Identifying and Overcoming the Barriers to Smoking Cessation in Rheumatoid Arthritis

Phillipa Claire Aimer

A thesis submitted for requirements for the degree of

Doctor of Philosophy

At the University of Otago, Christchurch

New Zealand

30 October 2015
Abstract

The association between smoking and rheumatoid arthritis (RA) is well established. The risk of developing RA is higher among smokers. Smoking may also affect the severity of disease and reduce the efficacy of medications. People with RA who smoke have an increased risk of comorbid disease from pulmonary disease and osteoporosis, and premature death from heart disease. The combination of negative health effects associated with smoking in people with RA make a compelling case for smoking cessation. Smokers with RA may have specific medical and psychosocial issues that are not being met by generic smoking cessation programmes. However, there has been little research that has addressed RA-related barriers to smoking cessation and to date there has been only one arthritis smoking cessation intervention published. This suggests a gap in research and identifies the need for further research on smoking cessation in RA. The aim of this thesis was to identify barriers to smoking cessation in RA and develop an intervention to aid smokers with RA to overcome these barriers. By qualitatively investigating disease-related issues that make smoking cessation difficult for people with RA, five barriers to smoking cessation were identified: 1) people with RA felt isolated and unsupported when attempting smoking cessation; 2) people with RA were often unaware of the detrimental effects of smoking on RA and hence did not perceive this as a reason to quit; 3) smoking was used as a distraction from the pain associated with RA; 4) people with RA found it difficult to exercise and hence saw themselves as unable to use exercise as an alternative distraction from smoking, and 5) smoking was used as a coping mechanism for the frustrations of living with RA. A twelve week smoking cessation intervention, addressing these five barriers, was developed in association with Arthritis New Zealand and delivered by
Arthritis Educators. The efficacy of the tailored intervention was assessed in a pilot randomised controlled trial. There was no significant difference in smoking abstinence rates at six months, although quit rates for both intervention (26%) and control groups (21%) were high compared to similar intensity smoking cessation programmes in the general population and the published arthritis smoking cessation study. The key support and advice from the Arthritis Educators were the most valued intervention components, followed by the specific smoking cessation components. There were common factors in the study that equally facilitated or impeded smoking cessation for all participants, including nicotine replacement therapy (NRT) as a shared treatment and the stress resulting from the Canterbury earthquakes. In addition, control group participants had independently developed their own strategies to control their smoking. The implications of this study are that although physical limitations and disease-associated factors adversely affect smoking cessation in RA, the lack of added benefit of a tailored smoking cessation intervention suggests a combination of brief advice and NRT is currently the best practice for supporting people with RA who wish to quit smoking.
Acknowledgements

This PhD involved a successful partnership between the Department of Medicine, University of Otago, Christchurch and Arthritis New Zealand. Funding was generously provided by the Health Research Council of New Zealand and the University of Otago. I would like to take the opportunity to thank the following people individually.

To my three supervisors, Professor Lisa Stamp, Dr Gareth Treharne and Professor Vicky Cameron. Thank you so much for having the confidence in my research abilities to undertake this exciting and extremely worthwhile PhD project. I would particularly like to thank you each for your wonderful supervision over the period of the thesis, and your endless patience and willingness to mentor me and critique my work honestly. I could not have completed this thesis without your help and support: Lisa for her rheumatology expertise and her amazing ability to keep my writing and presenting succinct and on task; Gareth for his health psychology and qualitative research expertise, and for untangling the methodological issues that come with a project that combines quantitative and qualitative research; and to Vicky for her enthusiasm for the project, her attention to detail and her invaluable advice regarding each phase of study.

I would also like to thank Dr Simon Stebbings for his fantastic support and advice throughout the last few years, plus access to his rheumatology expertise. I was very grateful to have had a base to work from during the initial phase of research in Dunedin. Also thanks to the rheumatology consultants in Dunedin and Christchurch allowing me to recruit their patients into the various phases of study.
Thanks to Chris Frampton for all of the statistical support and advice to make sense of all of the data from the pilot study. Additionally, I would like to thank Janine Francis and Jan Ipenburg with recruitment, particularly with their willingness to help out with the randomisation of study participants and to administer the ‘ABC pathway’.

This project would not have been possible without the help and advice from Arthritis New Zealand, particularly the two Arthritis New Zealand Educators who were involved with the study intervention: Suzanne Croft and Alexe Hewitt. Thank you for your help with patient follow-ups and your enthusiastic approach to the project. Many thanks also to the study participants, both in Dunedin and Christchurch who willingly gave up their time to take part in the research and attempt smoking cessation. This research would not have been possible without their commitment.

Finally, to my wonderful family: my husband Ross and my three boys Jesse, Harry and Jack, who have supported me throughout this journey and who always knew I would complete the project, even when three years moved into nearly four. Thanks for being proud of me.
# Table of Contents

Abstract ........................................................................................................................... iii  
Acknowledgements ......................................................................................................... v  
List of Tables .................................................................................................................. xiii  
List of Figures .................................................................................................................. xv  
List of Abbreviations ....................................................................................................... xvi  
Conference Presentations and Publications ................................................................... xxi  

## 1 INTRODUCTION .............................................................................................................. 1
  1.1 Background .................................................................................................................. 1  
  1.2 Smoking Cessation in Rheumatoid Arthritis .............................................................. 1  
  1.3 Research Aim and Objectives .................................................................................... 2  
  1.4 Research in Action ...................................................................................................... 3  

## 2 LITERATURE REVIEW .................................................................................................... 7
  2.1 Chapter Overview ......................................................................................................... 7  
  2.2 The Burden of Smoking ............................................................................................... 8  
   2.2.1 Definitions of Smoking Status ............................................................................... 9  
   2.2.2 Definition of Smoking Prevalence ....................................................................... 9  
   2.2.3 New Zealand Smoking Prevalence ..................................................................... 11  
   2.2.4 The Addiction of Smoking .................................................................................. 12  
   2.2.5 Health Risks associated with Smoking ................................................................. 14  
   2.2.6 Smoking and Chronic Disease .......................................................................... 14  
  2.3 The Burden of Rheumatoid Arthritis .......................................................................... 15  
   2.3.1 Description of Rheumatoid Arthritis ................................................................. 16  
   2.3.2 Diagnosis of Rheumatoid Arthritis ..................................................................... 16  
   2.3.3 Aetiology of Rheumatoid Arthritis ..................................................................... 18  
   2.3.4 Risk Factors for Developing Rheumatoid Arthritis ............................................. 18  
   2.3.5 Incidence and Prevalence of Rheumatoid Arthritis ............................................ 21  
   2.3.6 Pathophysiology of Rheumatoid Arthritis ......................................................... 21  
   2.3.7 Subtypes of Rheumatoid Arthritis ..................................................................... 22  
   2.3.8 Articular Manifestations of Rheumatoid Arthritis ............................................. 22
# 2.3.9 Extra-articular Manifestations of Rheumatoid Arthritis

# 2.3.10 Comorbidities Associated with Rheumatoid Arthritis

# 2.3.11 Medical Management of Rheumatoid Arthritis

# 2.4 The Burden of Smoking and Rheumatoid Arthritis

## 2.4.1 The Gene-environment Interaction and Smoking in Rheumatoid Arthritis

## 2.4.2 Impact of Smoking on Radiological Progression and Disease Activity on Rheumatoid Arthritis

## 2.4.3 Impact of Smoking on Comorbidities and Extra-articular Manifestations on Rheumatoid Arthritis

## 2.4.4 Impact of Smoking on Medications to treat Rheumatoid Arthritis

# 2.5 Smoking Cessation

## 2.5.1 Benefits and Difficulties of Smoking Cessation

## 2.5.2 Smoking Cessation in New Zealand

## 2.5.3 New Zealand Smoking Cessation Support Programmes

## 2.5.4 Best-Practice Smoking Cessation Programme Components

## 2.5.5 Efficacy of Smoking Cessation Programme Components

## 2.5.6 Smoking Cessation in Rheumatoid Arthritis

## 2.5.7 Smoking Cessation for Special Populations

# 2.6 Barriers to Smoking Cessation

## 2.6.1 Demographic Barriers to Smoking Cessation

## 2.6.2 Physiological Barriers to Smoking Cessation

## 2.6.3 Psychosocial Barriers to Smoking Cessation

## 2.6.4 Barriers to Smoking Cessation in Chronic Disease

## 2.6.5 Barriers to Smoking Cessation in Rheumatoid Arthritis

# 2.7 Summary

---

## 3 DESIGN AND METHODS

### 3.1 Chapter Overview

### 3.2 The Nature of Research

### 3.3 Methodological Perspectives

#### 3.3.1 Quantitative Inquiry

#### 3.3.2 Qualitative Inquiry

### 3.4 Methods in Action

#### 3.4.1 Qualitative Methods
4 IDENTIFYING THE BARRIERS TO SMOKING CESSION IN RHEUMATOID ARTHRITIS

4.1 Introduction

4.2 Methods

4.2.1 Study Design

4.2.2 Participants

4.2.3 Settings and Locations

4.2.4 Sampling

4.2.5 Data Collection Measures and Verification

4.2.6 Analysis

4.3 Results

4.3.1 Study Recruitment

4.3.2 Baseline Characteristics of Study Participants

4.3.3 Thematic Analysis

4.3.4 Participant Attitudes to Smoking Cessation Attempts

4.4 Discussion

4.5 Conclusion

5 DEVELOPING A TAILORED SMOKING CESSION INTERVENTION FOR PEOPLE WITH RHEUMATOID ARTHRITIS

5.1 Introduction

5.2 Methods

5.2.1 Literature Review

5.2.2 Development of Resources for Intervention

5.3 Results

5.3.1 Intervention Structure

5.3.2 Content of the Targeted Smoking Cessation Intervention

5.4 Discussion

5.5 Conclusion

6 RANDOMISED CONTROLLED TRIAL: PILOT STUDY OF A RHEUMATOID ARTHRITIS SPECIFIC SMOKING CESSION PROGRAMME IN COLLABORATION WITH ARTHRITIS NZ
7.4 Results .......................................................................................................................... 185

7.4.1 Did the Study Intervention Overcame Barriers to Smoking Cessation in People with RA? .................................................................................................................. 185

7.4.2 What Other Factors Facilitated or Impeded Smoking Cessation in People with RA? ......................................................................................................................... 204

7.4.3 Participant Attitudes to their Smoking at Study Completion ................................ 211

7.5 Discussion .................................................................................................................... 218

7.6 Conclusion ................................................................................................................... 225

8 GENERAL DISCUSSION ............................................................................................... 227

8.1 Overview of Thesis Research Findings ........................................................................ 227

8.2 Discussion of Findings ............................................................................................... 229

8.2.1 Strengths and Limitations ..................................................................................... 235

8.3 Implications for Future Research ................................................................................. 235

8.4 Conclusion ................................................................................................................... 237

REFERENCES ................................................................................................................... 239

APPENDICES .................................................................................................................... 285

Appendix 1: Baseline and Follow-up Questionnaires ......................................................... 286

a) Standard Baseline and Follow-up Demographic Questions ........................................ 286

b) The Health Assessment Questionnaire (HAQ) .......................................................... 290

c) The Personal Impact HAQ (PI HAQ) ..................................................................... 293

d) The Perceived Stress Scale (PSS) .......................................................................... 294

e) The Arthritis Self-Efficacy Scale (ASES) ................................................................. 295

f) The Hospital Anxiety and Depression Scale (HADS) .............................................. 297

g) The Euroqol-5D (EQ-5D) .................................................................................... 298

h) The EQ-Visual Analogue Scale (EQ-VAS) ............................................................... 299

i) The Fagerström Test for Nicotine Dependence (FTND) ......................................... 300

j) The Smoking Self-Efficacy Questionnaire (SSEQ) .................................................... 301

k) Smoking History .................................................................................................... 302

Appendix 2: Original Article: Identifying Barriers to Smoking Cessation in RA ................................................................................................................................. 303

Appendix 3: Consent Form for Phase 1 Exploratory Study ............................................. 312

Appendix 4: Information Sheet for Phase 1 Study ......................................................... 314

Appendix 5: Māori Consultation ..................................................................................... 317
Appendix 6: Standardised Participant Information Form (Phase 1 and Phase 3 of study) ................................................................. 319

Appendix 7: Original Article: Developing a Tailored Smoking Cessation Intervention for people with RA .................................................. 321

Appendix 8: The ABC Approach to Smoking Cessation ........................................ 334

Appendix 9: Permission to use Quitline Smoking Cessation “Pip’s Tips” and Smoking Triggers Diary .......................................................... 336

Appendix 10: Smoking Cessation Email “Pip’s Tips” ........................................... 338

Appendix 11: Relationship between RA and Smoking Handout .................................. 339

Appendix 12: Arthritis NZ ‘Managing your Pain’ booklet ..................................... 340

Appendix 13: Exercise Resources for Smoking Cessation Intervention ............... 341
  a) Permission to use Abbott Laboratories NZ Exercise Sheets .......................... 341
  b) Hand Exercises for RA ........................................................................... 342
  c) General Exercises for RA ........................................................................ 344
  d) Arthritis: Exercises to Keep You Moving ................................................ 346
  e) Community Exercise Classes for RA ........................................................ 347
  f) Hydrotherapy Classes for RA .................................................................. 348

Appendix 14: Smoking Triggers Diary ................................................................. 349

Appendix 15: Conference Proceedings: A Pilot Randomized Controlled Trial of a Tailored Smoking Cessation Intervention for Rheumatoid Arthritis Patients [343] .......................................................... 350

Appendix 16: Advertising for Pilot Study ............................................................. 353

Appendix 17: Informed Consent Form for Pilot Study .......................................... 354

Appendix 18: Information Sheet for Pilot Study .................................................. 356

Appendix 19: Pilot Study RCT Participant Needs Assessment Checklist (week 0) ........................................................................... 359

Appendix 20: Pilot Study RCT Participant Follow-up Checklist (weeks 1, 4 and 8) ........................................................................... 363

Appendix 21: Three- and Six-Month Follow-up Interviews .................................. 368

Appendix 22: Exit Interviews with Educators ....................................................... 375
List of Tables

Table 2-1: Definitions of smoking status ................................................................. 10
Table 2-2: Cigarette smoking prevalence in smoking-related chronic diseases ........ 15
Table 2-3: ACR/EULAR 2010 standard classification criteria for RA .................... 17
Table 2-4: Summary of RA disease activity measures recommended by ACR ........ 24
Table 2-5: Therapeutic drugs used in the management of RA .............................. 30
Table 2-6: Effects of smoking on radiographic progression and disease activity in RA* 36
Table 2-7: Effects of smoking on comorbid conditions in RA* .............................. 41
Table 2-8: Effects of smoking on treatments in RA* ............................................. 46
Table 2-9: Outcomes from smoking cessation ....................................................... 53
Table 2-10: Smoking cessation support programmes available in NZ .................. 58
Table 2-11: Grading of smoking cessation recommendations in NZ .................... 59
Table 2-12: Demographic factors affecting smoking cessation in the general population 64
Table 4-1: Individual interview/focus group questions and prompts ..................... 100
Table 4-2: Demographic and disease details of participants ............................... 104
Table 4-3: Demographics of excluded versus included participants ..................... 104
Table 4-4: Smoking history of participants* ......................................................... 105
Table 4-5: Demographic characteristics and psychosocial data of participants* .... 106
Table 5-1: Efficacy of interventions to combat tobacco dependence in the general population ........................................................................................................ 127
Table 5-2: Details of targeted interventions for smoking cessation intervention in RA . 142
Table 5-3: Contacts and content for the smoking cessation intervention for people with RA ................................................................................................................................ 143
Table 6-1: Baseline demographic characteristics of participants .......................... 160
Table 6-2: Baseline functional and psychosocial data of participants.................................161
Table 6-3: Baseline smoking history of participants..............................................................162
Table 6-4: Secondary pilot study outcomes........................................................................166
Table 6-5: Disease duration in those who quit and those who did not.................................167
Table 6-6: Use of NRT vs number quit smoking .................................................................168
Table 6-7: Advised by a health professional to quit smoking during the last 12 months vs number quit smoking ..............................................................................................168
Table 6-8: Baseline demographics, disease and psychosocial factors associated with smoking cessation ..................................................................................................................169
Table 7-1: Number and percentage of participants who accepted intervention components ..........................................................................................................................190
Table 7-2: Use of NRT in the pilot study* ............................................................................206
List of Figures

Figure 2-1: Smoking prevalence trends in NZ by ethnicity from 1996 to 2013 ..........11

Figure 2-2: Odds ratios for different amount of smoking in combination with different
 copies of SE alleles ..............................................................................................34

Figure 2-3: Mortality by percentage survival from aged 35 years for smokers, ex-
 smokers, and non-smokers ..................................................................................52

Figure 2-4: Marlatt’s cognitive behaviour model of the relapse process ...............69

Figure 4-1: Participant flow diagram for this study .............................................103

Figure 5-1: Timeline of the 3-month smoking cessation intervention for people with RA
 ........................................................................................................................................137

Figure 6-1: Pilot study timeline ............................................................................150

Figure 6-2: CONSORT flow diagram illustrating participant flow .......................158

Figure 6-3: Monthly recruitment rates ...................................................................159

Figure 6-4: Days of continuous abstinence for all study participants .....................165

Figure 6-5: Absolute reduction in smoking .............................................................166

Figure 7-1: Comparison of acceptance and usefulness of intervention components .....191

Figure 7-2: Support website for designed for supporting Intervention participants .....195

Figure 7-3: Support webpage page-views ...............................................................196

Figure 7-4: Support webpage: mean time on page per view ...............................197

Figure 7-5: Smoking status at 6-months of participants who found the intervention
 components useful .................................................................................................203

Figure 7-6: Use of NRT and smoking status at 6-months in all study participants ......208
**List of Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>28SJC</td>
<td>28 swollen joint count</td>
</tr>
<tr>
<td>28TJC</td>
<td>28 tender joint count</td>
</tr>
<tr>
<td>ABC</td>
<td>‘ABC pathway’ for smoking cessation</td>
</tr>
<tr>
<td>ACPA</td>
<td>anti-citrullinated peptide antibody</td>
</tr>
<tr>
<td>ACR</td>
<td>American College of Rheumatology</td>
</tr>
<tr>
<td>ANOVA</td>
<td>analysis of variance</td>
</tr>
<tr>
<td>anti-TNF-α</td>
<td>anti-tumour necrosis factor-alpha</td>
</tr>
<tr>
<td>AS</td>
<td>ankylosing spondylitis</td>
</tr>
<tr>
<td>ASES</td>
<td>Arthritis Self-Efficacy Scale</td>
</tr>
<tr>
<td>BMI</td>
<td>body mass index</td>
</tr>
<tr>
<td>CABG</td>
<td>coronary artery bypass grafting</td>
</tr>
<tr>
<td>CDAI</td>
<td>Clinical Disease Activity Index</td>
</tr>
<tr>
<td>CHD</td>
<td>coronary heart disease</td>
</tr>
<tr>
<td>CI</td>
<td>confidence interval</td>
</tr>
<tr>
<td>CONSORT</td>
<td>Consolidated Standards of Reporting Trials</td>
</tr>
<tr>
<td>COPD</td>
<td>chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>CRP</td>
<td>C-reactive protein</td>
</tr>
</tbody>
</table>
CVD cardiovascular disease
DAS disease activity score
DMARDs disease-modifying anti-rheumatic drugs
DVT deep vein thrombosis
EQ-5D Euroqol-5D
EQ-VAS Euroqol-visual analogue scale
ESR erythrocyte sedimentation rate
EULAR European League Against Rheumatism
FTND Fagerström test for nicotine dependence
GP general practitioner
H₀ null hypothesis
H₁ alternate hypothesis
HADS Hospital Anxiety and Depression Scale
HAQ Health Assessment Questionnaire
HLA human leukocyte antigen
HPLC high performance liquid chromatography
IFX infliximab
ISCHP International Society of Critical Health Psychology
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>IP</td>
<td>inflammatory polyarthritis</td>
</tr>
<tr>
<td>ITT</td>
<td>intention-to-treat</td>
</tr>
<tr>
<td>MDHAQ</td>
<td>multidimensional HAQ</td>
</tr>
<tr>
<td>MHC</td>
<td>major histocompatibility complex</td>
</tr>
<tr>
<td>MI</td>
<td>myocardial infarction</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MS</td>
<td>multiple sclerosis</td>
</tr>
<tr>
<td>MTX</td>
<td>methotrexate</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>NNT</td>
<td>number needed to treat</td>
</tr>
<tr>
<td>NRT</td>
<td>nicotine replacement therapy</td>
</tr>
<tr>
<td>NSAIDs</td>
<td>non-steroidal anti-inflammatory drugs</td>
</tr>
<tr>
<td>NZ</td>
<td>New Zealand</td>
</tr>
<tr>
<td>NZRA</td>
<td>New Zealand Rheumatology Association</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OMERACT</td>
<td>Outcome Measures in Rheumatology</td>
</tr>
<tr>
<td>OR</td>
<td>odds ratio</td>
</tr>
</tbody>
</table>
pack years  number of packets of cigarettes smoked per day multiplied by the number of years an individual has smoked

PAD  peptidylarginine deiminases

PAS  patient activity scale

PE  pulmonary embolism

PHARMAC  Pharmaceutical Management Agency

PI HAQ  personal impact Health Assessment Questionnaire

PMS  patient management system

PsA  psoriatic arthritis

PSS  perceived stress scale

Pt Global VAS  patient global assessment of disease activity

Pr Global VAS  provider global assessment of disease activity

QALYs  quality adjusted life years

QUEST-RA  the questionnaires in standard monitoring of patients with RA program

RA  rheumatoid arthritis

RAPID  routine assessment of patient index data

RCTs  randomised controlled trials

RF  rheumatoid factor

xix
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>RR</td>
<td>risk ratio (relative risk)</td>
</tr>
<tr>
<td>SD</td>
<td>standard deviation</td>
</tr>
<tr>
<td>SDAI</td>
<td>simplified disease activity index</td>
</tr>
<tr>
<td>SE</td>
<td>shared epitope</td>
</tr>
<tr>
<td>SES</td>
<td>socioeconomic status</td>
</tr>
<tr>
<td>SMR</td>
<td>standardised mortality ratio</td>
</tr>
<tr>
<td>SvdH</td>
<td>van der Heijde modification of the Sharp scoring system</td>
</tr>
<tr>
<td>TIA</td>
<td>transient ischaemic attack</td>
</tr>
<tr>
<td>TSS</td>
<td>total sharp score</td>
</tr>
<tr>
<td>TTM</td>
<td>Transtheoretical Model</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual Analog Scale</td>
</tr>
</tbody>
</table>
Conference Presentations and Publications

Publications – papers and published abstracts


Presented as a poster at the 2014 American College of Rheumatology Conference (ACR) in Boston, MA, November 2014.

Conferences Attended


**Presentations**


3. 3-minute thesis competition: *Barriers to Smoking Cessation in Rheumatoid Arthritis*. University of Otago, Christchurch. July 2013


**Scholarships and Awards Received**


c) University of Otago Arthritis Research Theme: Student Funding for ACR Conference Attendance. NZD1500. November 2014.
1 INTRODUCTION

1.1 Background

Tobacco use remains one of the biggest public health threats around the world and is a major contributor to health inequalities. Smoking remains a leading cause of preventable morbidity and premature death [1]. Smoking cessation is a key health target in New Zealand (NZ), which reflects the major priority given by the NZ government to focus action and resources to better help smokers to quit [2]. To date, smoking cessation in the general population has received considerable attention and research has identified the most efficacious treatments, which include both pharmacological and behavioural interventions [3]. Smoking rates in the NZ general population are declining as more and more people are able to successfully quit [4]. However, there are some communities of smokers whose smoking rates remain high, thus health policy strategies have emerged that propose tailoring smoking cessation programmes to high-risk groups to increase the chances of quitting smoking long-term [5].

1.2 Smoking Cessation in Rheumatoid Arthritis

Traditionally smoking cessation interventions have been designed for smokers without long-term medical conditions [6]. The association between smoking and rheumatoid arthritis (RA) is well established [7]. Because smoking has been implicated in the pathophysiology of RA, the prevalence of smokers in RA is higher than the general
population and thus meets the criteria for being defined as a ‘special population’ of smokers [8]. This definition includes understudied and undertreated smokers who have been underrepresented in smoking cessation research. Although smoking is a significant risk factor for developing RA and smoking cessation is recommended for people with RA to reduce risk of heart disease, pulmonary disease and osteoporosis, there has been little research that has addressed RA-related barriers to smoking cessation. It is feasible that people with RA could have specific medical and psychosocial issues that are not being met using traditional smoking cessation programmes. Importantly, there has been only one arthritis-specific smoking cessation intervention published to date [9]. This identifies the need for further research on smoking cessation in RA. This thesis addresses key issues for smoking cessation in people with RA in order to determine if a targeted programme designed to meet the medical and psychosocial needs of individual people with RA would be an effective strategy for use in clinical practice.

1.3 Research Aim and Objectives

The overall aim of this thesis is to identify barriers to smoking cessation in people with RA and develop an intervention to assist smokers with RA to overcome these barriers. A comprehensive literature review provides the background information necessary to undertake the research for this thesis. The original research in this thesis will be undertaken in three distinct phases of study to investigate the following objectives:

Phase 1: Identify RA-specific barriers to smoking cessation in order to inform components for an effective RA-specific smoking cessation intervention.
Phase 2: Translate the findings about smoking cessation needs of people with RA into a targeted intervention that could be used in clinical practice.

Phase 3: Determine whether the targeted smoking cessation intervention programme tailored for individuals with RA increases smoking cessation rates at six months compared to standard smoking cessation advice.

Obtain participant feedback to ascertain which aspects of the intervention were most accepted.

Identify the most useful aspects of the pilot study from all study participants.

1.4 Research in Action

The review in Chapter 2 is designed to provide a summary of the literature regarding the relationships between smoking and RA. The deleterious effects smoking has on the management of RA are explored in depth. Particular emphasis is given to disease outcomes that might be improved if an individual quit smoking, including the effects of smoking on disease progression, comorbidities, and RA medications. Gaps in research on smoking cessation in RA are highlighted and critiqued.

The methods employed to further the objectives of this thesis as a whole are outlined in Chapter 3. Different methodological approaches were applied depending upon their appropriateness to the type of study outcome measurements required. The exploratory and evaluation phases of research both employed qualitative methodologies with support from quantitative data. Translating the findings from the first phase of exploratory research into a novel psychosocial intervention required a planning process, thus a collaborative
approach between key stakeholders and researchers was utilised, with the remit of selecting and packaging intervention content and support. The CONSORT 2010 Clinical Trials Checklist provided the framework for reporting the findings from the pilot randomised controlled trial (RCT) [10]. The pilot study was quantitatively based and statistically analysed using SPSS software to compare study outcomes between groups.

The first study phase designed to investigate disease-related issues that make smoking cessation difficult for people with RA is described in Chapter 4. This phase provided a valuable insight to the specific RA-related barriers to smoking cessation in a stratified sample of smoking and ex-smoking individuals with RA. By gaining an understanding of these specific factors from the perspective of individuals, the opportunity to plan an effective targeted intervention that may increase the chance of smoking cessation was facilitated. These ‘lived’ experiences provided the foundations for a smoking cessation intervention tailored for people with RA.

The translation of the findings from the exploratory phase into a 12 week novel psychosocial smoking cessation intervention, tailored specifically to meet the goals and preferences of individual people with RA is outlined in Chapter 5. This intervention was developed in association with Arthritis New Zealand (NZ) and was designed to be used in clinical practice. It had two major methodological components: the intervention structure and intervention content. The intervention structure was designed using key components of existing evidence-based smoking cessation programmes as identified in a systematic literature review. The process for developing and refining resources for people with RA addressed the previously identified barriers for quitting smoking. This provided the intervention content and is reported separately in detail.
Chapter 6 presents the results from testing the efficacy of the tailored intervention in a pilot study. People with RA who were current smokers were randomised on a 1:1 ratio into the control or the intervention arms of the study. All participants received the current standard of care for smoking cessation, the ‘ABC pathway’ however; those randomised to the intervention arm received additional advice, education and support from Arthritis NZ Educators as outlined in Chapter 5.

To study implications for future practice and research, Chapter 7 presents an in depth exploration of the qualitative secondary outcomes of the pilot study. Feedback from study participants was analysed to evaluate what aspects of the smoking cessation intervention and overall study were most useful and valuable to the participants.

Chapter 8 provides an overview and integration of the findings in the three phases of study to address the overall research aim and present the findings from the thesis study. The thesis will show that although physical limitations and disease-associated factors adversely affect smoking cessation in RA, the lack of added benefit of a tailored smoking cessation intervention suggests a combination of brief advice and nicotine replacement therapy (NRT), which is offered routinely and was the usual standard of care treatment for the control group (the ‘ABC pathway’), is the best practice supporting people with RA who wish to quit smoking. Adding a disease-specific educational component that outlines the relationship between RA and smoking may be beneficial. RA smokers with less education or a longer history of smoking may require particular cessation support.
The study presented in this thesis adds to current literature on smoking cessation in RA because it tested the value of a smoking cessation programme for people with RA based upon comprehensive and intensive support, whilst allowing for the individualisation of the support package based on the needs and preferences of individual people with RA. Overall, this intervention enabled the targeting of smoking cessation barriers in people with RA by empowering them with problem-solving strategies, which may lead to improvements in life expectancy through addressing barriers to smoking cessation in RA.
2 LITERATURE REVIEW

2.1 Chapter Overview

Identifying barriers to smoking cessation in RA and then developing an intervention to aid smokers with RA to overcome these barriers is the overarching aim of this thesis. The purpose of this review is to highlight how smoking is a significant health issue in people with RA, particularly the risk of premature death from comorbid cardiovascular disease (CVD) and justifies why smoking cessation in RA would be of particular benefit. The review identifies the gap in the literature pertaining to smoking cessation in RA.

The review begins with an outline of the burden that smoking presents to the general population, with a strong emphasis on the health risks associated with smoking. The added burden of smoking with chronic disease is examined, and the discussion highlights the increased risk smoking poses to disease progression, recurrent events and death from smoking in smoking-related chronic diseases. The review then narrows its focus to describe RA including aetiology, pathophysiology, and known risk factors for development of the disease. Smoking is identified as a modifiable risk factor for RA, followed by an in depth examination of the deleterious impacts of smoking on health in established RA, particularly comorbid smoking-related diseases which can dramatically reduce people with RA’ quality of life and be associated with premature death.

The focus of the review progresses to consider smoking cessation and the benefits of smoking cessation. The review presents a background of the strategies and programmes
adopted by national and international governments to increase quitting in their populations including evidence-based smoking cessation interventions. Because smoking has such strong adverse associations with RA, quitting smoking is now viewed as an important modifiable risk for people with RA and one of the few areas that they can take control of their own health with potential to improve disease outcomes. However, there has been little research into smoking cessation in RA. Physical and disease-associated factors may make quitting smoking more difficult in people with RA and so particular prominence is given to identifying potential barriers that may be relevant to people with RA who smoke.

2.2 The Burden of Smoking

“It’s the most dangerous weapon of mass destruction. In fact, in your country, tobacco use is responsible for more deaths than World War II, HIV/AIDS, cocaine, heroin, alcohol, accidents, homicide and suicide – combined!” (Excerpt from an open letter from Indian cancer surgeon Prof Pankaj Chaturvedi to USA screenwriter Woody Allen) [11]

Cigarette smoking is a highly prevalent and addictive habit that is the leading cause of preventable death and disability, and will kill an estimated one billion people during the 21st century [1]. However, for each death caused by tobacco there are 20 smokers suffering from a smoking-related disease [12]. Smoking is directly related to six of the eight most frequent causes of death [1]. Overall, life-long smokers experience a higher prevalence of common diseases, a reduced quality of life, and die an average of 14 years earlier than non-smokers [13]. A recent study in Australia found that tobacco kills an estimated two-thirds
of smokers, a much higher rate than previously recognised, ultimately causing about five million premature deaths annually worldwide [14].

2.2.1 Definitions of Smoking Status

The definitions of smoking status used by the national tobacco surveys in NZ are described in Table 2-1. These definitions are comparable with the definitions used in international surveys in Australia, Canada, United Kingdom (UK), and United States (USA), although the terminology for ‘ex-smoker’ is interchangeable with ‘former’ smoker [15]. Ninety percent of current smokers have been reported as persistent daily smokers, which demonstrates the major difference between the definitions of ‘current’ smoker versus ‘daily’ smoker [16]. In this thesis, the term ‘current’ smoker will be used to identify the smoking status in people with RA.

2.2.2 Definition of Smoking Prevalence

The prevalence of smoking is determined by the number of current smokers in a specific population divided by the total population at a specific time [15]. Smoking prevalence is often referred to as a ‘smoking rate’ [15]. Prevalence of smoking in any population varies by socio-economic status (SES), ethnic group, age, gender, and level of education [17]. Smoking prevalence is higher in some population groups of smokers including those with smoking-related chronic illnesses such as CVD, chronic obstructive pulmonary disease (COPD), and diabetes [6, 18]. Because Australia, Canada, UK and USA have similar tobacco control environments to NZ, prevalence rates from these countries are often compared [15].
Table 2-1: Definitions of smoking status
(Adapted from [15])

<table>
<thead>
<tr>
<th>Smoking status and individual definitions</th>
<th>Definition includes</th>
<th>Definition excludes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Smoking</strong>: smoking of tobacco via cigarettes or loose tobacco</td>
<td>Manufactured cigarettes</td>
<td>Smoked non-tobacco products e.g. cigars and pipes, marijuana, non-smoked tobacco products</td>
</tr>
<tr>
<td></td>
<td>Loose tobacco</td>
<td></td>
</tr>
<tr>
<td>‘Current smoker’: individual who has smoked greater than 100 cigarettes in their lifetime and currently smokes at least monthly</td>
<td>Daily smokers</td>
<td>People who currently smoke less often than once a month</td>
</tr>
<tr>
<td></td>
<td>Weekly smokers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monthly smokers</td>
<td></td>
</tr>
<tr>
<td>‘Daily smoker’: individual who currently smokes at least once per day</td>
<td>Daily smokers</td>
<td>Weekly smokers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Monthly smokers</td>
</tr>
<tr>
<td>‘Non-daily smoker’: individual who currently smokes at least monthly, but not daily</td>
<td>Weekly smokers</td>
<td>Daily smokers</td>
</tr>
<tr>
<td></td>
<td>Monthly smokers</td>
<td></td>
</tr>
<tr>
<td>‘Ex-smoker’: individual who has smoked greater than 100 cigarettes in their lifetime and does not currently smoke</td>
<td>Ex-daily smokers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ex-weekly smokers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ex-monthly smokers</td>
<td></td>
</tr>
<tr>
<td>‘Never smoker’: individual who has smoked less than 100 cigarettes in their lifetime and does not currently smoke</td>
<td>People who have never tried smoking</td>
<td>All ever smokers</td>
</tr>
<tr>
<td></td>
<td>People who may have experimented with smoking (up to 100 cigarettes)</td>
<td></td>
</tr>
<tr>
<td>‘Ever Smoker’</td>
<td>Current smokers</td>
<td>Never Smoker</td>
</tr>
<tr>
<td></td>
<td>Ex-smokers</td>
<td></td>
</tr>
</tbody>
</table>
2.2.3 New Zealand Smoking Prevalence

Data from the 2013 NZ census show 15.1% (463,000) NZ adults were current smokers, a decrease from 19.9% (598,000) in 2006/7 [19, 20]. This equates to a real reduction of 23% over seven years. Smoking rates (prevalence) have been gradually decreasing in NZ (Figure 2-1) and for the first time since 2006/7, there has also been a decrease in daily smoking for Māori (the indigenous population of NZ) from 42.2% to 32.7% [21]. Smoking is most prevalent among people living in the most deprived areas of NZ [19, 22] and the higher prevalence of smoking among Māori accounts for a significant proportion of the disparities in health seen between Māori and non-Māori in NZ [23]. International guidelines for smoking cessation have highlighted how specific groups of smokers face more difficulties with quitting, particularly those with long-term health conditions [6, 24]. Therefore, smoking cessation may also help close gaps in the health disparities that are seen in many long-term conditions including RA.

Figure 2-1: Smoking prevalence trends in NZ by ethnicity from 1996 to 2013 (adapted from [20, 25, 26])
2.2.4 The Addiction of Smoking

“If it were not for the nicotine in tobacco smoke, people would be little more inclined to smoke than they are to blow bubbles” (M.A.H Russell, tobacco researcher, 1974) [27]

Nicotine dependence is a recognised medical condition in the Diagnostic and Statistical Manual of the American Psychiatric Association where empirical data and observations provide checklist criteria to classify whether individuals are dependent or not dependent upon nicotine [28]. Most smokers use tobacco habitually because they become dependent upon nicotine. For much of the 20th century smoking was regarded as a socially learned habit and a personal choice. However, during recent decades, much more information has emerged on the fundamental role of nicotine dependence in sustaining smoking behaviour [27]. Although heroin and methamphetamine are more addictive when considering the proportion of users who will become dependent, nicotine causes more serious dependence because it is regarded as more difficult to quit [16].

Nicotine from smoke is absorbed through the nose and the mucosal linings of the mouth and lungs, and transported in the blood to the brain [27]. Nicotine binds to brain tissues with a high affinity within about 10 seconds from inhalation [29]. The receptor binding capacity of nicotine in smokers is increased compared to non-smokers due to a higher number of nicotinic cholinergic receptors in the brain, which are up-regulated by the act of smoking [30]. Nicotine triggers the release of the neurotransmitter dopamine in the brain, which is responsible for the commonly described positive effects of smoking such as pleasure, feelings of calmness and increasing alertness [31]. These acute effects of nicotine
dissipate rapidly along with the associated feelings of pleasure and reward, thereby causing the smoker to smoke again. Withdrawal symptoms from nicotine include headaches, anger, depression, anxiety, and sleep disturbances [31]. If nicotine is removed from tobacco smoke, or the nicotine’s effects on the central nervous system are blocked pharmacologically, the desire to smoke eventually ceases. This is the model that underpins pharmacological smoking cessation therapies and is considered in more depth in section 2.5.5 [27].

Over time, continued nicotine exposure leads to a craving for more nicotine to feel the same positive effects from smoking [31]. The Fagerström Test for Nicotine Dependence (FTND) is a tool used to evaluate the level of physiological dependence on nicotine [32]. Higher levels of nicotine dependence are indicated by an earlier time of the first cigarette of the day, more frequent smoking in the morning, and a higher number of cigarettes smoked per day.

However, pharmacological factors alone do not drive smoking behaviour. Social, economic, political, and personal aspects influence patterns of smoking prevalence and smoking cessation [27]. The habit of smoking is socially influenced due to the close coupling of behavioural rituals and the sensory aspects of smoking with nicotine uptake, which leads to secondary conditioning [27]. The habit of smoking is also linked to the sight of the packet, the smell of the smoke, and the “scratch” in the throat from inhaling [27]. Smoking habits can also be formed by behaviour and linked to activities of daily life, for example when having a cup of coffee or after a meal [33]. Emotions also play a role such that smokers often habitually reach for a cigarette when bored, angry or stressed [31].
2.2.5 **Health Risks associated with Smoking**

“Cigarettes are not merely tobacco leaves rolled up in paper. The modern cigarette is the most highly engineered product meant to be taken into the human body” [34]

Smoking tobacco harms nearly every organ in the body [35]. Because smoking has a fundamental role in the pathogenesis of many diseases, the health risks from tobacco have been widely investigated [36]. Most smoking-related deaths are from one of the three following types of disease: 1) CVD; 2) COPD, including emphysema and chronic bronchitis; and 3) cancers, particularly those of the lung, larynx and tongue [12, 13, 37, 38]. On a global scale, smoking is responsible for over one third of all respiratory deaths, over one quarter of all cancer deaths, and about 15% of all CVD deaths [12].

2.2.6 **Smoking and Chronic Disease**

Smoking has been causally linked with heart disease and lung cancer since the 1960’s [39, 40]. Individuals with chronic diseases including COPD, CVD and cancers, have a higher smoking rate than the general population [18, 41]. In 2006 in the USA, the prevalence of current smoking among individuals with smoking-related chronic disease was 36.9% (range: 29.3–49.1%) compared to 19.3% of the general population (Table 2-2) [18, 42]. Individuals with chronic disease who currently smoke are at a higher risk of disease progression, recurrent events and have a higher mortality rate [43].
Table 2-2: Cigarette smoking prevalence in smoking-related chronic diseases (Adapted from [42])

<table>
<thead>
<tr>
<th>Chronic Disease</th>
<th>Smoking Prevalence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking-related cancers (other than lung cancer)</td>
<td>38.8</td>
</tr>
<tr>
<td>Coronary Heart Disease (CHD)</td>
<td>29.3</td>
</tr>
<tr>
<td>Stroke</td>
<td>30.1</td>
</tr>
<tr>
<td>Emphysema</td>
<td>49.1</td>
</tr>
<tr>
<td>Chronic Bronchitis</td>
<td>41.1</td>
</tr>
</tbody>
</table>

Rheumatoid arthritis is an example of a smoking-related chronic disease. Current- or past-smoking is more prevalent amongst people with RA as shown by studies in several countries [44-47]. The importance of smoking in the aetiology of RA has been recognised for some years. More recently the impact of smoking and smoking cessation on RA disease activity, disease progression and response to treatment has been recognised as important. Smoking cessation is recommended in international RA treatment guidelines but there is little research on the RA related barriers to smoking cessation and ways to assist people with RA quit [48-50].

2.3 The Burden of Rheumatoid Arthritis

The purpose of this section is to provide a background on the epidemiology of RA and its burden in contemporary society. The term ‘burden’ when applied to RA refers to the impact the disease has on an individual’s quality of life with respect to pain, suffering, disability,
and risk of premature death, and the impact on society resulting from the prevalence of the disease [51].

### 2.3.1 Description of Rheumatoid Arthritis

Rheumatoid arthritis is a chronic autoimmune inflammatory disease characterised by inflammation of the synovial lining of the joints. This leads to joint pain, swelling and stiffness [52]. Inadequately controlled, RA may result in irreversible joint damage [7, 53, 54]. RA is associated with a higher premature mortality rate, particularly in women (standardised mortality ratio (SMR) 1.41, 95% confidence interval (CI) 1.22-1.61) compared to men (SMR 1.08, 95% CI 0.86-1.32) [55]. The increased mortality is largely caused by CVD and infections that become apparent eight to ten years after disease onset [55, 56]. Individuals with more severe RA disease (i.e. those with extra-articular manifestations such as rheumatoid nodules) have a greater than four-fold increase in mortality rates compared with the general population [54, 55, 57]. While mortality rates are decreasing over time due to the advances in disease management and medical treatments available, they remain elevated compared to the general population with 40-50% more premature deaths among people with RA, largely due to CVD [57].

### 2.3.2 Diagnosis of Rheumatoid Arthritis

There is no single ‘gold-standard’ diagnostic test for RA, so diagnosis is based on a combination of clinical features supported by laboratory tests. Because there are no definitive diagnostic tests for RA, classification criteria are used to define a group of individuals with broadly similar disease who can be included in RA clinical trials. The
classification criteria for RA were updated by a joint working group from the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) in 2010 [54]. Prior to this update, the 1987 American Rheumatism Association (ARA) criteria were used routinely, although they were criticised for their lack of sensitivity in early disease [54, 58]. The ACR/EULAR 2010 criteria for classification of RA are outlined in Table 2-3. The cut-point for RA classification is a total of ≥6 points.

Table 2-3: ACR/EULAR 2010 standard classification criteria for RA (adapted from [52])

<table>
<thead>
<tr>
<th>RA Features</th>
<th>Number of points attributed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Joint involvement</strong></td>
<td></td>
</tr>
<tr>
<td>• One medium-to-large joint</td>
<td>0</td>
</tr>
<tr>
<td>• Two to ten medium-to-large joints</td>
<td>1</td>
</tr>
<tr>
<td>• One to three small joints (large joints not counted)</td>
<td>2</td>
</tr>
<tr>
<td>• Four to ten small joints (large joints not counted)</td>
<td>3</td>
</tr>
<tr>
<td>• More than ten joints (at least one small joint)</td>
<td>5</td>
</tr>
<tr>
<td><strong>Serology</strong></td>
<td></td>
</tr>
<tr>
<td>• Negative RF and negative ACPA</td>
<td>0</td>
</tr>
<tr>
<td>• Low positive RF or low positive ACPA</td>
<td>2</td>
</tr>
<tr>
<td>• High positive RF or high positive ACPA</td>
<td>3</td>
</tr>
<tr>
<td><strong>Acute-phase reactants</strong></td>
<td></td>
</tr>
<tr>
<td>• Normal CRP and normal ESR</td>
<td>0</td>
</tr>
<tr>
<td>• Abnormal CRP or abnormal ESR</td>
<td>1</td>
</tr>
<tr>
<td><strong>Duration of symptoms</strong></td>
<td></td>
</tr>
<tr>
<td>• Less than 6 weeks (0)</td>
<td>0</td>
</tr>
<tr>
<td>• 6 weeks or more (1)</td>
<td>1</td>
</tr>
</tbody>
</table>

RF=rheumatoid factor; ACPA=anti-cyclic citrullinated peptide antibody; CRP=C-reactive protein test; ESR=erythrocyte sedimentation rate test
Some individuals may have RA despite not fulfilling the above criteria. Therefore, individuals can also be classified as having RA if they fulfil the following three criteria:

1) Typical radiographic erosions.
2) Long-standing disease that previously satisfied the American Rheumatism Association 1987 criteria [58].
3) Not fulfilling new criteria at initial presentation, but may do so as their condition evolves over time [54].

2.3.3 Aetiology of Rheumatoid Arthritis

Although the exact aetiology of RA is still not entirely understood, it is considered to develop in genetically predisposed individuals after exposure to specific environmental factors [59]. Together these genetic and environmental factors interact to activate the immune system resulting in inflammation and in some cases production of the autoantibodies rheumatoid factor (RF) and/or anti-citrullinated peptide antibody (ACPA) [59, 60]. The development of these antibodies which are associated with RA can occur many years ahead of the development of clinical symptoms (pre-clinical autoimmunity) [61].

2.3.4 Risk Factors for Developing Rheumatoid Arthritis

Risk factors for developing RA include a combination of hormonal, genetic, environmental and lifestyle factors [62]. The following section examines each of these risk factors individually. Understanding the causes that lead to RA disease is important, not only for
developing treatments, but also to understand how certain factors, e.g. smoking may have an impact on the efficacy on treatments.

**2.3.4.1 Hormonal and age risks for Rheumatoid Arthritis**

Rheumatoid arthritis is more prevalent in females than males [63]. This predominance suggests that sex hormones and reproductive factors may be involved in the aetiology of the disease. A number of hormonal risk factors have been suggested including age at menarche, parity, breastfeeding, use of oral contraceptives, and termination of pregnancy [64, 65]. However, results have been conflicting and no definitive association has been observed [66, 67].

**2.3.4.2 Genetic risks for Rheumatoid Arthritis**

Up to 60% of RA risk has been attributed to genetic factors [68]. This has been demonstrated through twin studies, family studies and genome-wide association studies [62]. RA was one of the first inflammatory diseases where major histocompatibility complex (MHC) class II genes, specifically the human leukocyte antigen beta chain (HLA-DRB) complex, were related to disease risk [69-72]. The HLA-DRB1 gene provides instructions for making a protein that has a critical role in the immune system [73]. The MHC class II molecules are only found in antigen-presenting cells [74]. It has been nearly three decades since the existence of common structural features of these genes were identified and termed the ‘shared epitope’ (SE) [69]. The HLA-DRB1 SE alleles are involved in the development of seropositive RA, and more specifically ACPA positive RA [75].
2.3.4.3 *Environmental and lifestyle risk factors for Rheumatoid Arthritis*

Environmental and other non-genetic factors account for the remaining 40% of the risk of developing RA, and interactions between genetic and environmental risk factors have been associated with the risk of developing RA [53]. This means RA risk models that use genetic and environmental risk factors will be more accurate in modelling the risk for developing RA than each alone [53]. Evidence also suggests that some risk factors are significant only in ACPA-positive disease [76]. Regular smoking and ACPA-positive RA is one example of a causal association, and as this is a major factor of interest in this thesis, it will be discussed in depth in section 2.4.1. Apart from smoking, other environmental and lifestyle risk factors, as listed below, are less certain and particularly difficult to generalise within RA [76]:

1) Social class: relationships have been identified between lower level of education and a greater RA risk in some studies [77, 78], but this remains controversial because they may be confounded with other risks, such as smoking and other environmental exposures.

2) Occupational exposure to silica dust, mineral oils and other immune system activators [79, 80].

3) Infections: the Epstein-Barr virus (EBV) has been associated with RA [81, 82].

4) Diet: caffeine, antioxidants and oily fish have been examined by many studies but associations with RA still remain contentious [83].
2.3.5 Incidence and Prevalence of Rheumatoid Arthritis

Rheumatoid arthritis is regarded as a common autoimmune disease affecting all ethnic groups. In prevalence studies, RA is more common in women than men [84]. The incidence of RA from European studies during the 1990’s was estimated at 13-36 per 100,000 women >19 years and 4-13 per 100,000 men [84, 85]. Estimates of the prevalence of RA range from 3-12 per 1,000 women and 1-6 per 1,000 men in Europe during the same time-frame [84]. World-wide, RA is prevalent in up to 0.5 to 1% of the adult population and usually begins in adults between the ages of 40 and 60 years, although it can occur at any age [7, 51, 86-88]. There is scant data on the prevalence of RA in NZ but based upon the prevalence rates in comparable European countries, RA prevalence in NZ adults was estimated to be approximately 0.53% in 2010, making it the second most common form of arthritis [51]. Prevalence rates are broadly similar by gender across all ethnic groups in NZ [51].

2.3.6 Pathophysiology of Rheumatoid Arthritis

The pathogenesis of RA appears to involve both cellular and humoral immunity; although the specific role that each arm of the immune system plays in the initiation and perpetuation of the autoimmune disease process remains unclear [89]. The dominant cells in joints affected by RA are cartilage and synovial cells [52]. The overproduction by inflammatory cells of pro-inflammatory cytokines including tumour necrosis factor-alpha (TNF-α), interleukin-1, and interleukin-6 drives both synovial inflammation and subsequent joint damage [52]. Chronically affected joints are characterised by thickened synovium, [90]. Uncontrolled inflammation leads to cartilage damage and bone erosion. [90]. Section 2.3.11 describes the treatments used to control the inflammation in RA.
2.3.7 Subtypes of Rheumatoid Arthritis

The division of RA into subtypes has been determined since the 1940s by the presence/absence of RF [72]. Contemporary studies have seen 70-75% of people with RA positive for RF [88]. More recently the presence/absence of the more specific anti-CCP antibodies (ACPA) has become recognised as an effective and informative marker for the subdivision of RA. Sixty percent of people with RA are ACPA-positive [91]. ACPA-positive and ACPA-negative disease are believed to be genetically distinct, where HLA-DRB1 SE alleles are restricted to ACPA-positive RA. In established RA, ACPA-positive individuals may also develop a more severe form of the disease. High levels of ACPA are associated with higher disease activity, worse radiographic progression, and more severe clinical outcomes [92].

2.3.8 Articular Manifestations of Rheumatoid Arthritis

Joints classically affected by RA include the small joints of the hands and feet as well as wrists, elbows, knees, ankle and cervical spine. Affected joints are swollen and painful [93]. Once acquired, RA persists and over time RA can lead to significant joint destruction with loss of function and ensuing disability. Joint damage starts early in the course of RA and once present is largely irreversible [94]. Persisting joint inflammation (disease activity) is an important predictor of progression of joint damage and the long-term requirement for joint replacement surgery [94]. Disease activity has also been shown to be the main determinant of functional capacity in RA, even in those with long-standing disease [95].
Radiological progression and disease activity are used to ascertain the severity of RA in individuals and are important outcome measures in clinical trials or observational studies in RA [96]. Inflammatory activity in the joints leads to joint damage which is visible radiographically and can be monitored over time for progression. Radiographic damage correlates with physical function in people with RA [96]. Radiological progression and disease activity are important concepts because they frame the well-being of people with RA. While inflammation in joints fluctuates over time in individuals, the radiographic damage is considered to reflect cumulative joint inflammation over time [96]. Disease activity is used by health providers to quantify an individual’s status into either high or low disease activity, which is used to guide treatment aiming toward a state of low disease activity or remission [97].

Radiographic progression in clinical trials or observational studies can be measured by the van der Heijde modification of the Sharp scoring system (SvdH) [96], which collects information on erosions and joint space narrowing. The SvdH is measured by the presence of erosions in 16 joints of hands and wrists (graded 0-5), six joints in the feet (graded 0-10), and the presence of narrowing in joint spaces in 15 joints of hands and wrists (graded 0-4), six joints in the feet (graded 0-4), giving a maximal range of 280 units for erosion and 168 units for joint space narrowing, which adds up to 448 units for the total Sharp score (TSS) [96]. This measurement is taken at two subsequent time points and the difference between the two is the outcome measure.

Because there is no definitive ‘best’ test for disease activity in RA, the ACR has recommended six tools for the systematic measurement of disease activity in RA (Table 2-4) [98]. These tools broadly fall into four categories: 1) individual questionnaires such as
the Health Assessment Questionnaire (HAQ), which asks how much difficulty an individual has performing daily activities such as bathing, dressing and getting in and out of cars; 2) joint counts where a physician examines a specific number of joints (28) and tallies how many are swollen or tender; 3) laboratory tests that measure markers of inflammation such as the erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP), and 4) validated composite disease activity scores such as the disease activity score (DAS28) that include variables from the preceding categories.

Table 2-4: Summary of RA disease activity measures recommended by ACR (Adapted from [98])

<table>
<thead>
<tr>
<th>Category ++</th>
<th>Measure/scale</th>
<th>Number of items</th>
<th>Response format</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PAS</td>
<td>3</td>
<td>HAQ, Pain VAS, Pt Global VAS</td>
</tr>
<tr>
<td>1</td>
<td>PAS-II</td>
<td>3</td>
<td>HAQ-II, Pain VAS, Pt Global VAS</td>
</tr>
<tr>
<td>1</td>
<td>RAPID-3</td>
<td>3</td>
<td>MDHAQ, Pain VAS, Pt Global VAS</td>
</tr>
<tr>
<td>1 &amp; 2</td>
<td>CDAI</td>
<td>4</td>
<td>28TJC, 28SJC, Pt Global VAS, Pr Global VAS</td>
</tr>
<tr>
<td>1, 2 &amp; 3</td>
<td>DAS28</td>
<td>4</td>
<td>28TJC, 28SJC, ESR or CRP, Pt Global VAS</td>
</tr>
<tr>
<td>1, 2 &amp; 3</td>
<td>SDAI</td>
<td>5</td>
<td>28TJC, 28SJC, Pt Global VAS, Pr Global VAS, CRP</td>
</tr>
</tbody>
</table>

*PAS=Patient Activity Scale; RAPID-3=Routine Assessment of Patient Index Data; CDAI=Clinical Disease Activity Index; DAS=Disease Activity Score; ESR=Erythrocyte Sedimentation Rate; CRP=C-reactive protein; SDAI=Simplified Disease Activity Index; HAQ=Health Assessment Questionnaire; MDHAQ=multidimensional HAQ; VAS=visual analogue scale; Pt Global VAS=patient global assessment of disease activity; Pr Global VAS=provider global assessment of disease activity; 28TJC=28 tender joint count; 28SJC=28 swollen joint count; ++1=Patient tools; 2=Patient, Physician tools; 3=Patient, Physician, Laboratory tests
2.3.9 Extra-articular Manifestations of Rheumatoid Arthritis

Extra-articular manifestations of RA are systemic features of the disease that occur outside the joints and occur in about 40% of people with RA at some stage of their disease course [99]. Organs that may be affected include the eyes, heart, skin, lungs, and the gastrointestinal, nervous, and renal systems [93]. Extra-articular damage can occur at any stage after the onset of RA and is more common in males [100]. The most common extra-articular manifestation of RA is subcutaneous rheumatoid nodules, which can affect up to 30% of people with RA and typically occur in RF positive individuals [75]. Effects from systemic inflammation contribute significantly to the risk of disease-related premature death in RA [93]. Of particular importance, the presence of extra-articular manifestations in RA places individuals at an increased risk of developing CVD or severe infections [93]. A study that examined the trends in incidence of risk factors for extra-articular disease in 609 people with RA over a 46 year period found the most frequent predictor of severe extra-articular manifestations of RA disease was current or past smoking (risk ratio (RR) 2.94, 95% CI 1.68-5.13) [101]. Other less strong predictors included an individual having a positive RF and the HLA-DRB1 SE [93, 101].

2.3.10 Comorbidities Associated with Rheumatoid Arthritis

Comorbidity refers to the presence of two or more illnesses in the same person where the appearance of illnesses may reflect a causal relationship or vulnerability between one disease and another [102]. Comorbidities may be associated with the underlying disease itself or the medications used to treat the underlying condition. Cardiovascular disease, COPD, osteoporosis and infections are common comorbidities of RA and can result in a
significant health burden to the individual over and above the articular manifestations of the disease [75, 103]. Comorbid diseases in RA are a key cause of a higher mortality in people with RA compared to the general population. The leading causes of comorbid death in RA are CVD (31%) and pulmonary problems including respiratory infection (29%) [104]. The mean number of comorbidities per RA individual is 1.6, which increases with age [105]. Around 80% of people with RA have one or more comorbidities [106].

2.3.10.1 Cardiovascular Disease

The prevalence of CVD in RA was measured in the 2005-6 Questionnaires in Standard Monitoring of Patients with RA Program (QUEST-RA) in 4,363 patients from 15 countries. Prevalence was estimated to be 9.3% (range 3.6 to 17.8%), with considerable variation found between different countries [107, 108]. In addition, having RA almost doubles the risk of myocardial infarction (MI) within the first 10 years after the onset of RA [109]. The predicted risk of CVD for people with RA is similar to individuals without RA who are around 10 years older, and similar to individuals who have diabetes mellitus [110]. The risk of CVD death is increased by 50% in people with RA [111].

Traditional and non-traditional CVD risk factors are intimately interconnected and may act synergistically to increase CVD risk in people with RA [110, 112]. Traditional risk factors for CVD in RA include smoking, hypertension, dyslipidaemia, diabetes mellitus, and metabolic syndrome [110]. A paradox within RA is that a low body mass index (BMI) is associated with a three-fold increased risk of cardiovascular death rather than the more common risk factor of a high BMI [110]. Non-traditional CVD risk factors specific to RA
include systemic inflammation and medications used in the management of RA such as non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids [110].

2.3.10.2 Chronic Obstructive Pulmonary Disease

A recent population-based case-control study of 9,039 people with RA and 15,070 controls without RA estimated the prevalence of COPD in people with RA is 8.6% compared to 4.4% in controls [113]. Chronic obstructive pulmonary disease is a collective term for conditions that impede the flow of air in the trachea and bronchi [114]. Symptoms include shortness of breath, cough, and phlegm. Smoking is the risk factor most strongly associated with COPD in the general population [114]. Current or ex-smokers make up 80% of individuals with COPD. The World Health Organisation estimates over 50 million people are affected world-wide (between 5 to 10% prevalence in the adult population), causing close to three million deaths annually [115]. The World Health Organisation also predicts that deaths from COPD are likely to increase by more than 30% in the next 10 years, unless tobacco smoke exposure is prevented. Although once developed COPD cannot be cured, but further deterioration can be prevented by smoking cessation.

2.3.10.3 Osteoporosis

Osteoporosis is a progressive bone disease characterised by a decrease in bone mass and density that can lead to an increased risk of bone fractures [75, 103]. The lifetime risk for a hip, vertebral or wrist fracture due to osteoporosis has been estimated to be between 30 to 40% in developed countries, which is similar to the risk of CVD [116]. Osteoporosis has been reported to occur in 10-56% of all people with RA and is the most common
comorbidity in RA [117, 118]. The prevalence of osteoporosis is greater in postmenopausal female people with RA compared to premenopausal female people with RA or male people with RA of any age [118], and is doubled in people with RA as compared to the general population [119].

Osteoporotic fractures of the hip incur the highest morbidity and mortality [116]. The risk of fractures in RA has been estimated to be increased 1.5-fold (95% CI 1.4-1.6) compared to healthy controls [120]. The increased risk of osteoporosis in RA is thought to be attributed to a number of RA disease-specific factors, including: disease activity, physical inactivity, low BMI, medication effects (particularly corticosteroids); and traditional risk factors such as smoking, postmenopausal status and an older age [116, 118, 120].

### 2.3.10.4 Infections

Infections of the skin, soft tissues, respiratory tract, and the bones and joints (septic arthritis) are a cause of significant morbidity and mortality in RA, although little is known about the rates of infections apart from septic arthritis [75, 103, 121]. A study in 2002 of 609 people with RA designed to identify predictors of infections in people with RA reported a 70% increase in confirmed infections and 85% increase in infections requiring hospitalisation in a cohort of RA compared to non-RA [121]. Whether this is because people with RA are more predisposed to develop infections or whether infections in RA may take a more severe course is not known [122]. In that study statistically significant predictors of increased infection risk included: smoking (hazard ratio (HR) 1.4, 95% CI 1.1-1.8, p=0.008); male gender (HR 1.4, 95% CI 1.1-1.9, p=0.016); comorbid COPD (HR 2.6, 95% CI 2.0-3.4, p<0.001); and extra-articular manifestations of RA (HR 3.1, 95% 2.2-
4.4, p<0.001) [121]. As is evident from these statistics, extra-articular manifestations were the strongest predictor of infections in RA, although smoking also provides a significant risk [121].

