (SD) age of 69 (11) years. At baseline, the participants had severe airway obstruction (median FEV_1 36 [IQR: 27, 48] percent predicted), significant respiratory disability (MRC dyspnoea score of 4 [IQR: 3, 5]) and a normal BMI (25.5 [IQR: 21.9, 31.0] kg/m^2). 52% had previously completed PR. There were no differences in the baseline characteristics between the intervention and control groups (Table 3.3).

Table 3.3. Baseline characteristics for whole group and according to group allocation

Variable	Whole group (n=196)	Intervention group (n=98)	Control group (n=98)	p value
Male (n (%))	95 (49)	49 (50)	46 (47)	0.668
Age (years)	69 (11)	70 (11)	68 (11)	0.391
FEV_1/FVC	0.53 (0.17)	0.53 (0.16)	0.53 (0.17)	0.757
FEV_1^* (% predicted)	36 (27, 48)	38 (28, 49)	34 (26, 47)	0.454
MRC score	4 (3, 5)	4 (3, 5)	4 (3, 5)	0.791
BMI (kg/m^2)	25.5 (21.9, 31.0)	26.2 (22.5, 31.9)	24.9 (21.8, 30.3)	0.285
Index of multiple deprivation	15170 (7213)	15783 (7508)	14550 (6886)	0.234
Smoking status: never/former/current (n (%))	4 (2) / 138 (70) / 54 (28)	1 (1) / 70 (71) / 27 (28)	3 (3) / 68 (69) / 27 (28)	0.598
Pack year history (years)	40 (27, 60)	40 (26, 55)	40 (28, 60)	0.562
Charlson Comorbidity Index	2 (1, 2)	2 (1, 2)	2 (1, 2)	0.926
Self-reported all-cause hospital admissions in previous year	1 (0, 2)	1 (0, 2)	1 (0, 2)	0.486
Self-reported courses of antibiotics in previous year	2 (1, 4)	2 (1, 3)	2 (1, 4)	0.979
Self-reported courses of steroids in previous year	1 (0, 3)	1 (0, 3)	2 (1, 4)	0.630
Home oxygen required at hospital discharge (n (%))	7 (4)	4 (4)	3 (3)	0.684
Acute non-invasive ventilation during admission (n (%))	22 (11)	11 (11)	11 (11)	0.944
Walking aid required on admission (n (%))	51 (26)	22 (22)	29 (30)	0.254
Own transport (n (%))	116 (59)	56 (57)	60 (61)	0.561
Living alone (n (%))	83 (43)	39 (40)	44 (45)	0.470
Hospital length of stay (days)	3 (1, 6)	3 (2, 7)	2 (1, 5)	0.129
Previous experience of PR (n (%))	101 (52)	50 (51)	51 (52)	0.886
4MGS: <0.60 m/s (n (%))	99 (51)	50 (51)	49 (50)	0.944
COPD Assessment Test	23 (8)	23 (8)	23 (8)	0.888

Data reported as mean (SD) or median (25^{th} centile, 75^{th} centile) unless stated otherwise; Independent T-Test (or Mann-Whitney for non-normally distributed data) or Chi-Squared test was used to compare groups.

Abbreviations: 4MGS: four metre gait speed; BMI: body mass index; COPD: chronic obstructive pulmonary disease; FEV_1: forced expiratory volume in one second; FVC: forced vital capacity; kg: kilogram; m: metres; MRC: Medical Research Council dyspnoea scale; m/s: metres per second; PR: pulmonary rehabilitation; s: seconds.

3.5.2 PR uptake rate

Table 3.4 summarises the results of the primary outcome (PR uptake rate) for the whole group and according to group allocation. Overall uptake of PR was 37%, with no difference in uptake between the control (41%) and intervention (34%) groups, p=0.370.

Table 3.4. Referral rate, uptake, completion and adherence to early PR for whole group and according to group allocation

Outcome	Whole group (n=196)	Intervention group (n=98)	Control group (n=98)	p value
Primary Outcome				
Uptake of PR within 28 days (n (%))	73 (37)	33 (34)	40 (41)	0.370
Secondary Outcomes				
Referral to PR received within 28 days of hospital discharge (n (%))	138 (70)	70 (71)	68 (69)	0.754
Completion: Proportion of those taking up PR who complete PR (n (%))	38 (52)	15 (46)	23 (58)	0.305
Adherence: PR sessions completed by those taking up PR	9 (6)	8 (6)	10 (6)	0.268
Uptake of PR within 12 weeks (n (%))	107 (55)	52 (53)	55 (56)	0.911
Change in CAT from discharge to 12 weeks	-3.6 (7.6)	-2.9 (7.7)	-4.3 (7.4)	0.212
Change in 4MGS from discharge to 12 weeks (m/s)	0.24 (0.26)	0.25 (0.26)	0.23 (0.26)	0.568

Data reported as mean (SD) unless stated otherwise. Independent T-Test or Chi-Squared Test were used to compare groups. The pulmonary rehabilitation program offers 2 supervised sessions per week for 8 weeks (i.e. 16 sessions).
Abbreviations: 4MGS: four metre gait speed; CAT: COPD Assessment Test; PR: pulmonary rehabilitation.

The Kaplan-Meier curve demonstrated no significant between group difference in time to uptake of PR (Figure 3.10; log rank test p=0.490).

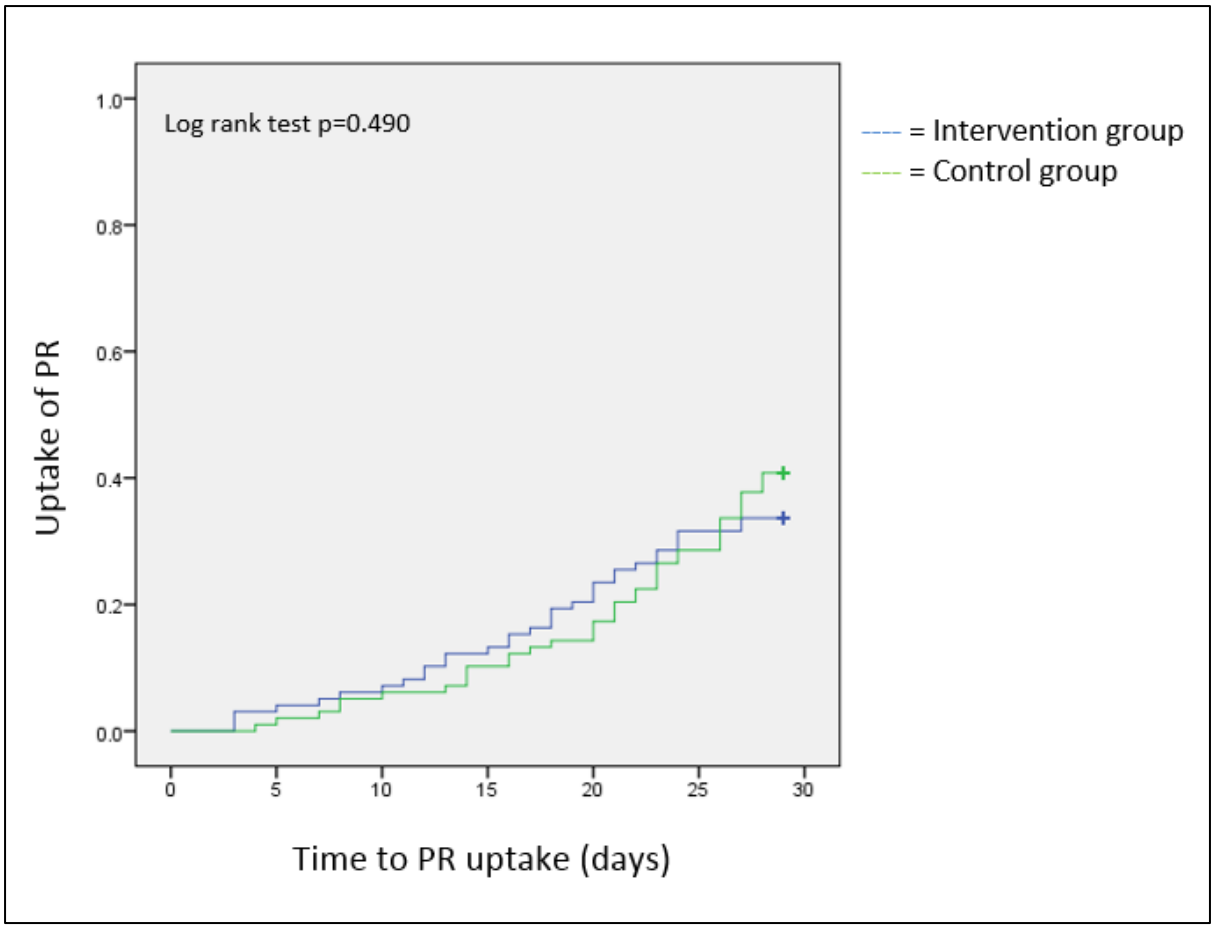


Figure 3.10. Kaplan-Meier curve demonstrating uptake of pulmonary rehabilitation within 28 days of discharge after hospitalisation for an acute exacerbation of COPD according to group allocation. Reprinted with permission of the American Thoracic Society, copyright © 2020 American Thoracic Society. All rights reserved. Barker *et al*, 2020, Am J Respir Crit Care Med Vol 201, Iss 12, pp 1517–1524. The American Journal of Respiratory and Critical Care Medicine is an official journal of the American Thoracic Society.

3.5.3 PR referral, adherence and completion rates

Table 3.4 summarises the results of the secondary outcomes (PR referral, completion and adherence rates) for the whole group and according to group allocation. Overall referral rate was 70%, with no difference in referral between the control (71%) and intervention (69%) groups; p=0.754. For PR completion, again, there was no difference in completion between the control (58%) and intervention (46%) groups; p=0.305, with an overall completion rate of 52%. The adherence to PR for the whole

group was mean (SD) 9 (6) sessions, with no difference in adherence between the control and intervention groups (mean [SD]: 10 [6] and 8 [6] respectively, p=0.268).

With regards to the timing of when the referrals to PR were generated, 135 of the 138 referrals recorded in this study originated on the day of hospital discharge at the time of bundle completion. Three referrals occurred after hospital discharge (range three to 18 days from hospital discharge) when the hospital respiratory team were asked to initiate referral by a participant. There were no direct patient self-referrals to PR.

3.5.4 Change in Physical Performance and HRQoL

There were clinically and statistically significant improvement in physical performance in both groups, with no between group differences (mean [SD] change in 4MGS: Intervention: 0.25 [0.26] m/s; Control: 0.23 [0.26] m/s, p=0.568) (Table 3.4). Similarly, although CAT improved in both groups, no between group differences were observed (mean [SD] change: Intervention: -2.94 [7.68]; Control: -4.33 [7.38], p=0.212) (Table 3.4). There was also no significant difference in the natural recovery between those who completed PR compared to those who did not complete PR, irrespective of group allocation (mean [SD] change in 4MGS: completed PR: 0.32 [0.24]; did not complete PR: 0.22 [0.26], p=0.137, median [IQR] change in CAT: completed PR: -4 [-7, 0]; did not complete PR: -3 [-8, 1], p=817). These improvements seen in both groups, irrespective of PR completion, are likely to indicate natural recovery following a hospitalisation for an acute exacerbation.

3.5.5 Clinical safety

There were no between group differences observed in the clinical safety endpoints. During the 12-week follow-up period, the mortality rate was 2% and 1% for the control group and intervention groups respectively (p=1.000). All-cause readmission rates for the control and intervention groups were 15% and 22% respectively during the 12-week follow-up period (p=0.871), with no difference in all-cause or respiratory-cause acute hospital bed days.

3.5.6 Sensitivity analysis

Of the 196 participants randomised, 95 (48%) had no previous PR experience before recruitment to the study (termed PR-naïve). Table 3.5 included the baseline characteristics for all the PR-naïve participants, and according to group allocation. 41% of the PR-naive participants were male, with a mean (SD) age of 69 (10) years and a normal BMI (mean [SD]: 26.7 [7.1] kg/m^2). At baseline, the PR-naïve participants had (median [IQR]) severe airway obstruction (FEV_1 33 [25, 43] percent predicted) and significant respiratory disability (MRC dyspnoea score of 4 [3, 5]). There were no differences in the baseline characteristics of the PR-naïve participants between the intervention and control groups (Table 3.5).

Table 3.5. Baseline characteristics for all PR-naïve and according to group allocation

Variable	All PR-naïve (n=95)	PR-naïve intervention group (n=48)	PR-naïve control group (n=47)	p value
Male (n (%))	39 (41)	21 (44)	18 (38)	0.589
Age (years)	69 (10)	71 (10)	67 (11)	0.053
FEV_1/FVC	0.54 (0.17)	0.54 (0.16)	0.54 (0.17)	0.696
FEV_1 (% predicted)	33 (25, 43)	33.5 (27, 43)	32 (25, 42)	0.739
MRC score	4 (3, 5)	4 (4, 5)	4 (3, 5)	0.971
BMI (kg/m^2)	26.7 (7.1)	26.1 (6.6)	27.3 (7.6)	0.599
Index of multiple deprivation	15611 (7430)	15981 (7235)	15233 (7684)	0.626
Smoking status: never/former/current (n (%))	2 (2) / 29 (31) / 64 (67)	0 (0) / 13 (27) / 35 (73)	2 (4) / 16 (34) / 29 (62)	0.239
Pack year history (years)	40 (25, 60)	40 (20, 54)	42.5 (28, 68)	0.350
Charlson Comorbidity Index	1 (1, 2)	1 (1, 2)	2 (1, 2)	0.459
Self-reported all-cause hospital admissions in previous year	1 (0, 2)	1 (0, 2)	1 (0, 2)	0.968
Self-reported courses of antibiotics in previous year	2 (1, 5)	2 (1, 3)	2 (1, 6)	0.297
Self-reported courses of steroids in previous year	2 (0, 3)	1 (0, 3)	2 (0.5, 5)	0.225
Home oxygen required at hospital discharge (n (%))	4 (4)	3 (6)	1 (2)	0.334
Acute non-invasive ventilation during admission (n (%))	9 (10)	4 (8)	5 (11)	0.676
Walking aid required on admission (n (%))	27 (28)	10 (21)	17 (36)	0.098
Own transport (n (%))	29 (31)	16 (33)	13 (28)	0.548
Living alone (n (%))	43 (45)	21 (43)	22 (47)	0.765
Hospital length of stay (days)	3 (2, 7)	4 (2, 7)	3 (1, 5)	0.323
4MGS: <0.60 m/s (n (%))	43 (45)	20 (42)	23 (49)	0.477
COPD Assessment Test	23 (8)	22 (8)	25 (7)	0.060

Data reported as mean (SD) or median (25^{th} centile, 75^{th} centile) unless stated otherwise; Independent T-Test (or Mann-Whitney for non-normally distributed data) or Chi-Squared test was used to compare groups.

Abbreviations: 4MGS: four metre gait speed; BMI: body mass index; FEV_1: forced expiratory volume in one second; FVC: forced vital capacity; kg: kilograms; m: metres; MRC: Medical Research Council; m/s: metres per second; PR: pulmonary rehabilitation.

Similar to the overall study population data, the intervention had no effect on the primary outcome (uptake of post-hospitalisation PR) in PR-naïve participants (uptake rate for all PR-naïve participants,

PR-naïve control group and PR-naive intervention group: 34%, 32% and 35%; p=0.347) (Table 3.6). The overall referral, completion and adherence to post-hospitalisation PR for PR-naïve participants were 63%, 47% and mean (SD) 9 (6) sessions respectively (Table 3.6). The intervention had no effect on the secondary outcomes, with no between group differences observed between the control and intervention groups (Table 3.6).

Table 3.6. Referral rate, uptake, completion and adherence to early PR for all PR-naïve and according to group allocation

Outcome	All PR-naïve (n=95)	PR-naïve intervention group (n=48)	PR-naïve control group (n=47)	p value
Primary Outcome				
Uptake of PR within 28 days (n (%))	32 (34)	17 (35)	15 (32)	0.347
Secondary Outcomes				
Referral to PR received within 28 days of hospital discharge (n (%))	60 (63)	28 (58)	32 (68)	0.325
Completion: Proportion of those taking up PR who complete PR (n (%))	15 (47)	8 (47)	7 (47)	0.804
Adherence: PR sessions completed by those taking up PR	9 (6)	10 (6)	8 (6)	0.805
Uptake of PR 12 weeks (n (%))	45 (47)	21 (44)	24 (50)	0.616
Change in CAT from discharge to 12 weeks	-3.2 (7.5)	-2.4 (8.6)	-3.9 (6.1)	0.320
Change in 4MGS from discharge to 12 weeks (m/s)	0.24 (0.27)	0.27 (0.28)	0.20 (0.26)	0.227

Data reported as mean (SD) unless stated otherwise. Independent T-Test or Chi-Squared Test were used to compare groups.
Abbreviations: 4MGS: four metre gait speed; CAT: COPD Assessment Test; PR: pulmonary rehabilitation.

There were clinically and statistically significant improvements in 4MGS and CAT in both groups for the PR-naïve participants, with no significant between group differences (Table 3.6). As indicated

previously, these improvements may represent natural recovery following a hospitalisation for an acute exacerbation.

There were no between group differences observed in the clinical safety endpoints for the PR-naïve participants. During the 12-week follow-up period, the mortality rate was 1% for both the control group and intervention groups (p=1.000). All-cause readmission rates for the control and intervention groups were 30% and 27% respectively during the 12-week follow-up period (p=0.921), with no difference in all-cause or respiratory-cause acute hospital bed days.

3.5.7 Post-hoc analysis

Additional post-hoc analysis was completed to determine patient factors associated with PR uptake and treatment effect in subgroups. Table 3.7 shows univariate and multivariate analysis of factors, selected based on biological plausibility, associated with PR uptake in those referred for PR. Increasing age was associated with increased PR uptake, whilst hospital length of stay ≥ 8 days was associated with reduced PR uptake. No other patient factors were associated with uptake, including sex, FEV_1 percent predicted, MRC dyspnoea score, index of multiple deprivation, admissions in the preceding year, oxygen use, own transport, previous PR experience, 4MGS or CAT score. Smoking status was not calculated in the model due to insufficient never smokers, which was the group of reference. Further post-hoc sensitivity analyses were performed in two specific subgroups. These were those patients under the age of 70 and those with a hospital stay of ≥ 8 days. The subgroups were selected as they were factors associated with reduced PR uptake in the multivariate analysis. From this post-hoc analysis, the intervention had no effect upon PR uptake in these subgroups (Table 3.8).

Table 3.7. Logistic regression for predictors of uptakeof early PR following hospitalisation for an acute exacerbation of COPD

Variables		Uptake (n=138)			
		Univariate analysis*		Multivariate analysis*	
		OR (95% CI)	p value	Adjusted OR (95% CI)	p value
Sex (ref cat: female)		0.828 (0.423, 1.619)	0.581	-	-
Age		1.029 (0.997, 1.062)	0.077	1.045 (1.009, 1.082)	0.014+
FEV_1 % predicted		1.006 (0.986, 1.027)	0.537	-	-
MRC score (ref cat: MRC 5)	2	1.631 (0.591, 4.500)	0.345	-	-
	3	1.129 (0.438, 2.914)	0.801	-	-
	4	0.612 (0.255, 1.465)	0.270	-	-
Index of multiple deprivation		1.000 (1.000, 1.000)	0.620	-	-
Self-reported all-cause hospital admissions in previous year		0.928 (0.809, 1.064)	0.285	-	-
Oxygen required during hospital admission (ref cat: no)		0.952 (0.463, 1.957)	0.894	-	-
Own transport (ref cat: yes)		0.885 (0.443, 1.765)	0.730	-	-
Hospital length of stay (ref cat: 0 to 1 days)	2 to 3 days	0.605 (0.241, 1.521)	0.286	0.649 (0.248, 1.697)	0.378
	4 to 7 days	0.472 (0.181, 1.232)	0.125	0.472 (0.175, 1.274)	0.138
	≥ 8 days	0.281 (0.096, 0.821)	0.020+	0.202 (0.064, 0.633)	0.006+
Previous experience of PR (ref cat: yes)		1.031 (0.525, 2.024)	0.928	-	-
4MGS (ref cat: <0.60 m/s)		0.950 (0.485, 1.864)	0.882	-	-
CAT§		0.987 (0.944, 1.032)	0.574	-	-

*All variables were included in the multivariable analysis; enter method was used for the univariate analysis; backwards selection procedure was used for the multivariate analysis, with variables excluded from the multivariate model if p value <0.16; final multivariate model reported; smoking status not able to be calculated due to low numbers in the never smoker group; +p=<0.05.

Abbreviations: 4MGS: *four metre gait speed; CAT: COPD Assessment Test; CI: confidence interval; FEV_1: forced expiratory volume in one second; m: metres; MRC: Medical Research Council dyspnoea scale; m/s: metres per second; OR: odds ratio; PR: pulmonary rehabilitation; s: seconds.*

Table 3.8. Subgroup analyses for factors associated with reduced PR uptake from logistic multivariate analysis

Outcome	Intervention	Control	p value
Patients aged <70 years			
Uptake of PR within 28 days	14 (42)	17 (50)	0.627
Referral to PR received within 28 days of hospital discharge	33 (77)	34 (71)	0.635
Length of stay ≥ 8 days			
Uptake of PR within 28 days	5 (36)	4 (36)	1.000
Referral to PR received within 28 days of hospital discharge	14 (74)	11 (73)	0.877

Data reported as n (%) for all variables. Chi-Squared Test was used to compare groups.
Abbreviations: PR: pulmonary rehabilitation.

3.6 QUALITATIVE RESULTS

Of the 15 participants in the intervention group who took part in qualitative interviews, eight participants did not take up PR, with six of the seven interviewees who did take up PR completing the programme. Six of those interviewed did not recall previously seeing the video. Four of these six interviewees did take up PR (three completing the programme), and the remaining two declined referrals to PR. None of the interviewed participants reported using the weblink to access the video after hospital discharge. The findings from the interviews are presented as a narrative summary with supporting indicative anonymised quotes.

3.6.1 Perceptions of the method

Participants who did recall viewing the video thought it was well-presented, a good length and that the information provided was clear. Most participants thought it was an effective method of delivery:

"*I think it's a good combination with the iPad, because you've got somebody they're sitting with you, where if you've got any questions you can ask at the time. And you interact with that person."* [P06, male, aged 69, decliner]

Some participants also reported preference of the video to a leaflet or verbal information to allow them to retain more information:

"Because you can see it in greater detail….. I mean a piece of paper like that; you can read it; certain things will sink in but not all of it. Whereas if you watch a video it's going into greater detail and you can actually see what it involves, rather than a piece of paper. A video stays in your head. You can see the exercises. Piece of paper doesn't." [P13, female, aged 62, completer]

Moreover, despite one participant who was partially deaf stating he usually liked leaflets better because of his hearing problems, he also reported that he liked being able to see the patients in the video.

Participants also liked that patients were talking about PR, not just health care professionals:

"It's harder for them [Healthcare professionals] to explain what other people experience. So, the video's a good idea, because you can tell from the patients themselves what they got out of it." [P06, male, aged 69, decliner]

All participants stated that they found the information delivered by a physiotherapist in the video easy to understand and the explanation about PR was clear:

"*I thought the way they [the physiotherapist] were talking about it didn't make it complicated. You could pick it up very easy"* [P14, female, aged 69, completer]

"*Yes, I thought even when that lady [physiotherapist] was explaining it, she made it as if you could pick it up quick. She wasn't being hurried in her conversation. She was taking it all slowly and it could sink in."* [P07, female, aged 91, decliner]

Six participants could not remember seeing the video in hospital or they could not recall the content as they felt too ill or overwhelmed:

> "*I remember watching a video, but I couldn't really remember what it was about"* [P11, female, aged 63, completer]

However, those who could not remember being shown the video in hospital, or could not remember the specific content within the video, thought it was a good method of delivery and suitable content when shown the video before their research interview.

The topic guide also briefly probed participants about accessing the video using the weblink. None of the participants reported accessing the video via the link provided. However as this was largely intended for the benefit of carers, in-depth specific questions were not included. As such, reasons for not accessing the weblink, and levels of digital literacy, were not fully explored in the qualitative interviews.

3.6.2 Impact of video perceptions and understanding of PR

Most participants stated it was helpful to see patients with lung conditions in the video talking about their experiences and the benefits of rehabilitation:

> "B*ecause I know how she feels because I felt exactly the same as she did*." [P13, female, aged 62, completer]

> "*They [potential PR patients] would, sort of, resonate more with a real person. It would mean more, you know. Otherwise they're just somebody reading a script. They seem that they are kosher, didn't they?"* [P08, male, aged 79, completer]

One participant reported it aided her understanding of the type of exercise to anticipate from PR:

"*Well it gives people, as you said, the understanding and knowledge of, they're not going to pull you about, they're not going to make you run a mile and all that sort of thing"* [P12, female, aged 70, decliner]

Seven participants had no prior understanding about PR:

"*So the video showed me you know, what it was about. It is useful, it made it clear what was about to happen.*" [P04, male, aged 51, completer]

One participant reported she learned some information about PR from the video, with additional information about PR being obtained when she attended the programme:

"*No, I got the full information when I did the actual exercises"* [P14, female, aged 69, completer]

The same participant also said listening to the patients on the video gave her hope:

"Yes, you knew that was coming from the heart exactly, you know. They [patients on video] were quite pleased with how they had progressed. So, it gave you some hope." [P14, female, aged 69, completer]

3.6.3 Proposed strategies to enhance the video intervention

Views were mixed regarding the timing of the delivery of the video. Some participants thought it was the right time to show the video (just before discharge from hospital):

"I think you've got to get people whilst they're in hospital and I think the initial video is the right way to do it." [P10, female, aged 52, decliner]

Other participants thought that showing the video in hospital was not the best time because patients might be too ill or tired:

"*What I remember of it… I mean I was in a tiswas at the time as well... You got to be back on your feet to fully digest what's going on"* [P08, male, aged 79, decliner]

Suggestions for improvements to the video content were elicited from the interviews. Firstly, two participants thought there should be patients who were 'sicker' in the video as the patients looked too well, for example including an oxygen user:

"*Just put one of those people that have those oxygen things on. That would help other people who are going to watch this video."* [P02, male, aged 46, decliner]

A second suggestion was to include younger patients:

"*All people of all ages get the condition, but it appeared that only the older people had it. So, it would have been nice to have had a younger person in there."* [P10, female, aged 52, decliner]

Thirdly, one participant thought emphasising social aspects of attending a PR programme were important:

"*Well it also helps you to meet other people with the same condition as you got. There's a lot of people who got COPD or whatever, are quite lonely. Because they don't go out, they don't meet people. Well anyone who's not well, so it's that as well. Knowing you're not the only one."* [P12, female, aged 70, decliner]

In terms of delivery method, one participant was partially deaf and although he could hear most of the video with the sound up, he suggested subtitles aided him whilst watching the video:

"*Just get subtitles in, yeah"* [P08, male, aged 79, completer]

Another suggestion was to show a greater variety of exercise equipment:

"The only thing on that DVD was the one exercise I didn't like was the two-handle thing. But you put me on those bikes and those treadmills and I'd go all day long on them. I started thinking it should be [on the video]" [P08, male, aged 80, decliner]

This included the simpler equipment used in community settings:

"*I think it might have appeared it's the gym or nothing but the exercises that I saw them doing scared me. Yes, I find that a bit scary oh gosh. Is it doable? Yes, they'll tailor make the exercises but they all look like they have to be doing that [the gym machines] so maybe more informative about more the gentler, more gently exercises perhaps"* [P10, female, aged 52 years, decliner]

"*With the video was, as I said, about the equipment. It surprised me there wasn't none where I went [community rehab]. But it helped me actually. I thought, I can't do all them machines. So, it was easier, you know"* [P14, female, aged 69, completer]

Finally, it was highlighted that the video could show the other elements of the exercise programme:

"*I think if they did a little piece on there where you're actually doing the warm up and then the exercise and then the cool down. They can't transport all that [gym] equipment [for the community programme]"* [P14, female, aged 69, completer].

Only one participant thought the video should be longer to allow it to impart more information:

"*It should be 15 minutes. You should put more knowledge in there. What it can do for you. How to help yourself out*." [P05, male, aged 62, completer]

3.6.4 Experiences of post-hospitalisation PR

For the six participants who attended PR, their first thoughts were to try it out:

"I thought they want you to do this, you might as well take it, you're not going to lose anything. You know I thought after a few weeks I'd just stop coming anyway, if I'm honest. So, I thought it's worth giving a try" [P04, male, aged 51, completer]

They all thought the assessment process was good with no negative comments. The exercise sessions were also seen as good by most participants who attended rehab:

> "*Yes, they were good [exercise sessions]. You were doing different things and obviously if somebody [the physiotherapist] saw you weren't doing it right, that's not the right way, do it this way. But it was always done in a fun way."* [P06, female, aged 69, completer]

The exception was one participant who stopped going to PR after six sessions because she did not like the treadmill:

> "*The only thing that annoyed me was the treadmill sort of thing because he [the physiotherapist] would put me on that every time we had to do the exercises and the treadmill was literally taking my breath away and my oxygen was getting really low."* [P15, female, aged 62, stopper]

Education sessions were also well evaluated, with sessions on breathing exercises and inhaler medication seen as the most valuable. However, one participant who was partially deaf, said he could not hear most of the education session presentations. He said he did not want to tell the healthcare professionals even though he could not hear all of the lectures:

> "*The PowerPoint, there was no problem at all. It was only when they decided to launch into a lecture. Some I could hear, but there was a girl, she was there to tell you about benefits [of PR] and things like that. I couldn't hear her at all."* [P06, male, aged 69, completer]

When asked about the benefits of PR, all the participants said they felt fitter since doing the course and they could do more:

> "*I felt better, I felt fitter. I wasn't getting as out of breath as I used to. It's taught me things… the actual programme I think was very good for me."* [P04, male, aged 51, completer]

Another participant said she can now do more housework than before:

"*I can go around, do the housework what needs doing, what... Any household things, yes.*" [P14, female, aged 69, completer]

One participant reported the best thing about PR was that it gave him encouragement to keep exercising at a gym after the programme had finished, whilst another participant thought that learning more about her condition during PR was the best thing for she took away from attending the PR programme.

3.6.5 Reasons for declining post-hospitalisation PR

Of the eight interviewed participants who declined to take up PR, three could not attend as they stated they were too unwell or had other significant co-morbidities:

"*But I couldn't do nothing like that now. No dear, oh no, I couldn't do that.*" [P07, female, aged 91, decliner]

"*I declined because I've got other health issues at the moment. So, that's why I declined because I couldn't guarantee that I'd be there week in week out.*" [P10, female, aged 52, decliner]

Two participants declined because they thought they were doing enough exercise already:

"*So, people would come to see me, they were quite happy with what I was doing. With the walking I was doing.*" [P08, male, aged 79, decliner]

For the three remaining participants who did not take up PR, one was still working and the times did not suit, one could not attend as his wife was unwell, and the other stated they didn't have transport and it was too far to travel.

In terms of barriers to PR once attending a programme, one participant reported the car parking at a hospital site being a barrier, whilst another participant stated taking time off work to have to attend was problematic. Finally, one participant who initially started PR reported she dropped out as she did not enjoy using the gym equipment as part of the programme.

3.7 DISCUSSION

In this assessor- and statistician- blinded, randomised controlled trial, a co-designed education video intervention shown on the day of hospital discharge had no effect upon patient uptake of post-hospitalisation PR. Furthermore, the intervention did not increase referral, adherence or completion rates. From the convergent qualitative interviews embedded within this mixed methods trial, a significant proportion of the patients interviewed were unable to recall watching the video at hospital discharge (suggesting the timing was inappropriate for some). Nonetheless, participants revealed positive feedback regarding the co-designed education video content and delivery method. Furthermore, participants made suggestions for improvements to further refine the intervention.

3.7.1 Comparisons to previous studies

Observational studies have consistently shown low patient uptake and completion. Jones *et al.* demonstrated that very few patients were referred for early PR post-acute exacerbation of COPD, with less than 10% of eligible patients completing the programme following a hospital admission for an exacerbation (52). An analysis of Medicare beneficiaries showed that only 4225 (1.9%) of 223,832 individuals hospitalised with acute exacerbation of COPD in 2012 received PR within six months of the index hospital admission (159). In a retrospective analysis of Veterans Health Administration and Medicare data of patients hospitalized with COPD between 2007 - 2011, only 1.5 – 2% were revealed to have attended at least one session of PR (159).

Despite the problematic clinical implementation being well-documented internationally, there have been surprisingly few studies that have tried to address this implementation gap. In a systematic review of the available evidence on interventions for increasing uptake and completion of PR, Jones *et al.* were only able to identify one quasi-randomized controlled trial. This study was assessed to be at high risk of bias (59). Furthermore, it was undertaken in stable COPD as opposed to the population of interest in this study (post-hospitalised AECOPD) (59). In a subsequent systematic review, that was not limited to RCTs, Early and colleagues were able to identify five studies that included uptake of PR as an outcome (60). However uptake of PR was not the primary outcome in any of these studies, and they were all conducted in primary care or outpatient settings (60). Finally, of the five studies identified by Early *et al.*, many were at high risk of bias due to study design (for example, uncontrolled and controlled before and after studies) (60). Therefore, this current study is unique in being the first RCT of an intervention designed to improve patient uptake of PR.

There were several possible reasons why no increase in PR uptake in the video intervention group was seen. The video was provided without additional counselling as the intervention was designed to be low cost, easily implementable, and not burdensome on healthcare professional time. Previous studies that have used device-based interventions with minimal counselling have also been unsuccessful in changing the behaviour of patients with COPD (160). With hindsight, a greater focus on behavioural aspects, for example with health coaching (161) or a behaviour change model (162), or the video content itself being developed based upon the domains which influence behaviour change (122), may have enhanced the benefits of showing the video. For example, as suggested by patients, including patients on oxygen may have dealt with issues with modelling.

The involvement of key stakeholders in the design of the intervention may have provided vital education for the healthcare professional responsible for referrals by improving their knowledge regarding PR, with a positive knock-on effect upon referral rates in both control and intervention groups. Evidence to support this was the observation that overall referral (70%) and uptake (34%) rates in this study compared favourably with previous data collected from the same setting; Jones *et al.* observed PR referral and uptake rates of 31% and 24% respectively despite consistent delivery of a COPD discharge bundle. The results from Chapter 2 corroborate this observation. Nonetheless, this does suggest one possible intervention which may warrant further investigation is the provision of more comprehensive training on the components of a COPD discharge bundle to all healthcare professionals involved in provision at hospital discharge.

Third, the high PR referral rates in both control and intervention settings may reflect the so-called "Hawthorne effect" (163). In other words, the healthcare professionals responsible for referring to PR may have modified their behaviour in response to being observed during the trial. Evidence to support this include the significantly higher referral rates observed in this trial compared with the real-world observational study described in Chapter 2 of this thesis. Provision of regular feedback to healthcare professionals, and benchmarking against their previous achievements, may be another strategy which could merit further investigation to determine whether formal monitoring of performance improves referral and uptakes rates to post-hospitalisation PR.

Fourth, the barriers to post-hospitalisation PR uptake are complex (54), and the simple intervention tested in this trial may not have been able to address all the potential barriers. More comprehensive, and likely more expensive and time-consuming, interventions may therefore be required to fully address the plethora of barriers to post-hospitalisation PR. As previously intimated, this could be combining a video with health coaching or motivational interviewing. Alternatively, it could involve

more radical strategies such as a service redesign to address patient transport and travel barriers to accessibility.

Fifth, significant improvements in physical performance and HRQoL were observed in both intervention and control groups, likely to reflect natural recovery from an exacerbation requiring hospitalisation, as observed in other trials (164). This recovery may have influenced the decision of participants to take up PR. Further research is needed to explore the optimal timing of a post-hospitalisation PR programme.

Finally, the qualitative component of the study highlighted that a proportion of the intervention group (six of fifteen of those interviewed) had no recall of seeing the video at hospital discharge. A previous observational study showed that 57% of patients awaiting discharge following an exacerbation had cognitive impairment, with 20% considered to have pathologic impairment of processing speed (165). Cognitive impairment was not formally assessed in this study and so it is unclear whether this impacted on the lack of efficacy of the intervention. This adds to the aforementioned suggestion that delivering the video intervention at a later date (for example later in post-discharge period rather than on day of hospital discharge), or adding health coaching or motivational interviewing, requires further evaluation.

Although an increase in uptake, referral, adherence or completion rates was not demonstrated, this patient co-designed intervention may have value in other settings or for other purposes, particularly given the intervention is cheap, easily implementable and not associated with any known adverse effects. Further studies could investigate the value of the video in facilitating the implementation and

delivery of COPD discharge bundles, or as part of a more comprehensive behavioural intervention designed to educate patients.

3.7.2 Strengths

A strength of this study was that this was the first RCT to test an intervention designed with the primary intention to increase uptake of PR in the post-exacerbation setting. The trial was adequately powered, with an intention to treat analysis, and all participants randomised to the intervention group received the treatment as intended at hospital discharge. Both control and intervention groups received best standard care, including the provision of a COPD discharge bundle (126) which included an information leaflet about post-hospitalisation PR. Previous studies have observed that effective and consistent delivery of a COPD discharge bundle is associated with an increase in PR referrals (126), however acknowledging the difficulty of consistent delivery is required (76). The outcome assessors were blinded, as was the statistician and researcher undertaking analysis, who were blinded to group allocation throughout the data analysis process. This successful implementation of robust strategies to maintain blinding reduced the biases introduced during treatments and outcome assessments, and in turn lessen the likelihood of the study findings being biased estimates of treatment effect (166). In addition, the trial included a qualitative element which identified potential refinements to the intervention content and timing of delivery.

A further strength relates to the intervention being co-designed by key stakeholders, including patients who had previously experienced an acute exacerbation of COPD requiring hospitalisation, as well as healthcare professionals. An EBCD approach was adopted to develop the intervention (135). This approach has been previously used in a range of clinical settings in the NHS (167), including PR (74). As a result, this ensured the intervention tested in trial was designed using an established

methodology and based upon consensus decisions made by the key stakeholders to ensure essential information was included.

The interviews explored patient perspectives of the video, with participants reporting positive feedback on the intervention. They commented that the video was delivered using effective method, and that it was well presented, a good length and the information provided was clear. Participants felt the information delivered from multiple perspectives was important, and that the video enhanced their understanding of what to anticipate from a PR programme. They also provided vital suggestions regarding strategies to improve the video. As a result, the convergent qualitative interviews within this study added depth and understanding to the quantitative findings from the RCT (158).

Finally, living within catchment area of Harefield PR programme was a trial inclusion criterion. This was to ensure that all PR referrals and assessments were managed centrally at Harefield Hospital by the Harefield PR Unit. Therefore, collection of referral, uptake, adherence and completion data required interrogation of a single database only, which is known to be well maintained and have data recorded systematically and in real time.

3.7.3 Limitations

This was a single-centre study, using a specific video in a particular setting. Therefore, as suggested above, these results do not preclude the success of future video interventions that might be developed for other settings, delivered at different stages of the patient pathway, or as part of a more comprehensive intervention.

A significant proportion of eligible patients declined consent to the research study. This reflects the difficulties of recruiting acutely unwell, hospitalised patients into research studies, as reported in previous trials (45). Therefore, a potential limitation of the study is the generalisability of the trial population.

The reason for non-uptake were also not comprehensively collected from the trial participants. However, reasons for declining PR were explored with the participants interviewed as part of the embedded qualitative interviews which found a breadth of reasons for non-referral and non-uptake including feeling too unwell, having other significant co-morbidities or an unwell partner, perception of doing enough exercise already, still working and lack of own transport (158).

It was also observed that a proportion of participants did not attend the face-to-face visit at three months. This shows the unwillingness of this population to attend an appointment, even with the provision of free, door to door transport. This corroborates the findings by Eaton and colleagues that provision of transport is unlikely to resolve low completion rates alone (58).

Despite the pre-planned sensitively analysis of the PR-naïve participants being undertaken, additional post-hoc analysis beyond the statistical analysis plan was completed. This was in response to reviewers' comments to the manuscript submitted for publication to the American Journal of Respiratory and Critical Care Medicine. One reviewer asked whether there were any patient factors associated with PR uptake, with another interested in whether there was presence of a sub-group of participants who the intervention may be effective with. Despite this posteriori testing increasing type one error risk, it can be justified as this post-hoc analysis addressed practical questions related to the trial intervention, and was undertaken only in sub-groups who may have a substantially different

treatment response (168). As such, trends from the logistic regression have been interpreted in order to add depth to the pre-planned quantitative analysis (168).

3.8 CONCLUSION

In summary, this assessor- and statistician- blinded RCT with convergent qualitative interviews demonstrated that a patient co-designed education video shown on the day of hospital discharge had no effect upon patient uptake of post-hospitalisation PR, nor on referral, adherence or completion rates. Nonetheless, participants' experiences of the video intervention were positive, and as such do not preclude the success of future video interventions, or application of the intervention in other settings. Further interventional trials are required to address the low uptake rates of post-hospitalisation PR.

In Chapters 2 and 3, the PR programme has been delivered as a traditional outpatient centre-based model, which is the standard of care in the UK. However, data from both studies demonstrate that there are suboptimal patient uptake rates, suggesting that the current PR model might not be acceptable to some patients. For subsequent chapters, the focus will switch to exploring the possibility of a home-based model of post-hospitalisation PR.

Chapter 4: Intervention development Stage 1: Home-based exercise training for patients following hospitalisation for acute exacerbation of COPD – a mixed methods systematic review

Some of the results from this chapter have previously been reported in a conference abstract presented at the European Respiratory Society Virtual International Conference 2020 (169). These results are reprinted with permission of the European Respiratory Society and with permission of the authors, copyright © 2020 European Respiratory Society. All rights reserved.

4.1 BACKGROUND

Uptake of traditional outpatient-based pulmonary rehabilitation (PR) is low following hospitalisation for an acute exacerbation of chronic obstructive pulmonary disease (AECOPD) (107). To date, no interventions, including a co-designed education video (the results of which are presented in the previous chapter of this thesis) (123) have been shown to increase uptake in this population (59, 60). As a result, alternative models of PR, such as delivery in the home setting, have been proposed to address accessibility issues (133).

Although home-based PR has yet to be rigorously tested in the post-exacerbation setting, there is some evidence from randomised trials of patients with stable COPD to suggest this delivery strategy may be non-inferior to the current gold-standard model for delivery (79-81). Nonetheless, the trials

conducted in stable COPD have employed different strategies (face-to-face, web-based, telephone support, video telerehabilitation). The only known study which has investigated home-base exercise training in the post-exacerbation setting tested an intervention which was delivered face-to-face (47). Murphy and colleagues sought to utilise the well-established, widely-adopted HaH model of care (94), and expand its remit to be inclusive of exercise training. However, this trial was a pilot study (n=13 per arm) and only provides signals towards feasibility, acceptability and clinical benefits of such an intervention post-hospitalisation. The optimal delivery method for home-based PR remains unknown for the post-exacerbation population.

This chapter aims to synthesise the current evidence-base from multiple key stakeholder perspectives regarding home-based exercise training for this population. This will form the basis for the development of an intervention described in the next chapter (170).

4.2 OBJECTIVE

4.2.1 Intervention development objective

The objective of the intervention development phase was to develop a home-based exercise training intervention as an adjunct to a standard HaH service post-hospitalisation for AECOPD. There were two stages undertaken to achieve this objective. This chapter reports the findings from the first stage, a mixed methods systematic review.

4.2.2 Systematic review objectives

The objectives of the mixed methods systematic review were to:

1. Outline feasibility of providing home-based exercise training interventions following AECOPD;
2. Understand the experiences and acceptability of home-based exercise training to service users and providers; and
3. Examine the clinical effects of home-based exercise training in relation to patient physical function, HRQoL, and health service utilisation.

4.3 METHODS

4.3.1 Design and registration

This was a mixed methods systematic review. It was prospectively registered (International Prospective Register of Systematic Reviews [PROSPERO]: CRD42018104648) to increase the robustness and quality (171) and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement to aid reporting transparency and completeness (172).

4.3.2 Types of evidence

Randomised controlled trials (RCTs), non-randomised or quasi-experimental controlled trials, observational papers, case studies and qualitative studies were included. This broad range of study designs were retained as it was considered important to include papers that might assist in addressing the review objectives, despite the non-experimental study designs not constituting the best level of evidence (171). However, narrative reviews and other opinion papers such as letters to editors without new data were excluded.

4.3.3 Participants

Adults, hospitalised with an AECOPD and subsequently provided with either HaH, supported discharge or home-based care following hospital discharge incorporating a home-based exercise training component, were included. In addition, papers which recruited family members, informal carers or healthcare professionals who had observed or delivered home-based exercise training for patients who met the criteria above were also included. Inclusion of papers which recruited a broad range of service users (patients, family members and informal carers) was considered important due to the deleterious effects of exacerbations not only on patients (17, 22), but also to family members and informal carers (28, 30). Furthermore, care provider (healthcare professionals) perspectives were sought to comprehensively understand the practicability of implementing the intervention of interest (170, 173).

4.3.4 Interventions

In the absence of a formal definition, home-based exercise training was defined as a supervised or unsupervised programme, consisting of physical exercise training components (e.g. aerobic or resistance exercises) and delivered in the home setting. Both supervised and unsupervised programmes were included given the varying degrees of supervision in home-based programmes within trials in stable COPD (79-81)

The rehabilitation programme could have commenced whilst participants were an inpatient provided that:

1. Completion of some sessions in the home setting following hospital discharge was evident; and

2. The components of the exercise training provided in the home setting were distinguishable from other exercise training delivered within the paper.

Papers were excluded when the home-based exercise training in the intervention group did not focus on physical exercise training or rehabilitation. For example, an intervention which delivered no exercise training in the home setting, with an intervention focussed around motivational interviewing, cognitive behavioural therapy or neuromuscular electrical stimulation.

4.3.5 Comparators

Eligible comparators were usual care, including home-based medically-focused or nurse-led interventions (e.g. nebulised medication) that did not include physical exercise training or exercise components of PR which met the intervention definition.

4.3.6 Outcomes

4.3.6.1 Feasibility

Feasibly outcomes focused on home-based exercise training delivery and considerations required for a future research protocol which would test a home-based exercise training intervention. Outcomes related to feasibility included participant recruitment and retention rates, compliance and attrition, to cover common reasons for failure of efficacy trials (101).

4.3.6.2 Experiences and acceptability

Experiences and acceptability outcomes were considered from multiple stakeholder perspectives, for example, using feedback and qualitative data. This included the service users (patients, family members and informal carers) as well as service providers (healthcare professionals) as acceptability is considered to be multi-factorial, and to be experienced from numerous, and potentially diverse, viewpoints (173).

4.3.6.3 Clinical effectiveness

Clinical effectiveness was considered in relation to physical function, HRQoL and health service utilisation. These were selected *a priori* as the latest Cochrane review for post-exacerbation PR demonstrated moderate to large effects on exercise capacity and HRQoL, as well as moderate evidence to suggest reduced risk of readmission (46). Therefore, these were considered the most clinically relevant outcomes which justified specific attention.

