DEVELOPMENT AND EVALUATION OF A NOVEL INTERVENTION FOR REHABILITATION FOLLOWING WHIPLASH INJURY

By

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A thesis submitted to the University of Birmingham for the degree of

DOCTOR OF PHILOSOPHY

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January 2017

ABSTRACT

Whiplash-associated disorder (WAD) causes substantial social and economic burden, with ≥70% patients classified as WADII. Effective management in the acute stage is required to prevent development of chronicity for approximately 60% patients. A novel *Active Behavioural Physiotherapy Intervention* (ABPI) addressing both physical and psychological components of WAD was developed and evaluated as a complex intervention for acute WADII through a sequential multiphase project. Each phase was conducted using rigorous, precise and transparent methodologies according to pre-defined protocols.

A systematic review and meta-analysis found that the combination of active physiotherapy and behavioural interventions may be a useful strategy.

A modified Delphi study (international research and UK clinical whiplash experts) identified the underlying principles, and physiotherapy and behavioural treatment components of the ABPI. As no underpinning psychological theory was identified, the ABPI was further developed employing self-efficacy enhancement from social-cognitive theory to enable individualised management.

A cluster-randomised, double-blind, parallel two-arm (ABPI: standard physiotherapy) pilot and feasibility trial (evaluating procedures, feasibility and acceptability ABPI) employed both quantitative and qualitative methods. Findings supported that the ABPI was potentially valuable (95% ABPI participants fully recovered with low number treatment sessions) and acceptable to physiotherapists and patients, supporting a definitive trial (with minor modifications).

ACKNOWLEDGEMENTS

This thesis was accomplished with the assistance and support of many people, to whom I will always be grateful.

Before anyone else, I would like to express my deepest gratitude and sincere appreciation to my primary supervisor Dr. Alison Rushton, who was abundantly helpful and offered her invaluable support and guidance during my PhD. Furthermore, she gave opportunities in presenting my work in several prestigious national and international conferences and publishing my work in several prestigious peer-reviewed journals to fulfil my academic skills.

My grateful also goes to Prof. Joan Duda (secondary supervisor) and Dr. Sayeed Haque (territory supervisor) for the guidance and supervision including useful comments and feedback throughout my PhD.

I would like to acknowledge the National Science and Technology Development Agency, Ministry of Science and Technology, the Royal Thai Government for the financial supports both master and PhD studies in the UK.

I would like to thank Physio 1st LTD for supporting patient recruitment and provision of assessment centres. I must also acknowledge Jonathan Price who was one of my team and substantially contributed for setting up the system of participant recruitment, booking system and monitoring physiotherapists. Also, I would like to thank Fotios

Stathopoulos, Josh Slater, Andy Ross, Isaak Tyros, Mark van Daalen, Georgia Arapitsa, Rachel Jolly and all Physio 1st staff for contributions and cooperations in this project.

I would like to extend my grateful to Dr. Nicola Heneghan for the chair of the Steering and Data Monitoring Committee of a pilot and feasibility trial and contributing throughout my PhD. Additionally, I wish to thank Dr. Esther Williamson from Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford for joining the committee as an external member and providing useful suggestions. I would like to thank Simon Smith, a patient with WADII who joined the committee and gave a useful feedback for a non-clinical view.

I would like to thank all the administrative and support staff of School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, UK; the Office of Education Affairs (OEA), the Royal Thai Embassy, UK; the National Sciences and Technology Development Agency under Ministry of Science and Technology, the Royal Thai Government and Faculty of Allied Health Sciences, Naresuan University, Thailand for their contributions and supports.

ACKNOWLEDGEMENTS *(continued)*

I would like to thank Monika Tarkar for assessing participants of a pilot and feasibility trial and Mohamad Madi for becoming the second reviewer of my systematic review including all staff, PhD students and Motor Control & Rehabilitation group of the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham for involving a part of my life.

I would like to thank all participants who involved in this multiphase project for their contributions, Proof-Reading-Service.com Ltd. for editing my thesis and King-Audio-Transcription & Tying Services for transcribing a focus group.