It is possible that contemporary RA treatments might predispose individuals to infection, particularly the use of immunosuppressive drugs [75, 103, 121]. Studies of non-biologic disease-modifying anti-rheumatic drugs (DMARDs) use have shown either no increase, or a decrease in infections in people with RA but corticosteroid use (both alone or concomitantly with DMARDs) has been found to significantly increase the rate of both mild and serious infections (HR 1.9, 95% CI 1.5-2.5, p<0.001) [75, 103, 121].

### 2.3.10.5 Periodontitis

Periodontitis is more common in smokers and more common in RA. It is also related to the same genes as RA and there may be a putative mechanistic link between periodontitis and RA via protein citrullination [123]. Smoking increases oral inflammation and the prevalence of a specific bacteria *Prevotella gingivalis*, which is a leading pathogen in chronic periodontitis [124]. Periodontitis is characterised by inflammatory destruction of the periodontal attachment and alveolar bone and ultimately causes tooth loss. In addition, periodontal pathogens have direct systemic access to blood circulation, which is thought to have a modulating role in comorbid CVD in people with RA [124].
2.3.11 Medical Management of Rheumatoid Arthritis

The primary goal of drug therapy in RA is to achieve rapid and sustained disease control to prevent long-term damaging effects on joint structure, function and mortality. The medical management of RA has changed over the last 15 years where the fundamental emphasis has moved toward controlling inflammation early and completely [54]. By controlling joint inflammation, joint damage and disability can be avoided thereby leading to improved outcomes [51, 54]. With modern treatment strategies remission or at the very least, low disease activity, are obtainable. The following table describes the therapeutic drugs that are currently used in the medical management of RA (Table 2-5).

Table 2-5: Therapeutic drugs used in the management of RA (adapted from [52, 125])*

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Examples</th>
<th>Expected reduction in symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSAIDs</td>
<td>ibuprofen, diclofenac, naproxen</td>
<td>Decrease in joint pain and stiffness and to improve joint function</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No role in preventing joint damage</td>
</tr>
<tr>
<td>Glucocorticoids</td>
<td>prednisone</td>
<td>Decrease in joint pain and tenderness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Decrease bone erosion</td>
</tr>
<tr>
<td>DMARDs</td>
<td>methotrexate, hydroxychloroquine, sulfasalazine, leflunomide, gold, azathioprine, cyclosporin</td>
<td>Decrease inflammatory disease activity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Decrease bone erosion</td>
</tr>
<tr>
<td>Biological therapies</td>
<td>adalimumab, etanercept, infliximab, tocilizumab, rituximab</td>
<td>Reduce inflammation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Decrease bone erosion</td>
</tr>
</tbody>
</table>

*NSAIDs=non-steroidal anti-inflammatory drugs; DMARDs=disease-modifying anti-rheumatic drugs
Disease-modifying anti-rheumatic drugs are a group of heterogeneous agents grouped together by convention and use in RA. They typically take weeks to months to become effective. The DMARD methotrexate (MTX) has been regarded as the ‘gold standard’ treatment for RA since the 1990’s [126]. MTX is first line therapy unless there are contra-indications, principally because it has a very high response rate (85%), low cost, ease of administration, and a predictable side-effect profile [127]. When MTX does not adequately control inflammation or when an individual has MTX related adverse effects, other DMARDs are available, including sulfasalazine, leflunomide, and hydroxychloroquine [127]. DMARDs in combination have yielded proven efficacy, e.g. MTX, sulfasalazine and hydroxychloroquine (‘triple therapy’) [52]. The choice of combination is a matter of clinical judgement, but in NZ this choice is influenced to some extent by the funding restrictions from the NZ Crown agency: the Pharmaceutical Management Agency (PHARMAC) that decides which medicines and related products are subsidised for use in NZ public hospitals and in the community [128].

The availability of new biological DMARDs has significantly improved RA management [51, 54]. Biological therapies are antibodies directed at specific cytokines or cell surface molecules [127]. In NZ the anti-TNF-α agents adalimumab, etanercept, and infliximab along with the anti-interleukin 6 agent tocilizumab and anti-CD20 agent rituximab are funded for use in RA [128]. Clinical trials of these agents show they are highly effective at controlling inflammation, and preventing the progression of joint damage. Adverse effects include reactivation of latent tuberculosis and serious infections [129].

Non-steroidal anti-inflammatory drugs are still used widely in inflammatory and non-inflammatory rheumatic diseases, including RA. This group of drugs include diclofenac,
ibuprofen, and naproxen [75, 130]. NSAIDs are used principally to reduce symptoms of pain and stiffness and improve joint function [75, 130]. They have no role in the prevention of joint damage. The most important mechanism of action is inhibiting prostaglandin production; prostaglandin E₂ in particular is involved in pain signalling and the inflammatory process [75, 130]. However, the use of NSAIDs is associated with potential side effects including an increased risk of adverse CVD effects in people with RA [75, 130]. A meta-analysis has shown that all NSAIDs are associated with some degree of increased CVD risk, e.g. rofecoxib was associated with the highest risk of MI (RR 2.1, 95% CI 1.3-3.6); ibuprofen was associated with the highest risk of stroke (RR 3.4, 95% CI 1.0-11.6); and etoricoxib (RR 4.1, 95% CI 1.2-15.7) and diclofenac (RR 4.0, 95% CI 1.5-12.7) were associated with the highest risk of CVD death [131].

Glucocorticoids were first used in the management of RA over 60 years ago. Short-term use reduces joint inflammation; long-term use may reduce joint damage but is associated with significant adverse effects including an increased risk of osteoporosis, CVD and infections [52]. Consequently, they are particularly useful as bridging therapy until DMARDs take effect.

Contemporary treatment goals for RA are designed for rapid and sustained disease control; thereby avoiding long-term articular damage (joint structure and function), lessening the risks of associated RA comorbid conditions, and decreasing premature mortality. The next section explores in depth the relationships between smoking and RA, and the deleterious effects smoking has on the management of RA. Particular emphasis is given to disease outcomes that might be improved if an individual quit smoking and include disease progression, comorbidities, and RA medications.
2.4 The Burden of Smoking and Rheumatoid Arthritis

Smoking has a direct and significant impact on RA in multiple respects. Smoking is implicated in the risk of developing RA. Significantly, once acquired smoking may increase the severity and mortality rates in RA. This section is particularly relevant to this thesis because it identifies compelling reasons for smoking cessation in RA.

2.4.1 The Gene-environment Interaction and Smoking in Rheumatoid Arthritis

The association between smoking and RA meets the Bradford Hill criteria for causation [132] with regard to strength, consistency, plausibility, evidence from cohort studies, coherence, temporality, and biologic gradient of association [133]. The risk of developing ACPA-positive RA was found to be significantly higher among smokers with two copies of the HLA-DR SE (RR 21.0, 95% CI 11.0-40.2) compared to those with one or no copies of the SE (RR 1.5, 95% CI 0.8-2.6) [134]. The amount of smoking is also associated with the risk of developing RA (Figure 2-2). An ACPA-positive individual with a 20 pack year smoking history and 2 copies of the SE has a 38 times higher risk of developing RA (OR 37.6, 95% CI 18.3-77.4, p<0.0001) as compared to an ACPA-positive smoker with a 20 year pack-year smoking history but no SE alleles (OR 1.9, 95% CI 1.1-3.5, p=0.11) [7]. The overall risk of developing RA while smoking is dose-related, stronger for carriers of the SE (significantly two copies of the SE), and selectively associated with the risk of ACPA-positive RA [36, 135, 136]. Overall, smoking is thought to contribute up to 25% of population risk of developing RA [135] and over 50% of RA cases can be attributed to smoking in individuals who carry two copies of the HLA-DRB1 SE genes [7].
Since smoking predisposes to ACPA-positive RA, a higher proportion of people with RA are smokers. Recent studies have reported 21-35% of individuals with RA are current smokers and between 50-69% are past or current smokers [137-140]. There is no evidence to suggest that male or female people with RA either take up or quit smoking differently when they develop RA [133]. Thus, a key issue for people who have already developed RA is whether smoking alters the course of the disease or its response to treatments. The following section focuses on the impact of smoking on established RA and considers the effects of smoking on disease activity and severity in RA, the major comorbidities of RA, and the front-line RA treatments.

*Figure 2-2*: Odds ratios for different amount of smoking in combination with different copies of SE alleles (adapted from [7])
2.4.2 Impact of Smoking on Radiological Progression and Disease Activity on Rheumatoid Arthritis

It remains unclear what specific effects smoking has on the severity and disease activity in RA, although there has been extensive research undertaken to ascertain this over the last 20 years. Some studies suggest current smoking increases radiographic damage and/or disease activity, whilst others have reported that current smoking could have a protective effect due to the anti-inflammatory properties of nicotine (Table 2-6) [141]. These conflicting data have several explanations including methodological issues such as small sample sizes and short follow-up periods; differences in RA populations; and different measurements of smoking [142]. Importantly, in studies with small sample sizes or studies in early RA, the effect of smoking may be difficult to ascertain, particularly if there are few heavy smokers in the sample or the follow-up period is limited [142]. However, components of smoke have been shown to effect have pro-inflammatory effects in the synovium, which can reverse with smoking cessation [143].
<table>
<thead>
<tr>
<th>Author, year and country</th>
<th>Study method and objectives</th>
<th>Number of patients</th>
<th>Outcome measure</th>
<th>Study findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Saag et al</strong> <em>(1997), USA [144]</em>)</td>
<td>Observational study to determine if smoking is associated with RA severity. Followed for 18 months.</td>
<td>336</td>
<td>Disease severity (radiographs)</td>
<td>Smokers with a &gt;25 pack-year history were 2.4 times more likely to show radiographic erosions (p=0.02). Smoking may adversely influence the severity of RA in a dose-dependent manner</td>
</tr>
<tr>
<td><strong>Wolfe</strong> <em>(2000), USA [145]</em>)</td>
<td>Cross-sectional study to determine: 1) The degree to which RF+ associated with smoking.  2) The quantitative effect of smoking on RF.  3) If the effect of smoking on male and female is similar.  4) Effect of smoking on disease status, severity and activity.</td>
<td>640</td>
<td>Disease severity (radiographs)  Disease activity (swollen joint count)</td>
<td>A dose dependent relationship found between smoking and radiographic progression after 20 years of smoking (p=0.05)  No relationship between smoking and disease activity (p=0.70)</td>
</tr>
<tr>
<td><strong>Masdottir et al</strong> <em>(2000), Iceland [146]</em>)</td>
<td>Cross-sectional study to examine the effect on smoking on the severity of RA.</td>
<td>63 female</td>
<td>Disease severity (radiographs)  Disease activity (swollen joint count)</td>
<td>Smoking had an adverse effect on radiological progression in RA. Correlation between heavy smoking (≥20 pack-years) and more radiological joint damage (p=0.02). No association with disease activity (p&gt;0.05).</td>
</tr>
<tr>
<td><strong>Author, year and country</strong></td>
<td><strong>Study method and objectives</strong></td>
<td><strong>Number of patients</strong></td>
<td><strong>Outcome measure</strong></td>
<td><strong>Study findings</strong></td>
</tr>
<tr>
<td>----------------------------</td>
<td>--------------------------------</td>
<td>------------------------</td>
<td>--------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td><strong>Harrison et al</strong> (2001), UK [147]</td>
<td>Longitudinal study to examine the influence of smoking on disease outcome at 3 years with newly presenting RA patients. Followed for 3 years.</td>
<td>323</td>
<td>Disease severity (radiographs) Disease activity (swollen joint count)</td>
<td>Smokers did not have higher levels of radiologic damage (p=0.65). Smokers had fewer swollen joints (p=0.11). Smoking may limit joint inflammation and damage.</td>
</tr>
<tr>
<td><strong>Mattey et al</strong> (2002), UK [148]</td>
<td>Cross-sectional study to determine whether the relationship between smoking and disease severity in female RA patients is associated with polymorphism at the glutathione S-transferase M1 locus.</td>
<td>164 female</td>
<td>Disease severity (radiographs and HAQ)</td>
<td>Ever having smoked was associated with a worse radiographic progression (p=0.05) and HAQ (p=0.02) than never smokers.</td>
</tr>
<tr>
<td><strong>Manfredsdottir et al</strong> (2006), Iceland [141]</td>
<td>Prospective observational study to examine the effect of tobacco smoking and RF isotypes on disease activity and joint damage in early RA. 2 year follow-up.</td>
<td>100</td>
<td>Disease severity (radiographs) Disease activity (swollen and tender joint counts)</td>
<td>Smoking status did not influence radiological progression (p=0.08). A gradient increase in disease activity (swollen and tender joint counts) observed from never smokers (p&lt;0.001) to ex-smokers (p=0.02) to current smokers (p=0.005).</td>
</tr>
<tr>
<td>Author, year and country</td>
<td>Study method and objectives</td>
<td>Number of patients</td>
<td>Outcome measure</td>
<td>Study findings</td>
</tr>
<tr>
<td>---------------------------</td>
<td>----------------------------</td>
<td>--------------------</td>
<td>----------------</td>
<td>----------------</td>
</tr>
<tr>
<td><strong>Finckh et al</strong> (2007), Switzerland [149]</td>
<td>Longitudinal observational study to compare the rates of radiographic damage progression in current smokers and non-smokers in a large prospective RA cohort. 3 years follow-up.</td>
<td>2004</td>
<td>Disease severity (radiographs)</td>
<td>Reduced radiographic progression among heavy smokers who smoked &gt;1 pack/day (p&lt;0.001), thus smoking does not accelerate RA disease progression.</td>
</tr>
<tr>
<td><strong>Westhoff et al</strong> (2008), Germany [150]</td>
<td>Prospective observational study to investigate the influence of smoking on disease activity, and radiographic joint damage in RF+ and RF-negative patients with early RA. 3 year follow-up.</td>
<td>896 early</td>
<td>Disease severity (radiographs)  Disease activity (swollen joint count)</td>
<td>Smoking did not affect radiological progression.  Smoking did not affect swollen joint count in either RF+ (p=0.17) or RF- patients (p=0.32).</td>
</tr>
<tr>
<td><strong>Mikuls et al</strong> (2008), USA [151]</td>
<td>Observational study to examine the association of smoking with clinical and serological features in African Americans with recent-onset RA.</td>
<td>300</td>
<td>Disease severity (radiographs)</td>
<td>Dose-dependent smoking was associated with rheumatoid nodules, but not with radiographic erosions among African Americans with recent-onset RA (OR 1.4, 95% CI 0.6-3.4).</td>
</tr>
<tr>
<td><strong>Ruiz-Esquide et al</strong> (2011), Spain [142]</td>
<td>Prospective open-label study to analyse the effects of cigarette smoking on disease activity and radiographic damage in early RA. 2 year follow-up.</td>
<td>156</td>
<td>Disease severity (radiographs)  Disease activity (DAS28)</td>
<td>Smoking was an independent factor for radiographic progression in early RA (p=0.03).  Disease activity similar in smokers and non-smokers (p=0.36).</td>
</tr>
<tr>
<td>Author, year and country</td>
<td>Study method and objectives</td>
<td>Number of patients</td>
<td>Outcome measure</td>
<td>Study findings</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Soderlin et al (2011), Sweden [152]</strong></td>
<td>Observational study to assess the effects of smoking on disease outcome in a large cohort of patients with early RA. 8 year follow-up.</td>
<td>1787</td>
<td>Disease activity (DAS28)</td>
<td>Current smokers had less improvement in DAS28 from baseline to 12 months (p=0.0001) compared to never or previous smokers but no difference in HAQ.</td>
</tr>
<tr>
<td><strong>Rojas-Serrano et al (2011), Mexico [153]</strong></td>
<td>Longitudinal study to determine factors associated with a failure to achieve ACR 50 response. 6 months follow-up in early RA.</td>
<td>144</td>
<td>Clinical response (ACR 50 non-responders and responders)</td>
<td>Smokers with RA appeared to have a worse prognosis in terms of achieving ACR 50 response (OR 3.6, 95% CI 1.2–11.2, p&lt;0.01).</td>
</tr>
<tr>
<td><strong>Vesperini et al (2013), France [154]</strong></td>
<td>Prospective observational study to investigate the initial response to treatment and risk of radiographic progression in current smokers and to analyse the influence of smoking cessation on outcomes in early RA. 3 year follow-up.</td>
<td>641</td>
<td>Disease severity (radiographs)</td>
<td>Smoking reduced the 1-year radiographic progression (OR 0.5, 95% CI 0.3-0.9 p=0.03). Smoking status had no influence on DAS28 in the first 12 months of follow-up (p&gt;0.05).</td>
</tr>
<tr>
<td><strong>Saevarsdottir et al (2014), Sweden [139]</strong></td>
<td>Observational study to study clinical predictors for radiographic progression after 1 year in an early RA trial. 1 year follow-up.</td>
<td>311</td>
<td>Disease severity (radiographs)</td>
<td>Current smoking status was a strong predictor of rapid radiographic progression in early RA (OR 2.2, 95% CI 1.1-4.5) compared to non-smokers.</td>
</tr>
<tr>
<td><strong>de Rooy et al (2014), [140]</strong></td>
<td>Observational study of 6 cohorts to determine the effect of smoking on joint damage progression. Followed 3-15 years.</td>
<td>3,158</td>
<td>Disease severity (radiographs)</td>
<td>Smoking was associated with more radiologic progression (p=0.01) but the effect was mediated through ACPA.</td>
</tr>
</tbody>
</table>

*HAQ= Health Assessment Questionnaire; ACPA=anti-cyclic citrullinated peptide antibody; RF+=rheumatoid factor positive; IP= inflammatory polyarthritis; OR=odds ratio; CI=confidence interval; DAS28=disease activity score 28 joint counts*
2.4.3 Impact of Smoking on Comorbidities and Extra-articular Manifestations on Rheumatoid Arthritis

As described previously in this chapter, people with RA have a higher prevalence of the comorbid diseases CVD, COPD and osteoporosis than the general population and smoking is a significant additional risk factor for these comorbidities. Smoking has also been identified as the main predictor of severe extra-articular manifestations in RA [101]. Table 2-7 summarises the effects of smoking on comorbid conditions and extra-articular manifestations in RA. Because smoking is a shared risk-factor for RA and many of its comorbidities, people with RA consequently suffer the morbidity of a cumulative disease burden as well as excess mortality [155]. The relationships between smoking and RA comorbid diseases are complex and are thought to involve interactions between smoking, ACPA and the SE [155].

The risk of premature death from CVD in RA and the connections between CVD and smoking is an important consideration in the management of RA. Both smoking and RA cause inflammation, which is known to increase traditional CVD risk factors but it is difficult to untangle the independence or dependence of smoking as a CVD risk factor in RA [155] as demonstrated by the research in Table 2-7.
Table 2-7: Effects of smoking on comorbid conditions in RA*

<table>
<thead>
<tr>
<th>Author, year and country</th>
<th>Study method and objectives</th>
<th>Number of patients</th>
<th>Study findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiovascular disease, smoking and RA</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Solomon et al (2004), USA [47]</strong></td>
<td>Observational study to examine the distribution of known CVD risk factors and biomarkers of CVD in RA in the Nurses’ Health Study.</td>
<td>287 RA women, 87,019 non-RA women</td>
<td>Women with RA were more likely to be past-smokers (47% versus 38%) p&lt;0.001. No other CVD risk factors differed between RA and non-RA.</td>
</tr>
<tr>
<td><strong>Chung et al (2005), USA [156]</strong></td>
<td>Observational study to compare the prevalence and severity of coronary artery atherosclerosis in early and established RA and non-RA.</td>
<td>70 early RA, 71 RA, 86 non-RA</td>
<td>More severe coronary artery calcification in established RA (OR 3.4, 95% CI 1.4-5.5, p=0.002) after adjusting for CVD risk factors. Prevalence and severity of coronary calcification increased in established RA and related to pack-years of smoking (OR 1.02, 95% CI 1.00-1.04, p=0.04) and increased ESR (OR 1.02, 95% CI 1.00-1.04, p=0.05).</td>
</tr>
<tr>
<td><strong>Naranjo et al (2008), Europe [107]</strong></td>
<td>Observational study to determine the prevalence of CVD morbidity in a large international sample of RA patients, its association with traditional CVD risk factors, clinical features of RA, and with the use of DMARDs.</td>
<td>4,363</td>
<td>Ever-smoking was an independent risk factor for CVD morbidity (HR 1.6, 95% CI 1.2-2.1, p&lt;0.001)</td>
</tr>
<tr>
<td><strong>Farragher et al (2008), UK [157]</strong></td>
<td>Prospective study to examine the role of the variants of the PTPN22 and HLA–DRB1 genes as predictors of mortality in IP and RA.</td>
<td>1,022 IP including 751 RA</td>
<td>An interaction of smoking, SE alleles, and anti-CCP antibodies was observed and was associated with the greatest risk of death from CVD in RA (HR 7.8, 95% CI 2.6–23.2).</td>
</tr>
<tr>
<td>Author, year and country</td>
<td>Study method and objectives</td>
<td>Number of patients</td>
<td>Study findings</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------------------</td>
<td>--------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Gabriel et al (2010), USA [56]</td>
<td>Retrospective cohort study to investigate the increased risk of CVD morbidity and mortality from traditional and RA specific factors. Follow-up between 14-16 years.</td>
<td>822 RA 603 non-RA</td>
<td>Cigarette smoking significantly more prevalent in RA patients (p&lt;0.001). Other traditional CVD risk factors did not differ between RA and non-RA patients.</td>
</tr>
<tr>
<td>Innala et al (2011), Sweden [112]</td>
<td>Five year prospective study to investigate: 1) the presence of traditional and RA-related risk factors for CVD at the onset of RA and during the first five years following diagnosis 2) Evaluated the potential for predicting CVD during the five-year follow-up period and the modulatory effect of pharmacological treatment.</td>
<td>442</td>
<td>Smoking not statistically significant independent predictor for CV event (MI, CABG, TIA, DVT, PE and/or ruptured aortic aneurysm) in this cohort. Smoking is an independent risk factor for CVD in the general population. Smoking has a relatively small contribution to the overall CVD risk in patients with chronic inflammation. CV events were decreased by DMARD treatment.</td>
</tr>
</tbody>
</table>

**Chronic obstructive pulmonary disease, smoking and RA**

<p>| Wolfe (2000), USA [145] | Cross-sectional study to determine: 1) The degree to which RF+ associated with smoking. 2) The quantitative effect of smoking on RF. 3) If the effect of smoking is same for male and female. 4) Effect of smoking on disease status, severity and activity. | 640 | A linear quantitative relationship found between number of years of smoking and pulmonary disease (defined as patient reported pneumonia or lung problem) in RA (OR 4.55, 95% CI 2.25-9.20 p=&lt;0.001) |</p>
<table>
<thead>
<tr>
<th><strong>Author, year and country</strong></th>
<th><strong>Study method and objectives</strong></th>
<th><strong>Number of patients</strong></th>
<th><strong>Study findings</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bieber et al (2013), Israel [113]</strong></td>
<td>Cross-sectional population-based case controlled study to assess the association between smoking, RA and COPD.</td>
<td>9,039 RA 15,070 non-RA</td>
<td>The proportion of individuals with COPD significantly higher in RA than non-RA subjects (8.6 versus 4.4%, p&lt;0.0001). RA significantly associated with COPD (OR1.98, 95% CI 1.77-2.21, p&lt;0.0001). Smoking more common in RA patients (29% vs 24%, p&lt;0.001, OR 1.27, 95% CI 1.20-1.35).</td>
</tr>
<tr>
<td><strong>Nannini et al (2013), USA [158]</strong></td>
<td>Population-based incident cohort of RA and non-RA subjects to assess the incidence, risk factors, and mortality of COPD in RA</td>
<td>594 RA and 596 non-RA</td>
<td>COPD more prevalent in RA patients who smoke (HR 4.4, 95% CI 2.1-9.0). Higher risk of developing COPD and higher risk of premature mortality from COPD in RA.</td>
</tr>
<tr>
<td><strong>Cooper et al (1995), UK [159]</strong></td>
<td>Case-controlled study to identify the risk of hip fracture in RA patients and those taking corticosteroids.</td>
<td>300 RA 600 Non-RA</td>
<td>Hip fracture risk in all ever-smokers was increased compared to never-smokers (OR 1.7, 95% CI 1.2-2.3). Hip fracture risk in ever-smoking RA patients was increased with corticosteroid use (OR 2.5, 95% CI 1.1-5.9, p=0.04) but similar to RA never-smokers who also had an increased risk (OR 2.7, 95% CI 1.2-5.8, p=0.01).</td>
</tr>
<tr>
<td>Author, year and country</td>
<td>Study method and objectives</td>
<td>Number of patients</td>
<td>Study findings</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----------------------------</td>
<td>--------------------</td>
<td>---------------</td>
</tr>
<tr>
<td><strong>Extra-articular manifestations, smoking and RA</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turesson et al (2003), Sweden [101]</td>
<td>Observational study to investigate the incidence of extra-articular manifestations of RA and to examine possible predictors; Followed for mean 11.8 years</td>
<td>609 RA</td>
<td>Extra-articular RA occurred in 41% of patients and 13% had severe extra-articular disease. Main predictors were smoking at diagnosis of RA (RR 2.9, 95% CI 1.7-5.1) and early disability (RR 2.5, 95% CI 1.5-4.0).</td>
</tr>
<tr>
<td>Nyhall-Wahlin et al (2006), Sweden [160]</td>
<td>Nested case-control study to examine whether smoking is a risk factor for RA nodules in early RA and to quantify any effect. Follow-up for mean 91 months</td>
<td>112 RA and 224 non-RA</td>
<td>Ever smoking associated with RA nodules in RF+ (OR 7.3, 95% CI 2.3-23.6, p=0.001). No obvious dose-dependency of smoking.</td>
</tr>
<tr>
<td>Nyhall-Wahlin et al (2009) Sweden [138]</td>
<td>Nested case-control study to identify patients with severe extra-articular manifestations in early RA and to investigate potential risk factors. Follow-up for mean of 91 months</td>
<td>40 RA and 120 non-RA</td>
<td>Smoking (p=0.02) and RF (p&lt;0.001) predicted the development of severe extra-articular RA.</td>
</tr>
</tbody>
</table>

*HR=hazard ratio; RR=relative risk; OR=odds ratio; CI=confidence interval; AS=Ankylosing Spondylitis; PsA=Psoriatic Arthritis; IP=inflammatory polyarthritis; COPD=chronic obstructive lung disease; ESR=erythrocyte sedimentation rate; MI=myocardial infarction; CABG=coronary artery bypass grafting; TIA=transient ischaemic attack; DVT=deep vein thrombosis; PE=pulmonary embolism
2.4.4 Impact of Smoking on Medications to treat Rheumatoid Arthritis

Optimising the suppression of RA disease activity using biologic and non-biologic DMARDs is viewed as key to disease management, and these therapies may be more effective if people with RA stop smoking [155]. Individuals with early RA who are current smokers are less likely to have a good response to MTX or TNF inhibitors than those who never smoked or those who smoked in the past [161]. Smoking may thus impact adversely on disease control by reducing the effects of medications used to treat RA. The use of the DMARDs (particularly MTX) or anti-TNF therapy enables inflammation to be controlled in RA and may therefore effectively reduce CVD events [162, 163]. This may be due either to smoking weakening the effects of medications increasing the risk of drug related adverse effects, or a higher medication requirement reflecting higher disease activity in smokers. The following Table 2-8 summarises the deleterious effects of smoking on therapies for RA:
Table 2-8: Effects of smoking on treatments in RA*

<table>
<thead>
<tr>
<th>Author, year and country</th>
<th>Study method and objectives</th>
<th>Number of patients</th>
<th>Outcome measurement</th>
<th>Findings of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alarcon et al (1997), USA [164]</td>
<td>Case-control study to identify risk factors for MTX induced lung injury in RA.</td>
<td>29 RA 29 non-RA</td>
<td>Lung injury modified criteria of Searles and McKendry [165]</td>
<td>MTX was associated with a risk of drug-induced pneumonitis and smoking increased this risk (OR 2.9, 95% CI 1.0-8.5).</td>
</tr>
<tr>
<td>Hyrich et al (2006), UK [166]</td>
<td>Cross-sectional study to predict which RA patients will respond to TNF-α therapies; 6 months follow-up.</td>
<td>2,879</td>
<td>DAS28</td>
<td>Lower response rate among RA current smokers receiving infliximab (OR 0.8, 95% CI 0.6-1.0). No association between smoking and outcome seen in RA patients receiving etanercept (OR 1.1, 95% CI 0.8-1.4).</td>
</tr>
<tr>
<td>Naranjo et al (2008), Europe [107]</td>
<td>Observational study to determine the prevalence of CVD morbidity in a large international sample of RA patients, its association with traditional CVD risk factors, clinical features of RA, and with the use of DMARDs.</td>
<td>4,363</td>
<td>CVD morbidity (MI, angina, coronary disease, coronary bypass and stroke)</td>
<td>Prolonged use of treatments reduces the risk of CVD morbidity in RA p &lt; 0.05: MTX (HR 0.82, 95% CI 0.79-0.86) leflunomide (HR 0.52, 95% CI 0.38-0.72) sulfasalazine (HR 0.92; 95% CI 0.87 to 0.98) glucocorticoids (HR 0.95; 95% CI 0.92 to 0.98) biologic agents (HR 0.42; 95% CI 0.21 to 0.81)</td>
</tr>
<tr>
<td>Author, year and country</td>
<td>Study method and objectives</td>
<td>Number of patients</td>
<td>Outcome measurement</td>
<td>Findings of study</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------------------</td>
<td>--------------------</td>
<td>---------------------</td>
<td>------------------</td>
</tr>
<tr>
<td><strong>Westhoff et al (2008), Germany [150]</strong></td>
<td>Prospective observational study to investigate the influence of smoking on disease activity, drug need and radiographic joint damage in RF+ and RF- early RA. 3 year follow-up.</td>
<td>896</td>
<td>Drug therapy use</td>
<td>At 3 years, the % of patients having a DMARD combination or ever having had biologics was higher in RF+ current smokers (35.8%) compared to RF+ never-smokers (20.3%) p=0.02. The higher use of DMARDs may indicate smoking weakens the potency of these drugs.</td>
</tr>
<tr>
<td><strong>Mattey et al (2009), UK [167]</strong></td>
<td>Observational study to determine whether there is a quantitative relationship between smoking history and response to therapy with TNF antagonists in RA. Follow-up 1 year.</td>
<td>154</td>
<td>DAS28</td>
<td>RA patients with a history of smoking more likely to show a poor response to TNF inhibitors at 3 months and 12 months (p=0.008 and 0.003, respectively). Response failure to TNF antagonists associated with intensity of previous smoking (pack years), irrespective of smoking status at initiation of anti-TNF therapy.</td>
</tr>
<tr>
<td><strong>van der Woude et al (2009), The Netherlands [168]</strong></td>
<td>Observational study to determine the prevalence of and predictive factors for DMARD-free sustained remission from 2 RA cohorts. Follow-up at 1 year.</td>
<td>1,349</td>
<td>Drug free remission defined as: 1) no current DMARD use, 2) no swollen joints 3) Classification as DMARD-free remission by the patient’s rheumatologist.</td>
<td>RA smokers were less likely to achieve sustained drug-free remission compared to RA non-smokers (HR 0.6, 95% CI 0.3-1.0 p=0.028).</td>
</tr>
<tr>
<td>Author, year and country</td>
<td>Study method and objectives</td>
<td>Number of patients</td>
<td>Outcome measurement</td>
<td>Findings of study</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------------------</td>
<td>--------------------</td>
<td>---------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td><strong>Stamp et al (2009), NZ [169]</strong></td>
<td>Observational study to determine non-genetic factors that influence red blood cell MTX concentrations in RA.</td>
<td>192</td>
<td>Methotrexate concentrations</td>
<td>Smoking was associated with lower red blood cell concentrations of MTX ($r=0.5$, $p=0.015$).</td>
</tr>
<tr>
<td><strong>Abhishek et al (2010), UK [170]</strong></td>
<td>Observational study to assess if smoking status when commencing anti-TNF-α treatment for RA reduces EULAR response criteria at 3-month assessment.</td>
<td>395</td>
<td>EULAR response criteria (DAS28)</td>
<td>Current smoking at commencement of anti-TNF treatment reduced likelihood of achieving a moderate response when compared with non-smokers (OR 0.2, 95% CI 0.05-0.8).</td>
</tr>
<tr>
<td><strong>Rojas-Serrano et al (2011), Mexico [153]</strong></td>
<td>Observational study to determine factors associated with failure to achieve ACR 50 response at 6 months in early RA.</td>
<td>144</td>
<td>ACR50 response</td>
<td>Smokers with RA appeared to have a worse prognosis in terms of DMARD response. The only factor associated with failure to achieve ACR 50 was current smoking (OR 3.6, 95% CI 1.2–11.2, $p&lt;0.008$).</td>
</tr>
<tr>
<td><strong>Ruiz-Esquide et al (2011), Spain [142]</strong></td>
<td>Prospective open-label study to analyse the effects of cigarette smoking on disease activity and radiographic damage in early RA after the introduction of DMARDs; 2 year follow-up</td>
<td>156 early RA</td>
<td>DAS28</td>
<td>DMARD response similar in smokers and non-smokers thus not affected by smoking in early RA ($p=0.46$).</td>
</tr>
<tr>
<td>Author, year and country</td>
<td>Study method and objectives</td>
<td>Number of patients</td>
<td>Outcome measurement</td>
<td>Findings of study</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------------</td>
<td>--------------------</td>
<td>---------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Saevarsdottir et al (2011), Swedish [161]</td>
<td>Cross-sectional study to determine if cigarette smoking influences response to treatment in early RA.</td>
<td>1,430 early RA</td>
<td>EULAR response criteria (DAS28)</td>
<td>Compared with never-smokers, current smokers were less likely to achieve a good response at 3 months following the start of MTX (27% versus 36%; p=0.05) and at 3 months following the start of TNF inhibitors (29% versus 43%; p=0.03).</td>
</tr>
<tr>
<td>Soderlin et al (2012), Sweden [171]</td>
<td>Observational study to examine the effect of response and drug survival in RA patients treated with their first anti-TNF drug. Follow-up at 3, 6 and 12 months.</td>
<td>934 RA</td>
<td>EULAR response criteria (DAS28)</td>
<td>Current smoking was predictive of poor response to anti-TNF treatment at 3 months (OR 0.6, 95% CI 0.4–0.9) and heavy smokers had the poorest drug survival (OR 0.6, 0.3-1.2).</td>
</tr>
<tr>
<td>Vesperini et al (2013), Italy [154]</td>
<td>A prospective early arthritis cohort study to investigate: 1) the initial response to treatment and risk of radiographic disease progression in current smokers, ex-smokers, and non-smokers 2) The influence of smoking cessation on arthritis outcome. Follow-up for 6 months.</td>
<td>641 RA</td>
<td>EULAR response criteria (DAS28)</td>
<td>Smoking status had no influence on use of either DMARDs or biologic therapy in the first 12 months of follow-up (P&gt;0.05).</td>
</tr>
</tbody>
</table>

*HR=hazard ratio; OR=odds ratio; CI=confidence interval; r=coefficient of correlation; MTX=methotrexate; TNF-α=tumour necrosis factor-alpha; DMARD=disease modifying antirheumatic drugs; DAS=Disease Activity Score; MI=myocardial infarction; EULAR=European League Against Rheumatism; DAS28=disease activity score 28 joints;
2.5 Smoking Cessation

“Giving up smoking is the easiest thing in the world. I know because I’ve done it thousands of times” Mark Twain (1835-1910)

Changing entrenched smoking habits is difficult for smokers, and most smokers attempt to quit many times before succeeding. Surveys in the USA have consistently reported 70% of smokers want to quit; nearly half of these will have attempted during the previous year but only four to seven percent are successful [172]. Recent trends in the UK have shown that although fewer smokers are attempting to quit smoking each year (43% in 2007 down to 34% in 2011/12), more smokers are making successful quitting attempts [173].

The following section begins with an examination of the benefits and difficulties of smoking cessation. Smoking cessation is a key health goal of the NZ Government and this goal is described. Internationally recognised best-practice smoking cessation programme components are then briefly identified as this topic will be examined in specific detail in Chapter 5 (The Development of a Tailored Smoking Cessation Intervention for People with RA). The following section on smoking cessation is particularly relevant to this thesis because the review provided the structural design that would be utilised for the design of a pilot randomised controlled trial (RCT) tailored smoking cessation intervention for people with RA.
2.5.1 Benefits and Difficulties of Smoking Cessation

Smoking cessation is beneficial to all smokers regardless of their age or the number of cigarettes smoked. The immediate benefits include increased oxygen and decreased carbon monoxide levels in the blood, and nicotine is almost completely removed from the body within 24 hours [174, 175]. In the longer term, there is a reduction in risk of developing heart disease and some cancers [174, 175]. Even smokers who already have smoking-related diseases can expect to gain health benefits and increase life expectancy with smoking cessation [176].

A gain in life expectancy following smoking cessation has been demonstrated in a cohort study of 34,439 resident male British doctors born between 1900 and 1930 and followed over a 50 year period [177]. Information about their smoking habits was first obtained in 1951 and then collected periodically, with cause-specific mortality monitored for the following 50 years. Up to two-thirds of lifelong smokers died from a smoking-related illness and half of these deaths occurred prematurely [177]. Cessation at age 30, 40, 50, or 60 years gained respectively, an average of 10, 9, 6, or 3 years of life expectancy [177]. The authors predicted that cessation by age 50 years halves the risk of death associated with continued smoking and cessation by age 30 years avoided almost all risks [177]. Figure 2-3 shows the survival from age 35 years for continuing cigarette smokers, ex-smokers and lifelong non-smokers among British male doctors born 1900-1930, with each decade showing percentages alive. This figure demonstrates that almost 10 years of life years may be lost due to smoking in middle age (between 70 to 80 years) when comparing smokers to non-smokers:
Figure 2-3: Mortality by percentage survival from aged 35 years for smokers, ex-smokers, and non-smokers
(Adapted from [177])

Whilst there are many benefits with smoking cessation, there are short-term negative effects which may make cessation more difficult. Stopping smoking leads to immediate nicotine withdrawal symptoms, including headaches, fatigue, restlessness, anxiety, irritability, sleep disturbance, mood swings, sweating, dizziness, increased appetite, nausea, stomach cramps, and a craving for more tobacco [178]. These symptoms are most noticeable for the first few weeks after quitting [178]. The first two weeks have been found to be the most critical time in determining quitting failure rates [179]. In the short-term, smokers may find nicotine withdrawal symptoms worse for their well-being than any immediate or long-term benefits from quitting (Table 2-9). The benefits of decreasing the risk of death from CVD by quitting smoking are particularly salient to people with RA.
**Table 2-9: Outcomes from smoking cessation**  
(adapted from [30, 180, 181])

<table>
<thead>
<tr>
<th>Time</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 min</td>
<td>After 20 minutes the heart rate starts to drop (from the cigarette-induced spike)</td>
</tr>
<tr>
<td>2 hours</td>
<td>The heart rate and blood pressure will have decreased to normal levels. Nicotine withdrawal symptoms usually start</td>
</tr>
</tbody>
</table>
| 8 hours     | Nicotine starts to leave the body (nicotine levels will accumulate with continued smoking throughout the day and therefore will persist for 6 to 8 hours after cessation)  
The level of oxygen in blood will start to increase |
| 12 hours    | There will be almost no nicotine remaining in the body                                                                                    |
| 24 hours    | The level of carbon monoxide in blood will have dropped to normal
Risk for developing CVD or having an immediate heart attack has begun to diminish                                           |
| 2 days      | Sense of taste and smell will improve as nerve endings start to regrow                                                                      |
| 3 days      | Nicotine is completely out of body, therefore withdrawal symptoms will be at their peak                                                   |
| 2-3 weeks   | Nicotine withdrawal symptoms will have dissipated                                                                                         |
| 1-9 months  | The immune system begins to show signs of recovery
There will be less shortness of breath and able to exercise more easily
Blood circulation will improve and blood will flow more easily to hands and feet
The cilia in the lungs will have recovered to efficiently clean the lungs and airways |
| 1 year      | The risk of dying from CVD will be half that compared to when smoking                                                                      |
| 5 years     | The risk of cancer of the mouth, throat and oesophagus will be half that of a continuing smoker                                           |
| 10 years    | The risk of lung cancer will be less than half of a continuing smoker.                                                                     |
| 15 years    | The risk of dying from any cause will be almost the same as that of a person who has never smoked The risk of CVD is back to that of a non-smoker |
2.5.2 Smoking Cessation in New Zealand

2.5.2.1 Key Health Goals: Smoking Cessation in New Zealand

Smoking cessation is a key goal of the NZ Health Strategy [2], which was first published in 2000 and sets the platform for the Government’s action on health [182]. Progress on implementing the strategy is assessed annually. In NZ, tobacco control includes a large number of policy, service development and operational activities. The principal aims of these policies and activities are to reduce the uptake of smoking, increase quit rates, and reduce second-hand smoke exposure. Examples of public policies in NZ include the removal of product labelling, consistent price increases and targeted cessation programmes for prioritised population groups [183]. NZ was the first country to set a government tobacco control endgame goal: ‘Smokefree 2025’ (adopted in 2011), which has the principal goal of making NZ a smoke-free nation by the year 2025 [184].

In 2009, the NZ Ministry of Health’s (MOH) target ‘better help for smokers to quit’ was introduced to ensure all smokers are offered advice and support to quit smoking when they have contact with a health professional [185]. This target is part of the national performance measures designed to improve the performance of health services and provide a focus for action [186]. It was also designed as a prompt for NZ health professionals to routinely ask about the smoking status as a clinical ‘vital sign’, then provide brief advice and offer support for current smokers who want to quit [187, 188]. This policy is significant because there is strong evidence that brief advice is effective at prompting quit attempts and long-term quit successes [187]. The addition of effective cessation therapies further improves quit rates, including NRT gum, lozenges and transdermal patches; medications such as bupropion and varenicline; and behavioural counselling including telephone, internet, or
face-to-face support [17]. These therapies are examined in detail in Chapter 5 because they provide the pharmacological and behavioural components of best practice smoking cessation programmes which were utilised in this thesis.

In 2012/13 the ‘target’ was to ensure 95% of hospitalised smokers and 90% of patients who smoke and are seen by a health professional in primary care are provided with advice and help to quit [187]. International research has shown that having a screening system in place to identify the smoking status of patients can lead to a doubling of smoking abstinence rates, from 3.1% (no screening) to 6.4% (with screening) [189]. Meeting the target for hospitalised patients in the 20 District Health Boards (DHBs) in NZ has been progressing steadily since quarter one of 2009/10 when 18% of inpatients were given smoking cessation advice nationwide, to 96% in quarter four of 2012/13 [190]. The target for primary care patients to receive smoking cessation advice is more variable with only one of the 20 DHBs attaining the 90% goal, and an overall NZ DHB mean result of 65% (range 35 to 96%) during quarter four in 2012/13 [191].

It is important to note that there are currently no similar guidelines or specific health targets for patients seen in the outpatient setting. The absence of guidelines or specific health targets for outpatients is a significant issue, as the majority of patients with chronic diseases such as RA are only seen as outpatients; therefore they will not be captured by general smoking cessation initiatives within the hospital setting. This equates to a missed opportunity given the primary care sector has not yet reached their 90% goal of providing smoking cessation advice. International research on outpatient smoking rates has been limited, identifying a lack of progress in this area. A study in 1997 reported physicians knew the smoking status of their patients in 67% of outpatient visits, although in most specialities
(with the exception of cardiology and tobacco-related visits) the smoking cessation advice given to outpatients was negligible [192]. Therefore, although most outpatients who were smoking were identified, the vast majority did not receive any smoking cessation advice. In a similar but more recent study, outpatient visits were followed over a 10 year period between 1994 and 2003. Although only a minimal increase in the identification of smokers was found (68% in 2003 compared to 67% in 1994), only 20% of patients were subsequently counselled with less than 2% of those patients using any smoking cessation medication [193].

### 2.5.2.2 New Zealand Smoking Cessation Guidelines

In 2007, the NZ Smoking Cessation Guidelines were published and structured around the newly adopted ‘ABC pathway for Smoking Cessation’ (Appendix 8). The ‘ABC pathway’ was developed by the NZ MOH and was designed to make the health sector’s approach to smoking cessation more systematic for all healthcare workers who have contact with smokers [188]. The main goal was to provide a system where all smokers are surrounded by a culture of support for quitting thereby generating more supported quit attempts [188]. These guidelines were based on evidence of best practice in smoking cessation [194] and were updated in 2014 [195]. Recommendations from these guidelines outline evidence-based interventions for smoking cessation in the NZ general population, plus the following targeted priority population groups: young people, pregnant women, Māori and Pacific peoples, the hospital and preoperative environment, and those who use addiction and mental health services [196]. However, this means there are many long-term health conditions including RA that are not currently being targeted for assistance, thereby identifying a gap in smoking cessation priorities.
The NZ smoking cessation guidelines include the following key messages for healthcare providers [194]:

1) Give brief advice to stop smoking to all people who smoke, regardless of whether they say they are ready to stop smoking or not
2) Provide evidence-based cessation support for people who express a desire to stop smoking
3) Only recommend smoking cessation treatments of proven efficacy, as identified in the guidelines, to people interested in stopping smoking

The ‘ABC pathway’ is a brief intervention model that incorporates these messages and includes three key steps to help smokers quit [194]:

1) Ask about smoking status;
2) give Brief advice to stop smoking to all smokers
3) provide evidence-based Cessation support for those who wish to stop smoking

The principal goal of this intervention model is to generate more supported quit attempts more often. It is a simple and easy memory aid tool prompting all healthcare workers regardless of their seniority, speciality or location, to ask patients about their smoking status.
2.5.3  **New Zealand Smoking Cessation Support Programmes**

The smoking cessation support programmes available in NZ are listed in Table 2-10. These services are provided free of charge apart from pharmacological support, which is $5 per course if fully subsidised (NRT, Bupropion, and Varenicline).

*Table 2-10: Smoking cessation support programmes available in NZ*

<table>
<thead>
<tr>
<th>Support Programme</th>
<th>Support Services Offered to Smokers</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quit card Providers</td>
<td>‘ABC pathway’: including general practices, hospitals and Māori providers</td>
<td>[197]</td>
</tr>
<tr>
<td>Quitline</td>
<td>Free smoking cessation services, including a helpline, face-to-face support, online support, text support, online blogs, NRT and other tools. Reactive and subsequently proactive service</td>
<td>[197]</td>
</tr>
<tr>
<td>Aukati KaiPaipa</td>
<td>A face-to-face support service, aimed at reducing smoking prevalence and consumption amongst Māori. Reactive and subsequently proactive service.</td>
<td>[198]</td>
</tr>
</tbody>
</table>

2.5.4  **Best-Practice Smoking Cessation Programme Components**

The two key components of best-practice smoking cessation programmes are evidence-based support including: 1) behavioural based support (e.g. advice and counselling); and 2) pharmacological based support (e.g. NRT, bupropion, varenicline). Combining both support options is recommended, although it is unclear which combinations are more effective than others, or if any combination works better in some populations or settings.
than others [199]. A recent Cochrane update of systematic reviews of RCTs within the
general population and within specific healthcare settings has, for the first time, established
the efficacy of behavioural support over and above that of pharmacological support [200].

Smoking cessation components are graded based upon strength of evidence, effect size,
and relevance to a population’s healthcare system and graded recommendations are used
to guide practice [201]. Table 2-11 identifies the NZ grading of recommendations for best-
practice smoking cessation interventions based on international guidelines.

*Table 2-11:* Grading of smoking cessation recommendations in NZ
(adapted from [194, 195])

<table>
<thead>
<tr>
<th>Grade</th>
<th>Support for recommendation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>GOOD (strong) evidence</td>
<td>Body of evidence can be trusted to guide practice</td>
</tr>
<tr>
<td>B</td>
<td>FAIR (reasonable) evidence</td>
<td>Body of evidence can be trusted to guide practice in most situations</td>
</tr>
<tr>
<td>C</td>
<td>EXPERT OPINION only</td>
<td>Body of evidence provides some support for recommendation(s) but care should be taken in its application</td>
</tr>
<tr>
<td>D</td>
<td>INSUFFICIENT evidence</td>
<td>Body of evidence is weak and recommendation must be applied with caution</td>
</tr>
<tr>
<td>✓</td>
<td>GOOD PRACTICE POINT</td>
<td>Recommended best practice based on clinical experience and expert opinion</td>
</tr>
</tbody>
</table>

The NZ MOH recommends the key components of a smoking cessation programme should
include a combination of [194]:

- Multisession behavioural support of at least four follow-up contacts; support may be face-to-face (individually or in a group) and/or via telephone (proactive or
reactive). Adding additional telephone support to face-to-face support is effective in situations of single counselling sessions, otherwise both are equally effective.

- Pharmacotherapies: medications that have proven to be efficacy should be recommended to all nicotine dependent people.

### 2.5.5 Efficacy of Smoking Cessation Programme Components

This section contains a brief introduction to the efficacy of evidence-based smoking cessation programme components as they apply to the general population. This topic will be considered in depth when describing the development of a tailored smoking cessation intervention (Chapter 5). The standard measure of a quit rate is calculated by the number of individuals who received a smoking cessation treatment who subsequently quit smoking divided by the number of individuals who received the smoking cessation treatment in total, and is reported as a percentage rate [202].

Unassisted quitting in the general population is low at 2 to 3% [194]. Brief advice of three to ten minutes from a health provider approximately doubles the unassisted quit rate [203, 204]. The use of NRT increases the quit rate by 50-70% compared to unassisted quitting [205]. Increasing the number of types of NRT used can increase quitting by 20-50% over using a single NRT [205]. Individually tailored self-help materials in an intervention can increase quitting rates by 20-55% compared to brief advice [206]. Individual counselling and telephone counselling have been found to increase quitting rates by 25-57% and 20-38% respectively compared to no advice [207, 208].
There is consistent evidence that behavioural interventions increase the likelihood of smoking cessation. However, while more intensive counselling can enhance smoking cessation rates (as compared to less intensive counselling), this strategy runs the risk having a more limited reach as not all smokers are interested in participating in intensive interventions. Therefore, choosing the intensity of behavioural interventions requires careful consideration as is not just a case of ‘more is better’.

2.5.6 **Smoking Cessation in Rheumatoid Arthritis**

The negative health effects associated with smoking in people with RA make a compelling case for smoking cessation. However, people with RA commonly do not recall receiving advice to quit smoking from healthcare providers [44, 209]. One survey from the UK assessing the quality of service for patients with inflammatory arthritis identified 30.9% of patients as current smokers, whilst less than half (48.5%) recalled being advised to stop smoking by their rheumatologist [44]. A more recent study in 25 countries found that less than one quarter of rheumatology departments had either a specific protocol or written advice for smoking cessation [209]. Therefore, specifically targeting smoking cessation for people with RA could be extremely beneficial for RA smokers.

In 2002, a pilot study was undertaken to modify adverse lifestyle variables in RA, including smoking, unhealthy diet and excessive alcohol consumption. Participants were briefly advised on quitting smoking and were provided with a generic quitters pack [210]. Of the eight RA participants who smoked, none quit during the 11 month study period [210]. The impact of a RA and smoking cessation awareness campaign has previously been studied [45]. Only one in 20 people with RA were aware of a link between smoking and RA and
almost half of the people with RA questioned were ex-smokers. The study concluded that smokers with RA may be motivated to quit by learning that RA is a smoking-related disease [45]. This concept was explored in a RCT in 2013 that evaluated an educational intervention designed to 1) increase RA patients’ knowledge of modifiable CVD risk factors and 2) measure intentions to change risk factor behaviours, including stopping smoking, increasing exercise, healthy low-fat eating and losing weight [211]. At six months the intervention group had significantly higher knowledge of all CVD risk behaviours and had intentions to change many risk behaviours except stopping smoking [211]. This suggests there may be a need for interventions specifically focused on smoking cessation in people with RA as was developed in this thesis.

The only specific smoking intervention study in patients with rheumatic disease reported to date evaluated a smoking cessation intervention in patients with various rheumatic diseases, including 55 patients with RA. The intervention consisted of brief (3-5 minutes) smoking cessation advice from a rheumatologist, followed by 20 minutes of verbal and written advice from a Rheumatology Nurse, with the offer of pharmacological support to patients with high nicotine dependence. Quit rates were 11.8% at three months and 15.7% at 12 months. In addition 29 of 152 patients (19%) had reduced their smoking by ≥50% at 12 months [9]. These authors hypothesised that when advice emphasising specific risks for an illness is given by the patients’ regular physician, backed up with nurse collaboration, the probability of smoking cessation rate is increased [9]. This is an area that could benefit from more research, particularly with regard to smoking cessation specifically for people with RA.
2.5.7 Smoking Cessation for Special Populations

Smoking cessation interventions have traditionally been designed for smokers without long-term illness. Recently, targeting smoking cessation interventions to special populations of smokers has been suggested. Targeting in this instance refers to the process of designing smoking cessation programmes based on the needs and characteristics of a particular population [212]. Special populations of smokers have been defined as those who have 1) ≥10% higher smoking prevalence than the general population, 2) disproportionate health disparities due to tobacco use, 3) less access to smoking cessation treatments, and 4) few prospective smoking cessation treatment trials [8]. Smoking in RA shares the above characteristics defining a special population hence providing the impetus to develop a targeted intervention in this thesis research.

In summary, this section has described efficacious and innovative smoking-cessation treatments (behavioural and pharmacologic) that have been developed to aid smoking cessation in the general population. Over the last 50 years hundreds of millions of smokers worldwide have stopped smoking permanently. However, it remains unclear whether these evidence-based smoking cessation interventions are suitable or require tailoring for the growing populations of individuals who live with a chronic disease such as RA. To address the needs of special sub-groups of smokers, smoking cessation programmes could benefit from addressing specific disease-related issues including physical limitations, and specific medical and psychosocial issues that could be targeted in a smoking cessation programme. Understanding the barriers to smoking cessation in the general population in addition to separate sub-group of smokers (including people with RA) is therefore an important aspect, which is explored in the next section.
2.6 Barriers to Smoking Cessation

Smoking has been likened to a chronic relapsing illness [213]. Typically a smoker will make numerous attempts to quit, followed by periods of relapsing before they finally quit forever [5]. Because smokers face many obstacles when quitting smoking, it is essential to gain an understanding of the barriers people face during a quit attempt to enable more successful quitting. This section reviews barriers to smoking cessation in the general population, followed by identifying barriers that may be specifically relevant to individuals with RA.

2.6.1 Demographic Barriers to Smoking Cessation

The demographic factors in the general population, which increase or decrease smoking cessation success are shown in Table 2-12. Because these demographic barriers are quite generic, there is no reason to suggest these barriers would be any different in people with RA as a population.

Table 2-12: Demographic factors affecting smoking cessation in the general population (adapted from [18, 214, 215])*

<table>
<thead>
<tr>
<th>Lower Smoking Cessation Success</th>
<th>Higher Smoking Cessation Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Income</td>
<td>Higher Income</td>
</tr>
<tr>
<td>Early age at smoking onset</td>
<td>Older age at smoking onset</td>
</tr>
<tr>
<td>Younger current age</td>
<td>Older current age</td>
</tr>
<tr>
<td>Less Education attainment</td>
<td>Higher Educational attainment</td>
</tr>
<tr>
<td>Non-European descent</td>
<td>European descent</td>
</tr>
<tr>
<td>Low BMI</td>
<td>High BMI</td>
</tr>
<tr>
<td>Female gender</td>
<td>Male gender</td>
</tr>
<tr>
<td>Single Marital Status</td>
<td>Married Marital Status</td>
</tr>
</tbody>
</table>

*BMI=body mass index
2.6.2 Physiological Barriers to Smoking Cessation

Addiction and the resulting dependence on nicotine is a significant barrier to smoking cessation. As previously discussed (Chapter 2), nicotine activates reward pathways in the brain, specifically the neurotransmitter dopamine. There are many evidence-based pharmacotherapies that are available to aid the withdrawal process of nicotine (Table 5-1) and the provision of pharmacotherapies is regarded as an essential component in successful smoking cessation programmes [205]. Nicotine replacement therapies are widely available in NZ in various forms and prescriptions and NRT is heavily subsidised by the NZ Ministry of Health. Due to the addictive nature of nicotine, all smokers (including people with RA) are likely to benefit from using NRT strategies during a quitting attempt.

Demographic and physiological barriers alone do not encompass all the difficulties smokers face in a quit attempt. The most commonly reported reason for relapsing during a quit smoking attempt is the desire to relieve the discomforting withdrawal effects including anxiety, depression, and stress as explored further in the following section. Because demographic and physiological barriers to smoking cessation are likely to be similar in the general population and people with RA, identifying other barriers to smoking cessation relevant in people with RA will be a key research activity in this thesis. It is anticipated that by identifying novel barriers in this group psychosocial and behavioural interventions could be developed to assist smoking cessation in people with RA.
2.6.3 **Psychosocial Barriers to Smoking Cessation**

2.6.3.1 **Stress**

Elevated levels of psychological distress are known to impede smoking-cessation efforts [6]. Research from Quitline NZ in 2013 showed that stress was the primary reason given by quitters who start smoking again [216]. The study involved in depth interviews with people who had relapsed three months after using Quitline NZ services. The authors suggested relapsing was due to a smoker’s perception that smoking was a major source of relief from the stress caused from everyday living, such as family issues, bereavement, health concerns, and financial worry [216]. It is generally accepted that stress triggers smoking relapses [217].

2.6.3.2 **Anxiety**

Anxiety is known to associate with smoking dependence and to adversely affect long-term abstinence rates [218]. Smokers with symptoms of social anxiety often report using smoking as a way to cope with negative affect [219] and have been reported to show a tendency to experience more severe nicotine withdrawal symptoms [218]. Smoking is highly prevalent in individuals with anxiety disorders such as agoraphobia, and panic disorders although less common in generalised anxiety disorder and social phobia [218]. However, clinical trials do not always demonstrate anxiety as a barrier to quitting smoking, possibly because individuals with anxiety are less likely to enrol in smoking cessation clinical trials [218].


2.6.3.3 Depression

Depression is overrepresented in smokers [220]. Smokers are significantly more likely to be diagnosed with depression than non-smokers (27% vs. 13%; p<0.001) [221]. However, the relationship between smoking and depression is contentious. There is some evidence indicating that those who experience depression use nicotine as a self-medication or coping strategy [222, 223]. Other literature suggests that exposure to smoking increases the individual’s susceptibility to depression [224]. Smoking and depression may share common attributes (such as environment, genetic and social) thereby increasing the risk for both depression and smoking [221]. It has also been noted that relapsing back to smoking is more likely in individuals who are depressed, and that women who smoke are considered at an increased risk for depressive symptoms [221].

Smoking cessation has been associated with reduced stress, depression and anxiety and improved positive mood and quality of life compared with continuing to smoke. This finding has been seen equally in the general population and populations with physical or psychiatric conditions [225]. A meta-analysis of 26 studies that assessed the mental health of both ex-smokers and continuing smokers found the effect sizes for improvements in mental health were equal to or larger than those of antidepressant treatments for anxiety or mood disorders [225]. This is an important issue because although smokers may think their smoking is beneficial from a mental health state, a strong association between smoking and poor mental health has been found. In essence, smokers experience anxiety, irritability, and depression if they have not smoked for a while and these feelings are mitigated by smoking, but it may be that smoking contributes to the onset of these mood disorders [225].
information is relevant when considering helping people with RA who smoke develop alternate coping strategies away from smoking.

**2.6.3.4 Relapsing**

Relapsing from an attempt to quit smoking is common. Relapsing can be considered a barrier to smoking cessation because nearly three-quarters of smokers who quit will relapse within two weeks [179]. Abstinence self-efficacy, that is the confidence in one’s ability to abstain from smoking, has become an established predictor and possible determining factor of smoking cessation outcomes. The Transtheoretical Model (TTM) [226] suggests that a high self-efficacy is associated with successful smoking cessation, whilst the relapsing prevention model [227] suggests that relapses may result when a smoker is exposed to high-risk situations such as being with other smokers. Becoming aware of individual triggers and then choosing to do something else to alleviate or prevent the craving, i.e. using coping strategies to overcome relapses, thereby increasing self-efficacy could be beneficial to smokers. This is the central tenet of the cognitive-behavioural model of the relapse process [228] as illustrated in Figure 2-4:
2.6.4 **Barriers to Smoking Cessation in Chronic Disease**

Although it is known that smoking contributes to the development of many chronic illnesses, little is known about the relationship between quitting smoking and chronic disease. While it might be expected that having a smoking-related illness may facilitate quitting, research has been inconsistent in this area [17]. Barriers to smoking cessation in chronic diseases, including RA may be more prevalent than in the general population, although there is no published data specifically regarding barriers to smoking cessation in RA. However, quitting smoking has been shown to be difficult for other long-term conditions such as CVD, COPD, diabetes, asthma, cancer and HIV/AIDS [6]. Identifying barriers to smoking cessation in chronic disease is an emerging area of research. One study has investigated the association between the presence of diabetes, hypertension, and/or high cholesterol and smoking behaviour to see whether having one or more of those diseases...
was associated with increased quitting [17]. Of the 3,104 participants, 768 (25%) were current smokers and 521 (17%) were former smokers [17]. Thirty-six percent of participants had one chronic disease and a further 18% had multiple chronic diseases. The likelihood of being a former smoker did not increase as number of chronic diseases increased [17]. It is likely this is the same for people with RA.