4.3.7 Search strategy

Five databases were searched from inception until July 2018, and then updated to March 2021,(MEDLINE, EMBASE, CI-NAHL, AMED and PsycINFO) using terms informed by key phrases. These terms were piloted to ensure inclusivity and that the search was iterative in nature (172). The Boolean operators OR and AND were used within and across the exposure, population, setting, and additional search terms of interest. No language or publication status restrictions were imposed. Database searches were supplemented with forwards and backwards citation tracking. Screening of records was conducted using Endnote X7. The search strategy and terms used are shown below (Table 4.1).

Table 4.1. Search strategy employed in this review

Electronic searches

The following electronic databases were searched from their inception up to 19 July 2018:

- MEDLINE
- EMBASE
- CI-NAHL
- AMED
- PsychINFO

Search terms

Search terms were informed by literature scoping for key phrases and piloted to ensure inclusivity. Final search terms used are included below.

Concept 1: Exposure	Concept 2: Population	Concept 3: Setting	Concept 4: Additional
• Home-based • Home based • Home care* • Home monitor* • Home from hospital* • Hospital at home* • Hospital-at-home* • Community* • Early supported discharge • Discharge support • Integrated care • Pulmonary rehab* • Rehab* • Pulmonary* • Exercise* • Supervised exercise* • Structured* • Unsupervised exercise* • Training program* • Physical activit** • Activit* • Walk* • Physical therap* • Physiotherap* • Therap*	• Chronic obstructive* • Pulmonary disease • Chronic obstructive pulmonary disease • COPD* • Emphysema • Chronic bronchitis • Family member* • Famil* • Carer* • Caregiver • Care-giver • Informal care* • Healthcare profess* • Staff* • Clinician*	• Infective exacerbation • Acute exacerbation • Severe exacerbation • Exacerbation • Hospital admission • Hospitali* • Post-hospitali* • Admission	• Qualitative* • Interview • Narrative • Assessment • Experienc* • Perspectiv* • Perception • Expectat* • Prefer* • Priori* • Concern • Burden • Impact • Patient reported* • Patient-reported* • PRO* • Person-centred*

4.3.8 Screening

I completed the initial screening of titles and abstracts alongside a second independent reviewer. Any paper selected by either me or the second reviewer was included. The reason for exclusion was recorded. I undertook a second screening of potentially eligible full texts with the same second independent reviewer. Again, any paper selected by either me or the second reviewer was included, with reason for exclusion recorded. I checked reference lists of papers selected at the second screening to identify additional relevant papers. This has been reported to be a useful approach to elicit further related papers not found within a search strategy (174). The final selection of full papers was undertaken by me and the second independent reviewer. At each stage, a minimum of two reviewers assessed eligibility to reduce the risk of relevant papers being excluded (175). A third independent reviewer evaluated any papers where a difference of opinion occurred at the final selection stage (171).

4.3.9 Data extraction, analysis and interpretation

I extracted details regarding the design, intervention (frequency, intensity, type and time), comparator, participant characteristics, primary and secondary outcome measures, flow of paper participants and findings. Quantitative and qualitative results from papers were extracted, with information to augment data extraction obtained from primary, secondary and protocol papers (including grey literature), to address each objective according their related outcome measures. The segregation method was used in preference to an integrated method for the data extraction process (154, 176).

For the qualitative findings, particular focus was on similarities and differences between multiple stakeholder perspectives. This was considered important due to the inherently linked, but potentially divergent experiences, of these key stakeholders (177).

The quantitative and qualitative data were integrated at the analysis stage following data extraction, using the four key stages of the Pillar Integration Process: listing, matching, checking, and pillar building (178). The integrated analysis is reported using a modified joint display table (178).

During the interpretation phase of this review, when the quantitative and qualitative data were used to explore the same phenomenon, they were compared to 'confirm' or 'refute' each other (e.g. questionnaire scores and qualitative interview data on HRQoL). When differing constructs were explored in the quantitative and qualitative data, these data were used to 'complement' each other. 'Silence' exists when an aspect of a phenomenon was only present in either quantitative or qualitative data set. Using this process of triangulation allowed further comparison beyond the joint display and a richer interpretation without undermining the integrity of the data by attempting to transform either the quantitative or qualitative data (179).

4.3.10 Quality assessment process

I assessed the quality of RCTs and non-RCTs using the Cochrane Collaboration risk-of-bias assessment tool (180) alongside a second independent reviewer. These were subsequently compared for between-assessor consistency. This was completed in Excel to compare the risk of bias reporting according to each parameter (1: Random sequence generation, 2: Allocation concealment, 3: Blinding of participants and personnel, 4: Blinding of outcome assessment, 5: Incomplete outcome data, 6: Selective Reporting, and 7: Other bias) as reported the same (yes / no). Discordant parameters were

discussed between the two assessors to determine consensus. Information to aid quality assessment was obtained from primary, secondary and protocol papers (including grey literature).

4.4 RESULTS

4.4.1 Outline of included papers

From 1380 records identified and 17 full texts screened in the first search, 10 papers were eligible for inclusion (Figure 4.1). The included papers were published in the period from 2000 to 2018. The majority of papers were excluded as they were abstracts only, or they did not include the participants or intervention of interest defined *a priori*. The other reason for exclusion was due to the papers not meeting the type of evidence criteria, with editorials and letters to editors which did not include either quantitative or qualitative data excluded. From the updates search, of the 674 additional titles and abstracts retrieved, 12 potentially eligible full papers were screened, but no additional papers added.

Table 4.1 includes the details of the intervention (frequency, intensity, type and time), comparator, participant characteristics, outcome measures and flow of participants for the 10 papers included. Three papers were RCTs (47, 181, 182) and four were mixed methods trials (183-186). The remaining three papers included one case study (187), one Delphi study (188) and one quality improvement project (189). Five of the included papers were from the UK (47, 184-186, 189). The remaining papers were from Germany (181), Switzerland (182), Australia (183), Netherlands (190) and Canada (188). A narrative review is presented for the 10 eligible papers. Nine of the 10 papers contained data included in the quantitative synthesis (47, 181-186, 189, 190) though a lack of continuity in outcome measures and timing limited meta-analysis. Six of the 10 papers contributed data to the qualitative synthesis (183-186, 188, 189). All 10 papers contributed to the integrated synthesis (Figure 4.1).

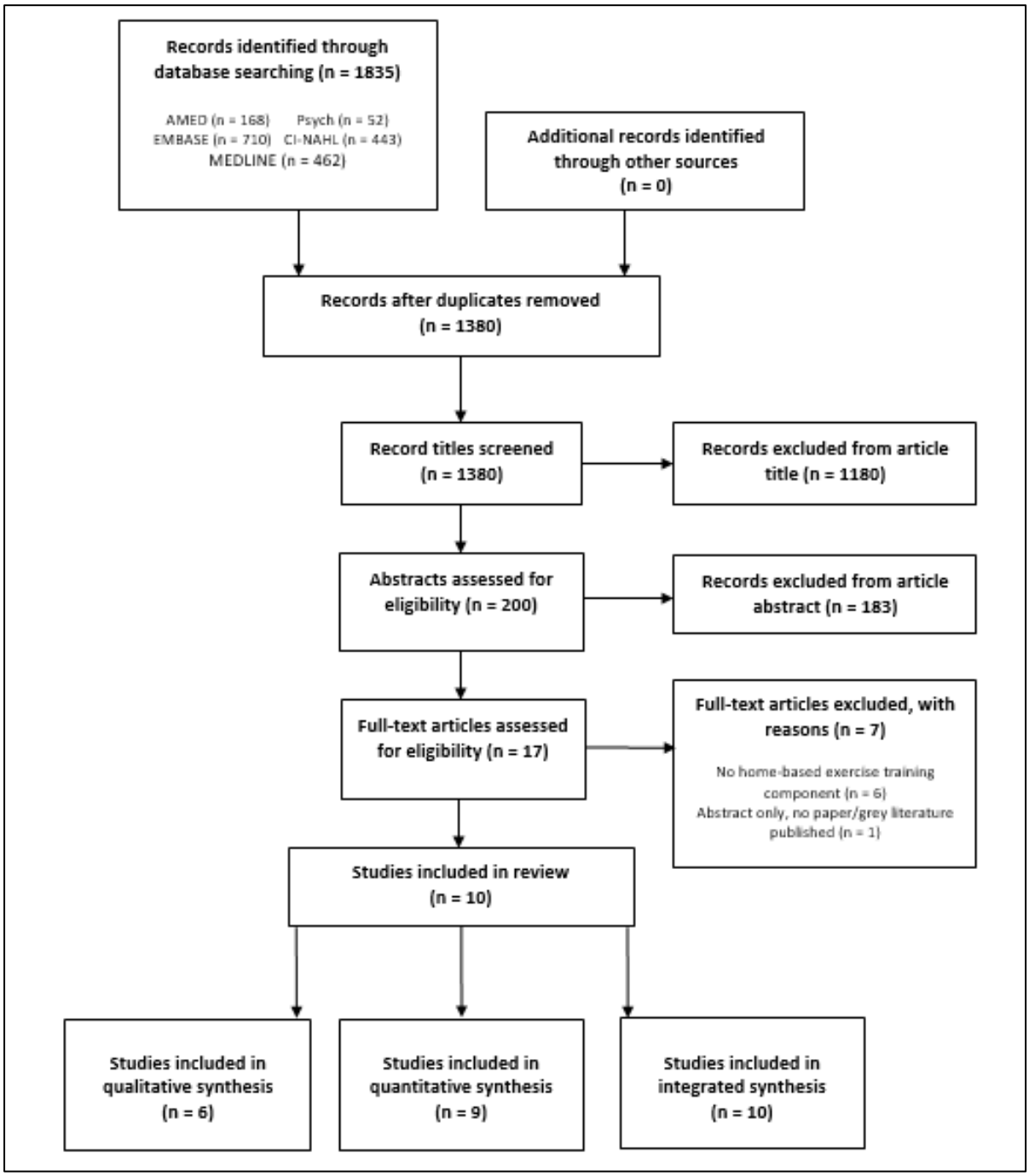


Figure 4.1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis flow diagram for this review

Table 4.2. Summary of included papers

Paper	Design	Participants	Intervention	Comparator	Outcomes and timepoints	Attrition (reasons)
Behnke, 2000 (181)	RCT	Severe COPD following AE (n=46)	Hospital-based (day 0-10): Walking (corridor / treadmill), 1-5x/day, 75% max. 6MWD Home-based (6 months): Walking, 3x/day, 125% max. 6MWD Plus education and advice	Education on breathing techniques Advice to exercise "without specific instructions"	6MWD, CRQ Day 0 and 11, month 1-3 and 6 post-discharge	16/46 (35%) did not complete (6 lack of motivation, 4 repeat AE, 4 co-morbidity, 2 death)
Murphy, 2005 (47)	RCT	COPD following AE (n=30)	Home-based (week 0-6): Resistance and aerobic exercises, 2x/weekly, Borg 3-5 Plus advice to complete 15 min. of exercise daily when intervention or usual care	Usual care: Undefined	ISW, 3MST, MVC (hand grip and quadriceps), SGRQ, EQ5D5L, HSU, unintended breaks >1minute Hospital discharge, week 6 and month 3 and 6 post-discharge	4/30 (13%) did not complete (1 repeat AE, 1 car accident, 1 on holiday, 1 withdrew)
Puhan, 2006 (182)	RCT	Severe COPD (n=98, 60% following AE)	Hospital-based (weeks 0-3): Cycle ergometer, 12-15 sessions, 20 min. interval training (50% max. capacity/20 secs, 10% max. capacity/40 secs) Home-based (weeks 4-5): Cycle ergometer (or walking / stair climbing), 1x/day, 20 min. Plus education	Hospital-based (weeks 0-3): Cycle ergometer, 12-15 sessions, 20 min. continuous training (70% of usual capacity) Home-based (weeks 4-5): Cycle ergometer / walking / stair climbing, 1x/day, 20 min. Plus education	6MWD, workload per session, CRQ, HADS, feelings thermometer Day of admission, week 3 and 5 post-admission	11/98 (11%) did not complete (5 repeat AE, 3 MSK pain, 1 chest pain, 1 accident, 1 lung Ca)
Johnston, 2015 (183)	Mixed methods study	Moderate-severe COPD following AE (n=29) Qualitative interviews: patients, GP, practice nurse	Home-based (weeks 0-8): Walking programme, 2x/day, 2x/10min., Borg 3-4 at 40% peak 2MWT speed; lower and upper limb strengthening, 4-5x/weekly, 1-3x/sets of 10x/reps; reducing sedentary time (pedometer) Plus care co-ordination	Usual care: Care co-ordination from nurse practitioner	Accelerometery, CRQ, CCQ, HSU, feasibility outcomes, qualitative data Hospital discharge, beginning of intervention, day 28 post-discharge, end of intervention	0/29 (0%) did not complete

Vincent, 2017 (184)	Mixed methods study	Chronic respiratory disease: COPD, chronic asthma, bronchiectasis or interstitial lung disease following AE (n=100)	Hospital-based (during admission): NMES, strength exercises and aerobic training, 1x/day Home-based training (4 weeks post-discharge): NMES and walking programme, 1x/day	N/A	Confidence completing walking and strength exercises, perceptions of recovery, HSU, qualitative data 48 hours, week 2 and 4 post-discharge	7/100 (7%) did not complete (3 died, 4 withdraw without reason reported)
Cox, 2018 (185)	Mixed methods study	COPD following AE (n=58) Qualitative interviews: patients, physiotherapists	Hospital-based (day 0-5): Upper and lower limb cycle ergometer, 3x/day, 1x/16 reps, 2 reps max. resistance Home-based training (2 weeks post-discharge): Strength exercises and walking programme, 4 sessions Plus exercise manual and education on breathing exercises	Usual care: Offer referral to community-based PR (2x/weekly, 6- 8 weeks, commence within 28 days)	6MWD, accelerometery, LCADL, CAT, EQ5D5L, HSU, modified CSRI, feasibility outcomes, PNaC, qualitative data Day 7, 30 and 90 post-discharge	17/58 (10%) did not completed (16 withdrew without reasons reported, 1 lung Ca)
Orme, 2018 (186)	Mixed methods study	COPD following AE (n=33) Qualitative interviews: patients, HCPs	Home-based feedback (weeks 0-2): Inclinometer connected to smart device, haptic feedback following individually-tailored periods of prolonged sedentary time Plus education and usual care	Education: Modified 'on your feet to earn your seat' booklet Usual care: COPD discharge bundle, advice regarding regular exercise, discharge assessments for function and mobility	Accelerometery, CAT, FACIT-F, FESI, HADS, feasibility outcomes, qualitative data Day of discharge and 14 post-discharge	16/33 (49%) did not complete (11 unable to attend follow-up, 1 uncontactable, 4 readmitted with AE)
van Isselt, 2013 (187)	Case study	COPD following AE (n=1)	Hospital-based (day 0-30): Upper and lower limb exercises Home-based (3 months): 2x/weekly Plus smoking cessation and dietary advice	N/A	6MWD, Barthel index, CCQ, HADS Day of admission and day of discharge	N/A
Camp, 2015 (188)	Delphi study	Rounds 1-3:	N/A	N/A	Tool development (parameter identification, finalise	9/29 (31%) did not complete

		9 researchers, 13 HCPs, 7 COPD patients Focus groups: HCPs			parameters, rating of items), focus group data Round 1-3, post-Round 3	(1 after Round 1, 2 between Round 1 and 2, 6 after Round 2)
Richards, 2016 (189)	QI project	A&E admissions provided with AHaH care (n=223, 10% following AE)	Home-based: Mobility and strength exercises Plus tailored education	N/A	Health resource utilisation, patient satisfaction Peri- and post- hospital discharge	N/A

Abbreviations: 2MWT: 2-minute walk test; 3MST: 3-minute step test; 6MWD: 6-minute walk distance; A&E: Accident and Emergency; AE: Acute exacerbation; AHaH: Acute hospital at home; Ca: cancer; CAT: COPD Assessment Test: CCQ: Clinical COPD Questionnaire; COPD: Chronic obstructive pulmonary disease; Chronic Respiratory Disease Questionnaire: CRQ; EQ5D5L: Euro-Qol five-dimension five-level questionnaire; FACIT-F: Functional Assessment of Chronic Illness Therapy – Fatigue; FESI: Falls Efficacy Scale – International; GP: General Practitioner; HADS: Hospital Anxiety and Depression questionnaire; HCP: healthcare professional; HSU: health service utilisation; ISW: Incremental shuttle walk; LCADL: London Chest Activities of Daily scale; max: maximum; min: minimum; modified CSRI: modified Client Service Receipt Inventory; MSK: Musculoskeletal; MVC: Maximum voluntary contraction; N/A: not applicable; NMES: neuromuscular electrical stimulation; PNaC: Perceived necessity and concerns questionnaire; PR: Pulmonary Rehabilitation; QI: quality improvement; RCT: randomised controlled trial; reps: repetitions; secs: seconds; SGRQ: St George's Respiratory Disease questionnaire.

4.4.2 Quality assessment of included papers

Table 4.3 includes the final risk of bias assessment for the RCTs and non-RCTs. The papers included showed some variation in the risk of bias, however most were limited by a lack of blinding (for both participants and personnel as well as outcome assessments). This lack of blinding can partially be attributed to the nature of the intervention.

Table 4.3. Assessment of risk of bias for RCTs and non-RCTs included in this review

Paper	Design	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective Reporting	Other bias
Behnke, 2000 (181)	RCT	U	U	H	H	L	L	L
Murphy, 2005 (47)	RCT	U	L	H	H	L	L	L
Puhan, 2006 (182)	RCT	L	L	H	H	L	U	L
Johnston, 2015 (183)	N-RCT*	H	H	H	H	L	U	L
Vincent, 2017 (184)	N-RCT*	L	L	H	H	L	L	L
Cox, 2018 (185)	RCT*	L	L	H	H	L	L	L
Orme, 2018 (186)	RCT*	L	L	H	H	L	L	L

*Abbreviations: H: High risk; L: Low risk; N-RCT: Non-randomised controlled trial; U: Unclear; RCT: randomised controlled trial; *: within a mixed methods study.*

4.4.3 Integrated synthesis

Table 4.4 includes the integrated synthesis. Section 4.3.9 details the process adopted for the integrated synthesis. The findings from the integrated synthesis are presented in sections 4.4.4 to 4.4.6.

Table 4.4. Integrated synthesis of outcomes from home-based exercise training for patients hospitalised with AECOPD

Quantitative data source →	Interpretation →	MAIN PILLARS	← Interpretation	← Qualitative data source
Physical Function				
Exercise capacity Measures: 6MWD, ISW, 3MST, workload	Unclear effect due to contradictory findings	**Wide variety of sub-domains and measures used, inconsistent measures across studies** **Optimal sub-domain and measures remain unclear** **Most emphasis on exercise capacity and PA** **PA and sedentary behaviour perceived to improve with exercise training and be positive, however no consensus on optimal timepoint for implementation of interventions**	*Silence*	
Strength Measures: MVC (hand grip and quadriceps)	No evidence of effect due to lack of data		*Silence*	
Physical activity (PA) Measures: accelerometery (PAL, step count, stepping time, sitting time, standing time), response to feedback	Some evidence to suggest there may be a benefit Some evidence that technology could be used as an adjunct to promote bouts of PA after prolonged sedentary periods		Within stakeholder agreement that exercise programmes and interventions to promote increased PA and reduced sedentary behaviours are valuable Within stakeholder disagreement that interventions to increase PA can be initiated early Single perspective suggesting use of technology may be effective to promote PA, with potential barriers to use identified	**PA and sedentary behaviours** Measures: patient (F2F interviews, telephone interviews) and HCP (F2F interviews)
Daily function Measures: Barthel index, LCADL, FACIT-F, FESI, confidence completing walking and strength exercises, perceptions on recovery	No evidence of effect due to lack of data		*Silence*	
Health-related quality of life (HRQoL)				

Health status Measures: CRQ, SGRQ, EQ5D5L, CAT, CCQ, feelings thermometer	Some evidence to suggest there may be a benefit	**Wide variety of sub-domains and measures used, inconsistent measures across studies** **Optimal sub-domain and measures remain unclear** **Exercise interventions may be difficult to comply with due to ongoing feelings of being unwell despite potentially positively improving HRQoL** **Interventions delivered in the home setting may have a greater impact on perceived HRQoL** **A negative psychological status may exist post-AE, however limited data available to determine effect on psychological status**	Single perspective suggesting feeling towards of HRQoL vary between patients, with feeling unwell influencing ability to remain in research and engage with programmes Single perspective suggesting exercise can have positive influence perceived HRQoL Single perspective suggesting home-based interventions may improve patients' HRQoL more compared to interventions delivered in other settings	**HRQoL** Measures: patient (F2F interviews, telephone interviews, free-text feedback)
Psychological status Measures: HADS, perception of recovery	No evidence of effect due to lack of data		Single perspective suggesting anxiety may be an important and prevalent symptom post-discharge	**Psychological status** Measures: patient (telephone interviews)
Health service utilisation (HSU)				
Peri-hospitalisation use Measure: number of inpatient bed days	Some evidence to suggest a reduction in secondary care outcomes	**Inconsistent measures across studies** **Effect on primary and secondary care HSU outcomes may vary** **Optimal measures remain unclear, however avoidance of self-reported measures recommended due to potential for poor patient recall**	*Silence*	
Post-hospitalisation use Measures: readmissions, readmission LOS, re-exacerbations, modified CSRI, recall (actual and self-reported)	Some evidence to suggest a reduction in secondary care outcomes, but not primary care outcomes Difference exists between self-reported and record-based outcomes		*Silence*	
Feasibility outcomes				

Recruitment and retention Measures: eligibility, recruitment, dropouts	Wide range of eligibly rates between studies, with completion rates and reasons for attrition more consistent between studies	**Forecasting eligibility rates appears more difficult than completion rates** **Optimal sub-domain and tools / technology remain unclear** **Compliance with different training modalities, location of delivery and tools / technology vary** **Use of tools / technology may not be feasible to implement unless barriers to implementation are addressed**	*Silence*	
Compliance Measures: requirement for unintended breaks, adherence, adherence with activity diary, adherence to PA tools (monitors / devices / mobile applications)	Some evidence that compliance of interval training is better than continuous training Some evidence of greater adherence with home-based than hospital-based exercise sessions Some evidence that patients adhere to a home exercise diary, however tools may be more challenging to comply with		Single perspective suggesting delivery of HET may increase compliance with exercise training compared with other settings Within stakeholder agreement that adherence to data collection tools and technology have barriers to implementation	**Adherence to HET** Measures: patient (F2F interviews) **Adherence to data collection tools and technology** Measures: Patient (F2F interviews) and HCP (F2F interviews)
Experiences and acceptability				

Experiences Measure: PNaC	Some data to suggest home-based programmes increases patients perceived necessity for further exercise training	**Home-based interventions are acceptable, and may positively improve patients' motivation to engage in further exercise training** **Exercise training modality requires greater consideration than equipment used to ensure acceptability** **Optimal timing of delivery remains unclear** **Supervision, individualisation and flexibility were important elements of successful interventions**	*Silence*

Acceptability Measures: requirement for unintended breaks, use of equipment, degree of supervision, PNaC, confidence completing walking and strength exercises, tool developed	Some evidence that interval training is more acceptable due to less unintended breaks required Some evidence to suggest equipment does not influence ability to conduct exercise training, and cycle ergometry may be used as effectively as no equipment Some data that confidence completing walking and strength exercises does not change from 48 hours to 2 weeks post-discharge		Within stakeholder agreement suggesting home-based interventions are acceptable to deliver, and may improve accessibility from patient and HCP perspectives Within stakeholder disagreement regarding early initiation of exercise training post-discharge between patients and HCP perspectives Single perspective suggesting inability to complete studies was related to feeling unwell despite acknowledgement interventions would likely be beneficial Within stakeholder agreement that supervision during exercise sessions was important Single perspective that flexibility and individualisation a benefit of a one-to-one intervention delivered in the home setting	**Acceptability** Measures: Patient (F2F interviews, F2F focus groups, telephone interviews, free-text feedback), HCP (F2F interviews, F2F focus groups)

Abbreviations: 3MST: 3-minute step test; 6MWD: 6-minute walk distance; CAT: COPD Assessment Test: CCQ: Clinical COPD Questionnaire; CRQ: Chronic Respiratory Disease Questionnaire; CSRI: Client Service Receipt Inventory; EQ5D5L: Euro-Qol five-dimension five-level questionnaire; F2F: face-to-face; FACIT-F: Functional Assessment of Chronic Illness Therapy – Fatigue; FESI: Falls Efficacy Scale – International; HADS: Hospital Anxiety and Depression questionnaire; HCP: healthcare professional; HET: home-based exercise training; HRQoL: Health-related quality of life; HSU: health service utilisation; ISW: Incremental shuttle walk test; LCADL: London Chest Activities of Daily Living scale; LOS: length of stay; MVC: Maximum voluntary contraction; PA: Physical activity; PAL: Physical activity levels; PNaC: Perceived necessity and concerns questionnaire; SGRQ: St George's Respiratory Disease questionnaire.

4.4.4 Feasibility

Nine papers reported findings related to feasibility according to: 1) recruitment and retention, and 2) compliance. Table 4.4 above includes details of the integrated synthesis.

4.4.4.1 Recruitment and retention

There was a wide range of eligibility (between 9% and 81%) of screened patients (183, 186, 189). Completion rates for those recruited were more consistent (between 65% and 100%) (47, 181, 182, 185, 186). Reasons for attrition were also consistent between papers (47, 181-185). The main reasons reported for attrition (discontinuation of home-based exercise training and/or further study assessment) were re-exacerbation or readmission, co-morbidity (e.g. chest pain, musculoskeletal pain or diagnosis of cancer) and death.

There was also data to suggest patients were willing to consent to be interviewed despite not wishing to provide consent to take part in trial interventions or assessments (185), and patients appeared comfortable to provide brief feedback regarding reasons for dropping out despite no longer wishing to remain in a study (186).

Multiple studies have shown that recruitment of healthcare professionals from a range of different clinical background and roles to trials is also possible (183, 185, 186, 188) (general practitioners (183), practice nurses (183), physiotherapists (185, 186, 188), and clinically-trained researchers (185, 188)). However, there was no data from the papers included to determine ability to recruit family members and informal carers.

4.4.4.2 Compliance

Greater compliance was observed with interval training compared to continuous training (182) and also for home-based exercise sessions compared with hospital-based exercise sessions where programmes started in the hospital and continued at home (183, 185). In interviews, patients felt that exercising at home provided easier access to training (183).

Compliance in relation to study protocols, outcome measures and devices was also extracted. The evidence suggests patients satisfactorily completed home exercise diaries (183), however struggled to adhere to the requirements of wearable devices and mobile applications (185, 186): in interviews, patients reported discomfort affected compliance with wearable devices (186) and that technical difficulties in using mobile applications reduced compliance (186). Similarly, healthcare professionals considered the wearability of devices and usability of mobile applications to be key factors which could impact patient compliance. Furthermore, healthcare professionals felt older patients or those with more advanced disease were less likely to use technology and comply with wearable devices (186). No data was found on perspectives of family members or informal carers.

4.4.5 Experiences and acceptability

Six papers reported findings which helped understand the experiences of, and as a result inform acceptability of, home-based exercise training. Table 4.4 includes details of the integrated synthesis.

Patients felt receiving a home-based intervention was a positive process (183). Some reportedly felt better rested and nourished, more comfortable and able to maintain usual routines during home-based care (189). Patients valued individualisation, ease of access, one-to-one supervision (where

supervised), fewer distractions and the increased flexibility of home-based exercise training (183, 185). In addition, patients who received home-based exercise training subsequently reported an increased perceived need to undertake PR (185). They felt exercise training was required to improve their condition, to help achieve their goals and their ability to complete activities of daily living was greater if they received exercise training (185). One paper suggested interval training was more acceptable to patients, with fewer unintended breaks in the intended programme (182). Use of equipment to provide exercise training, such as a cycle ergometer, did not appear to influence patients' acceptability of home-based exercise training (182).

There was some data to suggest early initiation of exercise programmes were acceptable from the patient perspective as confidence to complete walking programmes and strength exercises did not change between 48 hours, two weeks and four weeks post-hospital discharge (184). However, patients also reported that commencing exercise training in hospital or immediately post-discharge may be too early as they would prefer to allow their health to improve before starting a programme (185). This contrasts with healthcare professionals who felt that the sooner the exercise training was delivered, the more beneficial the intervention was for patients (185, 186).

Healthcare professionals reported enjoying the continuity of care they were able to deliver as well as the flexibility to provide more individualised exercise training with home-based exercise training (185). In addition, many healthcare professional preferences were for home-based exercise training to include supervised sessions, supplemented by unsupervised exercise (185). A clinical decision-making tool, developed in a Delphi study which included both patients and healthcare professionals, identified home-based exercise training delivered in the post-hospitalisation setting as a core component of AECOPD management (188). It included three key elements related to exercise training post-

exacerbation (monitoring requirements, types of exercises to prescribe, and exercise progression) (188). No data was found on perspectives of family members or informal carers

4.4.6 Clinical effectiveness

4.4.6.1 Physical function

Eight papers reported findings related to physical function. Physical function was considered in relation to: 1) exercise capacity, 2) strength, 3) physical activity, and 4) daily function. Table 4.4 includes details of the integrated synthesis. Complementary evidence exists for physical activity within the integrated synthesis.

4.4.6.1.1 Exercise capacity

The most common measure of exercise capacity was the six-minute walk test (n=4) (181, 182, 185, 187). Two other measures of exercise capacity were used: the incremental shuttle walk test (47), and self-paced three-minute step test (47). These measures were assessed in a hospital-based setting (either during hospitalised period or returned as an outpatient) in all the papers which reported assessment location (47, 181, 182, 185, 187). Workload per session has been included in this review as an indication of, but not a direct measure of, exercise capacity (182). The available outcome data is contradictory, and the potential clinical effect remains unknown due to a large amount of unreported data, the wide range of measures and diverse data collection points.

4.4.6.1.2 Strength

Two different measures of strength were recorded in one paper. There was no significant improvement in either hand grip strength or quadriceps maximum voluntary contraction (47). However, limited data was reported (47).

4.4.6.1.3 Physical activity

Multiple measures were recorded within each paper that assessed physical activity. One for example reported physical activity levels, steps per day and physical responses to vibration feedback using an accelerometer worn 24 hours/day for 14 days (186). Another measured steps per day, stepping time, sitting time and standing time using an accelerometer worn 24 hours/day for two to seven days (183). Overall, the findings indicated some evidence of increased steps per day, stepping time, and standing time with home-based exercise training. However, due to limited data, definitive conclusions could not be drawn. Moreover, due to the numerous measures used, the optimal objective measure of physical activity from accelerometery remains unknown.

Qualitatively, healthcare professionals and patients reported that reducing sedentary behaviours were as important as increasing in physical activity levels (183, 185). Healthcare professionals also felt that using technology early during the inpatient phase of care could reduce sedentary time and promote physical activity sooner for patients (186).

4.4.6.1.4 Daily function

Daily function was measured across four papers using six different outcomes, although no data was reported for four of these outcomes (Barthel index, London Chest Activities of Daily living

Questionnaire, Functional Assessment of Chronic Illness Therapy – Fatigue and Falls Efficacy Scale-International) (185-187). Using a rating scale for confidence completing unsupervised strength exercises and a walking programme at home (184), confidence remained similar between 48 hours to one month post-discharge.

Almost half of patients in one paper reported they felt the prescribed exercises completed at home had a positive effect on their recovery one month following hospital discharge; however data for the remaining patients were lacking (184). Patients also reported they intended to continue completing their exercises as a direct consequence of feeling their daily function had improved after a period of exercise training (183). These available data suggest patients perceive home-based exercise training to be of benefit and potentially improve their daily function. However, lack of data precludes determination of an effect size.

4.4.6.2 HRQoL

Nine papers reported findings related to HRQoL. HRQoL was recorded in the quantitative data relating to: 1) health status, and 2) psychological status. Table 4.4 includes details of the integrated synthesis.

4.4.6.2.1 Health status

Health status was measured using six different tools: the Chronic Respiratory Disease Questionnaire (181-183), St George's Respiratory Questionnaire (47), Euro-Qol 5-Dimension 5-Level (47, 185), COPD Assessment Test (186), Clinical COPD Questionnaire (187), and feelings thermometer (182). Overall, the findings suggest potential benefit of home-based exercise training on health status. However, disparities between data collection points, the wide variety of measures and incomplete data reporting within some papers limit the conclusions which can be drawn at present.

Qualitative data suggest that home-based care, as well as home-based exercise training, may have a positive impact upon perceived health status for some patients. In interviews patients reported better perceptions of health status with home-based care compared with receiving inpatient care (189), and 20% of patients felt generally better 48 hours post-hospital discharge (28). Despite this, 14% and 9% of patients were feeling tired and unwell respectively 48 hours post-hospital discharge (184). In relation to exercise training specifically, patients who were able to engage with home-based exercise training reported feeling better as a result of it (183). One patient stated they had returned to a sport they had previously given up and another reported being able to do activities which had been limited previously (183).

4.4.6.2.2 Psychological status

Psychological status was measured using the Hospital Anxiety and Depression Scale (182, 186, 187) and self-reported perceptions of mood (184). The findings show contradictory data related to the impact of home-based exercise training on psychological status however, there were limited data reported in in papers and diverse data collection points between papers.

Qualitative data indicate perceived psychological status for some patients could be affected either positively or negatively post-acute exacerbation as a result of receiving home-based care (16% percent of patients reported feeling relieved to be home 48 hours post-hospital discharge (184), yet 8% felt worried (184)). This suggests that home-based care did not have a substantial impact upon the perceived psychological status for the majority of patients and therefore could be considered an appropriate alternate method to deliver care.

4.4.6.3 Health service utilisation

Five papers reported quantitative findings on health service utilisation. Reported measures included number of inpatient bed days (185, 189), respiratory-cause and all-cause readmissions (including inpatient length of stay) (183), re-exacerbations (47, 185), general practitioner contacts (184) and contacts with healthcare professionals post-discharge using the Client Service Receipt Inventory (185). These data were recorded from a combination of self-reported (184, 185) and record-based (184, 185, 189) measures. Two papers did not report the source of their data (47, 183). There were trends to suggest secondary care health service utilisation (such as readmissions and length of stay) may be reduced. However, data regarding re-exacerbation rates not requiring hospitalisation and access to primary care services (such as general practitioner visits) appeared more heterogenous. There were no qualitative findings relating to this outcome.

4.5 DISCUSSION

This mixed methods review assessed feasibility and acceptability of home-based exercise training following hospitalisation for an acute exacerbation of COPD from multiple stakeholder perspectives, and appraised its clinical effectiveness. This review suggests provision of home-based exercise training following hospitalisation for AECOPD to be feasible and acceptable to both patients and healthcare professionals alike. However, no data was found on perspectives of family members or informal carers. This review also found a paucity of trials and heterogenous data regarding the clinical effectiveness in relation to physical function, HRQoL and health service utilisation.

4.5.1 Comparison to current guidelines

This systematic review corroborates the recently updated European Respiratory Society and American Thoracic Society guideline on the management of AECOPD, which states that studies are needed to define key elements of home-based models of care, including multidisciplinary team member roles (99). This is pertinent given the absence of interventions that improve uptake or completion of outpatient-based PR post-AECOPD (59, 60, 123).

4.5.2 Intervention development

The review findings regarding feasibility and acceptability aid a population-specific (post-hospitalisation for an AECOPD) intervention to be developed. The training modality used to deliver exercise training may affect compliance of a home-based exercise programme for patients post-hospitalisation, as better compliance was observed with interval training as compared with continuous training (182). Patient views of training modalities corroborates this as interval training appeared more acceptable as patients required less unintended breaks than when undertaking continuous training (182). In previous studies interval training has been shown to elicit similar training responses as continuous training in COPD patients (191). Therefore, interval training could be considered as a priority training modality when developing programmes for patients' post-acute exacerbation in the future. In addition, use of equipment (such as provision of a cycle ergometer) does not appear to affect patient acceptability of home-based exercise training. No specialist equipment was required for the exercises suggested within the clinical decision making tool developed within the Delphi study (188). A significant proportion of PR sites in the UK are located in community settings such as church halls, which have limited access to gym equipment (50), and a recent study comparing PR using specialist or minimal exercise equipment demonstrated similar improvements in exercise capacity and HRQoL (39). Moreover, the recent trials of home-based exercise training programmes for

patients with stable COPD have not provided access to gym equipment (79-81). Therefore, equipment used in interventions in future studies to deliver home-based exercise training are not mandatory and should perhaps be guided by healthcare professionals' assessment of what is required to achieve effective prescription and ongoing progression for an individual.

In addition, patients and healthcare professionals alike valued the individualisation, ease of access, one-to-one supervision, fewer distractions and flexible nature of home-based exercise training (183, 185). Moreover, the greater compliance observed with home- versus hospital- based sessions (183, 185) is likely to attributed to these factors. This is unsurprising given service users are more likely to take up interventions they feel will be beneficial, are achievable without excessive burden, and when they have confidence to partake (173). Therefore, these factors identified which were valued by patients and healthcare professionals could potentially be considered for home-based exercise training interventions trialled in the future to attempt to facilitate greater acceptability.

Finally, another strategy to aid with development of future home-based exercise training interventions would be to use the tool (see Appendix 3 for a copy of the clinical decision-making tool) developed in the Delphi study to identify strategies to inform delivery, monitoring and progression of exercise for this population (188). As aforementioned, service users are more likely to take up interventions which they feel will be of benefit, are achievable without excessive burden, and for which they have the confidence to undertake (173). The use of a clinical decision-making tool developed by service users and providers could optimise these criteria within a future exercise-training intervention.

4.5.3 Methodological considerations

The findings from this review regarding feasibility and acceptability indicate methodological considerations which could enhance the delivery of future trials investigating home-based exercise training for patients post-AECOPD. First, due to the wide range of recruitment rates from the trials included in this review, recruitment to future studies delivering home-based exercise training to this population will be difficult to predict. Challenges with recruitment of this population have previously been reported and shown to be multi-factorial (patient, protocol / infrastructure, seasonality and transport) (45). Despite this, this review indicates more consistent retention rates (>65%) could be anticipated. An additional consideration to optimise retention would be to offer study assessments in patients' homes, as opposed to attending the hospital, to reduce assessment burden (192) given transport and travel is a known barrier for these patients (133). Addressing known barriers to recruitment, and piloting proposed recruitment and retention strategies, is therefore required to optimise delivery and accurately forecast future trials.

There is also data to suggest patients may be willing to consent to be interviewed despite not wishing to provide consent to take part in trial interventions or assessments (185). Furthermore, patients appear comfortable to provide brief feedback regarding reasons for dropping out despite no longer wishing to remain in a study (186). This could allow for vital information collection at the piloting phase of future studies to understand reasons for declining consent, or for dropping out, of trials. The findings from this review also indicate that healthcare professionals (including research staff) can be engaged within qualitative elements of research studies (183, 185, 186, 188). Therefore, it would appear gaining the perspectives of care providers (including those delivering the intervention and completing study assessments) as well as service users could be feasible for future trials. However, it remains unknown from the papers included in this review whether it is feasible to recruit family members or informal carers as no studies attempted to recruit this key group of stakeholders.

Recruitment strategies to engage with family members or informal carers would also benefit from being comprehensively piloted, with reasons for declining to consent collected, prior to an efficacy trial in the future.

Compliance of data collection tools (including exercise diaries and wearable devices) and technology used to support intervention delivery (such as mobile applications) have been shown to be variable. This is unsurprising as patient preferences towards wearable devices have been shown to favour commercially available monitors versus research-grade accelerometers (193) despite limited studies formally validating commercially available monitors in the COPD population (194). In addition, previous studies with patients with COPD which tested interventions that required a degree of digital literacy showed more patients were excluded from the trial because of no internet access than those who were able to be recruited (195). Recent data shows that digital illiteracy is prevalent in patients with COPD, as although a large proportion of patients have access to a mobile phone, use of mobile phones were mostly limited to telephone calls and text messaging (196). In addition, access to other devices such as tablets or laptops was more varied, with over 30% of patients reported having never accessed the internet (196).

The current evidence-base suggests a disparity between patient and healthcare professionals' perspectives of when home-based exercise training should start in relation to hospitalisation. A previous systematic review found moderate quality evidence that initiation of PR post-AECOPD within four weeks of hospital discharge to reduce mortality and readmissions, with improvements in walking distance and HRQoL also reported in those who received early PR (197). Therefore, optimal timing (within four weeks from hospital discharge) needs to be established to ensure premature initiation of home-based exercise training does not negatively influence the adherence to home-based exercise

training programmes. This is important as sub-optimal timing was one of the factors hypothesised to have influenced the success of the intervention tested in Chapter 3 (123).

Future trials should also determine whether future uptake of outpatient centre-based PR is affected as a result of receiving home-based exercise training (164) and whether patients miss the peer-support (198) and socialisation (199) elements of centre-based group PR remains unknown.

No data are available to provide insights from family member and informal carer perspectives in relation to home-based exercise training. This is relevant given the previous described deleterious impact of AECOPD on the physical and emotional health, social life, relationships and employment of family members and informal carers (28). Potentially, family or caregiver burden might be reduced due to no longer needing to provide transport to attend PR, or increased due to less opportunity for respite (200). It is also not known whether family members and informal carers are enablers of home-based exercise training adherence/completion, and continuation beyond intervention delivery (201). Further exploration of the views and the role of this stakeholder group is required in future research.

The review showed that the available clinical outcome data was sometimes contradictory, and the potential clinical effect remains uncertain due to unreported data, wide range of heterogeneous measures used and diverse data collection points, thus limiting between-study comparisons and data aggregation. Nonetheless, the available data suggests home-based exercise training may increase physical activity but not improve strength. The qualitative data also indicates exercise training may have a positive impact on HRQoL for those patients engaged with home-based exercise training post-hospitalisation.

With regards to health service utilisation, there were trends to suggest secondary care health service utilisation may be reduced, which may be of interest to commissioners or hospitals. However, data regarding re-exacerbation rates not requiring hospitalisation and primary care service usage were more heterogenous, suggesting the societal consequences of exacerbations may remain unchanged. This is made yet more complex as the optimal data collection method remains unknown (record-based or self-reported) and significant differences between self-reported and record-based measures have been reported (184). Inaccuracy of self-reported measures is widely acknowledged (202), with accuracy of data retrieved directly from records also shown to vary (110, 111). Therefore, this review indicates careful consideration and robust piloting of health service utilisation outcomes is required.

As such, despite the paucity of data and the lack of definitive conclusions which can be drawn from this review, the usefulness of this review from a clinical or research perspective is not diminished. Reviews such as these provide the vital indicators for where research endeavours going forwards should best focus.

4.5.4 Critique of the method

The segregation method of extracting data, which relies upon quantitative and qualitative data being extracted from papers concurrently yet independently from each other (154), was implemented in this review in preference to the integrated method of data extraction in the systematic review. This was to ensure the inherent differences between quantitative and qualitative data were upheld and not compromised through attempting re-model data to fit a mode of enquiry which it was never intended to address (154, 176).

Synthesis of the quantitative and qualitative data was first undertaken at the data analysis stage within this review. Due to the relatively recent emergence of mixed methods research, there is no agreement regarding the best way to conduct a mixed method synthesis (179). For this review, there were two options available which would allow the quantitative and qualitative data initially be integrated during the analysis phase: joint display / matrix (203) or 'following a thread' (204). This data extraction had been planned *a priori* to be undertaken concurrently for the quantitative and qualitative data, with no further searches being undertaken as a result of the findings of this review. Therefore, joint display was considered the more suitable method of synthesis for this review over 'following a thread'. The pillar integration process was the joint display chosen (178). It was not only felt to be the best fit for this review, but it is also one of the more comprehensively-illustrated processes in the literature.

Following initial integration via application of the pillar integration process, triangulation was implemented. Triangulation is another strategy used within mixed methods designs to integrate quantitative and qualitative data sets (205) and occurs during the data interpretation phase as opposed to the analysis phase (205). Using triangulation whilst interpreting this data resulted in application of multiple mixed method approaches to data synthesis as confirmation, refutation, complementation or silence of the two data sets was also reported (154). Therefore, the data analysis and interpretation processes undertaken in this review were carefully considered to ensure a robust methodological process was followed.

4.5.5 Strengths

First, this review was inclusive in terms of design, outcomes, language, and publication status (172). Although the unpublished papers included may not have been subjected to peer review, they are considered important to capture relevant grey literature as not all quality improvement initiatives

seek or achieve academic publication. However, as this search strategy focused on academic resources, some grey literature publications may not have been identified in this search. Second, the screening process was robust: two independent reviewers assessed the eligibility of full papers and quality, with a third reviewer resolving any discrepancies (175). Third, in the absence of a formal definition, home-based rehabilitation was defined *a priori* for the purpose of this review. In addition, this review was prospectively registered on PROSPERO, with clear outcomes of interest stated. Moreover, although the description of the home-based exercise training interventions and usual care was limited to the information available in the papers, the authors considered the interventions using the frequency, intensity, type and time principles to elicit important components of exercise prescription (206, 207).

4.5.6 Limitations

There was limited capacity for meta-analysis due to the lack of continuity in outcome measures, diverse timings for data collection and a significant proportion of unreported data in the included papers for the quantitative data. Furthermore, the integrated analysis and triangulation identified significant amounts of silence between the quantitative and qualitative data. Nonetheless, this in itself was an important finding as it reflects a paucity of research in this field.

4.6 CONCLUSION

Home-based exercise training appears to be feasible and acceptable to patients hospitalised with an acute exacerbation of COPD and professionals providing healthcare to this population based upon the available evidence. Participants valued the individualised, accessible, and flexible nature of home-based exercise training, and models using interval training, regardless of equipment, had enhanced compliance. Evidence of clinical effectiveness on physical function, HRQoL and health service

utilisation is mixed, and limited by heterogenous measurement. No data is available to provide insights from the perspectives of family members or informal carers. As a result of the limited data currently available, future trials of home-based exercise training post-hospitalisation for an acute exacerbation of COPD should involve collaboration with stakeholders to optimise delivery as well efficacy of the treatment.

The results presented in this chapter form the basis of the topic guides used in the next thesis chapter, an experience-based co-design project, which is the second part of the intervention development phase of this programme of work.

Chapter 5: Intervention development Stage 2: Integrating home-based exercise training with a hospital at home service for patients hospitalised with exacerbations of COPD – an accelerated experience-based co-design project

Some of the results from this chapter were published in International journal of Chronic Obstructive Pulmonary Disease on 1st March 2021. These results are reprinted with permission of International Journal of Chronic Obstructive Pulmonary Disease, copyright © 2021 Dove Medical Press. All rights reserved. Barker RE, Brighton LJ, Maddocks M, Nolan CM, Patel S, Walsh JA, Polgar O, Wenneberg J, Kon SSC, Wedzicha JA, Man WDC, Farquhar M. Integrating Home-Based Exercise Training with a Hospital at Home Service for Patients Hospitalised with Acute Exacerbations of COPD: Developing the Model Using Accelerated Experience-Based Co-Design. *Int J Chron Obstruct Pulmon Dis*. 2021; 16:1035-1049. doi: https://doi.org/10.2147/COPD.S293048.