I would like to extend my thanks to my all friends in the UK and Thailand for sharing experiences together.

Last but not the least, I am truly thankful of my family in Thailand, who have always given me unending inspiration and support.

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LIST OF ABBREVIATIONS

ABPI	Active Behavioural Physiotherapy Intervention
AWIS	Acute Whiplash Injury Study
COREQ	COnsolidated criteria for REporting Qualitative research
CPT	Cold Pain Threshold
CROM	Cervical range of motion
DC	Direct Current
DE	Design Effect
DMC	Data Monitoring Committee
e-mail	electronic mail
EQ-5D	EuroQol-5 Dimensions
FABQ	Fear Avoidance Beliefs Questionnaire
FREMS	FRequency-modulated ElectroMagnetic neural Stimulation
GC	Galvanic Current
GHQ 28	General Health Questionnaire
GP	General Practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation system
HCPC	Health and Care Professions Councils
HF	High-Frequency external muscle stimulation
HPLT	High Power Laser Therapy
HPT	Hot Pain Threshold
HVGC	High Voltage Galvanic Current
I^2	Heterogeneity
IASP	International Association for the Study of Pain

LIST OF ABBREVIATIONS *(continued)*

IC	Confident Interval
ICC	Intracluster Correlation Coefficient
ICH GCP	International Conference on Harmonisation of Good Clinical Practice
IDC	Intermittent Direct Current
IES	Impact of Event Scale
IFC	InterFerential Current
IFOMPT	International Federation of Orthopaedic Manipulation Physical Therapists
IQR	Inter Quartile Range
IR	Infrared Radiation
MCID	Minimal Clinically Important Difference
MENS	Microcurrent Electrical Nerve Stimulation
micro-TENS	microcurrent Transcutaneous Electrical Nerve Stimulation
MRC	Medical Research Council
NDI	Neck Disability Index
NHS	National Health Service
NRS	Numerical Rating Scale
OR	Odds Ratio
PCI	Pain Coping Inventory
PEMF	Pulse ElectroMagnetic Field
PENS	Percutaneous Electrical Nerve Stimulation
PFActS-C	Pictorial Fear of Activity Scale-Cervical,
PPT	Pressure Pain Threshold
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses

LIST OF ABBREVIATIONS *(continued)*

PT	Physiotherapy
QALYs	Quality-Adjusted Life-Years
QoL	Quality of Life
RCT	Randomised Controlled Trial
ROM	Range of Motion
Rx	Treatment
SCS	electrical Spinal Cord Stimulation
SD	Standard Deviation
SF-36	Functional Health Status (Short Form 36)
SF-12	Functional Health Status (Short Form 12)
SMD	Standardised Mean Difference
SMFA	Short Musculoskeletal Function Assessment
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SS	Sample Size
TENS	Transcutaneous Electrical Nerve Stimulation
TIDieR	Template for Intervention Description and Replication
TSC	Trial Sterling Committee
TSK	Tampa Scale for Kinesiophobia
UV	UltraViolet
VAS	Visual Analogue Scale
WAD	Whiplash Associated Disorders
WADII	Whiplash Associated Disorder II
WCPT	World Confederation for Physical Therapy

LIST OF PEER-REVIEWED JOURNAL PUBLICATIONS

- **Wiangkham T,** Duda J, Haque S, Price J, Rushton A. (2016) Acute Whiplash Injury Study (AWIS): a protocol for a cluster randomised pilot and feasibility trial of an Active Behavioural Physiotherapy Intervention in an insurance private setting. *BMJ Open* 6(7):e011336. doi:10.1136/bmjopen-2016-011336

- **Wiangkham T**, Duda J, Haque S, Rushton A. (2016) Development of an active behavioural physiotherapy intervention (ABPI) for acute whiplash-associated disorder (WAD) II management: a modified Delphi study. *BMJ Open* 6(9): e011764. doi:10.1136/bmjopen-2016-011764

- **Wiangkham T**, Duda J, Haque S, Madi M, Rushton A. (2015) The effectiveness of conservative management for Acute Whiplash Associated Disorder (WAD) II: a systematic review and meta-analysis of randomised controlled trial. *PLoS ONE* 10(7): e0133415. doi:10.1371/journal.pone.0133415

- **Wiangkham T**, Duda J, Haque S, Madi M, Rushton A. (2015) The effectiveness of conservative management for Acute Whiplash Associated Disorder (WAD) II: a systematic review and meta-analysis of randomised controlled trial. *Physiotherapy* 101 (supplement 1): e1623-e1624.