There are many plausible hypotheses that might explain why chronically ill smokers have difficulty quitting. Because individuals with chronic disease may have to perform other self-care behaviours, such as taking medication or following a special diet, smoking cessation may be viewed as an even greater burden than it is among healthy smokers [229]. The higher rates of depression in chronic illnesses may make quitting more difficult [230]. Illness often restricts smokers from activities such as sports or hobbies, thereby rendering smoking particularly enjoyable and reinforcing [229]. Others have observed some smokers find quitting easy, whereas others do not [231].

However, when smokers are newly diagnosed with a chronic illness, they are confronted with the seriousness of their new health condition. This may prompt an emotional reaction that could increase motivation to change behaviour, including smoking cessation. ‘Teachable moments’ have been described as any naturally occurring life or health events that increase the motivation of a person to adopt new protective health behaviours [6]. During these teachable moments it may be beneficial to deliver smoking-cessation interventions concurrent with the diagnosis and lasting throughout the initial stages of the medical management [6, 17]. This concept will be explored later in the thesis when any differences in quitting rates between newly diagnosed people with RA and those with a longer disease history will be compared in the pilot study (Chapter 6).
2.6.5 Barriers to Smoking Cessation in Rheumatoid Arthritis

People with RA have described how it is difficult to focus on behaviours such as smoking cessation and getting regular exercise at the time of diagnosis because of ongoing pain, fatigue, and stress [232]. There are also the practical issues of frequent doctor visits and starting new medications to deal with, similar to other chronic conditions as described above.

Stress is an important psychosocial aspect in RA. It has been noted frequently in the literature that people with RA have linked a stressful life-event with their disease onset and/or a relationship between stress and disease flares [233]. A longitudinal observational study in the UK found patients with RA who were under more perceived stress appeared to be at a greater risk of psychological comorbidity than those with lower levels of stress [234]. Interpreting stress levels will be an important aspect in this thesis as a result of the exceptional circumstances of the Canterbury earthquakes that occurred in 2010/2011 and the thousands of continuing aftershocks [235].

Not only does living with a chronic disease lead to additional stress, but other psychological factors such as heightened anxiety are known to be prevalent in RA and have been demonstrated in a cohort of people with RA in New Zealand [236]. Anxiety occurs often in people with RA (21-70%) [237, 238], although there are some indications anxiety may be decreasing in prevalence as a result of improved treatments and the encouragement of physical activity in people with RA [239]. In RA, major depression is more prevalent than in the general population (22% vs 8%) [237]. Depression is a major concern in RA because
it is associated with higher levels of fatigue, work disability, pain and health service use but lower treatment adherence and an increased suicide risk and mortality risk [240-242].

Another barrier that may be important in people with RA is a lack of awareness of the relationships between smoking and RA. Educating individuals about such links may be an important facilitator for quitting. The impact of a RA and smoking cessation awareness campaign has previously been studied [45]. Only one in 20 people with RA were aware of a link between smoking and RA and almost half of the people with RA questioned were ex-smokers. The study concluded that smokers with RA may be motivated to quit by learning that RA is a smoking-related disease [45].

### 2.7 Summary

This literature review has highlighted how smoking is a significant health issue in individuals with RA and why smoking cessation would be particularly beneficial to this population of smokers. Because lifestyle changes are particularly difficult for people living daily with chronic diseases such as RA, it is possible that providing targeted interventions that address their barriers to quitting might be beneficial. However, the review highlights the need for further research to identify barriers to smoking cessation in RA and develop an intervention to aid smokers with RA to overcome these barriers, which is the overarching aim of this thesis. The original research in the following chapters identifies RA-specific barriers to smoking cessation in order to inform components for an effective RA-specific smoking cessation intervention. These findings are then translated into a targeted three-month intervention that could be used in clinical practice. Evaluation of the intervention
was determined in a pilot study comparing the intervention to standard smoking cessation advice and feedback was obtained from the participants as to which aspects of the intervention were most accepted.
3 DESIGN AND METHODS

3.1 Chapter Overview

This chapter provides an overview of the design and methods utilised in the three different phases of research undertaken in this thesis. The chapter includes a description of the various qualitative and quantitative methods for data collection, the choice of which was determined by the nature of the research questions that needed answering. Methods for data analysis and establishing rigour are also described.

3.2 The Nature of Research

“A paradigm is a worldview, a general perspective, a way of breaking down the complexity of the real world” p37 [243]

The research in this thesis is positioned within the paradigm of pragmatism, using a critical realism epistemology. Research within the paradigm of pragmatism is problem-centred, pluralistic and has a real-world orientation [244]. Pragmatism derives from the work of Pierce, James, Mead, and Dewey [245] and later Patton [243] and Cherryholmes [245]. Instead of the methods being the most important driver for a research project, the problem is most important driver; therefore researchers use a combination of approaches to understand the specific research problem. This means pragmatism is not committed to any one particular philosophy or method, and researchers are able to choose methods that best meet their needs and purposes [244]. This effectively opens the door to using multiple
methods and different forms of data collection and analysis, which was the strategy adopted throughout this thesis.

The critical realist epistemology is associated with Roy Bhaskar, a British sociologist, who introduced the concept during the 1970s [246]. The fundamental view of critical realism is our knowledge of reality results from social conditioning, thus cannot be understood independently of the social actors involved [247]. The approach recognises that social phenomena are intrinsically meaningful and the meaning has to be understood rather than measured or counted, hence there is always a hermeneutic (interpretive) element in social science research [246]. Rather than seek formal associations or regularities, critical realist research seeks substantial connections among phenomena [246].

The critical realism approach to data analysis was used in two phases in this thesis: firstly, in the exploratory phase of research as described in Chapter 4 (Identifying the barriers to smoking cessation in RA) and secondly, in the evaluation phase of research in Chapter 7 (Exploring participant attitudes to a targeted smoking cessation intervention for people with RA). The use of the critical realism approach enabled an amalgamation and interpretation of the complexity of the ‘lived’ experience of research participants; therefore the nature of the participants’ reality was the driving force as opposed to methodological or ideological predispositions.
3.3 Methodological Perspectives

There are three strategies of inquiry in research that are used to inform the methodological procedures used in this thesis [244]. These strategies are quantitative, qualitative and mixed methodologies. Quantitative and qualitative methodologies were used in this research as a form of sequential mixed-methods, and are described below.

3.3.1 Quantitative Inquiry

Quantitative research is grounded in the positivism paradigm and is based on the assumption that the resultant data are value-free and do not change because they are being observed [248]. Thus, the research in this model is independent of the researcher [248]. Quantitative research is empirical and systematic and its use in healthcare, as in other spheres of research, involves the collection and interpretation of statistics using deductive reasoning [248, 249]. In quantitative research, theories and hypotheses are generated and tested with the measurement of outcomes underpinning the approaches and techniques used [249]. Research questions are typically specific and have a narrow focus, and the research process falls into four phases: 1) conceptual, 2) planning, 3) operational, and 4) dissemination [249]. The design of quantitative research includes specifics, which include variables, reliability, validity and statistics [249]. The overarching aim of quantitative research is to produce findings that are objective, reliable, valid and reproducible, meaning the research should be replicable by anyone, including the original researcher, as long as the same protocols are followed and the same conditions of the original experiment are met [249].
Quantitative research is used in healthcare to test well-specified hypotheses such as determining whether an intervention is efficacious or not, or finding out how much a risk-factor predisposes an individual to a disease. With quantitative healthcare research, the emphasis is on causes of behaviour [250, 251]. Common approaches included in quantitative research methodologies are experiments, quasi-experiments and randomised controlled trials (RCTs) in which the data are gathered using processes such as surveys, structured interviews and questionnaires [249].

Experiments and quasi-experiments differ in their ethical considerations [249]. A RCT is a type of experiment in which participants are randomly assigned to different treatment groups to limit bias in outcomes thus enabling statistical comparisons to be made [249]. Quasi-experimental designs are similar to RCTs, but participants are not randomly allocated to the intervention or control groups therefore participants do not have the same chance of being assigned to either group as would occur in randomised studies [249]. Quasi-experimental designs are often conducted where there are ethical or practical barriers to conducting a RCT [249]. Randomised controlled trials are thus regarded as more rigorous because there is a stronger likelihood the independent variable caused the observed change in the dependent variable when testing an intervention [249]. For this reason, the RCT design was chosen as the methodology of choice for the smoking cessation intervention that was developed for testing in people with RA.

### 3.3.2 Qualitative Inquiry

Qualitative research provides the real world ‘lived’ experience to research [243]. By exploring ‘what’ ‘how’ and ‘why’, qualitative research offers an insight into human
emotions and experiential phenomena [250]. Within the paradigm of pragmatism, a qualitative approach is suited to investigation of a concept or phenomenon where there is little existing research [244]. With qualitative inquiry, the researcher seeks to establish the meaning of a phenomenon from the views of participants. Qualitative research is exploratory and is useful when the researcher does not know the important variables to examine [244]. Qualitative approaches allow room to be innovative and to work more within researcher-designed frameworks [244].

### 3.4 Methods in Action

This section begins by identifying the qualitative and quantitative methods used, followed by an explanation of rigour. The discussion here has a broad focus; the specifics of the methods used in each research phase in this thesis will be described in detail in the corresponding research chapters.

#### 3.4.1 Qualitative Methods

In qualitative research, there are various methods of data collection including interviews, focus group discussions, direct observations, and text or visual analysis [243, 252]. Focus groups and interviews are the most common methods of data collection in qualitative healthcare research. The key difference between focus groups and individual interviews is that interviews generate data by exploring an individual’s views, beliefs, experiences and motivations, while focus groups make use of group dynamics to generate their themes for
analysis [252]. The following section outlines and identifies their specific use and justification for use in the different phases of study in this thesis.

### 3.4.1.1 Data Collection

**Focus groups**

Focus group research involves an organised discussion with a group of people (usually six to ten) who are asked about their views and experiences of a particular topic [253, 254]. The group should be small enough for all participants to share their viewpoints whilst being large enough to provide an adequate diversity of perceptions [254]. Groups of four to five participants have distinct advantages with logistics because they can easily be accommodated plus the group is small enough to provide the opportunity for all participants to share their ideas [254]. Participants are invited to attend dependent upon their meeting certain defined characteristics that are important to the researcher [254].

A semi-structured discussion format is the norm for focus groups with the principle aim of allowing the discussion to develop among group members [254]. Focus groups were used in the exploratory phase of research for this thesis to identify specific barriers to smoking cessation in people with RA. It was a particularly useful method in this thesis due to the planning of several group meetings in Dunedin and Christchurch meaning it was flexible enough to allow participants to choose when to attend. This was an important consideration for people with RA due to their fluctuating symptoms, which can be difficult to predict and thus they were able to be flexible with attendance choices [255]. It was also important to have variation in times of the day or evening the groups were being held, so as to give all
participants a chance of attending. However, recruitment for group interviews was not entirely successful. Firstly, the winter weather was a consideration as many participants did not wish to go out when it was particularly cold and snowing. Secondly, many potential participants did not want to take part in group meetings. It was for these reasons that part-way through the recruitment phase an additional strategy of using one-on-one interviews was adopted.

**Individual interviews**

There are three models of qualitative research interviews, namely: structured, semi-structured and unstructured [252]. Structured interviews are essentially questionnaires with predetermined questions that have been verbally administered and they are a useful tool for enumerating responses from participants into pre-determined categories. In this form of interview, there is no scope for variations to questioning or for any follow-up probing, although they can involve extra lines of questions for people who give certain answers to initial questions. In contrast, unstructured interviews are conducted without any organisation and thus can be difficult to manage because they provide very little guidance to the interviewer or participant.

Between these two extremes of structured and unstructured interviews, semi-structured interviews consist of several key questions that help define the subject areas to be explored whilst allowing for follow-up probes, including detail-oriented, elaboration, and clarification probes [243]. This is the most used interview format in healthcare research because it provides the flexibility to discover or elaborate information that is important to both the participant and interviewer [252]. Semi-structured interviews are the main source
of data collection used in thematic analysis. The major benefits of semi-structured interviews include reliability because the same questions can be asked of all research participants, they provide in depth data, plus they can be used in a more informal setting as opposed to focus group discussions.

Semi-structured qualitative data collection was used in the exploratory and evaluation phases of research in this thesis, including the individual interviews and focus group discussions. The design process and structure of the question schedules used will be elucidated in the relevant Chapters 4 and 7.

3.4.1.2 Data Analysis

All of the quantitative and qualitative data from the different phases of study in this thesis were initially entered onto the Christchurch Rheumatology and Immunology Research Group database and then subsequently downloaded onto an Excel spreadsheet for analysis. The database is password protected and is held in a secure server that is backed up daily. Individual study participant data is de-identified so participants are only identified by their study number. The database administrator is the only person able to identify participants by their national health identification number and this information is downloaded to a separate file from the study data. The analysis of the qualitative data using a Word document for the first phase of research was the only exception to this methodology.
Thematic analysis

Thematic analysis was used to analyse the qualitative data in this thesis. The purpose of thematic analysis, a widely-used qualitative data analysis method, is to identify patterns of meanings (themes) across a dataset to provide an answer to the research question that is being addressed. This form of data analysis can be applied to focus group discussions, a number of interviews, or even a range of texts [256]. Patterns of meaning are identified through a rigorous process of data familiarisation, data coding, and theme development and revision [256]. One of the major advantages of thematic analysis is its theoretical and epistemological freedom, which makes it a flexible and useful research tool [256]. It is particularly suited to addressing research questions related to experiences, views and perceptions of participants [256]. Thematic analyses can be approached in a variety of ways. The analytical approaches utilised in this thesis were either inductive or deductive, and were done semantically [257]. Each approach is described briefly in the following section.

Inductive thematic analysis or the ‘bottom up’ way means themes or patterns identified from a dataset are derived from the data themselves, similar to the grounded theory approach [256]. In the inductive thematic analysis approach the resultant themes typically do not bear any resemblance to the original questions that were asked of the research participants, and the themes should not be steered by the researcher’s theoretical interests [256]. Thus, an inductive analysis is a process of coding data without trying to fit it into a pre-existing coding framework [256]. The resulting data is portrayed as being ‘rich’, which describes the notion the data collected is complex and in depth regarding the subject matter and answers the ‘how’ and ‘why’ questions [252]. This was the approach used to analyse
the data in the first phase of research where the barriers to smoking cessation in people with RA were identified (Chapter 4).

A deductive or theory-driven (‘theoretical’) thematic analysis tends to be directed by the researcher’s theoretical or analytic interest in the research area, therefore it is more explicitly analyst driven. In contrast to an inductive thematic analysis approach, deductive thematic analysis tends to provide a less ‘rich’ description of the data overall, but provides a more detailed analysis of a pre-defined aspect of the data [256]. This method of data analysis was used in the evaluation phase of the research (Chapter 7), where feedback from the study participants was analysed according to the pre-determined themes that were identified in the initial exploratory phase of research (Chapter 4).

Using a semantic analysis approach, the themes in a dataset are identified within the explicit or surface meanings of the data. This means the researcher does not interpret beyond what a participant has said or what data has been collected from written sources [256]. Latent interpretation is the opposite approach to semantic analysis where the emphasis on attempting to theorise the significance of the participant responses [256]. The semantic approach was best suited to answering the practical research questions about developing and evaluating the smoking cessation intervention as opposed to relating participant behaviours to particular theories of behaviour. Thus, the semantic approach aligns with the critical realism epistemology as described above.
3.4.1.3 Rigour in qualitative studies

Rigour in qualitative studies is essential. The overarching concept when considering rigour in qualitative methodology is ‘trustworthiness’. In Guba and Lincoln’s model of qualitative research, there are four components of trustworthiness: credibility, transferability, dependability, and confirmability [258]. Credibility is related to the trueness of the participant’s experiences and can be ensured by using the participant’s own words as quotes in qualitative studies. Transferability relates to how likely it is that study findings would be transferable from the study sample to the study population of interest and is can be evaluated by having adequate descriptions of the sample and settings [258]. Dependability relates to the consistency between the data and the findings. This is verified by documenting the processes of data collection, analysis and interpretation, and evidenced by either providing an audit trail or a peer review of the research [258]. Finally, using strategies to limit researcher bias in the research can safeguard the confirmability. Having colleagues check other researcher’s interpretations of data is important in this respect [258].

The rigour in the qualitative aspects of the studies in this thesis is ensured because all of four components of trustworthiness have been applied, as detailed in the relevant sections of each study.

3.4.2 Quantitative Methods

Quantitative research methods involve predetermined, instrument-based questions and tests so that enumeration of the resultant data is possible. The different types of data that are used include performance data, observational data, medical data and census data [244]. Analysis is performed using statistics with the overarching goal of measuring significant
differences between groups of data [244]. The quantitative methods used in this thesis include: 1) using a pilot study RCT approach to test the efficacy of a tailored smoking cessation intervention, and 2) administering standardised questionnaires for background information to enable comparisons to be made between the research in this thesis and other research on people with RA. Both are discussed below.

3.4.2.1 Pilot Study Randomised Controlled Trials

As previously described, participants in a RCT are randomly assigned to different experimental groups or treatments to limit bias in outcomes. Methods for allocating participants to different groups involve the use of random numbers generated by a computer program. The CONSORT (Consolidated Standards of Reporting Trials) Statement is a set of standard recommendations for reporting parallel-group RCTs [10]. The CONSORT 2010 Checklist and Flow Diagram were used to illustrate recruitment and retention in the RCT reported in this thesis.

Similar to RCTs, a pilot study RCT (referred to as pilot study in this thesis) requires explicit objectives and a testable hypothesis [259]. In contrast to definitive RCTs, sample size estimates for pilots are not derived from the estimated effect of an intervention of a clinically important outcome (as often the effect size is unknown at the pilot study design phase). However, pilot studies can be used to estimate sample sizes to power a definitive RCT and provide an essential first step for exploring novel interventions [260, 261].

Published guidelines for choosing sample sizes in pilot studies is limited, and recommend being guided by constraints of time, cost, and size and variability of the population to be
studied, with estimates between 10 to 40 participants per group suggested [262, 263]. A review of 24 published abstracts of comparative efficacy pilot studies using two groups of participants found the median number of participants to be 20.5 per group [263]. If a subsequent power analysis is a required outcome, then a larger sample size is required and 30-40 participants per group has been proposed [263].

Statistical analyses

The quantitative data collected for RCT outcomes was statistically analysed with the help of a biostatistician using appropriate statistical analyses including 1-way analysis of variance (ANOVA), $\chi^2$ tests or Fisher’s exact test of independence. The 1-way ANOVA is used to compare means from three groups or more from one variable. The $\chi^2$ test can be used to compare the proportion of subjects in each of two groups where there is a dichotomous outcome, e.g. smoking or not smoking [262]. The Fisher’s exact test of independence is used when two nominal variables are compared and is more accurate than the $\chi^2$ test when sample numbers are small [264].

Rigour in quantitative pilot studies

In clinical research, the validity of a particular study should include reviewing the risk of bias in the results, which is defined as the risk of overestimating or underestimating the true intervention effect [265]. Sources of bias in parallel group clinical studies can be broadly categorised into the following features of interest: 1) selection bias resulting from the inadequate sequence generation process and/or allocation sequence concealment, 2) performance bias resulting from inadequate blinding of participants and researchers, 3) detection bias resulting from inadequate blinding of outcome assessment, 4) attrition bias
from incomplete outcome data being collected, 5) reporting bias resulting from selective outcome reporting, and 5) any other biases that do not fit into these categories [265]. Because the parallel group trial was the method of choice for this pilot study, the source of biases will be reviewed in Chapter 6.

The alpha value ($\alpha$) is termed the ‘type 1 error’. The alpha value is the probability of type 1 error, which is incorrectly rejecting the null hypothesis because there appears to be a group difference when in ‘reality’ there is no difference between the two groups within the population. Setting the alpha value to 0.05 effectively means tolerating a maximum 1 in 20 chance of making this error.

The beta value ($\beta$) is termed the ‘type 2 error’. A type 2 error is when your sample leads you to incorrectly retain the null hypothesis because there appears to be no group difference when in ‘reality’ there is a difference between the two groups within the population. Setting the beta value to 0.20 means the researchers want at least an 80% chance of not making this error. This is associated with the risk of researchers drawing a false-negative conclusion from a RCT [266] and is referred to as statistical power. The concept of statistical power is positively associated with sample size, thus the power of a study increases with a larger sample size [267]. Higher values of power enable a higher chance of detecting a statistical difference between groups if one exists, or if there is no difference a researcher can be confident in concluding none exists [267]. A study with a low statistical power has a reduced chance of detecting a true effect [268]. A minimum of at least 80% power is considered desirable in a RCT but 95% is more common [267]. With a power of 95%, the research statistics would represent the probability of 95 of 100 results would be correctly rejecting the null hypothesis [266], as was used for this pilot study.
3.4.2.2 Baseline and Follow-up Questionnaires

In the first phase of exploratory research and during the RCT, information was gathered from all study participants for statistical analysis to enable comparisons of demographic, psychosocial, and smoking behaviours between groups, and to enable comparisons between other published studies. The next section details these data collection instruments and indicates how these measurements can be interpreted. The questionnaires detailed in the following section are attached in Appendix 1.

**Demographic Information**

Demographic information was recorded from a variety of sources including self-reporting by study participants (Appendix 1-a), from their medical files, and obtaining income statistics from their postcode. The demographic information included:

- Self-reported age, gender, ethnicity, level of formal education, employment status, any history of joint replacements, and duration of RA.
- A detailed medical history was obtained from medical records, including comorbidities, recent surgery, and use of medications.
- Socio-economic status was derived from a participant’s post-code using Statistics NZ census data.
- A detailed smoking history was obtained in order to calculate the number of pack-years of smoking, which provided a continuous variable.

**Functional and Psychosocial Assessments**

Evaluation of anxiety, depression, stress, function and self-efficacy were undertaken using validated questionnaires. This allowed comparison to norms from previous studies of
people with RA to be made, satisfying the concept of transferability discussed above with regard to the rigour of this research. The following questionnaires were used:

*Health Assessment Questionnaire (HAQ)*

The HAQ is a valid and reliable instrument designed to represent a model of patient-oriented outcome assessment [269]. The HAQ is recommended by Outcome Measures in Rheumatology (OMERACT), and is one of the ACR core set of outcome measurements for clinical trials. The HAQ is currently regarded as the best scale for measuring disability [270]. The questionnaire is based upon the belief that an individual desires to be free of pain; has normal functionality, and experiencing no detrimental side effects from treatments [270]. The short version of the HAQ (Appendix 1-b) allows an expedited assessment of three of the six ACR outcome measures for RA [269]. The disability index assesses an individual’s level of functional ability using 20 questions in eight categories that involve both upper and lower extremities [271], including dressing, rising, eating, walking, hygiene, reach, grip and usual activities. There are at least two sub-category questions for each of the eight categories. Scores for each question range from zero (no disability) to three (unable to carry out daily activities without assistance). The HAQ is calculated by using the highest sub-category score for each category, which are then averaged into an overall score that ranges from zero to three. Scores of 0-1 represent mild to moderate difficulty; 1-2 represent moderate to severe disability; and 2-3 indicate severe to very severe disability. Any physical aids used by an individual for dressing, rising, eating, walking, hygiene, or grip are factored into the final score [269].
The Personal Impact Health Assessment Questionnaire (PI HAQ)

Measuring facts about disability does not necessarily reflect their personal impact on an individual, thus the value a person places on having the ability to undertake a particular activity is important when considering the impact of disability [272, 273]. For example: if an individual prefers to shower and does not place a high value on being able to get into a bath, then the difficulty they may have with getting into a bath may have little impact on their value of being able to do that task [272]. This means small changes in valued highly activities can have a greater personal impact on an individual compared to large changes in activities of little personal value [272]. The PI HAQ (Appendix 1-c) is useful to place disability within the context of its meaning for a particular individual [272]. To enable a measurement of the PI HAQ, individual patient scores are used to weight their disability scores from the HAQ on a scale of 0 (not at all important), 1 (a little bit important), 2 (quite important) to 3 (very important) corresponding to the eight tasks categories. Therefore, if a person scored 3 in their HAQ for a particular category corresponding to a very severe disability, and valued the ability to be able to perform the task as very important (also scored 3), their PI HAQ score would be 9. If they thought it was not at all important to be able to undertake that task, then their score would be 0. The weighted scores for all of the eight categories are summed and averaged, giving an overall PI-HAQ score.

The Perceived Stress Scale (PSS)

The PSS (Appendix 1-d) was developed to measure the degree to which an individual appraises situations in their life as stressful and is the most widely used psychological instrument for measuring the perception of stress [274]. This instrument has ten questions that ask an individual about the frequency over the last month of how they felt or thought about stressful situations. The person scores each question on a scale of 0 (never) to 4 (very
often). The scoring gives a numerical value that can be used for comparison purposes and involves summing the ten scores. However, prior to summing, questions that are indicators of positive ways of handling stress are reverse scored (e.g. 0=4, 1=3, 2=2…) [275]. Total scores may range from 0 to 40, with higher scores indicative of greater perceived stress. The scores are interpreted as follows: 0-10 relatively stress-free; 11-20 low stress; 21-30 medium stress; and 31-40 high stress [275, 276].

The Arthritis Self-Efficacy Scale (ASES)

The attribute of perceived self-efficacy plays a role in mediating health outcomes in people with RA and the ASES is a valid and reliable instrument developed to measure the self-efficacy of people with RA [277]. For this thesis, a shortened version of the ASES using 11 of 20 items was used (Appendix 1-e). This version contained five items related to coping with pain and six items related to other symptoms of RA such as mood, medication and fatigue. The remaining nine items related to function in RA were not included as a person’s function was adequately assessed in the HAQ questionnaire. Individuals self-score the questions on a scale from 0 to 10 corresponding to their level of certainty they can perform certain tasks, where higher scores indicate higher self-efficacy. Scoring involves summing and averaging the two categories giving two measurements of self-efficacy: 1) pain and 2) other symptoms.

The Hospital Anxiety and Depression Scale (HADS)

The HADS (Appendix 1-f) is a reliable self-assessment instrument for detecting states of anxiety and depression and to measure the level of severity of each for individuals in the hospital outpatients environment [278]. Fourteen questions are answered by individuals to self-report their mood over the past week [279]. Each question is scored on a scale from 0
to 3, with higher scores indicating a more severe state of either anxiety or depression. There are seven questions related to each mood state, which are summed to give a final score on a scale from 0 to 21 for each state. A score of 0 to 7 is regarded as being within the normal range; 8 to 10 indicates the possibility of anxiety or depression, and a score of 11 or higher indicates the probability of the state of anxiety or depression [279].

The Euroqol-5D (EQ-5D) and the EQ-Visual Analogue Scale (EQ-VAS)

The EQ-5D (Appendix 1-g) is a standardised measure of health status developed to provide a simple and generic measure of health for clinical and economic appraisal that was introduced in 1990 [280]. It is a descriptive system comprising of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is self-scored on a scale from 1 (no problems) to 3, (extreme problems). The resulting five digit score provides quantitative information as a measurement of health outcome. There are two ways to present the EQ-5D results. Firstly, the five digit score can be presented as a health profile. There are 243 possible health states definable, where a score of 11111 indicates no problems and a score of 33333 would be the worst possible outcome. Secondly, the five digit score can be converted into a single summary index by applying a country specific weight. In the research in this thesis, the single summary index was used using the NZ value weights as it provided an easier score to compare individual outcomes for people with RA. Country specific value sets are based on the values of their general population [281]. In contrast, the EQ-VAS (Appendix 1-h) is an individual-based score thus is not based or representative of the general population. The EQ-VAS is a self-reported measurement of how an individual feels how good or bad their health state is on that particular day on a scale from 0 (worst imaginable health state) to 100 (best imaginable health state) [281].
Smoking Behaviour Measurements

The Fagerström Test for Nicotine Dependence (FTND):
The FTND (Appendix 1-i) is an instrument for assessing the severity of nicotine dependence [32]. The test was designed to provide an ordinal measure of nicotine dependence related to smoking cigarettes [282]. The FTND has been found to predict smoking abstinence and is correlated with biochemical measures of nicotine dependence. The self-reported questionnaire contains six questions that ask current smokers to evaluate their: 1) quantity of cigarette consumption, 2) their compulsion to smoke, and 3) their level of nicotine dependence. Yes/no questions are scored from 0 (no) to 1 (yes) and answers with multiple choices are scored from 0 to 3. The items are summed to a score that ranges from 0 to 10, with a higher score indicating a greater level of nicotine dependence, as follows: very low (0 to 2 points); low level (3 to 4 points); medium level (5 points); high level (6 to 7 points); and very high level (8 to 10 points) [282].

The Smoking Self-Efficacy Questionnaire (SSEQ)
The SSEQ (Appendix 1-j) is a questionnaire that is used to measure the confidence of current and former smokers to resist smoking in response to various high-risk emotional situations [283]. Self-efficacy is important in smoking cessation because an individual’s confidence in their ability to resist smoking predicts actual quitting [283]. The self-reported questionnaire asks a series of 12 questions: the first six questions ask how sure they would be able to refrain from smoking in high-risk emotional situations, and the second six questions ask how tempted they would be to smoke in several high-risk situations. The questions are answered on a five point scale from: 1 (not sure or not tempted) to 5 (absolutely sure or extremely tempted). The scores are summed for each six items, giving two scores: 1) ability to refrain from smoking, and 2) level of temptation to smoke, each
ranging from 6 to 30. A higher score indicates a higher level of self-efficacy regarding smoking cessation.

*Smoking History Questionnaire*

The smoking questionnaire (Appendix 1-k) is used to provide information about an individual’s personal smoking history and their exposure to environmental tobacco smoke [284]. This questionnaire is useful to define the current smoking status of an individual as defined in Table 2-1.

### 3.5 Summary

In summary, this chapter has provided an overview of the design and methods utilised in the three different phases of research undertaken in this thesis. The research in this thesis is based on a pragmatic paradigm with a critical realist theoretical epistemology. Both qualitative and quantitative methodologies have been employed in the different phases of research, the choice of which was determined by the nature of the research questions that needed answering.
4 IDENTIFYING THE BARRIERS TO SMOKING CESSATION IN RHEUMATOID ARTHRITIS

The original research in this chapter has been published as an article in Arthritis Care and Research [285]. Copyright clearance has been obtained from John Wiley and Sons via RightsLink on 25 June 2015: Licence Number 3656151264947. The article in its entirety has been appended to this thesis (Appendix 2). As primary author of the article I was responsible for: assisting with planning and study design; running all of the focus groups and interviews; collection of all the qualitative and quantitative data; verifying all transcripts after they had been typed by a professional transcriptionist; subsequent data analysis and interpretation of the data; drafting and revising all manuscripts; submitting the article; responding to peer-review comments; and giving final approval of the version of the article to be published. My thesis supervisors were involved in the initial planning concept of the project; assisted with validity of the data; and all co-authors made editorial comments on manuscript drafts prior to the final article submission.

4.1 Introduction

The literature review in Chapter 2 identified that smoking has been recognised as the most important environmental risk factor identified in the development of ACPA positive RA. Smoking may also exert an adverse effect on RA disease activity, joint damage and response to therapy. Components of smoke have been shown to have an effect on inflammation in the synovium which reverse with smoking cessation [143]. It has also been suggested that remission rates of RA may be lower in smokers compared to non-smokers [166, 286]. The literature review also highlighted associations between RA and comorbid
diseases, in particular CVD, COPD and osteoporosis, and identified smoking as an additional risk factor for these conditions. Therefore, the combination of negative health effects associated with smoking in people with RA makes a compelling case for smoking cessation. Indeed, smoking cessation is one of the EULAR recommendations for managing the CVD risk in RA [48].

Smoking cessation interventions have traditionally been designed for smokers without long-term illness. However, guidelines for smoking cessation have highlighted how specific groups of smokers face more difficulties with quitting, particularly those with long-term health conditions. To date, smoking cessation interventions for people with specific long-term diseases such as CVD, diabetes and COPD have received surprisingly little attention, and there has been only one arthritis smoking cessation intervention study published [9].

We hypothesised that people with RA have specific medical and psychosocial issues that are not being met using traditional smoking cessation programmes. The overall aim of this part of the research project was to investigate disease-related issues that make smoking cessation difficult for people with RA. The study explored the knowledge and beliefs of individuals with RA in relation to smoking as it affects their condition and specific RA disease-related factors that contributed to difficulties with smoking cessation.
4.2 Methods

4.2.1 Study Design

A qualitative methods study was undertaken. Participants who were current- or ex-smokers attended either a focus group or an individual interview and completed a set of standardised questionnaires.

Ethical approval was given by the New Zealand Multi-Region Ethics Committee (MEC/11/06/061). The trial identification number was ACTRN12611001045909 and was prospectively registered on 5 October 2011. All participants gave written informed consent (Appendix 3) and were given an information sheet that detailed the study design and procedures, which were verbally explained (Appendix 4). Consultation with Māori was undertaken with the Research Manager Māori, University of Otago, Christchurch in December 2010 (Appendix 5). Locality approval for both Christchurch and Dunedin Hospitals was obtained in 2011.

4.2.2 Participants

Participants were eligible to enter the study if they were aged ≥18 years, with a diagnosis of RA as defined by the 2010 ACR/EULAR Criteria for RA [54]. Participants must be current- or ex-smokers and adhere to the requirements of the study. Participants who were never smokers, unable or unwilling to give written informed consent or had significant serious medical illness or serious mental health issues were excluded.
4.2.3 **Settings and Locations**

Participants were identified from Christchurch and Dunedin Hospital Rheumatology outpatients, inpatients, and patient management systems. Potential participants were contacted by telephone and invited to participate. Those who attended were given a NZ$10 petrol voucher or taxi vouchers to assist with travel costs.

Focus group discussions were held in meeting rooms in either the Dunedin or Christchurch campuses of the University of Otago. Individual interviews were held at the participant’s private address, or at Outpatient Departments in either Dunedin or Christchurch.

4.2.4 **Sampling**

Convenience and stratified purposeful sampling [287] were used in order to balance gender, age, current smokers and ex-smokers, individuals with recent onset and long-standing disease, and to ensure inclusion of participants who identify as Māori, the indigenous people of New Zealand.

4.2.5 **Data Collection Measures and Verification**

The focus groups and individual interviews were all moderated by the researcher (PA). Focus groups and individual interviews followed a semi-structured format, where the discussions were guided but not limited by pre-determined questions. The participant question schedule and prompts are presented in Table 4-1. The content of the question
schedule was assembled from a variety of sources including consultation with specialists in rheumatology and psychology, and the literature [36].

Focus groups and individual interviews were audio-recorded and subsequently transcribed by a professional transcription service. Data saturation was sought based on the principle of theoretical saturation, when no new additional thematic material emerged from additional participants [256]. In practice, the number of required participants in a qualitative study usually becomes obvious as the study progresses when new categories, themes or explanations stop emerging [288].
1. What do you know about the relationship between smoking and rheumatoid arthritis? (*Prompts* – link to symptom severity, possibility affecting how well drugs work, increasing the risk of heart attacks and strokes)

2. What made you take up smoking?

3. Did the pattern of your smoking change when you developed arthritis?

4. What about the reasons for continuing smoking after you developed arthritis – did they change?

5. What specific features about living with arthritis can make it difficult for you to stop smoking? (*Prompts* – anxiety, stress, depression, pain, sleeplessness, fatigue, living circumstances, cues/associations, appetite/weight, loss of ability to work/activities of daily living/partake in usual hobbies or pastimes)

6. Can you tell me about any smoking cessation programmes you’ve tried? (*Prompts* – what aspects of the programme you tried worked and what did not?)

7. Who would you turn to for smoking cessation advice? (*Prompts* – family, friends, GP, pharmacist, rheumatologist, nurse, private therapist, internet support, Quitline)

8. If you have tried to quit smoking, how did you go about trying?


10. What advice would you give to someone with rheumatoid arthritis who was thinking about giving up smoking? (*Prompts* – could we add this into a programme?)

11. Have you ever received advice to stop smoking from your GP, Rheumatologist, rheumatology nurse?

12. What form did this take? (*Prompts* - verbal, written, referral to a service)
4.2.6 Analysis

The transcribed data were thematically analysed from a critical realist epistemology as described in the methods Chapter 3 [246]. The analysis of participant data was carried out manually using Word documents to compile extracts and develop themes. The analysis was inductive in that the data were coded into themes evident within the focus groups and individual interviews without starting from a pre-existing coding frame [256]. One of the thesis supervisors (GJT) independently analysed the first two focus group discussions, which were cross-checked and referenced with the researcher (PA) to confirm the same themes were being discovered. Tallying of responses to major themes was used to generate meaning and assess the level of support from the participants that could then be explored in future research [289, 290]. The analysis was guided by the qualitative data with support from the following quantitative data.

Quantitative baseline information was collected from a variety of sources. The participants’ duration of RA, comorbidities and use of DMARDs were extracted from hospital records (Appendix 6). Standardised questionnaires on demographic characteristics, health status, and smoking habits were used (Appendices 1a-k). Age, gender, ethnicity, level of formal education, and employment status were self-reported. Participants also completed the HAQ, PI HAQ, ASES, HADS, PSS, EQ-5D, and the EQ-VAS). A detailed smoking history was undertaken. Participants completed the SSEQ and the FTND (Chapter 3). Participants were questioned about exposure to secondary smoke in the home or at work, and whether they had received smoking cessation advice from a health practitioner during the past year. T-tests were used to test for significant differences between the current and ex-smokers psychosocial demographics and smoking self-efficacy.
4.3 Results

4.3.1 Study Recruitment

Fifty-six people with RA were invited to participate in the study. Figure 4-1 outlines the participant flow for the study.

Whilst originally a sample size between 40 to 80 participants was estimated to be sufficient for focus groups, theoretical data saturation was reached after 36 participants and no new additional thematic material was appearing so recruitment ended.

Of the 36 participants: 24 were current- and 12 ex-smokers. Nineteen participants were recruited from Christchurch and 17 from Dunedin. There were five group discussions (three in Dunedin and two in Christchurch). The focus groups averaged two to three participants with a mix of current- and ex-smokers. Many participants were not willing or able to participate in group discussions so the remainder of study involved 24 individual interviews. The mean average duration of the five group interviews was 60 (42-93) minutes and the 24 individual interviews averaged at 29 (10-65) minutes. The recruitment and data collection were conducted between February and September 2012.
4.3.2 Baseline Characteristics of Study Participants

4.3.2.1 Demographic and disease data of participants

The demographic and disease details of the 36 participants are presented in Table 4-2. Mean age was 59 (34-77) years. The mean disease duration was 13.6 (0.5-29) years.
Table 4-2: Demographic and disease details of participants

Data presented as number (percentage)*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total sample (n=36)</th>
<th>Current smokers (n=24)</th>
<th>Ex-smokers (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>24 (67%)</td>
<td>16 (67%)</td>
<td>8 (33%)</td>
</tr>
<tr>
<td>Male</td>
<td>12 (33%)</td>
<td>8 (67%)</td>
<td>4 (33%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>33 (92%)</td>
<td>22 (67%)</td>
<td>11 (33%)</td>
</tr>
<tr>
<td>Māori/PI</td>
<td>3 (8%)</td>
<td>2 (67%)</td>
<td>1 (33%)</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paid</td>
<td>14 (42%)</td>
<td>12 (86%)</td>
<td>2 (14%)</td>
</tr>
<tr>
<td>Other</td>
<td>19 (58%)</td>
<td>10 (53%)</td>
<td>9 (47%)</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>6 (17%)</td>
<td>6 (100%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>COPD</td>
<td>5 (14%)</td>
<td>4 (80%)</td>
<td>1 (20%)</td>
</tr>
<tr>
<td>CVD</td>
<td>2 (6%)</td>
<td>2 (100%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Joint surgery</td>
<td>15 (42%)</td>
<td>9 (60%)</td>
<td>6 (40%)</td>
</tr>
<tr>
<td>Interview site</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dunedin</td>
<td>17 (47%)</td>
<td>11 (65%)</td>
<td>6 (35%)</td>
</tr>
<tr>
<td>Christchurch</td>
<td>19 (53%)</td>
<td>13 (68%)</td>
<td>6 (32%)</td>
</tr>
<tr>
<td>DMARDs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methotrexate</td>
<td>26 (72%)</td>
<td>17 (65%)</td>
<td>9 (35%)</td>
</tr>
<tr>
<td>Combination therapy</td>
<td>14 (39%)</td>
<td>10 (71%)</td>
<td>4 (29%)</td>
</tr>
<tr>
<td>ACPA</td>
<td>Positive</td>
<td>23/27 (85%)</td>
<td>16/17 (94%)</td>
</tr>
<tr>
<td>RF</td>
<td>Positive</td>
<td>22/30 (73%)</td>
<td>16/21 (76%)</td>
</tr>
</tbody>
</table>

* PI=Pacific Island peoples; DMARDs=Disease-modifying anti-rheumatic drugs; ACPA=Anti-citrullinated protein antibodies; RF=Rheumatoid factor

There were no significant differences between the demographics of those who participated in the study compared to those who did not (Table 4-3).

Table 4-3: Demographics of excluded versus included participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>Excluded Participants (N=20)</th>
<th>Included Participants (N=36)</th>
<th>Excluded vs. Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Mean (range)</td>
<td>57.4 (45-88)</td>
<td>59.2 (34-77)</td>
</tr>
<tr>
<td>Gender</td>
<td># Female</td>
<td>14 (70%)</td>
<td>24 (67%)</td>
</tr>
<tr>
<td>Interview Site</td>
<td># Christchurch</td>
<td>8 (40%)</td>
<td>19 (53%)</td>
</tr>
</tbody>
</table>
4.3.2.2 Smoking History of Participants

Smoking history data of study participants are presented in Table 4-4. All except one participant began smoking as teenagers. All participants had smoked prior to acquiring RA and two-thirds were still smoking. The participants had smoked for a mean of 40 pack-years and most smoked the equivalent of 20 cigarettes a day. The Fagerström test for nicotine dependency indicated the current smokers had a low to moderate dependency on nicotine. Nearly all of the smokers (91%) reported having received advice from a health practitioner to quit smoking within the last year.

Table 4-4: Smoking history of participants*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total sample</th>
<th>Current smokers</th>
<th>Ex-smokers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=36)</td>
<td>(n=24)</td>
<td>(n=12)</td>
</tr>
<tr>
<td>Secondary smoke at home</td>
<td>9 (25%)</td>
<td>8 (89%)</td>
<td>1 (11%)</td>
</tr>
<tr>
<td>Secondary smoke at work</td>
<td>15 (42%)</td>
<td>11 (73%)</td>
<td>4 (27%)</td>
</tr>
<tr>
<td>Years smoking</td>
<td>43 (23-61)</td>
<td>44 (27-61)</td>
<td>38 (23-53)</td>
</tr>
<tr>
<td>Cigarettes per day</td>
<td>N/A</td>
<td>14.5 (1-30)</td>
<td>N/A</td>
</tr>
<tr>
<td>Age at smoking initiation</td>
<td>16 (12-25)</td>
<td>17 (12-25)</td>
<td>15 (12-18)</td>
</tr>
<tr>
<td>Fagerström test for nicotine dependency</td>
<td>N/A</td>
<td>3.7 (0-8)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Data presented as number (percentage) or mean (range)

4.3.2.3 Functional Status and Psychosocial Data

RA functional status and psychosocial data are presented in Table 4-5. There was no significant difference between smokers and ex-smokers in questionnaire scores for disability levels or impact, self-efficacy over mood or other symptoms of arthritis, nor in scores for anxiety, depression or stress. With respect to quality of life, EQ-5D scores were not significantly different between smokers and ex-smokers, but the EQ-VAS was higher.
for ex-smokers, suggesting this group had a more positive perception of their health status. There were significant differences between the current smokers and ex-smokers with respect to smoking self-efficacy.

Table 4-5: Demographic characteristics and psychosocial data of participants*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total sample (N=36)</th>
<th>Current smokers (n=24)</th>
<th>Ex-smokers (n=12)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>59.2 (34-77)</td>
<td>59.5 (34-75)</td>
<td>58.6 (39-77)</td>
<td>0.80</td>
</tr>
<tr>
<td>Disease duration (years)</td>
<td>13.6 (0.5-29)</td>
<td>12.2 (0.5-27)</td>
<td>16.3 (1-29)</td>
<td>0.18</td>
</tr>
<tr>
<td>HAQ</td>
<td>1.0 (0-3.00)</td>
<td>1.04 (0-3.00)</td>
<td>1.1 (0-2.25)</td>
<td>0.96</td>
</tr>
<tr>
<td>PI HAQ</td>
<td>2.6 (0-7.88)</td>
<td>2.5 (0-7.88)</td>
<td>2.7 (0-6.75)</td>
<td>0.82</td>
</tr>
<tr>
<td>ASES pain</td>
<td>5.4 (1.8-8.8)</td>
<td>5.2 (1.8-8.8)</td>
<td>5.5 (3-7.8)</td>
<td>0.67</td>
</tr>
<tr>
<td>ASES mood</td>
<td>5.6 (1.7-10.0)</td>
<td>5.2 (1.7-9.6)</td>
<td>6.2 (2.0-10.0)</td>
<td>0.24</td>
</tr>
<tr>
<td>HADS anxiety</td>
<td>7.6 (1-17)</td>
<td>8.2 (1-17)</td>
<td>6.3 (1-12)</td>
<td>0.24</td>
</tr>
<tr>
<td>HADS depression</td>
<td>6.2 (1-14)</td>
<td>6.5 (1-14)</td>
<td>5.6 (1-11)</td>
<td>0.54</td>
</tr>
<tr>
<td>PSS</td>
<td>25.0 (8-36)</td>
<td>25.7 (12-36)</td>
<td>23.8 (8-36)</td>
<td>0.43</td>
</tr>
<tr>
<td>EQ-5D</td>
<td>0.6 (0.1-1.0)</td>
<td>0.6 (0.1-1.0)</td>
<td>0.6 (0.2-1)</td>
<td>0.84</td>
</tr>
<tr>
<td>EQ-VAS</td>
<td>63.6 (30-95)</td>
<td>58.9 (30-90)</td>
<td>71.9 (40-95)</td>
<td>0.02</td>
</tr>
<tr>
<td>Smoking self-efficacy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>internal</td>
<td>19.0 (6-30)</td>
<td>13.4 (6-30)</td>
<td>28.8 (25-30)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Smoking self-efficacy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>external</td>
<td>21.0 (6-30)</td>
<td>15.9 (6-30)</td>
<td>28.5 (22-30)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* Data presented as mean (range);
PI HAQ = Personal Impact Health Assessment Questionnaire; ASES = Arthritis Self-Efficacy Scale; HADS = Hospital Anxiety and Depression Scale; PSS = Perceived Stress Scale; EQ-5D = Euroqol health utility; EQ-VAS = Euroqol visual analogue scale
4.3.3 Thematic Analysis

By using an inductive open coding format, five key barriers to smoking cessation from the study participants were identified: 1) lack of suitable support for smoking cessation; 2) lack of education about the links between smoking and RA; 3) pain management: use of smoking as a distraction to pain; 4) inability to exercise due to RA; and 5) using smoking as a coping strategy for RA. The following section examines these five barriers in depth. For the purposes of validity, individual participant quotes are identified by smoking status, gender and age.

4.3.3.1 Lack of suitable support for smoking cessation in RA

Six of the 36 participants in this study felt unsupported due to isolation from others with the same illness and a further 7/36 did not know anyone else with RA.

“I only know one other person with rheumatoid arthritis, distantly, a female a lot younger than me and it’s been quite interesting to hear somebody else has got exactly what I’ve got and yeah, knows what it’s like” [male smoker aged 38]

Most of the participants had tried on numerous occasions to quit smoking. However, during stressful life events they felt overwhelmed and due to their isolation many had returned to smoking. The participants were interested in getting smoking cessation support from RA specific sources such as groups or websites:

'Well why don’t they have groups like this so that people like us can go and actually talk to other people with arthritis? They used to have one years ago out ...and we’d sit down and we’d talk and we’d laugh and joke and it’s good, but this is probably
the most people I’ve talked to about rheumatoid arthritis in a group in my life…’
[male smoker aged 56]

‘…one blog that I read, I thought oh well that’s someone that actually sounds like she’s reading my mind…I never knew that rheumatoid could be so debilitating, I thought…you get arthritis and it’s painful and then you get over it but I didn’t realise it can set you back so much so that was a bit of a shock…so talking to people that have the same conditions is quite useful’ [female smoker aged 50]

While some participants were interested in attending group support, other participants were more reticent and expressed an interest in smoking cessation support in a one-on-one situation rather than a group:

‘I really don’t like groups; I’m not that type of person…I’m not interested’ [female smoker aged 34]

4.3.3.2 Lack of education about the links between smoking and RA

Twenty-three of the 36 participants were not aware of a relationship between smoking and RA, and thus did not perceive this as a reason to quit:

‘[My rheumatologist] said before that it would be a lot better for my rheumatoid if I wasn’t smoking but, I know loads of people that smoke who haven’t got it… so to me, it’s irrelevant’ [female smoker aged 34]

Fifteen of 36 participants did not recall having received any advice from their medical practitioners about the links between smoking and RA:
‘No. It’s never been spoken about in there [hospital], when I’ve been in there…I’ve had my knees done 6 times…I just don’t know, it doesn’t affect me with the arthritis… the last time that anything was said about the smoking interfering with the cortisones’ [male smoker aged 72]

Only 6 participants reported changes in their smoking patterns due to their RA diagnosis; all had increased their smoking after diagnosis.

4.3.3.3 Managing their RA pain

Twenty-two of 36 participants experienced difficulties managing pain associated with their arthritis. Whilst not explicitly using smoking to control their pain, they were using smoking as a diversion from pain, particularly during the night:

‘I can’t sleep because of the pain, umm that will make me go back to smoking. And it’s just you know, the poor me thing really. I feel so sorry for myself and, and what can I do you know. If I can’t hold a book…I can smoke. You know smoking honestly does seem the only thing I can do…And you know you’re going to be awake for hours and hours and hours… ’ [female smoker aged 69]

The participants also connected a decrease in pain and a decrease in anxiety when they smoked:

‘…some people might have a drink, others drink heaps of coffee and I choose to smoke…I probably don’t choose to smoke but yeah, smoking I’ve found that can take…my mind off it I guess… ’ [male smoker aged 38]
However, as the ex-smoking participants revealed, this association can be overcome and their smoking needs can be replaced by alternative strategies:

‘It’s the association with severe pain and the need to sit so you’re gonna sit down and you’re gonna grab a smoke, 'cause that’s gonna make you feel better, but then you find out no, you don’t need to do that, you could just sit down and rest anyway, it works the same’ [female ex-smoker aged 67]

### 4.3.3.4 Inability to exercise due to RA

Twenty-seven of 36 participants found it difficult to exercise or continue their usual activities (including paid employment) due to their RA:

‘I used to do lots of tramping [hiking], I don’t do any big tramps any more...the last one I did was earlier this year, was just a 4 hour walk in, 4 hour walk out, no strenuous hill work or anything and yeah my knee blew up on the way out... ’ [male smoker aged 38]

‘I gave up work as a result; I was going from working 60 hours a week and being busy to basically doing nothing... ’ [female smoker aged 50]

Participants described being unable to use exercise or movement as a distraction from smoking:

‘I’m just sitting there reading a book havin’ fag after fag after fag, 'cause you can’t do anything else’ [male smoker aged 56]
'It’s something to do with your hands when you don’t feel like doing anything…’
[female smoker aged 63]

4.3.3.5 Using smoking as a coping strategy

Smoking was or had in the past been used as a strategy for coping with life in general and specifically the frustration of living with RA in 33/36 individuals questioned. Some participants spoke emotionally about smoking, saying that quitting would be like losing a ‘good friend’, whereas other participants saw smoking as a social behaviour and did not want to lose those interactions:

‘I remember giving up once, patches and that, and I used to cry in morning. Honestly I did, I cried, it’s like losing your best friend’ [female smoker aged 64]

Many participants mentioned that they no longer consumed alcohol due to the contraindications with their RA medication such as methotrexate:

‘I haven’t had a drink since I got arthritis; I don’t drink much; I was a social drinker…I do find now that I don’t drink …I’m not as sociable; I know it’s wrong to smoke but it’s the only thing that I’ve, for me anyway that I feel, I don’t go anywhere, I can’t even flippin’ well have a glass of wine now, like I used to’ [male smoker aged 56]

Participants reported that they used smoking to cope with significant negative life events such as the death of a close family member or marriage break-up:

‘My marriage went to the pack, I took up smoking, I owned a dairy [shop], it [cigarettes] was right there’ [female ex-smoker aged 49]
‘I just lost my husband...so I bought a house in town and no way...was I gonna smoke inside, but...I don’t know... I was a bit of a mess’ [female smoker aged 67]

During late 2010 and throughout 2011, Christchurch was struck by a series of severe and intense earthquakes, with the most powerful at magnitude 7.1 in September 2010. This was followed by over 13,000 aftershocks [291], including a major 6.3 magnitude aftershock in February 2011. Due to the intensity, acceleration and violence of ground shaking, the February 2011 quake was one of the strongest ever recorded in an urban environment [235], resulting in 185 deaths and major destruction of the city causing substantial changes to local social, living and working conditions. Four of 19 Christchurch participants had returned to smoking after the earthquakes as a way of coping with their stress:

“...I gave up for a year and then the September earthquake, I got through that, I didn’t actually smoke with that one...and then the February one...yeah I just went for the smoke packet” [male ex-smoker aged 51]

“...a few of us at work that smoked and we were all trying to give it up at the same time but once the earthquakes and that came, I was smoking worse than ever again...” [male smoker aged 62]
4.3.4  Participant Attitudes to Smoking Cessation Attempts

Nearly all of the participants had made numerous attempts at quit smoking, and seven current smokers had previously been smoke-free for long periods of time:

‘I’ve done it before [stopped smoking] for 12 years…I still did find it hard to do but I never thought I’d ever go back after 12 years’ [female smoker aged 63]

The most common cessation methods used by the study participants were pharmaceutical based aids. Nicotine replacement therapy including patches (25/36 participants) and gum (13/36 participants) were the most prevalent. Just under a third of participants (11/36) had tried varenicline (‘Champix’). Other methods mentioned included bupropion (‘Zyban’), gradual reduction in smoking, acupuncture, and self-help books. Individual counselling by Quitline NZ, a free nationwide telephone helpline offering support for smoking cessation in New Zealand, was mentioned by three participants. Overall, these strategies were not considered effective by these participants. In particular pharmaceutical aids to quitting were often perceived as being inconvenient, tasting unpleasant or causing adverse effects such as nausea or allergic reactions:

‘Champix …they made me feel sick... so I just stopped taking them’ [female ex-smoker aged 53]

‘I’m allergic to sticking plasters…so then they gave me chewing gum but that stuck to the false teeth’ [female smoker aged 67]

Unsuccessful quitters mentioned stress and temptation as reasons to smoking again:
‘I gave up and there became a few stresses with my son… thought I’d only have one cigarette…bought a packet and smoked the lot’ [female smoker aged 64]

‘I had to give up for 7 years…my dad came over and he was smoking, I says oh yeah I’ll have one and just started again’ [female smoker aged 50]

The ex-smokers in this study had succeeded with the same smoking cessation methods. One key factor which seemed to set these participants apart from the continuing smokers was their perception that they were ready to stop:

‘I was just sick of the taste’ [male ex-smoker aged 53]

‘I knew I didn’t want to smoke anymore’ [female ex-smoker aged 55]

‘…something just clicked in my head and I just gave up’ [female ex-smoker aged 39]

Generally, these participants did not find quitting easy. Quitting to improve the efficacy of their RA medication was only mentioned by one participant:

‘…smoke free for nearly 2 years…I thought the drugs might’ve worked better than smoking, maybe that’s why I stopped… ’ [female ex-smoker aged 70]

Overall, the quitters had significantly higher internal and external smoking self-efficacy (p<0.001) as illustrated in Table 4-5, demonstrating their confidence in being able to resist smoking in both high-risk emotional and social situations.
4.4 Discussion

This phase of study explored disease-related issues that hinder smoking cessation in people with RA. The aim was to understand RA-specific barriers to smoking cessation in order to inform components for an effective RA-specific smoking cessation intervention. Thematic analysis revealed that people with RA have specific physical and psychosocial needs although some of these are similar to those seen in other long-term illnesses [6, 17], such as: less social support; a lack of education regarding associations between illness and smoking; chronic pain; inability to exercise or activities; and higher rates of depression and anxiety. In this study cohort there were no obvious patterns of direct connections between the individual five themes and any specific demographic or disease factor.

Smoking contributes to the disease burden in many long-term diseases including CVD, diabetes, COPD, and many cancers [6]. It has been argued that it is critical to evaluate smoking cessation for people with particular long-term illnesses to determine whether modifications to a cessation program should be made, based on disease-specific issues [6]. Smoking cessation has positive health benefits and can lead to improved disease outcomes in people with long-term conditions [292]. Intensive smoking cessation interventions that include both behavioural and pharmacological components have been demonstrated to improve quit rates compared to brief interventions for CVD [293] and COPD [294]. However, there have been few studies investigating the provision of smoking cessation interventions for other long-term conditions [292].

Providing smoking cessation support that includes RA disease-related advice, discussion, encouragement and activities designed to help quit attempts to succeed is likely to be
beneficial for people with RA. In this study, a small proportion of participants felt unsupported during their attempts at smoking cessation due to isolation from others with the same illness. The participants were interested in getting smoking cessation support from RA specific sources such as groups or websites. Some of these participants were interested in becoming involved in support groups, whilst others were more interested in individualised support. Therefore, tailoring advice and support to individual people with RA’ needs may improve quit attempts.

Whilst all the participants in this study recognised that smoking was detrimental to their health, most were unaware of the links between smoking and RA. Furthermore, the majority did not recall receiving any information from medical practitioners regarding links between smoking and RA. There is a need to develop appropriate educational material to enhance relevant lifestyle modifications in people with RA [232]. However, the main challenge is changing behaviour [211]. A RCT of a CVD education intervention in people with RA demonstrated that careful design of an education programme informed by qualitative stakeholder participation proved successful in increasing knowledge and intentions to modify adverse behaviours [211]. Whether such an approach with smoking cessation programmes will result in improved quit rates remains to be determined.

Chronic widespread pain is a common feature of RA [295]. It has been suggested that individuals with chronic pain may be motivated to smoke because of a belief that smoking could help them cope with their pain or that quitting smoking would be more difficult because of their pain. There is some evidence suggesting that it is particularly difficult for people with chronic pain to quit smoking [296]. Although recent studies have shown that smoking cessation was not associated with exacerbation or improvement in pain [297-299],
other studies have reported a strong association between improved reported pain and smoking cessation in chronic conditions such as spinal disorders [300] and those receiving treatment for chronic pain [301]. In a RA smoking cessation programme pain management is likely to be a key barrier to cessation and as such pain management strategies should form an integral part of any programme.

A systematic review and meta-analysis of trials that investigated the acute effects of short bouts of exercise on a desire to smoke found there is good evidence that physical activities reduce cigarette craving [302]. This review highlighted the potential of a single session of physical activity to reduce cravings, particularly when then cravings are high, and the effects are comparable and exceed the craving reduction seen with NRT use [302]. The general effects of exercising in RA have been shown to have specific health benefits and are considered to be fundamentally beneficial for all people with RA [303]. Benefits include lowering CVD risk; increasing body muscle mass to lessen rheumatoid cachexia; increasing bone mineral density; improving joint health; improving functional ability and psychological well-being; and reducing pain, morning stiffness, and fatigue [303]. Overall, exercise has not been shown to exacerbate RA disease activity [303]. Therefore, as part of a RA smoking cessation intervention, suitable targeted exercises should be offered. Aerobic and resistance exercises tailored for people with RA are likely to be of particular value.

Smoking as a coping strategy was or had been used by nearly all of the study participants to counter their perceived frustrations of living with RA, such as their inability to do usual tasks, issues with pain management, and their requirement to avoid alcohol whilst taking DMARDs. The most commonly cited reason for smoking unrelated to RA was the use of smoking to cope with significant adverse life events including the localised effects from a
natural disaster, death of a family member, and other specific individual stresses. Research shows that active coping skills lead to better health perceptions for people with RA [304]; those who do not use active coping strategies appear to be more at risk of psychological comorbidities [234]. Furthermore, individuals who perceive their RA to have a negative prognosis also report more depression, pain, morning stiffness, fatigue, and less satisfaction with their life [240]. Smokers with anxiety symptoms often report using smoking as a way of coping. Such use is associated with less success at smoking cessation [219]. The successful quitters in this study reported less anxiety and depression than the current smokers. They were significantly enabled with a sense of self-efficacy over the temptation to smoke. Therefore, providing individually tailored active coping strategies for living with RA could prove beneficial. Such strategies may include a greater awareness of their own personal smoking triggers, and strategies to cope with their associated RA symptoms. Theoretical models and contemporary research indicate that active coping leads to better psychological outcomes in RA [234, 240, 305].