Some of the results from this chapter have previously been reported in a conference abstract, which was presented at the American Thoracic Society International Conference in May 2020 (208). These results are reprinted with permission of the American Thoracic Society and with permission of the authors, copyright © 2020 American Thoracic Society. All rights reserved.

5.1 BACKGROUND

To date, supervised home-based pulmonary rehabilitation (PR) has only been piloted with patients

following hospitalisation for an acute exacerbation of chronic obstructive pulmonary disease (AECOPD) in a small trial (47), although data from studies undertaken in patients with stable COPD suggest it may be a viable alternative (79-81). Therefore, this accelerated experience-based co-design (EBCD) project was conducted to build-upon the evidence synthesis presented in Chapter 4. The intention of the EBCD project was to develop a population specific model of care which integrated home-based exercise training within a pre-existing, well-established HaH service through collaboration with patients, family members (who could also self-identify as informal carers, who would be then called family carers) and healthcare professionals.

5.2 OBJECTIVE

5.2.1 Intervention development objective

In this chapter, I describe the second stage of the intervention development phase (Phase 3) to develop a home-based exercise training intervention as an adjunct to a standard HaH service post-hospitalisation for AECOPD. From the systematic review conducted in the first stage of Phase 3, reported in the previous chapter, home-based exercise training appeared to be feasible and acceptable to patients and healthcare professionals post-AECOPD; however, no data was found regarding family member and informal carer experiences. There were also few trials and heterogenous data regarding the clinical effectiveness or optimal delivery of home-based exercise training post-AECOPD. As a result, involvement of key stakeholders, in particular exploration of the experiences and role of family members and informal carers, was essential to co-design an intervention prior to testing in future trials.

5.2.2 EBCD project objective

The objective of the EBCD project was to co-design an integrated home-based exercise training programme and HaH service for patients hospitalised with AECOPD by collaborating with patients, family members (who could also self-identify as informal carers) and healthcare professionals ready for testing within a future mixed methods feasibility trial.

5.3 METHODS

5.3.1 Study design

This was an accelerated EBCD project which included three stakeholder events followed by two co-design meetings. EBCD is a quality improvement approach that enables stakeholders to co-design services in partnership. Using a co-design method to facilitate the development of this model of care allowed for collective ownership and greater understanding of experiences from stakeholders (between service users and providers) (209). It also ensured consensus was obtained from all stakeholders regarding strategies to effectively trial the model of care (209). This development phase was considered vital as qualitative work has shown stakeholder acceptability and fulfilling the needs of the end-user to be key requirements for successful model of care development (210).

The PR service leads and HaH service managers were engaged with this project from the outset and endorsed this co-design process as a strategy to develop a model of care which would integrate home-based exercise training within the HaH service.

Ethical approval was not required as this EBCD project was considered a service improvement project by the Health Research Authority and The Point of Care Foundation (135). Nonetheless, it was conducted in accordance with the Declaration of Helsinki and good clinical practice guidelines, with written informed consent obtained from all service users and healthcare professionals involved.

Figure 5.1 is a schematic of the EBCD process. It involved taking existing knowledge from a variety of sources to generate key 'touchpoints' which formulated topic guides. The topic guides were used to support discussions at stakeholder events with healthcare professionals and service users. The 'touchpoints' included in the separate stakeholder event topic guides along with new insights raised at the separate events were subsequently discussed at the joint stakeholder event. Following these three stakeholder events, two co-design meetings were held to reach the final consensus.

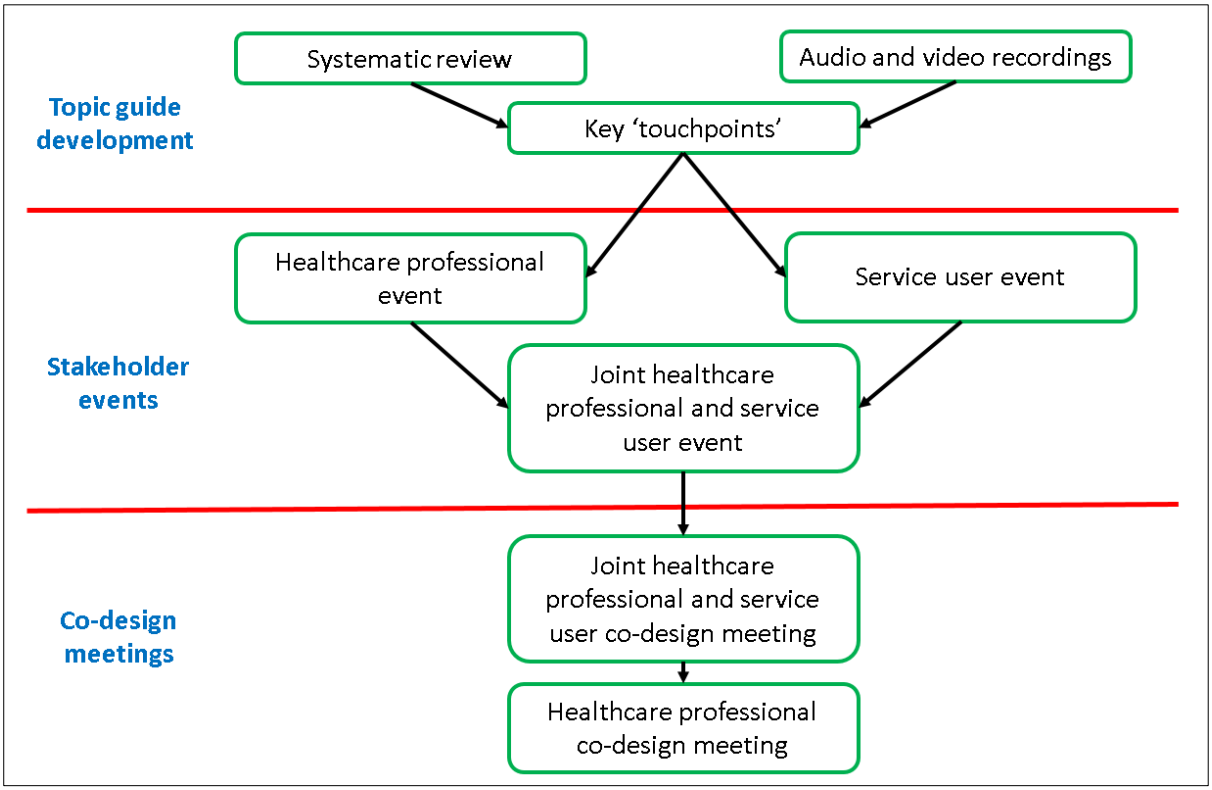


Figure 5.1. Schema of this accelerated experience-based co-design project.

5.3.2 Study setting

The healthcare professional stakeholder event was held at Harefield Hospital: a tertiary hospital in north west London, which hosts the PR programme. The service user and joint service user-healthcare professional stakeholder events were held in a community centre local to Harefield Hospital for the convenience of service users and to take the data collection out of a healthcare setting. These stakeholder events were audio-recorded and scheduled on afternoons for four hours, with catering and refreshments provided at each. The events began with introductions and were structured with 15- to 30-minute whole or small group discussions. Regular breaks were taken between these discussions and prior to a 'round-up' at the end.

After the stakeholder events were completed, the co-design meetings took place across two sites in north west London (Harefield Hospital and Hillingdon Hospital: the local district general hospital which hosts the HaH service). These two-hour co-design meetings were scheduled on afternoons, with catering and refreshments provided.

Transport via taxi was offered to all service users, and mileage paid to healthcare professionals, to attend the events and meetings.

5.3.3 Participants

Healthcare professionals from the PR and HaH services were invited via their line managers to attend the stakeholder events and co-design meetings. The invited healthcare professionals were purposively sampled to ensure all members of the multidisciplinary team were included: clinical nurse specialists,

respiratory consultants, qualified physiotherapists and physiotherapy assistants. The interested healthcare professionals were provided with an invitation pack from their line managers. Invited service users were also purposively sampled to include patients with COPD who had recently been treated or experienced delivery of the HaH service or outpatient-based PR programme, and their family members (who could also self-identify as informal carers). They were invited via the healthcare professionals delivering their usual care, who provided an invitation pack. The invitation packs included a stakeholder-specific information sheet and consent form to have access to all necessary project documents, including ways (email, post and telephone) to contact me if they were interested. I subsequently discussed the provided project documents via the telephone prior to attendance at an event or meeting and answered any questions. Written consent was received on arrival at an event or meeting once any additional questions were answered. To gain fresh perspectives, additional service users and healthcare professionals were invited from the same sources to attend the joint stakeholder event and subsequent joint co-design meetings.

5.3.4 Topic guides

I facilitated the separate healthcare professional and service user stakeholder events along with one of my PhD supervisors and another PhD student using the topic guides developed based on key 'touchpoints' informed by the findings from the systematic review presented in Chapter 4 (PROSPERO: CRD42018104648) (169) and previous qualitative interviews conducted as part of a different project involving patients attending PR following an AECOPD. The findings from this previous qualitative work illustrated a lack of understanding and information provision before hospital discharge regarding PR, positive perceptions of home visits to provide support after discharge from hospital, the impact hospitalisation had on a decision to attend PR as well as the elements of outpatient-based PR they enjoyed and disliked (including regarding the education delivered within the programme) and home-based PR as an alternative delivery option.

The topic guide for the joint service user-healthcare professional stakeholder event was developed inductively, informed by responses at the previous two separate stakeholder events and observational logs/field notes.

I facilitated the co-design meetings using meeting-specific agendas to ensure areas were addressed which required further clarification following the stakeholder events in order to finalise the integrated model of care.

5.3.5 Data analysis

Audio-recordings of the semi-structured discussions within the stakeholder events were anonymised. I transcribed the audio-recording verbatim and analysed them alongside observational logs/field notes and source documents, supported by a co-analyst, using inductive directed content analysis (211) in order to expand upon the knowledge acquired in Chapter 4. The separate healthcare professional and service user stakeholder events were analysed prior to the joint service user-healthcare professional event and used to inform the topics of the structured discussions. Minutes were produced summarising the discussions in the co-design meetings and subsequently approved for accuracy by the meeting attendees. These minutes were used as a record of the experiences and perspectives of the stakeholders who attended the meetings. The Table of Changes approach was used throughout the data analysis process to facilitate decision-making, provide an auditable decision-trail and finalise the model of care (212).

5.4 RESULTS

The two separate healthcare professional and service user stakeholder events were conducted in September 2018. The joint service user-healthcare professional stakeholder event was conducted in October 2018 following analysis of the data from the first two stakeholder events. Seven patients with COPD, two informal carers and nine healthcare professionals (from an existing outpatient-based PR service and HaH service) participated in these stakeholder feedback events. Two co-design meeting were conducted in February 2019. Two patients with COPD, one informal carer and three healthcare professionals participated in the first joint co-design group, with five healthcare professionals attending a second co-design group. Table 5.1 provides an overview of attendees at the stakeholder events and co-design meetings. Of interest, although perhaps unsurprisingly, all the attending family members also classified themselves as an informal carer on the demographic sheet. The findings of the events and meetings are presented as a narrative summary with supporting indicative anonymised quotes.

Table 5.1. Accelerated experience-based co-design project attendees at each stakeholder event and co-design meeting

Stakeholder feedback events	
Healthcare professional event	
Pulmonary rehabilitation team members n=5	Qualified physiotherapists (n=4 [female: n=4]) Physiotherapy assistant (n=1 [female: n=1])
Hospital at home service members n=2	Specialist nurse (n=1 [female: n=1]) Specialist physiotherapist (n=1 [male: n=1])
Service user event	
Patients with COPD n=5	Previously underwent pulmonary rehabilitation and received hospital at home care (n=2 [male: n=1; female: n=1]) Previously underwent pulmonary rehabilitation only (n=3 [male: n=1; female: n=2])
Relatives or carer of person with COPD n=2	Observed pulmonary rehabilitation (n=1 [female: n=1]) Observed hospital at home care (n=1 [female: n=1])
Joint service user-healthcare professional event	
Patients with COPD n=6	Previously underwent pulmonary rehabilitation and received hospital at home care (n=3 [male: n=2; female: n=1]) Previously underwent pulmonary rehabilitation only (n=3 [male: n=1; female: n=2]) Did not attend separate service user feedback event: 2/6
Pulmonary rehabilitation team members n=3	Qualified physiotherapists (n=2 [female: n=2]) Physiotherapy assistant (n=1 [male: n=1]) Did not attend separate healthcare professional feedback event: physiotherapy assistant
Hospital at home service members n=2	Consultant respiratory physician (n=1 [female: n=1]) Specialist physiotherapist (n=1 [male: n=1]) Did not attend separate healthcare professional feedback event: consultant respiratory physician

Co-design groups	
Service user and healthcare professional co-design group	
Patients with COPD n=2	Previously underwent pulmonary rehabilitation and received hospital at home care (n=2 [female: n=2]) Did not attend the stakeholder feedback events: 2/2
Relative or carer of person with COPD n=1	Observed pulmonary rehabilitation and hospital at home care (n=1 [female: n=1]) Did not attend stakeholder feedback events: 1/1
Pulmonary rehabilitation team members n=1	Qualified physiotherapist (n=1 [male: n=1]) Did not attend stakeholder feedback events: 0/1
Hospital at home service members n=2	Specialist nurses (n=2 [female: n=2]) Did not attend the stakeholder feedback events: 2/2
Healthcare professional co-design group	
Pulmonary rehabilitation team members n=5	Qualified physiotherapists (n=4 [female: n=4]) Physiotherapy assistant (n=1 [male: n=1]) Did not attend stakeholder feedback events: 2/4 qualified physiotherapists

Abbreviations: COPD: Chronic obstructive pulmonary disease; EBCD: experience-based co-design.

5.4.1 Stakeholder events

Four themes were identified from the three stakeholder events: (1) individualisation of the home-based exercise training, (2) progression and transitions during home-based exercise training and outpatient centre-based programme, (3) continuity between services and (4) communication between stakeholders. Subthemes were derived for continuity between services (A: content delivered, B: timing of delivery, C: skill set of the healthcare professionals, and D: types of assessments required) and communication between stakeholders (A: between healthcare professionals, and B: between

healthcare professionals and service users).

5.4.1.1 Individualisation of the home-based exercise training

All participants (patients, family carers and healthcare professionals) felt the home-based exercise training should include individually prescribed education and exercise, tailored to achieve patient-specific goals. For example:

> *'I think that [the types of exercises] need to be tailored to the individual, if we are talking about engagement, different goals for different patients, different anxieties and symptoms'* [SM08, physiotherapist, PR service team member]
>
> *'I think a bespoke programme, cos you're all going to be at different levels'* [SU05, patient living with COPD, previous experience of PR]

All participants also felt the home-based exercise training should include face-to-face supervision. The rationale for this supervision, which centred on adherence, was clearly stated by healthcare professionals, patients and family carer:

> *'I think a lot of people would openly say when you do offer the home programme is that they won't do it without anyone being there, so obviously [supervised] one to one, erm, yes, I think would definitely help'* [SM01, physiotherapist, PR service and HaH service team member]
>
> *'If he [healthcare professional] says 10 minutes, you do 10 minutes'* [SU08, patient with COPD, previous experience of PR and HaH]
>
> *'I also think that they haven't got enough self-discipline to actually do it [unsupervised]'* [SU03, relative to SU05, previously observed PR]

It was also noted that the frequency of supervised sessions should be similarly individually tailored:

> *'Well at the beginning you probably want shorter but more often, and then get more individual'*

[SM05, physiotherapist, PR service team member]

A minimum and maximum of one and three supervised sessions per week respectively was suggested:

> *'So it is [British Thoracic Society guidelines] 2 supervised and one unsupervised, … , but then obviously if we think healthy living advice is 30 minutes 5 times a week, so do we go out for 30 minutes 3 times a week'* [SM01, physiotherapist, PR service and HaH service team member]

This was to allow for individual patients to determine their own levels of motivation and confidence to complete unsupervised exercise at home, in between supervised sessions. Some patients felt more confident and motivated to exercise at home unsupervised and as a result felt that a once weekly supervised programme to deliver education and to support exercise progression was all that was required for them:

> *'I've got a garden back and front to keep up, which means quite a bit to me, so I do quite a lot of exercise, I am a member to a gym, … , I think I keep myself in good shape'* [SU06, patient with COPD, previous experience of PR]

However, other patients felt either less confident or reported they might lack motivated to exercise regularly unsupervised at home and so felt they would prefer more frequent supervised sessions for their home-based exercise training:

> *'When you live on your own it's very difficult, you don't have another person to push you, telling you to do it, … , it's hard'* [SU07, patient with COPD, previous experience of PR]

The need for individualised programmes, to meet patients' individual needs, was therefore clear.

Including a minimum and maximum contact number in the individually tailored frequency also allowed healthcare professionals to feel reassured that at least some face-to-face supervision was provided to ensure patient safety and effective exercise progression, without resulting in an unfeasible frequency (e.g. five days a week supervised exercise training) of supervised sessions being requested:

> *'If you had it five days a week, I'd want to go'* [SU08, patient with COPD, previous experience of PR and HaH]

All the participants felt the use of mobile applications or other online delivery mechanisms (such as patient portals) could address the transport and travel barriers to access to PR however acknowledged that these could result in digital illiteracy becoming a new barrier to accessibility:

> *'My kids do [have access to the internet or smart phone], but I don't use that'* [SU08, patient with COPD, previous experience of PR and HaH]

For family carers the best alternative to face-to-face sessions was a DVD of exercises, as this would also allow them to encourage and motivate the patient with COPD:

> *'If we had a video or a CD, put it on the television, and then I would be making him do it, because I would do it with him'* [SU01, relative to SU02, previously observed both PR and HaH]

As such, avoidance of models of care which relied upon digital literacy was deemed essential.

Family carers felt their role was to support the needs of the patient with COPD who had been hospitalised and having access to the patients' session would enable this:

> *'If someone's not on their own, like we're not, could I go to those [education sessions] so I know what they're talking about? … Because you hear things, but they can hear other things'* [SU01, relative to SU02, previously observed both PR and HaH]

They considered that it should be a collaborative process between themselves, healthcare professionals and the patient with COPD to identify the goals, this could then determine the individually tailored education programme content and frequency of exercise sessions.

5.4.1.2 Progression and transition during home-based exercise training and outpatient-based programme

A key finding was that some of the patients with COPD remained keen to attend traditional outpatient

centre-based PR when they felt well enough post-exacerbation. The reason for this was that they liked the social content and contact of an outpatient-based programme, and the access it gave them to specialist gym equipment:

> *'Prefer to go to the gym [outpatient-based PR] myself, … and see how you progress over the eight weeks, I don't think I would get that progress at home, with a one to one even'* [SU06, patient with COPD, previous experience of PR]
>
> *'I think it is a bit of both [doing rehab with others as well motivation from therapist], because you've got the other people literally in the same boat as you, and you can see people that have literally worked up the ladder from square one'* [SU08, patient with COPD, previous experience of PR and HaH]

However, this was disparate from other patients who felt entirely home-based exercise training was more suited to them given the difficulties they had previously leaving their house after being hospitalised with an acute exacerbation and that they would not attend traditional outpatient-based PR even if it was offered. This further supports the idea that programmes should be individually tailored to meet patients' needs.

Contrasting views were also found between healthcare professionals. Some healthcare professionals felt there would be some patients with COPD who would prefer entirely home-based exercise training:

> *'There is that whole cohort that you [outreach] probably more touch base with at Hillingdon that you can't convince to come [to outpatient-based PR]'* [SM08, physiotherapist, PR service team member]

Nonetheless, the viewpoint of co-offering outpatient-based PR was also held by some of the healthcare professionals, with one healthcare professional stating:

> *'For those that can get here but don't want to, you can use it [home-based PR] as a way to gradually convincing them, and erm obviously show exercise is beneficial and enjoyable, and those ones might go on to do it [outpatient-based PR]'* [SM01, physiotherapist, PR service and HaH service team member]

This was because some healthcare professionals perceived traditional outpatient-based PR to be the gold standard of care post-exacerbation. As such, they felt not offering traditional outpatient-based PR to those allocated to receive home-based exercise training whilst the home-based exercise training was being tested as part of a trial and not part of clinical practice guidelines could result in patients missing out on an evidence-based therapy. As a result, offering traditional outpatient-based PR to all patients was included as a requirement in the model of care developed. Therefore, a referral pathway, and strategies to allow seamless transition between home-based and outpatient-based PR, were co-designed.

5.4.1.3 Continuity between services

Subthemes for continuity between services included content delivered, timing of delivery, skill set of the healthcare professionals and types of assessments required. With regards to the content delivered, all participants felt it was important for the different healthcare professionals (for example a nurse and a physiotherapist) and services involved in the delivery of the co-designed model of care (for example within HaH, home-based exercise training and outpatient-based PR) to provide consistent information and education:

> *'[post-exacerbation PR] reinforcing messages and education provided in the hospital'* [SM08, physiotherapist, PR service team member]
>
> *'And that knowledge checking as well, you know, … , if the outreach team are doing at the beginning, you know, six weeks later, then you can check and see whether it has been retained'* [SM03, physiotherapist, PR service team member]

In order to deliver this desired consistency, a series of resources which would be used by all the services was agreed upon during this co-design project (for example a HaH service leaflet on self-management and PR service presentation slides).

In terms of timing of delivery, there were multiple views on when the home-based exercise training should commence. Most patients and family carers felt a period of readjustment of up to two weeks was needed after returning home from hospital before exercise training could commence. This same perspective was held by some of the healthcare professionals from the HaH service based on their experience – they felt that commencing exercise training too early could be detrimental to longer term patient adherence:

> *'I don't think starting it too early would be beneficial, often they're fighting for breath still, and, and I think they would decline it cos they are feeling like that, … so I think it needs to be timed right when we are offering this at home rather than straight away'* [SM07, nurse, HaH service team member]

Nonetheless, the more widely held view of healthcare professionals was that beginning exercise training as soon as possible (as soon as the day after discharge) was key from their experience:

> *'For patients whose breathlessness is very severe and limiting what they feel able to do, erm, it might be an option for something to start with to try and get those muscles working to erm, reduce the deficits that develop in that initial acute post-exacerbation period'* [SM05, physiotherapist, PR service team member]

Some patients also supported this, as this was the period when they were most limited by breathlessness to complete their daily activities. As such, beginning exercise training during the peri-exacerbation phase of their recovery was vital to some patients so that they could be guided by healthcare professionals on how hard to push themselves:

> '*That's why I went down so low, cos I wasn't doing anything, well not a lot, you know, I did try, I mean, I wasn't really, I was just kind of walking around, and I have to go upstairs the loo, I have to go upstairs to bed, that was basically my exercise, just being honest, … , I think this is, would be, excellent for that initial period to get you started again'* [SU05, patient with COPD, previous experience of PR]

This reinforced the idea that programmes should be individually tailored to meet patients' needs. A solution was to compromise and agree the most acceptable time point to begin delivering exercise

training within the programme. To enable this the initial session post-discharge would be focussed around goal setting, with the early sessions including more time devoted to deliver education. The proportion of time spent exercising would then gradually build up based upon individual need whilst reducing the proportion of time delivering education over the first few weeks post-discharge to allow for a readjustment period.

There was greater agreement on who should deliver the home-based exercise training. All participants felt those who delivered it should be competent to undertake a comprehensive respiratory assessment which would usually be completed as part of the HaH service visits as well as prescribe exercise:

> *'One person, both skills, also whether they are physio or nurse doesn't matter'* [SM06, physiotherapy assistant, PR service team member]

This was important as patients and family carers preferred the prospect that one person, regardless of professional background (physiotherapist or nurse), could deliver all elements of their management (exercise training at home and exacerbation management). To this end, both patients and carers felt comfortable as long as appropriate training had been provided:

> *'Someone trained in that kind of rehabilitation, doesn't necessarily have to be someone trained and been through university'* [SU05, patient with COPD, previous experience of PR]
>
> *'We wouldn't mind if someone came out with someone who had to learn'* [SU01, relative to SU02, previous experience of PR and HaH]

Healthcare professionals felt that only a limited number of team members across the two existing services (HaH service and outpatient-based PR) currently held this skill set and additional training was beyond the scope of the trial this model of care would be tested in:

> *'Yes, it's [training required] not going to happen in a week, it's going to happen over several years, realistically I think, but ultimately, yes, long term'* [SM01, physiotherapist, PR service and HaH service team member]

It was therefore agreed that the delivery of home-based exercise training, whilst being tested within a

feasibility trial, would be restricted to delivery by those who already held this skill set as opposed to providing training to up-skill all healthcare professionals.

Finally, consistency and continuity in the assessments undertaken between outpatient-based PR assessments and those undertaken as part of home-based exercise training were highlighted to be important by all participants. It was acknowledged that this could be a challenge where there was transition of patients into outpatient-based PR within this co-designed model of care at time points which differed to when the trial assessments would be conducted. Nonetheless, patients and their family carers felt being selective with the assessments undertaken to avoid duplication, and not being required to repeat assessments unnecessarily would be preferable. They also felt that this would make them more likely to consider taking part in the study if assessments were closely aligned. Healthcare professionals also highlighted that carefully considering the assessments undertaken within the trial itself to mirror the data collected in the clinical assessments wherever possible to be practicable in the home setting. As such, the healthcare professionals felt streamlined assessments could also be beneficial:

> '*And that's the key thing, an assessment of some sort, as they would not be able to do all of the assessment that we do, but some of it'* [SM05, physiotherapist, PR service team member]

This could, in turn, relieve some of the burden on patients and their family carers as the appointments would be shorter, and potentially less frequent in number.

5.4.1.4 Communication between stakeholders

Two subthemes were identified within communication between stakeholders: communication between healthcare professionals and communication between healthcare professionals and service users. All participants felt that communication was an integral part of developing a model of care:

'You don't want to have to keep repeating yourself do you' [SU07, patient with COPD, previous experience of PR service]

'Suppose it would be nice [for the healthcare professionals to meet face-to-face], as you could have been in the hospital with one crowd, and it would be nice for the two of them to get together' [SU08, patient with COPD, previous experience of PR service and HaH service]

Healthcare professionals felt a combination of formal face-to-face meetings (weekly multidisciplinary team meeting) and daily handovers (either face-to-face, by telephone or email) was important for effective and regular communication between all the healthcare professionals involved. Face-to-face communication was preferred to telephone or email by healthcare professionals, however they felt this may not always achievable and therefore having alternative strategies as a backup was required:

'If different people are going in, erm, obviously different people going in on different days, there needs to be communication at end, or during every single day … obviously it would be nice to have that face to face contact, erm, but realistically it is not going to happen' [SM01, physiotherapist, PR service and HaH service team member]

Family carers had no preferences regarding the channels of communication between healthcare professionals as long as two criteria could be met: the healthcare professionals were able to discuss the care of a patient proficiently to ensure safe care could be provided, and personal information was not shared beyond those who should have access to it.

In terms of the communication between healthcare professionals and service users, all patients reported they would prefer to verbally communicate with healthcare professionals face-to-face where possible (for example during sessions), or via telephone between sessions:

'I think most people prefer a human body in front of them' [SU08, patient with COPD, previous experience of PR and HaH]

Patients reported they did not feel confident, or have access, to communicate via email or other online platforms such as a patient portal or app:

> *'My kids do [have access to the internet or smart phone], but I don't use that'* [SU08, patient with COPD, previous experience of PR and HaH]

Healthcare professionals from the HaH service felt it was important to discourage use of their direct telephone number for calls regarding home-based exercise training as the workload would potentially become too overwhelming for them to manage:

> *'To be honest, it [hotline] is a job on its own… it can take up a large proportion of the day whilst trying to see other patients on the wards'* [SM01, physiotherapist, PR service and HaH service team member]
>
> *'It is a nightmare, it is a nightmare, you can have 20 to 30 calls a day'* [SM07, nurse, HaH service team member]

They also felt it could be misleading for patients who would then not receive the support they anticipated for their home-based exercise training queries between sessions. All patients and family carers felt that provision of a separate telephone number was satisfactory as long as calls were returned in a timely manner should an issue arise.

5.4.2 Co-design meetings

The themes from the stakeholder events were explored further in the two co-design meetings, prior to the model of care being finalised. Discussion at the first co-design meeting with service uses and healthcare professionals focussed around integration and related to the themes of: progression and transitions during home-based exercise training and outpatient-based programme, continuity between services, and communication between stakeholders.

The findings of the meeting confirmed the need to individualise the timing of initiation and frequency of home-based exercise training sessions delivered from the outset at the first home-based exercise training session through a discussion with the patient and relative where appropriate. It also provided a consensus of the resources which would be used by all services in order to deliver consistent education (for example a HaH service leaflet on self-management and PR service presentation slides). It was also determined that the healthcare professional delivering the home-based exercise training would be required to attend the daily HaH service handovers in person or via telephone to implement the preferred communication strategy as much as possible. A written handover was only to be relied upon when a face-to-face or verbal handover was not feasible. Finally, it was identified that the healthcare professional delivering the home-based exercise training would primarily be required to be based at Hillingdon Hospital, the site which delivers the HaH service, as opposed to Harefield Hospital, the site which delivers PR, to facilitate the handover process.

Discussions at the second co-design meeting with healthcare professionals was more focussed on home-based exercise training delivery and related to the themes of: individualisation of home-based exercise training, and progression and transition during home-based exercise training and outpatient-based programme. It was determined that the same, pre-existing standard operating procedures for exercise prescription and progression available from the outpatient-based PR service would be followed during the home-based exercise training in order to ensure individualised training was delivered and to ease the transition between home-based exercise training and outpatient-based PR. In addition, it was confirmed that patients attending outpatient-based PR assessments prior to commencing and on completion of the programme would complete a shorter assessment which included the outcome measures which had not been completed as part of the trial assessments.

5.4.3 Model of care developed

Following the three stakeholder events and two co-design meetings, delivery strategies for home-based exercise training were finalised and a pathway for integration within a HaH service developed based on the findings reported. Figure 5.2 shows a schematic of the final co-designed model of care which will be piloted within a single-centre mixed methods trial to determine its feasibility and acceptability.

The home-based exercise training programme is intended to last up to eight weeks to replicate the local eight week outpatient-based PR programme provided, with the focus upon similar outcomes to traditional outpatient-based PR (exercise capacity / HRQoL / dyspnoea) (43, 46). All eight weeks of the home-based exercise training programme would be delivered at home for patients who decline referral to traditional outpatient-based PR. The home-based exercise training programme would continue to be delivered until the patient has completed their pre-PR assessment and the outpatient-based PR programme begins for patients who are referred to the traditional outpatient-based PR programme. For the patients transitioning into traditional outpatient-based PR, the home-based exercise training programme will serve as a bridging programme.

The intention is to replicate the types of exercises offered in traditional outpatient-based PR programmes delivered in community settings which uses minimal, low cost and portable equipment. This 'minimal equipment' strategy for delivering PR has recently been shown to be non-inferior to PR delivered using specialist equipment (39). Prescription of the exercise training provided within the home-based exercise training programme is intended to be completed using the same standard operating procedures as the traditional outpatient-based PR programme. The intensity of the home-based exercise training programme may initially differ whilst patients are early peri-exacerbation,

however the exercises would be progressed, and the intensity increased, as symptom burden reduces.

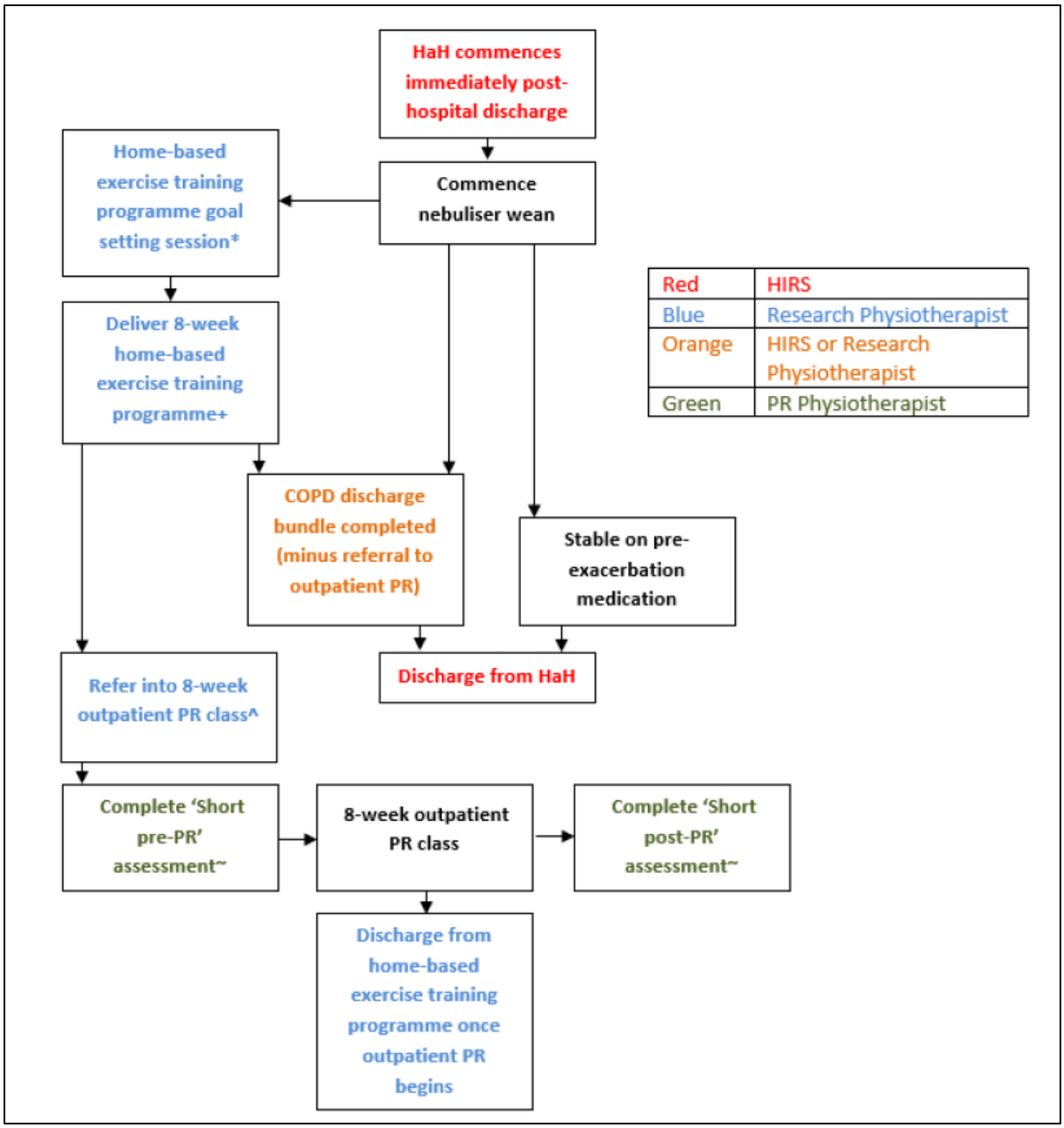


Figure 5.2. Schematic of the final co-deigned model of care.

Abbreviations: COPD: Chronic obstructive pulmonary disease; HaH: Hospital at home; HIRS: Hillingdon Integrated Respiratory Service; PR: pulmonary rehabilitation.

** Research Physiotherapist to ask participant re: preference for outpatient-based PR location, and when referral to outpatient-based PR may be acceptable to participant; Research Physiotherapist to identify availability for the preferred class at proposed start date.*

+ Deliver education topics alongside home-based exercise training using PR education pack/presentations and HIRS self-management plan; begin education with pacing, breathing control, positions of ease, anxiety management, self-management plan, smoking cessation, inhaler technique and airway clearance.

^ Research Physiotherapist to refer participant into outpatient-based PR if / when the participate consents to the referral; the same referral and triaging process to be followed when refereeing participants into an outpatient-based PR programme as usual care; continue the home-based exercise training programme until the outpatient-based PR class begins.
~ Research Physiotherapist to provide copy of home-based exercise training programme to outpatient-based PR; PR Physiotherapist to complete short pre-PR assessment; PR Physiotherapist to complete a short post-PR assessment at the end of the after 8 weeks of outpatient-based PR programme.

5.5 DISCUSSION

In this accelerated EBCD project, an integrated model of care, including home-based exercise training and HaH service, was co-designed by service users and healthcare professionals to address low uptake, referral and subsequent completion of PR following hospitalisation for an AECOPD.

5.5.1 Comparison of co-designed model of care to previous studies

Previous studies have shown barriers to post-hospitalisation PR to be complex and multifactorial. Commonly cited barriers to a traditional outpatient-based PR programme after an acute exacerbation include access to transport and travel (54, 133, 213). Delivery in the home setting was attractive given its potential as an equivalent alternative to outpatient-based PR in patients with stable COPD (79-81). It was felt that by looking for ways to embed home-based exercise training within an already established service (HaH), rather than attempting to establish an entirely new service, may result in a home-based programme being considered more feasible and acceptable post-hospitalisation to all stakeholders. This theory was supported by the pilot study by Murphy and colleagues, who demonstrated it may be viable to extend to scope of HaH services (47). As such, the primary intention of this project was to develop a co-designed model of care which integrates home-based PR within a well-established HaH service so that both could be seamlessly delivered together. It was also felt that simply mimicking home-based programmes delivered to those with stable COPD may render them unfeasible in the post-exacerbation population given the post-exacerbation population (suffering with

an acute worsening of symptoms) differs from those with stable COPD. This could allow for this intervention to be delivered at a point in the post-hospitalisation care pathway when it has the potential to achieve clinically meaningful outcomes (214).

5.5.2 Comparison of stakeholder perspectives to previous studies

As this was an accelerated EBCD project, it ensured the key stakeholders (patients with COPD, family carers and healthcare professionals) who participated were the drivers behind the model of care's design (135). To do this a wide range of stakeholder priorities were ascertained (210) but ensured a consensus was reached prior to investigation within a feasibility trial.

With regards to the model of care, there was agreement that home-based exercise training should be individualised, supervised and be sufficiently flexible to enable it to be tailored to meet the need of each patient. These findings reflect the results from the mixed methods systematic review presented in Chapter 4 (169). This suggests the findings from this EBCD project could have resonance for other services considering a redesign or for the development of other interventions specifically for this patient population.

There was also agreement from those involved in this EBCD project that delivery of a home-based exercise training programme using a mobile application, or another digital platform, might reduce accessibility. Recent data have shown 31% PR service users have never previously accessed the internet, less than half were confident using the internet and 29% reported no interest in accessing any component of PR through a web-based application (196). This degree of digital exclusion has been corroborated by a recent feasibility trial that found almost 50% of participants dropped out of a trial which tested an mHealth-based self-management intervention (215). The most common reason for

attrition was due to difficulties with the technology (215).

There was a strongly held desire among some patients to attend traditional outpatient-based PR when they felt well enough. However, other patients felt home-based exercise training was more suited to them and, even if offered, they would not attend traditional outpatient-based PR. The idea of offering outpatient-based PR was also welcomed by some of the healthcare professionals. Their belief was that outpatient-based face-to-face PR was the gold standard of post-exacerbation PR delivery, with an established evidence-base (46). The importance of ensuring evidence-based care continues was highlighted in a previous study which found people who received post-hospitalisation PR within three months of discharge to have lower mortality at one year compared to those who did not receive the programme (164). Therefore, to address this, progression and transition during the home-based exercise training and outpatient-based programme was explored in detail during the stakeholder events to ensure all patients would be provided with the opportunity to attend traditional outpatient-based PR.

Views on the timing of initiation of exercise training post-hospitalisation varied between, as well as within, the different stakeholder groups. This was unsurprising given a recent systematic review found disparities as to the optimal time to commence post-acute exacerbation exercise training (169). The results from Chapter 3 also demonstrated that the timing of intervention delivery may affect intervention efficacy and patient responsiveness (123). As such, in order to address these differences in perspectives of optimal timing for initiation, the decision was made to design a highly individualised model of care that could be sufficiently flexible and adaptable to meet the needs of each patient.

In addition to timing of initiation, the skill set required by the healthcare professional delivering home-

based exercise training was important. All the stakeholders involved felt those who delivered home-based exercise training to patients' post-exacerbation should be competent to undertake a comprehensive respiratory assessment as well as prescribe exercise. This led to discussions regarding the training requirements of the current healthcare professionals employed within the HaH service and PR service. However, given that there were already healthcare professionals employed, albeit a limited number, who had the skillset to deliver this comprehensive co-designed model of care, for the purpose of this project it was decided that up-skilling healthcare professionals was unnecessary. However, a training intervention which provides formal teaching and competency assessments surrounding exercise prescription and progression as well as respiratory assessment skills may be required in other settings or in the future. This might also address the issues around referrer knowledge identified in Chapter 2.

During this co-design process, additional learning was gained about what is important from key stakeholders' perspectives regarding home-based exercise training and integration of care following an AECOPD. This additional learning could be of value beyond this project, for example if other services are considering more closely integrated respiratory services, home-based exercise training programmes, or trying to enhance the delivery of traditional outpatient-based PR services for patients following hospitalisation for an AECOPD.

5.5.3 Interactions between stakeholders during project

Field notes of observations from the stakeholder events and co-design meetings were also included in the analysis. Of interest, it was noted by an event facilitator that healthcare professionals were keen to actively listen and make adaptations to their perspectives based upon the experience of patients and family carers. The healthcare professionals appeared to see the patients' perspectives as the most

important viewpoint during the decision-making process as patients and family carers had first-hand experience of living with COPD: they were the experts. Equally, patients and family carers seemed to look upon healthcare professionals as the experts. They were observed to defer their ideas back to healthcare professionals to prompt whether their suggestions were feasible and within the scope of a home-base exercise training programme. These observations could be interpreted in one of two ways. First, the observations could be interpreted as the stakeholder groups being deferential to one another, and as a result lead to the dampening down of stakeholder perspectives. Alternatively, it could be interpreted as a mutual respect between the different stakeholders, with recognition of the contribution each group and a desire to compromise in order to ensure acceptability and effectiveness. For this project, the latter interpretation was made for several reasons: 1) the intention of this project was to promote collaboration, which all the stakeholders were made aware of from the outset; and 2) both service users and providers were sufficiently confident to speak up during the discussions and 'stand their ground' on 'touchpoints' which they felt were particularly seminal, even if this viewpoint was divergent from others, both within and between their stakeholder group. Therefore, combining the field notes with the findings derived from the audio-recording transcripts was an important part of the interpretation as this elicited more in-depth understanding of the interactions and dynamics during the events. It also highlighted the truly collaborative process which was undertaken to develop this model of care, with the expertise of the healthcare professionals complementing the situational understanding of the service users (216).

5.5.4 Critique of the method

This model of care was developed using an accelerated EBCD process, a quality improvement approach that enables stakeholders to co-design services in partnership. This approach has been previously used in a range of clinical settings in the NHS (217, 218), including PR (219), and was the process used to develop the intervention tested in Chapter 3 (123). Other methodologies which actively engage with

stakeholders, including participatory action research (220) and multiple person-based approaches (221), were also considered. Nonetheless, as the end goal of this project was service design (EBCD was specifically developed for this purpose), and there was clear and comprehensive guidance produced by The Point of Care Foundation (135), the EBCD approach was adopted over other methodologies.

5.5.5 Strengths

A strength is that the accelerated EBCD process used to develop the model of care was informed by the findings of a mixed methods systematic review (PROSPERO: CRD42018104648) described in Chapter 4 (169). Consequently, the initial discussions at the stakeholder events, which were semi-structured in nature, were facilitated by seminal 'touchpoints' and evidence-based topics.

In addition, the systematic review of the previous chapter found no data on relative or informal carer perspectives of home-based exercise training following hospitalisation for an AECOPD (169). Therefore, this work in this chapter provided new insights into the experiences and perspectives from these key stakeholders. In so doing, this project provides some assurances that an integrated model of care which embeds home-based exercise training into a HaH service is not perceived by family carers as likely to increase their burden. This was important to ascertain given AECOPD has a negative impact upon family carers (28), and a home-based intervention may add unknowingly to this burden.

This project engaged a nationally accredited PR programme in the UK and a well-established respiratory-specific HaH service which has received recognition from the national clinical director for respiratory services at NHS England. Therefore, it was felt the perspectives of the healthcare professionals involved in this project included those with the expertise to provide valuable insights to aid decision-making, and as a result can be an exemplar for other services.

5.5.6 Limitations

This work only represents the perspectives of the participating stakeholders involved from one locality. Therefore, although these are perspectives of those with adequate expertise, it is acknowledged that the transferability of these insights may be limited, and the specific model of care developed in this project may require local adaptation and service-specific exploration before wider implementation is possible. Furthermore, all the family carers in attendance were female, who also self-identified as informal carers. As a result, there was a lack of male relative and informal carer perspectives reported within this project, and this requires further exploration in the future. Nonetheless, the background demographic sheets completed by the healthcare professionals and patients with COPD were more representative. For example, there were patients with COPD present from different genders, a range of ages, as well with a variety of experiences of post-hospitalisation care. For the healthcare professionals, it also appeared that there was a mix of genders, years of clinical experience and professional background present.

5.6 CONCLUSION

All the stakeholders involved in this project felt individualised, supervised and flexible home-based face-to-face exercise training was required. Disparate views between and within the different stakeholder groups regarding optimal timing for initiation of home-based exercise training further emphasised the need for a highly individualised and flexible model of care. This accelerated EBCD project also highlighted the need to carefully consider how a patient may transition and progress from home-based exercise training into outpatient-based PR, how continuity between services can be achieved and how to ensure effective communication between the varying stakeholder groups.

Based upon these findings, a model of care integrating home-based exercise training within a well-established HaH service has been co-designed by service users and healthcare professionals. This model of care was tested within an ethically approved, prospectively registered mixed methods feasibility trial (ISRCTN number: 78764132) described in the following chapter (Chapter 6).

Chapter 6: Testing the acceptability feasibility of a home-based exercise training intervention alongside a hospital at home service for AECOPD

Please note that recruitment to this study was suspended on 11th March 2020 due to the global Coronavirus Disease 2019 (COVID-19) pandemic. Recruitment to this study was unable to resume due to the ongoing COVID-19 restrictions and the study intervention not being viable whilst they remained in place

6.1 BACKGROUND

The results from Chapters 2 and 3 demonstrated suboptimal patient uptake rates to traditional outpatient-based pulmonary rehabilitation (PR) after an acute exacerbation of COPD (AECOPD). Subsequently, Chapters 4 and 5 described the co-design of an intervention that integrates home-based exercise training within a Hospital at Home (HaH) service. The current chapter reports the results of a mixed methods study (ISRCTN number: 78764132) exploring the acceptability and feasibility of such an intervention.