LIST OF PEER-REVIEWED CONFERENCE PRESENTATIONS

- **Wiangkham T**, Rushton A, Duda J, Haque S. (2016) The development of an Active Behavioural Physiotherapy Intervention (ABPI) for acute Whiplash Associated Disorder (WAD) II management: a modified Delphi study. *The International Federation of Orthopaedic Manipulation Physical Therapists (IFOMPT) Conference*. Glasgow, United Kingdom. 4th - 8th July. *(Interactive Poster).*

- **Wiangkham T**, Duda J, Haque S, Madi M, Rushton A. (2015) The effectiveness of conservative treatment for acute whiplash associated disorder (WAD) II management. *World Confederation for Physical Therapy (WCPT) Congress*. Suntec Singapore Convention and Exhibition Centre, Singapore. 1st- 4th May. *(Traditional Platform Presentation).*

- **Wiangkham T**, Duda J, Haque S, Madi M, Rushton A. (2014) The effectiveness of behavioural intervention for acute whiplash associated disorder (WAD) II management. *Physiotherapy UK Conference and Trade Exhibition*. International Convention Centre, Birmingham, United Kingdom. 10th-11th October. *(Traditional Platform Presentation).*

- **Wiangkham T**, Duda J, Haque S, Madi M, Rushton A. (2014) The effectiveness of active intervention for acute whiplash associated disorder (WAD) II management. *The 4th Health Challenge Thailand Academic Conference*. The Office of Educational Affairs, the Royal Thai Embassy, London, United Kingdom. 6th September. *(Traditional Platform Presentation).*

CHAPTER 1

Introduction of Acute Whiplash-Associated Disorder (WAD) II

Abstract

This chapter provides a range of whiplash-associated disorder (WAD) literature in terms of general WAD information, the situation of WAD, the presentation of WAD, the classification of WAD, the economic impact of WAD and the management of WAD. Furthermore, an overview of a multiphase PhD project is introduced in order to illustrate the principle structure of this thesis. The aims of this project were to development and evaluation of a potentially effective intervention in managing patients with acute WADII in order to prevent the development of chronicity, to improve WADII management for the patients' quality of life and to reduce economic burden.

1.1 Whiplash-associated disorder (WAD)

Whiplash-associated disorder (WAD) is a consequence of whiplash injury caused by rapid acceleration immediately followed by rapid deceleration of the head and neck, leading to bony and soft tissue injuries (Spitzer et al., 1995). Road traffic accidents are the most common cause of whiplash (Cassidy et al., 2000). There are a range of possible mechanisms of whiplash injury although there is considerable debate regarding the exact injury mechanisms (Elkin et al., 2016).

A range of factors (e.g. directional impact (front, side or rear) and speed of vehicle) can affect mechanism of injury, leading to hard and soft tissue damage (e.g. cervical spine, joints, intervertebral discs, muscles, tendons, ligaments, nerves, brain and vertebral arteries) depending on the severity of injury (Berglund et al., 2006,

Siegmund et al., 2009, Saari et al., 2011, Elkin et al., 2016). Consequently, this contributes to the considerable clinical heterogeneity manifested in patients following injury. Although the differentially directional force can lead to different mechanisms of injury, the highest risk and prevalence of whiplash injury is the rear-end collision (Jakobsson et al., 2000) which can transition to chronicity (Jull et al., 2011a). The mechanism of the rear-end collision is the initial retraction of the upper cervical (upper cervical flexion) and extension of lower cervical spine, followed by whole cervical spine extension prior to rebounding forward from the seat back and head restraint into flexion (Elkin et al., 2016).