There are robust, evidence-based, effective smoking cessation interventions available that have been shown to reduce smoking rates in the general smoking population, and include medications, counselling, or a combination of both. Smokers can increase their chance of successful cessation by up to three times by using evidence-based medications and counselling compared to those who use neither [306]. Specialist individual behavioural support used with combination NRT has shown to have a 20% quit rate at one-year and is five times as effective as unaided quitting according to results from selected NHS smoking cessation interventions from the Smoking Toolkit Study in England [307]. Therefore, tailored and individualised support for RA smokers is likely to be helpful.
Unfortunately, immediate benefits from smoking cessation are seldom apparent in terms of health status. Former smokers with long-term illnesses have been reported to take twice as long to reduce their medical costs compared to those without [308]. Although recognised health benefits to people with RA from smoking cessation include a reduced risk of mortality from CVD, and improvements in bone density, these may take some years to realise.

The main strength of this study is the use of qualitative methods. The qualitative data provides rich information about people with RA’s lived experience with their disease such as emotions, behaviours, needs, desires and personalities, which cannot be matched by quantitative data alone. The critical realism approach to data analysis demonstrates an amalgamation and interpretation of the complexity of the lived experience of the research participants; therefore, the nature of participants’ reality was the driving force as opposed to methodological or ideological predispositions. The combination of interview techniques and recruiting from two centres reduces the chance of homogenous bias. By interviewing in Christchurch and Dunedin, the effect of the Christchurch earthquakes in 2010/2011 was minimised. Eighty percent of individuals who were approached agreed to participate. Although the study was small, saturation was reached suggesting that new themes were unlikely to be identified with a larger sample size. Limitations of the study include the inability to identify specific issues for Māori due to the small sample size. There was also the tendency for participants to be self-selecting; hence the sample was not necessarily representative of all smokers with RA. It was not possible to quantify the smaller sub-themes because there were numerous complex issues independently identified by the participants, but answers regarding these specific issues were not consistently provided by the participants.
### 4.5 Conclusion

Physical limitations and disease-associated factors can adversely affect smoking cessation in people with RA. Smoking cessation is one of most important modifiable lifestyle factors in which people with RA can improve outcomes. Therefore, smoking cessation should be a critical aspect in the management of RA. Facilitation in areas of education, exercise, pain management, coping strategies, and support specifically tailored for RA may increase smoking cessation in RA. This study provides a valuable insight to the specific RA-related barriers to smoking cessation in a stratified sample of smoking and ex-smoking people with RA. By gaining an understanding of these specific factors from their perspectives, there is an opportunity to plan an effective targeted intervention that may increase the chance of smoking cessation. These ‘lived’ person experiences have provided the foundations for a smoking cessation intervention tailored for people with RA, the design of which is considered in the following chapter.
5 DEVELOPING A TAILORED SMOKING CESSATION INTERVENTION FOR PEOPLE WITH RHEUMATOID ARTHRITIS

The original research in this chapter has been published in an article in Musculoskeletal Care [309]. Copyright clearance has been obtained from John Wiley and Sons via RightsLink on 25 June 2015: Licence Number 3656160336274. The article in its entirety has been appended to this thesis (Appendix 7). As primary author of the article I was responsible for: identification of the key generic components of best practice, evidence-based, smoking cessation components for the intervention; structure and design of the 12-week timeline for the intervention; organising and chairing the steering committee and presenting the findings from phase 1 of this study (identifying the barriers to smoking cessation in RA); organising the final structure and content for the intervention; drafting and revising all manuscripts; submitting the article; responding to peer-review comments; and giving final approval of the version of the article to be published. My thesis supervisors were involved in the initial planning concept of the project; and all co-authors were involved with the development of the resources for the intervention content and made editorial comments on manuscript drafts prior to the final article submission.
5.1 Introduction

The previous chapter identified five RA-specific barriers to smoking cessation: 1) people with RA feel isolated and unsupported when attempting smoking cessation; 2) people with RA are often unaware of the detrimental effects of smoking on RA and hence do not perceive this as a reason to quit; 3) smoking is used as a distraction from the pain associated with RA; 4) people with RA find it difficult to exercise and hence see themselves unable to use exercise as an alternative distraction from smoking; and 5) smoking is used as a coping mechanism for the frustrations of living with RA [285]. Therefore, smoking cessation strategies in RA may be more effective if they provide education and advice on exercise, pain management, and coping strategies.

Whilst the themes identified from Chapter 4 are clear, translating these findings into a novel psychosocial intervention requires the development of a plan to design the structure and content of a novel smoking cessation intervention [310]. The aim of this chapter is to describe how the findings about smoking cessation needs of people with RA were translated into a targeted intervention that could be evaluated in a pilot study for potential use in clinical practice.

5.2 Methods

The steps of the intervention development process are described below in a linear fashion, although the process was iterative. There were two major methodological components in the development of this intervention:
1) Identification of key generic components of existing evidence-based smoking cessation programmes, which were used to provide the intervention structure.

2) Development of resources for people with RA that address the identified barriers for quitting smoking, which provided the intervention content.

5.2.1 Literature Review

A systematic literature review was carried out as an ongoing process between February to June 2012 in order to provide the structural design and identify key generic components of best practice, evidence-based, smoking cessation programmes. Sources of information included PubMed, OVID, Cochrane Library, Ebsco Databases and Google Scholar. The search was limited to smoking cessation policy and studies from 2000 onwards. The following terms were searched:

Smoking AND Cessation AND Cochrane; Smoking AND cessation AND ‘evidence-based’; ‘Smoking cessation’ AND USA; Smoking AND rheumatoid; Smoking AND cessation AND rheumatoid; Smoking AND chronic; Smoking AND cessation AND chronic; Smoking AND cessation AND Zealand; Smoking AND cessation AND ‘Ministry of Health’ AND Zealand; Smoking AND cessation AND UK; Smoking AND cessation AND chronic; Zealand AND ‘ABC’ AND smoking AND cessation
The literature review focussed on two main categories of evidence:

1) Systematic reviews and meta-analyses of RCTs to enable identification of evidence-based smoking cessation components. The Cochrane Reviews of smoking cessation components were the major source of information.

2) The most recent clinical practice guidelines on treating tobacco use and dependence from the World Health Organisation (WHO) European Strategy for Smoking Cessation Policy [311], the United Kingdom National Institute for Health and Care Excellence [312], the United States (USA) Department of Health and Human Services [189] and from the New Zealand (NZ) Ministry of Health [194, 313].

5.2.2 **Development of Resources for Intervention**

The intervention content was designed to address the identified barriers for quitting smoking in RA in the previous chapter. This process involved the development and refining of resources for people with RA, with modules created to address each of the five barriers. A steering group was convened from key stakeholders and researchers involved in the project with the remit of selecting and packaging the intervention content and deciding who would provide the necessary support. The steering group comprised of the following stakeholders, the researcher (PA), two consultant rheumatologists (LKS, SS), a health psychology researcher (GJT), and four health service providers from Arthritis NZ (the key support organisation for individuals with arthritis in NZ) [314]. The Arthritis NZ service providers included two Arthritis Educators who are the contacts for people with RA seeking advice and support, the Christchurch Regional Manager, and the National Service Development Manager. The interventions were chosen by the steering group with the following considerations:
1) Smoking cessation interventions needed to be appropriate and feasible, and based upon the best-practice intervention structure as identified in the literature review.

2) Wherever possible the interventions would be based upon existing resources and information available from Arthritis NZ or Christchurch Hospital Department of Rheumatology, Immunology and Allergy.

3) Interventions needed to fit within the existing service delivery structure of Arthritis NZ, which is a predominantly a telephone-based service.

4) Appropriate education of the Arthritis Educators who were providing smoking cessation advice was required.

Apart from the section specifically targeted to smoking cessation, the remaining resources and treatments used in the intervention were generically suitable for all people with RA regardless of their smoking status. The resources allowed for individual tailoring of the programme depending upon the goals and preferences of individual smokers with RA. The intervention structure is considered in detail in the results section following.

5.3 Results

5.3.1 Intervention Structure

The literature review highlighted three key components for an effective smoking cessation intervention that are recognised internationally: 1) the optimal duration of a smoking cessation intervention of three months; 2) pharmacological support (e.g. NRT); and 3)
behavioural based support (e.g. advice and counselling). These key components provided the structure for the intervention, which are as follows:

1) The minimum standard needed to establish the outcome measure (quit smoking), requires smoking status to be reported at two time-points: at four weeks following the date smoking ceased and at three months after this quit date, with optional follow-up at six months and 12 months.

2) Pharmacological support is recommended to all nicotine dependent people and should include medications that have proven efficacy, such as NRT.

3) Multisession behavioural support of at least four follow-up contacts offered face-to-face or via telephone, and weekly reminders in between.

The potential interventions considered by the steering group for inclusion in the current intervention are listed in Table 5-1. Risk ratios (RR) have been reported in preference to odds ratios (OR) when available. Although both are regarded as valid, risk ratios are regarded to be easier to interpret than odds ratios [265]. For interventions that increase the chances of an event occurring, such as smoking cessation, the calculated odds ratio will be larger than the risk ratio, so there is a risk of overestimating the effect of the intervention [265]. Risk ratios describe the multiplication of the risk that occurs from an intervention, for example, a risk ratio of 2.0 implies that smoking cessation from an intervention is two-fold more likely to occur than without that intervention (control group). A risk ratio of 1.0 indicates no difference between the intervention and control group and a value <1.0 is indicative that smoking cessation less likely in the intervention group. The success rates (%) of the treatments are included where known.
Table 5.1: Efficacy of interventions to combat tobacco dependence in the general population (Based upon systematic reviews and meta-analyses from the Cochrane Collaboration [3, 2001])

<table>
<thead>
<tr>
<th>Intervention Group (success rate of treatment)</th>
<th>Control Group (success rate of treatment)</th>
<th>RR (95% CI)</th>
<th>Number of Studies</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>No intervention</td>
<td>No advice</td>
<td>1.00 (reference)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Brief Advice</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brief advice to quit &gt;3mins to ≤ 10mins (8%)</td>
<td>No advice (5%)</td>
<td>1.76 (1.58-1.95)</td>
<td>26</td>
<td>[203, 315]</td>
</tr>
<tr>
<td><strong>Behavioural Interventions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage-based counselling</td>
<td>Standard advice</td>
<td>1.00 (0.82-1.22)</td>
<td>2</td>
<td>[316]</td>
</tr>
<tr>
<td>Self-help materials</td>
<td>No materials</td>
<td>1.45 (1.27-1.66)</td>
<td>14</td>
<td>[206]</td>
</tr>
<tr>
<td>Self-help materials (individually tailored)</td>
<td>Standard advice or staged-based counselling</td>
<td>1.36 (1.19-1.55)</td>
<td>7</td>
<td>[206]</td>
</tr>
<tr>
<td>Telephone counselling</td>
<td>No telephone counselling</td>
<td>1.29 (1.20-1.38)</td>
<td>44</td>
<td>[207]</td>
</tr>
<tr>
<td>Individual counselling (12%)</td>
<td>Minimal contact (9%)</td>
<td>1.39 (1.24-1.57)</td>
<td>22</td>
<td>[208, 315]</td>
</tr>
<tr>
<td>Group-based counselling (10%)</td>
<td>Self-help (6%)</td>
<td>1.98 (1.06-2.46)</td>
<td>13</td>
<td>[315, 317]</td>
</tr>
<tr>
<td><strong>Pharmacotherapies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combination NRT (21%)</td>
<td>Single NRT (16%)</td>
<td>1.34 (1.18-1.51)</td>
<td>9</td>
<td>[205, 315]</td>
</tr>
<tr>
<td>NRT (17%)</td>
<td>Placebo/ No NRT 10%</td>
<td>1.60 (1.53-1.68)</td>
<td>117</td>
<td>[205, 315]</td>
</tr>
<tr>
<td>Bupropion ‘Zyban’ (19%)</td>
<td>Placebo (11%)</td>
<td>1.69 (1.53-1.85)</td>
<td>36</td>
<td>[315, 318]</td>
</tr>
<tr>
<td>Bupropion ‘Zyban’</td>
<td>NRT</td>
<td>1.26 (0.73-2.18)</td>
<td>3</td>
<td>[319]</td>
</tr>
<tr>
<td>Varenicline ‘Champix’ ‘Chantix’ (28%)</td>
<td>Placebo (12%)</td>
<td>2.27 (2.02-2.55)</td>
<td>14</td>
<td>[315, 320]</td>
</tr>
<tr>
<td>Bupropion ‘Zyban’ &amp; NRT</td>
<td>Placebo</td>
<td>2.61 (1.65-4.12)</td>
<td>2</td>
<td>[205]</td>
</tr>
<tr>
<td><strong>Combined behavioural and pharmacotherapies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased behavioural support + pharmacotherapy</td>
<td>Less or no behavioural support + pharmacotherapy</td>
<td>1.16 (1.09-1.24)</td>
<td>38</td>
<td>[321]</td>
</tr>
<tr>
<td>Pharmacotherapy + behavioural interventions (Grade A)</td>
<td>Usual care/self-help/brief advice</td>
<td>1.82 (1.66-2.00)</td>
<td>40</td>
<td>[199]</td>
</tr>
</tbody>
</table>

*RR=risk ratio; CI=confidence interval*
Combining behavioural and pharmacological support is recommended by the Cochrane Collaboration since this combination can nearly double quit rates when compared with no intervention (RR 1.82, 95% CI 1.66-2.00) [199]. Adding behavioural support to pharmacological support improves efficacy when compared with pharmacological support alone (RR 1.16, 95% CI 1.09-1.24). However, evidence is lacking to support the superiority of the combination in some populations [199]. The success rate for smokers who quit smoking unassisted (i.e. using no pharmacotherapy or behavioural interventions) is low at 2-3% [194, 203]. Although quitting without assistance has been successful for nearly half of former smokers in the USA, this is likely a reflection that effective treatments have not been readily available in the past [322].

5.3.1.1 Behavioural Interventions

Brief advice from a healthcare provider

Brief advice from a healthcare provider (defined as advice from >3 to ≤10 minutes) almost doubles quit rates as compared to no advice (RR 1.76, 95% CI 1.58-1.95) [203]. Advice can either be in the form of a brief intervention (e.g. the NZ ‘ABC pathway’ - Appendix 8) [194, 195] or as part of a more intensive intervention such as behavioural counselling. As a minimum, brief advice simply means advising people to quit smoking [323]. In NZ it is recommended that brief advice be offered to all smokers regardless of their readiness to quit [194, 195]. Whilst evidence shows that brief advice delivered by physicians is the most effective [203], advice from other health professionals such as dentists, pharmacists, and nurses is likely to be beneficial and cost effective [324, 325].
Brief advice was included in the intervention in the form of the ‘ABC approach’ (Appendix 8), which is standard practice in NZ hospitals and primary healthcare institutions.

**Stage-based advice**

The ‘Stages of Change’ component of the TTM has been used extensively in smoking cessation. This model suggests that smokers move through a series of stages before they are able to stop smoking [316]. Five stages of change had been identified in this model: 1) *precontemplation* where a smoker is not thinking about quitting in the next six months; 2) *contemplation* where a smoker is thinking about quitting in the next six months; 3) *preparation* where a smoker is thinking about quitting in the next month; 4) *action* where a smoker has quit successfully for six months; and 5) *maintenance* is the time after quitting for more than six months. The period of six months is arbitrary but is commonly used [326]. Based upon this model, it has been suggested that smokers be matched with cessation programmes that relate to their stage of readiness to quit. However, the findings from a systematic review in 2010 revealed that although stage-based interventions are better than no intervention, they are not better than standard advice (RR 1.0, 95% CI 0.82-1.22) and are less helpful than self-help material (RR 0.93, 95% CI 0.62-1.39) [316]. Based on this evidence, the stage-based advice strategy was not included in the current intervention.

**Self-help materials**

Providing standardised written self-help materials alone has only a small effect on smoking cessation success, although is more beneficial than no advice at all (RR 1.45, 95% CI 1.27-1.66) [206]. The self-help materials included written, audio-visual and/or computer programmes. Self-help materials are relatively inexpensive to provide and can reach a wide
audience, but the quality of content has been found to vary widely [206]. There is evidence of a benefit from individually tailoring self-help materials as opposed to standardised materials (RR 1.36, 95% CI 1.19-1.55) although part of this benefit could be due to the additional assessment and contact from a healthcare provider [206]. It was agreed that treatment interventions addressing the individualised support needs of specific participants would be offered following an initial needs assessment.

**Person-to-person counselling**

The three key principles for smoking cessation counselling are: 1) setting a quit date; 2) emphasising complete abstinence; and 3) providing multi-session support [195]. Counselling, either individually or in a group situation, face-to-face or by telephone, has been demonstrated to help people stop smoking [207, 208, 317].

Individual counselling (either single or multiple sessions) from a trained smoking cessation professional can help smokers quit (RR 1.39, 95% CI 1.24-1.57) [208], but there is insufficient evidence on whether more intensive counselling is more helpful [325]. There is no evidence showing one behaviour change model is more effective than others (e.g. cognitive behavioural therapy, withdrawal-orientated treatment, and/or motivational interviewing) [189].

The chances of quitting are doubled in group programmes (compared to self-help) where individuals are given the opportunity to learn smoking cessation behavioural techniques whilst supporting other group members (RR 1.98, 95% CI 1.60-2.46) [317]. Although group therapy was better than self-help and less intensive interventions, there is not enough evidence to evaluate whether groups are more effective than intensive individual
counselling. Not all smokers want or can attend group sessions but they are regarded as helpful for those who do attend group sessions [317].

A Cochrane Collaboration systematic review found proactive telephone counselling (defined as those calls initiated by quit-lines to clients) was helpful (RR 1.29, 95% CI 1.20-1.38) [207], cost effective and can have a very wide reach geographically [194]. Although there is limited evidence about the optimal number of calls, there is some evidence of a dose-response where one or two brief calls are less likely to provide a measurable benefit. Three or more calls increases the chances of quitting compared to a minimal intervention such as providing standard self-help materials, or brief advice, or compared to pharmacotherapy alone [207]. Evidence suggests three or more telephone calls to a patient increase the chances of quitting when compared with a single telephone call (RR 1.37, 95% CI 1.26-1.50) [207].

Regarding the length and intensity of counselling sessions, interventions of >10 minutes session length are more successful than no contact (OR 2.3, 95% CI 2.0-2.7) or shorter session length (3-10 minutes) (OR 1.6, 95% CI 1.2-2.0) [325]. There is also a strong dose-response relationship between total contact time (i.e. the number of sessions multiplied by the session length) and successful treatment outcomes, but no extra benefits are seen for contact >90 minutes (OR 3.0, 95% CI 2.3-3.8) [325]. Four or more sessions appears to be particularly effective for smoking cessation (OR 1.9, 95% CI 1.6-2.2) [325].

In light of the evidence above, individual counselling was offered in the current intervention. Although it is standard practice for Arthritis NZ to offer a predominately telephone-based support service, it was decided that the initial needs assessment (week 0)
meeting would be face-to-face whenever possible to help encourage the development of a supportive relationship between the Arthritis Educator and the participant. If a face-to-face meeting was not possible, telephone support would be offered. For the current intervention three follow-up support telephone calls spaced at weeks one, four and eight from Arthritis NZ educators to aid quitting were included.

5.3.1.2 Pharmacological interventions

Smokers can be helped to quit smoking by using medications, including all types of NRT, antidepressants (bupropion ‘Zyban’), and nicotine receptor partial agonists (varenicline ‘Champix’ or ‘Chantix’). These smoking cessation aids are fully-subsidised in NZ and for this reason are examined in the following section.

Nicotine replacement therapy

There are five different NRT products available in NZ: transdermal patches, gum, lozenges, mouth spray, and inhalators, of which three are currently funded by the NZ government (patches, gum and lozenges) [195]. Nicotine replacement therapy of any type has been shown to help smokers quit relative to placebo (RR 1.60, 95% CI 1.53-1.68) and can increase the rate of quitting by 50-70% [205]. The main mechanism of NRT is replacement of the nicotine that would be otherwise be obtained by smoking. Nicotine replacement therapy reduces the severity of nicotine withdrawal symptoms and is beneficial because it does not contain the harmful chemicals that are found in tobacco. It is generally used continually for eight to 12 weeks but can be used for longer periods [327], and is considered safe to use and highly cost effective. Potential side effects are more likely when NRT is used in high doses, and include headaches, nausea and difficulties sleeping [205]. Over half
of patch users (54%) report skin sensitivity and this is the only side-effect that has been reported to interfere with use [205]. NRT can be used safely by people with CVD, but for those who have experienced a serious CVD event in the past two weeks or have uncontrolled hypertension, their consulting physician should be involved in the decision to recommend NRT [328, 329]. Use in pregnancy carries a small potential risk to the foetus but is seen as having less potential risks than continued smoking in pregnancy [195].

Evidence suggests NRT is more effective in people who smoke 10 or more cigarettes a day [330] and higher dose NRT products are more effective than lower doses, although the additional benefit is small (RR 1.14, 95% CI 1.01 to 1.29) [205]. Combining two or more forms of NRT also increases abstinence rates by one third (RR 1.34, 95% CI 1.18-1.51) [205]. The efficacy of NRT appears to be independent of the intensity of any additional support (RR 1.14, 95% CI 0.88-1.47) [205]. There is limited evidence that NRT can be effectively used to help smokers reduce the number of cigarettes smoked per day (RR 1.25, 95% CI 1.03-1.50) [205]. This strategy termed ‘cut down then quit’ approach or ‘preloading’ can be used by smokers to help cease smoking in the long term [205, 331].

**Bupropion**

Bupropion is an atypical antidepressant that reduces nicotine withdrawal severity. It is thought to act through its ability to inhibit the neuronal reuptake of noradrenaline and dopamine [332]. It may also work by improving depressed mood [319]. It is a funded stop-smoking medication in NZ and is cost-effective to use [195]. It is taken for seven weeks, and is only available by prescription due to known contraindications (e.g. if the person has a history of seizures; current or past eating disorders) and drug interactions (e.g. antidepressants, antipsychotics, anti-malarials, and systemic steroids). Overall, bupropion
is as effective as NRT and more effective than placebo (RR 1.69, 95%CI 1.53-1.85) [319]. It is safe and effective for use in people with stable CVD and respiratory diseases including COPD [332].

**Varenicline**

Varenicline was specifically developed as a smoking cessation medication and is an analogue of crytisine [333]. Although Varenicline is a nicotinic acetylcholine receptor partial agonist, it also possesses antagonist properties, and some combination of these actions is involved in the mechanism of Varenicline as a smoking cessation aid [333]. It is thought that Varenicline competes with nicotine for the same receptor sites in the brain, thereby reducing both nicotine withdrawal severity and the rewarding properties of nicotine to the individual [333].

Varenicline is very effective compared to placebo (RR 2.27, 95% CI 2.02-2.55) and is more effective than NRT (OR 1.57, 95% CI 1.29-1.91) or bupropion (RR 1.52, 95% CI 1.22-1.88) in the general population [319]. Because of its nicotine antagonist properties, it is not recommended to be used in conjunction with NRT [325]. In NZ, varenicline is funded subject to Special Authority criteria for patients, who must have completed two trials of NRT or one trial of bupropion prior to its use. It is available only by prescription for 12 weeks [195]. Post-marketing surveillance has raised some concerns about possible links between varenicline and serious CVD adverse events, although this association has since been questioned due to less than optimal methodology [334]. A recent meta-analysis of 22 RCTs did not find any significant increase in the risk serious CVD adverse events from using Varenicline [334], thus the USA Food and Drug Administration have stated the benefits of the drug outweigh the risks [335].
Bupropion and varenicline must be prescribed by a registered medical practitioner, but NRT can be prescribed by any health professional in NZ who has received the basic ABC pathway approach for smoking cessation training and registration [188]. For this reason NRT in the form of patches, gum or lozenges, was chosen as the form of NRT to be offered in the current intervention.

5.3.1.3 Combination Therapy Support

Clinical trials have supported combining behavioural support and pharmacological therapy [199]. However, there is currently no direct estimate of the benefits expected from combining these two types of treatment [199]. Combining behavioural support with pharmacotherapy significantly aids cessation by just over 80% as compared to a smoker who is not utilising either (RR 1.82, 95% CI 1.66 to 2.00) [199]. Increasing the amount of behavioural support interventions as an adjunct to pharmacotherapy minimally increased the chances of sustained smoking cessation by about 10 to 25% (RR 1.16, 95% CI 1.09-1.24) compared to pharmacotherapy alone. Although a small effect, this is still regarded as important [321].

Overall, the provision of combined behavioural and pharmacological support increases the success of people trying to quit smoking. This suggests that both types of smoking cessation aids should be used concurrently. Therefore, a combined therapy support approach was offered in this smoking cessation intervention designed for people with RA.
5.3.1.4 **Timing of interventions**

Condensing behavioural support into the first two weeks of smoking cessation is known as front-loading [179]. Front-loading the treatments in a smoking cessation programme could be beneficial because approximately 60-70% of smokers who quit will relapse by two weeks post-cessation [179]. Those who can remain abstinent for longer than two weeks have a 50% higher likelihood of remaining abstinent at one year post-cessation [179]. Although this is an area that requires further research, front-loading treatments has been suggested to be a promising treatment model.

The steering group therefore agreed that front-loading patient contact would be included in the current intervention. We planned the intervention to include an initial baseline needs assessment at week 0, followed by continuing support at weeks one, four and eight with generic emails sent at weekly intervals for 12 weeks with support, advice and tips for quitting.

5.3.1.5 **Length of intervention**

In accordance with international recommendations for smoking cessation programmes the optimum duration for the RA specific intervention was set at three months [202, 313, 336]. Figure 5-1 demonstrates the format for the 3-month smoking intervention designed for people with RA following the recommendations of the steering group.
Content of the Targeted Smoking Cessation Intervention

In order to address the five smoking cessation barriers in RA identified in the previous chapter [285], the steering group agreed upon the following intervention strategies for a tailored intervention in smoking cessation for people with RA.

5.3.2.1 Support

Lack of support was identified as a major barrier to smoking cessation in RA. Individuals feel unsupported in smoking cessation attempts and isolated from other people with RA [285]. The steering group agreed upon the following intervention strategies to address this issue:
1) An initial needs assessment by telephone or face-to-face with an Arthritis NZ Educator to identify individual barriers to smoking cessation and offer individualised support based on participant preferences.

2) Three follow-up contacts by telephone or face-to-face and continued counselling from Arthritis NZ to address barriers to quitting.

3) Generic weekly smoking cessation tips to be sent for 12 weeks (Appendix 9 and 10).

4) A support webpage where all support material could be accessed.

5) Smoking Cessation education course for the Educators: NZ Heart Foundation Stop Smoking Practitioner Training Course [337].

5.3.2.2 Education about the links between smoking and RA

As identified in Chapter 4, people with RA who participated in the qualitative study were aware of the general health risks associated with smoking, but many were not aware of specific relationships between smoking and RA. Those people with RA did not readily identify a link between the severity of their RA and their smoking [285]. Consequently, it was agreed that the novel intervention would include a single-page leaflet designed by the Steering Group outlining the association between adverse outcomes and smoking in RA. This leaflet included information on the risks of increased disease activity, reduced efficacy of RA medications, and the potential for more joint damage in those who smoke (Appendix 11). This leaflet also highlighted the additional risk posed by smoking in terms of CVD and osteoporosis: comorbid conditions which are more common in RA than the general population even in non-smokers.
5.3.2.3 Pain Management

Chronic widespread pain is a common feature of RA [338]. Participants in the qualitative study suggested that they used smoking as a distraction from the pain associated with RA [285]. Individuals with chronic pain may be motivated to smoke because of a belief that smoking could help them cope with their pain or that quitting smoking would be more difficult because of their pain, although recent studies refute this [297-299]. Therefore, pain management strategies formed an integral part of this intervention. Arthritis Educators are knowledgeable in discussing pain management issues, and hence the following interventions would be offered (Appendix 12):

4) Arthritis NZ ‘Managing your Pain’ booklet.
5) Advice on specific strategies for basic pain relief such as complementary therapies and taking medications as advised.
6) Advice on pacing, managing fatigue, and sleep hygiene.
7) Referral to rheumatologist or their GP for pain management if required.

5.3.2.4 Exercise

The people with RA in the qualitative study found it difficult to exercise due to joint pain and had a perception that exercise may worsen their arthritis. As a result many felt that they could not undertake exercise as an alternative distraction to smoking [285]. However, there is good evidence that physical activities not only reduce cigarette cravings [302] but have additional health benefits in RA [303]. Importantly, exercise has not been shown to exacerbate disease activity in RA [303]. The steering group agreed that the following exercise resources should be made available for the intervention, and participants were encouraged to make use of resources appropriate to their needs (Appendix 13):
1) A booklet with specific strengthening hand exercises (produced by the pharmaceutical company Abbott) (Appendix 13-a and-b).

2) A booklet on ‘general exercises for RA’ (also produced by Abbott) (Appendix 13-c).


4) A DVD presenting home-based exercise (produced by Arthritis NZ).

5) A handout on local community exercise resources (with details of places, dates and time schedule) (Appendix 13-e).

6) A handout on local hydrotherapy classes available locally (Appendix 13-f).

7) Referral to a physiotherapist or occupational therapist.

8) A pedometer.

5.3.2.5 Coping

In the qualitative study, smokers with RA reported that smoking helped them to cope with the frustrations of living with RA. Therefore, support for individuals to develop alternative coping mechanisms were seen as a key component of any intervention [285]. Research shows that active coping skills lead to better health perceptions for people with RA [304]; those who do not use active coping strategies appear to be more at risk of psychological comorbidities [234]. Smokers with anxiety symptoms often report using smoking as a way of coping [285]. Using smoking to cope with negative health perceptions is detrimental to successful smoking cessation [219], whereas high coping effectiveness leads to better general health perception for people with RA [304]. Helping people with RA to identify
triggers for smoking and providing alternative self-management strategies may assist with smoking cessation. The steering committee recommended the following interventions:

1) A smoking triggers diary to enable participants to identify their smoking triggers (Appendix 14).

2) A discussion with the Arthritis Educators of goals and self-management to change coping strategies away from smoking.

The following Table 5-2 outlines the key aspects of this smoking cessation intervention. Table 5-3 outlines the timing of interventions that were detailed above.
<table>
<thead>
<tr>
<th>Theme</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Education</strong></td>
<td>Handout: ‘The link between smoking and RA’</td>
</tr>
<tr>
<td><strong>2. Exercises</strong></td>
<td>Abbott Handout: ‘Hand exercises for RA’</td>
</tr>
<tr>
<td></td>
<td>Abbott Handout: ‘General exercises for RA’</td>
</tr>
<tr>
<td></td>
<td>Arthritis NZ Booklet ‘Exercises to keep you moving’</td>
</tr>
<tr>
<td></td>
<td>Arthritis NZ DVD: home based exercise ‘Keep moving’</td>
</tr>
<tr>
<td></td>
<td>Handout: ‘Community exercise classes for RA’ (times, dates and locations)</td>
</tr>
<tr>
<td></td>
<td>Handout: ‘Hydrotherapy classes’ (times, dates and location)</td>
</tr>
<tr>
<td></td>
<td>Physiotherapist or Occupational Therapist referral</td>
</tr>
<tr>
<td></td>
<td>Pedometer</td>
</tr>
<tr>
<td><strong>4. Support</strong></td>
<td>Advice from Arthritis Educator: Managing Pain / Keep a Pain Diary</td>
</tr>
<tr>
<td></td>
<td>Advice from Arthritis Educator: Complementary therapies</td>
</tr>
<tr>
<td></td>
<td>Advice from Arthritis Educator: Managing Medications</td>
</tr>
<tr>
<td></td>
<td>Advice from Arthritis Educator: Pacing</td>
</tr>
<tr>
<td></td>
<td>Advice from Arthritis Educator: Managing fatigue</td>
</tr>
<tr>
<td></td>
<td>Advice from Arthritis Educator: Disturbed Sleep</td>
</tr>
<tr>
<td></td>
<td>Referral to GP (to revise analgesia)</td>
</tr>
<tr>
<td></td>
<td>12 Weekly Smoking Cessation Advice Emails (from Quitline NZ)</td>
</tr>
<tr>
<td></td>
<td>Support Website: ‘Smoking Cessation and RA’</td>
</tr>
<tr>
<td><strong>5. Coping</strong></td>
<td>Handout: One week diary for ‘Identifying smoking triggers’</td>
</tr>
<tr>
<td></td>
<td>Advice from Arthritis Educator: Goals and Self-management</td>
</tr>
<tr>
<td></td>
<td>Discuss available support (social, psychological and physical)</td>
</tr>
<tr>
<td></td>
<td>Use of NRT documented and discussed</td>
</tr>
</tbody>
</table>
Table 5-3: Contacts and content for the smoking cessation intervention for people with RA

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Intervention Group</th>
</tr>
</thead>
</table>
| **Week 0** | (i) General information  
(ii) ABC pathway for smoking cessation intervention  
(iii) Standard intervention pack given and explained  
(iv) Needs assessment with Arthritis NZ Educator (1st contact)  
   Contact details  
   Assessment: Main concerns with RA  
   How is RA affecting daily activities?  
   How do they manage their RA?  
   Intervention Checklist - information discussed and tailored to study participant  
   1. Education (Handout)  
   2. Exercises (Handouts)  
   3. Pain management  
   4. Coping Strategies  
   5. Available support  
   Use of NRT documented |
| **Week 1** | Follow-up contact with Arthritis NZ Educator (2nd contact)  
General well-being since intervention  
Review of interventions requested and/or used/useful  
Review of current smoking status  
Email reminder: ‘Smoking and your body’ |
| **Week 2** | Email reminder: ‘Stress, feeling down and cravings’ |
| **Week 3** | Email reminder: ‘Money benefits’ |
| **Week 4** | Follow-up contact with Arthritis NZ Educator (3rd contact)  
General well-being since intervention  
Review of interventions requested and/or used/useful  
Review of current smoking status  
Email reminder: ‘Social Situations’ |
| **Week 5** | Email reminder: ‘Weight gain’ |
| **Week 6** | Email reminder: ‘The smoking addiction’ |
| **Week 7** | Email reminder: ‘Health benefits’ |
| **Week 8** | Follow-up contact with Arthritis NZ Educator (4th contact)  
General well-being since intervention  
Review of interventions requested and/or used/useful  
Review of current smoking  
Email reminder: ‘Nicotine patches, gum and lozenges’ |
| **Week 9** | Email reminder: ‘Why get help?’ |
| **Week 10** | Email reminder: ‘Setbacks and trying to quit again’ |
| **Week 11** | Email reminder: ‘Quit success stories’ |
| **Week 12** | Email reminder: ‘How are other quitters doing?’ (Quitline blogs) |
5.4 Discussion

This chapter describes how the findings about smoking cessation needs of people with RA from a qualitative study were translated into a targeted intervention. This process will enable researchers and rheumatology practitioners to replicate the process and/or make use of the intervention that was devised. This novel intervention adds to the current state of knowledge regarding smoking cessation in special populations, and provides the opportunity to evaluate the benefit and efficacy of a targeted smoking cessation intervention for people with RA.

Nicotine dependence can be regarded as a chronic condition that often requires repeated interventions and multiple attempts before successful cessation, particularly for people with RA [209]. The best evidence identified by Cochrane Systematic Reviews has established that smokers in the general population using a combination of evidence-based treatments which includes pharmacotherapy and behavioural support have almost three times of the rate of quitting when compared with those who use neither [3, 200, 306]. Smoking cessation is one of most important modifiable lifestyle factors for people with RA. Quitting can improve health outcomes; therefore smoking cessation should be a key goal in the management of RA. This process of designing a pragmatic tailored smoking cessation intervention for people with RA made use of evidence from the general population and addressed previously identified barriers for quitting smoking by matching intervention components that aimed to impart skills necessary for self-management of RA and thus increase the chance of smoking cessation.
This research builds on previous research on smoking cessation in RA, which has either focused on multiple health interventions for people with RA, including but not limited to smoking cessation, or tailored smoking cessation interventions in multiple rheumatic conditions (Chapter 2). The more intensive smoking cessation intervention as outlined in this chapter may improve quit rates over and above that observed in previous studies.

A healthcare intervention is considered complex if it includes a number of separate and interacting components that are important to the proper functioning of the intervention. The Medical Research Council’s framework for complex interventions to improve health provides guidance for developing and evaluating pragmatic RCT interventions with multiple and complex outcomes [339]. This framework recognises it is often difficult to identify which particular ingredient of a complex intervention is the most effective [339]. Developing a smoking cessation intervention for people with RA is an example of a complex intervention due to the interacting components within the experimental and control interventions (smoking cessation advice); the difficulty of the behaviour required by those receiving the intervention and controls (smoking cessation in both groups); and the flexibility or tailoring of the intervention that was required.

The strengths of this intervention’s development process were the ability to package the resources to be relevant for the individuals with RA depending upon their perceived support and educational needs. Therefore the participants could choose any of the intervention suggestions depending on their needs and goals. The active engagement of individuals with their own health care decisions has been shown to improve their health status (patient-centred care) and which is a goal of this intervention [340, 341]. The use of evidence-based
smoking cessation treatments enables the trial outcome regarding smoking cessation to be internationally comparable to other RCTs.

The process that was followed has limitations. Only two Arthritis Educators were involved in development of the intervention. Involving more Educators, and their international counterparts, would be beneficial in future research developing an international consensus on recommendations for smoking cessation interventions for people with RA. The intervention content was also bound by the support services available from Arthritis NZ, although this reflects pragmatic delivery of a complex intervention. Many of the difficulties of complex interventions are related to the difficulty of standardising the design and delivery of the interventions; local context sensitivity; the difficulty of applying the experimental methodology to general service delivery; and the length and complexity of linking the intervention with the chosen outcome [342].

5.5 Conclusion

The smoking cessation intervention for people with RA that was developed is grounded in previous research, informed by patient opinion, and incorporates successful methodologies and evidence-based smoking cessation intervention components used in recent RA, arthritis or rheumatology studies of health, lifestyle and smoking interventions. In contrast to previous studies in this field, this intervention is focused solely on smoking cessation support for people with RA and offers a more comprehensive and intensive support whilst allowing for the individualisation of the support package based on the support needs and preferences of individuals. Overall, this innovation enables the targeting of smoking
cessation barriers in people with RA by empowering individuals with problem-solving strategies, which may lead to improvements in life expectancy through addressing barriers to smoking cessation in RA. This approach, if successful, also enables an immediate translation into clinical practice, which could be rolled out internationally within existing arthritis service frameworks. A pilot study was undertaken to evaluate the efficacy of this intervention, which is described in the following chapter.
6 RANDOMISED CONTROLLED TRIAL: PILOT STUDY OF A RHEUMATOID ARTHRITIS SPECIFIC SMOKING ABORTION PROGRAMME IN COLLABORATION WITH ARTHRITIS NZ

The original research in this chapter was presented as a poster at the 2014 ACR/ARHP Annual Meeting in Boston, MA during November 2014. The published abstract [343] is included in Appendix 15.

6.1 Introduction

Recently, targeted and tailored smoking cessation programmes have been suggested for special populations of smokers, such as people with RA, recognising there are specific barriers that make smoking cessation more difficult for some groups of smokers [212]. Targeting smoking cessation programmes to particular populations of smokers enables specific medical and psychosocial issues to be addressed that are not being met using traditional programmes. Tailoring of programmes enables the individual needs of smokers to be accommodated depending upon their particular disease-related issues. Therefore, the next step in the research process was to test the efficacy of this tailored intervention outlined in the preceding chapter in a pilot study. This chapter describes and discusses the outcome from this pilot study.
6.2 Aim

The primary aim of this pilot study was to determine whether a targeted 3-month smoking cessation intervention programme for people with RA increases smoking cessation rates at 6 months compared to standard smoking cessation advice.

6.3 Methods

6.3.1 Study Design

The study design was a randomised parallel group RCT. Current smokers with RA were recruited. Participants were randomised on a 1:1 ratio into the control or the intervention arms of the study. All participants were given the current standard of care for smoking cessation at Christchurch Hospital, the ‘ABC pathway’ (Appendix 8). Those randomised to the intervention arm received additional advice, education and support from Arthritis NZ Educators, based on the needs of people with RA as identified in the qualitative study (Chapter 4) with the intervention design described in Chapter 5. Recruitment and data collection were conducted between November 2012 and March 2014.

Ethical approval was given by the New Zealand Multi-Region Ethics Committee (12/STH/28). All participants gave written informed consent. The trial identification number was ACTRN12612001076864 and was prospectively registered on 8 October 2012.
6.3.2 Study Timeline

The 6 month trial timeline for the study is shown in Figure 6-1.

![Figure 6-1: Pilot study timeline](image)

- **ABC**: The control arm received the current local standard of care (‘ABC pathway’) and structured follow-up interviews with me (the researcher) at three and six months.
- **ABC+**: The intervention arm received the same current local standard of care (‘ABC pathway’) and follow-up interviews PLUS additional targeted advice from trained Arthritis NZ Educators for three months, with regular contact face-to-face or by telephone, and weekly email contact, as described in the previous chapter. Advice was tailored to participants’ specific needs from a range of intervention tools developed from previous qualitative consultation and focused on the five
previously identified key barriers. These participants also undertook structured follow-up interviews with me (the researcher) at three and six months.

### 6.3.3 Study Intervention Timeline

The smoking cessation intervention continued over three months, as follows:

**Week 0:**
- Informed consent and baseline data collection with researcher
- Current local standard of care for smoking cessation: ‘ABC pathway’ programme administered by rheumatology specialist nurse
- Initial face-to-face meeting with Arthritis NZ Educators to determine relevant interventions (needs assessment)

**Week 1, 4 & 8:** Telephone intervention follow-up from Arthritis NZ Educators

**Week 1-12:** Email reminders and tips based on Quitline NZ

The schematic showing the timeline of the 3-month smoking cessation intervention is displayed in Figure 5.1 in the previous chapter.

### 6.3.4 Participants

#### 6.3.4.1 Eligibility Criteria

Participants were eligible to enter the study if they were aged ≥18 years, with a diagnosis of RA as defined by the 2010 ACR/EULAR Criteria for RA [54]. Participants must be current smokers and be able to adhere to the requirements of the study. Participants who
were unable or unwilling to give written informed consent or had significant serious medical illness or serious mental health issues were excluded.

### 6.3.4.2 Settings and locations

Participants were identified from Christchurch Hospital Rheumatology outpatients, inpatients, and patient management systems. Advertising was also undertaken in the local newspaper (The Christchurch Press) and on public noticeboards throughout Christchurch Hospital (Appendix 16). Potential participants were contacted by telephone and invited to participate.

### 6.3.5 Study Outcomes

#### 6.3.5.1 Primary outcome measure

The primary outcome measure was self-reported smoking abstinence at six month’s post-randomisation into the study.

A participant was recorded as having quit smoking based on:

a) Participant self-report of smoking abstinence, measured in days from their identified quit date with no subsequent smoking. This measurement is continuous abstinence.

b) The recalled smoking status at 6 months post-randomisation was used for participants who had their 6-month follow-up interview delayed longer than one month.
6.3.5.2 Secondary outcome measures

There were two secondary outcome measures:

1) Reduction in cigarette consumption at six months. This was defined as the difference between the baseline daily smoking rate and 6-month daily smoking rate.

2) Identification of the aspects of the intervention that were accepted by each participant. In addition, feedback was sought from participants about what aspects of the programme they felt were most helpful.

Smoking status for secondary outcomes was assessed in four categories in relation to behaviour over the last 4 weeks: no smoking; reduced consumption from normal; five or fewer cigarettes over the past month, and no change [313].

6.3.6 Sample Size

A biostatistician was consulted to determine a suitable sample size to test the feasibility of this intervention. A cohort of 40 participants was considered to be an appropriate sample size for this pilot study as described in Chapter 3.

6.3.7 Randomisation

The random allocation sequence for 48 potential participants was generated by a biostatistician using an Excel spreadsheet in six blocks times eight allocations. This meant for every eight participants, there would randomly be four control and four intervention
allocations, therefore improving the chance of an even allocation of participants regardless of the endpoint size of the study.

Implementation of randomisation was divided into two sections:

1. Enrolment, informed consent (Appendix 17), general study information sheet (Appendix 18), and baseline questionnaires (Appendices 1a-k) were undertaken by the researcher for all participants.

2. The ‘ABC pathway’ (Appendix 8) was provided by one of two rheumatology specialist nurses trained to deliver the ‘ABC pathway’ to all participants. The rheumatology specialist nurse opened the uniquely numbered sealed opaque envelope which contained the randomisation allocation: control or intervention. The standard intervention pack was given to intervention participants.

Until opening the sealed randomisation envelope, the nurse and participant were blinded to the randomisation allocation. The researcher remained blinded to participant allocation until the 3-month follow-up interview with all study participants.

6.3.8 Needs Assessment Visit

After completion of the randomisation process, the rheumatology specialist nurse notified the Arthritis NZ Educators of the participants contact details. The intervention participants were provided with a standard intervention information pack because the needs assessment meeting with the Educators could feasibly be by telephone. This also enabled the participants to be familiar with the material prior to the needs assessment. The standard intervention pack included an educational handout (Appendix 11) that explained the links
between smoking and RA, a pain management booklet for RA (Appendix 12), two RA specific exercise handouts (Appendices 13-b and 13-c), and a smoking triggers diary (Appendix 14).

One of two Arthritis NZ Educators subsequently contacted each participant to organise a needs assessment meeting that would be undertaken within the same week as randomisation into the study. The needs assessment meeting included a discussion to assist the participants to set a quit date, to identify their own perceived barriers to quitting smoking, and to decide which intervention components would be most suitable to meet their individual goals and preferences. Both of the Educators undertook a two-day intensive smoking cessation provider course as offered by the NZ Heart Foundation. The needs assessment checklist was developed in consultation with Arthritis NZ (Appendix 19).

### 6.3.9 Data Collection Measures and Verification

Quantitative baseline and follow-up data was collected from all study participants immediately following informed consent in week 0, and at the two follow up interviews at three and six months. The information was collected from a variety of sources. A participant’s duration of RA, comorbidities and use of DMARDs were extracted from hospital records. Age, gender, ethnicity, level of formal education, employment status, any joint surgery, and smoking history were self-reported. Standardised questionnaires on demographic characteristics, health status, and smoking habits were used. Participants completed the HAQ, the PI HAQ, the ASES, the HAD, the PSS, the EQ-5D, the EQ-VAS, the SSEQ, a smoking history questionnaire, and the FTND. The methods Chapter 3, discusses the use of these questionnaires in depth.
The data from the intervention contacts (needs assessment meeting at Week 0 and contacts at Weeks 1, 4 and 8) were recorded onto participant contact sheets by the Arthritis NZ Educators (Appendix 20). The needs assessment data included each participant’s RA management and smoking cessation concerns. Identification of which intervention components were accepted by each participant was recorded, as was their current smoking status and use of NRT. Written summaries were also completed regarding ongoing advice and support discussions. Feedback was sought from participants about what aspects of the programme were most useful during the 3- and 6-month follow-up interviews with the researcher (Appendix 21).

6.3.10 Statistical Methods Analysis

Quantitative data was analysed using SPSS software. Between group comparisons for primary (smoking cessation at 6 months) and secondary outcomes (sustained reduction in smoking at 6 months) were undertaken, together with baseline and follow-up demographics, disease and psychosocial factors associated with smoking cessation. Statistical analysis employed 1-way analysis of variance (ANOVA), \( \chi^2 \) tests or Fisher’s exact test of independence. An intention-to-treat (ITT) approach was utilised, in which data from all randomised smokers was included in the analysis.
6.4 Results

6.4.1 Introduction

The next section outlines the results from the quantitative aspects of this pilot study. The qualitative aspects of the study are explored in Chapter 7, which involve a closer look at the motivations, beliefs and individual experiences of study participants.

6.4.2 CONSORT Schematic of Study

The participant flow for the pilot study using the CONSORT flow diagram schematic is illustrated in Figure 6-2.
Enrolment

97 Assessed for eligibility

58 Excluded (60%)
- 23 Not smoking (24%)
- 23 Declined to participate (24%)
- 5 Unable to Contact (5%)
- 7 No contact after information sent (7%)

39 Randomised (40%)

Allocation

19 Allocated to ABC+ (3 month Intervention)
- 19 Received allocated ABC+ (100%)
- 0 Did not receive allocated ABC+

20 Allocated to ABC (Control)
- 20 Received allocated ABC (100%)
- 0 Did not receive allocated ABC

Follow-Up

3 Withdrawed from follow-up
16 Completed follow-up

0 Withdrawed from follow-up
20 Completed follow-up

Analysis

19 Analysed (Baseline)
11 Analysed (3 month follow-up)
16 Analysed (6 month follow-up)
0 Excluded from analysis

19 Analysed (Baseline)
15 Analysed (3 month follow-up)
19 Analysed (6 month follow-up)
1 Excluded from analysis: did not have RA

Figure 6-2: CONSORT flow diagram illustrating participant flow
6.4.3 Study Recruitment

Thirty-nine participants were enrolled in the study. Recruitment was undertaken between 26 November 2012 and 20 September 2013 (10 months). The recruitment process took longer than initially anticipated. In the first week of the study, seven participants were recruited and by the end of the fourth month half of the participants had been recruited. By the end of May 2013 there were 32 participants in the study. However, recruitment became increasingly difficult and by the end of September 2013 with only a further seven participants were added. A decision was made to stop recruiting at 39 participants so as to not delay the end of the study. As described in the CONSORT diagram above, one participant who identified as having RA was subsequently found not to have RA, but another rheumatic condition, giving a final number as 38 participants. The following Figure 6-3 demonstrates the trend in recruitment throughout the recruiting phase showing the drop-off in recruitment after May 2013.

![Figure 6-3: Monthly recruitment rates](image)

Figure 6-3: Monthly recruitment rates
6.4.4 **Baseline Characteristics of Study Participants**

The baseline demographics for this study are described in Table 6-1.

*Table 6-1: Baseline demographic characteristics of participants*

*Data are presented as number (%) or mean (SD)*

<table>
<thead>
<tr>
<th>Category</th>
<th>Intervention (n=19)</th>
<th>Control (n=19)</th>
<th>Total (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>56.0 (12.1)</td>
<td>57.0 (11.9)</td>
<td>56.5 (11.8)</td>
</tr>
<tr>
<td>Disease Duration (Years)</td>
<td>8.2 (10.1)</td>
<td>7.2 (6.3)</td>
<td>7.7 (8.4)</td>
</tr>
<tr>
<td>Education (years) (Years)</td>
<td>12.2 (1.9)</td>
<td>11.3 (1.0)</td>
<td>11.7 (1.5)</td>
</tr>
<tr>
<td>Socio-economic deprivation</td>
<td>5.2 (2.8)</td>
<td>5.0 (2.9)</td>
<td>5.47 (2.7)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>12 (63%)</td>
<td>9 (47%)</td>
<td>21 (55%)</td>
</tr>
<tr>
<td>Male</td>
<td>7 (37%)</td>
<td>10 (53%)</td>
<td>17 (45%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>European</td>
<td>17 (90%)</td>
<td>17 (90%)</td>
<td>34 (88%)</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>2 (10%)</td>
<td>0 (0%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0%)</td>
<td>2 (10%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full-time</td>
<td>11 (58%)</td>
<td>8 (42%)</td>
<td>19 (50%)</td>
</tr>
<tr>
<td>Part-time</td>
<td>2 (11%)</td>
<td>2 (11%)</td>
<td>4 (11%)</td>
</tr>
<tr>
<td>Not working</td>
<td>6 (32%)</td>
<td>9 (47%)</td>
<td>15 (39%)</td>
</tr>
<tr>
<td>ACPA Positive</td>
<td>18 (95%)</td>
<td>16 (84%)</td>
<td>34 (90%)</td>
</tr>
<tr>
<td>RF Positive</td>
<td>17 (90%)</td>
<td>13 (68%)</td>
<td>30 (79%)</td>
</tr>
<tr>
<td>DMARDs Methotrexate</td>
<td>15 (79%)</td>
<td>12 (63%)</td>
<td>27 (71%)</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CVD</td>
<td>2 (11%)</td>
<td>2 (11%)</td>
<td>4 (11%)</td>
</tr>
<tr>
<td>COPD</td>
<td>2 (11%)</td>
<td>1 (5%)</td>
<td>3 (8%)</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>4 (21%)</td>
<td>3 (16%)</td>
<td>7 (18%)</td>
</tr>
<tr>
<td>Previous Joint Surgery</td>
<td>3 (16%)</td>
<td>1 (5%)</td>
<td>4 (11%)</td>
</tr>
</tbody>
</table>

*ACPA= anti-cyclic citrullinated peptide antibody; RF=rheumatoid factor; DMARDs=disease-modifying anti-rheumatic drugs; CVD=cardiovascular disease defined as ischaemic heart disease, angina, myocardial infarction; COPD=chronic obstructive pulmonary disease*
Baseline questionnaires show the intervention and usual care groups to be similar in their baseline demographic and disease-related characteristics.

The baseline functional and psychosocial characteristics for participants in this pilot study are shown in Table 6-2.

**Table 6-2: Baseline functional and psychosocial data of participants**

*Data are presented as mean (SD)*

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Intervention (n=19)</th>
<th>Control (n=19)</th>
<th>Total (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAQ</td>
<td>1.0 (0.8)</td>
<td>0.6 (0.6)</td>
<td>0.8 (0.7)</td>
</tr>
<tr>
<td>EQ VAS</td>
<td>69.4 (17.3)</td>
<td>74.8 (19.5)</td>
<td>72.1 (18.4)</td>
</tr>
<tr>
<td>EQ-5D</td>
<td>0.6 (0.2)</td>
<td>0.7 (0.2)</td>
<td>0.7 (0.2)</td>
</tr>
<tr>
<td>PI HAQ</td>
<td>2.6 (2.0)</td>
<td>2.1 (2.0)</td>
<td>2.3 (2.0)</td>
</tr>
<tr>
<td>ASES Pain</td>
<td>5.9 (1.7)</td>
<td>6.7 (2.1)</td>
<td>6.3 (2.0)</td>
</tr>
<tr>
<td>ASES Mood</td>
<td>7.0 (2.1)</td>
<td>7.5 (2.1)</td>
<td>7.2 (2.1)</td>
</tr>
<tr>
<td>HADS Anxiety</td>
<td>6.4 (3.7)</td>
<td>7.1 (3.9)</td>
<td>6.7 (3.8)</td>
</tr>
<tr>
<td>HADS Depression</td>
<td>4.1 (3.1)</td>
<td>5.0 (3.3)</td>
<td>4.5 (3.2)</td>
</tr>
<tr>
<td>PSS</td>
<td>22.7 (8.7)</td>
<td>20.6 (8.4)</td>
<td>21.7 (8.5)</td>
</tr>
<tr>
<td>Smoking self-efficacy internal</td>
<td>13.5 (6.1)</td>
<td>12.5 (6.4)</td>
<td>13.0 (6.2)</td>
</tr>
<tr>
<td>Smoking self-efficacy external</td>
<td>13.6 (5.2)</td>
<td>14.1 (6.1)</td>
<td>13.8 (5.6)</td>
</tr>
</tbody>
</table>

*HAQ=health assessment questionnaire; PI HAQ= personal impact HAQ; ASES= arthritis self-efficacy scale; HADS= hospital anxiety and depression scale; PSS=perceived stress scale; EQ VAS= Euroqol visual analogue scale; EQ-5D=Euroqol-5D;*

The responses from the questionnaires demonstrated no statistical differences between the intervention and control group participants with regard to psychosocial data including disability levels or impact, self-efficacy over mood or other symptoms of arthritis, nor in
scores for anxiety, depression or stress. The EQ-VAS scores were similar, suggesting both groups had a positive perception of their health status. The lack of difference in smoking self-efficacy demonstrates the similarities in these study groups with regard to their ability to refrain from smoking.

The self-reported baseline smoking history of participants is outlined in Table 6-3. Both study groups were similar in their smoking history. The Fagerström test indicated the participants had moderate dependency on nicotine. The measure of the average time to first cigarette indicated participants in both study groups smoked within 31 to 60 minutes of waking (mean 1.9, 95% CI 1.6-2.2) indicating a ‘low’ dependent phenotype of smoker [344]. Nearly all of the participants (90%) reported having received advice from a health practitioner to quit smoking within the last year. A daily smoking rate averaging at 16.5 cigarettes suggests a moderate dependence on nicotine.

Table 6-3: Baseline smoking history of participants
Data presented as mean (SD) or number (%)

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Intervention (n=19)</th>
<th>Control (n=19)</th>
<th>Total (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cigarettes per day</td>
<td>16.6 (8.2)</td>
<td>16.4 (6.9)</td>
<td>16.5 (7.5)</td>
</tr>
<tr>
<td>Smoking history (years)</td>
<td>40.6 (12.2)</td>
<td>41.7 (12.0)</td>
<td>41.2 (12.0)</td>
</tr>
<tr>
<td>Fagerström Nicotine Dependence</td>
<td>4.0 (1.6)</td>
<td>4.0 (2.2)</td>
<td>4.0 (1.9)</td>
</tr>
<tr>
<td>Time to first cigarette</td>
<td>1.9 (0.9)</td>
<td>1.9 (1.1)</td>
<td>1.9 (1.0)</td>
</tr>
<tr>
<td>Pack Years of Smoking</td>
<td>38.1 (27.3)</td>
<td>37.4 (18.5)</td>
<td>37.8 (22.9)</td>
</tr>
<tr>
<td>Exposed to indoor tobacco smoke at home</td>
<td>4 (21%)</td>
<td>8 (42%)</td>
<td>12 (32%)</td>
</tr>
<tr>
<td>Advice from Health Professional to quit smoking during the previous year</td>
<td>17 (90%)</td>
<td>17 (90%)</td>
<td>34 (90%)</td>
</tr>
</tbody>
</table>
6.4.5  **Study Participant Follow-up Contacts**

Three intervention participants withdrew from follow-up, two at three months and one at six months, although these participants did complete the intervention visits. All three participants stated they no longer wished to quit smoking. At the 3-month follow-up interview 26 of 36 study participants were interviewed. The remaining ten participants were not able to be contacted within one month after their respective 3-month follow-up date so they were not contacted again until six months post-randomisation. Thirty-five participants were interviewed for the 6-month follow-up interview. Of these, 17 of 35 study participants were not able to be contacted within one month of six months post-randomisation, and the mean delay for the 6-month follow-up contact was 64 days. This delay was unavoidable because most of the participants were not willing to make a special visit to the hospital for follow-up; therefore the interviews were either timed to correspond with the participant’s next outpatient visit, or were interviewed by telephone at a time convenient to each participant if their next out-patient appointment was not within three months.

Participants who were interviewed by telephone for the 3-month follow-up were mailed the demographic, psycho-socio and smoking history questionnaires for completion and return by mail (return postage was included). This was unsuccessful as a strategy as only one participant returned a completed questionnaire. This strategy was abandoned and only those participants who attended face-to-face follow-up interviews with the researcher completed the questionnaires. In total, the questionnaires were answered by 20 participants at the 3-month follow-up and 15 participants at 6-month follow-up. There was no difference in the response rates between intervention and control group participants.
6.4.6  Primary Outcomes

The primary outcome for the study found smoking cessation rates at six months for intervention arm was five of 19 participants (26%) and the control arm was four of 19 participants (21%). The difference in quit rates between the intervention and control groups was not statistically different (p=0.70). Risk ratio is one method to assess an effect size for categorical measures of two treatment groups in a RCT [345]. The risk ratio for this pilot study was RR 1.25 (95% CI 0.40-3.96). The number needed to treat (NNT) is another method used to assess an effect size, and for this study the NNT was 20. This value is the estimated number of patients who need to be treated with the intervention for one additional patient to quit smoking compared to the control group. [346].

For both arms of the study, the quit rates were high compared to general smoking cessation rates for interventions. The three intervention participants who were withdrew from follow-up were included in the quit rate calculation as smokers, which produces a more conservative estimate of quit rates. This is referred to as an ITT analysis. An ITT is a method of analysis in RCT in which all participants are included in analysis regardless of whether or not they completed or received the treatment [347].

The continuous abstinence rates revealed the amount of time (in continuous days) during the study a participant had ceased smoking, and is calculated at the endpoint of the study (six months following randomisation). Figure 6-4 shows that six of nine study participants who quit smoking had quit within the first week of the study. Of the remaining three participants, one intervention participant had quit soon after the 3-month follow-up.
interview and two control group participants had quit smoking during the last two weeks of the study. These results suggest that the intervention participants were more likely to have quit smoking during the intervention phase of the study, whereas the control group participants were more variable in the timing of their quitting.

![Figure 6-4: Days of continuous abstinence for all study participants](image)

6.4.7 *Secondary Outcomes*

The sustained reduction in smoking rates at six months was calculated as the difference between the baseline number of cigarettes smoked daily and the number smoked at six months (Table 6-4). There was no statistically significant difference between the smoking rates at baseline and six months in either study group.
Table 6-4: Secondary pilot study outcomes

Data presented as mean (SD) or %

<table>
<thead>
<tr>
<th>Secondary Study Outcome</th>
<th>Intervention</th>
<th>Control</th>
<th>Overall</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (No. of cigarettes per day)</td>
<td>16.6 (8.2)</td>
<td>16.4 (7.0)</td>
<td>16.5 (7.5)</td>
<td>0.92</td>
</tr>
<tr>
<td>6 months (No. of cigarettes per day)</td>
<td>9.9 (10.7)</td>
<td>8.6 (6.7)</td>
<td>9.3 (8.8)</td>
<td>0.67</td>
</tr>
<tr>
<td>Sustained reduction smoking (6 months)</td>
<td>41%</td>
<td>47%</td>
<td>44%</td>
<td></td>
</tr>
</tbody>
</table>

The number of smokers in each group that 1) quit, 2) had ≥50% reduction in daily smoking, or 3) had <50% reduction in daily smoking is shown in Figure 6-5. The overall reduction in percent of daily smoking rates was similar for both groups, and ranged from 20 to 96% for those participants who cut down their daily smoking rates; this equated to a 60% mean reduction in daily smoking for intervention participants and 57% mean reduction for control group participants. The absolute total reduction in daily smoking for both groups combined at 6 months equated to 276 less cigarettes smoked per day compared to baseline smoking.