6.2 OBJECTIVES

To determine the acceptability of a home-based exercise training intervention for healthcare staff, patients and carers, and the feasibility of conducting a future efficacy trial.

6.3 HYPOTHESIS

A co-designed home-based exercise training intervention, delivered alongside a HaH service for AECOPD, is acceptable to service users and staff and feasible to implement in an efficacy trial.

6.4 METHODS

6.4.1 Study design

This was a mixed method feasibility study including a parallel, two-group RCT with convergent qualitative components (interviews with patients, family members and informal carers and researchers; focus groups with healthcare professionals) (100). Figure 6.1 provides a schematic of the study design.

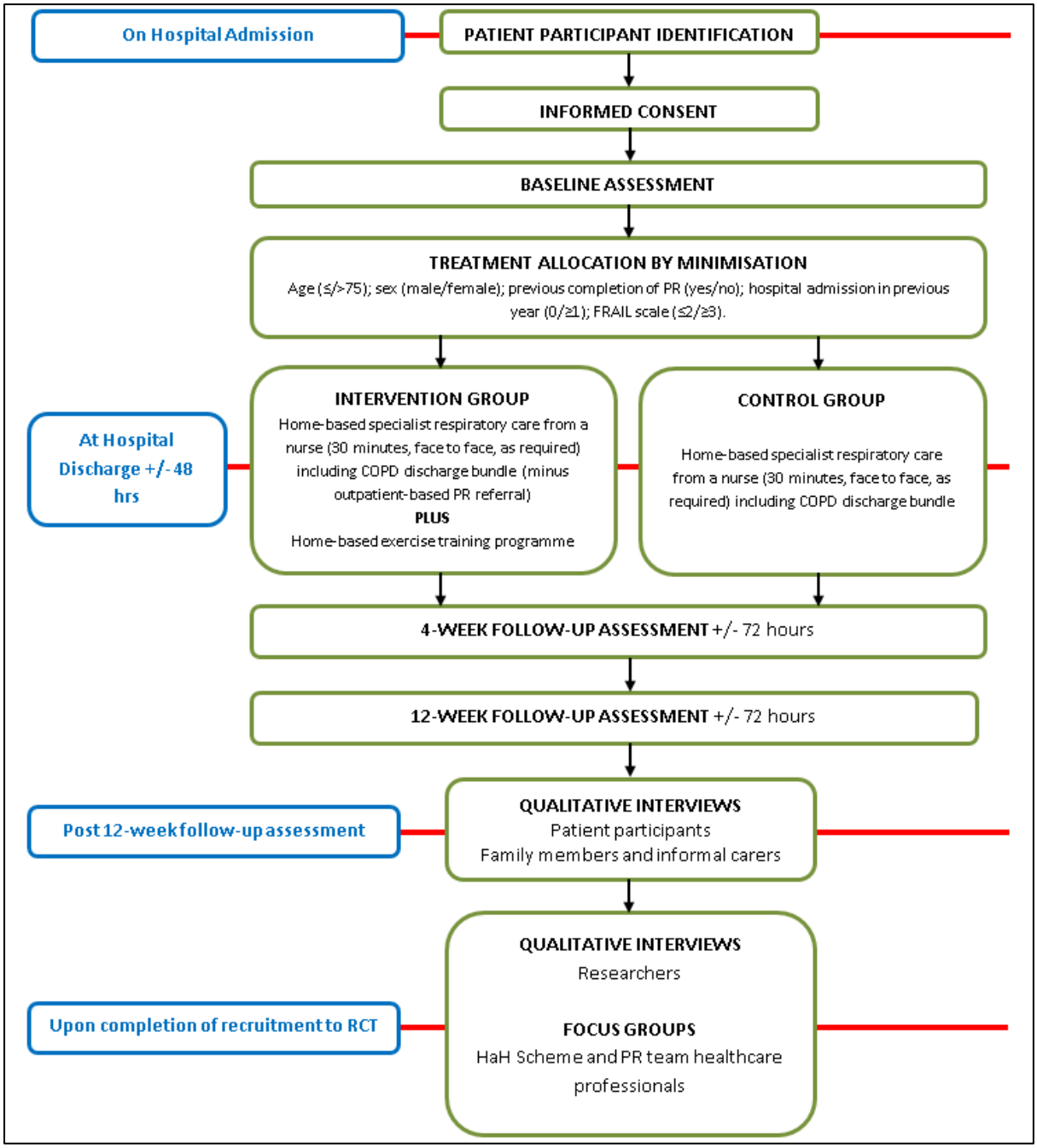


Figure 6.1. Schema of mixed methods feasibility study design.
Abbreviations: COPD: chronic obstructive pulmonary disease; HaH: Hospital at Home; hrs: hours; PR: pulmonary rehabilitation; RCT: randomised controlled trial.

6.4.2 Ethical approval and study registration

The study was approved by the London - Dulwich Research Ethics Committee (19/LO/1472). All patient participants provided written informed consent when recruited to the RCT, and additional written

informed consent was received from all patient participants who participated in the qualitative interviews. Written informed consent was also received from all family members or informal carers, researchers and healthcare professionals participating in qualitative interviews or focus groups. The study was prospectively registered on the ISRCTN registry (78764132).

6.4.3 Participants

6.4.3.1 Trial eligibility criteria

The original planned recruitment period was November 2019 and October 2020. Unfortunately, due to the Coronavirus pandemic, recruitment was limited to between November 2019 and 11th March 2020.

The local HaH service is delivered by the Hillingdon Integrated Respiratory Service (HIRS), the single provider for all patients registered with a general practice within Hillingdon borough. HIRS were actively involved in the co-design process detailed in Chapter 5.

Inclusion criteria included aged 40 years or over, with a diagnosis of COPD, hospitalised with a primary diagnosis of an AECOPD and a DECAF score of ≤1 (85) on admission as this is associated with low risk of mortality, an important consideration for home-based intervention. Exclusion criteria included being ineligible for HaH service due to local HIRS criteria. The full inclusion and exclusion criteria are presented in Table 6.1.

Table 6.1. RCT eligibility criteria

Eligibility criteria	
Inclusion criteria	**Exclusion criteria**
Aged 40 years or over	Receiving specialist palliative care with expectation of death within three months as judged by the specialist palliative care service
Known diagnosis of COPD	No fixed abode or evidence of an environment that would make delivery of study intervention and/or usual care unsafe
Hospitalised with a primary diagnosis of an AECOPD	Evidence of acute coronary syndrome, unstable ischaemic heart disease or any condition that would make exercise unsafe.
DECAF score of ≤1	Does not fulfill inclusion criteria for HaH care according to HIRS local Standard Operating Procedures. Inclusion criteria for HaH care are: • Presenting condition is COPD not asthma • Medically stable • No nocturnal dyspnoea • pH within normal limits and no acidosis • PaO_2 >7kPa and SaO_2 >90% (unless known baseline = ≤90%-≥88%) on room air or on usual prescribed domiciliary oxygen • No acidosis • No pneumothorax on CXR • Minimal consolidation on CXR • Minimal wheeze on auscultation • No signs of worsening pulmonary oedema • No acute confusion • Lives within designed area of service • Access to property (patient / key safe / entry phone) • Does not live alone (or is safe to do so) • Telephone access (mobile or landline) • Able to transfer independent and walk to bathroom (or with usual support, which is available) • Self-caring at home (or with usual support, which is available) • Self-medicating (or with usual support available)
Able to give valid informed consent	

Abbreviations: COPD: chronic obstructive pulmonary disease; CXR: chest x-ray; HIRS: Hillingdon Integrated Respiratory Service; kPa: kilopascal; PaO_2: partial pressure of oxygen; pH: potential of hydrogen; RCT: randomised controlled trial; SaO_2: arterial oxygen saturation.

6.4.3.2 Qualitative interviews and focus group purposive sampling criteria

Using purposive sampling (222), a sub-group of patient participants (from both control and intervention groups), family members or informal carers, researchers and healthcare professionals were invited and consented to qualitative interviews or focus groups (sections 6.4.9.2 and 6.4.9.3 details the target sample size for the interview sand focus groups respectively). For patient participants and their family members or informal carers, the interviews occurred following the 12-week follow-up visit. Table 6.2 includes the purposive sample criteria for the patient participants, the purposive sampling frame for the family members or informal carers, researchers and healthcare professionals. The invited healthcare professionals included all members of the multidisciplinary team: clinical nurse specialists, qualified physiotherapists and physiotherapy assistants. Researchers were invited via their line manager to be interviewed. The embedded qualitative interviews and focus groups were conducted by independent researchers from King's College London (Lisa Jane Brighton and Joanne Bayly). The qualitative interviews and focus groups were audio recorded and transcribed verbatim, with transcripts offered for verification of accuracy to interviewees prior to anonymisation and analysis (223). Observational logs/field notes were recorded to describe the flows, contextual factors, participant responses and researcher reflections.

Table 6.2. Purposive sampling criteria for qualitative components

Patient participants	
A. Protocol completion	1) Completed course of care per protocol 2) Did not complete course of care per protocol
B. Readmission in 12 weeks of hospital discharge	1) Readmitted 2) Not readmitted
C. Social situation	1) Lives alone 2) Does not live alone
D. Improvement in HRQoL in 12 weeks from hospital discharge	1) Change in CAT score of ≥2 points 2) Change in CAT score of <2 points
Family member and informal carers	
Person nominated by the participant as giving them the most help and support due to their COPD and who is not a healthcare professional	1) Aged >18 years of age 2) Able to understand and speak English 3) Able to give valid informed consent
Researchers and healthcare professionals	
Those involved in study delivery	1) Provision of usual care 2) Provision of outpatient-based pulmonary rehabilitation 3) Provision intervention procedures 4) Provision of research assessments

Abbreviations: CAT: COPD Assessment Test; COPD: chronic obstructive pulmonary disease; HRQoL: health-related quality of life.

6.4.4 Randomisation procedure

Patients were randomised 1:1 using minimisation to either the control (HaH care alone) or intervention (home-based exercise training integrated within HaH care). The allocation sequence was computer-generated (Minim) (130). Minimisation was used to balance pre-defined variables, especially as planned sample sizes was not large (131).

The groups were balanced according to five criteria: 1) age (years: ≤/>75), 2) sex (male/female), 3) physical frailty status (4MGS: ≤/>0.6 metres/second (224)), 4) previous hospital admissions in past year (0/≥1), and 5) age-adjusted Charlson Comorbidity Index (0/≥1). These five criteria were factors that were considered clinically relevant and which could mediate post-hospitalisation outcome (224).

6.4.5 Blinding

Baseline assessments were conducted prior to randomisation. I (as a clinically trained Highly Specialised Respiratory Physiotherapist in early supported discharge and exercise-training in chronic respiratory disease) delivered the home-based exercise training intervention. The follow-up research assessments were completed by researchers from the Harefield Respiratory Research Group (Jessica Walsh, Suhani Patel, Oliver Polgar and Claire Nolan) blinded to group allocation. Due to the nature of the study intervention, participants were unable to be blinded to group allocation. The statistical analysis plan was determined *a priori*.

6.4.6 Study interventions

The control group received a nursing-focused HaH service delivered by specialist respiratory healthcare professionals, typically comprising: 'as required' face-to-face sessions incorporating monitoring of vital signs, provision of oral antibiotics and/or steroids, nebulised bronchodilators, and oxygen if needed for hypoxaemia. This treatment was provided in line with the British Thoracic Society guideline recommendations (83).

The intervention group received the same usual care as the control group. The intervention group also received a home-based exercise training intervention integrated within their usual HaH service care.

This involved face-to-face supervised, individually tailored (and subsequently progressed) exercise training and education. Chapters 4 and 5 comprehensively described this intervention development process. The intervention was provided by the same specialist respiratory healthcare professional providing usual care.

6.4.7 Study measurements

A structured history taken prior to discharge from hospital included smoking status, index of multiple deprivation, comorbidity burden (age-adjusted Charlson Comorbidity Index), respiratory disability (extended MRC [eMRC] dyspnoea score (138)), and DECAF score (85)). In addition, the following were measured on the day of hospital discharge, or at home within 48 hours of hospital discharge if collection of outcome measures would delay hospital discharge, prior to randomisation:

- Independence in activities of daily living (London Chest ADL Questionnaire [LCADL]);
- Accelerometer-measured daily physical activity (ActiGraph GT3X);
- Short Physical Performance Battery (SPPB);
- Hand grip strength;
- HRQoL (COPD Assessment Test [CAT]);
- Health utility (Euro-QoL 5-dimensions 5-levels [EQ5D5L]);
- Anxiety and depression (Hospital and Anxiety Depression Scale [HADS]);
- Fatigue (modified Center for Epidemiologic Studies Depression [mCES-D] score);
- Six-minute step test (6MST); and
- Body composition (bioelectrical impedance analysis [BIA]).

The same measures were re-measured at four weeks and 12 weeks following hospital discharge.

6.4.7.1 Smoking status (smoking history and pack years)

Smoking history and pack year history were recorded at baseline to determine smoking status as described in sections 2.4.5.4 and 3.4.7.1.

6.4.7.2 Index of multiple deprivation

Index of multiple deprivation was calculated at baseline using the patients' home postcode as described in section 2.4.5.5.

6.4.7.3 Comorbidity burden (age-adjusted Charlson Comorbidity Index)

The age-adjusted Charlson Comorbidity Index was recorded at baseline to determine comorbidity burden, and subsequent morality risk for patients admitted to hospital (141) as described in section 3.4.7.2.

6.4.7.4 DECAF score

DECAF score was calculated at baseline as it is a well-established, validated prognostic marker for hospitalised AECOPD (85) as described in section 2.4.5.6.

6.4.7.5 Respiratory disability (eMRC dyspnoea scale)

The eMRC dyspnoea score was recorded to measure respiratory disability at baseline, four weeks and 12 weeks as described in section 3.4.7.7. The eMRC dyspnoea scale divides those in category 5 "too

breathless to leave the house" into 5a (those able independently to manage washing and/or dressing) and 5b (those requiring assistance with both washing and dressing) to include an assessment of a patient's capacity to manage personal care. It is used to predict in-hospital mortality as part of the DECAF score (225).

6.4.7.6 Ability to complete activities of daily living (ADL) (LCADL scale)

The LCADL scale was recorded to measure difficulty and ability to complete ADLs at baseline, four weeks and 12 weeks. This is a measure of ability to perform activities of daily living, and has 17 items, and four sub-domains: self-care, domestic, physical, and leisure (Figure 6.2) (226). Total score ranges from 0 to 75, with sub-domain scores 0 to 20, 0 to 30, 0 to 10 and 0 to 15 for self-care, domestic, physical, and leisure respectively. The higher the score, the greater breathlessness experienced completing ADLs. The LCADL scale has been shown to be reliable and valid for use in COPD and correlate with other established measures (226, 227), as well as responsive to PR (227). The proposed minimal detectable change of LCADL scale is 4 points (228).

TABLE A1 THE LONDON CHEST ACTIVITY OF DAILY LIVING SCALE

NAME. . . . . .
DATE OF BIRTH. . . . . .
DO YOU LIVE ALONE Yes ☐ No ☐
Please tell us how breathless you have been during the last few days whilst doing the following activities.

SELF-CARE						
Drying	0	1	2	3	4	5
Dressing upper body	0	1	2	3	4	5
Putting shoes/socks on	0	1	2	3	4	5
Washing hair	0	1	2	3	4	5
DOMESTIC						
Make beds	0	1	2	3	4	5
Change sheet	0	1	2	3	4	5
Wash windows/curtains	0	1	2	3	4	5
Clean/dusting	0	1	2	3	4	5
Wash up	0	1	2	3	4	5
Vacuuming/sweeping	0	1	2	3	4	5
PHYSICAL						
Walking up stairs	0	1	2	3	4	5
Bending	0	1	2	3	4	5
LEISURE						
Walking in home	0	1	2	3	4	5
Going out socially	0	1	2	3	4	5
Talking	0	1	2	3	4	5

How much does your breathing affect you in your normal activities of daily living?
A lot ☐ A Little ☐ Not at all ☐

The London Chest Activity of Daily Living Scale. (Score sheet)

Please read carefully and circle the relevant number next to each activity.
This questionnaire Is designed to find out whether there are activities that you can no longer do because of your breathlessness, and how breathless the things that you still do, make you. All answers are confidential.
If you do not do an activity because it is not relevant, or you have never done it, please answer;
0 Wouldn't do anyway
If an activity is easy for you, please answer;
1 Do not get breathless
If the activity makes you a bit breathless, please answer;
2 I get moderately breathless
If the activity makes you very breathless, please answer;
3 I get very breathless
If you have stopped doing this **because of your breathlessness** and ***have no one else to do It for you***, please answer;
4 I can't do this anymore.
If someone else does this for you, or helps you, BECAUSE you are too breathless eg. The home help does your shopping, please answer;
5 I need someone else to do this.

Figure 6.2. London Chest Activities of Daily Living questionnaire.

6.4.7.7 Accelerometer-measured daily physical activity (ActiGraph wGT3x)

In order to measure physical activity, patient participants were invited to wear a tri-axial accelerometer (ActiGraph wGT3x (229)) for seven days and nights (for 24 hours a day, except when performing personal hygiene tasks) at baseline, four weeks and 12 weeks. This ActiGraph monitor has been validated for use in patients with COPD to measure physical activity when worn on the hip (229). Figure 6.3 illustrates the position the Actigraph wGT3x is worn.

Figure 6.3. Position for wearing ActiGraph wGT3x.

6.4.7.8 The Short Physical Performance Battery (SPPB)

The SPPB was recorded to measure lower limb functional performance and physical frailty status at baseline, four weeks and 12 weeks (230-232). It comprises an assessment of three components: standing balance, usual walking speed (as detailed in section 3.4.7.5) and ability to stand from a chair. Each component is scored from 0-4, with a total score out of 12. Higher scores indicate better functional performance. Appendix 4 provides the standard operating procedure for measuring and scoring SPPB.

6.4.7.9 Hand grip strength

Hand grip strength was recorded at baseline, four weeks and 12 weeks. This was measured using a Jamar Hand Grip Dynamometer which has an adjustable grip to accommodate the users hand size (Figure 6.4). Measurement was standardised (233) and normalised to population values (234). Grip strength has been correlated with overall body strength, and associated with mortality in COPD (235).

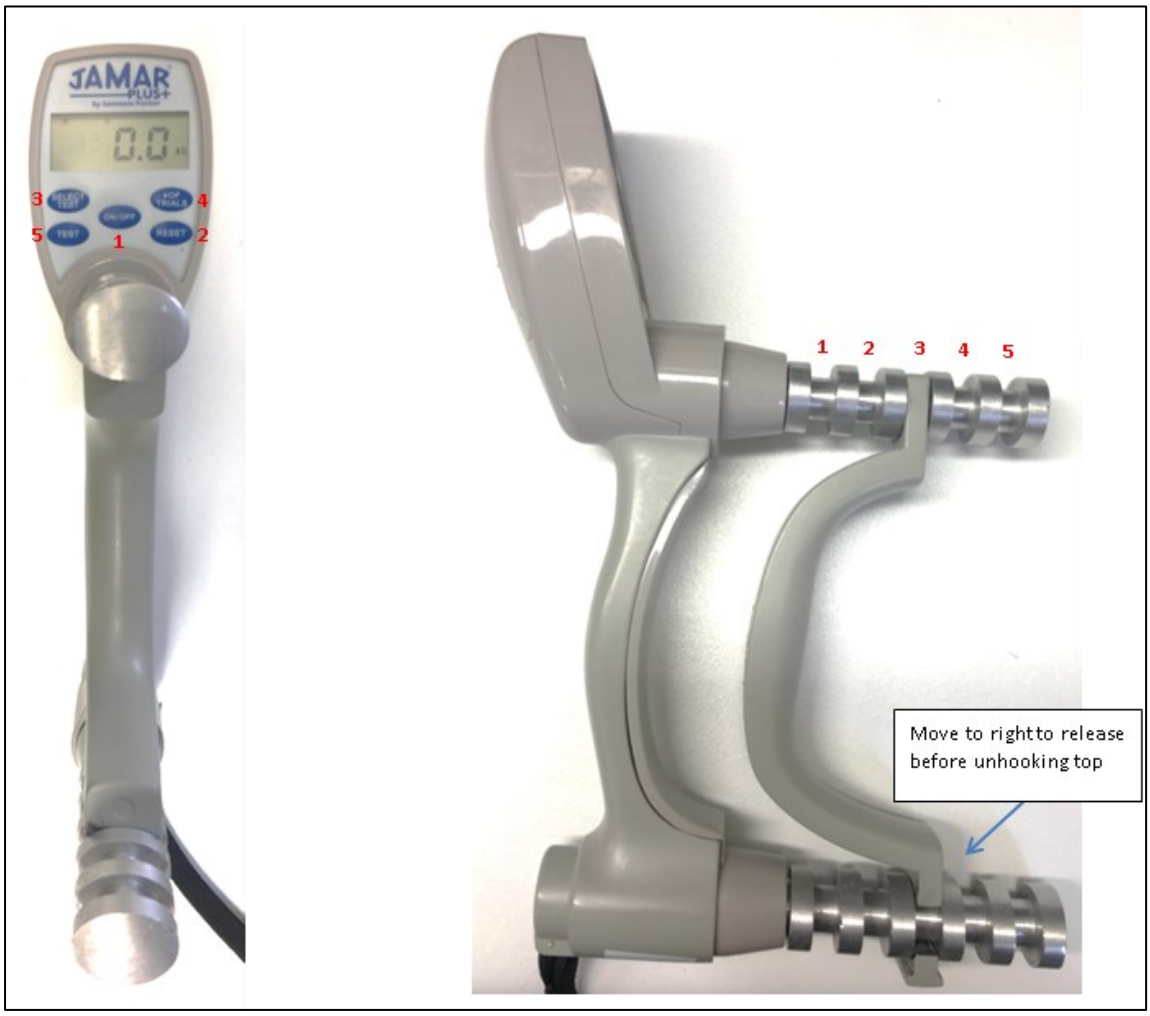


Figure 6.4. Jamar Hand Grip Dynamometer.

6.4.7.10 HRQoL (COPD Assessment Test [CAT])

The CAT was recorded to measure HRQoL at baseline, four weeks and 12 weeks as detailed in Section 3.4.7.8. Figure 3.7. includes the CAT questionnaire.

6.4.7.11 Health utility (Euro-QoL 5-dimensions 5-levels [EQ5D5L])

The EQ5D5L questionnaire was recorded to measure health utility at baseline, four weeks and 12 weeks. The EQ5D5L comprises a visual analogue scale and five-item questionnaire with the following domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (Figure 6.5) (236). It has been shown to be valid in COPD, as well responsive to PR, with a minimum clinically important difference of 0.051 and 7 for utility index and visual analogue scale respectively (236).

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about	❑
I have slight problems in walking about	❑
I have moderate problems in walking about	❑
I have severe problems in walking about	❑
I am unable to walk about	❑

SELF-CARE

I have no problems washing or dressing myself	❑
I have slight problems washing or dressing myself	❑
I have moderate problems washing or dressing myself	❑
I have severe problems washing or dressing myself	❑
I am unable to wash or dress myself	❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities	❑
I have slight problems doing my usual activities	❑
I have moderate problems doing my usual activities	❑
I have severe problems doing my usual activities	❑
I am unable to do my usual activities	❑

PAIN / DISCOMFORT

I have no pain or discomfort	❑
I have slight pain or discomfort	❑
I have moderate pain or discomfort	❑
I have severe pain or discomfort	❑
I have extreme pain or discomfort	❑

ANXIETY / DEPRESSION

I am not anxious or depressed	❑
I am slightly anxious or depressed	❑
I am moderately anxious or depressed	❑
I am severely anxious or depressed	❑
I am extremely anxious or depressed	❑

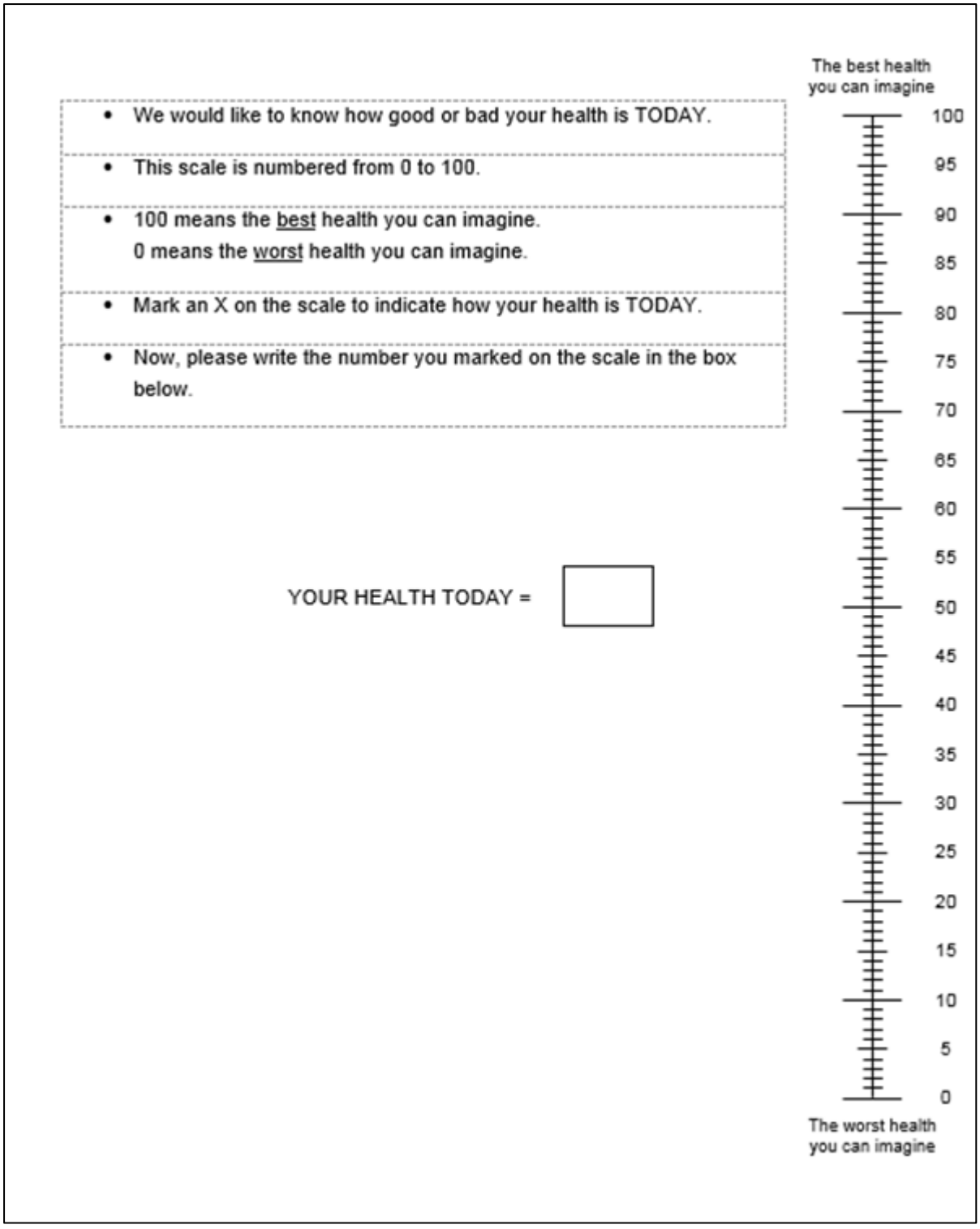


Figure 6.5. Euro-QoL 5-dimensions 5-levels questionnaire.

6.4.7.12 Anxiety and depression (HADS)

The HADS was used to measure levels of anxiety and depression at baseline, four weeks and 12 weeks. The 14-item scale is comprised of seven items related to anxiety and seven related to depression. Each item is scored from 0 to 3. Scores for the seven anxiety and seven depression items both range from 0 to 21, with scores of ≤7, 8 to 10 and ≥11 indicating normal mood, presenting with anxiety or depression and probable mood disorder respectively (Figure 6.6) (237). The minimal important difference in patients with COPD is -1.5 for both anxiety and depression (238).

HAD SCALE

Study ID: .....

Date: .....

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be able to help you more. This questionnaire is designed to help your doctor to know how you feel. Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response.

TICK ONLY ONE WHITE BOX IN EACH SECTION

I feel tense or wound up:			**I feel as if I am slowed down:**		
Most of the time			Nearly all the time		
A lot of the time			Very often		
Time to time			Sometimes		
Not at all			Not at all		
I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like butterflies in the stomach:**		
Definitely as much			Not at all		
Not quite so much			Occasionally		
Only a little			Quite often		
Hardly at all			Very often		
I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**		
Very definitely and quite badly			Definitely		
Yes, but not too badly			I don't take so much care as I should		
A little, but it doesn't worry me			I may not take quite as much care		
Not at all			I take just as much care as ever		
I can laugh and see the funny side of things:			**I feel restless as if I have to be on the move:**		
As much as I always could			Very much indeed		
Not quite as much now			Quite a lot		
Definitely not so much now			Not very much		
Not at all			Not at all		
Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**		
A great deal of the time			As much as ever I did		
A lot of the time			Rather less than I used to		
From time to time but not too often			Definitely less than I used to		
Only occasionally			Hardly at all		
I feel cheerful:			**I get sudden feelings of panic:**		
Not at all			Very often indeed		
Not often			Quite often		
Sometimes			Not very often		
Most of the time			Not at all		
I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV programme:**		
Definitely			Often		
Usually			Sometimes		
Not often			Not often		
Not at all			Very seldom		

Figure 6.6. Hospital Anxiety and Depression Scale.

6.4.7.13 Fatigue (mCES-D)

Two questions from the CES-D scale (239) were recorded to measure levels of fatigue at baseline, four weeks and 12 weeks. Each question is scored 0 to 3, and a higher the score indicates higher levels of fatigue (Figure 6.7).

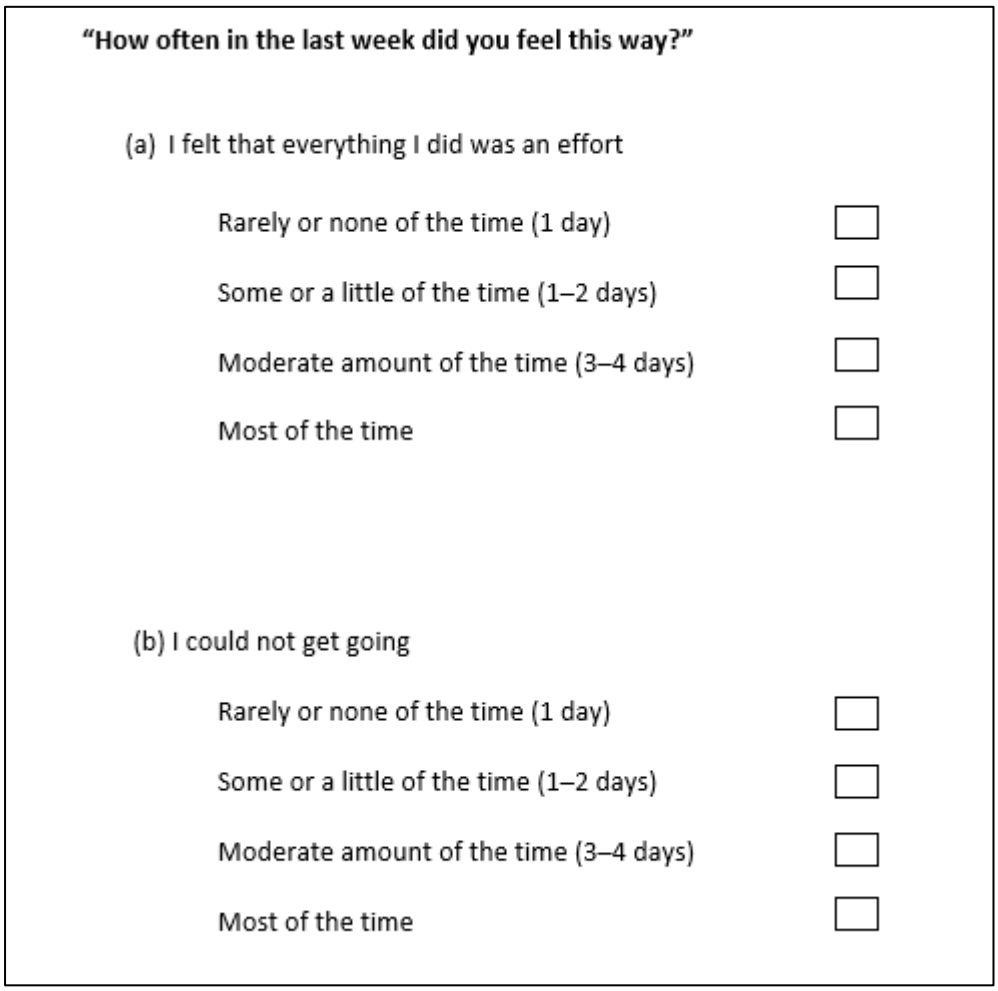


Figure 6.7. Modified Centre for Epidemiologic Studies Depression questionnaire.

6.4.7.14 Six-minute step test (6MST)

Participants were invited to perform the 6MST at baseline, four weeks and 12 weeks to measure functional capacity. Participants were asked to step-up and down a 20cm portable step for six minutes. Measures of breathlessness, perceived exertion and leg fatigue, oxygen saturation levels and heart

rate were recorded pre-, during and post- test. The total number of steps achieved in six minutes were used for analysis. The 6MST of free cadence was developed from the same principles as the six-minute walk test. In patients with COPD the 6MST has been shown to have excellent intra-rater reliability (240) and correlate strongly with exercise capacity (241). A cut-off point of 78 steps was able to identify patients with poor exercise capacity (240). Staff trained to follow the local standard operating procedure performed the 6MST assessments (Appendix 5).

6.4.7.15 Body composition (bioelectrical impedance analysis)

Bioelectrical impedance analysis was recorded to measure body composition using a Bodystat Quadscan 4000 (Figure 6.8) at baseline, four weeks and 12 weeks (242). This procedure involves sending a very small current through the body (800 mA at 50 kHz) and measuring its resistance via electrodes placed on the hands and feet (Figure 6.9 shows correct electrode placement). The current cannot be felt by the patient. This method of measuring body composition has been shown to be reproducible in patients with COPD undergoing PR (243). Staff trained to follow the local standard operating procedure performed the bioelectrical impedance analysis assessments.

Figure 6.8. Bodystat Quadscan 4000.


Figure 6.9. Correct electrode placement using Bodystat Quadscan 4000.

6.4.8 Study outcomes

6.4.8.1 Study feasibility outcomes

Outcome measures to determine study feasibility of a future efficacy trial included:

1. Number of patients screened for eligibility, proportion of eligible patients randomised; proportion of participants remaining in the study at four weeks and 12 weeks;

2. Proportion of patients for which assessor blinding is maintained at four weeks and 12 weeks; and

3. Completion rates and missing data for clinical outcome measures at baseline, four weeks and 12 weeks (detailed in section 6.4.7).

6.4.8.2 Intervention feasibility outcomes

Outcome measures to determine intervention feasibility of a future efficacy trial included:

1. Number of HaH visits and type of HaH care provided; proportion implemented by different healthcare professionals; contamination in usual care group;
2. Home-based exercise training uptake and adherence;
3. Proportion referred to outpatient-based PR at discharge and on discharge from HaH service; and
4. Uptake and completion of outpatient-based PR.

6.4.8.3 Clinical outcomes

The outcome measures detailed in section 6.4.7 were collected at baseline, four weeks and 12 weeks.

6.4.8.4 Safety outcomes

Safety outcomes in the 12-week follow-up period were:

1. Adverse events;
2. Mortality (including time to death); and

3. Hospital readmissions (including number of hospital admissions and number of inpatient bed days).

6.4.8.5 Qualitative outcomes

The qualitative outcomes were to understand experiences of people living with COPD, their family members or informal carers and healthcare professionals of the HaH model of care, including acceptability and integration across services. Each stakeholder group had a stakeholder group specific topic guide (Appendix 6 includes the final versions of the topic guides). The patient participant, family carer and healthcare professional interviews were primarily focused around feasibility and acceptability of the study intervention and integration between PR and HaH; the researcher interviews were primarily focussed around feasibility of study delivery and acceptability of study assessments.

The two researchers who conducted the interviews and focus groups were involved in devising and inductively updating the topic guides throughout the qualitative components of this study. This was done via initial scoping meetings to ensure the researchers conducting the interviews and focus groups understood the nuances of the prompts I had suggested within the first iteration of the topic guides, and through routine verbal debriefing between myself and the two researchers after each interview or focus group. The debriefs were supported by field notes regarding contextual factors and reflections. Appendix 7 includes the reflective proforma completed after each interview or focus group.

The first iteration of the patient participant interview topic guide underwent minor revisions prior to the first interview. This was to create separate patient participant and family carer interview topic guides as the first iteration of the topic guide was generic. Some of the prompts were also reworded

to aid the clarity of the probing information for the researchers. Sections related to the context of why the interviews were being conducted and the qualitative objectives was also added to the beginning of this iteration of the topic guide to support the two researchers in opening an initial dialogue with the interviewees.

The topic guides were subsequently inductively updated at two of the debriefing meetings. The first meeting resulted in the additional prompts to aid exploration of unmet needs and barriers to the intervention more fully. Another adaptation was to refine the language used in the family carer interview topic guide to make the prompts more relevant to family carers.

The final adjustments made to the topic guides were to more specifically tailor the topic guides for telephone or online interviews and focus groups as opposed to face-to-face data collection. This occurred as a result of the restrictions imposed due the COVID-19 pandemic. The amendments included additional checks at start and end of interview regarding consent and participant well-being respectively, as well as prompts to understand the impact of COVID-19.

All the iterations of the topic guides were approved by both researchers and myself prior to use to confirm the amendments reflected both the researcher's perceptions of the updates required as well as to ensure I felt the objectives of the study were retained.

6.4.9 Sample size

6.4.9.1 Trial sample size

There was no formal sample size calculation based on an effect size as this is not appropriate for feasibility studies (244). However, sample sizes of 24-50 participants (in each group) have been recommended for assessing the feasibility of an intervention (245, 246), whilst Browne *et al.* state that at least 30 patients should be included to estimate a parameter for any future sample size calculation (247). Therefore, allowing for up 25% attrition, 80 patient participants (40 per group) was the recruitment target.

6.4.9.2 Qualitative interviews sample size

The sample size for the embedded qualitative interviews was based on the predicted minimum number of interviews likely required to achieve saturation based upon the concept of Information Power (152). Section 3.4.9.2 provides further detail regarding data saturation and Information Power. A minimum number of 12 interviews were thus intended to be completed in this study (153).

6.4.9.3 Qualitative focus groups sample size

Using the same concept of Information Power (152) as applied for the interview sample size, a minimum of two, and up to six focus groups were anticipated to be required (248). Therefore, a minimum of two focus groups were planned to be conducted.

6.4.10 Data analysis

A segregated analysis method (154), which complements the convergent mixed methods design selected for this study (100)) commenced with initial analysis of the quantitative and qualitative data undertaken separately. The statistical analysis plan (section 6.4.10.1) and qualitative analysis plan (section 6.4.10.2) are outlined below. Following initial analysis of the quantitative and qualitative data separately, the findings were subsequently integrated. Section 6.4.10.3 provides details of the integrated analysis plan.

6.4.10.1 Statistical analysis

A CONSORT flow diagram was drawn up to detail the number of eligible patients and the number consenting. A breakdown of the numbers of participants completing the study protocol and analysed was included with the missing data summarised overall and by study group. Feasibility outcomes were described using proportions and corresponding 95% CIs, or for continuous variables, mean (SD) and median IQR). Clinical and safety outcomes were described without effect size or inferential testing.

6.4.10.2 Qualitative analysis

I analysed the qualitative data, supported by a co-analyst for a subsample of transcripts, using inductive thematic analysis (249) involving five key stages (familiarisation, coding, theme development, defining themes and reporting), facilitated by NVivo (250, 251). Analysis of interviews and focus groups explored the views of patient participants, family members and informal carers, and healthcare professionals. A particular focus was on similarities and differences between stakeholder groups. This was considered important due to the inherently linked, but potentially divergent experiences, of these key stakeholders (177).

6.4.10.3 Integrated analysis

A mixed method matrix (205) of patient participants and family member and informal carer key qualitative and quantitative data was used to illuminate barriers and facilitators for intervention completion to inform intervention optimisation prior to a efficacy trial. The data sets were also compared according to the study feasibility, clinical outcomes and safety to gain a more in-depth understanding of these outcomes. The integrated analysis is reported using a modified joint display table (178).

During the integration phase, when the quantitative and qualitative data were used to explore the same phenomenon, they were compared to 'confirm' or 'refute' each other. When differing constructs were explored in the quantitative and qualitative data, these data were used to 'complement' each other. 'Silence' exists when an aspect of a phenomenon was only present in either quantitative or qualitative data set. Section 4.3.9 provides the rationale for using this process of triangulation (179).

6.5 QUANTITATIVE RESULTS

Study screening took place from 1st November 2019 to 11th March 2020. Sixteen patients were recruited, and all 16 were randomised (eight per group). Section 6.5.1 provides the baseline characteristics (demographics, questionnaire scores and physical assessment results). Section 6.5.2 provides a commentary of participant flow along with results related to the other study feasibility outcomes. The remaining sections report the findings related to intervention feasibility, clinical outcomes and safety.

6.5.1 Baseline characteristics

The baseline demographics of the 16 participants randomised are shown in Table 6.3. 56% of the randomised participants were male, with a mean (SD) age of 74 (9) years. At baseline, the participants had severe airway obstruction (median [IQR]: FEV_1 29 [21, 40]) percent predicted), significant respiratory disability (87% with an eMRC dyspnoea score of 4, 5a or 5b) and a normal BMI (mean [SD]: 27.3 [6.6] kg/m^2). Inpatient length of stay was a median (IQR) of 4 (2, 6) days, with 31% requiring non-invasive ventilation during their hospital admission.

The baseline questionnaire scores and physical assessment findings for the whole group, and according to group allocation, are presented in Tables 6.4 and 6.5 respectively. Patients had a high burden of COPD (mean [SD] CAT score: 22 [9] (149)), were physically frail (mean [SD] SPPB score of 7 [3] (252), and had poor exercise capacity (median [IQR] number of steps completed during 6MST of 21 [9, 36] (240)) at hospital discharge.

Table 6.3. Baseline demographics for whole group and according to group allocation

Variable	Whole group (n=16)	Intervention (n=8)	Control (n=8)
Age* (years)	74 (9)	74 (8)	74 (11)
Male* (n (%))	9 (56)	4 (50)	5 (63)
BMI (kg/m^2)	27.3 (6.6)	25.5 (7.7)	29.2 (5.0)
FEV_1 (% predicted)	29 (21, 40)	38 (19, 44)	28 (27, 34)
FEV_1/FVC ratio	0.43 (0.17)	0.44 (0.21)	0.43 (0.12)
DECAF (n=12)	2 (1, 3)	2 (1, 3)	2 (1, 3)
eMRC (3; 4; 5a; 5b) (n)	2; 4; 8; 2	1; 1; 6; 0	1; 3; 2; 2
Previous respiratory-cause hospitalisations in past 12 months*	3 (2)	4 (3)	2 (1)
Age-adjusted Charlson Comorbidity Index*	4 (3, 5)	5 (4, 6)	4 (3, 5)
Index of multiple deprivation decile	5 (2)	6 (2)	5 (3)
Index of multiple deprivation rank	16568 (8476)	18203 (7856)	14934 (9280)
Inpatient length of stay (days)	4 (2, 6)	3 (2, 5)	6 (3, 9)
Smoking status (ex-smoker; current smoker; ex-smoker, current vapor) (n)	10; 5; 1	6; 2; 0	4; 3; 1
Triple inhaled therapy prescribed prior to admission (yes) (n)	13	5	8
Pack year history (years)	51 (30, 61)	45 (23, 56)	56 (33, 117)
Car driver (yes) (%)	31	25	38
Usual walking aid (none; stick, frame) (%)	81; 13; 6	75; 25; 0	88; 0; 13
Independence with ADLs (independent; informal care from family;	38; 50; 13	50; 38; 13	25; 63; 13

formal carers) (%)			
Usually able to climb stairs (yes) (%)	56	63	50
Living arrangements (lives alone; with partner) (%)	38; 63	38; 63	38; 63
Working status (paid employment; unemployed; retired) (%)	6; 13; 81	0; 12; 88	13; 12; 75
Self-reported moderate exacerbations in past 12 months	3 (1, 4)	0 (2, 7)	3 (2, 5)
Non-invasive ventilation required during admission (yes) (%)	31	13	50
Domiciliary oxygen required on discharge (yes) (%)	13	13	13
History of falls in past 12 months (yes) (%)	13	25	0

Date reported as mean (SD) or median (25^{th} centile, 75^{th} centile) unless otherwise stated. N=16 for whole group unless otherwise stated.

Abbreviations: DECAF: dyspnoea, eosinophils, consolidation, acidaemia, atrial fibrillation; eMRC: extended Medical Research Council; FEV_1: Forced expiratory volume in one second; FRAIL: fatigue, resistance, ambulation, illnesses, loss of weight; FVC: forced vital capacity; kg: kilogram.

* = minimisation variable

Table 6.4. Baseline questionnaire scores for whole group and according to group allocation

Variable	Whole group (n=16)	Intervention (n=8)	Control (n=8)
LCADL – total	38 (14)	33 (14)	42 (13)
LCADL – self-care	11 (5)	10 (5)	12 (5)
LCADL - domestic	15 (9)	12 (9)	17 (10)
LCADL – physical	5 (2)	5 (3)	6 (1)
LCADL – leisure	7 (2)	7 (2)	8 (2)
CAT	22 (9)	21 (9)	23 (8)
EQ5D5L Utility Index	0.80 (0.60, 0.85)	0.80 (0.68, 0.84)	0.74 (0.41, 0.86)
EQ5D5L Visual Analogue Scale	60 (16)	66 (16)	53 (14)
HADS-Anxiety	7 (6)	4 (1, 15)	8 (6)
HADS-Depression	8 (3)	7 (3)	8 (4)
mCES-D scale: "I felt that everything I did was an Effort."	2 (1, 3)	1 (1, 3)	3 (1, 3)
mCES-D scale: "I could not get "going"."	2 (1, 3)	2 (1, 3)	3 (1, 3)

Date reported as mean (SD) or median (25^{th} centile, 75^{th} centile) unless otherwise stated.
Abbreviations: CAT: COPD Assessment Test; EQ5D5L: Euro-Qol 5-dimentions 5-levels; HADS: Hospital Anxiety and Depression; LCADL: London Chest Activities of Daily Living scale; mCES-D: Modified Center for Epidemiologic Studies Depression.