The initial cervical hyperextension resulting from a rare-end car impact (MacNab, 1965), can lead to cervical facet joint compression and anterior structure damage (Pearson et al., 2004). However, the head-restraint which tries to prevent neck hyperextension can reduce neck injury by 20% (Nygren et al., 1985). Thus, the S-shaped cervical spine curvature (opposite curvature between upper and lower cervical spine) has been introduced as contributing to a complex mechanism of injury (Grauer et al., 1997, Panjabi et al., 1998, Ivancic, 2016). For example, the mechanism of injury from a rear-impact is hyperextension of the lower cervical spine concurrent with upper cervical spine flexion (Elkin et al., 2016, Ivancic, 2016) as detailed above. In addition, understanding of the mechanism of whiplash injury (including the minimal speed of vehicle or the impact force which can lead to whiplash injury) is unclear (Elkin et al., 2016, Ivancic, 2016) owing to inadequate investigation of protective muscular mechanisms.

1.2 The situation of WAD

Over the past 20 years, the incidence of traffic-related whiplash has risen in most Western countries (Holm et al., 2008). The prevalence of whiplash injury has been reported as being 3/1,000 people in North America and Western Europe (Holm et al., 2008), with around 450,000–550,000 individuals experiencing WAD annually in the UK (Ellman et al., 2013). Up to 60% of WAD patients have been documented as progressing to chronicity, with approximately 30% of patients experiencing moderate to severe pain and disability (Merrick and Stalnacke, 2010, Jull et al., 2011b, Sterling, 2014), leading to an decrease in quality of life (Borsbo et al., 2008, Borsbo et al., 2009). The management of both acute and chronic WAD is reported as having limited success (Jull et al., 2007, Stewart et al., 2007, Verhagen et al., 2007, Jull et al., 2013, Lamb et al., 2013, Michaleff et al., 2014). Therefore, an effective intervention in the acute stage is required to prevent chronicity and/or improve the quality of life of the patients.

In the UK, an adequately powered phase III trial for acute WAD I-III management in the National Health Service used a pragmatic, two-step, cluster randomised trial design to compare active management to usual consultations (step 1) and a package of up to six physiotherapy sessions with a single advice session (step 2) (Lamb et al., 2013). Results demonstrated that the provision of active management consultation did not differ from the usual care in terms of Neck Disability Index (NDI), Functional Health Status (Short Form: SF-12, both physical and mental components), and work days lost throughout the trial (at 4-, 8- and 12- months). However, physiotherapy package (up to six physiotherapy sessions) demonstrated a modest acceleration to early recovery of persisting symptoms compared with the advice (e.g. NDI at four months and work days lost) but was not for cost-effective. According to the

results of the MINT trial, an effective intervention for the WAD management is still required.

1.3 The presentation of WAD

Whiplash patients commonly experience neuromusculoskeletal problems including pain (Lord et al., 1996, Thompson et al., 2010), reduced cervical range of motion (Spitzer et al., 1995, Hartling et al., 2001) and cervical muscle weakness (Prushansky et al., 2005), based on the severity of the injury (Spitzer et al., 1995, Berglund et al., 2006). Neck pain and decreased cervical movement have been reported as the most common symptoms of WAD (Stovner, 1996, Sterling, 2004a). Individuals with WAD also experience psychological symptoms (Richter et al., 2004, Sterling et al., 2005, Carroll et al., 2006) including cognitive disturbance (Spitzer et al., 1995), fear of movement, depression and anxiety reflective of post-traumatic stress disorder (Sterling et al., 2005, Sterling and Chadwick, 2010, Buitenhuis and de Jong, 2011, Carroll, 2011, Sterling et al., 2011a). Thus, WAD patients can experience both physical and psychological problems, leading to a decrease in their quality of life (Rebbeck et al., 2006, Wallin and Raak, 2008, Haines et al., 2009, Borsbo et al., 2009, Borsbo et al., 2010, Sterling and Chadwick, 2010, Myran et al., 2011, Nijs et al., 2011). The nature of both physical and psychological problems varies across patients. For example, some patients may have predominantly physical rather than psychological problems or vice versa or equality.