Figure 6-5: Absolute reduction in smoking
6.4.8   **Factors Predicting Quitting in the Study**

The preceding sections identified that there were no statistically significant differences between the intervention and control arms in this study with regard to the primary outcome (quitting smoking at six months) and secondary outcome (sustained reduction in smoking at six months). The next section examines if there were any factors that predicted smoking cessation in the study participants.

6.4.8.1 **Disease duration and smoking cessation in RA**

There was no statistically significant difference in RA disease duration between the individuals who quit smoking and those who did not. This result is demonstrated in Table 6-5.

<table>
<thead>
<tr>
<th>Smoking Status at 6 months</th>
<th>≤2 years RA</th>
<th>&gt;2 years RA</th>
<th>Total</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quit</td>
<td>3</td>
<td>6</td>
<td>9</td>
<td>0.74</td>
</tr>
<tr>
<td>Non-quit</td>
<td>8</td>
<td>21</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>11</td>
<td>27</td>
<td>38</td>
<td></td>
</tr>
</tbody>
</table>

6.4.8.2 **Use of NRT**

All study participants were asked by the researcher to recall their NRT use during the two follow-up interviews. Twenty-six of 35 participants (74%) who were interviewed used NRT during the study period. Nicotine replacement therapy was used by more quitters...
(89%) than non-quitters (69%) but this result was not statistically significant, as demonstrated in Table 6-6.

Table 6-6: Use of NRT vs number quit smoking

<table>
<thead>
<tr>
<th>Smoking Status at 6 months</th>
<th>Intervention</th>
<th>Control</th>
<th>Used NRT</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quit (n=9)</td>
<td>4</td>
<td>4</td>
<td>8</td>
<td>0.60</td>
</tr>
<tr>
<td>Non-quit (n=26)</td>
<td>7</td>
<td>11</td>
<td>18</td>
<td></td>
</tr>
</tbody>
</table>

6.4.8.3 Advice by a health professional to quit smoking

Thirty-four of 38 participants had been advised by a health professional to quit smoking during the year prior to enrolment in this pilot study. There was no statistically significantly difference between the participants who quit and those who did not with respect to previous advice about quitting, as shown in Table 6-7.

Table 6-7: Advised by a health professional to quit smoking during the last 12 months vs number quit smoking

<table>
<thead>
<tr>
<th>Smoking Status at 6 months</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quit</td>
<td>8</td>
<td>1</td>
<td>9</td>
<td>0.95</td>
</tr>
<tr>
<td>Non-quit</td>
<td>26</td>
<td>3</td>
<td>29</td>
<td></td>
</tr>
</tbody>
</table>

6.4.8.4 Other factors associated with smoking cessation

Table 6-8 identifies baseline demographic, disease and psychosocial factors associated with smoking cessation. This table demonstrates that successful quitters showed a tendency towards having a greater number of years in education beyond high school and had smoked less across their lifetime but these findings were not significant. No other demographic, disease or psychosocial variables predicted quitting.
Table 6-8: Baseline demographics, disease and psychosocial factors associated with smoking cessation

All data are presented as mean (SD)*

<table>
<thead>
<tr>
<th>Baseline disease and psychosocial factors</th>
<th>Successful Quitters (n=9)</th>
<th>Non-quitters (n=29)</th>
<th>Total (n=38)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education (years)</td>
<td>12.6 (1.9)</td>
<td>11.5 (1.3)</td>
<td>11.7 (1.5)</td>
<td>0.06</td>
</tr>
<tr>
<td>Cumulative pack-years of smoking (years)</td>
<td>25.6 (10.4)</td>
<td>41.7 (24.5)</td>
<td>37.8 (22.9)</td>
<td>0.07</td>
</tr>
<tr>
<td>Current age (years)</td>
<td>55.2 (12.3)</td>
<td>56.9 (11.8)</td>
<td>56.5 (11.8)</td>
<td>0.72</td>
</tr>
<tr>
<td>Socio-economic deprivation</td>
<td>5.0 (3.3)</td>
<td>5.3 (2.6)</td>
<td>5.2 (2.8)</td>
<td>0.77</td>
</tr>
<tr>
<td>ASES pain</td>
<td>6.9 (2.2)</td>
<td>6.2 (2.0)</td>
<td>6.3 (2.0)</td>
<td>0.36</td>
</tr>
<tr>
<td>ASES mood</td>
<td>7.5 (2.0)</td>
<td>7.2 (2.1)</td>
<td>7.2 (2.1)</td>
<td>0.62</td>
</tr>
<tr>
<td>HADS anxiety</td>
<td>6.7 (3.4)</td>
<td>6.7 (4.0)</td>
<td>6.7 (3.8)</td>
<td>0.97</td>
</tr>
<tr>
<td>HADS depression</td>
<td>3.7 (1.9)</td>
<td>4.8 (3.5)</td>
<td>4.5 (3.2)</td>
<td>0.36</td>
</tr>
<tr>
<td>PSS stress</td>
<td>19.0 (7.5)</td>
<td>22.5 (8.8)</td>
<td>21.7 (8.5)</td>
<td>0.29</td>
</tr>
<tr>
<td>HAQ</td>
<td>0.6 (0.4)</td>
<td>0.9 (0.8)</td>
<td>0.8 (0.7)</td>
<td>0.26</td>
</tr>
<tr>
<td>PI HAQ</td>
<td>2.0 (1.4)</td>
<td>2.5 (2.2)</td>
<td>2.3 (2.0)</td>
<td>0.52</td>
</tr>
<tr>
<td>EQ VAS</td>
<td>76.3 (15.6)</td>
<td>70.8 (19.2)</td>
<td>72.1 (18.4)</td>
<td>0.44</td>
</tr>
<tr>
<td>EQ-5D</td>
<td>0.7 (0.2)</td>
<td>0.7 (0.2)</td>
<td>0.7 (0.2)</td>
<td>0.31</td>
</tr>
<tr>
<td>Smoking self-efficacy internal</td>
<td>12.7 (6.0)</td>
<td>13.1 (6.4)</td>
<td>13.0 (6.2)</td>
<td>0.85</td>
</tr>
<tr>
<td>Smoking self-efficacy external</td>
<td>14.3 (3.5)</td>
<td>13.7 (6.2)</td>
<td>13.8 (5.6)</td>
<td>0.77</td>
</tr>
<tr>
<td>Fagerström Nicotine Dependence</td>
<td>3.8 (1.6)</td>
<td>4.3 (1.9)</td>
<td>4.0 (1.9)</td>
<td>0.72</td>
</tr>
</tbody>
</table>

*Abbreviations: ASES, Arthritis Self-Efficacy Scale; HADS, Hospital Anxiety and Depression Scale; PSS, Perceived Stress Scale; HAQ, Health Assessment Questionnaire; PI-HAQ, Personal Impact Health Assessment Questionnaire; EQ-VAS, Euroqol visual analogue scale; EQ-5D, Euroqol health utility
6.5 Discussion

This chapter describes the outcomes from a pilot study designed to test the efficacy of a tailored smoking cessation intervention targeted for people with RA. The study did not find any statistically significant differences between quit rates at 6 months (p=0.70) or in sustained reduction in smoking rates (p=0.67). As no difference was observed in quitting rates between participants with less than two years RA disease duration compared to those with a longer disease duration (p=0.74), there was no evidence of a ‘teachable moment’ [6] in early diagnosis that might facilitate smoking cessation in people with RA. There were no statistically significant demographic, disease-related or psychosocial factors associated with smoking cessation in the study population, although people with fewer years of education (p=0.06) or longer history of smoking (p=0.07) were less likely to quit and may require particular cessation support. However, the findings from this study are clinically relevant due to the high number of smokers who were able to quit smoking and the high amount of sustained reduced smoking during the six month study period. The absolute reduction in number of cigarettes smoked by the study participants as a group equated to 276 less cigarettes every day, or over 100,000 cigarettes on an annual basis.

By comparing the quit rates from other studies of similar intervention intensity and/or similar study populations, it is apparent both arms of this smoking cessation intervention achieved a high quitting rate. Intensive clinical smoking cessation programmes provided by the NHS for the general population in the UK entail regular meetings (group or one-to-one) with a trained adviser using structured, withdrawal-oriented behavioural therapy combined with smoking cessation medications such as NRT, bupropion or varenicline [348]. These services were routinely monitored from 2003-2007, thereby providing an
overview of the treatment of over two million smokers in a clinical setting. A systematic
review in 2010 found intensive NHS treatments for smoking cessation resulted in 15% abstinence at one year [348]. Although the length of follow-up differs from the current study (one year versus six months), it is recognised smokers are most likely to relapse in the first six months following treatment rather than the second six months [349].

Despite the evidence that smoking increases the impact of many chronic diseases, including RA, the little research that has examined smoking cessation in chronic disease has primarily been focused on lung cancer, stroke and CVD [17]. The only study published to date of a smoking intervention designed specifically for patients with rheumatic diseases was a prospective study with an educational intervention in a single hospital in Spain. Quit rates of 11.8% at three months and 15.7% at 12 months respectively were reported, compared to previously recorded unassisted quitting rates of 4.6% over the past five years in the same patient population [9]. One hundred and fifty-two patients with rheumatic disease received verbal and written advice from a rheumatologist: the advice lasted from three to five minutes and was designed to be given at the end of regular medical visits. The advice included general benefits of quitting smoking, in addition to advice describing potential benefits in reduced CVD risks and specific advice involving the development of rheumatic diseases from smoking [9]. This advice session was followed by a more intensive session of 20 minutes of verbal and written advice from a rheumatology nurse, designed to detect individual barriers for not quitting. Personalised motivational advice of the best way to quit smoking was then provided. An offer of pharmacological support (varenicline) to patients with high nicotine dependence was given following their standard practice but NRT was not offered. Follow-up consisted of a telephone call in the third month from the rheumatology nurse that included further motivational advice [9]. The quit rates from the
study by Naranjo et al (11.8% at three months and 15.7% at 12 months) were similar to the NHS studies of intense general population smoking interventions. Interestingly, only nine percent of the study participants patients used varenicline, which included 12% of quitters (three of 24) [9]. Quit rates in that study may have been higher if pharmacological support was more widely used.

However, the context of that study means it is difficult to compare their findings to this pilot study. In NZ, the use of NRT is widespread because it is an essential component of the ‘ABC pathway’ and its efficacy as a pharmacological smoking cessation aid has been firmly established (Table 5.1). Thus, if NRT had been routinely offered in the Spanish study, they could have expected higher quit rates than were observed. In this study, being able to attribute the educational component to the quitting rates seen is not possible due to the highly complex nature of the intervention and the use of NRT. In addition to this, by including other rheumatic diseases in the participant pool, the results are not directly comparable to smoking cessation in RA.

In this pilot study, there was no difference between participants who quit smoking and those who did not with regard to their level of education (p=0.06), although this may have been a sample size issue. This finding differs to smoking cessation studies undertaken in the general population where demographic barriers to quitting smoking include less educational attainment (Table 2-12) [215, 350]. A USA study in 2005 examined the association between educational level and smoking status in a community-based sample of employed adults [350]. They found the prevalence of current-smoking was nearly three times higher in adults with less than high school diploma compared to those with a college degree (37% versus 14%), and the number of never-smokers was twice as high as those
with a college degree compared to having less than a high school diploma (60% versus 29%). In NZ, the equivalent of a college degree would be a university degree and less than high school diploma would be leaving high school with no or level one NCEA qualifications. A causal link between smoking and lower educational attainment has been established in a study of 1445 participants in the USA that found pack-years of smoking was higher in individuals who did not complete a high school education (RR 1.6, 95% CI 1.3-1.9) [215]. These individuals were also less likely to attempt to quit smoking (OR 0.3, 95% CI 0.2-0.6) [215]. Thus, the lower level of education in the study participants who did not quit in the pilot study, which averaged at one year less high school education (11.5 non-quitters versus 12.6 years quitters) might have had a small effect on quitting rates. Another USA study found that for individuals born between 1937 and 1956, one year of college education decreases smoking prevalence by 3.8% and increases smoking cessation by 5% [351]. In that study, an advanced education is theorised to raise awareness about the damaging effects of smoking.

In this study, there was no statistical difference found regarding participants who had a longer history of smoking and their likelihood to quit (p=0.07), although this finding may have been due to the small sample size. This finding also differs from smoking cessation studies where the number of cigarettes smoked per day has been shown to effect smoking cessation behaviour, where those who smoke a higher number of cigarettes are less likely to quit smoking [352, 353]. Either way, a lower educational attainment and a higher rate of smoking have been identified as predictors of less smoking cessation success (Table 2-12) [350].
Measuring a sustained reduction in daily smoking was the secondary outcome from this pilot study. The positive benefit of ≥50% reduction of smoking on established CVD risk factors has been recognised for many years [354]. An open study in 2001 in Sweden measured the effects on blood based CVD risk factors of eight weeks of reduced smoking prior to a quit smoking attempt at nine weeks. They found the eight weeks of smoking reduction resulted in clinically significant improvements in established CVD risk factors including high-density/low-density lipoprotein ratio [354]. Therefore, the sustained reduction in smoking in this pilot study can be regarded as helpful for people with RA given their elevated CVD risk factors associated with RA and smoking.

The smoking cessation intervention in this study was designed to utilise a combination of internationally recognised best-practice evidence-based smoking cessation treatments to maximise quitting probabilities for participants, whilst at the same time allowing for tailoring of intervention components to meet the needs of individual RA participants. The Cochrane Collaboration systematic reviews have established the most efficacious smoking cessation treatments include a combination of pharmacotherapy and behavioural interventions, which can demonstrate a quitting rate of 60-100% higher than brief advice alone [199]. The intervention in this study incorporated a large proportion of the recommendations for evidence-based smoking cessation treatments. The lack of significant difference between the intervention and control groups in primary outcome quit rates in this study could be the result of several factors. This lack of difference may have been due to unintentional biases being introduced into the trial. Randomised controlled trials are designed to anticipate, detect, quantify, and control bias as much as possible but it is not possible to be absolutely sure the results of a particular study are not biased in some way [355].
Biases in behavioural intervention studies can occur because participants who agree to take part in studies may be more motivated to achieve the study outcome as opposed to those who refuse. This is termed ‘participation effects’ [356]. A review of literature that examined patients’ reasons for participation in clinical trials was undertaken in 2002 by the Emergency Care Research Institute [356]. Information was gathered from 14 studies of 2,189 patients who provided reasons for participating in a trial, in addition to 6,498 patients who declined to participate. Potential health benefits from participating (45%), physician influence (27%), and the potential to benefit others (18%) were the main reasons for participating [356]. Reasons for not participating in studies included inconvenience (25%), concern over experimentation (20%), potential lack of benefit (19%) and physician influence (19%) [356]. Thus, in the study presented in this chapter, the participants who agreed to take part may have had a higher motivation for quitting smoking regardless of their study allocation. It is equally possible the 30 people (Figure 6.2) who declined to participate in this study did so because they had no intention or desire to quit smoking.

A further possibility of bias in this pilot study that added to the increased quit rates of the control group could have been occurred during the information (Appendix 18) and consent process for all study participants because the relationships between smoking and RA was discussed. This information could have acted as an unpredicted educational intervention thereby providing extra motivation for control group participants to quit. The Spanish study of smoking cessation in rheumatic diseases described above demonstrated a two-threefold increase in baseline smoking cessation that could have been due in part to the brief disease-specific educational component that was added to the initial consultation with a Rheumatologist [9].
Although these factors probably played a part in this study, another source of the high quitting rate of participants in the control group was the use of NRT as a common treatment. The success of using NRT to help smokers quit has led to its use being recommended as first-line treatment in many international clinical guidelines, including the ‘ABC pathway’ for smoking cessation in NZ [205]. In addition to NRT, the ‘ABC pathway’ also incorporated brief advice, which independently increases the changes of quitting smoking by nearly double again. Thus, the primary outcome quit rates of 21% in the control group in this pilot study were a reflection of the success of the ‘usual care’ treatment of using NRT in combination with brief advice.

The Cochrane Collaboration has reviewed behavioural smoking cessation interventions used as an adjunct to pharmacological treatments [321] to ascertain whether an increase in quitting rates over and above the pharmacological interventions rate is seen. In total, 38 randomised or quasi-randomised smoking cessation studies were evaluated. All but two of these studies provided behavioural support in four or more sessions, and 27 studies used NRT as the control treatment [321]. In that review, the mean quit rate in the control groups after pooling studies was 21%. This is very similar to that of the control group in this study, although the review did include all types of pharmacotherapy including varenicline and bupropion, which have higher quit rate success (Table 5.1). The median quit rate for adding behavioural interventions to pharmacological treatments in that review was 24% (95% CI 23-26%), which was slightly less than this study (26% quit rate). Thus, the difference in primary outcome quit rates in the study presented in this chapter was within the range expected. Specifically, the recommendations from the Cochrane Collaboration state that although the benefit of adding behavioural to pharmacological support is small, it is a
statistically and clinically significant outcome, particularly for interventions that have four or more support contacts [321].

6.5.1 **Strengths and Limitations**

Randomised controlled studies are considered the ‘gold standard’ for evaluation health care interventions [357]. The key advantages of using a pilot study are the ability to predict the feasibility and operational acceptability of an intervention and they are cost-effective to run [260]. There were few exclusion criteria for entry into this study, thus minimising population choice bias [355]. The random allocation of study participants to the different arms of the study decreased the potential of allocation bias [355]. The strengths of this pilot study were the development of a focused research question, using allocation concealment, use of blinding, and the use of the ITT analysis. Continuous abstinence rates as the primary endpoint enable this pilot study to be compared to similar studies. There was also a high retention of participants: none of the 19 intervention participants withdrew from the intervention and only three of 38 participants withdrew from follow-up.

The study had several limitations. Pilot studies by their design are underpowered to adequately detect reliable measureable estimates of benefits or harms [260]. However, the sample size in this pilot study was adequate based on the published guidelines as outlined in Chapter 3. Additionally, self-reporting of smoking status rather than using a formal test of smoking cessation (e.g. measuring serum cotinine) and self-reporting of quit dates can be a source of error due to recall bias [358]. The delay in some six month follow-up interviews with the researcher could have been a source of recall bias error as the participants may not have remembered their exact smoking status at that time-point. Recall
bias would have also evident with participant’s recollections of recognising the specific interventions that were provided during the first week of the study. Selection bias was evident in this study because 30 of 97 individuals declined to participate (Figure 6-2). It is most likely these individuals did not want to quit smoking thus did not see any benefit to enter the study.

6.6 Conclusion

This pilot study evaluated the efficacy of an individually tailored smoking cessation programme in people with RA. Although, this was no more effective than usual care, the smoking cessation rate was high compared to previous smoking cessation studies [9, 348]. The lack of added benefit of the tailored intervention suggests brief advice plus pharmacotherapy is the best practice supporting people with RA who wish to quit smoking. People with RA with fewer years of education or longer history of smoking may require particular cessation support.

In order to explore whether this targeted smoking cessation programme had benefits not readily identified in the quantitative outcomes of the pilot during this study, detailed follow-up interviews were undertaken at three and six months post-randomisation. The results of that research are discussed in the next chapter.
7 EXPLORING PARTICIPANT ATTITUDES TO A TARGETED SMOKING CESSATION PROGRAMME FOR PEOPLE WITH RA

7.1 Chapter Overview

The previous chapter presented the quantitative findings from the pilot study designed to evaluate the efficacy of an individual tailored smoking cessation programme in people with RA. Despite no significant difference in the primary outcome of smoking cessation rates between intervention and control group participants, the study did result in a high quitting rate among participants in both groups. In view of this, an evaluation of the implications for future practice and research exploring the acceptability and feasibility of the smoking cessation programme from the participants’ perspective is warranted. This chapter provides an in depth exploration and analysis of qualitative secondary outcomes of the pilot study as described below.

7.2 Aims and Objectives of Exploratory Research

The aim of the exploratory research phase of the pilot study was to seek feedback from participants about which aspects of the intervention were most useful. The analysis is presented in the following order to answer that research aim:

1) Did the study intervention overcome barriers to smoking cessation in people with RA?
   a) Exploration of perceived barriers to smoking cessation in the intervention participants.
   b) Identification of intervention components accepted by each participant.
   c) Identification of intervention components that the participants found to be useful.

179
d) Analysing whether the intervention components were successful in facilitation of smoking cessation.

2) What other factors facilitated or impeded smoking cessation in people with RA?

3) What were the study participants’ attitudes to their smoking status at the end of the study?

### 7.3 Methods

#### 7.3.1 Study Design

This study design was a qualitative study adjunct to the pilot study of the RA specific smoking cessation programme in collaboration with Arthritis NZ (Chapter 6).

#### 7.3.2 Data Collection Measures and Verification

##### 7.3.2.1 Interviews

The two sources of information for the qualitative evaluative analysis included: 1) the notes documented by the Arthritis NZ Educators at the four contacts with the intervention participants, and 2) the notes documented from the two follow-up interviews between the researcher and the participants in both intervention and control groups at three and six months post-randomisation. The interviews followed a combined structured and semi-structured format, were undertaken on a one-to-one basis, and the interview notes were written summaries as opposed to full transcripts.
The initial needs assessment meeting occurred between the Arthritis NZ Educator and each intervention participant during week 0 of the programme (Appendix 19). Participants were asked questions regarding their main concerns with their RA, how their RA affected their daily activities, and how they managed their disease. A structured checklist of all the intervention components offered and accepted was completed by the Educator. This checklist also enabled discussion points to be noted for referencing and referring back to during the three subsequent intervention contacts at weeks 1, 4 and 8. Nicotine replacement therapy use was recorded at each intervention contact.

The checklist for the following three intervention contacts between the Educator and participant was a variation on the initial needs assessment question-schedule (Appendix 20). The participants were asked open-ended questions to: 1) establish how they have been since the last contact, and 2) encourage an open discussion about how they had used the intervention components they had chosen. This format not only allowed for documenting the expected large variations in responses from individual participants, but also allowed for an accurate recording of the interventions offered, accepted, and subsequent usage by each participant.

The two follow-up interviews at three and six months (Appendix 21) with the researcher (PA) were conducted in person unless this was inconvenient to the participants. The preferred location was the Outpatients Department of Christchurch Hospital or by telephone if the participants were not able or willing to attend a follow-up meeting. The interview questions were structured and closed-ended to enable tallying of responses to the previously identified themes/barriers (described in Chapter 4). Each closed-ended question was completed with open-ended questioning to enable deductive themes to be examined in
more detail, whilst still allowing for any new emergent themes to be identified. The interview schedule had both generic and separate question areas for intervention and control group participants, which included the following subject areas:

**Generic interview questions for all study participants**

- Did you change your smoking behaviour over the last 3 months? How? Why? When?
- Did you use smoking cessation medications over last 3 months? Which? How useful?
- Did you access other smoking cessation services? Which? Why? How useful?
- Smokers: Are you planning to quit? When?
- Smokers: How could you improve your ability to quit smoking?

**Interview questions for intervention participants about success of the intervention**

- Which intervention components were accepted? How useful?
- Any suggestions to improve intervention?

### 7.3.2.2 Data Analysis

The data were analysed in three stages, as follows:

#### 1. Data Cleaning

The data were screened and simplified to identify suitable qualitative data fields to analyse. The screening method involved sorting the data into the most relevant and data-rich fields that addressed the aims of the study. These fields subsequently become the data source for the resulting deductive analysis (11 fields in total).
2. Deductive Categories

Data was thematically analysed using a deductive analysis format (Chapter 3). This form of analysis enabled an evaluation of the aspects of the intervention or the study as a whole that were feasible, acceptable and overcame the participants’ barriers to smoking cessation to be undertaken. The rationale was to: 1) ascertain if the five previously identified barriers to smoking cessation were addressed for each of the individuals in the intervention arm of the study, and 2) identify which components of the intervention and overall study were useful (i.e. feasible and acceptable). For each participant in the intervention arm the notes from their four intervention contacts and two follow-up visits were reviewed on a case-by-case basis. The control group participants had their two follow-up visit notes reviewed, looking for similar themes if they were apparent. Analysis of the intervention participants will be presented first to establish the resident themes. In total, the data were coded into nine deductive categories for each study participant, as listed below:

Deductive categories:

1) Support: lack of suitable support for smoking cessation in RA.
2) Education: lack of knowledge of the links between RA and smoking.
3) Pain Management: use of smoking as a distraction to pain.
4) Exercise: inability to exercise due to RA.
5) Coping Strategies: smoking used as a coping strategy for RA.

Other research questions

6) Intervention group participant feedback to identify if there were any novel themes in the intervention that had not been previously identified in the exploratory phase of study.
7) Participant feedback from all study participants to identify any novel themes in the pilot study as an entity that had not been previously identified in the exploratory phase of the study.

8) All study participant attitudes to their particular study results.

9) Relationships to Canterbury earthquakes.

### 3. Tallying of Responses

The decision as to whether the intervention components overcame the five identified barriers to smoking cessation was made using the data from the intervention participants. The more formal method of structured questions was used for data collection thus enabling participant responses to be tallied for analysis. For example, under the theme of education: the number of participants who made a reference to the handout that outlined the connections between RA and smoking was tallied. Participant quotes sourced from the records written by the Educators the researcher were also analysed because they provided a rich source of information to understand more clearly the context of their responses. Any novel themes not captured in the original exploratory research were inductively analysed using thematic analysis as described in Chapter 3. Tallying of the control group participant data for the same nine individual and global themes was also undertaken using the same analysis method, with the purpose of assessing if they were able to overcome their own barriers to smoking cessation.

To confirm that there was consistency in discovered themes (internal validity), one of the thesis supervisors (GJT) independently analysed two intervention participants’ data sheets, which were cross-referenced with my analysis in the early stages of the analysis phase.
Having colleagues check other researcher’s interpretations of data is important in regard to rigour in qualitative studies, and this is referred to as confirmability (Chapter 3).

7.4 Results

7.4.1 Did the Study Intervention Overcome Barriers to Smoking Cessation in People with RA?

7.4.1.1 Identification of Participants’ Barriers to Smoking Cessation

The needs assessment was the first meeting between individual intervention participants and an Arthritis Educator from Arthritis NZ so participants could identify any difficulties they experienced with controlling their RA, and to decide which resources and treatments from the intervention component package would assist them to quit smoking. Apart from the components specifically targeted to smoking cessation, the remaining resources and treatments used in the intervention were suitable for all people with RA, regardless of their smoking status.

Although 19 participants were enrolled into the intervention arm of the study and received the standard intervention pack and ‘ABC pathway’, only 18 participants undertook the needs assessment, since one participant was difficult to contact and the Arthritis NZ Educator was unable to book an appointment. However, this participant did receive the standard intervention pack handed out by the rheumatology specialist nurse at the study entry and did complete the 3- and 6-month interviews.
The next section classifies and quantifies the intervention participants’ barriers to smoking cessation into the five previously identified categories, as ascertained in the needs assessment meeting.

1. Support

There were limited comments from the participants regarding support and isolation. Whilst only three participants mentioned they had a good support network of friends and family, isolation from others was not mentioned as problematic by the participants. Participants were asked by the Educator about their support network, but support with regard to past smoking cessation attempts was not discussed in the needs assessment.

2. Education

As part of the information and consent process for the study, all participants (including control group participants) were informed of the relationship between RA and smoking, which was discussed prior to giving consent to enter the study (Appendix 18). While the majority of participants were not aware of the deleterious relationships specifically between smoking and RA, they were very aware of the negative health effects from their smoking habit. Their specific responses to the links between RA and smoking were not detailed at the time but were discussed with the researcher. This meant this intervention component was discussed with all study participants and essentially became included in the ‘usual care’ aspect of the study.
3. Pain Management

Pain and swelling in joints was identified as a concern by 16/18 of the intervention participants, which led to difficulties with low mood, sleep disturbances and stress. The associated joint pain and swelling had an adverse effect on the day-to-day activities and hobbies of these participants, which affected movement and mobility, e.g.

“Pain in hands, shoulders and feet – makes working [heavy lifting] harder”
(SRA024, male aged 58 years)

“Don’t fix cars anymore due to dropping things…hands and sensation changes”
(SRA032, male aged 61 years)

“[RA] slows me down in everything I do” (SRA033, female aged 65 years)

Low mood, sleep disturbances, fatigue and stress as a result of RA pain and limited mobility were commonly stated (7/18 participants):

“Feeling down at times at not being able to do what she used to” (SRA028, female aged 31 years)

“Stressed out that RA is back after a 6-year remission” (SRA037, female aged 43 years)

However, 12/18 felt their RA pain was well controlled by medication and a further three participants were currently having their medications altered to help control their RA:

“Getting medications right is current priority” (SRA003, female aged 64 years)
4. Exercise

Two participants reported they were able to use physical activity in association with medication as a mechanism of controlling their RA:

“RA controlled by medication, heat, rest, gentle exercise and hobbies such as reading, gardening & music” (SRA006, female aged 56 years)

However, most of the remaining participants (12/18) mentioned they had difficulty with daily living and exercise due to restricted movement from swollen and/or painful joints:

“Some difficulty with daily life due to aching wrists and knees... limit distance I can walk” (SRA019, female aged 61 years)

“Not able to work, can’t lift or hold things” (SRA016, female aged 47 years)

In addition to RA, four participants had serious comorbidities including COPD, stroke, diabetes and cancer. These comorbid conditions were viewed by these participants as having a greater effect on their daily lives than RA at the time:

“RA least of her [health] troubles” (SRA021, female aged 68 years)

Only one participant felt that their RA was not affecting their daily activities in any way.

5. Coping

Overall, five participants specifically revealed that they use smoking to cope with their RA, principally to cope with their pain, but also as a mechanism for coping with RA in general:

“Reluctant to be on ibuprofen, so have a cigarette when in pain” (SRA004, male aged 56 years)
“Having a cigarette takes her mind off pain” (SRA003, female aged 64 years)

7.4.1.2 Intervention Components Accepted by Participants

The number and percentage of participants who accepted specific intervention components are identified in Table 7-1. All of the participants were offered exactly the same components and were encouraged by the Arthritis NZ Educator to choose the components that were most appropriate for their own needs and requirements. The standard intervention pack components (Appendices 11, 12, 13b-c and 14) provided to each participant are identified in bold. The table below reflects interventions accepted by all 19 participants, because all of the participants were provided with the standard intervention pack during randomisation. The information in Table 7-1 demonstrates the support and advice components of the tailored intervention were the most accepted optional intervention components. The exercise components were less accepted. No participants were referred to their GP for analgesic advice.
Table 7.1: Number and percentage of participants who accepted intervention components

<table>
<thead>
<tr>
<th>Theme</th>
<th>Intervention</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support &amp; advice</td>
<td>Managing Pain / Keep a Pain Diary</td>
<td>12 (63)</td>
</tr>
<tr>
<td></td>
<td>Complementary therapies</td>
<td>6 (32)</td>
</tr>
<tr>
<td></td>
<td>Managing Medications</td>
<td>10 (53)</td>
</tr>
<tr>
<td></td>
<td>Pacing</td>
<td>14 (74)</td>
</tr>
<tr>
<td></td>
<td>Managing fatigue</td>
<td>16 (84)</td>
</tr>
<tr>
<td></td>
<td>Disturbed Sleep</td>
<td>16 (84)</td>
</tr>
<tr>
<td></td>
<td>Referral to GP (to revise analgesia)</td>
<td>0 (0)</td>
</tr>
<tr>
<td></td>
<td>12 Weekly Smoking Cessation Advice Emails</td>
<td>16 (84)</td>
</tr>
<tr>
<td></td>
<td><strong>Support Website: ‘Smoking Cessation and RA’</strong></td>
<td><strong>19 (100) #</strong></td>
</tr>
<tr>
<td>Education</td>
<td><strong>Handout: ‘The link between smoking and RA’</strong></td>
<td><strong>19 (100) #</strong></td>
</tr>
<tr>
<td>Pain</td>
<td><strong>Arthritis NZ: ‘Managing Your Pain’ Booklet</strong></td>
<td><strong>19 (100) #</strong></td>
</tr>
<tr>
<td>Exercise</td>
<td><strong>‘Hand exercises for RA’ handout</strong></td>
<td><strong>19 (100) #</strong></td>
</tr>
<tr>
<td></td>
<td><strong>‘General exercises for RA’ handout</strong></td>
<td><strong>19 (100) #</strong></td>
</tr>
<tr>
<td></td>
<td>‘Exercises to keep you moving’ booklet</td>
<td>5 (26)</td>
</tr>
<tr>
<td></td>
<td>‘Keep moving’ DVD</td>
<td>6 (32)</td>
</tr>
<tr>
<td></td>
<td>‘Community exercise classes for RA’ handout</td>
<td>4 (21)</td>
</tr>
<tr>
<td></td>
<td>‘Hydrotherapy classes’ handout</td>
<td>5 (26)</td>
</tr>
<tr>
<td></td>
<td>Physiotherapist or Occupational Therapist referral</td>
<td>3 (16)</td>
</tr>
<tr>
<td></td>
<td>Pedometer</td>
<td>10 (53)</td>
</tr>
<tr>
<td>Coping</td>
<td><strong>Handout: 1 week diary for ‘Identifying smoking triggers’</strong></td>
<td><strong>19 (100) #</strong></td>
</tr>
<tr>
<td></td>
<td>Advice from AE: Goals and Self-management</td>
<td>18 (95)</td>
</tr>
<tr>
<td></td>
<td>Discuss available support (social, psychological and physical)</td>
<td>18 (95)</td>
</tr>
<tr>
<td></td>
<td>Use of NRT documented and discussed</td>
<td>18 (95)</td>
</tr>
</tbody>
</table>

*NZ=New Zealand; AE=Arthritis Educator; NRT=nicotine replacement therapy

# Standard Intervention pack components
7.4.1.3 Identification of the Usefulness of Intervention Components

This section analyses the usefulness of the intervention components as informed by the participants who had accepted each component. To verify whether the components were ultimately useful in helping people with RA give up smoking, the study outcome quit status of the participants who found the components useful is described.

The intervention components found most useful by participants are identified in green in Figure 7-1 and are ranked from most to least accepted (in red). Because NRT was a shared treatment with the control group, its usefulness will be discussed later in this section.

![Figure 7-1: Comparison of acceptance and usefulness of intervention components](image)

Figure 7-1: Comparison of acceptance and usefulness of intervention components
1. Support and Advice Intervention Components

a) Arthritis Educator Support and Advice

It was recognised in the exploratory research and design phase of this research that some participants may have different needs for support and advice. Therefore, support was individualised for each participant and their support choices were monitored by the Arthritis NZ Educators at subsequent contacts throughout the intervention. The following topics were discussed:

1) Pain management and encouraging participants to keep a diary to identify when they had pain.
2) Complementary therapies.
3) Managing medications.
4) Using pacing to cope with their energy levels.
5) Managing their fatigue.
6) Disturbed sleep.
7) Referral to their general practitioner to revise analgesia if appropriate.

Although participants were asked whether they received support and advice for each of the identified issues, for the purposes of the following analysis all support and advice components were combined into one category rather than being added up across each component. This was necessary because individual participants were not able to identify each support or advice component separately in the two follow-up interviews at three and six months. Overall, the support and advice received by the participants was found to be useful by 11/16 of the participants (the three participants who were withdrew from follow-up were not included in this analysis). Of these 11 participants, three subsequently quit smoking, five reduced their daily smoking, and three had not changed their smoking at the
end of the 6-month follow-up period. Their comments were very positive and suggested that the support and advice offered from the Arthritis Educators was valued and appreciated:

“Absolutely, definitely helpful and really liked the educator” (SRA009, female aged 47 years, no change, 3 months post-randomisation)

“…was disappointed that tonight was our last phone call” (SRA024, male aged 58 years, reduced, 8 weeks post-randomisation)

“…thought the face-to-face support worked really well for her” (SRA037, female aged 43 years, quit, 6 months post-randomisation)

One participant did not find the support and advice useful and felt they did not require this type of intervention to accomplish their goal:

“…received phone calls, emails and information; didn’t find them helpful as was very motivated to quit smoking” (SRA023, female aged 62 years, quit, 6-months post-randomisation)

**b) Weekly emails “Pip’s Smoking Cessation Tips”**

Twelve weekly emails based on Quitline NZ smoking cessation tips were sent to the participants who supplied an email address (16/19). Topics were varied (Appendix 10) and included, e.g. how smoking affects your body, cravings and mood, addiction, and the use and effects of NRT. The exact order of sending the 12 emails was not crucial, thus the Educators were able to send out the same email to all participants on the same week.
Twelve participants commented upon the usefulness of weekly support emails. Of these, six participants found the emails useful, although some tips were thought to be more useful than others depending upon the interests and knowledge of the participants:

“Is printing out weekly emails so she can read at her leisure” (SRA021, female aged 68 years, reduced, week 1 post-randomisation)

“Was emailed the tips and would look at them – some were good” (SRA024, male aged 58 years, reduced, 6 months post-randomisation)

Of six the participants who found the emails useful, one subsequently quit smoking, three reduced and two did not change their smoking at six months post-intervention.

Two participants did not find the emails useful: one participant did not read the emails and one participant felt they were already familiar with the information supplied in the emails. Of the remaining four participants: one participant did not supply a valid email address and three participants did not have access to emails or the internet:

“Didn’t have a private email at the time and didn’t receive the emails at work – thinks they were filtered out” (SRA032, male aged 61 years, no change, 6 months post-randomisation)

c) Support Website

The support website was designed as a reference tool that provided links to other smoking cessation community providers, an email link to an ‘Ask an Expert’ via the webpage of
Arthritis NZ, and links to the intervention handouts and weekly emailed smoking cessation tips (Figure 7-2).

Figure 7-2: Support website for designed for supporting Intervention participants
The address for the website was only available to intervention participants and was referred to in each weekly email tip that was sent to the intervention participants, in addition to being detailed on the Education Handout. The website was hosted on the University of Otago Arthritis theme site. Initially, the support website was intended to be linked to the Arthritis NZ website, but this was not possible due to administrative compliance issues. The support website was used by the participants but less than anticipated. Access data is presented below.

The website received most views on the homepage, and very few participants followed through to view associated links or pages. Figure 7-3 illustrates the number of page-views were steady throughout the study, averaging at 21.8 views per three-month period (range 17-27). The mean time spent on each page view was 2.4 minutes per view (range 0.44 to 4.22) (Figure 7-4). The usefulness of the support webpage was not specifically asked in the follow-up interviews.

![Figure 7-3: Support webpage page-views](image-url)
2. Educational Intervention Component

The educational handout was designed to explain the links between RA and smoking. All 19 in the intervention arm received the education handout, and nine participants provided feedback on usefulness of the information. This lack of feedback may be a recall issue as many participants did not remember receiving the handout, although several were familiar with the information contained in the handout when asked during interviews.

Six participants found the handout on smoking and RA to be useful:

“Motivated to give up this time especially after reading effects of smoking on RA”

(SRA0023, female aged 62 years, quit, week 0 post-randomisation)
“We did discuss this and [participant] found this a major motivating factor for giving up smoking” (SRA028, female aged 31 years, quit, week 0 post-randomisation)

Of the six participants who found this information useful, three subsequently quit smoking during the intervention, two participants reduced their daily smoking, and one did not change their smoking behaviour.

3. Management of Pain Intervention Component

The Arthritis NZ booklet ‘Managing your Pain’ was provided to each participant as part of the standard intervention pack. Two participants reported that they had no recollection of receiving this booklet. None of the other 14 participants specifically referred to the usefulness of this booklet per-se in the 3- or 6-month follow-up interviews, although 12 participants were given support and advice regarding pain management by the Arthritis NZ Educators. No participants were referred to their GP to revise their analgesia, suggesting the participants felt their pain management was satisfactory. This view was supported by the needs assessment in week 0 that indicated the participants felt their RA pain was either already controlled by medication or were currently in the process of having their medications altered by their RA specialist.

4. Exercise Intervention Components

This intervention offered a variety of components that were designed to provide information about exercises that were appropriate for people with RA, including handouts and a DVD. Opportunities were also provided for participants to join community exercise
and hydrotherapy classes, and a pedometer was offered to each participant as a motivational
tool.

Apart from the two handouts in the standard pack given to all intervention participants, the
other exercise components were accepted by less than half of the participants; the
pedometer was accepted by 10 participants; the other components were accepted less. Three
participants were already receiving physiotherapy or other exercise classes to aid with joint
movement, and seven other participants felt they were active enough with their daily
activities, including work or sports and hobbies. However, some participants did report they
had increased the amount of exercise they undertook as a result of the intervention, even if
this had no effect on their smoking outcomes:

“Since the intervention, she has been walking a lot more – plus she now has a puppy
so more motivation to walk – goes walking for about an hour three times a week”
(SRA009, female aged 47 years, no change, 3 months post-randomisation)

a) Pedometer

Five participants commented upon the usefulness of the pedometer: three found the
pedometer useful, although these participants did not use their pedometer more than a
couple of times during the intervention period. The other two participants did not find the
pedometer useful. Of the three participants who found the pedometer useful, two reduced
their daily smoking and one did not change their smoking.

“Pedometer good when feeling fit and healthy, but not during flare-ups” (SRA003,
female aged 64 years, reduced, week 4 post-randomisation)
Of the two participants who did not find the pedometer useful, one did not use it although did quit smoking during the study. The other participant had unsuccessfully attempted use if their pedometer:

“Pedometer not useful...firstly, I didn’t know how to use it – no instructions given, secondly, batteries were flat – keeps forgetting to get new battery when she goes shopping...” (SRA009, female aged 47 years, no change, 3 months post-randomisation)

b) Exercise Handouts and Booklet

Two RA specific exercise handouts were provided in the standard intervention pack: hand exercises and gentle full-body exercises (Appendices 13b and 13c). Four of the participants found these handouts useful and two did not. The hand exercise handout received the most positive feedback:

“Yes, has used the Abbot hand exercises...now able to make a fist, fingers follow each other in the right direction and able to write better” (SRA006, female aged 56 years, reduced, week 1 post-randomisation)

[Hand exercises] “Useful until hands get sore...need to keep moving, good to keep fingers moving” (SRA020, male aged 41 years, reduced, 3 months post-randomisation)

The two participants who did not find the handouts useful felt they were exercising enough already:
“Doesn’t do the exercises because get enough exercise at work – does lots of climbing and walking” (SRA024, male aged 58 years, reduced, 6 months post-randomisation)

The availability of an Arthritis NZ exercise booklet by order form was discussed with the participants and five participants were interested, although none followed through with purchasing a copy.

c) Home-based exercise DVD

Although six participants indicated an interest in the home-based exercise DVD, it was not purchased by any of the participants in this intervention. It was not commented upon by any participants.

d) Hydrotherapy and Community Exercise Classes handouts

The community exercise and hydrotherapy classes (Appendices 13e and 13f) were not undertaken by any of the participants. Many of the participants had indicated either they were not interested in community exercise classes or the classes were not local enough. For those participants who were in employment, the timing of the classes during work hours was not convenient. The hydrotherapy pool was closed on the 21 February 2013 for earthquake repairs so this intervention was unavailable during this study, although some participants were offered the hydrotherapy option prior to the pool being closed.
5. Coping strategies

As described in Chapter 5, the smoking triggers diary enabled participants to identify the situations when they are most likely to smoke. The diary (Appendix 14) had three columns: in the first column the participants recorded the times of the day when they usually smoke and what they are doing that causes a craving to smoke, e.g. a cigarette with a cup of coffee at 7.00am; the second column records their feelings at the time of smoking, e.g. stressed or angry; and in the third column the participant is encouraged to come up with an alternative activity to take their mind off smoking during the craving, e.g. go for a walk or have a drink of water.

The triggers diary was commented upon by 12 participants; being able to identify what triggered their own smoking was found useful by 9/12 of these participants. The triggers included emotional triggers such as stress, smoking as a habit related to certain activities, or smoking to fill in time and to overcome boredom:

“Boredom is still an issue with smoking. [Participant] has identified this as a trigger to smoking” (SRA031, male aged 38 years, reduced, week 1 post-randomisation)

“It was emotional triggers that had her reaching for a cigarette” (SRA003, female aged 64 years, reduced, week 8 post-randomisation)

As noted in the needs assessment, participants also identified smoking to cope with pain, although this was not mentioned in association with the triggers diary. Four of nine participants who found the diary useful subsequently quit smoking; four had reduced their
daily smoking, and the remaining participant had not changed their smoking by the end of the 6-month follow up period.

Of the three participants who did not find the diary useful, one did not remember receiving the diary and the other two decided not to use it, although both of these participants had reduced their daily smoking at the end of the study:

“Don't remember receiving this” (SRA009, female aged 47 years, no change, 3 months post-randomisation)

### 7.4.1.4 Success of Interventions in Facilitation of Smoking Cessation

The following Figure 7-5 summarises the smoking status at six months post-randomisation of the participants who found the various individual intervention components useful.

![Figure 7-5: Smoking status at 6-months of participants who found the intervention components useful](image-url)

Figure 7-5: Smoking status at 6-months of participants who found the intervention components useful
This figure demonstrates the components that were most useful to the participants who accepted and used them were: the Arthritis NZ Educator support and advice, the smoking triggers diary, the educational handout, and the email support. These components might have had a positive effect facilitating the quitting (primary outcome) or sustained reduction in daily smoking at six months (secondary study outcome) of intervention participants.

7.4.2 What Other Factors Facilitated or Impeded Smoking Cessation in People with RA?

A potential risk in any study intervention is the possibility of unidentified mediators or difficulties being discovered during the analysis phase that may have independently facilitated or impeded the study outcomes. The next section begins by examining responses from intervention participants to establish whether there were any barriers that were not captured by the intervention components that could have affected smoking cessation rates. The emphasis of the analysis then changes to include all study participants, to see if there were any common facilitators or barriers that could have augmented or impeded smoking cessation for all participants in the study. Nicotine replacement therapy, the use of other community smoking cessation programmes, and effects from the Canterbury earthquakes are considered.

7.4.2.1 Novel Barriers to Smoking Cessation

Three intervention participants identified other health-related barriers that might have had an effect on their ability to quit or reduce their daily smoking during the intervention phase.
of the study. One of these participants (SRA019) was identified as having multiple novel barriers including comorbid ill health and other extreme personal life stresses:

“Toes removed in Jan 2014...not in a good mental state [death of a family member]...house flooded” (SRA019, female aged 61 years, no change)

A further two participants were experiencing ill-health from comorbid conditions that had a larger effect on their daily lives other than RA:

“[Participant] has had a very difficult six weeks, and is unable to even hold a cup of tea or a pen” (SRA003, female aged 64 years, reduced)

7.4.2.2 Common Study Factors Facilitating or Impeding Quitting

1. Nicotine Replacement Therapy

Nicotine replacement therapy was offered to all participants as ‘usual care’ regardless of their randomisation status. The usefulness of NRT was commented on by 19/19 intervention and 18/19 control group participants at various time-points during the study. In total NRT was used by 14 intervention and 15 control group participants, equating to three-quarters of all the study participants who commented (Table 7-2):
Table 7-2: Use of NRT in the pilot study*

<table>
<thead>
<tr>
<th>Use of NRT</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>No</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Quit using NRT</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Non-quit using NRT</td>
<td>10</td>
<td>11</td>
</tr>
</tbody>
</table>

*This table differs from Table 6-7 because the NRT use by the three participants who were withdrew from follow-up had been recorded by the Educators

Although the study participants had varying opinions regarding NRT, the experiences between the intervention and control groups were similar; the patches were found to be more useful initially; the gum and/or lozenges were used long-term for whenever they felt a craving:

“[Participant] hasn’t had a cigarette since starting the patches. Both herself and her partner have given up smoking” (SRA028, female aged 31 years, quit, intervention arm)

“Still using the gum quite a bit; Initially, I used the patches for 2 months until I got a reaction to the adhesive, then I stopped” (SRA037, female aged 43 years, quit, intervention arm)

“Found the patches were great...didn’t envisage that the patches would have worked so well...will still use patches when completely given up for a while just to make sure he doesn’t start smoking again” (SRA038, male aged 73 years, reduced, control arm)
Others mentioned a dislike for the gum and lozenges:

“...gum makes me dry retch”, tried patches but stopped, cut down smoking, parent in hospital, cold & cranky & sore [winter]” (SRA020, male aged 41 years, reduced, intervention arm)

“Used the gum and lozenges; Lozenges tasted like cardboard...tried patches and gave up smoking for 4 days but found they didn’t work” (SRA001, male aged 63 years, no change, control arm)

The participants who did not find the NRT useful mentioned side effects to the patches such as skin sensitivity and sleep disturbances:

“...got nightmares from using patches, and when I took them off at night, I stopped getting any effect from them so I stopped using them” (SRA004, male aged 56 years, quit, intervention arm)

One participant, having initially tried to quit using NRT and had side effects, had been prescribed varenicline (Champix) by his GP. As previously described, participants were permitted to use other smoking cessation aids in this study. Unfortunately, varenicline also caused side effects for this particular participant:

“Tried using Champix for 3 and half weeks...couldn’t eat and another side effect was developing a great fear of water...had to have time off work” (SRA018, male aged 58 years, reduced, control arm)

Not filling their NRT prescriptions was commonly mentioned (8/37 participants). Some were also not interested in taking extra medications:
“NRT script not filled yet as [participant] not ready to give up smoking” (SRA009, female aged 47 years, no change, intervention arm)

“Not interested in using NRT...don’t like it...doesn’t want more medication” (SRA033, female aged 65 years, no change, intervention arm)

Overall, there was no difference between the intervention and control group participants with regard to the use and success of NRT in the study. However, it appeared that those who were more successful in quitting or reducing their smoking rate in either study arm had used NRT during the study (Figure 7-6). Nearly all of those who quit during the study had used NRT (8/9), as had 13/16 participants who reduced their smoking rate. Not using NRT or not finding it useful was more common for those who showed no change in their smoking status during the trial.

![Figure 7-6: Use of NRT and smoking status at 6-months in all study participants](image-url)
2. Use of Other Community Smoking Cessation Programmes

One intervention participant and two control group participants used Quitline NZ services during the study period. The intervention participant who used Quitline as an adjunct to their intervention did quit smoking but the two control group participants were still smoking at the end of the study. One further participant joined a smoking cessation community group near the time of the 6-month follow-up; subsequently this participant quit smoking, but this did not occur during the study follow-up period. Compared to the intervention participants, slightly more control group participants utilised other smoking cessation services (two in control arm compared to one in intervention arm), but these numbers were too low to suggest a difference.

3. Canterbury Earthquakes

The Canterbury earthquakes during 2011-2012 and the thousands of aftershocks [359] were mentioned by three intervention participants and one control group participant as having a continuing and major effect on their stress levels, and consequently affecting their ability to contemplate quitting smoking. One intervention participant had housing issues after the earthquake with the effect of seeking alternative accommodation proving very stressful to him personally and for his family, while his house was repaired. All three of these participants did not change their smoking status during the study:

“Smoking because land/house shakes because of road-works/repairs – feel nervous – repairs for at least one month longer” (SRA010, female aged 77 years, no change, withdrew from follow-up, intervention arm)
“…the earthquakes and the stress around that time was her trigger to take up smoking again – not being able to answer questions to [her] children about the earthquakes and whether they would happen again/for how long.” (SRA009, female aged 47 years, no change, intervention arm)

Only one control group participant mentioned the stressful effect of the earthquakes on their well-being during the study, mainly due to “lots of niggles about repair work” to their house. This participant was initially reticent about taking part in the study and had delayed their randomisation until their house repairs had been completed, but subsequently was able to quit smoking between the 3-month and 6-month follow-up interview. This delayed entry into the study may have had a positive effect on the outcome for this participant as their major life-stress factor had been reduced due to their house repairs. The effects from the earthquakes were not mentioned by any other participants.

In summary, three intervention participants had other health-related conditions that may have impeded their ability to contemplate quitting smoking. The common study factors affected each study group equally: NRT facilitated both the primary outcome (quitting) and the secondary outcome (reducing smoking rates); too few participants used other smoking cessation programmes to make a decision regarding facilitation of quitting. The earthquakes were identified by three participants as impacting on their stress levels and possibly impeding their attempts at smoking cessation.
7.4.3 Participant Attitudes to their Smoking at Study Completion

7.4.3.1 Intervention Participants

The 16 intervention participants who completed the six month follow-up were asked how they felt about their smoking status outcomes. The major theme evident was the participants had become more conscious of their smoking and 14/16 participants had developed coping strategies to control their smoking even if they had not quit. These coping strategies included controlling, cutting-down and delaying their smoking. This was particularly evident with the seven participants who had reduced their daily smoking rates during the study:

“Goes and does something else when she has the urge to smoke... goes for a walk, cleans out a drawer, tidy something up” (SRA016, female aged 47 years, reduced)

“Uses a rubber band around wrist and ‘pings’ it” (SRA027, male aged 71 years, reduced)

“Rolls 5 cigarettes a day, but breaks off the top third of each one before smoking” (SRA24, male aged 58 years, reduced)

Financial benefits of quitting or cutting down were important to three participants. Health benefits were mentioned by seven participants, although these were focused on overall health, rather than their RA specifically:

“Has noticed [her] complexion has improved and taste improved” (SRA016, female, aged 47 years, reduced)
“Starting to exercise more now...feels healthier and can inhale deeper...has been
told that the whites in her eyes are brighter” (SRA028, female aged 31 years, quit)

Four participants were already planning their next quit attempt:

“Going to try Champix...has filled prescription already and is ready to make
another attempt in the next month” (SRA016, female aged 47 years, reduced)

“Going to try and quit smoking this weekend” (SRA024, male aged 58 years,
reduced)

The five participants who quit smoking during the study felt very positive about their
quitting, and strong motivation to quit was the overarching theme evident:

“Was very motivated to quit; found it easy to quit” (SRA023, female aged 62 years,
quit)

“Empowering to be able to give up smoking” (SRA037, female aged 43 years, quit)

However, being in the right “headspace” to quit or having a desire to quit was a dominant
theme for eight of 14 who did not quit:

“Still smoking and not able to stop at the moment...one day I will, when the time is
right” (SRA019, female aged 61 years, no change)

“Has to change his mindset” (SRA027, male aged 71 years, reduced)
Additional life stresses in addition to their RA was particularly relevant for some of these participants, and giving up smoking at this time was seen as a considerable additional stress:

“Currently, is sorting out other issues rather than quitting smoking...can only do one thing at a time, she has given up drinking alcohol, which she thought was more harmful to her family, whereas smoking is only harmful to her” (SRA009, female aged 47 years, no change)

“Will look at quitting smoking when it is a less stressful time at work” (SRA031, male aged 38, reduced)

One participant, who was withdrew from follow-up at 6 months, admitted he did not want to give up smoking (when interviewed at three months), although he did acknowledge that he “should” give up smoking:

“Was trying to give up…particularly with heart issue last year...had a lot of enthusiasm, but now don’t want to give up smoking” (SRA011, male aged 51 years, no change, withdrew from follow-up)

7.4.3.2 Control Group Participants

The 19 control group participants were also asked how they felt about their smoking status at the end of the study. Their comments were positive and reflected the progress they felt they had made independently including: controlling, cutting down, and delaying their smoking (10 participants); financial savings (three participants); health benefits (10 participants); and their high motivation to attempt another quit attempt (eight participants). Two participants did not comment on their outcome, and a further one participant did not
feel she had made any changes, and her smoking is still the “first thing she does at the start of the day”.

When commenting upon controlling their smoking, the main themes identified by 10 participants included: they were smoking later in the day; smoking less at night time; and not taking cigarettes out with them to social occasions. Similar to the intervention participants, the overarching theme was they had gained more power over when they chose to smoke, even if they had not changed their amount of daily smoking during the study:

“Recently had a weekend away and hardly smoked at all – can leave it for several hours” (SRA013, female aged 76 years, no change)

“…down from 25 a day to 3 a day: Smokes one in morning, one at lunch time, and one mid-afternoon” (SRA018, male aged 58 years, reduced)

Health benefits were mentioned by 10 control group participants where they commented they felt better physically and/or mentally at the end of the study period. Although this was particularly evident with the four participants who quit during the study, it was also apparent from many of the other participants as well. Weight gain was mentioned positively by one participant as they had lost weight while on RA medications:

“Is eating better and more – has put on 5 kg, which is a good thing as he was losing weight – he had lost 13kg from RA medications” (SRA018, male aged 58 years, reduced)

Improved general health (physical and mental) was mentioned by participants, but again, this did not generally include any improvements found in their RA:
“He feels better and finds his arthritis is not as bad – joints still quite stiff but not as bad as it was prior to giving up smoking” (SRA002, male aged 48 years, quit)

“Big change: for a couple of weeks at the beginning, was coughing up phlegm from lungs, but not coughing now” (SRA008, male aged 62 years, quit)

“Feel a lot better – not physically but mentally” (SRA017, female aged 47 years, no change)

Generally, similar to the intervention participants, the control group participants were quite motivated to try another quit attempt:

“Will shortly get hold of one of these electronic cigarettes by buying on-line and will give up tobacco slowly” (SRA026, male aged 40 years, no change)

“Expects to be completely off smoking in a couple of weeks” (SRA029, male aged 65 years, reduced)

Only one participant disclosed they did not put any effort into the study:

“Didn’t really put any effort into the trial but always thinking about giving up” (SRA017, male aged 48 years, no change)

Although three participants found positive financial benefits from smoking less or quitting, generally this was not reported as a motivating factor in this study:

“...have an amount of money each week to spend on entertainment and smoking and was used up each week. Hadn’t checked the account for quite some time, but
did recently, and have over $500 still in the account...money not spent on cigarettes” (SRA002, male aged 48 years, quit)

Eleven of 19 control group participants had independently developed their own coping strategies to in an attempt to regulate their daily smoking. Seven of these 11 participants developed strategies focused on substituting their smoking with other activities including psychological strategies:

“Devised a mental picture of how to give up smoking” (SRA002, male aged 48 years, quit)

“Never worried about smoking before entering into the trial, but now thinks about it more” (SRA007, male aged 65 years, reduced)

“...has one packet of cigarettes locked away in the boot of his car so he can’t get them, but doesn’t stress as he knows he has some” (SRA018, male aged 58 years, reduced)

Nine of 11 participants used physical activities to take their mind off smoking, including swimming, household chores, walking dogs, hobbies, and drinking water:

“If she needs a cigarette between the hour, she will put it off by doing other activities such as dishes or take the dog for a walk” (SRA034, female aged 65 years, no change)

“Plays soccer...is a process of keeping herself distracted” (SRA015, female aged 52 years, reduced)
“Try to keep busy – the more she does, the less she smokes…keep moving, which is important with arthritis” (SRA005, female aged 30 years, no change)

One participant mentioned they were spending more time with family members since they had reduced their smoking, and four participants controlled the places they let themselves smoke:

“…will only smoke pipes at home outside on the porch – if he goes out, he doesn’t take pipe out with him” (SRA038, male aged 73 years, reduced)

“Getting out in his boat and pottering around – smoke-free boat, can go out on the boat for long days and not smoke” (SRA018, male aged 58 years, reduced)

Similar to the intervention participants, stress was impeding their ability to quit for seven of 13 control group participants:

“Trying to deal with a lot at once at the moment so not ready” (SRA005, no change)

“Waiting to get normality back into life before giving up” (SRA007, male, reduced)

“Stress factor is the main reason he continues to smoke” (SRA029, reduced)

In summary, this section has presented and examined the study participants’ attitudes to their smoking status at the end of the study. Interestingly, their attitudes and outcomes were very similar in the intervention and control arms, and the control group participants had independently devised their own coping strategies to controlling their smoking
behaviours. Their outcomes demonstrated that study participants were either very motivated to give up during the study or else they felt they did not have the desire to quit at that time and this was regardless to receiving extra support from the intervention.

7.5 Discussion

This chapter provided an in depth exploration and analysis of the qualitative secondary outcomes from the pilot study and provided detailed information concerning the experiences of the study participants. The aim of the research was to evaluate which aspects of the intervention were most useful to the study participants. To achieve this aim, feedback was sought from participants at pre-determined time points, namely the four intervention contacts with the Arthritis NZ Educator (intervention participants), and the two follow-up interviews at three and six months with the researcher (all study participants).

The use of a deductive thematic analysis method revealed the tailored intervention components had addressed the five previously identified barriers to smoking cessation in RA. Analysis of the individual needs assessments established each participant had identified their concerns with RA, which as expected, varied considerably between individuals. However, as a trend, the participants in this study recognised they used smoking to cope with their RA, particularly as a diversion to RA associated pain. Pain and swelling in joints was a predominate concern of the participants as a group, which ultimately affected their day-to-day activities by restricting movement and mobility. Some participants experienced difficulties with low mood, sleep disturbances, fatigue and stress due to disease-related pain. Prior to the study, most of the participants were not aware of
the relationships between RA and smoking, which was observed during the information and consent process of the study. The only novel barriers apparent from using an inductive thematic analysis method were comorbid ill health and extreme personal life stresses. These barriers only affected three participants but may have impeded their smoking cessation attempts during the study timeframe.