Table 6.5. Baseline physical assessment findings for whole group and according to group allocation

Variable	Whole group	Intervention	Control
Hand grip strength (% predicted) (n=15)	86 (75, 98)	83 (74, 105)	86 (86, 93)
SPPB – total score (n=14)	7 (3)	7 (3)	7 (3)
SPPB – 5STS time (secs) (n=15)	14.25 (13.44, 16.07)	14.25 (12.23, 16.07)	14.22 (13.24, 19.91)
SPPB – 4MGS (secs) (n=13)	7.26 (3.01)	7.60 (3.30)	6.70 (2.74)
SPPB – 4MGS* (m/s) (n=13)	0.65 (0.26)	0.63 (0.29)	0.67 (0.24)
SPPB – balance score (n=15)	3 (1)	4 (2, 4)	2 (2, 4)
6MST (number of steps) (n=7)	21 (9, 36)	18 (8, 56)	21 (3, 36)
Fat-free mass index (kgm^{-2}) (n=12)	21.5 (15.3, 45.3)	19.8 (13.4, 24.2)	23.6 (15.4, 57.0)

Date reported as mean (SD) or median (25^{th} centile, 75^{th} centile) unless otherwise stated. N=16 for whole group unless otherwise stated.

Abbreviations: 4MGS: four metre gait speed; 5STS: five repetition sit to stand; 6MST: 6 minute step test; kg: kilogram; m: metres; m/s: metres/second; secs: seconds; SPPB: Short Physical Performance Battery.

* = minimisation variable

SPPB data: n=5 tried but were unable to complete 5STS; n=1 tried but was unable to walk 4 metres; n=1 insufficient space to attempt 4MGS assessment in home.

6.5.2 Study feasibility

Figure 6.10 provides a study flow diagram, which includes the study feasibility outcomes for study flow and participant attrition.

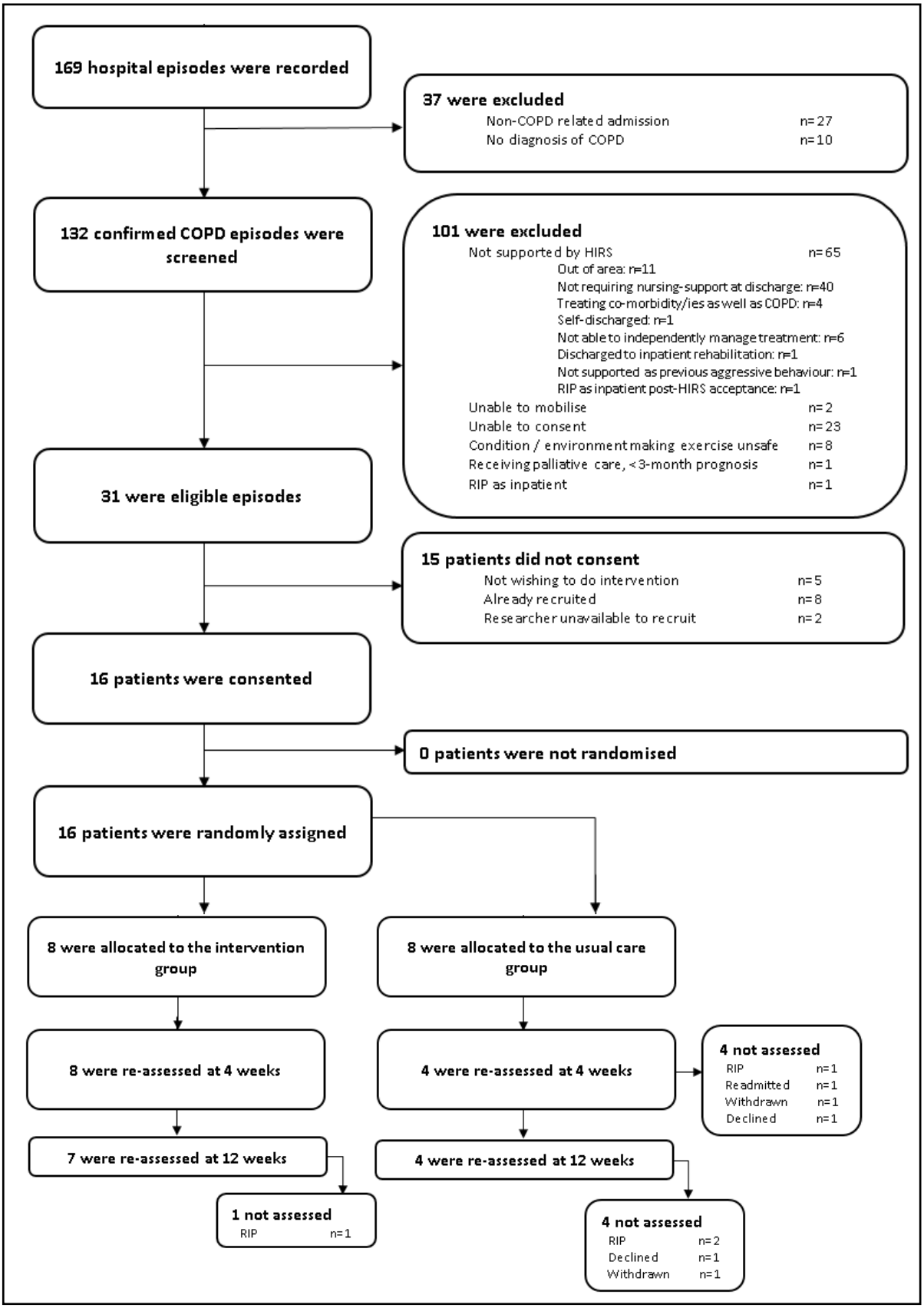


Figure 6.10. Study flow diagram.

Abbreviations: COPD: chronic obstructive pulmonary disease; HIRS: Hillingdon Integrated Respiratory Service.

Of 169 hospital episodes screened, 132 were confirmed hospitalisation for an AECOPD, with cases excluded because admission was non-COPD related (n=27) or a diagnosis of COPD could not be confirmed (n=10). Of the remaining 132 hospital episodes, only 31 were eligible for randomisation with not fulfilling criteria for HaH support the most common reason for exclusion (n=65). Forty-one of those not fulfilling criteria for HaH was due to not requiring nursing-support at discharge.

Eight out of 15 eligible episodes were not approached for recruitment as they had already been trial participants. Other reasons for non-recruitment were: not wishing to undertake intervention (n=5), and researcher unavailable to recruit (n=2). All 16 recruited participants were randomised, with one withdrawn from the study post-randomisation due to no longer being suitable for HIRS support at discharge due to a bed bug outbreak. Retention rates at four weeks and 12 weeks, with reasons for attrition, are included in Figure 6.10.

Assessors were unblinded for 4 out of 12 (33%) and 2 out of 11 (18%) assessments at four weeks and 12 weeks respectively. Reasons for unblinding at four weeks included: assessments were completed by an unblinded researcher (n=2), researcher unblinded by a patient participant (n=1), and researcher unblinded by a patient's relative (n=1). Two 12-week assessments were completed by an unblinded researcher.

Completion rates and missing data for clinical outcome measures at baseline, four weeks and 12 weeks are reported in Table 6.6 for the whole group.

Table 6.6. Completion rates of clinical outcome measures at baseline, 4 weeks and 12 weeks for whole group

Study outcome	Baseline (n=16)	4 weeks (n=12)	12 weeks (n=11)
CAT	16	12	11
HADS	16	12	11
mCES-D	16	12	11
LCADL	16	12	11
EQ5D5L (UI)	16	12	11
EQ5D5L (VAS)	16	11	10
eMRC	16	11	10
Hand grip strength*	15	9	2
SPPB*	14	9	3
BIA*	12	7	3
Agreement to complete 6MST* (yes; no; unable as at home-based assessment)	12; 2; 2	5; 1; 3	2; 2; 1
6MST completion[$] (yes; unable to do a step unsupported)	7; 5	4; 1	2; 0
Physical activity levels	3	4	2

Data reported as n.

[$] Denominator for 6MST completion is those who agreed to complete the 6MST.

*at 4 weeks: 3 out of the 12 participants outcomes and assessments were completed via telephone as face-to-face contact due to COVID-19 was suspended therefore outcomes and assessments which required face-to-face contact could not be completed; At 12 weeks: 6 out of the 11 participants outcomes and assessments were completed via telephone as face-to-face contact due to COVID-19 was suspended therefore outcomes and assessments which required face-to-face contact could not be completed.

Abbreviations: 6MST: 6 minute step test; BIA: bioelectrical impendence analysis; CAT: COPD Assessment Test; eMRC: extended Medical Research Council; EQ5D5L: Euro-Qol 5-dimentions 5-levels; HADS: Hospital Anxiety and Depression; LCADL: London Chest Activities of Daily Living scale; mCES-D: Modified Center for Epidemiologic Studies Depression; SPPB: Short Physical Performance Battery; UI: utility index; VAS: visual analogue scale.

There was no discernible difference between the completion of outcomes according to study groups. At all three assessments, collection of questionnaire data was most complete. Of the physical measures assessed, hand grip strength and SPPB were the most complete measures. Floor effect of the 6MST was evident at baseline, with 41% of the participants who agreed to complete the measure

unable to complete one step. However, the data suggests a greater proportion of participants who agreed to complete a 6MST at four weeks and 12 weeks were able to complete one step (80% and 100% respectively). Finally, there was a low level of participant agreement to monitoring of physical activity levels using a hip-worn accelerometer.

6.5.3 Intervention feasibility

The median (IQR) number of HaH visits provided was 4 (2, 6) for the whole group, with no difference between the two group (median [IQR]: 5 [3, 10] and 4 [2, 4] number of visits for the intervention and control group respectively, p=0.281). Four of the five patients who received additional care beyond usual HaH care (e.g. advice on airway clearance techniques, pacing, position of ease and relaxed breathing techniques) were in the intervention group, suggesting contamination of the intervention into usual care group was limited. Fourteen of the participants who received the COPD discharge bundle received all its constituent parts at both discharge from hospital and at the end of HaH care. When delivered at hospital discharge, ten of the COPD discharge bundles delivered were by a hospital practitioner not involved in PR delivery. Nine of the COPD discharge bundles delivered at discharge from hospital at home were by a current PR practitioner. The number of patients referred to outpatient-based PR when discussed as part of the COPD discharge bundle at discharge from hospital and at the end of HaH care was 3 and 2 respectively. Three of the five patients referred took up PR; two completed the programme however one only stopped prematurely due to COVID-19 pandemic.

The fidelity of the home-based exercise training programme is reported in Table 6.7, with the main reasons for session non-completion reported. One participant had 8 home-based PR sessions planned prior to commencing outpatient-based PR, at which point home-based PR was stopped.

Table 6.7. Home-based exercise training uptake and adherence according to each participant allocated to the intervention group

Study outcome	P02	P04	P06	P08	P11	P12	P14	P16
Number of sessions planned	16	16	16	16	16	16	16	16
Sessions completed	9 (56)	0 (0)	3 (19)	6 (38)	9 (56)	0 (0)	1 (6)	1 (6)
Not completed due to re-exacerbation or readmission	6 (38)	11 (69)	9 (56)	2 (13)	4 (25)	11 (69)	0 (0)	0 (0)
Not completed due to another hospital appointment	1 (6)	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Not completed due to COVID-19	0 (0)	0 (0)	0 (0)	0 (0)	3 (19)	0 (0)	15 (94)	15 (94)
Not completed due to starting outpatient-based PR	0 (0)	0 (0)	0 (0)	8 (50)	0 (0)	0 (0)	0 (0)	0 (0)
Not completed due to other reasons*	0 (0)	5 (31)	3 (19)	0 (0)	0 (0)	5 (31)	0 (0)	0 (0)

Data reported as n or n (%). Denominator=16 sessions.
*Other reasons for non-completion of sessions included taking care of grandchildren; chronic low back pain; declined following a poor night's sleep.

Four of the five participants referred to outpatient-based PR were in the control group. All three who attended a pre-PR assessment took up outpatient-based PR, with two completing the programme. One participant discontinued the PR course due to COVID-19. Of interest, the participants recruited to this study were not a PR-naïve group: 15 of the 16 participants recruited had previously been referred to outpatient-based PR (seven and eight in the intervention and control groups respectively), with 11 having previously completed a programme (five and six in the intervention and control groups respectively).

6.5.4 Clinical outcomes

Table 6.4 and Table 6.5 in section 6.5.1 shows the clinical outcome measures at baseline for the whole group and according to group allocation. Table 6.8 reports the change in clinical outcome measures between the baseline and four-week assessment and the baseline and 12-week assessment according to group allocation.

Table 6.8. Change in clinical outcome measures between the baseline and 4-week assessment and baseline and 12-week assessment according to group allocation

Study outcome	Baseline and 4 weeks				Baseline and 12 weeks			
	Intervention group		Control group		Intervention group		Control group	
	n		n		n		n	
Δ LCADL – total	8	7 (16)	4	-1 (3, 15)	7	4 (13)	4	-8 (-11, -5)
Δ LCADL – Self-care	8	0 (0, 5)	4	-2 (-4, 1)	7	1 (6)	4	-11 (-20, 2)
Δ LCADL – domestic	8	5 (0, 9)	4	-1 (-4, 3)	7	2 (5)	4	-3 (-6, -1)
Δ LCADL – physical	8	0 (2)	4	-1 (-1, 1)	7	0 (4)	4	0 (0, 1)
Δ LCADL – leisure	8	0 (3)	4	1 (0, 2)	7	1 (4)	4	-1 (-2, 1)
Δ SPPB – total score	6	1 (-2, 1)	3	-1 (-4; 0)	1	1	2	-1; 2
Δ SPPB – 5STS time (secs)	3	0.47 (-1.18; 0.06)	3	0.25 (-2.40; 5.29)	1	0.09	2	-0.38; 0.19
Δ SPPB – 4MGS (m/s)	5	-0.01 (0.17)	3	-0.6 (-0.25; 0.08)	1	0.07	2	-0.09; 0.12
Δ SPPB – balance score	5	1 (0, 2)	3	0 (-1; -1)	1	1	2	0; 0
Δ Hand grip strength (% predicted)	6	-9 (-29, -4)	3	-3 (-14; -4)	1	-11	1	9
Δ CAT	8	2 (-2, 6)	4	1 (-3, 3)	7	2 (8)	4	-1 (-3, 4)
Δ EQ5D5L UI	8	-0.10 (-0.47, 0.01)	4	0.05 (-0.15, 0.38)	7	-0.03 (-0.43, 0.01)	4	0.13 (-0.13, 0.37)
Δ EQ5D5L VAS	7	-11 (27)	4	5 (-11, 10)	6	-5 (16)	3	11 (0; 15)
Δ HADS-A	8	2 (0, 2)	4	3 (-6, 4)	7	3 (-3, 4)	4	-4 (-9, 0)
Δ HADS-D	8	1 (-2, 5)	4	2 (-1, 6)	7	-2 (-3, 5)	4	0 (-1, 6)
Δ mCES-D “I felt that everything I did was an effort.”	8	-2 (0, 1)	4	0 (-1, 0)	7	0 (-1, 0)	4	-1 (-1, 0)

Δ mCES-D "I could not get "going"."	8	-1 (-1, 1)	4	-1 (-1, 1)	7	0 (-1, 0)	4	0 (-1, 0)
Δ 6MST	3	1 (-2; 23)	0	-	1	36	0	-

Data reported as mean change (SD) or median change (25th centile, 75th centile) for variables where n=≥4. Data reported as median change (minimum; maximum) for variables where n=3. Data reported as raw change values for variables where n=≤2.

Abbreviations: Δ: change; 6MST: 6 minute step test; CAT: COPD Assessment Test; EQ5D5L: Euro-Qol 5-dimentions 5-levels; HADS-A: Hospital Anxiety and Depression-Anxiety; HADS-A: Hospital Anxiety and Depression-Depression; LCADL: London Chest Activities of Daily Living; mCES-D: Modified Center for Epidemiologic Studies Depression; secs: seconds; SPPB: Short Physical Performance Battery; UI: utility index; VAS: visual analogue scale.

6.5.5 Clinical safety

Safety data is presented in Table 6.9. The majority of re-hospitalisations were respiratory-related (10 of the 12 serious adverse events were respiratory-related re-hospitalisations). One non-serious adverse event was worsening of chronic low back pain that was related to study intervention; all other non-serious and serious adverse events were not related to study intervention.

Table 6.9. Safety outcomes (adverse events, readmissions and mortality) according to whole group and group allocation by participants reporting event, event classification and event nature

Study outcome	Whole group (n=16)	Intervention (n=8)	Control (n=8)
Participants reporting events			
Participates reporting an adverse or serious adverse event in 12 weeks	12/16	6/8	6/8
Participants reporting 1 adverse or serious adverse event in 12 weeks	2/12	0/6	2/6
Participants reporting >1 adverse or serious adverse event in 12 weeks	10/12	6/6	4/6
Non-serious adverse events			
Adverse events reported which were non-serious	12/27	8/17	4/10
Serious adverse events			
Adverse events reported which were serious	15/27	9/17	6/10
Adverse events reported which were serious which required hospitalisation	12/27	8/17	4/10
Adverse events reported which were serious which resulted in death	3/27	1/17	2/10
Nature of events			
Adverse or serious adverse events of respiratory nature	22/27	14/17	8/10
Non-serious adverse events which were re-exacerbations of COPD	10/12	7/8	3/4
Serious adverse events which required hospitalisation and respiratory-cause for readmissions	10/12	6/8	4/4
Serious adverse events which required hospitalisation and resulted in death and	1/3	0/1	1/2

were respiratory-cause for readmissions			
Mortality			
Mortality rate in 12 weeks	3/16	1/8	2/8

Data reported as n.
In total 27 adverse events were reported; 17 adverse events were reported in total by those in the intervention group, 10 adverse events were reported in total by those in the control group.
Other causes of non-serious or serious adverse events reported: dermatological, n=1; gastro-intestinal, n=1; musculoskeletal, n=1; fall, n=1; haematological, n=1.
The median (IQR) length of inpatient stay for the 15 serious adverse events was 5 (4, 7) days.
Time to death was 60 days for the participant in the intervention group, and 18 and 49 days for the participants in the control group.

6.6 QUALITATIVE RESULTS

Table 6.10 provides a summary of the qualitative components, and the number of participants from each: as stated in section 3.4.61, the differing participant types are described as 'stakeholders' given that all can either affect, or be affected by, the intervention (136). For this qualitative analysis, the hospital admission when the patient was approached and recruited to this study was termed their 'index admission'. Section 6.6.1 provides a between-stakeholder summary of the qualitative results, which compares the perspectives between the specific stakeholder groups.

Table 6.10. Qualitative component participants

1:1 interview	
Stakeholder group	**No. completed**
Patient with COPD	5
Family carer of patients with COPD	2
Researcher	4
Focus group	
Stakeholder group	**No. per group**
Pulmonary Rehabilitation team	6
Hillingdon Integrated Respiratory Service	4

The findings from the patient participant and family carer interviews are presented as a narrative summary with supporting indicative anonymised quotes in section 6.6.2. The focus groups were conducted with healthcare professionals to explore care-provider perspective. The final qualitative component to this study were four interviews with members of the research team involved in study delivery. The findings from the healthcare professional focus groups and researcher interviews are presented as a narrative summary with supporting indicative anonymised quotes in section 6.6.3.

Of interest, none of the participants, family carers, healthcare professionals or researchers who took part in an interview or focus groups accepted the offer to review their transcripts prior to anonymisation and analysis. Nonetheless, this is postulated to have had minimal impact upon the study findings (253).

6.6.1 Between-stakeholder analysis

Table 6.11 provides an overview of the findings for the between-stakeholder analysis. The four potential findings for the between-stakeholder analysis were: 1) complementary (multiple stakeholder group data sets which include findings that address different aspects of the same phenomenon whilst enhancing the understanding of the each other); 2) confirmation (multiple stakeholder group data sets which findings that address the same aspect of the same phenomenon, with results that are consistent between the data sets); 3) refutation (multiple stakeholder group data sets which include findings that address the same aspect of the same phenomenon, with results that are divergent between the data sets); and 4) silence (aspect of a phenomenon only present in the findings from one stakeholder group) (154).

The ‘original source’ for each theme was the stakeholder group data set where themes and subtheme(s) were first identified. Therefore, should multiple stakeholders have reported the same theme or subtheme, the stakeholder group which it was first identified was overtly reported. The stakeholder group designated as the ‘original source’ was subsequently used as the reference stakeholder group for the qualitative analysis comparing the between-stakeholder perspectives.

Of interest, the presence of confirmation or refutation for the themes and subthemes were only found between the patients and family carers stakeholder groups, and in one instance, the findings were found to both confirm and refute each other. The between-stakeholder findings for the PR team, HIRS team and researcher perspectives were all complementary to the original source.

Lastly, the presence of silence was only found in the qualitative themes and subthemes in the researcher and family carer stakeholder groups. The most silence was found between researchers and the other stakeholder groups. This is likely be resultant from the more un-structured nature of the researcher interviews, with the interviewer was guided by the experiences and role of the researcher interviewee, and the different focus of these interviews.

Table 6.11. Between-stakeholder analysis according to specific stakeholder groups

Major theme and subtheme(s)	Minor theme and subtheme(s)	Stakeholder group BETWEEN- STAKEHOLDER FINDING/S Related theme(s) and subtheme(s)				
				Healthcare professionals		
		Patients	Family carers	PR team	HIRS team	Researchers
Theme: • Experiences of exercise training Subtheme: • Previous PR experiences		**ORIGINAL SOURCE**	**SILENCE**	**COMPLEMENTARY** **Major theme:** Delivery of usual care **Subtheme:** Usual PR service delivery; perceptions of patients' ability to engage with outpatient-based PR post-exacerbation **Major theme:** Perceived patients' perceptions of outpatient-based PR	**COMPLEMENTARY** **Major theme**: Delivery of usual care **Subtheme:** Usual PR service delivery	**SILENCE**
Theme: • Experiences of exercise training Subtheme:		**ORIGINAL SOURCE**	**CONFIRMATION** **Major theme:** Experiences of index admission	**COMPLEMENTARY** **Major theme:** Perceptions of intervention	**COMPLEMENTARY** **Major theme:** Perceptions of the intervention	**SILENCE**

• Home-based and outpatient-based PR post-index admission			**Subtheme:** Perceptions and experiences of home-exercises post-discharge	**Subthemes:** Benefits of home-based PR; limitations of home-based PR; home-based PR as a bridge to outpatient-based PR; safety considerations **Minor theme:** Skills of the professional delivering intervention **Minor theme:** Role home-based PR has within a toolbox of services	**Subthemes:** Benefits of home-based PR; limitations of home-based PR; home-based PR as a bridge to outpatient-based PR; timing of intervention delivery	
Theme: • Impact of COPD Subtheme: • Post-index admission ability to complete ADLs		**ORIGINAL SOURCE**	**CONFIRMATION** **Major theme:** Experiences of index admission **Subtheme:** Ability to re-engage with 'home-life'	**SILENCE**	**SILENCE**	**SILENCE**
Theme: • Impact of COPD Subtheme: • Impact beyond ability to complete ADLs		**ORIGINAL SOURCE**	**COMPLEMENTARY** **Major theme:** Impact of COPD **Subthemes:**	**SILENCE**	**SILENCE**	**SILENCE**

			Impact of symptoms; impact beyond symptoms			
Theme: • Research processes		**ORIGINAL SOURCE**	**COMPLEMENTARY** **Major theme:** Research processes **Subthemes:** Experiences of study; perceived lack of personal knowledge and expertise regarding research	**COMPLEMENTARY** **Major theme:** Experiences and perceptions of the study **Subthemes:** Experiences and perceptions of the study assessments and processes; considerations for future studies	**COMPLEMENTARY** **Major theme:** Experiences and perceptions of the study assessments and processes	**COMPLEMENTARY** **Major theme:** Individuals role in the study **Subthemes:** Perception of significance of role; perception of requirements from role in study; understanding of study assessment time points and crossover with usual care **Major theme:** Communication between researchers **Major theme:** Experiences and perceptions of the study **Subthemes:** Experiences of study assessments and processes; knowledge of other people's role

						in study; perceptions of outcomes **Major theme:** Learning for future studies
Theme: • Perceptions of support Subtheme: • Support received		**ORIGINAL SOURCE**	**SILENCE**	**SILENCE**	**SILENCE**	**SILENCE**
Theme: • Perceptions of support Subtheme: • Impact of support received		**ORIGINAL SOURCE**	**CONFIRMATION & REFUTATION** **Major theme:** Support and encouragement **Subthemes:** Team mentality; provision of equipment	**COMPLEMENTARY** **Major theme:** Perceptions of impact on family members or carers **Subthemes:** Impact of outpatient-based PR; role of family members or carers in facilitating exercise training	**SILENCE**	**SILENCE**
Theme: • Perceptions of integration		**SILENCE**	**SILENCE**	**SILENCE**	**ORIGINAL SOURCE**	**SILENCE**
	Theme:	**ORIGINAL SOURCE**	**SILENCE**	**SILENCE**	**SILENCE**	**SILENCE**

	• Experiences of index admission					
	Theme: • Impact of COVID-19	**ORIGINAL SOURCE**	**SILENCE**	**COMPLEMENTARY** **Major theme:** Delivery of usual care **Subtheme:** Impact of COVID-19 on PR service delivery	**COMPLEMENTARY** **Major theme:** Delivery of usual care **Subthemes:** Impact of COVID-19 on HIRS service delivery	**COMPLEMENTARY** **Major theme:** Learning for future studies **Subthemes:** Impact of COVID-19 on studies processes and assessments

Between-stakeholder qualitative analysis: **Complementary**: multiple stakeholder group data sets which include findings that address different aspects of the same phenomenon, yet which enhance the understanding of the each other; **Confirmation**: multiple stakeholder group data sets which findings that address the same aspect of the same phenomenon, with results that are consistent between the data sets; **Refutation**: multiple stakeholder group data sets which findings that address the same aspect of the same phenomenon, with results that are divergent between the data sets; **Silence**: aspect of a phenomenon only present in the findings from one stakeholder group (adapted use from the methodology proposed by Sandelowski *et al*. Res Sch. 2006; 13(1): 29 for integrating and synthesising data). **Original source**: stakeholder group data set where themes and subtheme(s) were first identified, the original sources is the stakeholder group used as reference for determining the between-stakeholder qualitative finding.

Abbreviations: ADLs: activities of daily living; COPD: chronic obstructive pulmonary disease; COVID-19: Coronavirus disease; HIRS: Hillingdon Integrated Respiratory Service; PR: pulmonary rehabilitation.

6.6.2 Patient and family carer perspectives

A combination of both male and female patient participants, aged between 64 and 83, were interviewed. Two of the interviewees had been allocated to the control group: the remaining three to the intervention group. All the patient participants interviewed completed all three study assessments and none lived alone. Four of the patient participants reported a clinically significant improvement in their HRQoL at 12-week follow-up according to their change in CAT score, and two were readmitted within 12 weeks of discharge from their index admission. Two family carers were interviewed: one was the relative of a patient participant allocated to the intervention group, the second was the relative of a patient participant allocated to the control group. Both family carer interviewees were male, aged 65 and 72, who self-identified as an informal carer to their wives who lived with COPD.

There were some similarities between key themes identified from the family carer interviews and patient participant interviews, but also some disparities. Table 6.12 and 6.13 include the themes and subthemes identified from the patient participant and family carer interviews respectively. It may be notable that although qualitative analysis is not numerical, the major themes were raised in the patient participant interviews by either all or the majority of the patient participant interviewees and were commonly perspectives or experiences patient participants reiterated multiple times. A joint narrative on the patient participant and family carer themes and subthemes are presented with supporting quotes.

Table 6.12. Themes and subthemes from the patient participant interviews

Major themes	Subtheme/s (if applicable)
1. Experiences of exercise training	a) Previous PR experiences b) Home-based intervention and outpatient-based PR post-index admission
2. Impact of COPD admission	a) Post-index admission ability to complete activities of daily living (ADLs) b) Beyond the ability to complete ADLs
3. Research processes	N/A
4. Perceptions of support	a) Support received b) Impact of support received
Additional themes	**Subtheme/s (if applicable)**
5. Experiences of index admission	N/A
6. Impact of COVID-19	N/A

Table 6.13. Themes and subthemes from the family carer interviews

Major themes	Subtheme/s (if applicable)
1. Support and encouragement	a) Team mentality b) Provision of equipment
2. Perceived impact of COPD	a) Impact of symptoms b) Impact beyond symptoms
3. Experiences of index admission	a) Ability to re-engage with 'home-life' b) Perceptions and experiences of home-exercises post-discharge [*intervention group only*]
4. Research processes	a) Experiences of study b) Perceived lack of personal knowledge and expertise regarding research)

6.6.2.1 Experiences of exercise training

The theme of exercise training from the patient participant interviews encompassed subthemes of: a) previous PR experiences, and b) home-based intervention and outpatient-based PR post-index admission.

Most of the patients who had previously experienced outpatient-based PR reported positive experiences of the programme. One patient also specifically stated he found the education component of programme beneficial. However, multiple patients reported acute exacerbations negatively impacted upon their ability to complete a PR programme in the past, resulting in disruption and either missing sessions or dropping out of the PR course altogether:

> *"This last time, what with going in and out of hospital, it has been somewhat disruptive."* [P08, male, aged 80, intervention group, readmitted, significant improvement in HRQoL]

In addition, one patient perceived himself to be unable to attend another PR programme due to requiring ambulatory oxygen therapy.

Patients also identified that maintaining exercise training after completion of the PR programme was considered difficult:

> *"I more or less got lazy […] and stopped doing the exercises."* [P08, male, aged 80, intervention group, readmitted, significant improvement in HRQoL]

All the patients allocated to the intervention group had a positive experience of exercise training at home. Patients also made informative comparisons between their experiences of exercising at home and in an outpatient setting. One patient reported group exercise within the outpatient-based programme was a format of delivery she felt less comfortable with:

> *"It [home-based programme] was better [than the outpatient-based programme] because I am not a great joiner […] it is not that I don't like people, but I am not a group sort of person"* [P02, female, aged 70, intervention group, readmitted, significant improvement in HRQoL]

Comparatively, another patient reported she would prefer to attend outpatient-based PR, however lacked the confidence.

Patients who received the home-based programme reportedly found the frequency, length, type of exercises and exercise progression during the intervention acceptable. Patients found the supervision of the home-based programme to be beneficial and motivating, and reported the timing of delivery to be acceptable:

> *"For the first 10 days or so, I was being attended by the outreach team and I had a nebuliser still here for a few days. Then we weaned off of that and then we started the exercises, made sense as I was feeling bit better by then"* [P08, male, aged 80, intervention group, readmitted, significant improvement in HRQoL]

Similar to the perspectives of the education delivered within the outpatient-based programme, patients who were allocated to the intervention group who received the home-based programme found the education provided to be individually tailored and informative.

> *"[Education on pacing] was a pivotal thing which I probably would not have thought of"* [P02, female, aged 70, intervention group, readmitted, significant improvement in HRQoL]

A patient in the control group discussed how they perceived home-based exercise training would have compared to outpatient-based exercise programmes from their previous experiences of PR. They felt a home-based programme could be modelled around the format of delivery for a minimal equipment outpatient-based PR class.

The subtheme of experiences of home-exercise post-discharge was identified in the interview with the family carer of the patient participant allocated to the intervention group. He repeatedly reported feeling the programme not only had positive physical but also psychological benefits to the patient undergoing the home-based exercise training intervention:

> *"In every one of them she was cheerful afterwards"* [FMC01, male, aged 72, wife allocated to intervention group]

6.6.2.2 Impact of COPD admission

The theme of the impact of COPD admission from the patient participant interviews encompassed subthemes of: a) ability to complete activities of daily living (ADLs) post-index admission, and b) the impact of COPD beyond their ability to complete ADLs from the patient participant perspectives.

Unsurprisingly, patients reported a significant decrease in their ability and confidence to complete ADLs early post-index admission.

> "*I didn't do very much at all"* [P02, female, aged 70, intervention group, readmitted, significant improvement in HRQoL]

However, most patients report their ability to complete ADLs improved over time.

Some also discussed the impact of COPD beyond their ability to complete ADLs, and how they felt it may affect them in the future. Patients spoke of their COPD impacting upon their desire to socialise. One patient also spoke about the impact of COPD on the ability to do things they wanted to with their family and on being unable to work.

A similar theme and related subtheme emerged from the family carer interviews; the theme of experiences of index admission encompassed the subtheme of: a) ability to re-engage with 'home-life'. Both family carers reported enjoying the person returning home after their hospital admission:

> *"I was always pleased to get her back home."* [FMC02, male, aged 72, patient allocated to intervention group]

However, one family carer reported feelings of doubt when their wife was discharged from hospital regarding their medical stability:

> *"You're never sure if everything is fully dealt with"* [FMC01, male, aged 65, wife allocated to control group]

Both family carers perceived their wives to have slowly begun to re-engage with home-life and observed their health to have slowly improved after discharge home from the index admission:

> *"We could see there was an improvement, […] now she gets up. She gets around. She has a shower. We try to go out when we can. She tries to get out and do some walking, some exercise."* [FMC01, male, aged 65, wife allocated to control group]

6.6.2.3 Experiences of research processes

The third theme from the patient participant perspectives related to the research processes themselves. All of the patients reported they felt the research was a good idea and understood why it was being conducted. Patients also appeared to be altruistic in why they were taking part:

> *"I'll be happy to support, if there's anything I can do to give back, you know"* [P03, female, aged 64, control group, not readmitted, significant improvement in HRQoL]

All patients reported the recruitment strategy, and being approached in hospital, was acceptable, with none of the patients reporting any issues or complications which arose as a result of taking part in the research.

All the patients remembered completing the questionnaires aside from one. All the patients who remembered the questionnaires reported they had no concerns or complaints regarding completing the number or type of questionnaires included in the study. A few patients did however specifically provide feedback regarding the home exercise diary. One patient reported he struggled with compliance with the home exercise diary. Another patient reported he adapted the diary to a format more suited to how he wanted to record his daily activity. None of the patients who spoke about the exercise diary was able to offer solutions to improve usability going forward:

> *"When you're trying to make it with all people, to do everything for everybody, there's nothing much you can do about that."* [P15, male, aged 77, control group, not readmitted, non-significant improvement in HRQoL]

The theme related to research processes was also found in the family carer interviews, which encompassed subthemes of: a) experiences of the study, and b) perceived lack of personal knowledge and expertise regarding research.

The family carers reported they felt the information provided regarding the study was sufficient. Both also reported they were involved in the decision-making process to assist the person living with COPD to decide whether they should consent to the study. During the research process, the two family carers had different experiences. One was heavily involved in supporting the patient in completing the questionnaire pack and home exercise diary:

> *"I filled it [the home exercise diary] in daily for her […] she's not very good at dealing with paperwork."* [FMC01, male, aged 65, wife allocated to control group]

In comparison, the other family carer reported his wife (the patient participant recruited) was independent in completing the study paperwork.

Both family carers reported a perceived lack of personal knowledge and expertise regarding how the research could be improved:

> *"That's difficult to say because I'm not medically equipped to do or to assess what should or shouldn't be done or how questions should be posed."* [FMC01, male, aged 65, wife allocated to control group]

One family carer, like the patient participants, reported feelings of altruism towards the research project:

> *"I just said […] if it maybe down the line, it will help anybody else, why not do it"* [FMC01, male, aged 65, wife allocated to control group]

6.6.2.4 Perceptions of support

The theme of perceptions of support encompassed subthemes of: a) support received, and b) impact of support received emerged from the patient participant interviews.

The majority of patients discussed the type of support received. All the patients reported they had no formal (paid) carers, and the support they received was informally provided by family, friends and neighbours in an unpaid capacity. Some patients were also more specific about the household chores

and day-to-day activities for which they needed assistance as they had difficultly completing them, for example, shopping, cooking and hoovering.

A couple of the patients also explained the impact of support they received. One patient stated that although the person providing support intended well, they wondered if it meant they were more dependant as a result of it:

> *"I've thought, 'Well, maybe if he wasn't here, I would do more.', I'd have to."* [P03, female, aged 64, control group, not readmitted, significant improvement in HRQoL]

This same patient however also felt that she would not be able to cope if she lived alone, suggesting the most vital support she felt she received was potentially the emotional support and comfort provided as opposed to the physical support with tasks. This was corroborated by other patients.

The last finding related to perceptions of support was the dynamic nature of the amount of support provided by a husband and wife, which varied depending on the health status of the patient:

> *"A lot of those minor things devolved onto her, when I wasn't feeling so good […] one way or another we can do it"* [P15, male, aged 77, control group, not readmitted, non-significant improvement in HRQoL]

A similar theme emerged in the family carer interviews; the theme of support and encouragement encompassed subthemes of: a) team mentality, and b) provision of equipment.

The subtheme of team mentality was felt by the family carers. One family carer stated:

> *"We obviously rally round with the cooking and what have you […] we are truly a good team"* [FMC02, male, aged 72, wife allocated to intervention group]

As a result, for these older couples, team mentality seemed to be an important element of managing life with COPD.

Both family carers were keen to provide any equipment and devices they felt would benefit the person living with COPD. Both returned to speak about this regularly throughout the interviews. The first reason for providing equipment and devices appeared to be related to improve their ability to better monitor their health:

> *"We've got everything here probably that we need to try and assess that if she's got problems, I've brought an oxygen monitor which does heart rate. I've also got a blood pressure monitor and things like that."* [FMC01, male, aged 65, wife allocated to control group]

The second reason identified for providing equipment was to encourage the person with COPD to be more active (e.g. a pedometer) and complete formal exercise training. Provision of this type of equipment appeared to be prompted by the clinical care the family carers had observed:

> *"I bought her leg weights for Christmas, […] they gave them to her to use while I was there [at outpatient-based PR]. And I thought, "Oh, that's not a bad idea. We'll get her some for Christmas"."* [FMC01, male, aged 65, wife allocated to control group]

6.6.2.5 Perceived impact of COPD

The theme of perceived impact of COPD encompassed subthemes of: a) impact of symptoms, and b) impact beyond symptoms. The two subthemes which were identified suggested the impact of COPD could be attributed to the direct impact of symptoms as well as the impact of COPD beyond the

symptoms of the disease. This theme and its related subthemes emerged from the family carer interviews only.

Breathlessness was reported to be the symptom of COPD which had the largest impact on their family carers. Along with breathlessness, dealing with exacerbations were the other major direct impact of the COPD which was repeatedly mentioned by family carers:

> *"She was having so many problems with infections"* [FMC01, male, aged 65, wife allocated to control group]

Family carers also reported the impact of the COPD beyond the symptoms of the disease and resultant exacerbations. They noted the impact COPD had on the person living with the diseases' mental health:

> *"She can panic, […] and now that she's not doing any of the things that she has always liked doing and enjoyed doing, it's difficult for her to accept mentally, […] she can't get out on her own easily, it's hard for her."* [FMC01, male, aged 65, wife allocated to control group]

Both family carers also reported COPD affected the ability to complete day-to-day activities:

> *"She has always been a very active person, taking the dog out, doing all the housework, cleaning. She used to do all the garden. All that has changed. She can't do any of that anymore. She can't do any cooking."* [FMC01, male, aged 65, wife allocated to control group]

They also reported the impact of COPD to result in a loss of ability of the person living with COPD to be able to engage with life as they previously would have. For example, one family carer discussed the impact of the person being required to give up work as a result of their worsening COPD:

> *"It hit her hard when the doctor, GP said to her, "You've got to give up work" […] that hit her badly, it started, if you like, to go downhill"* [FMC01, male, aged 65, wife allocated to control group]

The same family carer also reported the uncertainty COPD has upon their day-to-day lives: a recurring discussion point during the interview:

> *"Hopefully, she's going to make that 12 months. We don't know. It's difficult to say."* [FMC01, male, aged 65, wife allocated to control group]

Both family carers reported the adaptions they were making to facilitate as much engagement with 'normal' life as they previously would have despite the patient living with COPD:

> "W*e've got used to sort of shortening the distances and you know, in that sense dropping her either in the carpark or right outside"* [FMC02, male, aged 72, wife allocated to intervention group]

6.6.2.6 Additional noteworthy perspectives

Two additional noteworthy patient participant perspectives covered: 1) experiences of their index admission, and 2) impact of COVID-19.

Patients reported different feelings towards their index admission. This was identified to potentially be dependent on the stage of disease they were. A patient who had never been admitted to hospital for their COPD prior to their index admission reported feelings of stress and anxiety:

> *"I have not been in hospital before with this […] I think I was quite sort of, a bit bewildered"* [P02, female, aged 70, intervention group, readmitted, significant improvement in HRQoL]

Comparatively, a patent who had previously been admitted with an acute exacerbation of COPD was matter of fact regarding their index admission and did not report any anxiety related to being

hospitalised. For a patient with more advanced COPD known to palliative care services, an admission to hospital resulted in them being worried about whether or not they would survive the exacerbation:

> *"We [patient and her husband] both thought I was going to die. Didn't think I was going to make it out."* [P03, female, aged 64, control group, not readmitted, significant improvement in HRQoL]

Although experiences of the index admission were also reported from the family carer perspective, the findings are reported in sections 6.6.2.1 and 6.6.2.2 as the subthemes more closely fit within other themes or subthemes from patient participant interviews.

Another noteworthy patient perspective identified related to the impact of COVID-19. The majority of the patients felt they were less active as a result of ensuring they were compliant with the COVID-19 shielding advice. In comparison, experiences or perspectives around the impact of COVID-19 were not expressed by the two family carers.

6.6.3 Healthcare professional perspectives

Two topic-guided focus groups were conducted: one included six healthcare professionals from the PR team; the other included four healthcare professionals from the HIRS team. Half of the healthcare professionals who participated in the PR team focus group were qualified physiotherapists, the other half were assistant practitioners. The physiotherapists had been qualified for between 11 and 18 years and had a range in years of experience delivering PR (from three years to 11 years). Some of the physiotherapists had worked within other PR services to the one they were employed within. The assistant practitioners also had a range in years of experience delivering PR, having worked in a PR service for between 18 months and seven and a half years. None of the assistant practitioners had

experience of working in another PR service to the one they were employed in. By contrast, all the healthcare professionals who participated in the HIRS team focus group were nurses. They had been qualified for a diverse length of time (between three and 18 years) with varying length periods of employed within the HIRS team (between seven months and four years). The majority of the PR team and all the participating HIRS team were female. There was one male physiotherapist and one male assistant practitioner who contributed to the PR team focus group.

Interpreting the interactions of participants included within the focus groups offers valuable additional insights beyond the themes and subthemes presented in sections 6.6.3.1 and 6.6.3.2 for the PR and HIRS teams (254). First, the HIRS team and PR team were largely unified in their perceptions and viewpoints, and there were no obvious divergent opinions between them. However, there did appear to be some differences in perspectives between these professional groups. The PR team were more focused on the logistics for delivery of home-based PR. Comparatively, the HIRS team were focused on viewing the intervention from the patient's perspective. Therefore, it appeared that the HIRS team reported more patient-orientated viewpoints towards home-based PR whereas the PR team were keen to promote practicability of the intervention. This provides a possible explanation for why the PR teams focus group resulted in proportionally more barriers to the intervention being raised, and their specific interest in safety considerations of home-based PR. It could also explain why the HIRS team reported more benefits of the intervention, and their greater concern for optimising timing of delivery. One justification for these between-stakeholder differences could be related to the professional backgrounds of the HIRS and PR teams (255).

Another interaction noted in both focus groups related to the amount each focus group participant contributed. The physiotherapists were more vocal than the assistant practitioners within the PR team focus group; the clinical nurse specialists dominated more of the discussion than the junior nurses

within the HIRS team focus group. It was also noted in both focus group that those who had spent more time working within the team appeared to be more outspoken than newer team members. This could be as a result of differentials in power (256) due to perceived professional hierarchy and self-assurance of their own knowledge and expertise.

The final healthcare professional qualitative component were four topic-guided interviews with members of the research team involved in the delivery of the study. Given the researchers had different roles, the researcher interviews were the least structured of the qualitative components. The majority of the researchers were physiotherapists by clinical background, however one was a respiratory and sleep clinical scientist. Most of the researchers interviewed were also female. They had a range of research experience within the research group they were employed within (between one year and eight years), and one had experience working in a different research role prior to commencing their current role. A narrative on each theme is presented with supporting quotes.

6.6.3.1 PR team perspectives

Table 6.14 outlines the themes and subthemes identified from the PR team focus group.

Table 6.14. Themes and subthemes from the PR team focus group

Major themes	Subtheme/s (if applicable)
1. Delivery of usual care	a) Usual PR service delivery b) Impact of COVID-19 on PR service delivery c) Perceptions of patients' ability to engage with outpatient-patient PR post-exacerbation
2. Views of patients' perceptions of outpatient-based PR	N/A
3. Perceptions of intervention	a) Benefits of home-based PR b) Limitations of home-based PR c) Home-based PR as a bridge to outpatient-based PR d) Safety considerations
4. Perceptions of impact on family members or carers	a) Impact of outpatient-based PR b) Role of family members or cares in facilitating exercise training
5. Experiences and perceptions of the study	a) Experiences and perceptions of the study assessments and processes b) Considerations for future studies
Additional themes	**Subtheme/s (if applicable)**
6. Skills of the professional delivering intervention	N/A
7. Role home-based PR has within a toolbox of services offered	N/A

6.6.3.1.1 Delivery of usual care

The theme of delivery of usual care encompassed subthemes of: a) usual PR service delivery, b) impact of COVID-19 on PR service delivery, and c) perceptions of patients' ability to engage with outpatient-patient PR post-exacerbation.

All the healthcare professionals from the PR team were able to contribute to the discussion around usual PR service delivery and the roles of the qualified physiotherapist and assistant practitioners appeared to be well-defined. In addition, all the PR team felt COVID-19 had had a significant impact upon the usual delivery of PR assessments and classes.

The PR team felt that patients were less likely to attend an outpatient-based PR programme following an acute exacerbation than those referred with stable COPD:

> *"We found that with our post exacerbations we definitely had a higher DNA or UTA , […] there was often a feeling that they weren't ready to exercise, or they didn't feel well enough to engage with the rehab course"* [SM04, Physiotherapist, 17 years post-qualification, 11 years PR delivery experience]

6.6.3.1.2 Views of patients' perceptions of outpatient-based PR

The second main theme identified was the team's view of patients' perceptions of outpatient-based PR. The PR team felt patients did not want to exercise after an exacerbation:

> *"They don't really want to exercise when they've just had a chest infection"* [SM03, Physiotherapist, 12 years post-qualification, 7.5 years PR delivery experience]

They felt this was because exercising was not considered a priority when patients were recovering from being acutely unwell:

> "*It wasn't top of patients agenda"* [SM02, Physiotherapist, 11 years post-qualification, 3 years PR delivery experience].

The PR team expressed the view that patients found the prospect of attending PR overwhelming, particularly early-post exacerbation. They also felt patients' perceptions of outpatient-based PR was that it was purely an exercise intervention.

6.6.3.1.3 Perceptions of intervention

The theme of perceptions of the intervention encompassed subthemes of: a) benefits of home-based PR, b) limitations of home-based PR, c) home-based PR as a bridge to outpatient-based PR, and d) safety considerations.