1.4 The classification of WAD

Spitzer et al. (1995) described five classifications (0–IV) of WAD (Spitzer et al., 1995, Hartling et al., 2001) (**Table 1.1**). The most common grade of WAD is WADII, which

has been found to account for at least 70% of WAD patients (Sterling, 2004a, Williamson et al., 2015b). A neck complaint and musculoskeletal sign(s) is characteristic of WADII patients, and this subgroup reflect the patients that are commonly managed by physiotherapists (Spitzer et al., 1995, Lamb et al., 2013, Michaleff et al., 2014). Patients with WADIII in contrast, present with neurological signs and therefore require wider professional input and physiotherapy may or may not be of value. Patients with WAD 0-I represent the less severe WAD populations that can commonly obtain spontaneous recovery within a month of injury (Spitzer et al., 1995) and therefore require minimal/no physiotherapy intervention. To further improve management a focus on the WADII classification is essential. Therefore, it would be useful to develop an effective intervention for the management of acute WADII to optimise physiotherapy management in order to reduce the number of WAD patients progressing to chronicity.

Table 1.1: The classification of whiplash-associated disorders (Spitzer et al., 1995)

Grade	Classification
0	No neck complaint(s) or sign(s)
I	Neck complaint of pain, stiffness or tenderness but no physical sign(s)
II	Neck complaint and musculoskeletal sign(s) (decreased range of motion, point tenderness, etc.)
III	Neck complaint and neurological sign(s) (decreased or absent tendon reflex, weakness, sensory deficits)
IV	Neck complaint and fracture or dislocation

1.5 The economic impacts of WAD

WAD contributes to a substantial economic burden throughout the industrialised world. Increased direct and indirect costs have been reported including health-care costs, reduced work productivity, lost earning capacity, higher socio-economic costs and time contributed by carers (Leth-Petersen and Rotger, 2009, Jennum et al., 2013). For example, within the first two years after a whiplash injury, employment propensity declined by approximately 20%–25% (Leth-Petersen and Rotger, 2009, p. 1003). Consequently, the potential impact on both the individual and national economy may be considerable. The estimated annual economic cost related to motor vehicle crashes is $242 billion in the USA (Blincoe et al., 2015) and €180 billion in Europe (Elvik et al., 2007). The annual economic cost related to WAD is estimated at approximately $3.9 billion in the US (Eck et al., 2001) and €10 billion in Europe (Galasko et al., 2002), thereby contributing an economic burden internationally.

Over the past decade, an increase in minor cervical spine injuries and related costs after whiplash has also been reported among insurance companies (Buitenhuis et al., 2009). In the Western world the cost of insurance claims is considerable in Sweden, France, Germany, Italy, Canada, the US and particularly in the UK where most patients with WAD are managed within the private sector through insurance companies (Cote et al., 2007, Chappuis and Soltermann, 2008, Holm et al., 2008, Mooney, 2012, Hyde, 2013, FSCO, 2014). The UK has been described as the 'Whiplash Capital of Europe' by the Association of British Insurers, who estimated that one person in 140 claims for whiplash injury annually (Mooney, 2012). In the UK, it is estimated that the cost of claims for personal injury has risen from £7 billion to £14 billion over the last decade (Mooney, 2012).

1.6 The management of WAD II

A range of management interventions are commonly used for patients experiencing WADII, including pharmacological therapy, acupuncture, education, and manual and physical therapy (Moore et al., 2005, TRACsa, 2008, Jagnoor et al., 2014). Conservative management of WADII is recommended by some existing systematic reviews and guidelines (Moore et al., 2005, Verhagen et al., 2007, Hurwitz et al., 2008, TRACsa, 2008, Rushton et al., 2011, Michaleff and Ferreira, 2012, Jagnoor et al., 2014). In a systematic review and meta-analysis of randomised controlled trials (RCTs), Rushton et al. (2011) evaluated the effectiveness of physiotherapy management in WADII. They found that active physiotherapy management with very low/low-quality evidence may reduce pain and improve cervical mobility in the short term. Unfortunately, there is no systematic review evaluating WADII management in the acute stage and addressing both physical and psychological aspects. The definition of acute WAD is within four weeks after injury (Sterling and Kenardy, 2006, TRACsa, 2008, Jull et al., 2013, Jagnoor et al., 2014, Sterling, 2014). Therefore, the important starting point of this PhD was that a rigorous systematic review was required to evaluate the effectiveness of conservative management of acute WADII in order to summarise what is known about effective management in the acute stage.