The range of intervention components used in this study had been selected by a steering group of stakeholders including researchers, rheumatologists, and arthritis service providers (Chapter 5), with modules created to address the previously identified barriers to smoking cessation in RA (Chapter 4). Some of the intervention components were provided as a standard intervention (Table 7-1), while others were optional. There was only one component not utilised in the intervention, which was the option of referral to the participant’s GP to revise their analgesia; this was not unexpected since participants had identified they felt their pain management was either under control or they were currently having their pain medications altered.

The most accepted and useful intervention component was the individually tailored support and advice from the Arthritis NZ Educators. This component included support and advice on managing pain, medications, fatigue, disturbed sleep, and how to pace activities to manage RA. Overall, the Educators support was a key component and was fundamental to this intervention. The participants particularly enjoyed the one-to-one support from the Educators and appreciated this aspect of the study. This finding was corroborated using supplementary information from the Educator’s exit interviews (Appendix 22) [360], where the Educators felt their support was a valued and core component of the intervention.
The next most accepted and useful intervention components were predominately focused on facilitating smoking cessation, and included the use of a smoking triggers diary and smoking cessation advice that was emailed weekly over the period of 12 weeks. Both the triggers diary and the email tips were focused on participants recognising their triggers for smoking and providing alternative self-management strategies that may aid smoking cessation. Participants needed to have access to the internet to receive the weekly emails, and for some participants, this was not possible.

The educational handout that explained the links between smoking and RA was particularly useful to some intervention participants principally, with three of the five quitters specifically mentioning being motivated to quit from learning this information. Other participants may have believed the information was given too late for them, as they already had developed RA. This type of resistance was noted by the Educators [360]. A study in 2013 evaluated patient education to address CVD aspects in RA and demonstrated educating patients about their personal risk did significantly increase their knowledge about disease related factors long-term [211]. However, in that study, smoking behaviours were recognised as more difficult to change than other behaviours such as increasing exercise and eating a healthy diet [211]. Difficulty in changing smoking behaviours is most likely related to the physiologically addictive behaviour of nicotine [16], in addition to the social and emotional aspects of smoking where smokers often habitually reach for cigarettes when bored, angry, or stressed [31].

As has been stated earlier in this thesis (Chapter 4), physical activity is not only beneficial in RA for health reasons [303], there is also good evidence that short bouts of exercise can reduce cigarette cravings [302]. As elucidated in Chapter 4, people with RA face additional
barriers to physical activity compared to the general population due to perceptions that exercise makes their arthritis worse with respect to pain and fatigue. This issue has also been explored in a review of literature on perceived barriers, facilitators and benefits of physical activity in RA [361]. That review suggested there were no differences in barriers between those who exercise and those who do not, but differences in how people with RA negotiate and overcome those barriers were found to influence exercise behaviour [361]. Individuals with a higher self-efficacy were found to be more physically active and have a higher attendance at exercise programmes regardless of their barriers [361]. Education about exercise programmes in RA is recognised as important but a RCT exploring different ways of providing educational information found changing RA patient’s intention to increase their physical activity was more easily achieved than changing their actual behaviours [211]. However, a recent study has found increased physical activity on high-fatigue days may be beneficial to people with RA’s mood in everyday life [362]. Thus, physical activity and exercise programmes may be more beneficial if they promote the development of coping strategies to overcome perceived barriers to exercise in addition to providing physical activity opportunities [361].

In the current study, the intervention participants did not find the exercise components of the intervention useful. This may have been due to the extra monetary cost for some of the components such as the exercise DVD, the booklet, and the community classes, or they had been simply overlooked. It could also have been as a result of the high number of intervention participants in full-time or part-time employment (69%) because the classes were held during traditional work hours. It is also possible the participants were not keen on group classes or were managing to meet their exercise needs by other means. The participants who had other serious health conditions were receiving physiotherapy and
occupational therapy from other health service providers, so that need had already been met. Providing exercise options at times more suited to those who work may have been more helpful to the participants. The pedometer was initially found appealing by some of the participants, but it was not subsequently used for any length of time. However, other participants mentioned that they had taken up other forms of physical activity such as swimming, walking their dog, and going to the gym as a result of being motivated from taking part in the study intervention. Physical employment also provided adequate physical activity for some participants. Thus, the participants who increased their physical activity may have had a higher self-efficacy with regard to changing their exercise behaviours, rather than the exercises being inconvenient.

In summary, within the intervention arm, the Educator support and advice were identified as the most accepted and useful to the intervention participants in this study. In addition, there were common factors in the study had either facilitated or impeded smoking cessation for all the study participants in both study arms. These factors included use of NRT, the use of other community smoking cessation programmes, and the stress from the Canterbury earthquakes and the resulting aftershocks. The next section explores these issues, as they may provide reasons as to why the study outcomes of quitting and reducing smoking were similar for both arms of the study.

Nicotine replacement therapy acts by replacing the nicotine that have would be provided by smoking, and research has demonstrated the use of NRT can increase quitting rates by 50-70% [205]. The intervention and control group participants had similar experiences of NRT that was offered as part of the usual care ‘ABC pathway’. Nearly all of the study participants had commented upon the usefulness of NRT and three-quarters had made an
attempt to use NRT during the study. The participants who quit or reduced their smoking rate during the study had done so with the assistance of NRT. Therefore, it was a successful shared treatment facilitator for smoking cessation in this study.

The use of other community smoking cessation programmes was not widespread by study participants. The use of other programmes was encouraged as part of the usual care ‘ABC pathway’ and all of the participants received handouts with other programme contact details, including Quitline-NZ and Aukati KaiPaipa. Therefore, there was insufficient information from this study to comment upon their usefulness, although they might have had a positive influence on quitting for two participants, one who quit smoking during the study and one who quit after the study ended.

The Canterbury earthquakes were a specific and substantial barrier for some participants, although these participants were in a minority in the study as a whole. One participant delaying entry into the study that was negatively affected by the earthquakes exemplifies how extreme personal life stressors can affect smoking cessation outcomes, because this participant was able to quit smoking once that stress had been resolved. Local research that studied changes in smoking prevalence following the Canterbury earthquakes interviewed 1,001 participants in a high flow pedestrian area in Christchurch. That study reported one quarter of ex-smokers had resumed smoking and one third of smokers had increased their smoking rate as a result of their stress from the earthquakes [235]. This relapsing was found to be consistent with other studies where stress was found to be a trigger for increased smoking behaviours [363, 364].
The earthquakes also had an effect on the study regarding the availability of the hydrotherapy exercise component as it was closed for repairs for nearly all of the intervention timeframe. This component may have been popular with the intervention participants if it was available; an opinion that was confirmed by the Educators in their exit-interviews [360]. Hydrotherapy has been found to useful for reducing pain and improving the health status of people with RA in the short-term [365] so this was a missed opportunity for the quarter of participants who indicated a desire to use this component.

The participants’ attitudes to smoking and strategies for quitting were similar in both the intervention and control group participants. The similarities in their quitting strategies could have explained the lack of difference between the study outcomes. Whilst the intervention participants were given extra support and advice to assist with quit smoking attempts, the control group participants independently developed their own strategies, which were often similar, particularly with respect to their attempts to gain control of their smoking. Overall, participants were either very motivated to give up during the study or else they felt they lacked, or did not have, the desire to quit at that time as shown by similar comments from participants in both study arms. Therefore, there was an element of the participants needing to be ready and determined to quit smoking. The Arthritis NZ Educators [360] observed some intervention participants were ready to quit (based upon Prochaska’s ‘stages of change’ model of smoking cessation [366]), so made sure they provided support that included self-management skills. The Educators also recognised other participants were resistant to quitting smoking and surmised this was due to their smoking habit being ingrained and enjoyed [360].
The findings regarding motivations to quit smoking in this study fit well with the findings from a small-scale qualitative research project undertaken by the Quit Group in 2005 [367]. That study explored quitting motivations and barriers in 16 smokers with the goal of providing information for future media and communication smoking cessation campaigns in NZ [367]. Smokers who were assessed to be in contemplation and preparation stages (as defined in the ‘stages of change’ theory) [226] were interviewed in depth to ascertain their motivations to quit. A ‘tipping point’ was argued where smokers are motivated to quit smoking when the benefits of smoking are outweighed by the benefits of quitting smoking. Their findings suggested that every individual has a unique ‘tipping point’, which will change over time and can occur at any time [367]. They suggested there is a residual belief in smokers that willpower is the key to quitting and there is still a strong perception amongst smokers that ‘smokers who fail to quit do not really want to quit’ [188].

7.6 Conclusion

In conclusion, this chapter provided an in-depth exploration of the qualitative secondary outcomes of the pilot study by analysing the detailed information concerning the experiences of the study participants. The analysis demonstrated the support and advice from the Educators was the key component in the intervention that was most valued by the participants. Components that successfully contributed to smoking cessation included a smoking triggers diary and emailed generic smoking cessation advice, both commented on by participants as being helpful. There were common factors to both intervention and control groups, which had either facilitated or impeded smoking cessation. These were:
NRT, the use of other community smoking cessation programmes, and the stress from the Canterbury earthquakes. Control participants had independently developed their own strategies to control their smoking.
8 GENERAL DISCUSSION

8.1 Overview of Thesis Research Findings

The purpose of this thesis was to identify specific barriers to smoking cessation in people with RA and then develop an intervention to assist smokers with RA to overcome these barriers. The literature review identified a significant body of research demonstrating a link between smoking and the onset of RA. There is also increasing evidence to suggest that smoking impacts outcomes in RA both in terms of poorer responses to treatment, and increasing risk of comorbid conditions such as CVD, COPD and osteoporosis. Smoking cessation is one of the ten EULAR evidence-based recommendations for managing the CVD risk in people with RA [48]. Smoking cessation is also a recommendation of the ACR guidelines for the prevention of glucocorticoid-induced osteoporosis because the fracture risk in people with RA may be increased in current smokers [49].

Thus, smoking is a key risk factor and contributor to morbidity and mortality in people with RA. Although smoking prevalence is higher in people with RA compared to the general population [137-140], best practice, evidence-based, smoking cessation interventions have traditionally been designed for smokers without long-term medical conditions. However, there has been very little research on smoking cessation and RA and to date only one RCT of brief smoking cessation advice for rheumatology outpatients has been published [9]. Therefore, the literature review confirmed there was a need for a targeted smoking cessation for people with RA to be researched.
In the first phase of study, five disease-related barriers to smoking cessation in RA were identified: 1) lack of support; 2) lack of knowledge of the relationship between smoking and RA; 3) RA associated pain; 4) difficulty with exercise, and 5) smoking was used to cope with the frustrations of living with RA. Overall, this first phase established that people with RA have particular physical limitations and disease-associated factors that make quitting smoking challenging. Based on these findings a novel tailored smoking cessation intervention targeted for people with RA was developed in collaboration with Arthritis NZ.

In the final phase a pilot study demonstrated no difference in quit rates between those who received the novel targeted smoking cessation intervention in conjunction with ‘ABC pathway’ brief advice and NRT and those who only received the ABC. Despite this lack of benefit the intervention was well received. The number and timing of counselling sessions received, the way support was offered (by telephone or face to face), the location where sessions took place, the speed of progress in quitting or reducing smoking, and additional tailored support (e.g. education about smoking and RA, exercise opportunities, coping strategies, pain management, support for smoking cessation) all contributed to the delivery of an empowering and client-centred intervention that was valued by the participants. Interestingly, the control group participants had independently developed their own strategies to control their smoking. These strategies were similar to the intervention participants who had received intensive support from the Educators.

Of particular importance it is apparent from this research that the current standard of care for smoking cessation, the ‘ABC pathway’, which includes NRT and brief advice is effective for smoking cessation in people with RA.
8.2 Discussion of Findings

For healthcare providers including individual practitioners and organisations such as New Zealand’s district health boards, this research demonstrates that the best practice, evidence-based, smoking cessation pharmacological aids, such as NRT and brief behavioural advice as included in the ‘ABC pathway’ are an effective tool for smoking cessation in RA. It is most likely to be applicable to other chronic diseases, particularly if specific disease-related information regarding the relationship between an individual’s disease and smoking is offered in parallel. Whilst most of the general public is aware of the connections between smoking and lung cancer [368, 369], there are many other chronic diseases that are directly affected by smoking such as diabetes [370, 371], MS [372, 373] and Crohn’s disease [374, 375] in addition to RA. The Cochrane Collaboration have concluded that although the benefit of adding behavioural to pharmacological support is small, it is a statistically and clinically significant outcome, particularly for interventions that have four or more support contacts. However, increasing the number and amount of behavioural and pharmacological interventions does not result in equivalent increases in abstinence [321].

The ‘Stages of Change’ component of the TTM has been used extensively in smoking cessation. The basic principle of the TTM, as outlined by Prochaska and colleagues, is that smokers are in five different stages of readiness to quit, and smoking cessation interventions should be individualised and personalised based on the stage of readiness a smoker has to quitting [326]. But there is juxtaposition between the Cochrane Collaboration reviews and the viewpoint of Prochaska. The Cochrane reviews are focused on efficacy in clinical trials with no consideration for the impact on the overall population smoking rates. In contrast, Prochaska is concerned with the impact of smoking cessation interventions in
populations [376]. Impact is defined as the participation rate multiplied by efficacy. Thus if a smoking cessation intervention has a 30% abstinence rate but only 5% participation, it has an impact of 1.5%, whereas an alternative intervention that generates 20% abstinence but has 75% participation has a much higher impact of 15%. The tenet of this argument is that because less than 8% of daily smokers in the USA are in the preparation stage and prepared to quit within the next month, evidence-based smoking cessation programmes are not having an impact on the other 92% of the smoking population [376].

The difference of viewpoints between the Cochrane reviews and Prochaska as discussed above is interesting. Increasing smoking cessation rates using successful interventions is the primary outcome goal of any smoking cessation programme. However, population smoking cessation rates have not increased measurably in the USA in any population group since the early 1990’s although tobacco control policies and smoking cessation programmes have increased dramatically [376]. Research from the USA based on responses from 39,000 smokers has shown that although varenicline is very effective in smoking cessation, it’s use has merely displaced NRT and bupropion [377]. Quitting rates in the USA have remained relatively stable with only a slight increase from 4.5% in 2003 to 4.7% in 2010-11 [377]. Quitters were defined as the amount of smokers who had quit for at least three months over the last 12 months [377]. Thus, there appears to be a limit to increased quitting rates from using traditional smoking cessation treatments, and a more novel approach may be required in the future to increase quitting rates. Hence, it has been suggested that more effective smoking programmes are more likely to emerge from new approaches rather than from variations of already tested interventions [326].
In NZ, the quitting smoking rates as reported in the 2012/3 NZ Health Survey had increased from 8% (2006/7) to 11% (2012/3) in the general population [378], although those quit rates had remained steady from 2006 to 2009 [379]. Successful quitters were defined as having quit smoking between a month and a year from when they participated in the health survey and remained quit [378]. Nicotine replacement therapy was used by 25% of quitters in 2012/3, which was an increase from 20%, in 2009 [378, 379]. Varenicline and bupropion were used by 18% of quitters in 2012/13 [378], but bupropion was used rarely in 2006 (<7%) and varenicline was not yet available [377, 380]. The ‘ABC pathway’ was reported to have been offered to 48% of current smokers from their GP during 2012/13 [378] and was not available in 2006, although some form of quit advice was received by 26% of smokers from their GP [380]. While it is difficult to compare the NZ quit rates with the USA quit rates due to differences in time frames and outcome measurements, the USA has seen a decrease in smoking prevalence from a steady 21% during 2004-2009 to 17.8% in 2013 [381]. Therefore, the emerging emphasis of targeted smoking cessation programmes, as evident by recent reviews from the Cochrane Tobacco Addiction Group may be having an impact on the USA quit rates 2009 onwards [382].

When evaluating healthcare research it is prudent to go beyond purely reporting results and to take a step back to consider the rigour of the research in ways that fit the research methodologies that were used [258, 383]. The lack of observed differences in the quitting rates and reduction in daily smoking rates in this pilot study were surprising given the level of intensity of the designed intervention and the high level acceptability of the intervention by participants.
A pilot study can give valuable insights into the efficacy of a behavioural or pharmacological intervention even if they cannot provide definitive support for specific therapeutic claims [260]; hence this method was chosen to address the research problem in this thesis. However, the small sample sizes typically seen in clinical pilot studies (and 38 people with RA in this study specifically) mean the likelihood of observing statistically significant differences is low [260]. The effect size of a study is an important driver in clinical decision making regardless of whether the difference is statistically significant or not [357]. The NNT for the pilot study was 20, which shows the small effect size of the intervention. Another notion is they could have independently been ready to quit smoking before they entered the study, meaning the study was opportune in timing. The RR was 1.25 (95% CI 0.40-3.95) giving a small positive non-significant effect size of 25%, which is interpreted as the probability of quitting smoking was one quarter larger from the intervention (ABC+) compared to the control treatment (ABC). This result was similar to the Cochrane systematic review of 38 RCTs (15,506 participants) that added behavioural interventions as adjuncts to pharmacotherapy (principally NRT) finding a small but statistically significant benefit from more intensive support (RR 1.16, 95% CI 1.09-1.24) [321]. Thus, the effect from the intervention in the pilot study fit well with other smoking cessation clinical trials in the general population with similar intervention structure and content.

Effect sizes can be used to calculate sample sizes required for future studies [384]. A sample size calculation for a full RCT using the pilot study primary smoking cessation outcomes gives an indication of the number of participants required to show a statistically significant difference between the intervention and the control arms of the study. The sample size required for a full RCT study to show an effect of the tailored smoking cessation
intervention using 95% power would be **3472 participants** (1736 participants per study arm). If a lower power was desirable, then a somewhat smaller sample would be required: e.g. 80% power would require a sample size of 2100 participants, and 90% power would require 2800. Overall, the requirement for participant numbers for a full RCT is high, reflecting the small effect that was detected between the intervention and control groups in the pilot study. As discussed, this is most likely due to the use of the highly efficacious NRT in both arms of the study. Given the costs of such a large study, undertaking a full RCT would not be financially judicious at the public health level given the high success and efficacy of the ‘ABC pathway’ and the small effect size of the intervention.

Biases in behavioural intervention studies can occur from participation effects with participants having extra motivation for quitting regardless of their study allocation [385]. As outlined in Chapter 6, research has suggested that it is likely that individuals who volunteer to participate in a research study may be more motivated to change than those who do not volunteer [385]. This suggests the pilot study findings may only be generalisable to highly motivated individuals and not to individuals that do not have any motivation to change [385]. This potential for this type of bias is virtually ubiquitous in clinical outcome research and there has been no agreed upon solution for this bias [385].

The participants in the study in this research were volunteers who were interested in either helping identify barriers to quitting smoking in RA, or were people with RA who smoked who wanted to attempt to quit. The control group participants may have been highly motivated to quit because of these reasons. Those who chose not to participate may not have wanted to quit smoking.
Study design alone is not an adequate marker of the evidence of quality in a public health intervention evaluation [383]. Public health interventions, such as the novel smoking cessation intervention described in this pilot study, tend to be complex, pragmatic, and context dependent which make it difficult to use traditional evaluation methods [386]. The smoking cessation intervention for people with RA that was developed for this pilot study was an example of a complex intervention due to the interacting components within the experimental and control group interventions (smoking cessation advice); the difficulty of the behaviour required by those receiving the intervention and controls (smoking cessation in both groups); and the flexibility or tailoring of the intervention that was required. Interpretation of the final outcome result should be applied in this context.

The evidence of effectiveness for complex interventions must be comprehensive enough to encompass the appropriate level of complexity [383]. It may not be feasible to judge the quality of a complex intervention using the well-established criteria designed to appraise large clinical RCTs because there are many aspects of evidence that will not covered [383]. For example: it may not be possible to distinguish between the reliability of the evaluation process in detecting the success or failure of the intervention and the success or failure of the intervention itself [383]. This is because proper interpretation of evidence depends upon descriptive information on the intervention and its context being available, so that the transferability of the evidence can be determined [383]. This is currently an area of contention. The development of clearly defined standards for evidence around population-level interventions, including the need for contextual information, is a current area of research for several stakeholders in the evaluation and systematic review fields, including the Cochrane Collaboration, and the Centers for Disease Control and Prevention’s Community Preventive Services Task Force [386]. However, a well conducted RCT is still
the best way to determine a causal relationship between an intervention and its predefined outcomes [383]. Overall, it is important to recognise in a pilot study that there are many issues surrounding rigour of the result, and the outcome from the study for this pilot study could have been affected from any one of these, or a combination.

8.2.1 Strengths and Limitations

The strengths of this research in this thesis included the key role of the Arthritis NZ Educators, and the support network from Arthritis NZ. The Educators are experienced in providing support and advice to people with RA, and the pilot study intervention was designed to fit within their existing service delivery structure, and was based where possible upon existing resources and information from Arthritis NZ. The wide range of intervention components available and offered to participants was a key strength of intervention because of the ability to tailor to each participant, whilst providing facilitators for both the management of RA and smoking cessation. The limitations of the thesis study are encompassed in aspects of rigour of the exploratory research and pilot study phases as discussed in Chapters 4 and 6.

8.3 Implications for Future Research

This thesis has important implications for future research on the treatment for smoking cessation in people with RA. In particular, the findings highlight the strategies that can be focused on for improving smoking cessation rates in people with RA. Promoting health self-management in chronic illnesses, including RA has long-term benefits including
improving health status whilst reducing health care costs at the individual and population level [387].

There is the possibility that the educational component from the intervention had a larger effect than was recognised, therefore disease-related information given in addition to brief advice may be beneficial. Thus, for future studies, re-piloting the smoking intervention using the key education component should be undertaken. There is considerable evidence demonstrating education the causal link with health behaviours [351]. An Organisation for Economic Co-operation and Development (OECD) symposium in 2006 examined the effects of education on health and reported there was robust evidence that confirmed appropriately designed and delivered education interventions have the potential to change both health beliefs and behaviours, including substantial evidence that education can change smoking behaviours [351]. The educational handout in the pilot study was well received by the intervention participants and may have aided in their smoking cessation attempts. It is a simple aid that could be used in clinical practice when individuals are newly diagnosed or when smoking cessation is being discussed and could be offered by Rheumatologists, Nurse Practitioners and/or psychologists where available in the outpatient setting. It is likely this type of intervention would take approximately five minutes extra time to a medical appointment, and may prove to be cost and time efficient.

Further studies might examine whether particular help with smoking cessation should be offered to RA smokers with a lower educational attainment and those with a larger pack year smoking history because these participants seemed to be the least likely to quit during the pilot study. Although these two findings were non-significant in the pilot study from this thesis, there is evidence that recognises these as specific demographic barriers to
smoking cessation in the general population [215, 350]. People with RA who smoke are likely to have similar barriers to quitting. Referral to Arthritis support agencies, such as Arthritis NZ may be the most practical route for RA smokers who require extra assistance with quitting because these organisations already provide advice and support specifically targeted to people with RA. The intervention components used in the pilot study were largely based upon existing resources and information from Arthritis NZ and fitted within their existing service delivery structure, which is a predominantly telephone-based service.

Future research that followed the study participants long-term who managed to quit smoking would be valuable to ascertain if they experience any changes in RA disease activity and severity, and to measure any changes in comorbid disease outcomes and RA treatments.

8.4 Conclusion

The novel intervention developed for this research was grounded in previous research, was informed by patient opinion, provided support and advice from Arthritis NZ, and incorporated evidence-based smoking cessation treatments. The methods used in the different phases of research in this thesis give strength to the findings. Both quantitative and qualitative methodologies were utilised depending upon the nature of the research question and the particular outcome sought. Qualitative methodologies were used in the exploratory and evaluative phases enabling the participants the opportunity to share their lived experience and difficulties of RA and smoking cessation. As is usual practice in RCT’s, quantitative methodology was the method of choice for this pilot study enabling
the efficacy of this smoking intervention to be tested in a rigorous manner. This research adds to knowledge by providing feedback from both intervention and control group participants on a comprehensive intervention specifically targeted to people with RA, which resulted in a high quitting rate among all participants.

The tailored smoking cessation intervention for people with RA had no significant impact on quit rates, suggesting the ‘ABC pathway’ is currently the best practice for supporting people with RA who wish to quit smoking. Adding a disease-specific educational component that outlines the relationship between RA and smoking may be beneficial. Because smoking has a direct and significant impact on RA, particularly the risk of increased disease severity and mortality, assisting people with RA with smoking cessation is crucial.
REFERENCES


92. Bizzaro, N., Bartoloni, E., Morozzi, G., et al., *Anti-cyclic citrullinated peptide antibody titer predicts time to rheumatoid arthritis onset in patients with*


   08(1124): p. 1-44.


Westhoff, G., Rau, R., and Zink, A., *Rheumatoid arthritis patients who smoke have a higher need for DMARDs and feel worse, but they do not have more joint


New Zealand Ministry of Health. Implementing the ABC Approach for smoking cessation: framework and work programme. 2009 [accessed 26 September 2014];


214. Ockene, J.K., Emmons, K.M., Mermelstein, R.J., et al., Relapse and maintenance


216. Quitline New Zealand. Quitline encourages relapsed smokers to try quitting again
this world smokefree day. 2013 [accessed 13 June 2013]; Available from:
http://www.quit.org.nz/file/mediaReleases/quitline-encourages-relapsed-smokers-
to-try-quitting-again.pdf.

217. Cohen, S. and Lichtenstein, E., Perceived stress, quitting smoking, and smoking

218. Becona, E., Vazquez, F., and del Carmen Miguez, M., Smoking cessation and

interrelationships between social anxiety, smoking to cope, and cigarette craving.

220. Anthenelli, R., Morris, C., Ramey, T.S., et al., Effects of varenicline on smoking
cessation in adults with stably treated current or past major depression. Ann

221. Payne, T.J., Ma, J.Z., Crews, K.M., et al., Depressive symptoms among heavy
cigarette smokers: the influence of daily rate, gender, and race. Nicotine Tob Res,


John, H., Hale, E.D., Treharne, G.J., et al., *'Extra information a bit further down the line': rheumatoid arthritis patients' perceptions of developing educational...*


Appendix 1: Baseline and Follow-up Questionnaires

a) Standard Baseline and Follow-up Demographic Questions

Smoking Cessation in Rheumatoid Arthritis

<table>
<thead>
<tr>
<th>Please write your name here</th>
<th>Study Number</th>
</tr>
</thead>
</table>

This questionnaire includes information not available from blood tests or any source other than you. Please try to answer each question even if you do not think it is related to you at this time. There are no right or wrong answers. Thank you.

1. What is your current AGE?  
   _______ years

2. Are you  
   Male OR Female

3. What year was your rheumatoid arthritis diagnosed?  
   __________

4. Ethnicity

Which ethnic group do you belong to?  
Mark the space or spaces which apply to you.

- NZ European
- Māori
- Samoan
- Cook Island Māori
- Tongan
- Niuean
- Chinese
- Indian
- Other (such as DUTCH, JAPANESE, TOKELAUAN).

Ko tēhea momo tāngata e whai pānga atu ana koe? Tohua te katoa o raro nei e hāngai ana ki a koe.

- Pākehā
- Māori
- Hāmoa
- Māori Kuki Airani
- Tonga
- Niue
- Hainamana
- Īnia
- tētahi atu (pērā i TATIMANA, HAPANĪHI, TOKELAU). Tuhia mai:
5. What treatments have you had for your arthritis in the past?

6. Have you had any joint surgery? YES / NO
   If yes, what and when?

7. Please list any other medical problems you have.
8. **At this time are you? (Please circle all that apply)**

- Are you in paid employment / self-employed?
- Are you working full time / part time?
- Are you in physical / manual or non-physical employment?
- Are you retired?
- Are you a home maker full time or student
- Are you unemployed?
- Are you not working because of ill health / disability?
  Other (describe) ________________________________

9. **What is your CURRENT OCCUPATION? (If you are not working what was your past occupation?)**

10. **How many YEARS OF EDUCATION have you completed?**

    Please circle the NUMBER OF YEARS AT SCHOOL, COLLEGE, UNIVERSITY etc.

    | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 (5th form) | 12 | 13 (7th form) | 14 | 15 | 16 | 17 | 18 | 19 | 20 |

11. **Smoking history**

    Have you ever smoked?

    - [ ] No
    - [ ] Yes, if yes what year did you start smoking? __________
12. On average how many packs per day have you smoked? ________ packs

13. Do you smoke now?
   
   ☐ YES

   ☐ NO, if no what year did you stop smoking _____________
**b) The Health Assessment Questionnaire (HAQ)**

For the items below, please tick the **ONE** response which best describes your usual ability over the past week.

<table>
<thead>
<tr>
<th></th>
<th>Without any difficulty</th>
<th>With some difficulty</th>
<th>With much difficulty</th>
<th>Unable to do</th>
</tr>
</thead>
</table>
| **1. DRESSING AND GROOMING**  
*Are you able to:*  
- Dress yourself, including tying shoelaces and doing buttons?  
- Shampoo your hair? |   |   |   |   |
| **2. RISING**  
*Are you able to:*  
- Stand up from an Armless straight chair?  
- Get in and out of bed? |   |   |   |   |
| **3. EATING**  
*Are you able to:*  
- Cut your meat?  
- Lift a full cup or glass to your mouth?  
- Open a new carton of milk (or powder)? |   |   |   |   |
| **4. WALKING**  
*Are you able to:*  
- Walk outdoors on flat ground?  
- Climb up five steps? |   |   |   |   |
<table>
<thead>
<tr>
<th>Please tick any aids and devices that you usually use for any of these activities:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Cane</td>
</tr>
<tr>
<td>□ Walking frame</td>
</tr>
<tr>
<td>□ Crutches</td>
</tr>
<tr>
<td>□ Wheelchair</td>
</tr>
<tr>
<td>□ Special or built-up chair</td>
</tr>
<tr>
<td>□ Devices used for dressing</td>
</tr>
<tr>
<td>(button hook, zipper pull,</td>
</tr>
<tr>
<td>long handled shoe horn etc.)</td>
</tr>
<tr>
<td>□ Built-up or special utensils</td>
</tr>
<tr>
<td>□ Other (please specify)</td>
</tr>
<tr>
<td>..................................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Please tick any categories for which you usually need help from another person:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Dressing and grooming</td>
</tr>
<tr>
<td>□ Rising</td>
</tr>
<tr>
<td>□ Eating</td>
</tr>
<tr>
<td>□ Walking</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Please tick any aids or devices that you usually use for any of these activities:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Raised toilet seat</td>
</tr>
<tr>
<td>□ Bath seat</td>
</tr>
<tr>
<td>□ Jar opener</td>
</tr>
<tr>
<td>(for jars previously opened)</td>
</tr>
<tr>
<td>□ Bath rail</td>
</tr>
<tr>
<td>□ Long handled appliances for reach</td>
</tr>
<tr>
<td>□ Other (please specify)</td>
</tr>
<tr>
<td>..................................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Please tick any categories for which you usually need help from another person:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Hygiene</td>
</tr>
<tr>
<td>□ Reach</td>
</tr>
<tr>
<td>□ Gripping and opening things</td>
</tr>
<tr>
<td>□ Errands and housework</td>
</tr>
</tbody>
</table>
For the items below, again please tick the **ONE** response which best describes your usual ability over the past week.

<table>
<thead>
<tr>
<th></th>
<th>Without any difficulty</th>
<th>With some difficulty</th>
<th>With much difficulty</th>
<th>Unable to do</th>
</tr>
</thead>
</table>
| **5. HYGIENE**  
 *Are you able to:*  
 - Wash and dry your entire body?  
 - Take a bath?  
 - Get on and off the toilet? | | | |
| **6. REACH**  
 *Are you able to:*  
 - Reach and get down a 5lb object (e.g. a bag of potatoes) from just above your head?  
 - Bend down to pick up clothing from the floor? | | | |
| **7. GRIP**  
 *Are you able to:*  
 - Open car doors?  
 - Open jars which have been previously opened?  
 - Turn taps on and off? | | | |
| **8. ACTIVITIES**  
 *Are you able to:*  
 - Run errands and shop?  
 - Get in and out of a car?  
 - Do chores such as Vacuuming housework or light gardening? | | | |
**c) The Personal Impact HAQ (PI HAQ)**

These questions ask about how important it is to you to be able to do different things. You might feel it is not important that you do the gardening yourself – it could be done by someone else. On the other hand you might feel that it is important to do the gardening yourself – even though it could be done by someone else. How **important** is it to you **this week** to be able to do the following things **yourself**?

<table>
<thead>
<tr>
<th></th>
<th>Not at all important</th>
<th>A little bit important</th>
<th>Quite important</th>
<th>Very important</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Carry out tasks involved in dressing and grooming, including tying shoelaces, doing buttons, and shampooing your hair?</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
<td>☒</td>
</tr>
<tr>
<td>2. Carry out the sort of tasks that involve getting up (e.g. from a chair or bed)?</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
<td>☒</td>
</tr>
<tr>
<td>3. Carry out the tasks involved in preparing and eating food?</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
<td>☒</td>
</tr>
<tr>
<td>4. Walk, including flat ground and stairs?</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
<td>☒</td>
</tr>
<tr>
<td>5. Carry out the tasks involved in personal hygiene, including using bath and toilet?</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
<td>☒</td>
</tr>
<tr>
<td>6. Carry out the sort of tasks that involve reaching up and bending down?</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
<td>☒</td>
</tr>
<tr>
<td>7. Carry out the sort of tasks that involve gripping things (e.g. turning taps)?</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
<td>☒</td>
</tr>
<tr>
<td>8. Carry out general activities such as light gardening, shopping, and housework?</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
<td>☒</td>
</tr>
</tbody>
</table>
d) The Perceived Stress Scale (PSS)

The next few questions ask about your feelings and thoughts during the LAST MONTH. Answer each question fairly quickly using the rating scale below:

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>never</td>
<td>almost never</td>
<td>sometimes</td>
<td>fairly often</td>
<td>very often</td>
</tr>
</tbody>
</table>

In the last month, how often have you…

a) Been upset because of something that happened unexpectedly? ……….0 1 2 3 4

b) Felt that you were unable to control the important things in your life? 0 1 2 3 4

c) Felt nervous and “stressed”?.................................................................0 1 2 3 4

d) Dealt successfully with irritating life hassles?.................................0 1 2 3 4

e) Felt that you were effectively coping
   with important changes occurring in your life?..................................0 1 2 3 4

f) Felt confident about your ability to handle your personal problems?.....0 1 2 3 4

g) Felt that things were not going your way?...........................................0 1 2 3 4

h) Found that you could not cope with all the things that you had to do?...0 1 2 3 4

i) Been able to control irritations in your life?.......................................0 1 2 3 4

j) Felt that you were on top of things?.....................................................0 1 2 3 4

k) Been angered because of things
   that happened that were outside of your control?.............................0 1 2 3 4

l) Found yourself thinking about things that you have to accomplish?......0 1 2 3 4

12. Been able to control the way you spend your time?.........................0 1 2 3 4

13. Felt difficulties were
   piling up so high that you could not overcome them?.......................0 1 2 3 4
e) The Arthritis Self-Efficacy Scale (ASES)

In the following questions we would like to know how your arthritis symptoms affect you. For each of the questions, please circle the ONE number which corresponds to your certainty that you can now perform the following tasks:

1. How certain are you that you can decrease your pain quite a bit?
   Very uncertain 1 2 3 4 5 6 7 8 9 10 very certain

2. How certain are you that you can continue most of your daily activities?
   Very uncertain 1 2 3 4 5 6 7 8 9 10 very certain

3. How certain are you that you can keep arthritis pain from interfering with your sleep?
   Very uncertain 1 2 3 4 5 6 7 8 9 10 very certain

4. How certain are you that you can make a small-to-moderate reduction in your arthritis pain by using methods other than taking extra medication?
   Very uncertain 1 2 3 4 5 6 7 8 9 10 very certain

5. How certain are you that you can make a large reduction in your arthritis pain by using methods other than taking extra medication?
   Very uncertain 1 2 3 4 5 6 7 8 9 10 very certain

6. How certain are you that you can control your fatigue?
   Very uncertain 1 2 3 4 5 6 7 8 9 10 very certain

7. How certain are you that you can regulate your activity so as to be active without aggravating your arthritis?
   Very uncertain 1 2 3 4 5 6 7 8 9 10 very certain

8. How certain are you that you can do something to help yourself feel better if you are feeling blue?
9. As compared to other people with arthritis like yours, how certain are you that you can manage arthritis pain during your daily activities?
Very uncertain 1 2 3 4 5 6 7 8 9 10 very certain

10. How certain are you that you can manage your arthritis symptoms so that you can take pleasure from the things that you enjoy doing?
Very uncertain 1 2 3 4 5 6 7 8 9 10 very certain

11. How certain are you that you can deal with the frustration of arthritis?
Very uncertain 1 2 3 4 5 6 7 8 9 10 very certain
f) The Hospital Anxiety and Depression Scale (HADS)

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he/she will also 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 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.

<table>
<thead>
<tr>
<th>I feel tense or “wound up”:</th>
<th>I feel as if I am slowed down:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most of the time</td>
<td>Nearly all the time</td>
</tr>
<tr>
<td>A lot of the time</td>
<td>Very often</td>
</tr>
<tr>
<td>Time to time, occasionally</td>
<td>Sometimes</td>
</tr>
<tr>
<td>Not at all</td>
<td>Not at all</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I still enjoy the things I used to enjoy:</th>
<th>I get a sort of frightened feeling like “butterflies” in the stomach:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitely as much</td>
<td>Not at all</td>
</tr>
<tr>
<td>Not quite so much</td>
<td>Occasionally</td>
</tr>
<tr>
<td>Only a little</td>
<td>Quite often</td>
</tr>
<tr>
<td>Hardly at all</td>
<td>Very often</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I get a sort of frightened feeling as if something awful is about to happen:</th>
<th>I have lost interest in my appearance:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very definitely and quite badly</td>
<td>Definitely</td>
</tr>
<tr>
<td>Yes, but not too badly</td>
<td>I don’t take so much care as I should</td>
</tr>
<tr>
<td>A little, but it doesn’t worry me</td>
<td>I may not take quite as much care</td>
</tr>
<tr>
<td>Not at all</td>
<td>I take just as much care as ever</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I can laugh and see the funny side of things:</th>
<th>I feel restless as if I have to be on the move:</th>
</tr>
</thead>
<tbody>
<tr>
<td>As much as I always could</td>
<td>Very much indeed</td>
</tr>
<tr>
<td>Not quite so much now</td>
<td>Quite a lot</td>
</tr>
<tr>
<td>Definitely not so much now</td>
<td>Not very much</td>
</tr>
<tr>
<td>Not at all</td>
<td>Not at all</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Worrying thoughts go through my mind:</th>
<th>I look forward with enjoyment to things:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A great deal of the time</td>
<td>As much as I ever did</td>
</tr>
<tr>
<td>A lot of the time</td>
<td>Rather less than I used to</td>
</tr>
<tr>
<td>From time to time</td>
<td>Definitely less than I used to</td>
</tr>
<tr>
<td>Only occasionally</td>
<td>Hardly at all</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I feel cheerful:</th>
<th>I get sudden feelings of panic:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>Very often</td>
</tr>
<tr>
<td>Not often</td>
<td>Quite often</td>
</tr>
<tr>
<td>Sometimes</td>
<td>Not very often</td>
</tr>
<tr>
<td>Most of the time</td>
<td>Not at all</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I can sit at ease and feel relaxed:</th>
<th>I can enjoy a good book or radio or TV programme:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitely</td>
<td>Often</td>
</tr>
<tr>
<td>Usually</td>
<td>Sometimes</td>
</tr>
<tr>
<td>Not often</td>
<td>Not often</td>
</tr>
<tr>
<td>Not at all</td>
<td>Very seldom</td>
</tr>
</tbody>
</table>
g) The Euroqol-5D (EQ-5D)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

**Mobility**
- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

**Self-Care**
- I have no problems with self-care
- I have some 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 with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

**Pain/Discomfort**
- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

**Anxiety/Depression**
- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed
h) The EQ-Visual Analogue Scale (EQ-VAS)

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.
i) The Fagerström Test for Nicotine Dependence (FTND)

For current smokers, for the items below, please tick the ONE response which best describes your smoking

<table>
<thead>
<tr>
<th>Questions</th>
<th>Tick</th>
<th>Answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How soon after you wake up do you smoke your first cigarette?</td>
<td>☐</td>
<td>Within 5 minutes</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>6-30 minutes</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>31-60 minutes</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>After 60 minutes</td>
</tr>
<tr>
<td>2. Do you find it difficult to refrain from smoking in places where it is forbidden, for example: in church, at the library, in a cinema?</td>
<td>☐</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>No</td>
</tr>
<tr>
<td>3. Which cigarette would you hate most to give up?</td>
<td>☐</td>
<td>The first one in the morning</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>All others</td>
</tr>
<tr>
<td>4. How many cigarettes per day do you smoke?</td>
<td>☐</td>
<td>10 or less</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>11 – 20</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>21 – 30</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>31 or more</td>
</tr>
<tr>
<td>5. Do you smoke more frequently during the first hours after waking than during the rest of the day?</td>
<td>☐</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>No</td>
</tr>
<tr>
<td>6. Do you smoke if you are so ill that you are in bed most of the day?</td>
<td>☐</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>No</td>
</tr>
</tbody>
</table>
### j) The Smoking Self-Efficacy Questionnaire (SSEQ)

The following are some situations in which certain people might be tempted to smoke. Please indicate by placing a tick in the box whether you are sure that you could **REFRAIN** from smoking in each situation.

<table>
<thead>
<tr>
<th>Situation</th>
<th>Not sure at all</th>
<th>Not very sure</th>
<th>More or less sure</th>
<th>Fairly sure</th>
<th>Absolutely sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>When I am nervous</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>When I feel depressed</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>When I am angry</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>When I feel very anxious</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>When I want to think about a difficult problem</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>When I feel the urge to smoke</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
</tbody>
</table>

The following are some situations in which certain people might be tempted to smoke. Please indicate by placing a tick in the box how much you are **TEMPTED** to smoke in each situation.

<table>
<thead>
<tr>
<th>Situation</th>
<th>Not at all tempted</th>
<th>Not very tempted</th>
<th>Somewhat tempted</th>
<th>Very tempted</th>
<th>Extremely tempted</th>
</tr>
</thead>
<tbody>
<tr>
<td>When having a drink with friends</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>When celebrating something</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>When drinking beer, wine or other spirits</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>When I am with smokers</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>After a meal</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>When having tea or coffee</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
</tbody>
</table>
### Smoking History

**SMK1** Have you smoked at least 100 cigarettes, cigars or pipefuls in your lifetime?  
1 = Yes  
2 = No (Go to question SMK8)  
3 = Uncertain (Go to question SMK8)

**SMK2** Have you ever smoked daily (= almost every day for at least one year)?  
1 = Yes  
2 = No (Go to question SMK8)  
3 = Uncertain (Go to question SMK8)

**SMK3** Do you now smoke?  
1 = Yes, daily (Go to question SMK5)  
2 = Yes, occasionally  
3 = Not at all

**SMK4** When did you stop smoking daily? (If you have quit smoking several times, give the time when you last stopped smoking daily?)  
1 = Today or yesterday  
2 = 2 days - 6 days ago  
3 = 1 week - less than 1 month ago  
4 = 1 month - less than 1 year ago  
5 = 1 - 5 years ago  
6 = More than 5 years ago

**SMK5** On average, how many times do you smoke per day (= number of cigarettes, cigars, pipefuls of tobacco etc.)?  

**SMK6** Which of the products do you frequently smoke?  
- Manufactured cigarettes (1=yes, 2=no)  
- Self-rolled cigarettes (1=yes, 2=no)  
- Pipe (1=yes, 2=no)  
- Cigars (1=yes, 2=no)

**SMK7** Have you during the past year (12 months) been advised by a health professional to stop smoking?  
1 = Yes  
2 = No  
3 = I have not smoked during the past 12 months

**SMK8** Are you exposed to indoor tobacco smoke at home?  
1 = Yes  
2 = No

**SMK9** About how many hours per day are you exposed to indoor tobacco smoke at your workplace?  
1 = I do not work outside the home  
2 = Almost never  
3 = Less than one hour a day  
4 = 1-5 hours a day  
5 = More than 5 hours a day
Appendix 2: Original Article: Identifying Barriers to Smoking Cessation in RA

Identifying Barriers to Smoking Cessation in Rheumatoid Arthritis

Pip Aimer, Lisa Stamp, Simon Stebbings, Natalia Valentino, Vicky Cameron, and Gareth J. Treherne

Objective. The aim of this study was to investigate disease-related issues that make smoking cessation challenging for patients with rheumatoid arthritis (RA). There is currently a lack of research on tailoring smoking cessation interventions for RA patients. Qualitative exploration is a necessary first step in planning targeted interventions.

Methods. A qualitative mixed-methods study was undertaken. Participants attended either a focus group or an individual interview and completed a set of standardized questionnaires. The sample consisted of 36 RA patients: 24 current smokers and 12 ex-smokers. The transcripts were analyzed thematically using a critical realist approach to inductively identify themes.

Results. Five key barriers to smoking cessation that are faced by RA patients were identified. First, participants were unaware of the relationship between smoking and RA and therefore did not perceive this as a reason to quit. Second, smoking was used as a distraction from pain. Third, participants found it difficult to exercise and therefore were unable to use exercise as an alternative distraction. Fourth, smoking was used as a coping mechanism for the frustrations of living with RA. Fifth, participants felt unsupported and isolated from other RA patients.

Conclusion. Disease-related issues may hinder smoking cessation for RA patients. Through an understanding of patients’ perspectives there is an opportunity to plan an effective targeted intervention that may increase the chance of smoking cessation in RA patients where smoking may adversely influence disease progression and comorbidities.

INTRODUCTION

Smoking tobacco is a highly prevalent and addictive habit that is the leading cause of preventable death (1). Smoking is recognized as the most important environmental factor identified to date in the pathogenesis of anti-citrullinated protein antibody-positive rheumatoid arthritis (RA) (2). Smoking may exert an adverse effect on disease activity, joint damage, and response to therapy (2–5). Components of smoke have been shown to have an effect on inflammation in the synovium that reverses with smoking cessation (6). Remission rates of RA may be lower in smokers compared to nonsmokers (7,8).

RA is associated with osteoporosis and cardiovascular disease (CVD), and smoking is an additional risk factor for these conditions. Osteoporosis has been attributed to a number of RA-specific factors, including disease activity, physical inactivity, and use of corticosteroids (9,10).

The risk of premature mortality due to CVD in RA is increased by 48% as compared to the general population (11,12). The increased risk of CVD in RA is associated with an increased prevalence of smoking, other traditional risk factors for CVD, and the chronic systemic inflammatory response in RA, which may all act synergistically (13,14).

The combination of negative health effects associated with smoking in RA patients makes a compelling case for smoking cessation. Indeed, smoking cessation is one of the European League Against Rheumatism (EULAR) recommendations for managing the CVD risk in RA (14).

Guidelines for smoking cessation highlight how specific groups of smokers face more difficulties with quitting, particularly those with long-term health conditions (15,16). Smoking cessation interventions have traditionally been designed for smokers without long-term illness. Smoking cessation interventions for patients with specific long-term diseases such as CVD, diabetes mellitus, and chronic obstructive pulmonary disease (COPD) have received surprisingly little attention (16), and no
Significance & Innovations

- Smoking is a significant risk factor for developing rheumatoid arthritis (RA), and smoking cessation is recommended for patients with RA to reduce risk of cardiovascular disease and osteoporosis, but little research has addressed RA-related barriers to smoking cessation.
- Smoking cessation is one of the most important modifiable lifestyle factors through which patients with RA can improve outcomes; therefore, smoking cessation should be a critical aspect of the management of RA.
- Physical limitations and disease-associated factors can adversely affect smoking cessation in RA patients.
- Strategies for smoking cessation need to be better integrated to support smokers with RA; facilitation in areas of disease education, exercise, pain management, coping strategies, and support tailored specifically for RA may increase smoking cessation in RA.

RA-specific smoking cessation interventions have been published. RA patients may have specific medical and psychosocial issues that should be targeted in a smoking cessation program. This study was designed to investigate disease-related issues that make smoking cessation difficult for patients with RA.

PATIENTS AND METHODS

A qualitative mixed-methods study was undertaken. Participants attended either a focus group or an individual interview and completed a set of standardized questionnaires.

Patients age >18 years with RA as defined by the 2010 American College of Rheumatology/EULAR criteria (17), were recruited from rheumatology departments at 2 large public hospitals in New Zealand. Convenience and stratified purposeful sampling (18) were used in order to balance sex, age, current smokers and ex-smokers, patients with recent-onset and long-standing disease, and to ensure inclusion of participants who identify as Māori, the indigenous people of New Zealand. Ethical approval was given by the New Zealand Multi-Region Ethics Committee (MEC/11/06/061). All participants gave written informed consent.

The focus groups (2–4 participants) and individual interviews were all moderated by the first author (PA). Focus groups and individual interviews followed a semi-structured format, where the discussions were guided but not limited by predetermined questions. The participant question schedule and prompts are presented in Table 1. The content of the question schedule was congregated from a variety of sources, including consultation with specialists in rheumatology and psychology, and the literature (19). The average duration of the group interviews was 60 minutes (range 42–93 minutes) and the individual interviews averaged at 29 minutes (10–65 minutes).

Focus groups and individual interviews were audio-recorded and transcribed. Data saturation was sought based on the principle of theoretical saturation, where no new additional thematic material emerges from additional participants (20,21). The transcribed data were thematically analyzed from a critical realist epistemology (21). The analysis was carried out manually using Word documents to compile extracts and develop themes. The analysis was inductive in that the data were coded into themes evident within the focus groups and individual interviews without starting from a preexisting coding frame (20,21). One of the authors (GT) independently

| 1. What do you know about the relationship between smoking and rheumatoid arthritis? (prompts: link to symptom severity, possibility affecting how well drugs work, increasing the risk of heart attacks and strokes)
| 2. What made you take up smoking?
| 3. Did the pattern of your smoking change when you developed arthritis?
| 4. What about the reasons for continuing smoking after you developed arthritis. Did they change?
| 5. What specific features about living with arthritis can make it difficult for you to stop smoking? (prompts: anxiety, stress, depression, pain, sleeplessness, fatigue, living circumstances, stress/associations, appetite/weight, loss of ability to work/activities of daily living/particles in usual hobbies or pastimes)
| 6. Can you tell me about any smoking cessation programs you’ve tried? (prompts: what aspects of the program you tried worked and what did not?)
| 7. Who would you turn to for smoking cessation advice? (prompts: family, friends, general practitioner, pharmacist, rheumatologist, nurse, private therapist, internet support, Quitline)
| 8. If you have tried to quit smoking, how did you go about trying?
| 9. What aspects of the way in which you tried worked and what did not? (prompts: nicotine gum/lozenges/patches, "cold turkey,") popular books, alternative therapies, Smoke Stink)
| 10. What advice would you give to someone with rheumatoid arthritis who was thinking about giving up smoking? (prompts: could we add this into a program?)
| 11. Have you ever received advice to stop smoking from your general practitioner, rheumatologist, rheumatology nurse?
| 12. What form did this take? (prompts: verbal, written, referral to a service)
RESULTS

Demographics. Fifty-six RA patients were invited to participate, 11 declined to participate, 1 patient did not meet the inclusion criteria, and 8 did not attend the interview (Figure 1). Demographic and disease data of the 36 participants who attended an interview are presented in Table 2. Mean age was 59 years (range 34–77 years). The average disease duration was 13.6 years (range 0.5–29 years). Nearly one-half (46%) of current smokers had been diagnosed with comorbid CVD, osteoporosis and/or chronic COPD, compared to 1 ex-smoker with mild COPD. Of the 20 who did not participate, the mean age was 57 years (range 45–81 years) and two-thirds (n = 14) were female. There were no significant differences between the demographics of those who attended an interview compared to those who did not.

Smoking history. Smoking history data are presented in Table 3. All but 1 participant began smoking as teenagers. All participants smoked prior to acquiring RA and two-thirds were current daily smokers. The participants had smoked for an average of 43 years and most smoked the equivalent of 20 cigarettes a day. The Fagerström test indicated the current smokers had a low to moderate dependency on nicotine. Nearly all of the smokers (91%) reported having received advice from a health practitioner to quit smoking within the last year.

Functional status and psychosocial data. RA functional status and psychosocial data are presented in Table 4. There was no significant difference between smokers and ex-smokers in questionnaire scores for disability levels or impact, self-efficacy over mood or other symptoms of arthritis, or in scores for anxiety, depression, or stress. With respect to quality of life, EQ-5D scores were not significantly different between smokers and ex-smokers, but the EQ-VAS score was higher for ex-smokers, suggesting this group had a more positive perception of their health status. There were significant differences between the current smokers and ex-smokers with respect to smoking self-efficacy.

Thematic analysis. By using an inductive and open coding format, 5 barriers to smoking cessation were identified by participants: lack of education about the links between smoking and RA, managing their pain associated with RA, inability to exercise, using smoking as a coping strategy, and lack of suitable support for smoking cessation.

Barrier 1: lack of education about the links between smoking and RA. Twenty-three of the 36 participants were unaware of a relationship between smoking and RA, and therefore did not perceive this as a reason to quit: “(My rheumatologist) said before but it would be a lot better for my rheumatoid if I wasn’t smoking but, I know loads of people that smoke who haven’t got it... so to me, it’s irrelevant” (female smoker, age 34 years).

Fifteen of 36 participants did not recall having received any advice from their medical practitioners about the links between smoking and RA: “No. It’s never
been spoken about in there (hospital), when I’ve been in there. I’ve had my knees done 6 times... I just don’t know, it doesn’t affect me with the arthritis...the last time that anything was said about the smoking interfering with the cortisones” (male smoker, age 72 years).

Only 6 participants reported changes in their smoking patterns due to their RA diagnosis; all had increased their smoking after diagnosis.

**Barrier 2: managing RA pain.** Twenty-two of 36 participants experienced difficulties managing pain associated with their arthritis. While not explicitly using smoking to control their pain, they were using smoking as a diversion from pain, particularly during the night: “I can’t sleep because of the pain, umm that will make me go back to smoking. And it’s just you know, the poor me thing really, I feel so sorry for myself and, and what can I do you know. If I can’t hold a book... I can smoke. You know smoking honestly does seem the only thing I can do...and you know you’re going to be awake for hours and hours and hours...” (female smoker, age 69 years).

The participants also reported a decrease in pain and a decrease in anxiety when they smoked: “...some people might have a drink, others drink heaps of coffee and I choose to smoke... I probably don’t choose to smoke but yeah, smoking I’ve found that can take...my mind off it I guess...” (male smoker, age 38 years).

However, as the ex-smoking participants revealed, this association can be overcome and their smoking needs can be replaced by alternative strategies: “It’s the association with severe pain and the need to sit so you’re gonna sit down and you’re gonna grab a smoke, ‘cause that’s gonna make you feel better, but then you find out no, you don’t

<table>
<thead>
<tr>
<th>Table 2. Demographics of participants*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>--------------------------------------</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
</tr>
<tr>
<td>New Zealand European</td>
</tr>
<tr>
<td>Māori/Pacific Islander</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
</tr>
<tr>
<td>Paid employment</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td><strong>Comorbidities</strong></td>
</tr>
<tr>
<td>Osteoporosis</td>
</tr>
<tr>
<td>COPD</td>
</tr>
<tr>
<td>CVD</td>
</tr>
<tr>
<td>Joint surgery</td>
</tr>
<tr>
<td>Interview site</td>
</tr>
<tr>
<td>Center 1</td>
</tr>
<tr>
<td>DMARDs</td>
</tr>
<tr>
<td>Methotrexate</td>
</tr>
<tr>
<td>Combination therapy</td>
</tr>
<tr>
<td>RF positive</td>
</tr>
<tr>
<td><strong>Note:</strong></td>
</tr>
</tbody>
</table>

* Values for the total sample are the number (percentage with denominator n = 36). Values for the current smokers and ex-smokers are the number (percentage with denominator determined by the number for the subgroup of the total sample; e.g., n = 24 in comparing the female current smokers and female ex-smokers). COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; DMARDs = disease-modifying antirheumatic drugs; ACPA = anti-citrullinated protein antibodies; RF = rheumatoid factor.

<table>
<thead>
<tr>
<th>Table 3. Smoking history of participants*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Secondary smoke at home</td>
</tr>
<tr>
<td>Secondary smoke at work</td>
</tr>
<tr>
<td>Years smoking</td>
</tr>
<tr>
<td>Cigarettes per day</td>
</tr>
<tr>
<td>Age at smoking initiation, years</td>
</tr>
<tr>
<td>Fagerstrom test</td>
</tr>
<tr>
<td><strong>Note:</strong></td>
</tr>
</tbody>
</table>

* Values for the total sample are the number (percentage with denominator n = 36) or mean (range). Values for the current smokers and ex-smokers are the number (percentage with denominator determined by the number for the subgroup of the total sample; e.g., n = 9 in comparing the prevalences of secondary smoke at home between the current smokers and ex-smokers). NA = not applicable.
need to do that, you could just sit down and rest anyway. It works the same." (female ex-smoker, age 67 years).

**Barrier 3: inability to exercise.** Twenty-seven of 36 participants found it difficult to exercise or continue their usual activities (including paid employment) due to their RA: "I used to do lots of tramping (hiking), I don’t do any big trumps any more … the last one I did was earlier this year, was just a 4 hour walk in, 4 hour walk out, no strenuous hill work or anything and yeah my knee blew up on the way out.” (male smoker, age 38 years).

“I gave up work as a result; I was going from working 60 hours a week and being busy to basically doing nothing.” (female smoker, age 50 years).

Participants described being unable to use exercise or movement as a distraction from smoking: "I’m just sitting there reading a book havin’ fog after fog after fog, ‘cause you can’t do anything else” (male smoker, age 50 years).

“It’s something to do with your hands when you don’t feel like doing anything…” (female smoker, age 63 years).

**Barrier 4: using smoking as a coping strategy.** Smoking was or had in the past been used as a strategy for coping with life in general and specifically the frustration of living with RA in 33 of 36 patients questioned. Some participants spoke emotionally about smoking, saying that quitting would be like losing a “good friend,” whereas other participants saw smoking as a social behavior and did not want to lose those interactions: "I remember giving up once, patches and that, and I used to cry in morning. Honestly I did, I cried, it’s like losing your best friend” (female smoker, age 64 years).

Participants mentioned that they no longer consumed alcohol due to the contraindications with their RA medication such as methotrexate: “I haven’t had a drink since I got arthritis; I don’t drink much; I was a social drinker … I do find now that I don’t drink … I’m not as sociable; I know it’s wrong to smoke but it’s the only thing that I’ve, for me anyway that I feel, I don’t go any-where, I can’t even flippin’ well have a glass of wine now, like I used to” (male smoker, age 56 years).

Participants reported that they used smoking to cope with significant negative life events, such as the death of a close family member or marriage break-up: “My marriage went to the pack, I took up smoking, I owned a dairy (shop), it (cigarettes) was right there” (female ex-smoker, age 49 years). "I just lost my husband so I bought a house in town and no way was I gonna smoke inside, but … I don’t know … I was a bit of a mess” (female smoker, age 67 years).

**Barrier 5: lack of suitable support for smoking cessation.** Six of the 36 participants in this study felt unsupported due to isolation from others with the same illness, and a further 7 of 36 did not know anyone else with RA. Most participants had tried unsuccessfully on numerous occasions to quit smoking but felt overwhelmed during stressful life events and due to their isolation had returned to smoking. Therefore, many were interested in getting support from RA-specific sources such as groups or web sites:

"Well why don’t they have groups like this so that people like us can go and actually talk to other people with arthritis? They used to have one years ago out … and we’d sit down and we’d talk and we’d laugh and joke and it’s good, but this is probably the most people I’ve talked to about rheumatoid arthritis in a group in my life…” (male smoker, age 56 years). "…One blog that I read, I thought oh well that’s someone that actually sounds like she’s reading my mind … I never knew that rheumatoid could be so debilitating. I thought… you get arthritis and it’s painful and then you get over it but I didn’t realize it can set you back so much so that was a bit of a shock … so talking to people that have the same conditions is quite useful” (female smoker, age 50 years).

Participants expressed interest in smoking cessation support in a one-on-one situation rather than a group: “I
really don’t like group; I’m not that type of person. I’m not interested” (female smoker, age 34 years).

Smoking cessation attempts. Nearly all of the participants had made numerous attempts at quitting smoking, and 7 current smokers had previously been smoke-free for long periods of time: “I’ve done it before (stopped smoking) for 12 years... I still did find it hard to do but I never thought I’d ever go back after 12 years” (female smoker, age 63 years).

The most common cessation method was nicotine replacement therapy including patches and gum. Just under a third of participants had tried varenicline. Other common methods included bupropion, gradual reduction in smoking, acupuncture, and self-help books. Individual counseling by Quitline, a free nationwide telephone helpline offering support for smoking cessation in New Zealand, was used by many participants. However, these strategies were not considered effective. In particular, pharmaceutical aids to quitting were often perceived as being inconvenient, taste unpleasant, or causing adverse effects such as nausea or allergic reactions: “Champix [varenicline]... they made me feel sick... so I just stopped taking them” (female ex-smoker, age 53 years). “I’m allergic to sticking plasters... so then they gave me chewing gum but that stuck to the false teeth” (female smoker, age 67 years).