The PR team saw the potential benefits of home-based PR as the PR team felt that getting to the class was often challenging for patients:

> *"Sometimes getting to the class is exercise in itself; gets them dressed up, take the bus or get driving in, come to a class, and if they don't exercise to a high level, that is exercise and activity"* [SM03, Physiotherapist, 12 years post-qualification, 7.5 years PR delivery experience]

The PR team was focused on the logistics and practicability of delivering home-based PR, and therefore the perspectives of the PR team appeared to be mainly related to the limitations of home-based PR. The PR team felt that compared to outpatient-based PR delivered to a group, one-to-one home-based PR required significantly more resources and time:

> *"Because it is a man-hour demanding task."* [SM03, Physiotherapist, 12 years post-qualification, 7.5 years PR delivery experience], *"I would second that in the sense that it's very time consuming"* [SM04, Physiotherapist, 17 years post-qualification, 11 years PR delivery experience]

They also felt that home-based PR may not promote self-management to patients:

> *"A member of staff going in, giving them one-to-one care and almost holding their hand […] doesn't give a good message of self-management and empowering that patient to do things by themselves"* [SM04, Physiotherapist, 17 years post-qualification, 11 years PR delivery experience]

Finally, the PR team reported that although patients may feel like they prefer the idea of home-based PR, there may be elements to a group, outpatient-based programme that patients were inadvertently not receiving. For example, they felt patients could miss out on peer support, social interaction and multidisciplinary expertise.

The PR team felt that they could foresee home-based PR being an effective bridge to outpatient-based PR, as opposed to a standalone programme:

> *"I can see the benefit in showing them initially how to do exercises in their home environment if you can't get them to a clinic"* [SM07, Assistant Practitioner, 7.5 years PR delivery experience]

This was based on their experiences of the patients who had received home-based PR intervention during this study who had then transferred into an outpatient-based programme:

> *"Kind of learning effectively at home first"* [SM05, Assistant Practitioner, 1.5 years PR delivery experience]

However, the PR team did raise issues related to disparity and inequality in the types of programmes offered to those not acutely exacerbating if home-based PR was only offered to those who were post-exacerbation:

> *"If the person who hasn't been unwell says that they want to have rehab at home, and you explain that, no, that was for a separate reason that we had that at home […] it would be unfair"* [SM05, Assistant Practitioner, 1.5 years PR delivery experience]

The PR team also felt there were additional safety considerations to be addressed for a home-based PR programme. They agreed the safety considerations, such as relating to lone working and additional manual handling of exercise equipment, were not unsurmountable but required formal risk assessments to be mitigated.

6.6.3.1.4 Perceptions of impact on family members or carers

The theme of perceptions of the impact on family members or carers encompassed subthemes of: a) impact of outpatient-based PR, and b) role of family members or cares in facilitating exercise training.

The PR team felt outpatient-based PR may have an impact on family members or carers both positively and negatively: *"A negative; if I am caring for somebody who has come home from hospital and I'm having to do, say, all their washing and their dressing and whatever, actually to get them ready and to get them, you know, both dressed and fit and ready to do a rehab might be an extra strain"* [SM04, Physiotherapist, 17 years post-qualification, 11 years PR delivery experience]. This was followed up by the potential benefits to a family member or carer: *"Maybe they [family member or carer] think, "Oh, whilst there at physio, I can have half an hour to have a cup of tea and a bit of a break."* [SM04, Physiotherapist, 17 years post-qualification, 11 years PR delivery experience].

The PR team also felt family members or carers may have a role in facilitating completion of exercise training outside of PR classes:

> *"It can help the carer to understand the limitations of the patient or the abilities, depending how they try and swing things at home"* [SM07, Assistant Practitioner, 7.5 years PR delivery experience]

However, they did feel that involving carers may increase the workload of the therapists if the patient had multiple carers supporting them. The PR team also felt that there could be instances where educating and subsequently asking the carer to facilitate exercise may not be appropriate. They felt this would depend on the relationship between the patient living with COPD and their carer.

> *"It might cause friction"* [SM07, Assistant Practitioner, 7.5 years PR delivery experience]

6.6.3.1.5 Experiences and perceptions of the study

The theme of experiences and perceptions of the study encompassed subthemes of: a) experiences and perceptions of the study assessments and processes, and b) considerations for future studies.

The PR team reportedly felt involved in the intervention design process. The PR team also did not feel any added pressure or increased burden on their workload as a result of integrating a home-based exercise training programme into the HIRS service. In some instances, the PR team felt that being involved in the study reduced their clinical workload:

> *"We were actually provided with the exercise grids [from the home-based exercise programme], so the patient that I saw […] he got stuck in, normally I spending just five or ten*

minutes to teach new patients, but he knew exactly what he wanted to do" [SM02, Physiotherapist, 11 years post-qualification, 3 years PR delivery experience]

The PR team felt the patients' clinical care was always a priority, and that the research assessments would be conducted in line with clinical care provision. They felt this co-ordination between the research team and clinical service was well-executed and undertaken in a way to not overburden patients with assessments.

As aforementioned, the PR team felt that the impact of the research to their usual clinical care was minimal. However, they felt this was due to the infrastructure already being in place for research to be conducted within the Harefield PR service. They were therefore conscious that should this study be conducted at different sites within PR services where research teams were less established or less embedded within the clinical team, ensuring sufficient space and equipment for the research to take place without affecting the PR teams would need to be considered:

"We're very fortunate here that the research team had their own office and their own lab to do assessments, so they can do that without impacting on us, […] if this was scaled up at other sites, and the researchers were having to share an assessment space, or share equipment, it would have an impact" [SM04, Physiotherapist, 17 years post-qualification, 11 years PR delivery experience]

They also felt it would be important for other service to ensure they continue to distinguish between the research team and clinical services to ensure patients knew who to contact to seek appropriate care and advice.

6.6.3.1.6 Additional noteworthy perspectives

Additional noteworthy perspectives encompassed: 1) skills of the professional delivering intervention, and 2) the role home-based PR has within a toolbox of services offered.

The PR team recognised that the patients being supported by the HIRS team remained in a clinically unstable phase of their exacerbation. As a result, they felt that being skilled and trained to be able to manage a deteriorating patient competently as well as deliver home-based exercise training was important:

> *"There is always the potential that patient might be deteriorating again or might be quite unwell, and so there is the training needed for the clinicians so that they are able to pick up red flags, and able to pick up when that patient needs more medical attention"* [SM04, Physiotherapist, 17 years post-qualification, 11 years PR delivery experience]

The PR team felt that home-based PR should not aim to simply replicate outpatient-based PR. They felt home-based PR could be a complementary service within a toolbox of management options as an alternative yet equally valuable method of delivering care peri-exacerbation:

> *"The mistake we keep making is we compare home exercises to pulmonary rehabilitation; we should just kind of accept that it is not pulmonary rehab, however, it is equally valuable in terms of getting that initial progress in the patient after an exacerbation"* [Physiotherapist, 12 years post-qualification, 7.5 years PR delivery experience]

6.6.3.2 HIRS team perspectives

Similar key themes were identified from the HIRS team focus groups as in the PR team focus group. However, there were some disparities in perspectives and emphases which resulted in some subtlety

different themes and subthemes. Table 6.15 includes the themes and subthemes identified from the HIRS team focus group. A narrative on each theme is presented with supporting quotes.

Table 6.15. Themes and subthemes from the HIRS team focus group

Major themes	Subtheme/s (if applicable)
1. Delivery of usual care	a) Usual PR service delivery b) Impact of COVID-19 on HIRS service delivery
2. Perceptions of intervention	a) Benefits of home-based PR b) Limitations of home-based PR c) Home-based PR as a bridge to outpatient-based PR d) Timing of intervention delivery
3. Perceptions of integration	N/A
4. Experiences and perceptions of the study assessments and processes	N/A

6.6.3.2.1 Delivery of usual care

The theme delivery of usual care encompassed subthemes of: a) usual PR service delivery, and b) impact of COVID-19 on HIRS service delivery.

The HIRS team felt that delivery of the usual PR programme in a group setting had the potential to be either beneficial or detrimental to patients. They also felt that patients attending outpatient-based PR programmes which used minimal equipment rather than a gym-based programme may contribute to why patients may be unmotivated to travel to attend an outpatient-based class:

> *"The church halls they use, a lot of them are just like, "I can do that at home"."* [SM11, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 4 years working within HIRS]

Like the PR team, the HIRS team felt COVID-19 had had a significant impact on their usual service delivery. The HIRS team have reported that they had had to prioritise certain patient groups in order to limit the risk of spreading COVID-19:

> *"We're now not taking early supported discharges, […] so it's just admission avoidance we're doing now"* [SM09, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 2.5 years working within HIRS]

The HIRS team also reported that they had changed their referral patterns to outpatient-based PR for a period due to their perceived impact of COVID-19 on the provision of outpatient-based PR:

> *"For quite a long while, there was no pulmonary rehab, so we weren't referring anybody"* [SM09, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 2.5 years working within HIRS]

6.6.3.2.2 Perceptions of intervention

The theme of perceptions of the intervention encompassed subthemes of: a) benefits of home-based PR, b) limitations of home-based PR, c) home-based PR as a bridge to outpatient-based PR, and d) timing of intervention delivery.

The general perspective of the HIRS team was that the intervention was proving an alternative to outpatient-based PR for patients who otherwise would not receive any exercise training or

rehabilitation. They felt providing a home-based programme removed lack of transport as a reason for declining exercise training:

> *"A lot of our patients are keen to increase their exercise activity, but the transport issues always used to put them off. X came along and offered it at home. They all really enjoyed it"* [SM08, Respiratory Nurse, 3 years of nursing experience, 1 year working within HIRS]

The HIRS team perceived there to be potential benefits to family members or carers if PR was delivered at home with regards to issues related to transport:

> *"When I've been speaking to people about pulmonary rehab, and we say that "You have to go to the Harefield for the first assessment," and they say, "My daughter has to bring me in"."* [SM10, Respiratory Clinical Nurse Specialist, 6 years of nursing experience, 6 months working within HIRS]

They also reported that delivering a programme peri-exacerbation had the potential to reduce the impact the exacerbation had upon patients:

> *"I think a lot of the time, when they exacerbate, they literally stop, don't they? Very quickly, they lose their muscle mass, exercise tolerance and things like that. I think they didn't lose as much, because the intervention was started at an earlier stage"* [SM11, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 4 years working within HIRS]

Finally, the HIRS team also suggested a home-based programme could potentially offer a solution to reduce the social isolation felt by patients despite not delivered within a group setting:

> *"Some of them are, obviously, elderly, can't get to rehab. They live alone and they are quite lonely, and having that regular contact, it would be good for them"* [SM11, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 4 years working within HIRS]

The main limitation perceived by the HIRS team was the cost of delivering a home-based programme:

> *"I actually think it's an intervention that's needed, but it's perhaps, not cost-effective, I don't think many teams are going to have the capacity to actually do home-based exercise programmes tailored – individually tailored – to patients"* [SM11, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 4 years working within HIRS]

Like the PR team, the HIRS team felt a home-based PR programme could also be effective as a bridge to outpatient-based PR:

> *"For some, they hadn't realised before how beneficial pulmonary rehab could be to them, because they'd never considered even doing it"* [SM09, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 2.5 years working within HIRS]

The HIRS team discussed timing of the intervention delivery from their perspective, indicating the optimal timing for delivery had been implemented within the study:

> *"She would wait for the patients to stop nebs, […] I think it was probably the right time. I think any earlier would have been too soon"* [SM11, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 4 years working within HIRS]

6.6.3.2.3 Perceptions of integration

The HIRS team felt there were three areas where integration occurred (home-based PR with HIRS, researcher within HIRS, and HIRS with outpatient-based PR). All the HIRS team felt integration improved patient care as there was a more seamless delivery of care and the ability to provide care to more patients:

> *"It was a lot more cohesive, like having, it's almost like passing the baton on to somebody else who's doing it at the same time"* [SM10, Respiratory Clinical Nurse Specialist, 6 years of nursing experience, 6 months working within HIRS]

They also stated that they felt that the closer integration with healthcare professionals from PR provided wider expertise and knowledge to the HIRS team which they perceived resulted in patients receiving better information about their care options:

> *"Encouraging patients to attend PR is actually better coming from a person who does it"* [SM11, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 4 years working within HIRS].

The HIRS team stated they found the integration of home-based PR within HIRS care to not only result in the provision of more care due to having an increase in the number of staff and a greater amount of information regarding their care options, but that it could also actively reduce the clinical workload for the HIRS team. Finally, they found benefits from integration which occurred not only at the care delivery level, but also in relation to sharing an office:

> *"It just works well that she is here and working "with us"."* [SM09, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 2.5 years working within HIRS]

They reported this physical integration through office sharing made them feel more connected to the PR team at Harefield:

> *"I feel more integrated with Harefield, really get an insight into what goes on over there"* [SM09, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 2.5 years working within HIRS]

6.6.3.2.4 Experiences and perceptions of the study

Overall, the HIRS team felt the intervention was of interest to patients admitted to hospital with an acute exacerbation of COPD. However, the HIRS team felt that an important patient group were not included in the eligibility criteria for the study:

> *"The idea of admission avoidance, is to avoid them having to come in, in the first place, but then they didn't have the opportunity to have that intervention at home, which is a real shame"* [SM09, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 2.5 years working within HIRS]

With regards to the impact of the study on them, the HIRS team felt the study had very little impact upon their day-to-day roles, and that there was only one additional questionnaire which they were required to complete which added to their workload:

> *"If they were interested, we would just leave them the leaflet and let X know. She would then go and speak to them, so it wasn't anything time-consuming. I think it was definitely worth those few extra minutes"* [SM11, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 4 years working within HIRS]

The HIRS team also reportedly found the elements of the study, which occurred during the HIRS phase of the patients care pathway, to have been delivered efficiently, and that they were well-informed about the study:

> *"To be honest, I think X was very proactive, and she was very good at keeping us informed, I can't think of anything we needed to know that we didn't or had to ask about."* [SM11, Respiratory Clinical Nurse Specialist, 18 years of nursing experience, 4 years working within HIRS]

6.6.3.3 Researcher perspectives

Table 6.16 includes the themes and subthemes identified from the researcher interviews. These were the most disparate themes and subthemes when compared to other themes raised by the other stakeholder groups. A narrative on each is presented with supporting quotes.

Table 6.16. Themes and subthemes from the researcher interviews

Major themes	Subtheme/s (if applicable)
1. Individual's role in the study	a) Perception of significance of role b) Perception of requirements from role in study c) Understanding of study assessment time points and crossover with usual care
2. Communication between researchers	N/A
3. Experiences and perceptions of the study	a) Experiences of study assessments and processes b) Knowledge of other people's role in study c) Perceptions of outcomes
4. Learning for future studies	a) Impact of COVID-19 on study assessments and processes

6.6.3.3.1 Individual's role in the study

The individual's role in the study encompassed subthemes of: a) perception of significance of role, b) perception of requirements from role in study, and c) understanding of study assessment time points and crossover with usual care.

The first subtheme was the researchers' perception of the significance of their role. The majority of the researchers perceived themselves to have small and insignificant roles in the delivery of the study, which was reiterated multiple times by each researcher. Only the researcher who had been tasked to undertake the majority of the research assessments during the planning of the study perceived themselves to have made a significant contribution to the study. All the researchers felt the

requirements of their role were well considered to ensure the workload they undertook was realistic and in line with their level of expertise:

> *"At the time I had a dual role, so it made sense that I was just the second assessor"* [SM14, Senior Research Physiotherapist, 8 years research experience]

The final subtheme related to the researchers' understanding of study assessment time points and the studies crossover with usual care. The majority of the researchers struggled to recall the time points of the assessments relative to the patients' index admission. The researchers also had difficulty recalling whether assessments were undertaken in relation to usual care.

6.6.3.3.2 Communication between researchers

There were multiple strategies identified which enabled effective communication between researchers. There appeared to be both formal handovers and updates as well as a combination of strategies (face-to-face, digital and case notes) which were utilised. These combined strategies resulted in the researchers perceiving the communication during the study to have been effective. Digital communication strategies were highlighted to be valuable tools to utilise. These included the use of shared diaries, email, and text messages with group conversations. The use of written communication within case notes supplemented by a brief verbal handover alongside digital strategies was also perceived to have contributed to effective communication.

The researchers also acknowledged that the person co-ordinating the study was required to have good organisation and communication skills. This related to organisation and communication that occurred before the study began as well as whilst the study was being conducted.

Another important factor which contributed to the quality of communication between researchers working on this study was that the team were well-established and had worked together on multiple studies:

> *"I think we're so used to working together because we do a lot of it without thinking"* [SM12, Research Physiologist, 5.5 years research experience]

6.6.3.3.3 Experiences and perceptions of the study

The theme of experiences and perceptions of the study encompassed subthemes of: a) experiences of study assessments and processes, b) knowledge of other people's role in study, and c) perceptions of outcomes.

The first subtheme was the researcher's experiences of the study assessments and processes. The location of the assessments was discussed by multiple researchers. The researchers felt that by offering home-based assessments, a greater proportion of visits were completed:

> *"I think a lot of them wouldn't have come into the hospital because they either hadn't started going out, some of them, just were still relatively housebound and only going out if absolutely necessary"* [SM01, Research Physiotherapist, 2.5 years research experience]

All the researchers felt the study assessments and processes were well-organised, which resulted in their involvement in delivery of the study being easier, and they felt that it was a seamless transition between contacts with different researchers:

> *"It flowed from one person to another"* [SM01, Research Physiotherapist, 2.5 years research experience]

Researchers also shared their knowledge of other people's role in study. All the researchers were able to identify the role they had, along with other members of the research team, within the study. None of the researchers reported any ambiguity or confusion regarding their role, even those who were newest to the research team:

> *"I think everything was clear right from the beginning"* [SM13, Research Physiotherapist, 1.5 years research experience]

The final subtheme identified related to perceptions of the outcomes. The researchers reported they understood the inclusion for the outcome measures. They felt given the challenges related to the variety of locations where outcomes would be assessed in the study, a comprehensive range of outcomes were assessed. Nonetheless, the researchers did report finding some of the outcome measures included in the assessments to be difficult to conduct in patients' homes:

> *"I thought four metres gait speed, that's dead easy to do in a patient's house but actually it wasn't"* [SM12, Research Physiologist, 5.5 years research experience]

In addition, some of the assessments appeared effortful (for example, spirometry, particularly when conducted in the home setting). Another of the outcomes also reported to be physically demanding for patients was the 6MST:

> *"It is probably one of the toughest tests [6MST] I have had to do with a patient"* [SM14, Senior Research Physiotherapist, 8 years research experience]

Despite this, it was identified that although this assessment was physically demanding, researchers perceived the 6MST to be acceptable to patients as it allowed them to self-pace and rest. As a result, the researchers reported that the study protocol did not seem to be too burdensome once they begun completing the assessments:

> *"I thought that there might have been too many measures, […] but in reality, the patients tolerated it really well*" [SM01, Research Physiotherapist, 2.5 years research experience]

6.6.3.3.4 Learning for future studies

The theme of learning for future studies encompassed a subtheme of impact of COVID-19 on study assessments and processes.

All four of the researchers interviewed provided insights related to this theme. First, although the researchers recognised the need to offer home-based as well as hospital-based assessments, their preference was hospital-based assessments where possible. They also highlighted some of the challenges of conducting assessments. These related to the difference in space availability depending on the location of the assessments, the number of staff required for undertaking the 6MST and the wide range of equipment required due to the diversity of assessments being completed.

One researcher highlighted an important element of planning the study was briefing the team who would be involved in delivery before commencing recruitment:

> *"[Meeting as a team] was probably one of the most useful things to do starting off […] all of us had knowledge of this study"* [SM12, Research Physiologist, 5.5 years research experience]

This was considered important to ensure the team who would be involved in the study delivery were involved from the outset to mitigate any potential areas for problems before they could occur. For example, strategies to ensure blinding was maintained were discussed prior to the study commencing, and reportedly worked effectively.

The researchers also highlighted the issues related to relying on one person to co-ordinate and deliver the majority of this study:

> *"If X went on sick leave or if she went- I don't think she did, but if she had time off, like annual leave, how is that covered?"* [SM14, Senior Research Physiotherapist, 8 years research experience], also stating: *"I think it [delivering the intervention] was an awful lot to do on top of recruiting, doing the baseline assessments, and if the study was to be done again, whether you would plan that differently"*

In terms of data collection tools, some researchers suggested that the use of electronic paperwork could have been useful. However, they also acknowledged this came with its own challenges of ensuring data security and issues with digital literacy which would require consideration.

It was also perceived that timing research assessments in relation to usual care was beneficial to patients so the patients could decide whether they preferred to complete the additional research outcome measures when attending their outpatient-based PR assessment, or on a separate day.

Overburdening patients with too many outcome measures was another consideration which researchers reported. They felt this to be something which was managed well in this study:

> *"The nice thing about the assessment with the balance of the questionnaires versus was the physical stuff, I think they didn't get overloaded with all of the maximal exercise tests"* [SM01, Research Physiotherapist, 2.5 years research experience]

For the majority of the researchers, this was the first study whereby patients had greater choice in where assessments, and which outcome measures, were completed:

> *"[This was] the first study really where they were having the option, the dynamic changes, they have more of a choice"* [SM12, Research Physiologist, 5.5 years research experience]

One researcher felt patients were altruistic when consenting to take part in research: something also reported by patients themselves and family carers. It was considered important from their perspective to ensure that patients were indeed giving their consent after fully understanding what was required, as opposed to taking part due to a feeling of obligation.

The final major learning point was that the researchers recognised the importance of the team delivering this study to be one that was well-established and well-organised, and that these factors played a part in this study being feasible. They felt these factors needed to be considered if the study was to be completed across multiple centres in the future:

> *"We're so used to working with each other as a team and so we have a trial and tested way of doing things that seem to work quite well. I suppose therefore if you're rolling out in other sites it would need adapting to work with the way that that team works."* [SM12, Research Physiologist, 5.5 years research experience], also stating: *"We're used to juggling different studies and sitting in different assessments for different people"*

All the researchers acknowledged rapid problem-solving was required to minimise the impact COVID-19 had upon the collection of outcome data for patients recruited to this study. The researchers also noticed the difference in the way they were able to communicate via the telephone rather than in person. Nonetheless, they felt that given that patients were in a position where they could have been feeling increasingly socially isolated, that the telephone assessments were well-received.

6.7 INTEGRATED RESULTS

A mixed method matrix was used to compare the quantitative and qualitative findings for the interviewed patient participants at an individual level, with family carer perspectives and experiences

combined where available. The integrated findings are reported in a modified joint display (Table 6.17). Section 6.4.10.3 details how the integrated findings were determined.

Some of the integrated findings include a single outcome. For example, P11 reported she felt the study was feasible and acceptable from her perspective during her qualitative interview. This was confirmed by the quantitative data as she completed the study per protocol (all three assessments within the allocated window for completion), did not drop out from the study and there were also no instances of accidental unblinding during her follow-up assessments. The only deviation made in relation to the types of outcomes collected during assessments was due to the COVID-19 restrictions which meant the 12-week assessment was prohibited from being face-to-face.

In comparison, other integrated findings include multiple outcomes. Multiple outcomes were possible when there were multiple different perceptions or experiences reported in the qualitative data and/ or multiple related quantitative endpoints. For example, there were multiple outcomes for P02 regarding the clinical outcomes of the intervention. P02 and her husband (family carer FMC02) both reported the patient participant had a reduction in her abilities to complete ADLs early post discharge, however that this had improved over the follow-up period. The LCADL scale total score confirms this perceived improved ability to complete ADLs as the LCADL scale total score was reduced at both four weeks and 12 weeks (a reduction in the LCADL total score indicates a decrease in impairment with ADLs). P02 also reported that she felt her strength had increased as a result of the intervention. However, her hand grip strength had reduced at both four weeks and 12 weeks. In this instance, the quantitative and qualitative data refute each other. Finally, there was evidence of complementary findings as P02 reported an improvement in her walking over the 12-week follow-up period. The 6MST, a surrogate test of exercise capacity (but not specifically a field walking test), showed the number of steps she achieved at both the four week and 12-week assessments to have increased.

With regards to study feasibility, the integrated findings were confirmatory and/or complementary between the patient participant and family carer qualitative findings and the quantitative results, which indicates the study to be both feasible and acceptable. This result is unsurprising given that all the patients interviewed completed the study as per protocol and did not include data for those who dropped out from the trial.

The integrated findings were confirmatory and/or complementary between the patient participant and family carer qualitative findings and quantitative results to suggest the intervention to also be feasible and acceptable. However, similar to the study feasibility, all the patient participants interviewed who were allocated to the intervention took up and were able to adhere to the intervention, and the control group patients were also actively engaged or had previously actively engaged in outpatient-based PR.

The integrated findings for the clinical outcomes are more complex, as detailed earlier in this section. All three integrated outcomes were found when comparing the qualitative and quantitative data according to each patient participant (and their family carer when the data was available) at an individual level. There were also between-patient participant differences in the integrated findings regarding which quantitative and qualitative outcomes were confirmatory, complementary and refutory.

The integrated findings related to clinical safety were complementary for all the patient participants. The qualitative data suggested patient participants and their family carers to have had positive experiences of intervention or outpatient-based PR, and of the other care they received post-index

admission. This is reflected in the quantitative data which showed neither group were more likely to present with an adverse event or be readmitted. The quantitative data also indicated that although the patient participants interviewed did report non-serious adverse events and/or were readmitted to hospital, none of the adverse events were related to the intervention.

Lastly, there was silence present for a number of themes and subthemes which were identified in the patient participant and/or the family care qualitative interviews. This arose from the fact the interviews were semi-structured in nature, and that the interviewer prompted the interviewee where required beyond the suggested probes in the topic guide to comprehensively explore perspectives (257).

Table 6.17. A joint display of the integrated findings according by individual patient participants (and their family carers where appropriate)

QUALITATIVE FINDINGS				QUANTITAIVE FINDINGS				INTEGRATED FINDINGS
Study feasibility								
Patient participant Study ID*	Patient participant perspectives	Family carer Study ID^	Family carer perspectives	Participant flow & attrition	Assessor blinding maintenance (T1 & T2)	Q. outcome measure completion (T0, T1 & T2)	Physical outcome measure completion (T0, T1 & T2)	
P02	Feasible & acceptable - altruistic regarding reasons for consenting	FMC02	Feasible & acceptable – no support required	Per-protocol & No	Yes & Yes	Yes, Yes & Yes	Yes, Yes & Yes	CONFIRMATION & COMPLEMENTARY
P03	Feasible & acceptable - altruistic regarding reasons for consenting	FMC01	Feasible & acceptable – support with study paperwork required	Per-protocol & No	Yes & Yes	Yes, Yes & Yes	Yes, Yes & Yes	CONFIRMATION & COMPLEMENTARY
P08	Feasible & acceptable – altruistic regarding reasons for consenting; struggled with home exercise diary compliance			Per-protocol & No	No & Yes	Yes, Yes & Yes	Yes, Yes & No<	CONFIRMATION & COMPLEMENTARY
P11	Feasible & acceptable			Per-protocol & No	Yes & Yes	Yes, Yes & Yes	Yes, Yes & No<	CONFIRMATION
P15	Feasible & acceptable – modified home exercise diary format			Per-protocol & No	Yes & Yes	Yes, Yes & Yes	Yes, No< & No<	CONFIRMATION & COMPLEMENTARY
Intervention feasibility								FINDING/S

Patient participant Study ID*	Patient participant perspectives	Family carer Study ID^	Family carer perspectives	HaH delivery> & between-group contamination	Intervention uptake & adherence>	PR referral	PR uptake & completion	
P02	Feasible and acceptable – preference of one-to-one over group exercise training; types (& progression) of exercises, length & frequency of intervention appropriate; supervision beneficial; education tailored & informative	FMC02	Feasible and acceptable – had minimal involvement in sessions; self-purchased pedometer to promote maintenance	4 & No	Yes & 9	No	-	CONFIRMATION & COMPLEMENTARY
P03	Outpatient-based PR feasible and acceptable – travelling to programme challenging; husband provided transport	FMC01	Transport provision to support attendance to outpatient-based PR – self-purchased weights to promote maintenance	3 & No	-	Yes	Yes & Yes	CONFIRMATION & COMPLEMENTARY
P08	Feasible and acceptable - types (& progression) of exercises & frequency of programme appropriate; well-timed delivery; supervision aided motivation			6 & No	Yes & 6+	Yes	Yes & No<	CONFIRMATION & COMPLEMENTARY

P11	Feasible and acceptable – preference of group over one-to-one exercise training however insufficiently confident to attend outpatient-based PR; supervised element important			5 & No	Yes & 9	No	-	CONFIRMATION & COMPLEMENTARY
P15	Declined outpatient-based PR as too unwell and due to ambulatory oxygen restrictions, home-based exercise training a preferred alternative			4 & No	-	No	-	CONFIRMATION & COMPLEMENTARY

Clinical outcomes												**FINDING/S**
Patient participant Study ID*	Patient participant perspectives	Family carer Study ID^	Family carer perspectives	T0 to T1 & T0 to T2								
				LCADL total score	SPPB total score	Hand grip	CAT	EQ5D5L (UI; VAS)	HADS (A; D)	mCES-D (a; b)	6MST	
P02	Reduced ability with some ADLs & walking initially post-discharge, some support was required; intervention	FMC02	Physical and psychosocial benefits of intervention; provided some support early post-	-13 & -11	1 & 1	-15% & -11%	-2 & -9	-0.144 & 0; 10 & 15	2 & -3; 0 & 0	0 & 0; 0 & 0	23 & 36	CONFIRMATION, REFUTATION & COMPLEMENTARY

	improved walking, activity levels and strength		discharge with some ADLs									
P03	Functionally limited pre-admission; ability to complete most ADLs reduced further initially post-discharge, some additional support was required; initially exercises at outpatient-based PR hard, gradually became easier	FMC01	Physical and symptom-reducing benefits of outpatient-based PR; provided some additional support post-discharge with some ADLs	-2 & -4	-1 & 0	-4% & 9%	-3 & -4	-0.167 & -0.188; 10 & 0	3 & -7; 1 & 0	0 & 0; 0 & 0	T0=UTC & NC	CONFIRMATION, REFUTATION & COMPLEMENTARY
P08	Reduced ability with some ADLs early post-discharge; took several weeks post-discharge to return to normal functional capacity; intervention improved strength			0 & -5	0 & NC	-14% & NC	4 & -2	0.050 & 0.078; 5 & 11	1 & -1; -2 & -3	-1 & -1; -1 & -1	-2 & NC	CONFIRMATION, REFUTATION & COMPLEMENTARY
P11	Insufficient confidence to leave home post-index admission, reduced confidence remains;			14 & 8	0 & NC	-3% & NC	-3 & -5	-0.046 & -0.031; 35 & 0	-5 & -5; 0 & -3	-2 & -2; -2 & -1	T0=UTC & NC	CONFIRMATION, REFUTATION & COMPLEMENTARY

	intervention improved strength											
P15	Levels of fatigue remain higher than pre-admission levels; reduced ability to complete most ADLs early post-discharge, some additional support was required; reassured to have wider support network (friends & neighbours) should they have been required			0 & -8	NC & NC	NC & NC	-2 & -1	0.200 & 0.230; 0 & 15	4 & 0; 3 & 0	0 & -1; 1 & 0	NC & NC	CONFIRMATION, REFUTATION & COMPLEMENTARY
Clinical safety												**FINDING/S**
Patient participant Study ID*	Patient participant perspectives	Family carer Study ID^	Family carer perspectives	Non-serious adverse event			Mortality			Hospital readmission		
P02	Stress and anxiety related to index admission prior to & during hospitalisation; well-supported by HaH service; positive benefits of completing intervention post-discharge	FMC02	HaH service care received was positive; practical way to deliver care; aided decisions regarding readmission	Yes			No			Yes		COMPLEMENTARY
P03	Worry about prognosis; well-supported by	FMC01	Worry about prognosis; unsure about ongoing self-	Yes			No			No		COMPLEMENTARY

	clinical services (HaH service, district nurses & palliative team)		management; worry about clinical stability early post-discharge; HaH service care received positive; has equipment to monitor patient at home				
P08	HaH service provided rapid assessments & aided decisions regarding readmission; positive benefits of completing intervention post-discharge; well-timed delivery of intervention			Yes	No	Yes	COMPLEMENTARY
P11	Positive benefits of completing intervention post-discharge; knowledgeable regarding HaH service support			No	No	No	COMPLEMENTARY
P15	Knowledgeable regarding HaH service & other community support; reassured to have wider support network (friends			No	No	No	COMPLEMENTARY

	& neighbours) should they have been required						

* The patient participants characteristics according to their Study ID by sex, age, group allocation, readmission status within 12 week follow-up period, change in HRQoL status as measured by change in CAT score between baseline and 12 weeks: P02: female, aged 70, intervention group, readmitted, significant improvement in HRQoL; P03: female, aged 62, control group, not readmitted, significant improvement in HRQoL; P08: male, aged 80, intervention group, readmitted, significant improvement in HRQoL; P11 female, aged 83, intervention group, not readmitted, significant; improvement in HRQoL; P15; male, aged 77, control group, not readmitted, non-significant improvement in HRQoL.
^ The family carer characteristics according to their Study ID by sex, age and group allocation of the related patient participant: FMC01: male, aged 65, wife allocated to control group; FMC02: male, aged 72, wife allocated to intervention group.
< Unable to complete due to COVID-19 restrictions
> Number of sessions
+Transitioned into outpatient-based PR therefore did not receive 8 weeks of the study intervention; completed 6/8 sessions planned prior to commencing outpatient-based PR.
- Outcome not applicable
Abbreviations: 6MST: 6 minute step test; a: "I felt that everything I did was an Effort" question; A: anxiety; ADLs: activities of daily living; b: "I could not get "going"" question; CAT: COPD Assessment Test; D: depression; EQ5D5L: Euro-Qol 5-dimentions 5-levels questionnaire; HADS: Hospital Anxiety and Depression scale; HaH: hospital at home; LCADL: London Chest Activities of Daily Living scale; mCES-D: Modified Center for Epidemiologic Studies Depression scale; NC: not calculable (due to outcome not able to be collected due to COVID-19 restrictions); PR: pulmonary rehabilitation; Q.: questionnaire; SPPB: Short Physical Performance Battery; T0: baseline assessment at hospital discharge; T1: 4-week follow-up assessment; T2: 12-week follow-up assessment; UI: utility index; UTC: unable to complete 1 step; VAS: visual analogue scale.

6.8 DISCUSSION

The findings presented are the results from a mixed methods feasibility study which was suspended as a result of COVID-19. The findings suggest the co-designed home-based exercise training intervention integrated within a well-established HaH service to be acceptable to patients, family carers and healthcare professionals alike. However, further piloting would be required to make fully informed refinements to the study protocol and realistic recruitment and retention trajectories to ensure an efficacy trial in the future would be feasible.

Limited conclusions could be drawn about clinical outcomes, but questionnaire-based outcomes appeared more acceptable to patients than physical measures, and in particular there was very poor uptake for monitoring via accelerometer. Qualitative findings indicated that patients, family carers and healthcare professionals found the integration of the home-based exercise training within a HaH service acceptable, however did not explain the disparity between outcome measure completion rates. The data obtained up to study cessation did not demonstrate any safety concerns associated with the intervention, corroborated by the qualitative findings.

6.8.1 Implications of the findings

6.8.1.1 Study feasibility

The quantitative results suggest that many hospital episodes would have to be screened to identify a sufficient number of eligible patients for an efficacy trial given that less than 10% of screened patients were recruited, with only half of those eligible recruited. In particular, within a single-centre, some hospital episodes were readmissions of trial participants (i.e. “revolving door” patients with multiple hospital admissions per year) which made them ineligible for recruitment. Furthermore, a significant

proportion of patients were ineligible for the trial because they did not meet the local HIRS criteria for HaH (most commonly, being too well to require nursing support on discharge). Future home-based exercise trials may need to consider widening the inclusion criteria to increase recruitment rates.

An interesting observation was that almost all the patient participants recruited had previously attended outpatient-based PR (15 out of 16). Explanations include the presence of an active integrated respiratory care service in the region with well-established PR pathways, or a potential selection bias whereby patients with past experience of PR were more likely to consent for the study. Moreover, of 15 patients who declined consent for the trial, five did so because they did not want to undergo the intervention. These data suggest this intervention may be most acceptable to those who are invested in engaging with exercise training.

Further observations include the better retention of patients within the intervention group (half the control group compared with none of the intervention group were lost from the trial at four weeks) and that the main reason for unblinding being assessments were completed by an unblinded researcher. The attrition in the control group appeared to be due to medically related issues rather than unhappiness about not receiving the intervention. Given the small numbers of this feasibility study, it is possible that the observation could be explained by chance. Additional pilot work is needed to see whether the attrition in the control group is consistent and whether by allocating more staff to support the completion of study assessments mitigates the risk of unblinding.

Moreover, feasibility outcomes relating to completion rates and missing data for clinical outcomes at baseline, four weeks and 12 weeks, also require further piloting given the impact COVID-19 restrictions had on the ability to complete face-to-face assessments.

With regards to the qualitative results, all three stakeholder groups found the study to be feasible and acceptable. The researcher stakeholder group provided the most information regarding feasibility of the study assessments and processes, and insights to enhance the delivery in a future efficacy trial. The other healthcare professional stakeholder groups provided valuable learning regarding integration and offered their perspectives on how this could be refined.

As was highlighted by the integrated analysis, all the patient participants who were interviewed also completed the RCT components of the study per protocol. As a result, it would be important to ensure patients who dropped out or missed an assessment were included in interviews prior to an efficacy trial. This would allow a more comprehensive understanding of the potential barriers to study feasibility from a patient perceptive to be obtained (258).

Finally, neither of the interviewed family carers reported any increased burden or worry as a result of the person living with COPD being involved in the research study. This finding is important given the already increased burden placed upon family carers during an acute exacerbation of COPD (28).

6.8.1.2 Intervention feasibility

The findings from this study suggest that the provided usual HaH care was similar between the two groups, and that contamination of the additional care provided to the intervention group into the control group did not appear to have occurred. Limited findings can be drawn from the data regarding intervention fidelity as 25% of the patient participants allocated to the intervention group were unable to receive the intervention due to COVID-19 restrictions. Nonetheless, given many of the sessions

were not delivered (>50%) to those who were able to receive the intervention, further exploration of compliance is required.

Another observation is that very few patients were referred to outpatient-based PR at discharge and on discharge from HaH service, with the numbers of those taking up and subsequently completing the programme similarly low. Given the small numbers of this feasibility study, further piloting is required to better understand referral, uptake, and completion patterns.

Most stakeholder groups (healthcare professional [HIRS team and PR team], patient participant and family carer) provided valuable qualitative insights regarding intervention feasibility and acceptability. These findings corroborated the perspectives raised in the co-design phase of this programme of work (Chapter 5), and suggest the designed intervention is both feasible and acceptable. As per the findings for study feasibility, family carers did not report any increased burden or worry as a result of the person living with COPD receiving the intervention.

Finally, as highlighted in section 6.7, further piloting is required to explore the perspectives of less engaged patient participants, in particular patient participants who were unable to take up and adhere to the intervention, in order to understand intervention acceptability and feasibility more comprehensively.

6.8.1.3 Clinical outcomes and safety

Although the aim of the feasibility study was not to assess clinical efficacy of the intervention, potential clinical outcomes for a future efficacy study were recorded to provide insight into data

completeness, acceptability to patients and feasibility within the study setting. Whereas the questionnaires appeared to be acceptable, there was poor uptake of the 6MST. The 6MST has been shown to generate a near maximal cardiorespiratory response despite being reproducible (259, 260) and may not be an appropriate clinical outcome in this highly symptomatic population. Of note, although only two out of 16 declined to complete at baseline, five out of the 12 patients who consented to attempt the test were unable to complete a single step at baseline. Furthermore, the qualitative data from the researchers pointed out that the 6MST required two researchers to supervise the test, thus limiting practicability in some settings.

There was also poor uptake of physical activity monitoring through the accelerometer, presumably because of the near continuous recording and intrusiveness. However, the qualitative findings did not provide further insights into the reasons for this to confirm or refute these postulations.

In contrast, data on the SPPB (which comprises balance tests, a four-meter walk and a sit to stand test) were more complete and this may be a more appropriate physical functioning outcome in this population. The SPPB has been widely used in geriatric populations (230-232, 261) and consistently been shown to be associated with poor prognosis. Given that the questionnaire data was consistently complete, consideration also needs to be given to questionnaire derived assessment of physical functioning for a future efficacy study.

Despite the limited conclusions from the quantitative results, the qualitative findings suggest patients, family carers and healthcare professionals all perceived there to be a clinical benefit of home-based exercise training intervention being integrated within a HaH service and being delivered early post-acute exacerbation. In addition, the most interesting results derived from the integrated analysis

relate to potential clinical outcomes despite being the most complex to interpret. Given the complexity and number of outcomes required to be considered when integrating the clinical outcome findings, collection of further data is warranted to gain a more in-depth understanding of the trends between perceived clinical benefit and objectively measured clinical effect.

Although there were limited number of participants, the adverse events findings of this study were reassuring, with only one adverse event (a non-serious event related to the worsening of chronic low back pain) determined to be possibly related to study intervention. This is corroborated by the initial qualitative results, evident from the complementary integrated findings. Additional exploration of patient participants perspectives who experienced an adverse event related to or possibly related to the study is required.

6.8.1.4 Potential application for a future efficacy trial

Initial insights and learning gathered from this study have been considered as if they were to be applied to an efficacy trial at this stage. The current data suggests the way the study was delivered, and the strategies for integration between the teams were felt to be proficient and generally acceptable by stakeholders. However, as discussed earlier, there were several issues that needed consideration for a future efficacy study, including the inclusion criteria (as recruitment was challenging), sample size (there were withdrawals largely due to medical issues) and the choice of clinical outcomes (particularly those related to physical functioning).

A consideration highlighted by the researchers was that an increase in the number of staff would be needed to deliver the trial to ensure better distribution of workload and availability of cover for annual leave (or other reasons). Should this become a multi-centre trial, site-specific modifications regarding

integration would need to be considered to ensure local, service-specific processes were understood. Understanding the expertise and how well-established the research team was at each site would also be essential for a multi-centre study, with modifications made at local, site-specific levels as required. These local modifications would be undertaken to mitigate the risk of intervention, study processes and strategies for integration becoming infeasible or unacceptable.

In the instance that insights raised from the PR team focus group were to be applied as standalone perspectives, adaptation to the intervention prior to an efficacy trial may be needed. The PR team were united in feeling that the intervention may be better delivered purely as a bridging programme into outpatient-based PR. However, the majority of the other stakeholders (patient participants, family carers and HIRS team) welcomed the option of a stand-alone home-based programme.

6.8.2 Adaption to study as result of COVID-19

Recruitment to this study was suspended on 11th March 2020 due to the global COVID-19 pandemic, and the restrictions in place as a result of the COVID-19 pandemic led to face-to-face data collection being prohibited. Consequently, those already enrolled within the RCT were still invited to complete their follow-up assessments, with as many outcomes as possible recorded via the telephone and/or post. No further patients were recruited to this study as the intervention being tested was underpinned by the best available evidence (Chapter 4) and involved a significant amount co-design work (Chapter 5). Therefore, it was deemed inappropriate to undermine the intervention development phases of this programme of work to adapt the intervention to comply with temporary COVID-19 restrictions.

It was however felt the qualitative elements of this study could be more easily collected through to an alternative method of data collection (via the telephone (262, 263) or videoconferencing (264)) to facilitate these being completed in line with the COVID-19 restrictions. As a result, three and one patient participant and family carer interviews respectively were successfully conducted via the telephone. Similarly, all the healthcare professional qualitative data was successfully collected via videoconferencing (four researcher interviews and two [HIRS and PR teams] focus groups).

6.8.3 Critique of the method

This mixed methods feasibility study used multi-methods within its constituent components: the qualitative methods included both interviews and focus groups, undertaken with varying degrees of structuredness, and the quantitative data included both prospective collection of study measures at pre-defined assessment points as well as interrogation of a service database to record outcomes.

The use of multi-methods for the qualitative components of the study was related to the desire to understand 'team' viewpoints from the healthcare professionals perceptive. Therefore, topic guided, semi-structured focus groups were determined to be the most appropriate qualitative method of choice to explore these stakeholder perspectives (265). Comparatively, as the previous co-design work from Chapter 5 illustrated, patients were found to have very individualised needs and preferences. In order to be able to fully explore each patient participants, and their family member or informal carers, individual experiences, topic guided, semi-structured interviews were determined to the appropriate choice of methods for these stakeholder groups (266).

That said, researchers, who were initially intended to be invited to attend a semi-structured focus group, were offered less structured interviews as an alternative (267). This change was reflective of a

discussion with one of my supervisors. It was noted that all the researchers involved in the delivery of the RCT element of this study had all undertaken distinctly different roles. It was felt that the researchers may have disengaged with the focus group as the focus group was unlikely to have been exploring topics which were sufficiently specific or relevant to them. The main component of the topic guide for the researcher interviews was to prompt the interviewee to provide a general description of their role within the delivery of the trial (Appendix 6). This prompt directed the follow-up questions and probes asked by the researcher (Appendix 6).

There are well-documented benefits and limitations to both homogenous and heterogenous samples within focus groups, with a proposed ideal that a focus group includes participants who provide sufficient diversity to generate discussion, without becoming overly different that no common discussion points can occur (268). This study attempted to use a pragmatic sampling strategy, in that the focus groups would include those from a single healthcare professional stakeholder group (focus groups with the HIRS team and PR team separately). However, in order to introduce a degree of heterogeneity, the focus groups would aim to include healthcare professionals from their respective teams who were from different professional backgrounds with varying degrees of clinical expertise. However, as shown in section 6.6.3, there could be an argument to either increase the heterogeneity or increase the homogeneity in the future. A focus group which was more heterogenous (inclusion of healthcare professionals from both the HIRS and PR teams, and across a more diverse range of professional backgrounds) could better facilitate exploration of the between-stakeholder perspectives; a focus group which was more homogenous (inclusion of those with a similar level of qualification and time employed within the team) could better ensure perspectives were more equally voiced.

6.8.4 Strengths

A strength of this study was that the overall objective sought to comprehensively assess the acceptability and feasibility of testing the co-designed home-based exercise training intervention in an efficacy trial in the future. The mixed methods design of this study, with the completion of integrated analysis, means the results of this study, although limited due to COVID-19, have to some extent addressed this overall objective despite the significant disruption due to the COVID-19 pandemic.

An additional strength relates to the two development phases of the intervention. The intervention being tested underwent a rigorous process of systematically synthesising the best-available evidence (results presented in Chapter 4) and is based upon consensus decisions made by the key stakeholders through co-design events and meetings (findings presented in Chapter 5).

The measures to collect the clinical outcome data moved away from traditional PR outcomes, such as field walking tests for exercise capacity or assessments for lower limb strength (269). The measures were instead selected to ensure similar outcomes were recorded, but using alternate methods suited to acute hospital, community and home settings, prioritising practicability and brevity. This was an important strength of this study given the assessments were required to be undertaken across multiple healthcare settings with patients who were acutely unwell.