1.7 Overview of a multiphase PhD project

A multiphase PhD project was conducted to develop a potentially effective intervention for acute WADII (the most common classification of WAD) management in order to prevent the development of chronicity, to improve WADII management for the patients' quality of life and to reduce economic burden. Subsequently, the developed intervention

was evaluated by a pilot and feasibility trial for its procedures, feasibility and acceptability in physiotherapy practice. There were three phases in the multiphase PhD project:

Phase 1: A systematic review and meta-analysis of conservative management of acute WADII investigated the effectiveness of existing interventions. Only RCTs for acute WADII management (except drug therapy) were included in the review. The rigorous systematic review found that the combination of active physiotherapy and a behavioural intervention termed the 'Active Behavioural Physiotherapy Intervention (ABPI)' may be a useful strategy for acute WADII management. The systematic review (**Appendix 1**) was published in PLoS ONE (Wiangkham et al., 2015b) and was orally presented at the World Confederation for Physical Therapy (WCPT) Congress 2015 (**Appendix 2**) (Wiangkham et al., 2015a).

Phase 2: The ABPI was developed using a rigorous modified three-round Delphi study. International research whiplash experts, UK private physiotherapists and UK postgraduate musculoskeletal physiotherapy students were recruited via e-mail to define and provide the underlying principles and treatment components of the ABPI. LimeSurvey (free open source software survey tool on the web) was used to collect the data. The study was approved by the University of Birmingham's Ethics Committee ***(ERN 14_1339)*** (**Appendix 3**). This study (**Appendix 4**) was published in *BMJ Open* (Wiangkham et al., 2016b) and presented in poster format (interactive poster) at the International Federation of Orthopaedic Manipulative Physical Therapists' (IFOMPT) conference 2016 in Glasgow, UK.

Due to the lack of theory to underpin and deliver the ABPI in physiotherapy practice, the ABPI was further developed by taking into consideration both empirical

(the modified Delphi study) (Wiangkham et al., 2016b) and theoretical (social cognitive theory focusing on the enhancement of self-efficacy) (Bandura, 1977) evidence in line with the Medical Research Framework of Complex Interventions (Craig et al., 2008). Finally, the ABPI was described in terms of concept, phases of the management and examples for the management of patients with acute WADII.

Phase 3: A cluster randomised pilot and feasibility trial of an ABPI in a private insurance setting was conducted to evaluate the feasibility of procedures and the acceptability of the developed intervention for acute WADII management within the UK private sector, in preparation for the design of an adequately powered definitive randomised controlled trial. The trial consisted of two parallel phases: 1] an external pilot and feasibility trial of a cluster randomised double-blind (assessor and participants) parallel two-arm clinical trial design, comparing the ABPI with standard physiotherapy management to evaluate the procedures and feasibility of the ABPI for acute WADII management; and 2] an embedded exploratory qualitative study using semi-structured in-depth individual interviews and a focus group to explore the physiotherapists' and participants' perceptions of the ABPI, respectively. The study was approved by the University of Birmingham's Ethics Committee ***(ERN_15-0542)*** (**Appendix 5**). The requirements of the Trial Steering Committee (TSC) and the Data Monitoring Committee (DMC) were combined into one committee to monitor the trial in line with its pilot and feasibility nature. The trial protocol (**Appendix 6**) was published in *BMJ Open* (Wiangkham et al., 2016a).

Chapter summary

There are many problems related to WAD in terms of the health status and quality of life of patients, and the economic burden at individual, national and international levels. Thus far, both acute and chronic WAD management have been reported as having limited success. In order to prevent WADII patients from progressing to chronicity, it is necessary to find an effective intervention for acute WAD management. Therefore, the purpose of my PhD project was to determine a potentially effective intervention for acute WADII management.