Unsuccessful quitters mentioned stress and temptation as reasons to start smoking again: “I gave up and then became a few stresses with my son... thought I’d only have one cigarette... bought a packet and smoked the lot” (female smoker, age 64 years). “I had to give up for 7 years... my dad came over and he was smoking, I says oh yeal. I’ll have one and just started again” (female smoker, age 50 years).

The ex-smokers in this study had succeeded with the same smoking cessation methods. One key factor that seemed to set those participants apart from the continuing smokers was their perception that they were ready to stop: “I was just sick of the taste” (male ex-smoker, age 53 years). “I knew I didn’t want to smoke anymore” (female ex-smoker, age 55 years). “…Something just clicked in my head and I just gave up” (female ex-smoker, age 39 years).

Generally, these participants did not find quitting easy. Quitting to improve the efficacy of their RA medication was only mentioned by 1 participant: “... smoke free for nearly 2 years... I thought the drugs might’ve worked better than smoking, maybe that’s why I stopped...” (female ex-smoker, age 70 years).

DISCUSSION

The present study explored disease-related issues that hinder smoking cessation in patients with RA. The aim was to understand RA-specific barriers to smoking cessation in order to inform possible components for an effective RA-specific smoking cessation intervention. Thematic analysis revealed that RA patients have specific physical and psychosocial needs although some of these are similar to other those seen in other long-term illnesses (16,33), such as a lack of education regarding associations between illness and smoking, chronic pain, inability to exercise or activities, higher rates of depression and anxiety, and less social support. In this study cohort there were no obvious patterns of demographic or disease factor.

Smoking contributes to the disease burden in many long-term diseases including CVD, diabetes mellitus, and cancer (16). Changing entrenched smoking habits is difficult for smokers, and most smokers attempt to quit many times before succeeding. Surveys in the US consistently report that 70% of smokers want to quit; nearly half of these will have attempted during the previous year, but only 4–7% are successful (34). Gritz et al argue that it is critical to evaluate smoking cessation for patients with particular long-term illnesses to determine whether significant modifications to a cessation program should be made based on specific disease-specific issues (16).

While all the participants in this study recognized that smoking was detrimental to their health, most were unaware of the links between smoking and RA. Furthermore, the majority did not recall receiving any information from medical practitioners regarding links between smoking and RA. There is a need to develop appropriate educational material to enhance relevant lifestyle modifications in RA patients (35). However, the main challenge is changing behavior (36). John et al demonstrated that careful design of an education program informed by qualitative stakeholder participation proved successful in increasing knowledge and intentions to modify adverse behaviors (36). Whether such an approach with smoking cessation programs will result in improved quit rates remains to be determined.

Chronic widespread pain is a common feature of RA (37). It has been suggested that individuals with chronic pain may be motivated to smoke because of a belief that smoking could help them cope with their pain or that quitting smoking would be more difficult because of their pain. However, recent studies have shown that smoking cessation was not associated with either the exacerbation or improvement in pain (38–40). In a RA smoking cessation program, pain management is likely to be a key barrier to cessation, and as such pain management strategies should form an integral part of any program.

There is good evidence that physical activities reduce cigarette cravings (41). The benefits of exercise in RA include lowering CVD risk, increasing body muscle mass to lessen rheumatoid cachexia, increasing bone mineral density, improving joint health, improving functional ability and psychological well-being, and reducing pain, morning stiffness, and fatigue (42). Overall, exercise has not been shown to exacerbate RA disease activity. Therefore, as part of a RA smoking cessation intervention, suitable targeted exercises should be offered.

Smoking as a coping strategy was or had been used by nearly all of the study participants to counter their perceived frustrations of living with RA, such as their
inability to do usual tasks, issues with pain management, and their requirement to avoid alcohol while taking DMARDs. The most commonly cited reason for smoking unrelated to RA was the use of smoking to cope with significant adverse life events. Research shows that active coping skills lead to better health perceptions for patients with RA (43); those who do not use active coping strategies appear to be more at risk of psychological comorbidities (44). Furthermore, patients who perceive their RA to have a negative prognosis also report more depression, pain, morning stiffness, fatigue, and a worse satisfaction with their life (45). Smokers with anxiety symptoms often report using smoking as a way of coping. Such use is associated with less success at smoking cessation (46). The successful quitters in this study reported less anxiety and depression than the current smokers. They were significantly enabled with a sense of self-efficacy over the temptation to smoke. Therefore, providing individually tailored active coping strategies for living with RA could prove beneficial. Such strategies may include a greater awareness of their own personal smoking triggers, and strategies to cope with their associated RA symptoms. Theoretical models and contemporary research indicate that active coping leads to better psychological outcomes in RA (44,45,47).

A small proportion of participants in this study felt unsupported during their attempts at smoking cessation due to isolation from others with the same illness. Some participants were interested in becoming involved in support groups, while others were more interested in individualized support.

There are robust evidence-based effective smoking cessation interventions available that have been shown to reduce smoking rates in the general smoking population, and include medications and counselling or a combination of both. Smokers can increase their chance of successful cessation by up to 3 times by using evidence-based medications and counselling as those who use neither (46). Therefore, tailored and individualized support for RA smokers is likely to be beneficial.

Unfortunately, immediate benefits from smoking cessation are seldom apparent in terms of health status. Former smokers with long-term illnesses have been reported to take twice as long to reduce their medical costs compared to those without (49). Although recognized health benefits to RA patients from smoking cessation include a reduced risk of mortality from CVD and improvements in bone density, these may take some years to realize.

The main strength of this study is the use of qualitative mixed methods. The qualitative data provide rich information about RA patients’ lived experience with their disease such as emotions, behaviors, needs, desires and personalities, which cannot be matched by quantitative data alone. The critical realism approach to data analysis demonstrates an amalgamation and interpretation of the complexity of the lived experience of the research participants; therefore, the nature of participants’ reality was the driving force as opposed to methodological or ideological predispositions. The combination of interview techniques and recruiting from 2 centers reduces the chance of homogenous bias. Eighty percent of patients who were approached agreed to participate. Although the study was small, saturation was reached, suggesting that new themes were unlikely to be identified with a larger sample size. Limitations of the study include the inability to identify specific issues for the Māori population due to the small sample size. There was also the tendency for participants to be self-selecting; therefore the sample was not necessarily representative of all smokers with RA. It was not possible to quantify the smaller sub-themes because there were numerous complex issues independently identified by the participants, but answers regarding these specific issues were not consistently provided by the participants.

Physical limitations and disease-associated factors can adversely affect smoking cessation in RA patients. Smoking cessation is one of the most important modifiable lifestyle factors in which patients with RA can improve outcomes. Therefore, smoking cessation should be a critical aspect in the management of RA. Facilitation in areas of education, exercise, pain management, coping strategies, and support tailored specifically for RA may increase smoking cessation in RA. This study provides a valuable insight to the specific RA-related barriers to smoking cessation in a stratified sample of smoking and ex-smoking RA patients. By gaining an understanding of these specific factors from the patients’ perspectives, there is an opportunity to plan an effective targeted intervention that may increase the chance of smoking cessation. These ‘lived’ patient experiences have provided the foundations for a smoking cessation intervention tailored for RA patients.

ACKNOWLEDGMENT
The authors wish to acknowledge the assistance of Janine Francis and Jan Ipenburg with recruitment.

AUTHOR CONTRIBUTIONS
All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Teahane had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analyses.

Study conception and design. Aimer, Stamp, Stebbings, Valentino, Cameron, Teahane.
Acquisition of data. Aimer, Stamp, Teahane.
Analysis and interpretation of data. Aimer, Stamp, Teahane.

REFERENCES
3. Westhoff G, Rui R, Zink A. Rheumatoid arthritis patients who smoke have a higher need for DMARDs and feel worse, but they do not have more joint damage than non-smokers


Appendix 3: Consent Form for Phase 1 Exploratory Study

CONSENT TO PARTICIPATE IN

Smoking cessation in rheumatoid arthritis

REQUEST FOR INTERPRETER

<table>
<thead>
<tr>
<th>Language</th>
<th>Request</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>I wish to have an interpreter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deaf</td>
<td>I wish to have a NZ sign language interpreter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Māori</td>
<td>E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pekehā korero</td>
<td>Ae</td>
<td>Kao</td>
</tr>
<tr>
<td>Cook Island Māori</td>
<td>Ka inangaro au i tetai tangata uri reo</td>
<td>Ae</td>
<td>Kare</td>
</tr>
<tr>
<td>Fijian</td>
<td>Au gadreva me dua e vakadewa vosa vei au</td>
<td>Io</td>
<td>Sega</td>
</tr>
<tr>
<td>Niuean</td>
<td>Fia manako au ke fakaaoaga e taha tagata fakahokohoko kupu</td>
<td>E</td>
<td>Nakai</td>
</tr>
<tr>
<td>Sāmoan</td>
<td>Ou te mana’o ia i ai se fa’amatala upu</td>
<td>Ioe</td>
<td>Leai</td>
</tr>
<tr>
<td>Tokelaun</td>
<td>Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika</td>
<td>Ioe</td>
<td>Leai</td>
</tr>
<tr>
<td>Tongan</td>
<td>Oku ou fiema’u ha fakatonulea</td>
<td>Io</td>
<td>Ikai</td>
</tr>
</tbody>
</table>

I have read the Information Sheet dated October 2012 and have had the study fully explained to me in a language that I understand.

I have also had the opportunity for full discussion with one of the investigators, a person of my choice, and have had adequate time to consider participating in this study.

I UNDERSTAND:

- Taking part in this study is voluntary (my choice). I may withdraw from the study at any time and this will in no way affect my continuing health care.
- My participation in this study is confidential and no material which could identify me will be used in any reports on this study.
- I know who to contact if I have any questions about the study.
- I will receive a copy of this Consent Form and the Information Sheet.
- This study has received ethical approval from the Multiregional Ethics Committee.
- I wish to receive a copy of the results. YES / NO
- I consent to my GP being informed of my participation in this study YES / NO
• I consent to the use of my data for future related studies, which have been given ethical approval from a New Zealand Accredited Ethics Committee  YES/NO
• I consent to being contacted in the future for follow-up studies  YES/NO

I ………………………………………… (Full name) hereby consent to take part in this study.

Signature: ………………………………………… Date:    /    /   .

Project explained by…………………………………………

Signature ……………………………………………

Signature of investigator: …………………………………… Date:    /    /   .

Christchurch
Ms Pip Aimer Phone (03) 364-0496 (work) or 021-048-3885
Assis Prof Lisa Stamp Phone (03) 364-0953 (work)

Dunedin
Dr Simon Stebbings Phone (03) 474-0999 ext. 8504 (work)
Dr Gareth Treharne Phone (03) 479-7630 (work)

Arthritis New Zealand
Dr Natalia Valentino Phone (09) 523-8907 (work)
Appendix 4: Information Sheet for Phase 1 Study

Smoking cessation in rheumatoid arthritis

INFORMATION SHEET

Investigators

Prof Lisa Stamp, Rheumatologist, Christchurch Hospital
Dr Simon Stebbings, Rheumatologist, Dunedin Hospital
Dr Gareth Treharne, Psychologist, University of Otago

You are invited to participate in a study looking at smoking cessation in patients with rheumatoid arthritis. Recent evidence has shown that smoking has a number of effects on rheumatoid arthritis. Smoking can increase the risk of developing RA, it can make rheumatoid arthritis more severe and it can make rheumatoid arthritis more difficult to treat. In addition, smoking is a recognized risk factor for heart disease, which is significantly increased in patients with RA. Quitting smoking is now recognized as an important part of managing arthritis. However, many people with arthritis find it difficult to stop smoking. This study aims to identify barriers to quitting smoking in patients with arthritis. This information will then be used to develop a quit smoking programme specifically for people with arthritis.

Study Procedure

If you agree to participate in the study the PhD student (Pip Aimer) will contact you to arrange a time to attend a group discussion on smoking. This discussion will be based on several areas relating to smoking and quitting smoking. This discussion will be videotaped so we can analyse the discussion in detail at a later stage.

You will be also asked to fill out a questionnaire about your arthritis and how it affects your life. You will have a blood test and your joints will be examined to see how many are swollen and tender.

Once we have analysed the information from the discussion we will develop a specific quit smoking programme for people arthritis. If you are a current smoker you will be invited to participate in this. This may include telephone contact with an arthritis educator from Arthritis New Zealand as well as the PhD Student. It may also involve nicotine replacement in the form of gum or patches.

Your participation is entirely voluntary and you may withdraw from the study at any stage without this affecting your treatment.

Nature and Duration of the Study

IF you agree to participate in this study you will need

- To complete the questionnaires
- Attend a focus group session to discuss aspects of smoking, smoking cessation and arthritis. This will take approximately 2 hours.
- The second part of the study involves a smoking cessation programme. This will entail monthly contact by phone and some visits to an arthritis educator.
- A sample of the blood will be stored indefinitely and may be used to measure other markers of arthritis that may be of interest. It may be necessary to send a sample of blood overseas to test for some markers of arthritis that we cannot test for in NZ. Once the samples have been sent overseas they will not be returned to NZ but will be destroyed after they have been tested for the markers of interest.

Some Common Questions

*Will my GP be told I am in the study? If you agree to participate in this study your GP will be advised.*

*What will happen at the end of the study? You will continue your treatment as prescribed by your doctor. You will continue to attend Outpatient clinics as required by your treating hospital specialist.*

*Where can I get more information about the study?* If at any time you have any concerns or questions about this study, do not hesitate to contact any of the study investigators or the PhD student.

*Are there any risks to me by being in the study?* There is the potential for some participants in the focus groups to experience some distress when discussing their condition. The moderator will have guidelines on appropriate ways to deal with this situation should it arise, including stopping the audio recording if requested to, allowing individuals to leave the focus group if they wish to.

It is possible that you may experience some bruising and discomfort after the blood sample is taken.

**Confidentiality:** No material which could personally identify you will be used in any reports on this study. Your study records will be stored in a locked cabinet in the Department of Medicine/Rheumatology and stored for a maximum of 20 years.

**Results:** Overall results of the study will be available from the investigators several months after the study has been completed.

**Compensation:** In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.
**Rights:** If you have any queries or concerns regarding your rights as a participant in this research study you can contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act.

Telephone (NZ wide): 0800 555 050.
Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT).
Email (NZ wide): advocacy@hdc.org.nz

**Statement of Approval:** This study has received ethical approval from the Multiregional Ethics Committee.

**Further Information**

If at any time you have concerns or questions about this study, do not hesitate to contact any of the study investigators.

- **Prof Lisa Stamp**
  Phone (03) 364-0953 (work)

- **Dr Simon Stebbings**
  Phone (03) 474-0999 ext. 8504 (work)

- **Dr Gareth Treharne**
  Phone (03) 479-7630 (work)

- **Pip Aimer (PhD student)**
  Phone (03) 364-0496 (work) or (021) 048-3885
Appendix 5: Māori Consultation

8 December 2010

Associate Professor Lisa Stamp
Department of Medicine
University of Otago, Christchurch

Mā te rangahau hauora e tautoko te whakapiki ake te hauora Māori
All health research in Aotearoa New Zealand benefits the hauora (health and wellbeing)
of tangata whenua

Tena koe, Lisa

Thank you for taking the time to meet with me at the University of Otago, Christchurch on
Tuesday 30\textsuperscript{th} November 2010, to discuss your research study titled:

Identifying and overcoming barriers to smoking cessation in rheumatoid arthritis

I note that your research is to explore the knowledge of rheumatoid arthritis patients about the
effects of smoking.

It was apparent in your summary of the research that there could be a small number of Maori
participants and that this research may have impact on Maori health and that is important.

It was heartening to know that you and your counterpart in Dunedin are establishing a focus
group in Dunedin specifically for Maori. I can assist along with Maori health workers, Maori
Health providers, and Maori Health professionals – such people should be relatively accessible
and well placed to advise you as to a relevance of your research and the outcomes which can
be achieved for Maori health and the population overall.

We also discussed the relevance of the research in regard to improving Maori health status and
referred to the HRC's Nga Pou Rangahau Hauora Kia Whakapiki Ake Te Hauora Maori 2004-
other reference that is available is Hauora Maori Standards of Health IV: A study of the years
2000-2005 by Bridget Robson and Ricci Harris, Maori Health Research Unit, Wellington School
of Medicine. All provide Maori specific information on a range of health issues.

The recent publication Tatau Kahukura: Maori Health Chart Book 2010, Ministry of Health, 2010
(2\textsuperscript{nd} edition), is an update relating to the socio economic determinants of health, health status
and service utilisation of the Maori population. Further references are available from the HRC's

All publications relate to individuals risk and protective factors. The prevalence of tobacco
smoking among Maori is higher than non-Maori.

It is also advisable that researchers review and refer to the District Health Board Annual Plan
and/or the current Health Targets published by the Ministry of Health (1 July 2009).

Research Office, Department of the Dean
University of Otago, Christchurch
PO Box 4345, Christchurch Mail Centre, Christchurch 8140, New Zealand
Tel +64 3 364 0237 • Fax +64 3 364 0525 • Email research.uoc@otago.ac.nz
www.uoc.otago.ac.nz
It was agreed that there is a need to acknowledge the issues pertaining to ethnicity and to consider how ethnicity data will be collected in your study. Also, given the poor ethnicity data collection in hospital databases this information should be collected in demographic information as part of the research. Through our discussion the Census 2006 ethnicity question was considered to be the preferred tool in recording ethnicity.

As findings from this study could contribute to the development of future research, it is therefore appropriate that Maori researchers, Maori health providers and Maori health professionals are aware of your successful outcome. The Research Office of the University of Otago, Christchurch and in particular myself, as the Research Manager Maori, would be willing to assist in the dissemination of your findings once your project has reached a conclusion.

It is a requirement of the ethics approval process that a final report be submitted when the research is complete. A copy of the report should be provided to me at that time as findings from this project may contribute to the development of future research hypotheses or projects. It is therefore important that appropriate Maori organisations, Maori health professionals and Maori researchers are aware of your findings. The Research Office of the University of Otago, Christchurch and in particular myself as the Research Manager - Maori would be willing to assist in the dissemination of your findings once your project has reached a successful conclusion.

My suggestions do not necessarily relate to ethical issues with the research, including methodology. Other committees may also provide feedback in these areas. I hope this letter will suffice in terms of the application. Please contact me should you need any other information that may not have been included in the letter relevant to our conversation.

I wish you well in your research.

"Mo tatou a mo ka ura a muri ake nei" Ngai Tahu 2025

Ka nui tonu nga mihi

[Signature]

Elizabeth Cunningham
Research Manager - Maori
Appendix 6: Standardised Participant information Form (Phase 1 and Phase 3 of study)

Name: ____________________________________________

NHI: ________________

Date: ________________

1. **DOB.** _____/_____/_____

2. **Diagnosis of RA:**
   Date: ________________

3. **Rheumatoid Factor** positive / negative
   If positive titre____________________________

4. **CCP** positive / negative
   If positive titre____________________________

5. **Other Medical Problems**
6. **Joint Surgery (what and date)**

7. **Current DMARDs**

<table>
<thead>
<tr>
<th>DMARD</th>
<th>Tick if yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methotrexate</td>
<td></td>
</tr>
<tr>
<td>Sulphasalazine (Salazopyrin)</td>
<td></td>
</tr>
<tr>
<td>Leflunomide (Arava)</td>
<td></td>
</tr>
<tr>
<td>Hydroxychloroquine (Plaquenil)</td>
<td></td>
</tr>
<tr>
<td>Humira (Adalimumab)</td>
<td></td>
</tr>
<tr>
<td>Etanercept (Enbrel)</td>
<td></td>
</tr>
<tr>
<td>Azathioprine</td>
<td></td>
</tr>
<tr>
<td>Gold (Myocrisin)</td>
<td></td>
</tr>
<tr>
<td>Prednisone (dose: __________ mg/day)</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 7: Original Article: Developing a Tailored Smoking Cessation Intervention for people with RA

RESEARCH ARTICLE

Developing a Tailored Smoking Cessation Intervention for Rheumatoid Arthritis Patients

Pip Aimer¹, Lisa K. Stamp¹, Simon Stebbings², Vicky Cameron¹, Sandra Kirby³, Suzanne Croft³ & Gareth J. Trehanne⁴

¹Department of Medicine, University of Otago, Christchurch, New Zealand
²Department of Medicine, Dunedin School of Medicine, University of Otago, Dunedin, New Zealand
³Arthritis New Zealand, New Zealand
⁴Department of Psychology, University of Otago, Dunedin, New Zealand

Abstract

Purpose: Smoking is associated with an increased risk of comorbidities in rheumatoid arthritis (RA) and may reduce the efficacy of anti-rheumatic therapies. Smoking cessation is therefore an important goal in RA. Our previous qualitative research identified five RA-related barriers to smoking cessation: lack of support; limited knowledge of the relationship between smoking and RA; uncontrolled pain; inability to exercise; and using smoking as a coping strategy. The aim of this article is to describe the process of developing a smoking cessation intervention for RA patients based on these themes.

Methods: A comprehensive review of the literature on smoking cessation was undertaken. A tailored smoking cessation programme was designed to address each RA-specific barrier. A meeting was convened with key staff of Arthritis New Zealand to develop a consensus on feasible design to deliver a smoking cessation programme based on existing best practice and smoking cessation resources, and tailored within existing Arthritis New Zealand service delivery frameworks.

Results: A three-month intervention was designed to be delivered by trained arthritis educators, with the following key components: nicotine replacement therapy for eight weeks; a telephone or face-to-face interview with each patient to determine their individual specific RA-related barriers to smoking cessation; and individualized education and support activities which addressed these barriers. The intervention also included three follow-up telephone calls; a support website; and 12 weekly smoking cessation advice emails.

Conclusions: A RA-specific smoking cessation intervention was developed, matching support to specific issues within each patient’s experience. A pilot study is in progress to evaluate the programme’s efficacy. Copyright © 2015 John Wiley & Sons, Ltd.

Keywords
Rheumatoid arthritis; smoking cessation; complex intervention; evidence-based practice; qualitative research

*Correspondence
Gareth J. Trehanne, Department of Psychology, University of Otago, PO Box 56, Dunedin 9054, New Zealand. Tel. +64 3 479 7630; Fax: +64 3 479 8335; Email: gtrehanne@psy.otago.ac.nz

Published online in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/mus.1106

Introduction

Tobacco smoking remains the leading cause of preventable death worldwide (Eriksen et al., 2012). It is also an important environmental risk factor for developing rheumatoid arthritis (RA), particularly in patients carrying the HLA-DRB1 genetic risk alleles that code for the ‘shared epitope’ (Kalberg et al., 2007; Klæesø et al., 2007; Lundberg et al., 2013; Sugiyama...
We have recently identified five RA-specific barriers to smoking cessation: 1) RA patients feel isolated and unsupported when attempting smoking cessation; 2) RA patients are often unaware of the detrimental effects of smoking on RA and hence do not perceive this as a reason to quit; 3) smoking is used as a distraction from the pain associated with RA; 4) RA patients find it difficult to exercise and hence see themselves as unable to use exercise as an alternative distraction from smoking; and 5) smoking is used as a coping mechanism for the frustrations of living with RA (Aimer et al., 2014). Therefore, physical limitations and disease-associated factors appear adversely to affect smoking cessation in RA patients. Strategies for smoking cessation need to be better integrated to support smokers with RA. Based on our previous research, smoking cessation strategies in RA may be more effective if they provide disease education and advice on exercise, pain management and coping strategies. Translating observational findings into novel psychosocial interventions requires a planning process (John et al., 2011). The aim of this article is to describe how we translated our observational findings about smoking cessation needs of RA patients into a targeted intervention so that researchers and rheumatology practitioners can replicate our process and/or make use of the intervention we have devised.

Methods
There were two major methodological components in the development of this intervention: 1) the identification of key generic components of existing evidence-based smoking cessation programmes, to be used to provide the intervention structure; 2) the development of resources for RA patients that address previously identified barriers for quitting smoking, to be used to provide the intervention content. The steps of the intervention development process are described below, in a linear fashion, although the process was iterative and undertaken after an initial planning period of over two years.

A comprehensive literature review, using a systematic approach, was carried out in order to provide the structural design and identify key generic components of best-practice evidence-based smoking cessation programmes. Sources of information included PubMed, OVID, the Cochrane Library, Ebsco Databases and Google Scholar. The literature review focused on two main categories of evidence: 1) systematic reviews and
meta-analyses of randomized controlled trials (RCTs); and 2) the most recent clinical practice guidelines on treating tobacco use and dependence from the World Health Organization (WHO) European Strategy for Smoking Cessation Policy (World Health Organization, 2004), the United Kingdom National Institute for Health and Care Excellence (National Institute for Health and Care Excellence, 2013), the United States (US) Department of Health and Human Services (US Department of Health and Human Services, 2008) and the New Zealand (NZ) Ministry of Health (New Zealand Ministry of Health, 2007, 2011).

The treatment intervention content was designed to address previously identified barriers for quitting smoking in RA. This process involved the development and refining of resources for RA patients, with modules created to address each of the barriers. A steering group was convened from key stakeholders and researchers involved in the project, with the remit of selecting and packaging the intervention content and deciding who would provide the necessary support. The steering group comprised stakeholders, including the project coordinator (PA), two consultant rheumatologists (LKS, SS), a health psychology researcher (GJT) and four health service providers from Arthritis New Zealand (the key support organization for individuals with arthritis in NZ (see Arthritis New Zealand, 2014). The Arthritis New Zealand providers included two arthritis educators, who were the primary contacts for RA patients seeking advice and support, and the Christchurch Regional Manager and the National Service Development Manager. The treatment interventions were chosen by the steering group with the following considerations: 1) smoking cessation interventions needed to be appropriate, feasible and based upon the best-practice intervention structure, as identified in the literature review; 2) wherever possible, the interventions would be based upon existing resources and information from Arthritis New Zealand or Christchurch Hospital Department of Rheumatology, Immunology and Allergy; 3) interventions needed to fit within the existing service delivery structure of Arthritis New Zealand, which is a predominantly telephone-based service; and 4) appropriate education of the Arthritis Educators who were providing smoking cessation advice. Apart from the section specifically targeted to smoking cessation, the remaining resources and treatments used in the intervention were generically suitable for all RA patients, regardless of their smoking status. The resources provided allowed for individual tailoring of the programme, depending on the goals required and the preferences of individual smokers with RA.

Results

Intervention structure

The literature review highlighted three key components for an effective smoking cessation interventions that are recognized internationally: 1) the optimal duration of a smoking cessation intervention of three months; 2) pharmacological support [e.g. nicotine replacement therapy (NRT)]; and 3) behavioural-based support (e.g. advice and counselling). These key components provided the structure for the intervention, which follows.

1. The minimum standard outcome measure requires smoking status to be reported at two time-points: at four weeks after the date that smoking ceased and at three months after this quit date, with optional follow-up at six months and 12 months.
2. Pharmacotherapies: NRT medications that have proven to be efficacious are recommended to all nicotine-dependent people.
3. Multisession behavioural support of at least four follow-up contacts offered face-to-face or via telephone, and weekly reminders in between.

Table 1 summarizes the efficacy of specific smoking cessation interventions in active treatment groups relative to controls populations. The following section outlines the components chosen for inclusion in the intervention from those identified as evidence-based best practice for smoking cessation. The potential interventions considered by the steering group for inclusion in the current intervention are listed in Table 1.

Combining behavioural and pharmacological support is recommended by the Cochrane Collaboration as this combination can double quit rates when compared with no intervention [relative risk (RR) 1.82, 95% confidence interval (CI) 1.66–2.00] (Stead and Lancaster, 2012a). Adding behavioural support to pharmacological support improves efficacy when compared with pharmacological support alone (RR 1.16, 95% CI 1.09–1.24). However, evidence is lacking to support the superiority of the combination in some populations (Stead and Lancaster, 2012a).
Table 1. Efficacy of interventions to combat tobacco addiction in the general population [based on systematic reviews and meta analyses from the Cochrane Collaboration (Hartmann-Boyce et al., 2013, 2014)]

<table>
<thead>
<tr>
<th>Intervention group (success rate of treatment)</th>
<th>Control group (success rate of treatment)</th>
<th>RR (95% CI)</th>
<th>Number of studies</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>No intervention</td>
<td>No advice</td>
<td>1.00 (control)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brief advice</td>
<td>No advice (5%)</td>
<td>1.76 (1.58–1.95)</td>
<td>26</td>
<td>New Zealand Ministry of Health, 2013; Stead et al., 2013a</td>
</tr>
<tr>
<td>Brief advice to quit ≥3 min to ≤10 min</td>
<td>Standard advice</td>
<td>1.00 (0.82–1.22)</td>
<td>2</td>
<td>Cahill et al., 2010</td>
</tr>
<tr>
<td>Behavioural Interventions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage-based counselling</td>
<td>No materials</td>
<td>1.45 (1.27–1.66)</td>
<td>14</td>
<td>Lancaster and Stead, 2005a</td>
</tr>
<tr>
<td>Self-help materials</td>
<td>Standard advice or staged-based counselling</td>
<td>1.36 (1.19–1.55)</td>
<td>7</td>
<td>Lancaster and Stead, 2005a</td>
</tr>
<tr>
<td>Telephone counselling</td>
<td>No telephone counselling</td>
<td>1.29 (1.20–1.38)</td>
<td>44</td>
<td>Stead et al., 2013b</td>
</tr>
<tr>
<td>Individual counselling (12%)</td>
<td>Minimal contact (9%)</td>
<td>1.39 (1.24–1.57)</td>
<td>22</td>
<td>New Zealand Ministry of Health, 2013</td>
</tr>
<tr>
<td>Group-based counselling (10%)</td>
<td>Self-help (6%)</td>
<td>1.98 (1.06–2.64)</td>
<td>13</td>
<td>New Zealand Ministry of Health, 2013; Stead and Lancaster, 2005</td>
</tr>
<tr>
<td>Pharmacotherapies</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combination NRT (21%)</td>
<td>Single NRT (16%)</td>
<td>1.34 (1.18–1.51)</td>
<td>9</td>
<td>New Zealand Ministry of Health, 2013; Stead et al., 2012</td>
</tr>
<tr>
<td>NRT (17%)</td>
<td>Placebo/ No NRT (10%)</td>
<td>1.60 (1.53–1.68)</td>
<td>117</td>
<td>New Zealand Ministry of Health, 2013; Stead et al., 2012</td>
</tr>
<tr>
<td>Bupropion ‘Zyban’ (19%)</td>
<td>Placebo (11%)</td>
<td>1.69 (1.53–1.85)</td>
<td>36</td>
<td>Hughes et al., 2014; New Zealand Ministry of Health, 2013</td>
</tr>
<tr>
<td>Varenicline ‘Champix’ ‘Chantix’ (28%)</td>
<td>Placebo (12%)</td>
<td>2.27 (2.02–2.55)</td>
<td>14</td>
<td>Cahill et al., 2012; New Zealand Ministry of Health, 2013</td>
</tr>
<tr>
<td>Combined behavioural and pharmacotherapies</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased behavioural support + pharmacotherapy</td>
<td>Less or no behavioural support + pharmacotherapy</td>
<td>1.16 (1.09–1.24)</td>
<td>38</td>
<td>Stead and Lancaster, 2012b</td>
</tr>
<tr>
<td>Pharmacotherapy + behavioural interventions (Grade A)</td>
<td>Usual care/self-help/brief advice</td>
<td>1.82 (1.66–2.00)</td>
<td>40</td>
<td>Stead and Lancaster, 2012a</td>
</tr>
</tbody>
</table>

NRT, nicotine replacement therapy; RR, risk ratio; CI, confidence interval.

Behavioural interventions

1. Brief advice (defined as advice from >3 minutes to ≤10 minutes) approximately doubles quit rates, compared with no advice (RR 1.76, 95% CI 1.58–1.95) (Stead et al., 2013a). Brief advice is a major component of the best-practice smoking cessation guidelines used in NZ; the ‘ABC’ pathway (New Zealand Ministry of Health, 2007, 2014). Brief advice was included in the intervention as ‘usual care’, and could serve as a protocol for control groups in clinical trials of the intervention.

2. Stage-based advice (based on the Stages of Change theory (Prochaska et al., 2007) is no more successful than no advice (RR 1.00, 95% CI 0.82–1.22) (Cahill et al., 2010). Based on this evidence, the stage-based advice strategy was not included in the current intervention.

3. There is good evidence that self-help materials are superior to no materials (RR 1.45, 95% CI 1.27–1.66) (Lancaster and Stead, 2005a). Tailoring materials to the specific needs of an individual is more beneficial than tailoring materials to specific population groups (RR 1.36, 95% CI 1.19–1.55) (Lancaster and Stead, 2005a). Therefore, it was agreed that treatment interventions addressing the individualized support needs of specific participants would be offered following an initial needs assessment.

4. Counselling carried out face-to-face or by telephone has been demonstrated to help people quit smoking. Individualized counselling helps smokers to quit when compared with no advice (RR 1.39, 95% CI 1.24–1.57) (Lancaster and Stead, 2005b). Individual counselling was offered in the current intervention. Although it is standard practice for Arthritis New Zealand to offer a predominantly telephone-based support service, the initial needs assessment (week 0) meeting would be face-to-face whenever possible, to help encourage the
development of a supportive relationship between the arthritis educator and RA patient. If a face-to-face meeting was not possible, telephone support would be offered. Evidence suggests that three or more telephone calls to a patient increase the chances of quitting when compared with a single telephone call (RR 1.37, 95% CI 1.26–1.50) (Stead et al., 2013b). Thus, for our current intervention we included three follow-up support telephone calls, spaced at weeks 1, 4 and 8, from Arthritis New Zealand counsellors to aid quitting.

Pharmacological interventions

1. NRT of any type increases smoking cessation rates independent of any additional support received (RR 1.60, 95% CI 1.53–1.68) (Stead et al., 2012). Combined NRT, as opposed to using a single NRT, also increases abstinence rates (RR 1.34, 95% CI 1.18–1.51) (Stead et al., 2012). NRT can be prescribed by any health professional in New Zealand who has received the basic ABC pathway training and registration, and includes subsidized patches, gum and/or lozenges (New Zealand Ministry of Health, 2009). This is the form of NRT that will be globally offered as ‘usual care’ and includes patches, gum and lozenges.

Timing of interventions

Condensing behavioural support during the first two weeks of smoking cessation is known as front-loading and is likely to be beneficial as 60–70% of smokers who quit will relapse within two weeks (Garvey et al., 2012). The steering group therefore agreed that front-loading patient contact would be included in the current intervention. We planned the intervention to include an initial baseline needs assessment at week 0, followed by continuing support at weeks 1, 4 and 8, with generic emails sent at weekly intervals for 12 weeks containing support, advice and tips for quitting.

Length of intervention

In accordance with international recommendations for smoking cessation programmes, the optimum duration for the current study was set at three months (North American Quitline Consortium Issues Paper, 2009; New Zealand Ministry of Health, 2011; West et al., 2005). Figure 1 demonstrates the format for the three-month smoking intervention designed for RA patients following the recommendations of the steering group.

Content of the smoking cessation intervention

In order to address the five smoking cessation barriers in RA identified in our previous research (Aimer et al., 2014), the steering group agreed upon the following intervention strategies for a tailored intervention in smoking cessation for RA patients; Table 2 outlines the timing of these interventions.

1. Support

Lack of support was identified as a major barrier to smoking cessation in RA. Patients feel unsupported in smoking cessation attempts and isolated from other RA patients (Aimer et al., 2014). The steering group agreed upon the following intervention strategies to address this issue: 1) an initial needs assessment by telephone or face-to-face with an Arthritis New Zealand Educator to

![Intervention timeline](image-url)

**Figure 1** The timeline of the three-month smoking cessation intervention for rheumatoid arthritis patients

Table 2. Contacts and content for the smoking cessation intervention for rheumatoid arthritis (RA) patients

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Intervention group</th>
</tr>
</thead>
</table>
| **Week 0** | (i) General information and informed consent  
  (ii) Baseline questionnaires  
  (iii) ABC pathway smoking cessation intervention  
  (iv) Randomization into study  
  (v) Standard intervention pack given and explained  
  (vi) Needs assessment with Arthritis New Zealand educator (first contact)  
  | Contact details  
  Assessment: Main concerns with RA  
  How is RA affecting daily activities?  
  How do they manage their RA?  
  Intervention checklist; information discussed and tailored to study participant  
  1. Education (handout)  
  2. Exercises (handouts)  
  3. Pain management  
  4. Coping strategies  
  5. Available support  
  Use of NRT documented |
| **Week 1** | Follow-up contact with Arthritis New Zealand educator (second contact)  
  General well-being since intervention  
  Review of interventions requested and/or used/useful  
  Review of current smoking status |
| **Week 2** | Email reminder: 'Smoking and your body' |
| **Week 3** | Email reminder: 'Stress, feeling down and cravings' |
| **Week 4** | Follow-up contact with Arthritis New Zealand educator (third contact)  
  General well-being since intervention  
  Review of interventions requested and/or used/useful  
  Review of current smoking status |
| **Week 5** | Email reminder: 'Social situations' |
| **Week 6** | Email reminder: 'The smoking addiction' |
| **Week 7** | Email reminder: 'Health benefits' |
| **Week 8** | Follow-up contact with Arthritis New Zealand educator (fourth contact)  
  General well-being since intervention  
  Review of interventions requested and/or used/useful  
  Review of current smoking status |
| **Week 9** | Email reminder: 'Nicotine patches, gum and lozenges' |
| **Week 10** | Email reminder: 'Stop checks and trying to quit again' |
| **Week 11** | Email reminder: 'Quit success stories' |
| **Week 12** | Email reminder: 'How are other quitters doing?'  
  (Quitline New Zealand blog) |

NRT, nicotine replacement therapy.

Identify individual barriers to smoking cessation and offer individualized support based on patient preferences; 2) three follow-up contacts by telephone or face-to-face and continued counselling from Arthritis New Zealand to address barriers to quitting; 3) generic weekly smoking cessation tips to be sent for 12 weeks; and 4) a support web page where all support material can be accessed.

2. Education about the links between smoking and RA

RA patients who participated in our previous qualitative study were aware of the general health risks associated with smoking, but many were not aware of specific relationships between smoking and RA. Patients with RA did not readily identify a link between the severity of their RA and their smoking (Aimer et al., 2014). Thus, the current intervention included a single-page leaflet outlining the association between adverse outcomes and smoking in RA, which included information on the risks of increased disease severity, reduced efficacy of RA medications and the potential for more joint damage in those who smoke. This leaflet also highlighted the additional risk posed by smoking in terms of CVD and osteoporosis – comorbid conditions which are more common in RA than in the general population, even in non-smokers.

3. Pain

Participants in our qualitative study suggested that they used smoking as a distraction from the pain associated with RA (Aimer et al., 2014). Chronic widespread pain is a common feature of RA (Andersson et al., 2012). It has been suggested that individuals with chronic pain may be motivated to smoke because of a belief that smoking could help them cope with their pain or that quitting smoking would be more difficult because of their pain, but recent studies have shown that smoking cessation was not associated with either the exacerbation or improvement in pain (Hahn et al., 2006; Patterson et al., 2012; Shi et al., 2011). Pain management strategies formed an integral part of our intervention. Arthritis educators are knowledgeable in discussing pain management issues, and hence the following interventions were offered: 1) the Arthritis New Zealand ‘Managing your Pain’ booklet; 2) advice on specific strategies for basic pain relief, such as complementary therapies and taking medications as advised; 3) advice on pacing, managing fatigue, and sleep hygiene; and 4) referral to a rheumatologist or their general practitioner for pain management.

4. Exercise

The RA patients in our qualitative study found it difficult to exercise owing to joint pain and had a
perception that exercise could worsen their arthritis. As a result, many felt that they could not undertake exercise as an alternative distraction to smoking (Aimer et al., 2014). However, there is good evidence that physical activities reduce cigarette craving (Haasova et al., 2012). Furthermore, exercise has additional benefits in RA, which include lowering CVD risk; increasing body muscle mass; increasing bone mineral density; improving joint health; improving functional ability and psychological well-being and reducing pain, morning stiffness and fatigue (Cooney et al., 2011). Overall, exercise has not been shown to exacerbate disease activity in RA (Cooney et al., 2011). The steering group agreed that the following exercise resources should be made available for the intervention, and participants were encouraged to make use of resources appropriate to their needs (available from the corresponding author upon request): 1) a booklet with specific strengthening hand exercises (produced by the pharmaceutical company Abbott); 2) a booklet on ‘General Exercises for RA’ (also produced by Abbott); 3) a booklet called ‘Arthritis: Exercises to Keep You Moving’ (produced by Arthritis New Zealand); 4) a DVD presenting home-based exercise (used by Arthritis New Zealand); 5) a handout on local community exercise resources (with details of places, dates and time schedule); 6) a handout on local hydrotherapy classes available locally; 7) a referral to a primary health provider, such as a physiotherapist or occupational therapist; and 8) a pedometer.

5. Coping

In our focus group survey, smokers with RA reported that smoking helped them to cope with the frustrations of living with RA. Therefore, support for patients to develop alternative coping mechanisms were seen as a key component of any intervention (Aimer et al., 2014). Research shows that active coping skills lead to better health perceptions for patients with RA (Engelbrecht et al., 2012); those who do not use active coping strategies appear to be more at risk of psychological comorbidities (Treharne et al., 2007b). Furthermore, patients who perceive their RA to have a negative prognosis also report more depression, pain, morning stiffness, fatigue and a worse satisfaction with their life (Treherne et al., 2005b). Smokers with anxiety symptoms often report using smoking as a way of coping (Aimer et al., 2014). Using smoking to cope with these negative health perceptions is detrimental to successful smoking cessation (Watson et al., 2012). High coping effectiveness leads to better general health perception for patients with RA (Engelbrecht et al., 2012). Helping RA patients to identify triggers for smoking and providing alternative self-management strategies may assist with smoking cessation. The steering committee therefore recommended the following interventions: 1) a smoking diary to enable participants to identify their smoking triggers; and 2) a discussion of goals and self-management to change coping strategies away from smoking. Table 3 outlines the key aspects of this smoking cessation intervention.

Table 3. Details of targeted interventions for smoking cessation intervention in rheumatoid arthritis (RA)

<table>
<thead>
<tr>
<th>Theme</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Education</td>
<td>Handout: ‘The link between smoking and RA’</td>
</tr>
<tr>
<td>2. Exercises</td>
<td>Abbott handout: ‘Hand exercises for RA’</td>
</tr>
<tr>
<td></td>
<td>Abbott handout: ‘General exercises for RA’</td>
</tr>
<tr>
<td></td>
<td>Arthritis New Zealand booklet: ‘Exercises to Keep you moving’</td>
</tr>
<tr>
<td></td>
<td>Arthritis New Zealand DVD: ‘Home-based exercise’</td>
</tr>
<tr>
<td></td>
<td>Handout: ‘Community exercise classes for RA’ (times, dates and locations)</td>
</tr>
<tr>
<td></td>
<td>Handout: ‘Hydrotherapy classes’ (times, dates and location)</td>
</tr>
<tr>
<td></td>
<td>Physiotherapist or occupational therapist referral</td>
</tr>
<tr>
<td></td>
<td>Pedometer</td>
</tr>
<tr>
<td>3. Pain</td>
<td>Arthritis New Zealand booklet: ‘Managing your pain’</td>
</tr>
<tr>
<td>4. Support</td>
<td>Advice from arthritis educator: Managing pain/keep a pain diary</td>
</tr>
<tr>
<td></td>
<td>Advice from arthritis educator: Complementary therapies</td>
</tr>
<tr>
<td></td>
<td>Advice from arthritis educator: Managing medications</td>
</tr>
<tr>
<td></td>
<td>Advice from arthritis educator: Pacing</td>
</tr>
<tr>
<td></td>
<td>Advice from arthritis educator: Managing fatigue</td>
</tr>
<tr>
<td></td>
<td>Advice from arthritis educator: Disturbed sleep</td>
</tr>
<tr>
<td></td>
<td>Referral to GP (to receive analgesia)</td>
</tr>
<tr>
<td></td>
<td>12-week smoking cessation advice emails (from Quitline New Zealand)</td>
</tr>
<tr>
<td></td>
<td>Support website: ‘Smoking cessation and RA’</td>
</tr>
<tr>
<td>5. Coping</td>
<td>Handout: ‘One week diary for Identifying smoking triggers’</td>
</tr>
<tr>
<td></td>
<td>Advice from arthritis educator: Goals and self-management</td>
</tr>
<tr>
<td></td>
<td>Discuss available support (social, psychological and physical)</td>
</tr>
<tr>
<td></td>
<td>Use of nicotine replacement therapy documented and discussed</td>
</tr>
</tbody>
</table>

GP, general practitioner.
Discussion

This article describes how we translated our observational findings about the smoking cessation needs of RA patients into a targeted intervention so that researchers and rheumatology practitioners can replicate our process and/or make use of the intervention we devised. This novel intervention adds to the current state of knowledge regarding smoking cessation in special populations, and provides the opportunity to evaluate the benefit and efficacy of a targeted smoking cessation intervention for RA patients.

Nicotine dependence can be regarded as a chronic condition that often requires repeated interventions and multiple attempts before successful cessation, particularly for RA patients (Naranjo et al., 2014b). The best evidence identified by Cochrane Systematic Reviews has established that smokers in the general population, using a combination of evidence-based treatments which includes pharmacotherapy and behavioural support, have almost three times the rate of quitting when compared with those who use neither (Harriman-Boye et al., 2013, 2014; Kotz et al., 2014). Smoking cessation is one of the most important modifiable lifestyle factors for patients with RA. Quitting can improve health outcomes; therefore, smoking cessation should be a key goal in the management of RA. Our process of designing a pragmatic tailored smoking cessation intervention for RA patients made use of evidence from the general population and addressed previously identified barriers for quitting smoking by matching intervention components that aim to impart the skills necessary for self-management of RA and thus increase the chance of smoking cessation.

Smoking cessation is one of the European League Against Rheumatism (EULAR) core recommendations for managing CVD risk in RA (Peters et al., 2010). CVD-associated health benefits can be attained within six months of smoking cessation, and the CVD risk approaches that of a never-smoker after 10–15 years of abstinence (Godtfredsen and Prescott, 2011). People with mild-to-moderate chronic obstructive pulmonary disease who quit smoking experience a sustained improvement in respiratory symptoms and a slowing in their loss of lung function within one year, and this translates into a markedly decreased mortality risk after 15 years (Godtfredsen and Prescott, 2011). Men who quit smoking have a reduced risk of hip fracture after five years, although this benefit of smoking cessation is not observed in women (Abrahamsen et al., 2014; Holdrup et al., 2000). Owing to the similar deleterious effects of smoking in these comorbid conditions in RA, parallel health benefits may accrue for RA patients who quit smoking. Thus, it is surprising that, to date, there has been little research undertaken regarding smoking cessation support for RA patients (Aimer et al., 2014).

Our research builds on previous research on smoking cessation in RA which has focused on either multiple health interventions for RA patients (including, but not limited to, smoking cessation) or tailored smoking cessation interventions in multiple rheumatic conditions, but not RA specifically. In 2002, a pilot study was undertaken to modify adverse lifestyle variables in RA, including smoking, unhealthy diet and excessive alcohol consumption. Patients were briefly advised on quitting smoking and were provided with a generic quitters pack (Gordon et al., 2002). Of the eight RA patients who smoked, none quit during the 11-month study period (Gordon et al., 2002). The impact of an RA and smoking cessation awareness campaign has previously been studied (Harris, 2013). Only one in 20 RA patients were aware of a link between smoking and RA, and almost half of the RA patients questioned were ex-smokers. This study concluded that smokers with RA may be motivated to quit by learning that RA is a smoking-related disease (Harris, 2013). An RCT in 2013 (John et al., 2013) evaluated an educational intervention designed to: 1) increase RA patients’ knowledge of modifiable CVD risk factors and 2) measure intentions to change risk factor behaviours, including stopping smoking, increasing exercise, healthy low-fat eating and losing weight. At six months, the intervention group had a significantly higher knowledge of all CVD risk behaviours and had intentions to change risk behaviours, except stopping smoking (John et al., 2013), which suggests that there may be a need for interventions specifically focused on smoking cessation, like the one we have developed.

The only specific smoking intervention study reported to date evaluated a smoking cessation intervention in patients with various rheumatic diseases, which included 55 RA patients. The intervention consisted of brief (3–5 minutes) smoking cessation advice from a rheumatologist, followed by 20 minutes of verbal and written advice from a rheumatology nurse, with the offer of undefined pharmacological support to patients with high nicotine dependence.
Quit rates were 11.8% at three months and 15.7% at 12 months, and 29/152 patients (19%) had reduced their smoking by ≥50% at 12 months. These authors hypothesized that when advice emphasizing specific risks for an illness is given by the patients’ regular physician, backed up with nurse collaboration, the probability of smoking cessation rate is increased (Naranjo et al., 2014a). Our more intensive smoking cessation intervention may improve the success of this brief intervention, which can be tested in future clinical trials.

It has become widely recognized that the psychological and sociological characteristics of chronically ill patients have an influence on health outcomes (Brekke et al., 2001; Lorig et al., 2001). Therefore, providing appropriate educational and self-management strategies for smoking cessation and living with RA (including supportive advice, educational material, pain management, exercise advice and opportunities, and alternative coping strategies to smoking) provided the major components for the content of the intervention developed in the present study. These materials were sourced from existing information brochures or exercise resources available from Arthritis New Zealand (2014) or Quitline New Zealand (2015), or were tailor-made from these two sources with their consent.

The Medical Research Council’s framework for the development and evaluation of RCTs for complex interventions to improve health provides a reference tool for developing a pragmatic intervention with multiple and complex outcomes (Medical Research Council, 2000). A healthcare intervention is considered complex if it includes a number of separate and interacting components that are important to the proper functioning of the intervention. However, it is often difficult to identify which ingredient of a complex intervention is most effective (Medical Research Council, 2000). Developing a smoking cessation intervention for RA patients is an example of a complex intervention because of the interacting components within the experimental and control interventions (smoking cessation advice); the difficulty of the behaviour required by those receiving the intervention and controls (smoking cessation in both groups); and the flexibility or tailoring of the intervention required.

The strengths of our intervention development process were the ability to package the resources to be relevant for the individual RA patient, depending on their perceived support and educational needs. Therefore, patients are not obliged to follow any of the intervention suggestions. The active engagement of patients with their own healthcare decisions and practices has been shown to improve their health status (patient-centred care) and is a goal of such an intervention (Barry and Edgman-Levitan, 2012; Gerteis et al., 1993; Stewart et al., 2000). The use of evidence-based smoking cessation treatments enables the trial outcome, in regard to smoking cessation, to be comparable with other RCTs, internationally.

The process we followed had limitations. Only two arthritis educators were involved in development of the intervention. The involvement of more educators, and their international counterparts, would be beneficial in future research on developing an international consensus on recommendations for smoking cessation interventions for RA patients. Our intervention development process was also bound by the support services available from Arthritis New Zealand, although this reflects the pragmatic delivery of a complex intervention. Many of the difficulties of complex interventions are related to the difficulty of standardizing the design and delivery of the interventions; local context sensitivity, the difficulty of applying the experimental methodology to general service delivery, and the length and complexity of linking the intervention with the chosen outcome (Craig et al., 2008).

Conclusion

The complex smoking cessation intervention for patients with RA that we have developed is grounded in previous research, informed by patient opinion, and incorporates successful methodologies and evidence-based smoking cessation intervention components used in recent RA, arthritis or rheumatology studies of health, lifestyle and smoking interventions. In contrast to previous studies in this field, our intervention is focused solely on smoking cessation support for RA patients and offers a more comprehensive and intensive support while allowing for the individualization of the support package based on the support needs and preferences of individual RA patients. Overall, this innovation enables the targeting of smoking cessation barriers in RA patients by empowering patients with problem-solving strategies, which may lead to improvements in life expectancy through addressing barriers to smoking cessation in RA. This approach, if successful, also enables an immediate translation into clinical practice.
which could be rolled out internationally within existing arthritis service frameworks. A pilot study is in progress to evaluate the potential benefit and efficacy of this intervention.

Acknowledgements

Funding was provided by the Health Research Council of New Zealand and Arthritis New Zealand. We acknowledge the assistance of Janine Francis and Jan Ipenburg with recruitment for the qualitative research that led to this intervention.

REFERENCES


Westhoff G, Rau R, Zink A (2008). Rheumatoid arthritis patients who smoke have a higher need for DMARDs and feel worse, but they do not have more joint damage than non-smokers of the same serological group. Rheumatology 47: 849–54.

Appendix 8: The ABC Approach to Smoking Cessation

Smoking Cessation ABCs

Ask
Ask about and document smoking status for all people
For those who smoke or have recently stopped smoking this should be checked and updated on a regular basis. For example you could ask: “Do you currently smoke cigarettes?”

Brief advice
Give clear advice
For example, you could say: “You may know the risks involved with smoking, but do you realise how harmful it is? I cannot stress enough how important it is to stop. It is the best thing that you can do to improve your health. I understand that stopping smoking can be difficult, but if you want to stop smoking I can help you.”

Personalise the advice
Link smoking to a current illness and discuss how stopping smoking might help, for example, improved health, benefits to children with reduced exposure to secondhand smoke, money saved.

Document that advice was provided

Cessation
Refer
Health care workers without the expertise or time to help people to stop smoking should make a referral to smoking cessation services or the Quitline tollfree 0800 778 778 or www.quit.org.nz.
*Give the Quitline a call. They will help support you and provide you with medication that will help make quitting easier. The number is 0800 778 778.*

Provide support
Health care workers able to provide cessation support and medication should do so.
Support includes:
- offering advice
- setting a quit date
- advising that complete abstinence from smoking is best
- arranging medication to aid the quit attempt
- Nicotine replacement therapy (NRT)
- Bupropion
- Varenicline
- Nortriptyline
- arranging for follow-up within a week.

1 Assessment of the degree of nicotine dependence helps guide treatment (see Appendix 2). If people smoke within 30 minutes of waking, they have a higher degree of tobacco dependence and are likely to benefit from more intensive smoking cessation support.

New Zealand Smoking Cessation Guidelines Launch, Ministry of Health, August 2007

334
Using NRT products

Transdermal patch
- Two types of patches are available: 16-hour 15 mg and 24-hour 21 mg (there is no difference in efficacy between the two).
- The advantage of patches is that they are very simple to use, and there is generally good adherence to treatment.
- They are applied to a clean, dry, hairless area of skin and removed at the end of the day (16 hours) or the next day (24 hours).
- Skin irritation is the most common side effect.
- They should be used for at least 8 weeks.
- There is no evidence that ‘weeping’ patches are necessary – people can stop from a full strength patch straight away. However, some clients may prefer to ‘wean’ themselves off.
- Gum
- Two strengths are available: 2 mg and 4 mg; those who are highly dependent should use 4 mg gum.
- Not all of the nicotine from the gum is absorbed (the 2 mg gum typically yields only about 1 mg of nicotine, whereas the 4 mg gum yields about 2 mg).
- People should aim to use between 10 and 15 pieces of gum a day.
- Instructing them to use a piece an hour is a convenient way to encourage the correct dosage.
- Each piece should be chewed slowly to release the nicotine, and a hot peppery taste will be experienced. The gum should then be ‘parked’ between the cheek and gums so that the nicotine can be absorbed. After a few minutes the gum can be chewed again, then parked and repeated, for 20–30 minutes.
- Gum should be used for at least 8 weeks.

Sublingual tablets (Microtabs)
- Available as 2 mg tablets placed under the tongue.
- Hourly use should be recommended to achieve the best effect, but can be used less frequently.
- Up to 60 microtabs can be used per day.
- The tablet is designed to dissolve completely.
- Tablets should be used for at least 8 weeks.

Inhaler
- The inhaler is a small plastic tube containing a replaceable nicotine cartridge.
- This may provide more behavioural replacement than the other products (some people miss the hand-to-mouth action of smoking when they quit), but there is no strong evidence for this.
- The user should puff on the inhaler for 20 minutes each hour. After four 20-minute puffing sessions, the cartridge should be changed.
- The average person should aim to use 4–6 cartridges a day.
- In cold weather it is advisable to keep the inhaler warm so that the nicotine vapour can be released from the cartridge.
- They should be used for at least 8 weeks.

Combination therapy
- Combining NRT products increases abstinence rates. The patch is usually combined with one of the oral products (gum, lozenge, microtab, inhaler). In this way users will receive a steady supply of nicotine from the patch and can obtain a more rapid ‘top up’ of nicotine from the oral products.
- There are no safety concerns in combining NRT products, although combination treatment is not normally recommended in pregnant women who smoke or smokers with unstable cardiovascular disease.
- There is insufficient evidence to recommend the combination of NRT with other pharmacotherapies.

Notes:
1. The highest quit rates are achieved when medications such as NRT are combined with support.
2. Only patches and gum are currently subsidised.
3. Regarding oral NRT products:
   - Nicotine absorption from oral NRT products, including the inhaler, is via the buccal mucosa (lining of the mouth).
   - While these products can be used on a regular (eg, hourly) basis, they can all be used more frequently or when urges to smoke are more intense or more frequent.
   - An initial unpleasant taste is common to all these products, and this can be a barrier to correct use. People can be reassured that they will become tolerant of this after a short period (usually a couple of days).
   - Incorrect use of oral products, for example chewing gum too vigorously, usually results in more nicotine being swallowed. This is not hazardous, but means that less nicotine is absorbed, and may cause local irritation and hiccup.
   - Drinking fluids while using these oral products should be avoided.

Coping with tobacco withdrawal

Urges to smoke
- People may report urges to smoke for many months after stopping, although these typically become less frequent over time.
- Urges to smoke are often precipitated by cues such as stress, seeing others smoke, social situations, and when drinking alcohol.
- Advise people not to give into these urges and instead adopt strategies to cope with these, such as distraction techniques, exercise, and avoidance of risky situations such as social events.

Withdrawal symptoms
- Include such things as urges to smoke, irritability, depressed mood, increased appetite, anxiety, poor concentration, restlessness, and sleep disturbance.
- Mouth ulcers and constipation may also occur when people stop smoking.
- Most disappear within four weeks of abstinence.

Weight gain
- On average people may expect to gain between 4–5 kg in the first year of abstinence.
- People stopping smoking should be advised against dieting whilst quitting as this may increase the risk of relapse. However, people with co-morbidities such as diabetes and morbid obesity may need special attention regarding weight gain during their quit attempt.
- Using medications such as NRT can reduce weight gain thus allowing people to deal with quitting first.
- Increasing physical activity is also a good way to decrease weight gain.

National providers
Quill-Line – national Quitline for people that want help in stopping smoking. Provides telephone support and subsidised NRT.
Tel: 0800 779 779
Website: www.quit.org.nz
Ashoki iwi palapa – smoking cessation service provided by Māori organisations for Māori who smoke. Provides support and subsidised NRT.
Tel: (09) 638 5800
Website: www.tehutumanawa.org.nz
Local providers

<table>
<thead>
<tr>
<th>Name</th>
<th>Contact details</th>
</tr>
</thead>
</table>

Benefits of stopping smoking
Stopping smoking is the best thing that a person can do to improve their current and future health. The earlier a smoker can stop the better, however it is never too late to stop – even for smokers in their 70s and 80s. Smokers who stop will benefit from:
- reduced risk of premature death
- reduced risk of developing lung cancer
- reduced risk of coronary artery disease and stroke
- reduced risk of dying from chronic obstructive pulmonary disease
- improvement in respiratory symptoms such as cough and shortness of breath
- reduced risks of other cancers related to smoking (eg, upper respiratory tract, oesophagus, bladder and pancreas)
- reduced risks of complications in pregnancy and childbirth (eg, placenta previa and placental abruption)
- improvement in some mental health symptoms
- fewer sick days off work
- improved recovery from surgery.

Quitting smoking will also ensure:
- a good example is set to children and young people
- the health of children of smokers is improved
- money will be saved.

335
Appendix 9: Permission to use Quitline Smoking Cessation “Pip’s Tips” and Smoking Triggers Diary

From: Pip Aimer [mailto:pip.aimer@vodafone.co.nz]
Sent: Thursday, 1 November 2012 4:25 p.m.
To: Jane MacPherson
Subject: Smoking Cessation tips

Hi,

I am a PhD student at the Department of Medicine at the University of Otago (Christchurch). I am currently designing a clinical trial for smoking cessation in rheumatoid arthritis (in conjunction with Arthritis NZ), which involves setting up a support webpage on the University’s website for participants to access during the trial. It will be linked from the Arthritis NZ website. I was wanting to have a helpful tip (“Pip’s Tips”) section that I would change weekly as a form of motivation. Is it possible to use quotes from your website, e.g. tips to help quit smoking, reasons to quit etc., plus use of your logo as a referral and/or useful link.

Many thanks for your help.

Kind regards, Pip

Pip Aimer
PhD Student, Department of Medicine
University of Otago, Christchurch
PO Box 4345
Christchurch 8140
03 364-0496 DDI
021 048-3885 Mobile
strph347@student.otago.ac.nz

---

From: Jane MacPherson [mailto:jane.macpherson@quit.org.nz]
Sent: Thursday, 1 November 2012 5:03 p.m.
To: Pip Aimer
Cc: Dominika White; Bruce Bassett
Subject: RE: Smoking Cessation tips

Hi Pip,

Yes that is fine – can you show me a screen shot before you go live of how it would look please?
I have cc’d in our web communication specialist Dominika – who can send you the best logo.
We also may be able to provide a link on your site to ours where viewers can link to Quitline and register – how does this sound to you?
Is there anything else we can provide to you – we have a resources section where people can download our marketing collateral also and in there are some great tips you can use – again just if I can view before going live would be great.