Finally, the participants recruited to this study were from a single centre (Hillingdon Hospital), with the usual outpatient-based PR programme delivered by a single PR provider (Harefield PR Service). As discussed in Chapter 3 (section 3.7.2), this has resulted in the outcome data relating to outpatient-

based PR referral, uptake and completion for this study to only require interrogation of the Harefield PR service database, which is known to be well maintained and systematically recorded.

6.8.5 Limitations

This was single-centre study, investigating a home-based exercise training intervention integrated within a single, well-established HaH service. The HaH team and PR team both had significant input into both the intervention development and study design. Therefore, although the data from this study appear positive for this type of intervention at this stage in the patient pathway, the results do not mean that this intervention is guaranteed to be feasible and acceptable in its current format should this study to be undertaken across multiple centres. Modification or adaptations at an individual site level may be needed should a multi-centre efficacy trial be undertaken in the future.

Recruitment to this study was suspended on 11th March 2020 due to the global COVID-19 pandemic. Recruitment to this study has been unable to resume due to the ongoing COVID-19 restrictions and the study intervention not being viable whilst they remain in place. Therefore, the amount of quantitative and qualitative data collected was less than planned. However, the data collected was able to help understand the acceptability and feasibility of the intervention and the study design.

The restrictions in place as a result of the COVID-19 pandemic resulted in face-to-face assessments being prohibited for a number of the participants who were recruited prior to the pandemic. As such, there is missing data regarding the feasibility of collecting the physical outcome data for some participants. Therefore, additional piloting is specifically required to fully understand the feasibility of collecting these outcomes prior to an efficacy trial.

6.9 CONCLUSION

The results from this mixed methods feasibility study indicate an efficacy trial which investigates home-based exercise training integrated within a HaH service following hospitalisation for an acute exacerbation of COPD to be acceptable to patients, family carers and healthcare professionals alike. Moreover, the intervention appears to be safe, and patients, family carers and healthcare professionals qualitatively feel it to be of clinical benefit. However, the results highlight areas requiring additional piloting prior to an efficacy trial to increase intervention feasibility and optimise study delivery given the low recruitment rates, high drop out and poor uptake of some physical assessments.

This chapter presents the results from the final stage of the four stage multi-phase mixed methods programme of work included within this thesis. The last chapter, Chapter 7, will include a summary of the results from the programme of work as a whole and draw conclusions based on the programme of work as a collective.

Chapter 7: Summary and future work

This final chapter provides a summary of the results from the programme of work as a whole (Chapters 2 to 6). This chapter will discuss the significance of the findings and offer suggestions for future work.

7.1 SUMMARY OF FINDINGS

Several novel and interesting findings emerged from the first two phases of this programme of work:

1. Provision of a COPD discharge bundle was an important factor in determining referral and uptake rates for post-hospitalisation PR delivered in the outpatient setting (Chapter 2).

2. Referral and uptake rates for post-hospitalisation PR delivered in the outpatient setting were significantly increased when the practitioner delivering the COPD discharge bundle also had responsibilities for and was involved in the delivery of PR (Chapter 2).

3. A co-designed education video intervention shown on the day of hospital discharge had no effect upon patient uptake of post-hospitalisation PR delivered in the outpatient setting (Chapter 3).

4. A significant proportion of the patients were unable to recall watching the co-designed education video at hospital discharge (suggesting the timing of delivery for the education video was not optimal) (Chapter 3).

Following consideration of the findings reported in Chapters 2 and 3, and re-evaluation of the current traditional delivery strategy of post-hospitalisation PR (traditionally an outpatient, centre-based programme), the priority of this programme of work focused on exploring the possibility of post-hospitalisation PR being delivered in the home setting. In order to investigate a home-based PR programme, development of a model of care which would provide the home-based exercise training was required.

Novel findings arose from stage one and two of the intervention development phases of this programme of work:

1. The current evidence-base suggests provision of home-based exercise training following hospitalisation for AECOPD to be feasible and acceptable to both patients and healthcare professionals (Chapter 4).

2. No data was found on perspectives of family members or informal carers regarding home-based exercise training (Chapter 4).

3. There was a paucity of trials and heterogenous data regarding the clinical effectiveness of home-based exercise training following hospitalisation for an AECOPD in relation to physical function, HRQoL and health service utilisation (Chapter 4).

4. An integrated model of care, including home-based exercise training and HaH service, was co-designed by service users and healthcare professionals to address low uptake, referral and subsequent completion of PR following hospitalisation for an AECOPD before testing in phase four (Chapter 5).

Testing of the feasibility and acceptability of this co-designed model of care began in phase four (a mixed methods feasibility study) of this programme of work. Despite this phase being significantly impacted due to the COVID-19 pandemic, the findings which emerged from the mixed methods feasibility study included:

1. The co-designed home-based exercise training intervention integrated within a well-established HaH service developed in phase three was found to be feasible and acceptable to patients, family carers and healthcare professionals alike (Chapter 6).

2. The qualitative findings indicate patients, family carers and healthcare professionals all perceived clinical benefit to integrating home-based exercise training within the HaH service (Chapter 6).

3. The quantitative data obtained regarding adverse events did not present any reasons for concern about the clinical safety of the home-based intervention, which was corroborated by the qualitative findings (Chapter 6).

4. The data also highlighted areas requiring additional piloting to further increase intervention feasibility and optimise study delivery given the low recruitment rates, high drop out rates and poor uptake of some physical assessments. Additional data collection is required to better understand the potential for clinical effectiveness and for determination of effect size prior to an efficacy trial in the future (Chapter 6).

The intervention developed and tested within this programme of work is reported in Table 7.1 according to Template for Intervention Description and Replication (TIDieR) checklist. The table includes the location of information to comprehensively describe the intervention (270).

Table 7.1 Completed TIDieR checklist with information from this thesis to describe the intervention developed within this programme of work

Number	Description	Information location
Brief name		
1	Provide the name or a phrase that describes the intervention	Chapter 5, section 5.1
Why		
2	Describe any rationale, theory, or goal of the elements essential to the intervention	Throughout Chapters 4 and 5
What		
3	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)	Chapter 5, section 5.4.1.3
4	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities	Chapter 5, section 5.4.3
Who provided		
5	For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given	Chapter 5, sections 5.4.1.3 and 5.4.3, plus Figure 5.2
How		
6	Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group	Chapter 5, section 5.4.3
Where		
7	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features	Chapter 5, section 5.4.3
When and how much		
8	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose	Chapter 5, section 5.4.3
Tailoring		
9	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how	Chapter 5, sections 5.4.1.1 and 5.4.1.2
Modifications		
10	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)	Chapter 6, section 6.8.2
How well		
11	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them	Chapter 6, section 6.4.8.2
12	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned	Chapter 6, section 6.5.3

7.2 SIGNIFICANCE OF FINDINGS

The rationale for the programme of work presented in this thesis was that improving access and uptake to PR following hospitalisation for AECOPD is urgently needed. As discussed in Chapter 1, post-hospitalisation PR for an AECOPD is recommended by the British Thoracic Society (34), and is included within the NICE COPD Quality Standards as a key priority of post-exacerbation care pathway (49). However, referral to, uptake (and subsequent completion) of outpatient, centre-based PR following hospitalised AECOPD are low (50, 52). Despite this, there has been limited data on interventions to improve access or uptake to such a programme.

One strategy derived from the service improvement literature which has sought to extend 'reach' of outpatient, centrebased post-hospitalisation PR was the use of COPD discharge bundles. These bundles are a structured aide memoire of evidence-based practices prior to hospital discharge. In the UK, COPD discharge bundles include assessment for suitability, and subsequently offering a referral for PR (75). However, COPD discharge bundles are challenging to deliver, with as few as 8% of patients who receive the bundle receiving all five components (76). Therefore, it is not clear whether COPD discharge bundles do indeed increase the 'reach' of post-hospitalisation PR in practice. Additionally, COPD discharge bundles are potentially limited further as they are focussed solely upon improving referral rates at hospital discharge, and it is unknown whether there is any downstream impact (for example upon patient uptake of a PR programme).

The results presented in Chapter 2 indicate that provision of a COPD discharge bundle in the local setting of the study was an important factor in determining referral and uptake rates for outpatient-based post-hospitalisation PR; no resulting PR referrals occurred when a COPD discharge bundle was not delivered to the patient. Of particular interest, COPD discharge bundles delivered by a practitioner

delivering PR within their workplan was an independent predictor of PR referral and uptake. The data from this study was hypothesis generating, and further studies are required to test whether improving referrer knowledge and experience, potentially through formal training or closer integration between hospital services and PR, might increase referral and uptake for outpatient-based PR post-hospitalisation for an AECOPD. The findings also suggest an intervention which standardises the information provided regarding post-hospitalisation PR within the COPD discharge bundle might increase referral and uptake rates.

In order to address the disparity of the information provided between PR and hospital practitioners regarding post-hospitalisation PR highlighted in the results in Chapter 2, a co-designed education video shown as part of the COPD discharge bundle was investigated in Chapter 3. However, when shown on the day of hospital discharge, the co-designed education video had no effect upon patient referral, uptake, adherence or completion of outpatient-based PR post-hospitalisation for an AECOPD. Possible reasons for failure to demonstrate intervention efficacy include a "Hawthorne effect" on referral rates across both groups, potential cognitive impairments (which were not formally assessed) at hospital discharge and delivery of the video intervention at a sub-optimal time during recovery from an acute exacerbation.

As a result of the findings from Chapters 2 and 3, I explored the feasibility of home-based PR as an alternative model to the current provision of outpatient-based PR delivered in hospital or community settings commonly adopted in the UK.

Chapters 4 and 5 presented the intervention development phase of this programme work. The two stages were essential to ensure the new home-based model of care was underpinned by the best

available evidence and designed around the needs of the key stakeholders (service users and providers). Findings from the mixed methods feasibility study (Chapter 6), which tested the intervention co-designed in stages one and two of phase three of this programme of work, indicated that home-based exercise training integrated within a HaH service following hospitalisation for an AECOPD was feasible and acceptable to patients, family carers and healthcare professionals. The intervention was also safe. However, there were concerns about the study feasibility with slow recruitment rates, low patient retention rates (as this is a highly symptomatic population) in the control group especially, and the feasibility of objective exercise testing in this population and setting. Furthermore, in order to maintain continuity and to ensure assessor blinding, more research staff resources would be needed than anticipated.

7.3 LIMITATIONS AND FUTURE WORK

This programme of work was undertaken with the intention of achieving an overall aim (to examine different ways of improving referral, uptake and completion of PR following hospitalised AECOPD) through completing multiple phases which addressed specific objectives, with each phase built upon the foundations from the previous phase/s. This phased approach was required to ensure the final phase (the mixed methods feasibility study) was undertaken with confidence that the intervention: 1) was an appropriate alternate strategy for delivery which would achieve the overall aim, 2) was underpinned by the best available evidence, and 3) was co-designed by key stakeholders. This was undertaken with the intention of following the Medical Research Council framework for developing and evaluating complex interventions (101). However, despite the robustness of the preparatory phases, the findings reported from the mixed methods feasibility study were limited by early termination of this study due to COVID-19. The global COVID-19 pandemic resulted in a suspension of recruitment to this study, meaning insufficient data were able to be collected to comprehensively answer the specific objectives of this phase. Nonetheless, analysis of the data gathered highlighted

key areas requiring additional piloting to further increase intervention feasibility and optimise study delivery in the future, particularly if a multi-centre efficacy trial is proposed. Areas where additional data collection is also required to better understand the potential for clinical effectiveness and for determination of effect size prior to an efficacy trial in the future have also been identified from this data.

There were also limitations within each phase, with additional research being required to corroborate and/or increase the generalisability or certainty of the findings reported. Phase one was a single centre cohort study. Although the *a priori* sample size was met, only a small proportion of bundles were completed by a hospital practitioner who contributed to PR delivery and the wide 95% confidence intervals suggest a degree of uncertainty. As a result, these findings may not be generalisable beyond our local population, and require corroboration within an external cohort to validate the findings which includes a greater proportion of bundles completed by hospital practitioners who contribute to PR.

Phase two (the VIRTUE study), was also a single-centre study which tested a specific video in a particular setting. Therefore, although the video intervention tested within VIRTUE did not successfully increase referral, uptake, adherence or completion of post-hospitalisation PR, these results do not preclude the success of future video interventions to attempt to improve these outcomes. Therefore, future studies which investigate video interventions that might be developed for other settings, or delivered at different stages of the patient pathway, or as part of a more comprehensive intervention are warranted.

In stage one of phase three (the mixed methods systematic review), the major limitation was the lack of capacity for meta-analysis of the quantitative data. This was due to the lack of continuity in outcome measures, diverse timings for data collection and a significant proportion of unreported data in the included papers for the quantitative data. This suggests future studies investigating home-based exercise training following hospitalisation for an AECOPD should include core outcomes to increase the comparability of results between trials.

For stage two of phase three (the EBCD project), similar to other phases within this programme of work, there is potentially a lack of transferability of the findings as the results only represent the perspectives of the participating stakeholders involved from one locality. Therefore, although these are perspectives of key stakeholders with adequate expertise, the specific model of care developed in this project may require local adaptation and service-specific exploration before wider implementation is possible. In addition, future research to further explore the perspectives of these stakeholders is warranted to corroborate or refute the findings from this EBCD project.

The final phase (the mixed methods feasibility study) was a single-centre study. The HaH team and PR team involved in the study both had significant input into both the intervention development and study design. These services were based in secondary and tertiary care due to the delivery of the HaH and PR for the local services. Therefore, although the findings from this study appear positive for this type of intervention at this stage in the patient pathway, the generalisability and transferability of these findings are not guaranteed. Consequently, modification or adaptations at an individual site level, potentially with input from other care settings (for example primary care if HaH or PR services are hosted within this care sector), may be needed should a multi-centre trial be undertaken in the future.

7.4 CONCLUSION

The burden of COPD remains significant. There are over 250 million cases of COPD worldwide and it is the third leading cause of death globally, with the burden from the disease predicted to continue to rise (2, 3). The impacts of acute exacerbations of COPD are far-reaching, resulting not only in pulmonary consequences, but also to deleterious physical, HRQoL and psychological effects on both patients and family carers. Outpatient-based PR has been shown to be effective in addressing some of these consequences. However, the accessibility and uptake of traditional outpatient-based PR programmes is currently poor, with barriers multifactorial and complex. Although there have been attempts to improve uptake of traditional outpatient-based PR, there are currently no known interventions that increase uptake of PR post-hospitalisation for an acute exacerbation of COPD. Therefore, a shift towards alternative models of delivery (such as in the home setting) may be required to comprehensively address the well-documented issues relating to accessibility of PR following hospitalisation for an acute exacerbation of COPD. This will reduce the requirement for a 'one size fits all' strategy for delivering post-exacerbation PR, and ensure a suite of delivery options can be offered to patients.

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46	Figure	Figure 1.1. Referral, uptake and adherence data to post-exacerbation pulmonary rehabilitation following an admission to hospital over 12 months in a north-west London hospital, UK.	Jones SE, Barker RE, Nolan CM, Patel S, Maddocks M, Man WD. Pulmonary rehabilitation in patients with an acute exacerbation of chronic obstructive pulmonary disease. J Thorac Dis 2018;10(Suppl 12):S1390-S1399. doi: 10.21037/jtd.2018.03.18	Journal of Thoracic Disease permissions@amegroups.com	02/07/2020	Yes; 07/07/2020	Published under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License (CC BY-NC-ND 4.0)
47	Figure	Figure 1.2. Reasons for poor referral, uptake and completion rates to post-exacerbation pulmonary rehabilitation.	Jones SE, Barker RE, Nolan CM, Patel S, Maddocks M, Man WD. Pulmonary rehabilitation in patients with an acute exacerbation of chronic obstructive pulmonary disease. J Thorac Dis 2018;10(Suppl 12):S1390-S1399. doi: 10.21037/jtd.2018.03.18	Journal of Thoracic Disease permissions@amegroups.com	02/07/2020	Yes; 07/07/2020	Published under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License (CC BY-NC-ND 4.0)
Chapter 2	Data	Published, peer-reviewed paper	Barker RE, Kon SS, Clarke SF, Wenneberg J, Nolan CM, Patel S, Walsh JA, Polgar O, Maddocks M, Farquhar M, Hopkinson NS. COPD discharge bundle and pulmonary rehabilitation referral and uptake	Thorax, journal of the British Thoracic Society customercare@copyright.com	07/03/2021	Yes; 09/03/2021	Published under the Creative Commons Attribution-NonCommercial 4.0 International (CC BY-NC 4.0)

			following hospitalisation for acute exacerbation of COPD. Thorax. 2021 Feb 5.				
Chapter 2	Data	Conference abstract	Barker RE, Kon SSC, Clarke SF, Sivarajah S, Nolan CM, Jones SE, Patel S, Walsh JA, Polgar O, Maddocks M, Farquhar M, Wedzicha JA, Man WDC. *Predictors of pulmonary rehabilitation referral and uptake following hospitalization for exacerbations of COPD – a cohort study.* (abstract) American Thoracic Society International Conference (May 2020).	Authors permissions@thoracic.org	02/07/2020	Yes; 03/07/2020	Written permission
Chapter 3	Data	Published, peer-reviewed paper	Barker RE, Jones SE, Banya W, Fleming S, Kon SS, Clarke SF, Nolan CM, Patel S, Walsh JA, Maddocks M, Farquhar M. The effects of a video intervention on Posthospitalization pulmonary rehabilitation uptake. A randomized controlled trial. American journal of respiratory and critical care medicine. 2020 Jun 15;201(12):1517-24.	American Journal of Respiratory Critical Care Medicine, journal of the American Thoracic Society permissions@thoracic.org	24/08/2020	Yes; 27/08/2020	Written permission
Chapter 3	Data	Conference abstract	Barker RE, Jones SE, Banya W, Kon SSC, Fleming S, Nolan C, Patel S, Clarke SF, Walsh JA, Wynne SC, Maddocks M, Farquhar M, Wedzicha JA, Man WDC. *A*	Authors permissions@thoracic.org	02/07/2020	Yes; 03/07/2020	Written permission

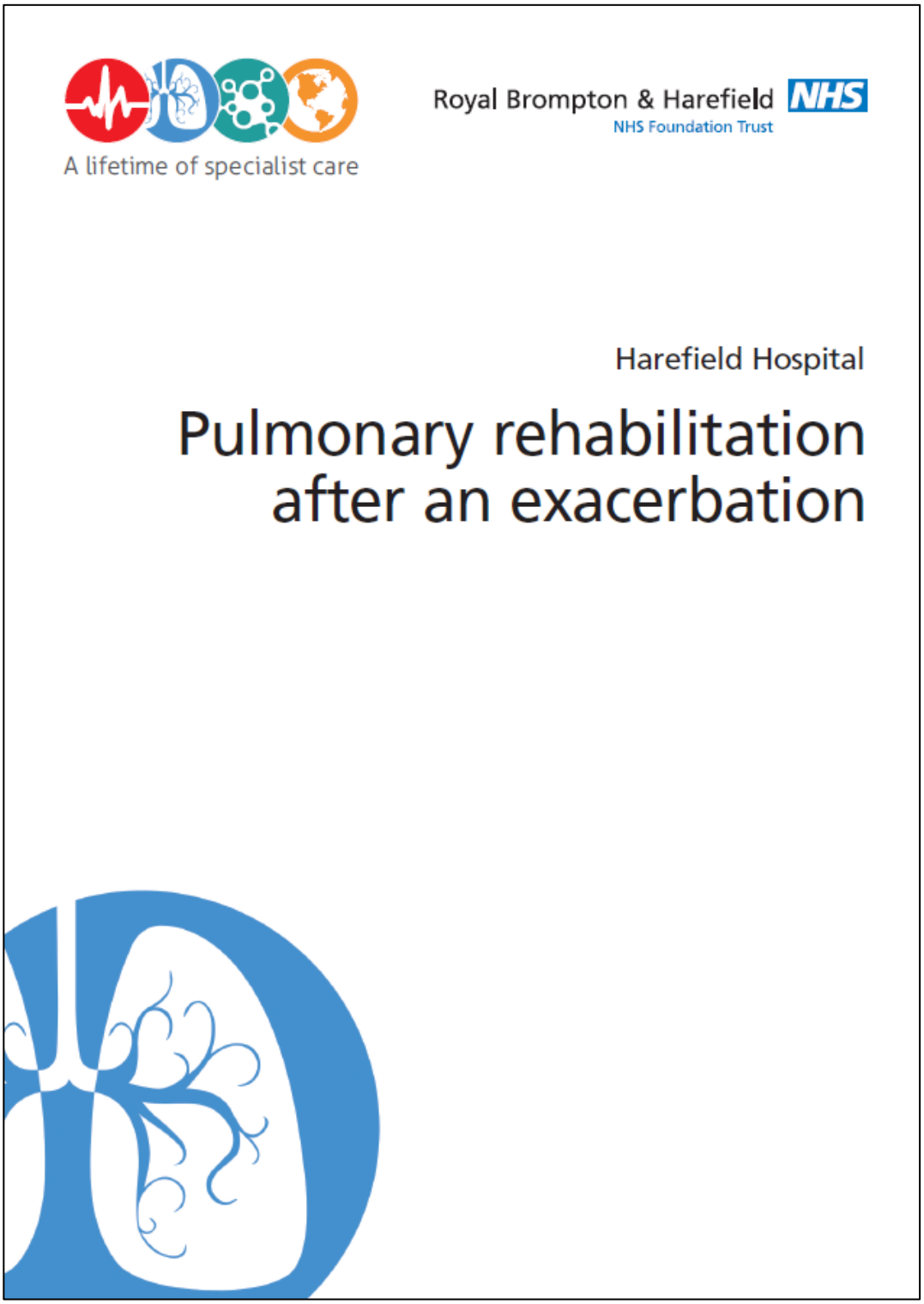
			video intervention to increase pulmonary rehabilitation uptake for patients hospitalized with acute exacerbations of COPD (VIRTUE) – a randomized controlled trial. (abstract) American Thoracic Society International Conference (May 2019).				
99	Figure	Figure 3.2. Schema of experience-based co-design process to develop the video intervention.	Barker RE, Jones SE, Banya W, Fleming S, Kon SS, Clarke SF, Nolan CM, Patel S, Walsh JA, Maddocks M, Farquhar M. The effects of a video intervention on Posthospitalization pulmonary rehabilitation uptake. A randomized controlled trial. American journal of respiratory and critical care medicine. 2020 Jun 15;201(12):1517-24.	American Journal of Respiratory Critical Care Medicine, journal of the American Thoracic Society permissions@thoracic.org	24/08/2020	Yes; 27/08/2020	Written permission
115	Figure	Figure 3.9. CONSORT diagram for flow of participants in VIRTUE trial.	Barker RE, Jones SE, Banya W, Fleming S, Kon SS, Clarke SF, Nolan CM, Patel S, Walsh JA, Maddocks M, Farquhar M. The effects of a video intervention on Posthospitalization pulmonary rehabilitation uptake. A randomized controlled trial. American journal of respiratory and	American Journal of Respiratory Critical Care Medicine, journal of the American Thoracic Society permissions@thoracic.org	24/08/2020	Yes; 27/08/2020	Written permission

			critical care medicine. 2020 Jun 15;201(12):1517-24.				
119	Figure	Figure 3.10. Kaplan-Meier curve demonstrating uptake of pulmonary rehabilitation within 28 days of discharge after hospitalisation for an acute exacerbation of COPD according to group allocation.	Barker RE, Jones SE, Banya W, Fleming S, Kon SS, Clarke SF, Nolan CM, Patel S, Walsh JA, Maddocks M, Farquhar M. The effects of a video intervention on Posthospitalization pulmonary rehabilitation uptake. A randomized controlled trial. American journal of respiratory and critical care medicine. 2020 Jun 15;201(12):1517-24.	American Journal of Respiratory Critical Care Medicine, journal of the American Thoracic Society permissions@thoracic.org	24/08/2020	Yes; 27/08/2020	Written permission
Chapter 4	Data	Conference abstract	Barker RE, Farquhar M, Brighton LJ, Nolan CM, Jones SE, Patel S, Walsh JA, Wedzicha JA, Man WDC, Maddocks M. *Home-based exercise training (HET) post-hospitalisation for acute exacerbation of COPD(AECOPD) - a mixed-method systematic review.* (abstract) European Respiratory Society International Congress (Sept 2020).	Authors permissions@ersnet.org	06/02/2021	Yes; 18/02/2021	Written permission
Chapter 5	Data	Published, peer-reviewed paper	Barker RE, Brighton LJ, Maddocks M, Nolan CM, Patel S, Walsh JA, Polgar O, Wenneberg J, Kon SSC, Wedzicha JA, Man WDC. Integrating Home-Based Exercise Training with a	International Journal of Chronic Obstructive Pulmonary Disease, journal of Dove Medical Press.	08/03/2021	Yes; 08/03/2021	Published under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International

			Hospital at Home Service for Patients Hospitalised with Acute Exacerbations of COPD: Developing the Model Using Accelerated Experience-Based Co-Design. International Journal of Chronic Obstructive Pulmonary Disease. In Press 2021.	viviennegee@dovepress.com			License (CC BY-NC-ND 4.0)
Chapter 5	Data	Conference abstract	Barker RE, Brighton LJ, Maddocks M, Nolan CM, Patel S, Walsh JA, Polgar O, Wenneberg J, Kon SSC, Wedzicha JA, Man WDC, Farquhar M. *Integrating Home-based Exercise Training with a Hospital at Home Service for Patients Hospitalized with Exacerbations of COPD: An Accelerated Experience-based Co-design Study.* (abstract) American Thoracic Society International Conference (May 2020).	Authors permissions@thoracic.org	02/07/2020	Yes; 03/07/2020	Written permission
365 (Appendix 2)	Leaflet	Appendix 2: VIRTUE usual care Pulmonary Rehabilitation leaflet	Harefield Hospital: Pulmonary Rehabilitation after an acute exacerbation.	Copyright © 2020 Royal Brompton and Harefield NHS Foundation Trust. j.thomas@rbht.nhs.uk (Director of Communications)	06/03/2020	Yes; 11/03/2020	Written permission

Appendix 2: VIRTUE usual care Pulmonary Rehabilitation leaflet

Leaflet given as standardised written information regarding PR in VIRTUE. Reproduced with permission of the Royal Brompton and Harefield NHS Foundation Trust, copyright © 2020 Royal Brompton and Harefield NHS Foundation Trust. All rights reserved.



Contents

What is an exacerbation?	3
What is pulmonary rehabilitation?	3
Why am I being offered PR now?	3
Is it safe for me?	4
How do I get referred?	4
What happens at the assessment?	5
What happens during the classes?	5
When and where are the classes?	7
Getting to the classes	7
Who can I contact for more information?	7

This leaflet gives general information on pulmonary rehabilitation after an exacerbation. It does not replace the need for personal advice from a healthcare professional. Please ask us if you have any questions.

What is an exacerbation?

When the symptoms of your lung condition suddenly become worse, it is called an exacerbation. This is usually treated in hospital as an inpatient or by a change in your medications (such as steroids or antibiotics).

What is pulmonary rehabilitation?

Pulmonary rehabilitation (PR) is a set of personalised classes to help you manage your breathlessness and gradually increase your fitness level.

Each class consists of an education and exercise session and lasts around two hours. Classes are held twice a week for eight weeks.

Why am I being offered PR now?

When you have an exacerbation, you may find you are less active. Even when you are starting to feel better, you may still find it harder to do your daily activities. Doctors have studied the effect of PR in patients after an exacerbation. They found that starting PR within two weeks of leaving hospital can help patients in the following ways:

- Make it easier to complete daily activities such as walking, climbing stairs or getting dressed
- Improve quality of life
- Reduce the risk of another exacerbation
- Reduce the possibility of needing another hospital stay
- Improve survival

What patients say about PR

PR is "making the best of what you have".

"It helps me on the road to recovery."

"I said 'that's for me' straight away. I accepted it as I did not want to get worse; I wanted to maintain what I have."

Is it safe for me?

Your healthcare professional will only recommend PR if you meet the medical criteria and it is safe for you to do so. A specialist physiotherapist will check what you can do and ensure it is safe for you to take part.

How do I get referred?

Your doctor, nurse or physiotherapist may recommend PR to you while you are in hospital. Your GP, practice nurses or community matron can also refer you. If you are unsure or would like help being referred, please contact us.

Once you have been referred, we will contact you within two weeks to talk to you about coming in for an assessment.

Please let us know if you have any questions about PR or why you have been referred.

What happens at the assessment?

A specialist physiotherapist will discuss your goals with you and complete a full lung health check-up. You can have the assessment even if your symptoms are worse than normal.

This will include checking:

- How well your lungs work
- How your lung condition affects your walking and daily activities
- Your medical history and medications
- How your lung condition affects you

You can bring a relative, friend or carer with you to all the appointments.

After the assessment, we will offer you a class within four weeks if appropriate.

What patients say about the assessment

"I was very nervous about the assessment but once I was there I was alright."

"The physio was great and explained everything. It was good that they spent a lot of time with me as I was feeling so vulnerable after my hospital stay."

What happens during the classes?

At your first class, we will introduce you to other patients with lung conditions. You will exercise with them in group sessions. Each class is split into an exercise session and education session.

Exercise
The specialist physiotherapist will design a programme specifically for you, based on your goals and medical history from your assessment. This will include a combination of arm and leg exercises with the option of using gym equipment.

What patients say about the exercises

"You are not alone; we are all in the same boat."

"I did a bit more than I thought so I was really pleased."

"They tailored it to my needs."

"It really helped me feel stronger."

Education
The education sessions are designed to provide you with the tools for managing your condition. Topics include:

- Question and answer session with a consultant
- Airway clearance and breathing techniques
- Inhaler technique
- How to manage a chest infection
- Coping with lung disease
- Relaxation and pacing yourself
- Benefits of exercise and how to exercise at home
- Medications
- Help on how to stop smoking
- Healthy lifestyle and diet

What patients say about the education classes

"I do not panic now when I am short of breath."

"It's great they spend time explaining things I've always wanted to know."

When and where are the classes?

There is a choice of classes at different times and locations, such as a hospital, gym or community hall, around North West London. Different patients prefer different environments, so we can discuss the most appropriate option for you.

Getting to the classes

If you do not have your own transport and are unable to use public transport, please ask a member of the team for advice.

Who can I contact for more information?

You can contact us on 01895 828 851 or send an email to hhpulmonaryrehab@rbht.nhs.uk.

A final word from our patients

"You don't know until you have a go."

"My quality of life improved. It does help."

"I'm so glad I did it. It was the best thing for my recovery."

If you have concerns about any aspect of the service you have received in hospital and feel unable to talk to those people responsible for your care, call PALS on 01895 826 572 or email pals@rbht.nhs.uk. This is a confidential service.

Royal Brompton Hospital
Sydney Street
London
SW3 6NP
tel: 020 7352 8121
textphone: (18001) 020 7352 8121

Harefield Hospital
Hill End Road
Harefield
Middlesex
UB9 6JH
tel: 01895 823 737
textphone: (18001) 01895 823 737

Website: www.rbht.nhs.uk

إذا كنت ترغب في الحصول على ترجمة فورية لمضمون هذه الوثيقة إلى اللغة العربية، يرجى منك الاتصال بأحد مستخدمينا بجناح المصلحة التي يتم فيها استشفائك. أحد موظفينا سيسعى لترتيب إجراءات الترجمة وإتمامها في الوقت المناسب لك.

Brosurteki bilginin Turkçe tercumesi için tedavi goruyor oldugunuz bolume bas vurunuz. Bolum personeli tercumenin gerçeklesmesini en kisa zamanda ayarlacaktir.

 December 2013

Appendix 3: Clinical decision-making tool from Delphi study

a place of mind

AECOPD-Mob

Clinical Decision-Making Tool for Safe and Effective Mobilization of Hospitalized Patients with AECOPD

Purpose, Scope & Disclaimer. The purpose of this document is to provide recently graduated or returning clinicians working in acute care settings with guidance on safe and effective mobilization of the hospitalized patient with an acute exacerbation of COPD. This decision-making tool is evidence- and expert-informed. It is not intended to replace the clinician's clinical reasoning skills and interprofessional collaboration.

Prior to any patient mobilization, ensure there is enough qualified staff available, the patient has consented to the treatment plan, and the patient's goals have been identified and effectively communicated between patient, staff and family.

WHAT TO ASSESS PRIOR TO MOBILIZATION

Equipment

- Mechanical lifts, poles, transfer belts etc. available
- Portable oximeter; portable oxygen tank and tubing, blood pressure unit
- Lines organized (i.e. cap feeding tubes, lines secure or capped as appropriate)
- Mobility aids in reach, used appropriately and maintained
- Glasses, footwear or hearing aids available

Review the chart:

- Comorbidities, medications, medical status, etc.

Review the patient:

- Not: combative, severely confused or agitated, or heavily sedated
- Medically stable and without significant pain, fatigue, or diaphoresis
- Cardiovascular signs and symptoms assessed – no angina at rest, untreated arrhythmia, decompensated left or right heart failure, severe postural hypotension
- Mobility assessment
  - Standing/balance assessed to determine fall risk (eyes open, eyes closed, tandem, reaching / Berg)
  - Adequate body strength and energy required to perform specific exercise, transfer, or ambulation
- Medications accessible and appropriate staff available to administer them if needed during activity
- Note: SpO_2 < 88% at rest or during exercise requires supplemental oxygen

WHEN TO CONSIDER NOT MOBILIZING OR TO DISCONTINUE MOBILIZATION

(For patients in critical care settings, see SAFEMOB*)

Cardiovascular status

- BP - A drop in systolic pressure (>20 mm Hg) or below pre-exercise level OR a disproportionate rise i.e. >200 mm Hg for systolic or >110 mm Hg for diastolic.[1]
- **HR -** < 40[2] or > 130[2,3]; requiring temporary pacer
- **Pulmonary embolus** – discussion with physician required to determine suitability.
- **Deep venous thrombosis** – May mobilize as tolerated immediately after low molecular weight heparin is given. If patient is on any other form of anticoagulation, check mobility orders with the physician. Monitor patient for changes in pain, swelling, colour and sudden shortness of breath.[4]
- **Angina** before, during or after activity
- **Untreated arrhythmia** or decompensated left or right heart failure

Respiratory status

- **SpO_2** <88%[2,5] at rest or during exercise
- RR - <5 or >40[2]
- **F_iO_2 -** >60%[3] or high flow oxygen > 6 lpm
- **Uncontrolled asthma**

Other

- Intermittent hemodialysis[2]
- Unstable fracture
- Excessive muscle soreness or fatigue that is residual from last exercise or activity session
- Other contraindications specific to a given setting/unit

WHAT TO MONITOR DURING MOBILIZATION FOR PATIENT SAFETY

Staff should be available to monitor patient signs and symptoms, and the need for O_2

Ensure supplemental oxygen and tubing are nearby to administer if SpO_2 drops below 88%

Patient -- Subjective:

- Dizziness, vertigo,
- Dyspnea, fatigue
- Nausea, pain
- Consider use of scales e.g., Borg Dyspnea Scale or Rating of Perceived Exertion

Patient -- Objective

- Cognition, balance
- Perspiration, cyanosis, heart rate, oxygen saturation, respiratory rate and blood pressure
- Other factors relevant to patient and mobility task, for example, cardiac rhythm in those patients when ECG is essential during mobilization or blood pressure monitoring in patient that is prone to postural hypotension.

WHAT TO MONITOR AND HOW TO PROGRESS MOBILIZATION TO ENHANCE EFFECTIVENESS

Written communication regarding daily targets for exercise activities and a record of exercise activities accomplished should be posted at bedside and documented

- Type of **exercise activities match patient's functional needs** upon discharge i.e. walk distance, stairs, balance, strength sufficient to carry and unpack groceries.
- **Targets for progression are determined daily** i.e. increase walk distance and/or increase number of walks, stair climbing, standing balance, U/E exercises.
- Pertinent **exercise parameters** i.e. heart rate and breathlessness, **increase** proportionately **with incremental activity and recover** to baseline within 5 minutes post activity

*SAFEMOB available at http://physicaltherapy.med.ubc.ca/physical-therapy-knowledge-broker/safemob-project/

AECOPD-Mob developed by Dr. P. Camp, Dr. D. Reid, F. Chung, Dr. D. Brooks, Dr. D. Goodridge, Dr. D. Marciniuk, and A. Hoens. The project was supported by the Canadian Institutes of Health Research, the UBC Faculty of Medicine Department of Physical Therapy, the Physiotherapy Association of British Columbia, Vancouver Coastal Health Research Institute, Providence Health Research Institute and the COPD Canada Patient Network.

Contact: Dr. Pat Camp pat.camp@hli.ubc.ca

AECOPD-Mob

HOW TO PROGRESS

For mobilization prior to Level V see **SAFEMOB***

	LEVEL V →	LEVEL VI →	LEVEL VII →	LEVEL VIII
Mobility Criteria for Entering this Level [6,7]	Patient is unable to transfer out of bed without moderate to maximum assistance and unable to sit independently.	Patient can transfer out of bed with minimal assistance, has independent sitting balance but unable to stand independently or walk without assistance.	Patient has independent standing balance. Patient can transfer/walk independently or with supervision, but has poor endurance. Unable to ascend/descend flight of stairs	Patient is independent with transfers and gait and has high level balance skills. Patient can do stairs with minimal assistance/supervision
TURNING AND BED MOBILITY	Q2H: Encourage patient to reposition self.	Q2H; Same as level V, **plus encourage patient to sit up in bed for meals.**	Q2H: Same as level VI, **plus encourage patient to sit up in chair for meals.**	Q2H: Same as level VII, **plus encourage patient mobilize as tolerated.**
EXERCISE PROGRAM [6,7]	Bed exercise program should include targeted lower limb, upper limb and abdominal strengthening exercises in supine as well as sitting balance exercises. (See Appendix I&II)	Sitting exercise program should include targeted lower limb, upper limb and abdominal strengthening exercises in sitting position, sit to stand exercises, marching on the spot and standing balance exercises. (See Appendix I&II)	Standing exercise program should include targeted lower limb, upper limb exercises as per level VI and ambulation. (See Appendix I&II)	Stairs exercise program should include targeted lower limb and upper limb exercises as per level VII (See Appendix I&II)
	Consider inclusion of: - Airway clearance techniques. Additional exercise / mobilization as indicated by PT assessment.	Consider inclusion of: - Cycle ergometry - Wheelchair mobility for wheelchair user.	Consider inclusion of: - Closed kinetic chain or functional strengthening exercises	Consider inclusion of: - Treadmill training
	Progress exercise duration/rep or train at a target rate e.g. percentage of the maximum load.	As per level V	As per level V	As per level V
MOBILIZATION	Sitting balance exercises with physio as appropriate, 5 to 10 minutes initially OD, then progress to BID and increased duration as tolerated.	Physio assesses ability to weight shift, and walk. Initial duration in chair 30 minutes, progress as indicated by OT/PT assessment.	Physio assesses walking and outlines walking program with appropriate aids. Patient able to manage O2 tanks, tubes, flow	Progress walking program with incline or stairs.
	Increasing time and/or frequency as patient tolerates. Ensure safe use of oxygen tank and tubing.	Same as level V. Patients with neuro/ortho status precluding WB require individualized mobilization prescription.	Progress walking time/distance or training at a target rate e.g. Borg scale,	As per level VII

WHAT TO CONFIRM PRIOR TO DISCHARGE

Patient status, Home Services

- D/C planning involves the patient/ friends/family/other caregivers where appropriate
- General health status, nutrition, mental health, sleep hygiene, bodyweight, and need for smoking cessation counselling has been assessed and deemed appropriate for D/C
- Able to feed independently while sitting without undue fatigue
- SpO2 > 88% during ambulation, with or without supplemental O2
- Assessed for home oxygen, under different conditions, and/or night-time mechanical ventilation completed
- Assessed for and set up with home health (PT, OT, SW, RN) and community supports if indicated, and/or has been provided with info on this
- Referred to pulmonary rehabilitation and physician follow-up appointment

Mobility

- Update mobility/balance assessment to determine if patient is safe for D/C.
- Prescribe mobility aids and/or hip protector if there is a fall risk.
- Patient should be able to ambulate a distance in accordance with home and community needs

Education -- consistent information, in understandable terms, to patient and family

- Written home activity/exercise plan provided
- Inhaler technique, use of oral medications, use of supplemental O2 (including connections, flow rates, use with gait aids, potential side effects
- Action plan for management of future AECOPD
- Patient has received education on self monitoring and self management of COPD (i.e. pacing, airway clearance, breathing techniques, smoking cessation etc.

*SAFEMOB available at http://physicaltherapy.med.ubc.ca/physical-therapy-knowledge-broker/safemob-project/

AECOPD-Mob developed by Dr. P. Camp, Dr. D. Reid, F. Chung, Dr. D. Brooks, Dr. D. Goodridge, Dr. D. Marciniuk, and A. Hoens. The project was supported by the Canadian Institutes of Health Research, the UBC Faculty of Medicine Department of Physical Therapy, the Physiotherapy Association of British Columbia, Vancouver Coastal Health Research Institute, Providence Health Research Institute and the COPD Canada Patient Network.
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June 2015

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AECOPD-Mob

Appendix I. Exercise frequency, duration and intensity

Type of Exercise	Frequency	Duration	Intensity	Overriding Principles for Intensity Consider interval training if dyspnea or exertion is severe	Implications of co-existing chronic conditions
Bed exercise	2x-3x/day 5 days/wk 5-10 reps/exercise 2 to 3 sets	20-30 min/session; exercise till D/C	Ex with resistance: 70% of 1RM; up to 80% of the sustainable load at baseline	• 10RM– fatigue @ 8th rep • No pain • Overall feeling of exertion	Diabetes (*): • Ensure blood glucose is assessed and within safe range prior to exercise. • Consider the impact of peripheral neuropathy or vision impairment on the safety of the exercise prescription. Osteoarthritis and musculoskeletal pain: • Adapt resistance exercises to minimize load on affected joints or muscles. No sharp pain or increased pain lasting more than 2 hours Stable Heart Failure (*): • moderate exercise intensity with a BORG Dyspnea Scale between 3-5
Sitting exercise	2x-3x/day 5 days/wk 5-10 reps/exercise 2 to 3 sets	20-30 min/session; exercise till D/C	Fatigue should occur but not lasting for >2 hours		
Standing exercise	2x-3x/day 5 days/wk 5-10 reps/exercise 2 to 3 sets	20-30 min/session; exercise till D/C	No sharp pain should be induced		
Walking/Stair exercise	2x-3x/day 5 days/wk 5-10 reps/exercise 2 to 3 sets	20-30 min/session; exercise till D/C	BORG Dyspnea scale between 3-5.	• Dyspnea may occur but should not be > 7 on Borg Dyspnea Scale • Heart rate is not a good measure of intensity in these patients as the HR is typically elevated, especially in patients with AECOPD	

Appendix II. List of Suggested Exercises ,[6,9-11] * = exercises where a weight could be used

Bed Based Strengthening (Level IV)		**Bed Based Flexibility (Level V)**		**Seated Strengthening (Level VI)**		**Seated Flexibility (Level VI)**	
Bench Press	Hip ab / adduction	Scapular retraction	Reaching*	Shoulder abduction*	Chest pull with resistive band	Shoulder circle	Side bend (hands behind head)
Inner range quads*	Bridging	Ankle Pump	Ankle inversion / eversion	Arm chair push	Knee extension	Side stretch (arm up)	Trunk rotation, arms crossed
Side lying to sitting	Heel drag	Knee to Chest (flexion)		Sit to stand		Forward bend to floor	
Seated Balance (Level VI)		**Standing strengthening (Level VII)**		**Standing Flexibility (Level VII)**		**Standing Balance (Level VII)**	
Forward lean for sit to stand	Trunk rotation, hands clasped	Diagonal arm pull down with resistive band	Diagonal arm pull up with resistive band	Scapular retraction	Lumbar extension in standing	Supported stepping on the spot	Supported calf raise
						Single step fwd/back	Single step side
						Turning on the spot	
Reaching / placing objects in horizontal, vertical, and diagonal pattern	Throwing / catching balloon	Alternating heel raise and toe raise	Partial knee bend	Trunk twist	Supported soleus stretch	**Walking / Stair Program (Level VIII)**	
						Walking	Picking up/carrying object
						Backward walking	Obstacle course
		Hip abduction	Hip extension*	Supported gastroc stretch	Reaching exercise	Step up	Flight of stairs

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Appendix 4: Short Physical Performance Battery Standard Operating Procedure

Part One

BALANCE TESTS

These allow an assessment of the participant's ability to hold three basic standing positions with the eyes open.

Required equipment

Stopwatch, SPPB protocol and score sheet (Appendix a).

Procedure

The positions are side-by-side stand, semi-tandem, and full tandem stand (heel-to- toe) performed in this order (foot stance detailed in Appendix a). For each position, the assessor describes and then demonstrates the appropriate stand. Show the participant strategies to help balance (arm out to the side, bent knees, move body, but do not move feet). If the participant is unstable with support, do not try the balance tests and code it on the score sheet as "not attempted" and circle "not attempted, you felt unsafe".

1. **Side-by-side stand:**

- The participant assumes the correct foot position (supported as necessary by the assessor).
- Once the participant confirms they are steady, withdraw support and say ***"ready begin"*** and start timing;
- Continue until ten seconds have elapsed, or until the participant moves their feet, or grasps the assessor for support. Watch the patient, not the stopwatch.
- Note the balance duration if they hold it for less than ten seconds to the nearest hundredth of a second. Record on the score sheet (Appendix a).

Participants who are unable to hold the stand for less than ten seconds do not proceed with the other balance tests and are given a score of zero for this section of the SPPB. Successful participants score one point and progress to the next stand.

2. **Semi-tandem stand:**

- The participant is asked to stand with the heel of one foot (either foot) placed to the side of the big toe of the other foot.

- Once the participant confirms they are steady, withdraw support and say ***"ready begin"*** and start timing; continue until ten seconds have elapsed, or until the participant moves their feet, or grasps the assessor for support. Watch the patient, not the stopwatch.

- Participants score one additional point if they hold the semi-tandem position for ten seconds and proceed to the final balance test. Failure to hold the position for ten seconds results in a score of zero and end of the balance tests (Appendix a).

3. **Tandem stand:**
   - The participant stands with the heel of one foot (either foot) placed directly in front of the toes of the other foot.

   - Once the participant confirms they are steady, withdraw support and say ***"ready begin"*** and start timing; continue until ten seconds have elapsed, or until the participant moves their feet, or grasps the assessor for support. Watch the patient, not the stopwatch.

   - Participants holding this position for ten seconds are awarded an additional two points. Those who hold it for 3-9.99 seconds are given one additional point and for less than 3 seconds the participant scores zero (Appendix a).

Part Two

GAIT SPEED TEST

Required equipment

Tape measure (if 4 metre course is not pre-marked), stopwatch, SPPB protocol and score sheet (Appendix a).