CHAPTER 2

Effectiveness of Conservative Management of Acute WADII:

A systematic review and meta-analysis of randomised controlled trials

Abstract

This chapter provides the systematic review and meta-analysis of RCTs evaluating the effectiveness of conservative management for acute WADII which was published in PLoS ONE. The aim of the review was to summarise regarding the potentially effective intervention for the management in patients with acute WADII. The systematic review of RCTs is at the top of hierarchy of evidence (Sackett et al., 1996), and was conducted in line with the Back Review Group of the Cochrane Collaboration (Furlan et al., 2009b), the *Cochrane Handbook* (Higgins and Green, 2011), and is reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009a). Interestingly, this systematic review suggested that the combination of active and behavioural intervention may be a potentially effective intervention for acute WADII management.

2.1 Background

WAD contributes to a substantial social and economic burden internationally. Up to 60% of WAD patients progress to chronicity with approximately 30% experiencing moderate to severe pain and disability (Merrick and Stalnacke, 2010, Jull et al., 2011b, Sterling, 2014). Unfortunately, chronic WAD management is reported to have limited success (Merrick and Stalnacke, 2010, Michaleff et al., 2014, Sterling, 2014, Sterling et al., 2015). A focus on effective management in the acute stage (within four weeks after

the road traffic accident) is therefore required to prevent patients from progressing to chronicity (Michaleff et al., 2014, Wiangkham et al., 2015a, Wiangkham et al., 2015b).

Although there are five grades of whiplash classification, at least 70% of patients post-whiplash can be classified as WADII (Sterling, 2004b, Williamson et al., 2015b), who are commonly managed by physiotherapists. Conservative management (non-invasive treatment) is commonly utilised for acute WADII, and mainly focuses on physical treatment in terms of active exercises, manual techniques and physical therapy (Moore et al., 2005, TRACsa, 2008, Jagnoor et al., 2014). Unfortunately, the effectiveness of conservative interventions is reported to be limited in managing acute WADII (Foley-Nolan et al., 1992, Borchgrevink et al., 1998, Bonk et al., 2000, Rosenfeld et al., 2003, Ferrari et al., 2005, Aigner et al., 2006, Vassiliou et al., 2006, Ottosson et al., 2007, Dehner et al., 2009, Picelli et al., 2011).

Patients with WAD exhibit both physical (e.g. pain and disability) and psychological (e.g. fear of movement, anxiety and depression) problems (Sterling et al., 2005, Sterling and Chadwick, 2010, Buitenhuis and de Jong, 2011, Myran et al., 2011, Nijs et al., 2011, Sterling et al., 2011b, Barnsley, 2013, Sterling, 2014). A biopsychosocial model of practice, focused to assessing and managing patients taking into account the biological, psychological and social aspects of their presentation was applied to patients with WAD (Ferrari and Schrader, 2001, Scholten-Peeters et al., 2002, McLean et al., 2005). Existing management interventions for WAD can broadly be divided into physical and psychological components reflecting this model (psychological components capturing the psychosocial aspects). Currently, the psychological components (e.g. cognitive behavioural therapy and other behavioural

approaches) of WADII management are underexplored, and this may be a factor contributing to the limited success of some approaches to management.

Some clinical guidelines have suggested the value of psychological strategies (e.g. cognitive behavioural therapy and multimodal therapy) in managing chronic WAD II (Moore et al., 2005, TRACsa, 2008), but these psychological components are not recommended in the latest guidelines for acute WAD management (Jagnoor et al., 2014) Moreover, there are few acute WAD studies involving the psychological facet of rehabilitation and recovery from WADII. No systematic review to date has specifically addressed both physical and psychological perspectives in the management of acute WADII. Effective conservative management of acute WADII, employing both physical and psychological strategies, is therefore important in order to summarise what we know about effective management in the acute stage.

Objective

The objective of this study was to evaluate the effectiveness of conservative management of acute WADII.

2.2 Methods

A systematic review of RCTs, the gold standard for intervention evaluation in health care (Juni et al., 2001), was conducted according to a predefined protocol using the methodological guidelines of the Back Review Group of the Cochrane Collaboration (Furlan et al., 2009b), the *Cochrane Handbook* (Higgins and Green, 2011), and is reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009a).