Regards Jane

Jane MacPherson | Acting Manager Communications
Quitline | Me Mutu
DDI: 04 460 9885
Email: jane.macpherson@quit.org.nz

For Quitline phone service call 0800 778 778:
Mon-Fri 8.00am - 9.30pm; Sun 10.00am - 7.30pm
For 24/7 support go to Quit.org.nz

www.facebook.com/quitlinenz

Please consider the environment before printing this email.
This e-mail message and any accompanying attachments may contain information that is in-confidence. If you are not the intended recipient, do not read, use, disseminate, distribute or copy this message or attachments. If you have received this message in error, please notify the sender immediately and delete this message and any accompanying attachments.
Appendix 10: Smoking Cessation Email “Pip’s Tips”

Sourced from Quitline NZ [197]

Week 1: Smoking and your body (http://www.quit.org.nz/19/reasons-to-quit/smoking-and-your-body)


Week 3: Money benefits (http://www.quit.org.nz/21/reasons-to-quit/money-benefits)

Week 4: Social situations (http://www.quit.org.nz/49/staying-quit/social-situations)


Week 7: Health benefits (http://www.quit.org.nz/20/reasons-to-quit/health-benefits)


Week 12: How are other quitters doing: Quitline Blogs (http://www.quit.org.nz/blog/)
The link between smoking and rheumatoid arthritis

Did you know?
- Rheumatoid Arthritis (RA) is a common disease affecting 1-2% of NZ population.
- Research shows that smoking makes RA worse, however up to 30% of RA patients are currently smoking.
- Giving up smoking is one of the ways to control your RA and get a better quality of life.

What are the effects of smoking on RA?

1. **Smoking increases the risk of developing RA**
   Smoking can increase the chances of developing RA by 40 times. If you have RA and your family smoke, it is important for them to be aware of this risk.

2. **Smoking reduces the effectiveness of the medication used to treat RA**
   - You may need more drugs to treat your disease.
   - Smokers with RA are less likely to be able to stop their arthritis medications when they are in remission or free of symptoms.

3. **Smoking may worsen joint damage**
   - Joint damage starts early in RA, and once this occurs, it is largely irreversible.
   - There is some evidence that smoking contributes to joint damage.

4. **Smoking leads to an increased risk of heart disease**
   - Risks of heart disease is already increased in RA
   - Smoking adds to this risk

5. **Smoking contributes to osteoporosis (thinning of the bones)**
   - The risk of osteoporosis is also raised because of RA and the use of steroids

Want more information?
Visit: [www.otago.ac.nz/christchurch/otago039021](http://www.otago.ac.nz/christchurch/otago039021)
Appendix 12: Arthritis NZ ‘Managing your Pain’ booklet

Accessed 10 September 2015

From: Natalia Valentino [mailto:Natalia.Valentino@arthritis.org.nz]
Sent: Wednesday, 14 November 2012 3:42 p.m.
To: Pip Aimer
Subject: RE: Copyright permission for smoking and RA project

Can we have only the cover page of our Exercise book on the website or link to our website – we have it there.

Natalia Valentino
Service Development Manager

Arthritis New Zealand
Kaiponapona Aotearoa

PO Box 74581 | Unit B, 383 Khyber Pass | Auckland | 1546
DDI: 09 5238907 | Mobile: 0272410979 | Tollfree: 0800 663 463

Donate to Arthritis New Zealand and help us support the 530,000 New Zealanders living with arthritis. Call 0900 33320 or visit www.arthritis.org.nz
Appendix 13: Exercise Resources for Smoking Cessation Intervention

a) Permission to use Abbott Laboratories NZ Exercise Sheets

Accessed 10 September 2015

From: Williams, Sheryl A [mailto:sheryl.williams@abbott.com]
Sent: Monday, 19 November 2012 1:05 p.m.
To: Natalia Valentino
Cc: Sutherland, Lucy V; Taylor, Charles; Millard, Helen
Subject: RE: RA & smoking - Abbott exercise sheets

Hi Natalia

I am well and I hope that you are also?

Yes we are happy to provide Abbott Laboratories NZ Ltd.’s permission for the exercise sheets to be used in this valuable research.

I look forward to seeing the research results.

Kind regards,
Sheryl
b) Hand Exercises for RA

Hand Exercises for Rheumatoid Arthritis

Strengthening

Wrist Extension
Rest your elbows on the table, with your palms together and hands pointing upward. Make sure to keep your palms together as you slide your elbows out sideways along the table. Hold for 5 seconds, then bring your elbows together again. Repeat 5 times.

Wrist Flexion
Hands resting on the little finger side, lightly hold an empty toilet roll or paper towel roll. Keeping the bottom surface of the roll in contact with the table, bend your wrists forward into flexion and then backward into extension. Make sure the movement is at your wrist and not at your elbow. Repeat 10 times.

Forearm Rolls
Place your palms on the table with your middle fingers in a straight line with your forearms. Roll your hands over so that your palms are facing the ceiling. Roll your hands back again. Repeat 10 times.

Thumb Exercise
Hands resting on the little finger side, lift your thumbs up towards the ceiling. Then stretch your thumbs towards each other without allowing your thumbs to drop below your index fingers. Bend the tips of your thumbs. Hold. Straighten your thumbs. Lift your thumbs up to the ceiling and return to the starting position.

Hand Span
Place your palms on the table with your middle fingers in a straight line with your forearms. Move your thumbs out sideways. Move the first fingers towards the thumbs, then the middle fingers towards the index fingers and so on. Lift your hands up from your wrists and then relax. Repeat 5 times.

The Marathon
Place your palms on the table with your middle fingers in a straight line with your forearms. Keeping your fingers straight, lift your hands up from your wrists as high as you can manage. Spread your fingers and thumbs apart slightly. Hold this position for 30 seconds and then relax. Repeat 2 times.

These exercises have been developed by a registered physiotherapist for general use. They are not intended to be a substitute for professional medical advice, diagnosis or treatment. Always seek the advice of a qualified healthcare provider prior to starting any new treatment, exercise or with any questions you may have in relation to these exercises. Reliance on these exercises is solely at your own risk and AbbVie Ltd advises against using these exercises without the supervision of a qualified and registered healthcare provider.

These exercises are for instructional use under the guidance of a physiotherapist or other trained health professional only. © Copyright, AbbVie Ltd and QE Health Physiotherapy Department, 2012. For enquiries please contact AbbVie Ltd on 0800 1900 003.
Pictures compiled for AbbVie Ltd by Ana Tahana, Physiotherapist, QE Health. NZ.HUMR-2012-4a. TAPS P2 1694.

Proudly sponsored by AbbVie Ltd, Wellington. See your doctor for further information.
Hand Exercises for Rheumatoid Arthritis

Strengthening

Proudly sponsored with an unrestricted educational grant from AbbVie Ltd.

These exercises are designed to strengthen and increase movement in the hands and wrists and should be done daily. It is important to use correct positioning before and during exercises. Correct positioning should ensure the following points:

- The middle finger lines up with the centre of the forearm.
- The hand does not tilt towards the thumb side at the wrist.
- The hand does not drop from the wrist but is kept straight or held back slightly.
- The thumb should be held away from the rest of the hand and not allowed to drop into the palm.

Hand Press
Place your palms on the table with your middle fingers in a straight line with your forearms. Press the fingers and palms of your hands flat against the table, allowing your elbows to lift off the table a little. Hold for 3-5 seconds. Repeat 10 times.

Making a Fist
Rest your hands on the little finger side. Bend the tips of your fingers towards the tops of your palms, then bend them right down to make a fist. Stretch them out straight again. Make certain that your thumbs go over your ring fingers to help your grip. Repeat 10 times.

Wrist Extension
Place your palms on the table with your middle fingers in a straight line with your forearms. Keeping your fingers relaxed, lift your hands up from your wrists. Hold for 2-3 seconds and then slowly lower again.

Finger Opposition
Rest your hands on the little finger side. Touch the tips of your thumbs with the tips of your first fingers to form a complete circle. Repeat with your 2nd, 3rd and 4th fingers. Spread your thumbs and fingers wide apart between each circle you make. Repeat 3 times.

These exercises are for instructional use under the guidance of a physiotherapist or other trained health professional only. © Copyright, AbbVie Ltd and QE Health Physiotherapy Department, 2012. For enquires please contact AbbVie Ltd on 0800 900 030. Pictures are compiled for AbbVie Ltd by Arna Tahana, Physiotherapist, QE Health.

Proudly sponsored by AbbVie Ltd, Wellington. See your doctor for further information.
c) General Exercises for RA

General Exercises for Rheumatoid Arthritis

Proudly sponsored with an unrestricted educational grant from AbbVie Ltd.

These exercises are designed to maintain mobility and reduce early morning stiffness. We recommend these exercises are done in the early morning and on a daily basis.

**Neck Retractions**
Sitting in a chair or standing against a wall, gently pull your chin in. You will feel the back of your neck lengthen and straighten as you make a double chin. Avoid a nodding action. Hold for two counts and then relax. Repeat 5 times.

**Head Tilt**
Sit straight in a chair. Slowly tilt your head to the right, moving your ear towards your shoulder. Try to keep your shoulder relaxed. Hold for two counts and return to the starting position. Repeat on the left. Repeat 5 times.

**Neck Rotation**
Sitting straight in a chair, gently look round over your shoulder. Make sure to keep your body and shoulder still. Hold for two counts and then return to the starting position. Repeat in the opposite direction. Repeat 5 times.

**Knee Extensions**
Sitting in a chair with your back supported, straighten your knee. Pull your toes back towards you and hold for two counts. Slowly lower your foot back down to the ground and repeat with the other leg. Repeat 20 times on each side.

These exercises are for instructional use under the guidance of a physiotherapist or other trained health professional only. © Copyright, AbbVie Ltd and QE Health Physiotherapy Department, 2012. For enquiries please contact AbbVie Ltd on 0800 900 030.

Pictures compiled for AbbVie Ltd by Ana Tanana, Physiotherapist, QE Health.

Proudly sponsored by AbbVie Ltd, Wellington. See your doctor for further information.
General Exercises for Rheumatoid Arthritis

Proudly sponsored with an unrestricted educational grant from AbbVie Ltd.

These exercises are designed to maintain mobility and reduce early morning stiffness. We recommend these exercises are done in the early morning and on a daily basis.

Shoulder Lifts
Lying on your back, lift one arm up and over your head towards the head of the bed. Hold for two counts and then slowly lower back to starting position. Repeat on the other side. Repeat 10 times on each side.

Bridging
Lie on your back with both knees bent and feet flat on the bed. Push through both feet and lift your bottom up off the bed to form a bridge. Tighten your stomach muscles, hold for two counts and slowly return to the starting position. Repeat 10 times.

Neck and Hip Extension
Lying on your back, gently push your heels and the back of your head into the bed. Hold for two counts and then relax. Repeat 5 times.

Hip Extension
Lie on your front with your forehead resting on your hands. Without arching your back, lift one leg just off the bed. Hold for two counts and return to the starting position. Repeat with the other leg. Repeat 10 times.

These exercises have been developed by a registered physiotherapist for general use. They are not intended to be a substitute for professional medical advice, diagnosis or treatment. Always seek the advice of a qualified healthcare provider prior to starting any new treatment, exercise or with any queries you may have in relation to these exercises. Reliance on these exercises is solely at your own risk and AbbVie Ltd advises against using these exercises without the supervision of a qualified and registered healthcare provider.

These exercises are for instructional use under the guidance of a physiotherapist or other trained health professional only. © Copyright. AbbVie Ltd and QE Health Physiotherapy Department, 2012. For enquiries please contact AbbVie Ltd on 0800 900 030.
Pictures compiled for AbbVie Ltd by Aroha Tahana, Physiotherapist, QE Health. NZ-HUM# 2012-0a. TAPS PP 9694.

Proudly sponsored by AbbVie Ltd, Wellington. See your doctor for further information.
d) Arthritis: Exercises to Keep You Moving

e) Community Exercise Classes for RA

Community Exercise Classes for Rheumatoid Arthritis

Cost: $4.00 per class for Arthritis New Zealand Members
$6.00 per class for non-members

To become an Arthritis New Zealand member or for further information, please phone (03) 379-6916 or visit www.arthritis.org.nz

<table>
<thead>
<tr>
<th>Suburb</th>
<th>Venue</th>
<th>Day</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parnell</td>
<td>St Paul's Anglican Church</td>
<td>Tuesday</td>
<td>9.15am</td>
</tr>
<tr>
<td></td>
<td>1 Harwood Road</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(03) 352-9571</td>
<td>Wednesday</td>
<td>9.45am</td>
</tr>
<tr>
<td>Avonhead</td>
<td>St Christopher’s Church</td>
<td>Tuesday</td>
<td>10.45am</td>
</tr>
<tr>
<td></td>
<td>244 Avonhead Road</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(03) 359-8780</td>
<td>Thursday</td>
<td>10.00am</td>
</tr>
<tr>
<td>Linwood</td>
<td>Linwood Ave Union Church</td>
<td>Tuesday</td>
<td>10.00am</td>
</tr>
<tr>
<td></td>
<td>378 Linwood Ave</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(03) 389-3303</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sumner</td>
<td>Union Parish Church Hall</td>
<td>Thursday</td>
<td>10.30am</td>
</tr>
<tr>
<td></td>
<td>76 Nayland St</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(03) 384-2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beavon</td>
<td>St Marks Methodist Church</td>
<td>Friday</td>
<td>9.30am</td>
</tr>
<tr>
<td></td>
<td>83 Malcolm Ave</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(03) 942-2715</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hornby</td>
<td>Presbyterian Church Hall</td>
<td>Friday</td>
<td>10.30am</td>
</tr>
<tr>
<td></td>
<td>27 Amyces Road</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(03) 349-9446</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Want more information? Visit www.arthritis.org.nz and click on the smoking and RA link

hrc
f) Hydrotherapy Classes for RA

Hydrotherapy Classes for Rheumatoid Arthritis

PLEASE NOTE: Participants in hydrotherapy classes need to be members of Arthritis New Zealand. To become an Arthritis New Zealand member or for further information phone (03) 379-6916 or visit www.arthritis.org.nz

<table>
<thead>
<tr>
<th>Suburb</th>
<th>Venue</th>
<th>Day</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burwood</td>
<td>Burwood Hospital Hydrotherapy Pool</td>
<td>Monday</td>
<td>4.00pm</td>
</tr>
<tr>
<td></td>
<td>255 Mairehau Road</td>
<td></td>
<td>3.00pm</td>
</tr>
<tr>
<td></td>
<td>(03) 383-6939</td>
<td>Saturday</td>
<td>9.30am</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10.30am</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>11.30am</td>
</tr>
</tbody>
</table>

Want more information? Visit: www.arthritis.org.nz and click on the smoking and RA link
Appendix 14: Smoking Triggers Diary

Resource from Quitline NZ (permission to use this tool in Appendix 9)

Appendix 15: Conference Proceedings: A Pilot Randomized Controlled Trial of a Tailored Smoking Cessation Intervention for Rheumatoid Arthritis Patients [343]

Pip Aimer¹, Gareth J Treharne², Simon Stebbings³, Chris Frampton¹, Vicky Cameron¹, Sandra Kirby⁴, Lisa Stamp¹

¹Department of Medicine, University of Otago, Christchurch, ²Department of Psychology, University of Otago, ³Department of Medicine, Dunedin School of Medicine, University of Otago, ⁴Arthritis New Zealand, New Zealand.

Background: Smoking adversely influences comorbidities in rheumatoid arthritis (RA) and may affect progression of RA. The combination of negative health effects makes a compelling case for smoking cessation in RA. The aim of this pilot study was to determine whether a targeted 3-month smoking cessation intervention for RA patients increases smoking cessation.

Methods: Thirty-eight RA patients who were currently smoking were recruited and randomized on a 1:1 ratio. All participants were given the current local standard of care for smoking cessation (brief advice and subsidised NRT: ABC). Participants randomized to the intervention arm (ABC+) received additional advice from trained Arthritis New Zealand educators for 3 months. Advice was tailored to participants’ specific needs from a range of intervention tools developed from previous qualitative consultation and focused on education about smoking and RA, pain control, exercise, coping, and support. The primary outcome measure was smoking cessation at 6 months. The secondary outcome was sustained reduction in smoking at 6 months. The assessor was blind to intervention allocation. Disease and psychosocial characteristics of quitters and non-quitters were examined statistically.
**Results:** Thirty-five participants completed the 6 month study; the 3 who withdrew were in ABC+. The overall smoking cessation rate was 24%. There was no significant difference in smoking cessation rate between the ABC+ and ABC groups (26% vs 21%; P=0.70). The mean number of cigarettes smoked per day reduced by 44% (P<0.001) but did not differ between ABC+ and ABC groups (41% vs 47% mean reduction; P=0.72). There was no difference in smoking cessation rates between participants with disease duration <2 years and disease duration >2 years (27% vs 22%; P=0.74). Successful quitters had a greater number of years in education beyond high school and had smoked less across their lifetime, but these differences were not statistically significant. No other demographic, disease or psychosocial variables predicted quitting (*Table 1*).

**Conclusions:** This pilot randomized controlled study evaluated the effects of an individually tailored smoking cessation programme in patients with RA. The smoking cessation rate and reduction in number of cigarettes smoked were high compared to previous smoking cessation studies. The lack of added benefit of the tailored intervention suggests brief advice is the best practice supporting RA patients who wish to quit smoking. RA patients with fewer years of education or longer history of smoking may require particular cessation support.
Table 1: Baseline disease and psychosocial factors associated with smoking cessation. All data are presented as mean (SD)

<table>
<thead>
<tr>
<th>Baseline disease and psychosocial factors</th>
<th>Successful Quitters (n=9)</th>
<th>Non-quitters (n=29)</th>
<th>Total (n=38)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education (years)</td>
<td>12.6 (1.9)</td>
<td>11.5 (1.3)</td>
<td>11.7 (1.5)</td>
<td>0.06</td>
</tr>
<tr>
<td><strong>Cumulative pack-years of smoking (years)</strong></td>
<td><strong>25.6 (10.4)</strong></td>
<td><strong>41.7 (24.5)</strong></td>
<td><strong>37.8 (22.9)</strong></td>
<td><strong>0.07</strong></td>
</tr>
<tr>
<td>Current age (years)</td>
<td>55.2 (12.3)</td>
<td>56.9 (11.8)</td>
<td>56.5 (11.8)</td>
<td>0.72</td>
</tr>
<tr>
<td>Socio-economic deprivation</td>
<td>5.0 (3.3)</td>
<td>5.3 (2.6)</td>
<td>5.2 (2.8)</td>
<td>0.77</td>
</tr>
<tr>
<td>ASES pain</td>
<td>6.9 (2.2)</td>
<td>6.2 (2.0)</td>
<td>6.3 (2.0)</td>
<td>0.36</td>
</tr>
<tr>
<td>ASES mood</td>
<td>7.5 (2.0)</td>
<td>7.2 (2.1)</td>
<td>7.2 (2.1)</td>
<td>0.62</td>
</tr>
<tr>
<td>HADS anxiety</td>
<td>6.7 (3.4)</td>
<td>6.7 (4.0)</td>
<td>6.7 (3.8)</td>
<td>0.97</td>
</tr>
<tr>
<td>HADS depression</td>
<td>3.7 (1.9)</td>
<td>4.8 (3.5)</td>
<td>4.5 (3.2)</td>
<td>0.36</td>
</tr>
<tr>
<td>PSS stress</td>
<td>19.0 (7.5)</td>
<td>22.5 (8.8)</td>
<td>21.7 (8.5)</td>
<td>0.29</td>
</tr>
<tr>
<td>HAQ</td>
<td>0.6 (0.4)</td>
<td>0.9 (0.8)</td>
<td>0.8 (0.7)</td>
<td>0.26</td>
</tr>
<tr>
<td>PI HAQ</td>
<td>2.0 (1.4)</td>
<td>2.5 (2.2)</td>
<td>2.3 (2.0)</td>
<td>0.52</td>
</tr>
<tr>
<td>EQ VAS</td>
<td>76.3 (15.6)</td>
<td>70.8 (19.2)</td>
<td>72.1 (18.4)</td>
<td>0.44</td>
</tr>
<tr>
<td>EQ-5D</td>
<td>0.7 (0.2)</td>
<td>0.7 (0.2)</td>
<td>0.7 (0.2)</td>
<td>0.31</td>
</tr>
<tr>
<td>Smoking self-efficacy internal</td>
<td>12.7 (6.0)</td>
<td>13.1 (6.4)</td>
<td>13.0 (6.2)</td>
<td>0.85</td>
</tr>
<tr>
<td>Smoking self-efficacy external</td>
<td>14.3 (3.5)</td>
<td>13.7 (6.2)</td>
<td>13.8 (5.6)</td>
<td>0.77</td>
</tr>
<tr>
<td>Fagerström Nicotine Dependence</td>
<td>3.8 (1.6)</td>
<td>4.3 (1.9)</td>
<td>4.0 (1.9)</td>
<td>0.72</td>
</tr>
</tbody>
</table>

*Abbreviations: ASES, Arthritis Self-Efficacy Scale; HADS, Hospital Anxiety and Depression Scale; PSS, Perceived Stress Scale; HAQ, Health Assessment Questionnaire; PI-HAQ, Personal Impact Health Assessment Questionnaire; EQ-VAS, Euroqol visual analogue scale; EQ-5D, Euroqol health utility*
Appendix 16: Advertising for Pilot Study

DO YOU HAVE RHEUMATOID ARTHRITIS?

Volunteers wanted for:
SMOKING CESSATION RESEARCH

The University of Otago is currently conducting a study of patients with rheumatoid arthritis to determine how we can improve smoking cessation. If you have rheumatoid arthritis and are a smoker or have tried to quit smoking and failed, you are eligible.

This study has ethical approval.

If you are interested in being part of this research, please contact us to get more information:

Pip Aimer (PhD student)
Department of Medicine
(03) 364-0496
strph347@student.otago.ac.nz
Appendix 17: Informed Consent Form for Pilot Study

CONSENT TO PARTICIPATE IN

Smoking cessation in rheumatoid arthritis

REQUEST FOR INTERPRETER

<table>
<thead>
<tr>
<th>English</th>
<th>I wish to have an interpreter</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaf</td>
<td>I wish to have a NZ sign language interpreter</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Māori</td>
<td>E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero</td>
<td>Ae</td>
<td>Kao</td>
</tr>
<tr>
<td>Cook Island Māori</td>
<td>Ka inangaro au i tetai tangata uri reo</td>
<td>Ae</td>
<td>Kare</td>
</tr>
<tr>
<td>Fijian</td>
<td>Au gadreva me dua e vakadewa vosa vei au</td>
<td>Io</td>
<td>Sega</td>
</tr>
<tr>
<td>Niuean</td>
<td>Fia manako au ke faka aoga e taha tagata fakahokohoko kupu</td>
<td>E</td>
<td>Nakai</td>
</tr>
<tr>
<td>Sāmoan</td>
<td>Ou te mana’o ia i ai se fa’amatala upu</td>
<td>loe</td>
<td>Leai</td>
</tr>
<tr>
<td>Tokelaun</td>
<td>Ko au e fofo ki he tino ke fakalili u te gagana Peletania ki na gagana o na motu o te Pahefika</td>
<td>loe</td>
<td>Leai</td>
</tr>
<tr>
<td>Tongan</td>
<td>Oku ou fiema’u ha fakatonulea</td>
<td>Io</td>
<td>Ikai</td>
</tr>
</tbody>
</table>

I have read the Information Sheet dated October 2012 and have had the study fully explained to me in a language that I understand.

I have also had the opportunity for full discussion with one of the investigators, a person of my choice, and have had adequate time to consider participating in this study.

I UNDERSTAND:

- Taking part in this study is voluntary (my choice). I may withdraw from the study at any time and this will in no way affect my continuing health care.
- My participation in this study is confidential and no material which could identify me will be used in any reports on this study.
- I know who to contact if I have any questions about the study.
- I will receive a copy of this Consent Form and the Information Sheet.
• This study has received ethical approval from the Southern Health and Disability Ethics Committee.
• I wish to receive a copy of the results. YES / NO
• I consent to my GP being informed of my participation in this study YES / NO
• I consent to the use of my data for future related studies, which have been given ethical approval from a New Zealand Accredited Ethics Committee YES / NO
• I consent to being contacted in the future for follow-up studies YES / NO

I …………………………………………. (Full name) hereby consent to take part in this study.

Signature: ………………………………….. Date: / / .
Project explained by………………………………
Signature ………………………………………
Signature of investigator: …………………….. Date: / / .

Christchurch
Ms Pip Aimer Phone (03) 364-0496 (work) or 021-048-3885
Prof Lisa Stamp Phone (03) 364-0953 (work)

Arthritis New Zealand
Dr Natalia Valentino Phone (09) 523-8907 (work) or (027) 241-0979
Appendix 18: Information Sheet for Pilot Study

Smoking cessation in rheumatoid arthritis

INFORMATION SHEET

Investigators

Ms Pip Aimer, PhD Student, University of Otago
Prof Lisa Stamp, Rheumatologist, Christchurch Hospital

You are invited to participate in a study looking at smoking cessation in patients with rheumatoid arthritis (RA). Recent evidence has shown that smoking has a number of effects on rheumatoid arthritis. Smoking can increase the risk of developing RA, it can make rheumatoid arthritis more severe and it can make rheumatoid arthritis more difficult to treat. In addition, smoking is a recognized risk factor for heart disease, which is significantly increased in patients with RA.

Quitting smoking is now recognized as an important part of managing arthritis. However, many people with arthritis find it difficult to stop smoking. This study aims to determine whether a targeted six month smoking cessation intervention programme for people with Rheumatoid Arthritis will increase smoking cessation rates. If you agree to participate you will either be allocated to the standard smoking cessation advice arm or the intervention arm. This is done randomly and we will not know which arm you will be in. All participants will be given the current standard of care for smoking cessation at Christchurch Hospital (the ABC programme).

Study Procedure

If you agree to participate in the study the PhD student (Pip Aimer) will contact you to arrange a time to attend an initial meeting. This meeting will explain the study in more detail and you will have the chance to ask any questions. You will be also asked to fill out a questionnaire about your arthritis and how it affects your life, and sign a consent form. You will also receive the ABC programme from one of the rheumatology nurses. You may also receive nicotine replacement in the form of gum, lozenges and/or patches if you wish.

Your participation is entirely voluntary and you may withdraw from the study at any stage without this affecting your treatment.

Nature and Duration of the Study

IF you agree to participate in this study you will need to:

- Attend an initial meeting with Ms Pip Aimer (PhD student) to discuss aspects of the study, consent to the study, and to fill in questionnaires related to your arthritis and
follow-up contact will be made by the PhD student at month 3 and month 6.

- Attend a visit at Christchurch Hospital outpatients to receive the ABC programme. You may also receive a targeted six month smoking cessation intervention programme to run concurrently with the ABC programme.

**Some Common Questions**

*Will my GP be told I am in the study?* If you agree to participate in this study your GP will be advised.

*What will happen at the end of the study?* You will continue your treatment as prescribed by your doctor. You will continue to attend Outpatient clinics as required by your treating hospital specialist.

*Where can I get more information about the study?* If at any time you have any concerns or questions about this study, do not hesitate to contact any of the study investigators or the PhD student.

*Are there any risks to me by being in the study?* Physical nicotine withdrawal symptoms are temporary, but it can be an unpleasant phase. Symptoms may mimic a cold or mild flu. However, these discomforts are short-lived. Nicotine patches, gum and lozenges are very safe, and serious side effects are rare. Sometimes patches can cause a slight reddening and itching of the skin. This is less likely if you change the area that you apply the patch to. Gum or lozenges might give you a slightly irritated mouth and throat and more spit than usual. If you chew or suck the gum or lozenges too often, you much swallow too much nicotine and this can cause wind, hiccups and indigestion.

**Confidentiality:** No material which could personally identify you will be used in any reports on this study. Your study records will be stored in a locked cabinet in the Department of Medicine/Rheumatology and stored for a maximum of 20 years.

**Results:** Overall results of the study will be available from the investigators several months after the study has been completed.

**Compensation:** In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.

**Rights:** If you have any queries or concerns regarding your rights as a participant in this research study you can contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act.

Telephone (NZ wide): 0800 555 050
Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT)
Email (NZ wide): advocacy@hdc.org.nz
**Statement of Approval:** This study has received ethical approval from the Southern Health and Disability Ethics Committee.

**Further Information**

If at any time you have concerns or questions about this study, do not hesitate to contact any of the study investigators.

- **Pip Aimer (PhD student)**  
  Phone (03) 364-0496 (work) or (021) 048-3885

- **Prof Lisa Stamp**  
  Phone (03) 364-0953 (work)

- **Arthritis New Zealand**

- **Dr Natalia Valentino**  
  Phone (09) 523-8907 (work) or (027) 241-0979
Appendix 19: Pilot Study RCT Participant Needs Assessment Checklist (week 0)

# Pilot Study: Smoking Cessation and Rheumatoid Arthritis

<table>
<thead>
<tr>
<th>Arthritis Educator: _______________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: <em><strong><strong>/</strong></strong></em>/_______ Randomisation #_____________</td>
</tr>
<tr>
<td>Initial Contact: Phone☐ Skype☐ Face-to-face ☐</td>
</tr>
<tr>
<td>Member of Arthritis NZ? Yes☐ No☐</td>
</tr>
<tr>
<td>Surname: _________________________</td>
</tr>
<tr>
<td>First-name: _________________________ NHI #: _________________________</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>Home Phone: _____________________ Mobile: ______________________</td>
</tr>
<tr>
<td>Email: _________________________</td>
</tr>
</tbody>
</table>

**Assessment:** prompts: fatigue, disturbed sleep, pain, feeling down, difficulty with ADL’s

**Main Concerns?**

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
How is their RA affecting daily activities?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

How do they manage their RA?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Intervention Checklist: Information discussed and provided to study participant (please tick)

☐ Education
  ☑ Link between smoking and rheumatoid arthritis handout

☐ Exercises to keep you moving
  ☑ Hand exercises for RA (Abbott Handout)
  ☑ General exercises for RA (Abbott Handout)
  ☐ Arthritis: exercises to keep you moving booklet (ordered or website link)
  ☐ DVD: Home based Exercise (ordered)
  ☐ Community Exercises Classes handout
  ☐ Hydrotherapy Classes handout
  ☐ Physiotherapy/OT/Dietitian referral
  ☐ Pedometer
**Pain Management**

- Managing your pain booklet
- Advice provided from Arthritis NZ:
  - Keep a journal of pain and look for patterns
  - Complementary therapies
  - Pacing
  - Take meds as advised
  - Managing fatigue
  - Sleep hygiene
  - Referral to GP

Pain ranges from 1 (low) to 10 (high)

Joint swelling:

Stiffness:

Restricted movement:

What makes it worse?

What makes it better?

**Coping Strategies**

- Smoking triggers diary handout
- Discuss Goals and Self-management: how do they cope with the following?

Pain:

Stiffness:

---

361
Fatigue: ____________________________________________________________
__________________________________________________________________
__________________________________________________________________
Sleep: ____________________________________________________________
__________________________________________________________________
Mood problems: ____________________________________________________
__________________________________________________________________

☐ Available Support
☐ Weekly email reminders
☐ Live with Family
☐ Lives Alone
☐ Other Support Person

☑ What NRT are they using? ____________________________________________
__________________________________________________________________
__________________________________________________________________
__________________________________________________________________
__________________________________________________________________

Comments:
__________________________________________________________________
__________________________________________________________________
__________________________________________________________________

Questions most commonly asked:
__________________________________________________________________
__________________________________________________________________
**Appendix 20: Pilot Study RCT Participant Follow-up Checklist (weeks 1, 4 and 8)**

**Pilot Study: Smoking Cessation and Rheumatoid Arthritis**

<table>
<thead>
<tr>
<th>Arthritis Educator: ______________________________</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: <em><strong><strong>/</strong></strong></em>/_______ Randomisation #_______________</td>
<td></td>
</tr>
<tr>
<td>Initial Contact: Phone□ Skype□ Face-to-face □</td>
<td></td>
</tr>
<tr>
<td>Member of Arthritis NZ? Yes□ No□</td>
<td></td>
</tr>
<tr>
<td>Surname: _________________________</td>
<td></td>
</tr>
<tr>
<td>First-name: _________________________ NHI #: _________________________</td>
<td></td>
</tr>
<tr>
<td>Address: ______________________________________________________________</td>
<td></td>
</tr>
<tr>
<td>Home Phone: _____________________ Mobile: ______________________</td>
<td></td>
</tr>
<tr>
<td>Email: ____________________________</td>
<td></td>
</tr>
</tbody>
</table>

**Intervention Follow-up Notes:**

**Follow-up Week # ____________**

*Notes: prompts: how have they been since the last phone call?*

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

363
Education

Notes:

Exercises to keep you moving

- Hand exercises for RA (Abbott Handout)
- General exercises for RA (Abbott Handout)
- Arthritis: exercises to keep you moving booklet (ordered or website link)
- DVD: Home based Exercise (ordered)
- Community Exercises Classes handout
- Hydrotherapy Classes handout
- Physiotherapy/OT/Dietitian referral
- Pedometer

Notes:
Prompts: Have they used any of these exercises or services? Did they find these useful?
□ *Pain Management*

□ Managing your pain booklet

□ Advice provided from Arthritis NZ:

□ Keep a journal of pain and look for patterns__________________________________________

□ Complementary therapies__________________________________________________________

□ Pacing __________________________________________________________________________

□ Take meds as advised________________________________________________________________

□ Managing fatigue____________________________________________________________________

□ Sleep hygiene_______________________________________________________________________

□ Referral to GP _______________________________________________________________________

Pain ranges from 1 (low) to 10 (high) ___________

Joint swelling: ________________________________

Stiffness: __________________________________________________________________________

Restricted movement: __________________________

What makes it worse? _____________________________

What makes it better? ____________________________

Notes:
☐ **Coping Strategies**

- Smoking triggers diary handout
- Discuss Goals and Self-management: how do they cope with the following?

Pain: __________________________________________________________

________________________________________________________________

Stiffness: ______________________________________________________

________________________________________________________________

Fatigue: _______________________________________________________

________________________________________________________________

Sleep: _________________________________________________________

________________________________________________________________

Mood problems: ________________________________________________

________________________________________________________________

**Notes:**
☐ Available Support

☐ Weekly email reminders

Notes:

☐ What NRT are they using? __________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

Comments:

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

Questions most commonly asked:

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________
# Appendix 21: Three- and Six-Month Follow-up Interviews

## 3 / 6 MONTH FOLLOW-UP

<table>
<thead>
<tr>
<th>Group</th>
<th>Control Group / Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study number</td>
<td></td>
</tr>
</tbody>
</table>

### A. Subject: Changes to your smoking over the last 3 months

1. Are you **still smoking**?  
   - YES / NO

   a. If NO, what **when did you quit**? (Date)………………………………………………

   b. If YES, have you stopped smoking for **any time** during the last 3 months?  
      - YES / NO

      i. If YES, what **date did you quit** (Date)………………………………………………

      ii. **How long** did you stop smoking for? (comment)

2. Over the **last 4 weeks** have you been  
   - (1) No, not smoking - not a single puff
   - (2) Yes, a few puffs but not a whole cigarette
   - (3) Yes, between 1 and 5 cigarettes
   - (4) Yes, more than 5 cigarettes

3. How many cigarettes do you currently smoke **per day**? …………………………………

4. Have you made any changes to your smoking habits over the **last 3 months** (since 3 month follow-up)  
   - YES / NO

5. If YES, what other changes have you made to your smoking habits?

   a. Have you **changed the time of day that you have your first smoke**?  
      - Date…………………………………………
      - How?

   b. Have you **changed the time of day that you smoke**?  
      - When……………………………………
      - How?
c. Have you reduced the number of cigarettes you smoke?  
   **YES / NO**
   When? ......................................................
   How?

d. Have you increased the number of cigarettes you smoke?  
   **YES / NO**
   When? ......................................................
   How?

e. Have you changed the type of cigarette smoked?  
   **YES / NO**
   When? ......................................................
   How?

f. Is your house smoke-free?  Prompt: never smoked inside  
   **YES / NO**
   When? ......................................................
   How?

g. Is your car smoke-free?  
   **YES / NO**
   When? ......................................................
   How?

h. Do you have longer periods without smoking?  
   **YES / NO**
   When? ......................................................
   How?

i. Other (comment)  
   **YES / NO**
   What and when?

6. Do you now do something else before/instead of smoking?  
   **YES / NO**

   a. If YES, what do you do instead of smoking?  (prompts: walk, drink, deep breaths, brush teeth)? (verbatim)
7. What are the best things about being Smokefree/reduced smoking? (verbatim)
### B. Subject: Use of smoking cessation medications

1. During the last 3 months have you used NRT (patches, gum, lozenges, or similar medication) to help reduce the number of cigarettes smoked per day?  
   **YES / NO**

2. During the last 3 months have you used NRT (e.g. patches, gum, lozenges, or similar medication) to try and quit?  
   **YES / NO**

3. Are you still using NRT?  
   a. If YES, what?  
   **YES / NO**

<table>
<thead>
<tr>
<th>Medication</th>
<th>mg</th>
<th>Medication Description</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine Patch</td>
<td>......mg</td>
<td>Zyban or bupropion medication</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Nicotine Gum</td>
<td>......mg</td>
<td>Champix/Varenicline medication</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Nicotine Lozenge</td>
<td>......mg</td>
<td>Didn't use anything</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

4. How has NRT been for you?  
   **Smokers, lapsers or relapsers ONLY**

<table>
<thead>
<tr>
<th>Question</th>
<th>YES / NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are you planning to quit smoking within the next month?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>2. Do you think you will quit during the next 6 months</td>
<td>YES / NO</td>
</tr>
<tr>
<td>3. Sometime in the future?</td>
<td>YES / NO</td>
</tr>
<tr>
<td>4. If yes, when do you consider quitting? (date)</td>
<td>YES / NO</td>
</tr>
<tr>
<td>5. When?</td>
<td>YES / NO</td>
</tr>
</tbody>
</table>
## C. Subject: Success of Interventions

### Intervention Arm only

1. Did you receive support by phone from Arthritis New Zealand? YES / NO
   *If YES, then:*

2. Have you continued with any of the support/activities offered? YES / NO
   *If YES, then what specifically?*

<table>
<thead>
<tr>
<th>THEME</th>
<th>INTERVENTION</th>
<th>Useful</th>
<th>Why?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education</td>
<td>Handout</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercises</td>
<td>Handouts</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Booklets</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>DVD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Community classes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydrotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physio/Diet ref</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pedometer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain Management</td>
<td>Managing Pain Booklet</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pain Journal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support and Advice from ANZ</td>
<td>Managing Pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Managing fatigue</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Managing Meds</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Weekly Emails</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UOC Website</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coping Strategies</td>
<td>Smoking triggers</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Goals and Self-management</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3. From your point of view, how would you improve the interventions? (verbatim)

4. Did you access any other smoking cessation programmes and/or support? YES / NO
   a. If YES, what other services did you access?

5. Did you find these other services useful? YES / NO
   a. If YES, which aspects did you find useful?

6. On a scale of 1 to 10 how motivated do you think you were to quit smoking?

   1  2  3  4  5  6  7  8  9  10
   Not Motivated → Extremely Motivated

7. From your point of view, what would improve your ability to quit smoking?
**Control Arm Only**

1. Did you access any other smoking cessation programmes and/or support during the last 3 months?  
   - YES / NO
   - a. If YES, what other services did you access?

2. Did you find these other services useful?  
   - YES / NO
   - a. If YES, which aspects did you find useful?
   - b. What aspects were not useful?

3. On a scale of 1 to 10 how motivated do you think you were to quit smoking?  
   - 1 2 3 4 5 6 7 8 9 10
   - Not Motivated ➔ Extremely Motivated

4. From your point of view, what would improve your ability to quit smoking?

5. Would you like smoking intervention support from Arthritis New Zealand?  
   - YES / NO
Appendix 22: Exit Interviews with Educators

Sourced from [360]

Findings of exit interviews with Arthritis Educators who delivered a tailored smoking cessation intervention for people with rheumatoid arthritis

Report prepared for Arthritis New Zealand to support the implementation report to the Health Research Council

Dr Gareth J. Treharne¹, Ms Pip Aimer², Prof Lisa K. Stamp²

¹ Department of Psychology, University of Otago, Dunedin
² Department of Medicine, University of Otago, Christchurch

Background
It is useful to carry out exit interviews with staff who have delivered a research intervention in order to 1) investigate the pragmatics of delivering the planned intervention and 2) determine the staff’s views on what worked well with the intervention and what could be improved for future trials or roll-out. Qualitative exit interviews allow the emergence of unexpected themes and useful insights into the delivery of the intervention (see e.g., Hale et al., 2013; Mulligan et al., 2013; Smith et al., 2013). These findings supplement the main quantitative and qualitative findings with trial participants by providing information about both sides or the intervention – delivery as well as receipt. In this framework, ‘exit interview’ refers to an interview at the end of the intervention trial.

The aim of this report is to detail the themes that evident within exit interviews with the two experienced Arthritis New Zealand Educators who were trained to deliver a novel smoking cessation intervention for people with rheumatoid arthritis (RA). The intervention incorporated findings of a consultation phase in which smokers and ex-smokers with RA were asked about what is important for successful smoking cessation in focus groups and interviews (see Aimer et al., submitted; Aimer et al., in preparation). Five sets of intervention tools were devised to help participants overcome five barriers to smoking
cessation raised during the consultation phase: 1) lack of awareness of the potential impact of smoking on their disease, 2) uncontrollable pain, 3) trouble exercising, 4) smoking to cope, and 5) isolation from support. Both Arthritis Educators delivered the intervention to around 10 participants with rheumatoid arthritis between November 2012 and September 2013.

The starting research questions for the qualitative analysis were:
1. What were the Arthritis Educators’ experiences of delivering the smoking cessation intervention?
2. What aspects of the intervention seemed most helpful for participants?
3. What aspects of the intervention were challenging for delivery?
4. What are the Arthritis Educators’ recommendations for the future of the intervention?

The questions were addressed using a qualitative research design embedded in the larger project.

Methods
Semi-structured interviews were carried out with the two Arthritis Educators in December 2013, approximately 3 months after the final trial participant was recruited and after all planned contact for the intervention was completed. The interviews were run by the postgraduate student (PA) who has been leading the intervention data collection, who trained the Arthritis Educators in delivering the intervention, and who has extensive experience of interviewing.

The questions for the semi-structured exit interviews were devised by the researchers (PA, GJT a health psychology researcher, and LKS a rheumatology professor and consultant). The questions covered the aims of the project and were asked in approximately the order planned (see appendix), but allowing for lines of questioning to be taken up earlier in the interview if the interviewee raised a point that was planned for later in the interview. This style of interviewing is essential for intervention exit interviews in order to discover unexpected issues that would be missed by strict structured questioning (see Hale et al., 2008). The interviewer (PA) had not yet been unblinded to the intervention allocation of the randomised controlled trial (and thus was not aware of exact participant details).
The interviews were audio recorded and were transcribed by a professional transcription service who work to a confidentiality protocol. The transcripts were checked for accuracy but a research fellow who had not been present at the interview but was familiar with the overall study.

Thematic analysis was used to extract common themes across the two interviews (following Braun & Clarke, 2006). The analysis was led by a researcher who was not present at the interviews (GJT) with verification by the interviewer (PA) and project lead (LKS). The specific type of thematic analysis applied involved a realist stance in seeking semantic themes within the experiential feedback given by the Arthritis Educators. An inductive approach was used to find themes that were not necessarily expected and to interrogate the existence of thematic issues in both interviews (confirmation across informants).

The thematic analysis was focused on the aspects of the dataset that inform the specific reflections on delivering the intervention and recommendations for applying the intervention. Six themes were devised to explain the feedback from the two Arthritis Educators: 1) participants’ personal responsibility; 2) smoking is an ingrained habit; 3) generic facilitators and barriers to smoking cessation; 4) specific local barriers to smoking cessation; 5) what worked well within the intervention; and 6) keeping the Arthritis Educators in the loop.

**Results**

**Theme 1: “It was up to them” – Participants’ personal responsibility**

Both Arthritis Educators a strong notion of participants ultimately having personal responsibility for smoking cessation, which captured to balance of providing support but making sure that the support provided self-management skills.

The inherently positive work role of providing support was important to the Educators:

P1: It was good, it felt like doing something useful for people.
The Educators had noticed a range in participants’ stage of change. For those who would be at the ‘preparation’ stage of change (see Prochaska et al., 2005), the intervention was seen as “catalyst” to go ahead and move into the ‘action’ stage of change:
P2: Others were more than ready to give up and I think this was a catalyst.
P2: If they themselves were actually ready and wanted to do it, they would do it.

The Educators noted that determination to stay in the ‘action’ stage of change and continue with the research was helpful to some participants:
P2: [The participants who quit] were very, very determined to continue with it.

Some participants valued the follow-up process of the intervention because it meant the personal responsibility for quitting was monitored, providing some external motivation:
P1: A lot of [participants] quite liked being accountable to someone they’d met.

Not all participants value this kind of monitoring of their personal responsibility (see Theme 2). The unsuccessful participants had a contrasting pattern of personal responsibility. The Educators noted that the range of intervention tools made the intervention flexible (see Theme 5) but these were turned down by many participants:
P2: I think yeah there were definitely plenty of options for people to take up if they wanted to.
P1: A lot of people didn’t take up the opportunities.
P2: On the whole yes, I think they were quite excited about hearing the information to start with. But again, very individual whether they took it up.

The Educators rationalised this rejection of the intervention tools as perhaps being too much to expect participants to take up immediately, but it was participants’ personal responsibility to make use of the tools later if not immediately:
P2: I think sometimes with people you can give them the information and because we had them for only that eight week period really was a relatively short amount of time, sometimes it can be quite a bit after the event if you like that the information, they’ll use it.
P2: We can only present that information to them and umm whether they actually take it up now or later umm yeah.
Part of the issue of personal responsibility was a reluctance to withdraw that led participants to be difficult to contact:
P1: I think sometimes people not returning the calls was their way of saying “No thanks.”

The structure of the contact process for the intervention was noted to be different from the Educators’ routine practice, emphasising the personal responsibility they expect from clients:
P2: Normally we would just have one contact with [a client] and give them the option of whether they want to have more information. And, yeah, put it back on them to come back to us rather than us continually following up.

The risk with emphasising personal responsibility is that it allows smokers to blame ‘information fatigue’ from continuous messages about the importance of quitting:
P2: They’ve been told for many years that they should stop smoking. But at the end of the day it was completely up to them whether they wanted to or not.
P2: Yeah some of them were “I know that information, you don’t need to tell me again that I need to give up smoking, it’s not good for me.”

Overall, the theme of personal responsibility captures the Educators’ awareness of participants’ readiness to change and raises issues of how monitoring and accountability might supplement participants’ determination to quit. This readiness and determination was, however, not universal across participants.

Theme 2: “They’re a bit resistant to make changes” – Smoking is an ingrained habit
Some RA-specific barriers to smoking cessation were evident in trial participants, many of whom were wanting to quit but were resistant to engaging with the intervention options:
P1: They’re a bit resistant to change with stopping smoking and some people are like that when you’re talking to them when they’re in a lot of pain and they’re a bit resistant to make changes as far as start moving despite the pain or take paracetamol coz it might help. You know so that same that same kind of resistance but a lot of them actually didn’t have much pain as far as the arthritis goes.
P2: For some they felt that their smoking was part of their coping with their rheumatoid. A stress reliever.

These RA-specific barriers reiterate the findings of the consultation process used to develop the intervention (Aimer et al., submitted). One of the Educators here particularly noted that the resistance seemed to arise from their being the management of their arthritis, but it was also noted by that Educator that the trial participants did not have the high levels of pain typical of their usual clients.

Another part of the resistance to change was that participants had smoked for a long time:

P2: For a majority of them they had lived with the rheumatoid for a long, long time so they had their own ways of coping and their own ways of dealing with things [...] and they have been smoking for many, many, many years. And I think equally they could see that they probably should stop smoking. They’ve been told for many years that they should stop smoking.

P1: A lot of people had smoked a very long time and knew it was bad for them but still quite enjoyed it I think. [...] “It hasn’t killed me yet so you know why bother and I’ve got to enjoy something in life.”

A common expectation is that all smokers want to quit and do not like smoking, but here the Educator raises the point that part of the resistance to quitting might be that participants enjoy smoking and have a fatalistic attitude.

Even when participants were surprised by the new information about possible links between smoking and their arthritis, they were resistant to seeing the future potential for increased wellness:

P2: Some certainly were quite surprised with the links to you know medication being less effective umm and also had some comments that “Well it’s, this information’s not really much good for me now, I’ve already got rheumatoid arthritis.”

In summary, despite having enrolled for a trial of smoking cessation, some participants were noted to have considerable but understandable resistance to giving up smoking.
Theme 3: Generic facilitators and barriers to smoking cessation

In addition to the resistance identified in Theme 2, there were some facilitators and barriers noted by the Arthritis Educators. These facilitators and barriers are generic in that they are not necessarily specific to people with arthritis.

The Educators used their experience to counsel participants as per the trial protocol and the intervention tool of support:

P1: I think people appreciated being listened to. [...] they did want to talk about life and their reasons why they smoke. [...] Yeah and I think some of them did feel a little bit accountable because they’d justify straight away, “I haven’t given up, don’t ask me about smoking.” But then they’d talk about you know their life so I think yeah. And then you could kind of twist it back round again afterwards.

P1: What worked well? I think actually meeting people and them realising they’re not alone and that there is support available. Ah I think that was really, really good. Coz some people seemed quite isolated and not just in their environment, but also in their knowledge of things.

Support went beyond the support delivered by the Educators, with one Educator noting the importance of family support for one participant who had successfully quit:

P1: And her partner was going to give up with her. So she was probably overall was more motivated, had more motivating factors.

Support was also delivered by electronic communications – a facilitator of the intervention:

P1: I think the resources for online you know the emails, were really, really good, [but] that wasn’t kind of fully utilised for some of [the older] generation

P2: And certainly not everybody had access to internet.

However, here it is noted that access to electronic communications is a barrier to some participants, particularly the older participants. Overall, support was delivered by the Educators and other individuals, and through means other than face-to-face contact, which excluded access for some participants.
Theme 4: Specific local barriers to smoking cessation

In addition to generic barriers, specific barriers existed due to local circumstances. These barriers centred on the aftermath of earthquakes but also include other minor local issues that highlight how the intervention tools have to be considered in terms of the ability for them to be delivered in various locations.

The earthquake was noted to have ongoing impact:

P1: Like one lady was having her street renovated and every time the digger went past the house shook. So it was just all too much. She was quite traumatised I think actually.

P1: And it was really obvious there was a lot of stress relating to earthquakes and I mean that if it’s redeveloped is different isn’t it? Because at the time I kept thinking “Gosh, there could be more supports here for those people for those issues.” But I didn’t really, I kept saying “Go back to your GP.”

Coming back to lack of internet access, it was noted than another contributor to electronic isolation was earthquake disruption to housing:

P1: Coz they just didn’t have access to the internet some of them. [...] I wonder if some of it was coz of the earthquakes though. Some people had shifted a lot and either not got stuff up and going again or they just didn’t have it.

One very important local barrier was the closure of the hydrotherapy pool, which was meant to be offered as one intervention tool to allow participants to exercise as a compensation to stress-relief of gained from smoking:

P1: Probably the one thing people would have done was the pool, and it wasn’t available so that didn’t help.

P2: Unfortunately with the hydrotherapy, with the pool being closed for earthquake repairs that was not an =option= which I think is unfortunate because umm, maybe that, yeah that would have been something that people did take up. I mean who knows, but we didn’t have; we ended up not having that as an option.

A more localised point about availability of exercise classes provides important insight into the relevance of facilities. It was noted that the local exercise classes were only run when
participants were working – this issue may exist in other locations, and some locations may have no classes at all. If classes were available at other times then participants could have attended:

P2: Quite a number of people were working so some of the exercise classes again were ruled out, or some, some of our arthritis exercise classes were ruled out but whether they took up other external exercise because of it umm.

In summary, the impact of the earthquakes highlighted how local facilities are important for this smoking cessation intervention, particularly if it is to be rolled out to other locations that may also have varying access to exercise classes, internet etc.

**Theme 5: “There were definitely plenty of options” – What worked well within the intervention**

The range of options provided within the intervention was raised by both Arthritis Educators as one of the biggest specific facilitators of its delivery:

P2: I think it worked well and I think it was, yeah, like I said before, there was a wide range of resources, media to present it in and I think it probably covered most bases.

However, one of the Educators noted that the generic resources that were used as intervention tools to support smoking cessation were things participants had already tried or were already aware of:

P1: Most of those people that were internet savvy had already looked at [the pre-existing arthritis self-management resources that were emphasised]. [...] So for future umm, if it was redesigned? Probably divide them into internet savvy and non-internet savvy

The notion of focusing on the internet savvy mooted here then would perhaps imply a need to have a wider range of high quality internet resources about issues such as finding manageable forms of exercise in addition to the Arthritis New Zealand resources and other resources used. Other Educators may already facilitate this kind of active information seeking with clients.

The specific information about the potential impact of smoking on the severity of RA and the efficacy of treatments was noted to be one particularly motivating point:
P2: And I think you know hearing that link between medications, the effect of the medication, I think for some that that was actually quite alarming. And maybe for the ones that were struggling a wee bit umm, yeah.

P1: The younger person had, I can’t remember how old she was, maybe early thirties and had a son, a school kid and it was to do with going on new medication and she thought if she smoked she would have to go on a higher dose of medication and didn’t want to. So she’s quite highly motivated.

The specifics here of the information being “alarming” or used to trade off the ramping up of medication dosage links back to the themes on personal responsibility (Theme 1) and resistance (Theme 2) but shows how the tools was used appropriately in relevant cases.

Another point of flexibility was the venue or means of communicating:

P1: And a couple of people I did that with as well, I met them at the hospital because umm they were coming in from out of town, some were coming from [town] or somewhere a little bit further away.

Similarly, one of the Educators noted difficulties liaising with people who were working but was even willing to work flexible hours to overcome this:

P2: From the point of view of trying to get hold of people who are working, coz certainly for a lot of rheumatoid people, they are working so trying to catch them when they’re, 1) not working, and 2) actually available and relaxed enough to be able to talk to you and yeah. [...] So if it is out of hours then you know I can work my work hours around that so, I don’t see that so much of as a problem

When asked if the intervention could be flexible enough to work in other locations, both Educators were positive:

R: And do you think this intervention could be used in other parts of New Zealand?


R: And umm, do you think this intervention could be used by other Arthritis New Zealand places, different regions?
P1: Yeah absolutely. Yeah. It could be more tailor-made for Māori people and probably look at more groups as opposed to individual connections with people but maybe running a group.

Here one of the Educators raises the possibility of further tailoring/tool, particularly the possibility of group meetings (which were not part of this intervention due to the reluctance of some participant who smoke to attend focus groups in the consultation phase: Aimer et al., submitted). Overall, the intervention was seen as positive, mostly due to its planned flexibility and as added by the Educators.

Theme 6: “Hopefully that’s what you can tell us” – Keeping the Arthritis Educators in the loop

The final theme encompasses some of the suggestions raised by the Arthritis Educators, the information about the results that they were not aware of, and the points they raised that have implications for training.

It was evident that the Educators were not aware of the outcome of the study. They had not been informed of the individual participants’ outcomes or what tools they had taken up, and the Educators only knew what they had garnered informally from interactions:

P1: I got one person to stop (laughs) smoking I think.

P2: A number of people said they were interested in the DVD, the exercise DVD. But again I’m not sure whether they actually did take that up.

One of the Educators raised issues with the data collection forms. Firstly, they had realised they were not using the appropriate form for follow-up data gathering:

P1: Halfway through the study I realised I was using the wrong form for something.

Secondly, they reported finding the form repetitive, cumbersome and/or irrelevant to many participants because the questions ask for very precise information without removing questions that are irrelevant based on initial answers:

P1: On the form when you’re going through it, umm, it seemed quite repetitive. Like umm especially on the follow-up phone calls.
It was also noted that the problems getting in touch with participants led to concerns about the protocol to follow:
P1: Yeah the other thing was getting hold of people. Sometimes that was really hard and so you know [name] and I used to think “Well how many times do you ring?” So we’d kind of ring three times and then we’d wait and then, do you give up or not? You know so it was sort of, it was a little unclear how much, how many times we’d ring.

Here, the difference between the Educators’ routine practice and the specific data collection practices of the research protocol are again evident. This theme is summed up by one Educator’s response to a question requesting an overall evaluation of the intervention tools:
R: So how successful do you think the interventions were?
P2: I don’t know, I honestly don’t know. Hopefully that’s what you can tell us with your research in the end.

Having the staff who deliver the intervention in the loop about what is working as the trial progresses is questionable from a perspective of bias reduction but it is important to disseminate the findings of the trial so that the evidence may be put into practice.

**Conclusions**
The findings of these exit interviews provided six themes that capture a range of issues about the delivery of the intervention and possible reasons for the success or difficulties experienced by individual participants. The following conclusions are posed as tentative suggestions for future application of the information arising from each theme.

1) Participants’ personal responsibility
Delivery of the smoking cessation intervention relies on participants who are ready to quit. Indeed, the Arthritis Educators noted that participants needed to be “determined” to quit. Motivational interviewing may be a useful framework to be added to the intervention and training of the Educators (see Shannon & Hillsdon, 2007). Seeing participants as personally responsible for making use of the intervention tools could be supported by a structured motivational discussion about the participants’ reasons for and against use of the tools, which can help them move closer to change. Providing paternalistic accountability may, in
certain cases, be another tool that participants would value, but would need to be delivered with clear guidance about respecting participants’ withdrawal from the intervention.

2) Smoking is an ingrained habit
The resistance to quitting due to smoking being an ingrained and enjoyed habit was not expected given these participants had agreed to take part in the intervention trial. However, this finding is in line with our previous research on the RA-specific barriers to smoking cessation (Aimer et al. submitted). Emphasis on smoking being a risk factor for the onset of RA should perhaps be put aside in favour of emphasis on the possible health gains of smoking cessation. Older individuals may particularly benefit from additional information about the health gains they could still achieve from smoking cessation.

3) Generic facilitators and barriers to smoking cessation
The Educators’ skills in listening to participants should not be overlooked. The value of an educated listener outside the family unit is a core component of the intervention. Family support was also raised as a key facilitator and this had not been factored into the intervention, which was planned only to focus on the individual with RA. Support by electronic communication was important but not universally accessible by participants.

4) Specific local barriers to smoking cessation
The situation with the local earthquake and its ongoing impact highlighted how the intervention was tested in only one location and how location is a very important frame for the tools provided in the intervention. Planning the availability of tools in other locations would be important for rolling out this intervention, and may be facilitated by an information network approach to log available resources and problem-solve where resources are not available in a specific location.

5) What worked well within the intervention
The range of resources was seen as one of the key strengths of this intervention – what worked for one person might not work for another and so having many options covered more participants’ needs. A difference between the “internet savvy” participants and others without access of information gathering skills should not be overlooked. Making information accessible is the key, and making sure the information is reliable and
motivational underlies that provision of the information. The Educators were positive about rolling out the intervention and suggested it could possibly apply to anyone with a form of arthritis, although further research would be needed to investigate that broadening and build a case for disease-specific delivery (e.g., the information about smoking possibly effecting RA treatment efficacy is not relevant beyond RA).

6) Keeping the Arthritis Educators in the loop.
The Educators noted that they were not in the loop about the success of participants and they were keen to know the results of the main quantitative component of the trial, including which resources were made use of. Further refining of the data collection forms may be required and would benefit from the input of Educators and participants to ensure the relevance of the questions and determine what questions are essential to ask. It may help to use an online data collection protocol that could be access directly by participants with internet access or could be completed by the Educator in person or over the telephone. Differentiating what is needed for research evaluation from what is needed for routine practice should be paid heed.

Acknowledgements
We would like to thank the two Arthritis Educators for sharing their experiences and ideas. We would also like to thank Dr Megan Johnston for checking the interview transcripts, and Dr Simon Stebbings, Prof John Highton, and Dr Natalia Valentino for their contribution to the larger project. This research was funded by a Healthcare Delivery Partnership grant from the Health Research Council and Arthritis New Zealand. Additional funding was received from the University of Otago Research Fund.

References


Appendix: Questions for the semi-structured exit interviews

1. What was your overall impression about the structure of the smoking cessation interventions?
2. How successful do you think the interventions were?
3. How did interactions with this patient group differ from the normal patient interactions you have with RA patients?
4. What do you think was different between people who were successful or not successful at smoking cessation during this trial?
5. What do you see as the future of this kind of intervention programme?
6. Would you be happy to continue with this intervention programme?
7. Do you think this intervention could be used by Arthritis New Zealand in other parts of New Zealand?
8. What worked well with this pilot study?
9. What didn’t work well with this pilot study?
10. If you had the opportunity to redesign the interventions, what would you do?