Course layout

- Use either a pre-marked 4 metre course

OR

- Identify a hard flat surface to prepare the course
- At a convenient starting point, mark the floor with tape (start line)
- Using the tape measure (laid straight and flat at 90° to the start tape) determine 4m and mark this with 1m of tape (the finish line)

Procedure

Show the patient the walking course and ask them to walk at their usual speed, as if they were walking to go to the shops, walking past the finish line before stopping. Use the standardised instructions in Appendix a. Demonstrate a walk at normal speed and ask if the participant feels safe to attempt the walk. The participant may use a cane or walking aid during the walk, but if the patient is able to walk a short distance without these, they should be encouraged to do so.

- Stand in a position so that you can observe the foot crossing the finishing line; the best position to maintain is to the side and slightly behind the participant, outside of the patients visual field.

- Ensure the participant's toes are just touching the starting line.

- **Start timing** when the participant begins to move. Do not start the watch when you say ***"begin"***.

- **Stop timing** when the participant's first foot crosses the 4m finish line. If the foot lands on the line but doesn't cross it do not stop timing; anticipate when a foot will fully cross the line and stop timing. Record the time to the nearest hundredth of a second.

- **Repeat the walking test.** Remind the patient to walk at their usual speed and to walk through the line.

Use the shorter of the two times for calculating the score as described (Appendix a) where if the time is more than 8.70 seconds the participant scores one point; between 6.21-8.70 seconds they score two points; if the time is 4.82-6.20 seconds the participant scores three points, and if the time is less than 4.82 seconds they are awarded four points.

Troubleshooting: If there are problems with the correct starting and stopping of the stopwatch, or the participant expresses concern that they did not reproduce their usual speed accurately the gait speed test should be repeated. If the walk was not attempted or completed, select a reason from the options on the score sheet and give the participant a score of zero.

Ambulatory Oxygen users

An additional helper is required to carry a small oxygen cylinder or concentrator during the gait speed test. In this case ensure you remain behind the patient and do not set the walking speed. Conversely, supply the patient with extra-long tubing (>6m) connected to wall supplied oxygen or an immovable cylinder.

Part Three

CHAIR STAND TEST

This assesses the participant's ability to rise from a chair (i.e. leg strength) without using their arms.

Required equipment

A straight-backed armless chair with a hard seat, stopwatch, SPPB protocol and score sheet (Appendix a).

Do not use a folding chair, a soft chair, a deep chair, or a chair on wheels. Place the chair next to the wall. There is no standardised floor to sitting surface height of chair described for this test. Each centre should use the same appropriate chair. As a guide, Harefield Hospital uses a chair with a floor to chair height of 48cm height (measured at the side and centre of the chair from the floor to the top surface of the seat).

Procedure

1. Single sit to stand

- Describe and then demonstrate the sit to stand manoeuvre. Fold your arms across your chest and stand up one time from an armless chair placed against a wall.

- Ask the participant to attempt the sit to stand. Record whether the participant was able to rise from the chair without the use of their arms. If the participant is unsuccessful ask them to repeat the stand using their arms. If the patient is unable to complete the chair stand test with their arms folded, or can only do it with the use of their arms, this will result in a score of zero for this section and the end of the test and do not attempt the five sit to stands. If the patient is successful note this down and proceed to the multiple chair stand test.

Five sit to stands

- Ask the participant to stand up straight as quickly as they can five times without stopping in between. Tell the participant to stand up, sit down and then stand up again, keeping their arms folded across their chest.

- Mention that you'll be timing the test with a stopwatch.

- Perform the demonstration, standing and rising as quickly as possible, emphasising the word quickly.

- **Start timing** when the command to ***"stand"*** is given (this is different to the gait speed test where timing begins only when the participant begins to move).

- Count out loud each time the participant straightens their body after the rise. Count the stand number only after the participant has straightened up; do not pace the test with your counting and do not encourage the participant during the test.

- **Stop timing** when the participant stands straight up at the end of the fifth rise.

Troubleshooting: If the participant does not attempt the test, or is unable to complete the test, note the reason on the score sheet. Do not record the time and score the patient zero for this part of the test. The test should be stopped if the participant becomes unduly tired during the repeated chair stands, uses their arms to rise at any time, or if the participant has not completed the five chair stands after one minute. The test may be stopped by the assessor if there are concerns about the participant's safety. If the participant stops before completing the five rises, ask if they can continue. If the participant says yes, continue timing; if no, stop the test and record reason on the score sheet and give the participant a score of zero.

Scoring of the chair stand test is based on established categories of completion times shown to divide the older population into four equal groups (Appendix a). Participants completing the test between 16.70 and 60 seconds score one point. Completion times falling into the range 13.70-16.69 seconds score two points, while those in the range 11.20-13.69 seconds score three points. If participants finish the five rises in less than 11.20 seconds they receive four points.

Overall scoring for the complete SPPB

- Add together the score from the Balance test (maximum 4 points), Gait Speed test (maximum 4 points) and Sit-to-Stand (maximum 4 points) to get an overall score. The summary score ranges from worst performance (0 points), to best performance (12 points).

ADDITIONAL SAFETY POINTS

The assessor should be completely familiar with the test procedures and have practiced them with a partner who is in training or trained, or with a volunteer under the observation of someone experienced in administering the battery before attempting to administer the test battery to a patient or research subject.

Clearly explain and demonstrate all procedures prior to testing. Participants should be queried to ensure that they understand the instructions. If a participant is uncomfortable performing a test or if you feel that it is not safe for an individual to continue, the test should not be performed. The assessor should stop the tests at any point if the participant appears unduly fatigued.

BALANCE TESTS

If required, the assessor may stabilise the participant by lightly holding his/her arm, or allow the participant to lean against them until their feet are in position. If the participant is not steady, even with support, do not continue with the balance tests. Ensure the participant is stable and feet are in the correct position before releasing him/her. The assessor should stand close enough so that it is possible to seize the patient's arm if they begin to falter, but not so close that the patient's balance is hindered if they use their arms to maintain balance.

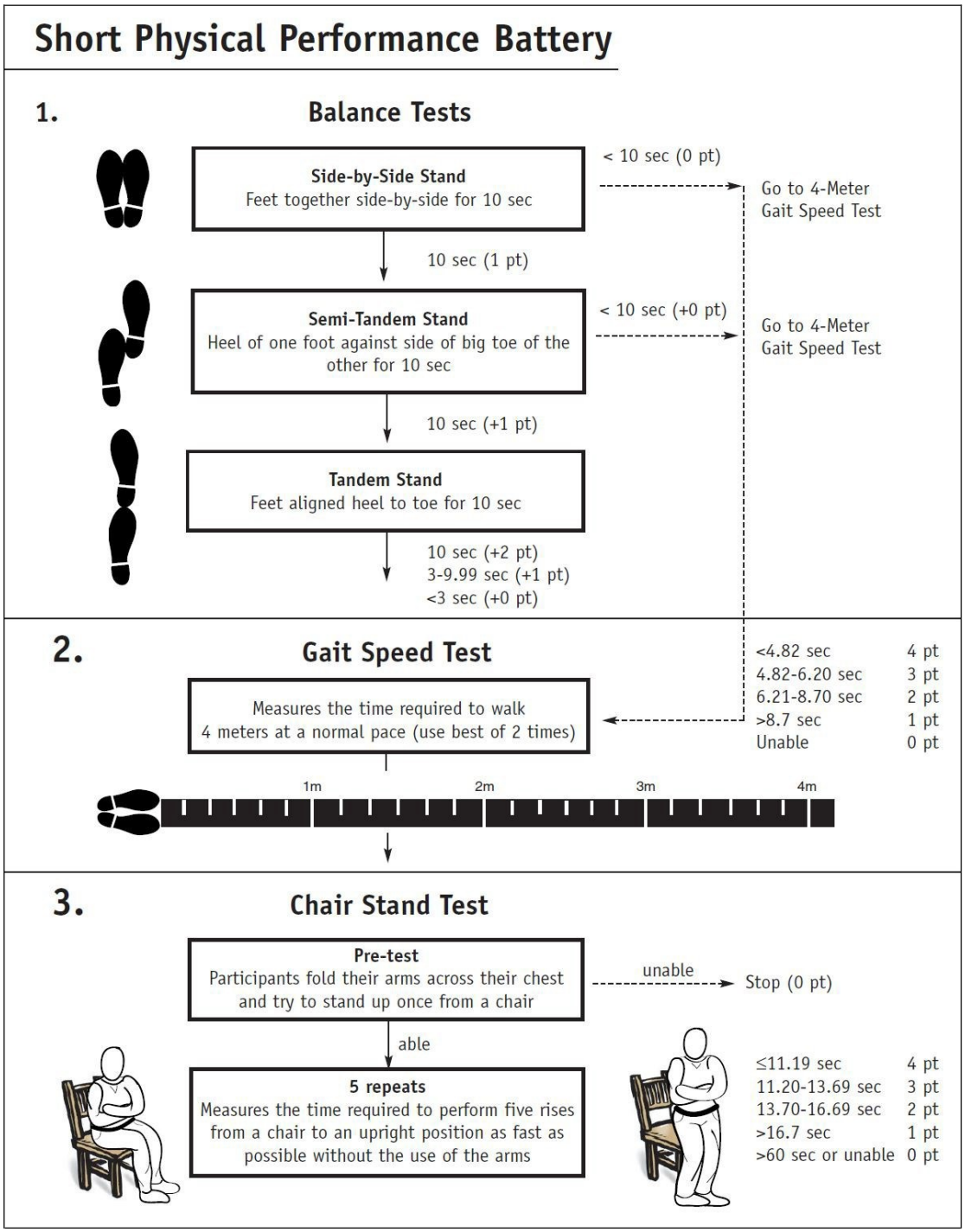
GAIT SPEED TEST

Ensure that the course is clear of obstructions before giving the command to walk. The assessor should stay behind and slightly to one side of the participant, outside of his/her visual field, but close enough to support the participant if they begin to fall. A cane or walker may be used during the walk, but if participants can walk without the devices they should be encouraged to do so as this gives a more accurate assessment of functional limitations.

CHAIR STAND TEST

The assessor should ensure that the chair is stable against a wall for example, and that they are close enough to provide support if the patient requires it, but not too close so as to impede movement.

Appendix a


Short Physical Performance Battery
1.
Balance Tests
Side-by-Side Stand
Feet together side-by-side for 10 sec
< 10 sec (0 pt)
Go to 4-Meter Gait Speed Test
10 sec (1 pt)
Semi-Tandem Stand
Heel of one foot against side of big toe of the other for 10 sec
< 10 sec (+0 pt)
Go to 4-Meter Gait Speed Test
10 sec (+1 pt)
Tandem Stand
Feet aligned heel to toe for 10 sec
10 sec (+2 pt)
3-9.99 sec (+1 pt)
<3 sec (+0 pt)
2.
Gait Speed Test
Measures the time required to walk 4 meters at a normal pace (use best of 2 times)
1m
2m
3m
4m
<4.82 sec 4 pt
4.82-6.20 sec 3 pt
6.21-8.70 sec 2 pt
>8.7 sec 1 pt
Unable 0 pt
3.
Chair Stand Test
Pre-test
Participants fold their arms across their chest and try to stand up once from a chair
unable
Stop (0 pt)
able
5 repeats
Measures the time required to perform five rises from a chair to an upright position as fast as possible without the use of the arms
≤11.19 sec 4 pt
11.20-13.69 sec 3 pt
13.70-16.69 sec 2 pt
>16.7 sec 1 pt
>60 sec or unable 0 pt

Study ID _____ Date _____ Tester Initials _____

SHORT PHYSICAL PERFORMANCE BATTERY PROTOCOL AND SCORE SHEET

All of the tests should be performed in the same order as they are presented in this protocol. Instructions to the participants are shown in bold italic and should be given exactly as they are written in this script.

1. BALANCE TESTS

The participant must be able to stand unassisted without the use of a cane or walker. You may help the participant to get up.

> ***Now let's begin the evaluation. I would now like you to try to move your body in different movements. I will first describe and show each movement to you. Then I'd like you to try to do it. If you cannot do a particular movement, or if you feel it would be unsafe to try to do it, tell me and we'll move on to the next one. Let me emphasize that I do not want you to try to do any exercise that you feel might be unsafe.***
>
> ***Do you have any questions before we begin?***

A. Side-by-Side Stand

1. ***Now I will show you the first movement.***
2. (Demonstrate) ***I want you to try to stand with your feet together, side-by-side, for about 10 seconds.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the side-by-side position.
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say, ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.
9. If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

Study ID _____ Date _____ Tester Initials _____

B. Semi-Tandem Stand

1. ***Now I will show you the second movement.***
2. (Demonstrate) ***Now I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the semi-tandem position
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.
9. If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

C. Tandem Stand

1. ***Now I will show you the third movement.***
2. (Demonstrate) ***Now I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the tandem position.
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say, ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.

Study ID _____ Date _____ Tester Initials _____

SCORING:

A. Side-by-side-stand

Held for 10 sec ❒ 1 point
Not held for 10 sec ❒ 0 points
Not attempted ❒ 0 points
If 0 points, end Balance Tests

Number of seconds held if less than 10 sec: ___.__ _sec

If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not hold position unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (specify) _____	6
Participant refused	7

B. Semi-Tandem Stand

Held for 10 sec ❒ 1 point
Not held for 10 sec ❒ 0 points
Not attempted ❒ 0 points *(circle reason above)*
If 0 points, end Balance Tests

Number of seconds held if less than 10 sec: ___.__ _sec

C. Tandem Stand

Held for 10 sec ❒ 2 points
Held for 3 to 9.99 sec ❒ 1 point
Held for < than 3 sec ❒ 0 points
Not attempted ❒ 0 points (circle reason above)

Number of seconds held if less than 10 sec: ___.__ _sec

D. Total Balance Tests score_____(sum points)

Comments: _____

_____

_____

_____

_____

_____

_____

Study ID _____ Date _____ Tester Initials _____

2. GAIT SPEED TEST

Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it.

A. First Gait Speed Test

1. ***This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.***
2. Demonstrate the walk for the participant.
3. ***Walk all the way past the other end of the tape before you stop. I will walk with you. Do you feel this would be safe?***
4. Have the participant stand with both feet touching the starting line.
5. ***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***
6. Press the start/stop button to start the stopwatch as the participant begins walking.
7. Walk behind and to the side of the participant.
8. Stop timing when one of the participant's feet is completely across the end line.

B. Second Gait Speed Test

1. ***Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course.***
2. Have the participant stand with both feet touching the starting line.
3. ***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***
4. Press the start/stop button to start the stopwatch as the participant begins walking.
5. Walk behind and to the side of the participant.
6. Stop timing when one of the participant's feet is completely across the end line.

Study ID _____ Date _____ Tester Initials _____

GAIT SPEED TEST SCORING:

Length of walk test course: Four meters ❒ Three meters ❒

A. Time for First Gait Speed Test (sec)

1. Time for 3 or 4 meters __ __.__ __sec
2. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not walk unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify) _____	6
Participant refused	7

Complete score sheet and go to chair stand test

3. Aids for first walk.....None ❒ Cane ❒ Other ❒

Comments:_____

_____

_____

B. Time for Second Gait Speed Test (sec)

1. Time for 3 or 4 meters __ __.__ __ sec
2. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not walk unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify)	6
Participant refused	7

3. Aids for second walk..... None ❒ Cane ❒ Other ❒

What is the time for the faster of the two walks?
Record the shorter of the two times __ __.__ __ sec
[If only 1 walk done, record that time] __ __.__ __ sec

If the participant was unable to do the walk: ❒ **0 points**

For 4-Meter Walk:		**For 3-Meter Walk:**	
If time is more than 8.70 sec:	❒ **1 point**	If time is more than 6.52 sec:	❒ **1 point**
If time is 6.21 to 8.70 sec:	❒ **2 points**	If time is 4.66 to 6.52 sec:	❒ **2 points**
If time is 4.82 to 6.20 sec:	❒ **3 points**	If time is 3.62 to 4.65 sec:	❒ **3 points**
If time is less than 4.82 sec:	❒ **4 points**	If time is less than 3.62 sec:	❒ **4 points**

Study ID _____ Date _____ Tester Initials _____

3. CHAIR STAND TEST

Single Chair Stand

1. ***Let's do the last movement test. Do you think it would be safe for you to try to stand up from a chair without using your arms?***

2. ***The next test measures the strength in your legs.***

3. (Demonstrate and explain the procedure.) ***First, fold your arms across your chest and sit so that your feet are on the floor; then stand up keeping your arms folded across your chest.***

4. ***Please stand up keeping your arms folded across your chest.*** (Record result).

5. If participant cannot rise without using arms, say ***"Okay, try to stand up using your arms."*** This is the end of their test. Record result and go to the scoring page.

Repeated Chair Stands

1. ***Do you think it would be safe for you to try to stand up from a chair five times without using your arms?***

2. (Demonstrate and explain the procedure): ***Please stand up straight as QUICKLY as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. I'll be timing you with a stopwatch.***

3. When the participant is properly seated, say: ***"Ready? Stand"*** and begin timing.

4. Count out loud as the participant arises each time, up to five times.

5. Stop if participant becomes tired or short of breath during repeated chair stands.

6. Stop the stopwatch when he/she has straightened up completely for the fifth time.

7. Also stop:
   - If participant uses his/her arms
   - After 1 minute, if participant has not completed rises
   - At your discretion, if concerned for participant's safety

8. If the participant stops and appears to be fatigued before completing the five stands, confirm this by asking ***"Can you continue?"***

9. If participant says "Yes," continue timing. If participant says "No," stop and reset the stopwatch.

Study ID _____ Date _____ Tester Initials _____

SCORING
Single Chair Stand Test

	YES	NO
A. Safe to stand without help	❒	❒

B. Results:

Participant stood without using arms	❒	→ Go to Repeated Chair Stand Test
Participant used arms to stand	❒	→ End test; score as 0 points
Test not completed	❒	→ End test; score as 0 points

C. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not stand unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify) _____	6
Participant refused	7

Repeated Chair Stand Test

	YES	NO
A. Safe to stand five times	❒	❒

B. If five stands done successfully, record time in seconds.

Time to complete five stands __ __.__ __ sec

C. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not stand unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify)	6
Participant refused	7

Scoring the Repeated Chair Test

Participant unable to complete 5 chair stands or completes stands in >60 sec:	❒ 0 points
If chair stand time is 16.70 sec or more:	❒ 1 points
If chair stand time is 13.70 to 16.69 sec:	❒ 2 points
If chair stand time is 11.20 to 13.69 sec:	❒ 3 points
If chair stand time is 11.19 sec or less:	❒ 4 points

Study ID _____ Date _____ Tester Initials _____

Scoring for Complete Short Physical Performance Battery

Test Scores

Total Balance Test score	_____ **points**
Gait Speed Test score	_____ **points**
Chair Stand Test score	_____ **points**
Total Score	_____ **points (sum of points above)**

Appendix 5: Six-minute step test Standard Operating Procedure

Purpose:

The 6-minute step test (6MST) of free cadence was developed from the same principles as the 6-minute walk test (6MWT). One of the advantages over the 6MWT is that it may be used to assess functional capacity when a 30-metre corridor is unavailable.

In patients with COPD the 6MST has been shown to have excellent intra-rater reliability (ICC > 0.8) (da Costa et al., 2014) and has been shown to correlate strongly with exercise capacity (Pessoa et al., 2014). Furthermore, a cut-off point of 78 steps was able to identify patients with a poor exercise tolerance (da Costa et al., 2014).

Equipment:

- 20cm height step (80cm in length and 40cm in width) with a non-slip rubber surface
- Stopwatch
- Tally counter
- Pulse oximeter
- Chair
- BORG dyspnoea score

Exclusion criteria

- Unstable cardiovascular disease i.e. unstable angina, uncontrolled AF.
- Neuromusculoskeletal impairment limiting participation in the Step Test.
- Any condition the examiner deems that it is unsafe to attempt a Step Test.
- Unable to perform one step up and down safely without using upper limbs.

Procedure

1. Calculate and record the patients submaximal heart rate (HR) before the step test using the equations below:

Submaximal HR men = (220-age) x 0.85

Submaximal HR women = (210-age) x 0.85

2. Two assessors are required to perform the test – one to monitor the time and safety of the test, the second to count the number of step.
3. Sit the patient in a chair prior to starting the test and allow them to rest for 5 minutes.
4. Measure and record baseline heart rate, oxygen saturation and BORG dyspnoea score.
5. Demonstrate one step up and step down without using upper limbs.

6. Ask the patient if they can perform one step up and step down without using upper limbs. If the patient cannot achieve this then **do not** proceed to the next step. Record as FAIL. If the patient can achieve this then continue with the assessment.
7. Read the instructions described in Appendix i to the patient.
8. Demonstrate ascending and descending the step using one leg first and then the opposite leg.
9. Position the patient at the step.
10. Ask the patient: *"Are you ready to start?"*
11. Instruct the patient to *"Start now or whenever you are ready".*
12. As soon as the patient starts to step – start the stopwatch.
13. Do not talk to the patient during the test only read the instructions as described in Appendix ii at the end of each minute in an even voice.
14. Use the tally counter to count each step (one step is one step up and one step down – so that the participant returns to their starting position).
15. Record the heart rate, oxygen saturation and the time when the patients stopped, as well as the duration of the stop.
16. If the patient's heart rate goes above the calculated submaximal heart or if oxygen saturation is less than 85% then the patient should be asked to rest until the heart rate is reduced by 10 beats/min under the submaximal heart rate or until the oxygen saturation increases to ≥88%. Instruct the patient as described in Appendix iii. Record the patient's heart rate and SpO_2 at the time they have stopped as well as the duration of the stop.
17. After six minutes ask the patient to stop, the patient may wish to return to their seat straight after completing the test.
18. Immediately record BORG dyspnoea score, heart rate and oxygen saturation.
19. Immediately begin timing the recovery only stop timing when the observations have returned to the pre-test levels or when six minutes has elapsed.
20. Make a note of how many steps the patient achieved.

Additional Points:

- If a patient stops to rest during the test, make a note of the number and duration of the rests.
- Only record the number of steps which were fully completed without using the upper limbs and which were completed with the correct technique of going up the step and then back down again to the place where the patients' feet started.

Appendix i: Instructions for 6 minute step test (6MST)

This is the 6 minute step test. The objective of this test is to climb the greatest number of steps you can in 6 minutes. The more steps you climb, the better your exercise capacity. You need to go up the step and then back down again to the place you started, with your feet on the floor. You can use either of your legs to begin, and you can change to the other whenever you want.

(Demonstrate one step up and down, starting with one leg, and then climb one more starting with the other leg).

You cannot use your arms to help you climb, but if you feel that you might fall, you can use them to regain your balance. You need to stop using your arms as soon as possible.

Six minutes is a long time to climb stairs, so you will be exerting yourself. You can slow down, stop, and even rest in the chair provided, but you should resume climbing as soon as you can. If your heart beats too fast, or the oxygen in your blood becomes too low, I will ask you to stop for a moment, and I will let you know when you can start again. Even if you stop, the countdown timer will not be stopped. Are you ready to start? Start now or whenever you are ready.

Appendix ii: Instructions during 6 minute step test (6MST)

After 1 minute: “You are doing well. You have 5 minutes to go”

After 2 minutes: “Keep up the good work. You have 4 minutes to go”

After 3 minutes: “You are doing well. You are halfway done”

After 4 minutes: “Keep up the good work. You have only 2 minutes left”

After 5 Minutes: “You are doing well. You have only 1 minute to go”

At 6 minutes: “Please stop where you are”

Appendix iii: Instructions during stoppages

If a patient should stop walking during the test. Say this every 30 seconds once $Sp0_2$ is ≥88%:

“Please resume walking whenever you feel able.”

Appendix 6: Mixed methods feasibility study topic guides

Patient participant interview topic guide

Complete consent and demographics form OR please obtain verbal consent the person, check the person has signed a consent form and check the person has completion of a demographics form.

Reminder of ground rules:

- You are being recorded but this will be transcribed and anonymised
- Everything said here is confidential
- If we quote anything you say we will do everything we can to ensure it is anonymous and not traceable back to you
- If you tell me anything that makes me concerned for your safety or the safety of others, I may have to inform a medical professional
- There are no right or wrong answers
- This should take about 30 to 45 minutes, but we can stop at any time and continue later if you wish.
- Because this over the telephone, can I check you are alone, and feel you can speak freely, or you are in the company of someone who you are happy to talk openly and honestly in front of.

Aim and introduction:

The aim of our study is to find out whether providing an exercise programme at home alongside your usual outreach care is acceptable. We are interested in your viewpoint as *someone who was hospitalised due to a flare up of your COPD.*

During this interview I'll ask you about… your experiences and preferences as a *person living with COPD* of the outreach care you received and any areas of the care which we could enhance to integrate your usual outreach care with pulmonary rehabilitation. We are also interested in what you think core elements of a home-based programme would be.

Experience of the trial processes	
To begin with, it is helpful for us to know a little about you found being part of the research study. **1) how did it feel to be approached about and take part in this research?**	How was the process of signing up to the study? How was the information you received? How was completing the study assessments at discharge, a month after you had been home and then three months after you had been home?
2) how did it feel to fill in the questionnaires?	How was it filling them in? How relevant did the questions seem? Was there anything else we should have asked about?
INTERVENTION GROUP ONLY ***Experience of the integrated rehabilitation - only prompt the intervention arm re: exercises / lung rehab programme***	
It is also really helpful for us to understand a bit more about how you found having rehabilitation at home. **3) So, how has it been receiving your rehabilitation at home?**	*e.g. intensity of the exercise, types of exercise, frequency of the exercise, and perceived ability to complete the exercises without supervision, equipment used, individualisation of the programme, benefits/limitations of home environment; timing of when the exercises started in relation to timing of hospital discharge, impact of someone attending their home*
4) Have you noticed any changes after taking part the rehabilitation at home?	*e.g. effects on mobility/activities of daily living*
5) How did it compare to other rehabilitation you've been to?	*e.g. different benefits/challenges, peer support / group dynamics during the outpatient based programme compared to home-based programme, transport / travel to outpatient classes*
Health, support and needs (Before their flare-up, after discharge, and now)	
The last thing it is really helpful for us to know a little bit about your day to day life, both before and after you were in hospital with a flare up of your breathing. **6) Could you tell me about how you were getting on before you were in hospital for a flare up of your breathing?**	How were you getting on? What were your concerns? What support did you have? Had you attended any lung rehabilitation? If so, how was it?
7) How did you feel when you first came home after your flare up?	How were you getting on? What were your concerns?

	What support did you have? What support was most helpful at this point? Were any of your concerns not being addressed? *(e.g related to emotional, social, spiritual and physical health)*
8) and how do you feel you're getting on now?	How were you getting on? What were your concerns? What support do you have? Are your concerns not being addressed? *(e.g related to emotional, social, spiritual and physical health)* Can you tell me what a normal day for you used to look like before you were in hospital 3 months ago? How does this compare to now? *If negative changes, are all of these changes in your health from then to now being met?* Impact of covid on your recovery *e.g. lockdown restrictions, social distancing / shielding, related to emotional, social, spiritual and physical health)*

Closing statements:

- Thank you for everything you have shared.
- Before we finish, I just want to check you are feeling ok, both emotionally related to what we have spoken about, and / or from a health perspective – *if anything emotional, and they would like onward support, advise RB will be in contact, who may refer to onward services as required; any respiratory health issues, prompt to access respiratory outreach team via the hotline, if any general health issues, prompt to access GP.*

Family member and informal carer interview topic guide

Complete consent and demographics form OR please obtain verbal consent the person, check the person has signed a consent form and check the person has completion of a demographics form.

Reminder of ground rules:

- You are being recorded but this will be transcribed and anonymised
- Everything said here is confidential
- If we quote anything you say we will do everything we can to ensure it is anonymous and not traceable back to you
- If you tell me anything that makes me concerned for your safety or the safety of others, I may have to inform a medical professional
- There are no right or wrong answers
- This should take about 30 to 45 minutes, but we can stop at any time and continue later if you wish.
- Because this over the telephone, can I check you are alone, and feel you can speak freely, or you are in the company of someone who you are happy to talk openly and honestly in front of.

Aim and introduction:

The aim of our study is to find out whether providing an exercise programme at home alongside your usual outreach care is acceptable. We are interested in your viewpoint as *a family member or informal carer of someone who was hospitalised due to a flare up of their COPD.*

During this interview I'll ask you about… your experiences and preferences as *a family member or informal carer of someone living with COPD* of the outreach care you received and any areas of the care which we could enhance to integrate your usual outreach care with pulmonary rehabilitation. We are also interested in what you think core elements of a home-based programme would be.

Experience of the trial processes	
To begin with, it is helpful for us to know a little about you found [ADD PATIENT PARTICIPANT NAME] being part of the research study. **1) how did it feel for [ADD PATIENT PARTICIPANT NAME] to be approached about and take part in this research?**	How do you think they found it? What was it like for you? How was the process of signing up to the study? How was the information you received as their family member or carer? How was completing the study assessments at: 1) discharge, 2) a month after they had been home and 3) then three months after they had been home?
2) how did it feel to fill in the questionnaires?	How was it filling them in? What support did you give them? How relevant did the questions seem? Was there anything else we should have asked about?
INTERVENTION GROUP ONLY - Experience of the integrated rehabilitation	
It is also really helpful for us to understand a bit more about how you found (ADD PATIENT PARTICIPANT NAME] having rehabilitation at home. **3) So, how has it been for [ADD PATIENT PARTICIPANT NAME] receiving their rehabilitation at home?**	How do you think they found it? What did you make of it? *e.g. intensity of the exercise, types of exercise, frequency of the exercise, and perceived ability to complete the exercises without supervision, equipment used, individualisation of the programme, benefits/limitations of home environment, impact of someone attending their home for home-base sessions timing of the exercises in relation to hospital discharge* Role you played during the exercise training *e.g. during supervised sessions, completing exercises unsupervised*
4) Have you noticed any changes since they have been taking part in their rehabilitation at home?	*e.g. effects on mobility/activities of daily living,*
5) How did it compare to other rehabilitation they have been to?	Can you tell me about the role you would play when X has been to other rehab programmes? *e.g. different benefits/challenges, peer support / group dynamics during the outpatient based programme compared to home-based programme, transport / travel support required to outpatient programme*
Health, support and needs (Before their flare-up, after discharge, and now)	
The last thing it is really helpful for us to know a little bit about is your	How were they getting on? What were your concerns?

day to day life, both before and after [ADD PATIENT PARTICIPANT NAME] were in hospital with a flare up of their breathing. **6) Could you tell me about how they were getting on before they were in hospital for a flare up of their breathing?**	What support did you give them? Had they attended any lung rehabilitation? If so, how was it?
7) How did you feel when they were when they first came home after their flare up?	How were they getting on? What were your concerns? What support did you give them? What support was most helpful at this point? Were any of your concerns not being addressed? *(e.g related to emotional, social, spiritual and physical health)*
8) and how do you feel they are getting on now?	How were they getting on? What were your concerns? What support do you give them? Are your concerns not being addressed? *(e.g related to emotional, social, spiritual and physical health)* Can you tell me what a normal day for you used to look like before they were in hospital 3 months ago? How does this compare to now? *If negative changes, are all of these changes in their health from then to now being met* Impact of covid on their recovery *e.g. lockdown restrictions, social distancing / shielding, related to emotional, social, spiritual and physical health)*

Closing statements:

- Thank you for everything you have shared.
- Before we finish, I just want to check you are feeling ok, both emotionally related to what we have spoken about, and / or from a health perspective related to your family member / person you care for – if anything emotional, and they would like onward support, advise RB will be in contact, who may refer to onward services as required; any respiratory health issues, prompt to access respiratory outreach team via the hotline, if any general health issues, prompt to access GP.

PR focus group topic guide

Please obtain verbal consent from each person, check each person has signed a consent form and check each person has completion of a demographics form.

Reminder of ground rules:

- You are being recorded but this will be transcribed and anonymised.
- Everything said here is confidential.
- If we quote anything you say we will do everything we can to ensure it is anonymous and not traceable back to you.
- If you tell me anything that makes me concerned for your safety or the safety of others, I may have to inform a medical professional.
- There are no right or wrong answers, and everyone is encouraged to express their opinion if it is different to other peoples.
- This should take up to an hour, but we can stop at any time, and continue after a break or even another time, if we need to.
- Please try to not talk over each other, and we encourage you to use the 'hands up' function to make sure I know that you have something to add so I can make sure you get a chance to say it.
- You can also use the chat function to add any comments to indicate you have something to add, and which I will then ask you to elaborate on so I can make sure you get a chance to share your thoughts.
- Finally, please also try to talk to the other people on the call rather than at me, so we can try and replicate a discussion that would happen if you were sat in a circle in a room together.

Aim and introduction:

The aim of our study is to find out whether providing an exercise programme at home alongside usual outreach care is acceptable. We are interested in your viewpoint as someone who is a member of staff in the PR service and who delivers exercise training to patients who were hospitalised due to a flare up of their COPD.

During this focus group I'll ask you about your experiences as members of staff in the PR service. This will be about the usual PR provided following an exacerbation, the delivery of home-based PR and what you think barriers and facilitators to this are. We are also interested in your experiences of the being involved in the clinical service when the trial was being conducted.

Icebreaker / introductions	
I know you all know each other, but before we start, it would be helpful if you could just introduce yourself with your first name, and I will do the same, for the purpose of the	*Go around screen and make sure everyone has introduced themselves.*

recording and so we know what each other's preferred name is.	
Usual PR programme	
To begin with, it is helpful for us to know a little about what the PR service would usually provide for patients post-acute exacerbation *(this can be brief for both – this is mainly to get people chatting by starting with something they are familiar and comfortable with).*	
1) pre-covid?	*a) Could you talk me through what happens from the point a patient gets referred to PR to when they are discharged from the programme, before covid? What does the pathway look like and how long is it for? How are they assessed? What would be included in the 'programme'?*
2) during covid?	*a) Could you talk me through what happens from the point a patient gets referred to PR to when they are discharged from the programme, since the covid restrictions? What does the pathway look like and how long is it for? How are they assessed? What would be included in the 'programme'?*
Experience of integrated rehabilitation component, positive and negative	
It is also really helpful for us to understand a bit more about how you feel about rehabilitation at home being delivered alongside the usual outreach service.	
3) So, could you tell me your thoughts about rehabilitation at home was delivered?	*Prompts re: the setting (in someone's home) itself, how rehab in the home-setting linked with usual outreach care, how this integration may impact the way day-to-day outreach care was delivered, were there any potential benefits to the integration, were there any challenges they could foresee to integration, both positive and negative.* *What about for those who may have been referred for outpatient PR, but were receiving home-based rehabilitation as part of the trial?* *In relation to the home-based exercises specifically: impact of someone attending the home of a patient to provide the rehab.* *In relation to covid: what impact do you feel covid has had on the ability to deliver rehabilitation at home alongside the usual outreach care?*
Perceived values, benefits and harms of the intervention content and delivery	
So we've talked a bit about how you found rehabilitation at home being delivered alongside the usual outreach service. It would also be good to know a little bit about	

what you feel the value, benefits and negatives of this might be from your perceptive as a healthcare professional.	
4) So how do you feel the home-based rehab compared to other rehabilitation which is offered to patients after an acute exacerbation?	*Prompts re: different benefits/challenges, peer support / group dynamics during the outpatient programme compared to home-based programme, transport / travel to outpatient classes, how well they feel patients may engage with the two different programmes, how they feel patients felt about home-based programme compared to outpatient programme.*
5) Did you notice any changes in patients who started usual outpatient PR who had been receiving the rehabilitation at home compared to those who attended outpatient PR without any home-based rehabilitation?	*a) effects on mobility* *b) activities of daily living* *c) breathlessness symptoms* *d) mood / psychologically* *e) re-exacerbation or admission* *f) engagement in outpatient PR*
Acceptability, dose and reach of the intervention in practice for patients / family carers	
It is also really helpful for us to understand a bit more about how you feel rehabilitation at home being delivered alongside the usual outreach service, but this time how you feel it might be experienced by patients and their informal carers / family members.	
6) So, how do you feel patients and their informal carers / family members felt about receiving rehabilitation at home?	*e.g. intensity of the exercise, types of exercise, frequency of the exercise, and perceived ability to complete the exercises without supervision, equipment used, individualisation of the programme, benefits/limitations of home environment; timing of when the exercises started in relation to timing of hospital discharge, impact of someone attending their home.*
Communication around the trial concept, introduction and delivery	
The last thing I wanted to discuss was the conduct of the trial, and what it felt like to be working in a service which was delivering a research project.	
7) Would you be able to tell me about what you were required to do alongside your normal job to support this trial?	*Prompts: and how did you feel about what you were required to do? What impact did what you were required to do have on your workload / caseload (increased or lesser burden of work)? Do you feel there any positives / negatives of working in a service where a trial was being conducted? Do you feel the patient care was affected or changed as a result of the trial (continuity of care / integration / skills of person delivering care)? Could you suggest any areas where improvements could be made?*

	Could you tell me about any elements of the process you feel were successful?
8) Would you be able to tell me about what the role of the researcher was who was conducting the trial who was delivering the home-based programme?	*Prompts: and how did you feel about what they were required to do (screening, recruitment, information giving re: trial, consent process and assessment process, and the actual delivery of the home-based programme)? Do you feel patient care was affected or changed as a result of the trial (continuity of care / integration / skills of person delivering care)? Could you suggest any areas where improvements could be made? Could you tell me about any elements of the process you feel were successful?*

Closing statements:

- Thank you for everything you have all shared.
- Before we finish, I just want to check everyone is feeling ok, both emotionally related to what we have spoken about – *if anything emotional, and they would like onward support, advise RB will be in contact, who may refer to onward services as required.*

HIRS focus group topic guide

Please obtain verbal consent from each person, check each person has signed a consent form and check each person has completion of a demographics form.

Reminder of ground rules:

- You are being recorded but this will be transcribed and anonymised.
- Everything said here is confidential.
- If we quote anything you say we will do everything we can to ensure it is anonymous and not traceable back to you.
- If you tell me anything that makes me concerned for your safety or the safety of others, I may have to inform a medical professional.
- There are no right or wrong answers, and everyone is encouraged to express their opinion if it is different to other peoples.
- This should take up to an hour, but we can stop at any time, and continue after a break or even another time, if we need to.
- Please try to not talk over each other, and we encourage you to use the 'hands up' function to make sure I know that you have something to add so I can make sure you get a chance to say it.
- You can also use the chat function to add any comments to indicate you have something to add, and which I will then ask you to elaborate on so I can make sure you get a chance to share your thoughts.
- Finally, please also try to talk to the other people on the call rather than at me, so we can try and replicate a discussion that would happen if you were sat in a circle in a room together.

Aim and introduction:

The aim of our study is to find out whether providing an exercise programme at home alongside usual outreach care is acceptable. We are interested in your viewpoint as someone who is a member of staff in the outreach service and who works with patients hospitalised due to a flare up of their COPD.

During this focus group I'll ask you about your experiences as members of staff in the outreach service. This will be about the usual outreach care provided, the delivery of home-based pulmonary rehabilitation within this service as part of our trial and what you think barriers and facilitators to this are. We are also interested in your experiences of the being involved in the clinical service when the trial was being conducted.

Icebreaker / introductions	
I know you all know each other, but before we start, it would be helpful if you could just introduce yourself with your first name, and I will do the same, for the purpose of the	*Go around screen and make sure everyone has introduced themselves.*

recording and so we know what each other's preferred name is.	
Usual outreach (hospital at home) care	
To begin with, it is helpful for us to know a little about what care and treatments the outreach service would usually provide *(this can be brief for both – this is mainly to get people chatting by starting with something they are familiar and comfortable with).*	
1) pre-covid?	*b) Could you talk me through what happens from the point a patient comes into hospital to when they are discharged home, before covid? What care and treatments do they receive?* *c) Could you tell me about what care and treatments might be provided when they return home after being in hospital, before covid? What did the patient pathway look like?*
2) during covid?	*b) Could you talk me through what happens from the point a patient comes into hospital to when they are discharged home, but what is happening now due to covid? What care and treatments do they receive?* *c) Could you tell me about what care and treatments might be provided when they return home currently during restrictions due to covid? And what does the patient pathway look like now?*
Experience of integrated rehabilitation component, positive and negative	
It is also really helpful for us to understand a bit more about how you found rehabilitation at home being delivered alongside the usual outreach service you have just told me about.	
3) So, could you tell me about your experiences of how the rehabilitation at home was delivered?	*Prompts re: the setting (in someone's home) itself, how rehab in the home-setting linked with usual outreach care, how this integration impacted the way day-to-day outreach care was delivered, were their any benefits to the integration, were there any challenges to integration, both positive and negative.* *In relation to the home-based exercises specifically: timing of when the exercises started in relation to timing of hospital discharge, impact of someone attending their home to provide the rehab.* *In relation to covid: what impact do you feel covid has had on the ability to deliver rehabilitation at home alongside the usual outreach care?*

Perceived values, benefits and harms of the intervention content and delivery	
So we've talked a bit about how you found rehabilitation at home being delivered alongside the usual outreach service. It would also be good to know a little bit about what you feel the value, benefits and negatives of this might be from your perceptive as a healthcare professional.	
4) So how do you feel the home-based rehab compared to other rehabilitation which is offered to patients after an acute exacerbation?	*Prompts re: different benefits/challenges, peer support / group dynamics during the outpatient programme compared to home-based programme, transport / travel to outpatient classes, how well they feel patients engaged between the two, how they feel patients felt about home-based programme compared to outpatient programme.*
5) Did you notice any changes in patients after they took part the rehabilitation at home?	*g) effects on mobility* *h) activities of daily living* *i) breathlessness symptoms* *j) mood / psychologically* *k) re-exacerbation or admission*
Acceptability, dose and reach of the intervention in practice for patients / family carers	
It is also really helpful for us to understand a bit more about how you feel rehabilitation at home being delivered alongside the usual outreach service, but this time how you feel it might be experienced by patients and their informal carers / family members.	
6) So, how do you feel patients and their informal carers / family members felt about receiving rehabilitation at home?	*e.g. intensity of the exercise, types of exercise, frequency of the exercise, and perceived ability to complete the exercises without supervision, equipment used, individualisation of the programme, benefits/limitations of home environment; timing of when the exercises started in relation to timing of hospital discharge, impact of someone attending their home.*
Communication around the trial concept, introduction and delivery	
The last thing I wanted to discuss was the conduct of the trial, and what it felt like to be working in a service which was delivering a research project.	
7) Would you be able to tell me about what you were required to do alongside your normal job to support this trial?	*Prompts: and how did you feel about what you were required to do? What impact did what you were required to do have on your workload / caseload (increased or lesser burden of work)? Do you feel there any positives / negatives of working in a service where a trial was being conducted? Do you feel the patient care was affected or changed as a result of the trial (continuity of care / integration / skills of person delivering care)? Could you suggest*

	any areas where improvements could be made? Could you tell me about any elements of the process you feel were successful?
8) Would you be able to tell me about what the role of the researcher was conducting the trial who was working with the outreach team?	*Prompts: and how did you feel about what they were required to do (screening, recruitment, information giving re: trial, consent process and assessment process, and the actual delivery of the home-based programme)? Do you feel there any positives / negatives of having this researcher working in the clinical service as well as working on the trial? Do you feel the patient care was affected or changed as a result of the trial (continuity of care / integration / skills of person delivering care)? Could you suggest any areas where improvements could be made? Could you tell me about any elements of the process you feel were successful?*

Closing statements:

- Thank you for everything you have all shared.
- Before we finish, I just want to check everyone is feeling ok, both emotionally related to what we have spoken about – *if anything emotional, and they would like onward support, advise RB will be in contact, who may refer to onward services as required.*

Research team interview topic guide

Please obtain verbal consent from the person, check the person has signed a consent form and check the person has completion of a demographics form.

Reminder of ground rules:

- You are being recorded but this will be transcribed and anonymised.
- Everything said here is confidential.
- If we quote anything you say we will do everything we can to ensure it is anonymous and not traceable back to you.
- If you tell me anything that makes me concerned for your safety or the safety of others, I may have to inform a medical professional.
- There are no right or wrong answers, and everyone is encouraged to express their opinion if it is different to other peoples.
- This should take up to an hour, but we can stop at any time, and continue after a break or even another time, if we need to.

Aim and introduction:

The aim of our study is to find out whether providing an exercise programme at home alongside usual outreach care is acceptable. We are interested in your viewpoint as someone who is a research member of staff who was involved in the delivery of the trial, in either a small or large capacity. During this interview I'll ask you about your experiences as research member of staff relating to how the trial was conducted and run.

Involvement in trial	
To begin with, it is helpful for us to know a little about what your role was during the trial? *(this will guide the rest of the questions a lot as there is a big difference in the amount of involvement people had with this trial)*	
1) pre-covid?	*d) Could you talk me through what happens from the point a patient gets referred to PR to when they are discharged from the programme, before covid? What does the pathway look like and how long is it for? How are they assessed? What would be included in the 'programme'?*
2) during covid?	*d) Could you talk me through what happens from the point a patient gets referred to PR to when they are discharged from the programme, since the covid restrictions? What does the pathway look like and how long is it for? How are they assessed? What would be included in the 'programme'?*
Communication around the trial concept, introduction and delivery	

This leads nicely into what I wanted to discuss about the delivery of the trial and the conduct of trial assessments. There may be things you can't answer or weren't involved in, which is anticipated, but it is useful to understand what was involved in working on this research project as a whole as well as for your individual role.	
3) Would you be able to tell me about what the different researcher roles there were within this trial?	*Prompts:* *Person who did:* *a) Screening / Recruitment* *b) Information giving re: trial to patients / consent process* *c) Assessment process (at baseline, 4 weeks and 3 months post discharge, who was required, where they were conducted)* *d) Delivery of usual outreach care* *e) Delivery of the home-based programme* *Could you talk me through the process of blinding in this trial? How do you feel this was achieved in this trial (e.g. able to be maintained easily, hard to be maintained)?* *How did it feel to complete the selected outcome measures? E.g. around whether the specific outcome measures selected reflected the areas where patients might benefit from the intervention being tested (e.g. quality of life or exercise capacity, how do you feel about the number of outcomes which were assessed, and how do you think patients felt about the outcomes assessed?* *Could you suggest any areas where improvements could be made in terms of the trial conduct? Could you tell me about any elements of the process you feel were successful?*

Closing statements:

- Thank you for everything you have all shared.
- Before we finish, I just want to check everyone is feeling ok, both emotionally related to what we have spoken about – *if anything emotional, and they would like onward support, advise RB will be in contact, who may refer to onward services as required.*

Appendix 7: Mixed methods feasibility study reflective proforma for qualitative components

Interview / focus group (date):

Facilitator (initials):

Setting:

Group dynamics (if applicable):

Content:

Interviewer reflections:

How did it go?

My own emotions and reflections:

Any surprises?

Most memorable part of the interview?

Best interview question?

What I'd ask / ask differently next time?

For Ruth:

Key themes and reflections:

Anything in line with what I expected?

How did my thoughts / attitudes change?

Other thought