2.2.1 Eligibility criteria

Table 2.1 details the study eligibility criteria using the Population Intervention Comparison Outcome Study Design (PICOS framework) (Moher et al., 2009a).

Table 2.1: Eligibility criteria for included trials

Population	Acute WADII (0–II or I–II participants were included when the grade was not classified in an individual study)
Intervention	Conservative treatment (inclusive of the range of intervention detailed as part of the search strategy in Box 1 [search stages 3–20], and excluding drug therapy)
Comparison	Standard/control intervention
Outcome	Pain, disability, function, patient satisfaction, social impact and physical impairment based on the International Classification of Functioning, Disability and Health (ICF) (WHO, 2001)
Study design	Randomised controlled trial

2.2.2 Information sources and searches

Two independent reviewers (doctoral researchers) searched:

- The PEDro, Medline, Embase, AMED, CINAHL, PsycINFO and Cochrane Library databases from inception to 15th April 2015
- Key journals manually, including *Spine*, *Manual Therapy*, *Physiotherapy*, *Physical Therapy*, *Australian Journal of Physiotherapy* and *Pain*, as well as article reference lists in relevant articles
- Dissertations and proceedings in the British National Bibliography for Report Literature, Center for International Rehabilitation Research Information & Exchange, Index to Scientific and Technical Proceedings, National Technical Information Service and System for Information on Grey Literature

Finally, authors who had published WAD trials within the last decade were contacted by e-mail to identify other relevant trials (e.g. proceeding, unpublished studies and studies published in local journals).

Examples of Search Strategies

Medline (Ovid) 1946 – 15th April 2015 and Embase 1974 – 15th April 2015

1. Acute whiplash OR acute whiplash injury* OR acute whiplash associated disorder* OR acute WAD OR acute whiplash associated disorder* II OR acute WAD II OR whiplash associated disorder* OR WAD OR whiplash associated disorder* II OR WAD II OR whiplash OR whiplash injury* OR whiplash patient* OR whiplash syndrome* OR cervical spine disorder* OR cervical spine injury*
2. Randomized controlled trial* OR randomised controlled trial* OR randomized clinical trial* OR randomised clinical trial* OR randomized controlled clinical trial* OR randomised controlled clinical trial* OR RCT*
3. Conservative treatment* OR conservative intervention* OR conservative management* OR conservative approach OR conservative therapy*
4. 1 AND 2
5. 3 AND 4
6. Physiotherapy OR physical therapy OR physical approach OR physical intervention OR physical management
7. 4 AND 6
8. Manual therapy OR manipulation OR mobilisation OR mobilization OR massage
9. 4 AND 8
10. Exercise OR exercise therapy OR active intervention* OR active treatment* OR active exercise OR range of motion exercise OR ROM exercise OR strengthening exercise OR stretching exercise OR therapeutic exercise OR endurance exercise OR endurance training OR home exercise OR proprioception exercise
11. 4 AND 10
12. Electrotherapy OR electrical stimulation OR transcutaneous electrical nerve stimulation OR TENS OR percutaneous electrical nerve stimulation OR PENS OR frequency-modulated electromagnetic neural stimulation OR FREMS OR

electromagnetic therapy OR electromagnetic field OR electromagnetic field therapy OR pulse electromagnetic field OR PEMF OR pulse magnetic field OR static magnetic field OR electrical spinal cord stimulation OR SCS OR microcurrent transcutaneous electrical nerve stimulation OR micro-TENS OR high-frequency external muscle stimulation OR external muscle stimulation OR HF OR interferential current OR IFC OR Russian current OR faradic current OR intermittent direct current OR IDC OR galvanic current OR GC OR direct current OR DC OR diadynamic current OR high voltage galvanic current OR HVGC OR microcurrent electrical nerve stimulation OR MENS OR electroacupuncture

13. 4 AND 12

14. Thermotherapy OR heat OR hot pack OR ultraviolet OR UV OR infrared radiation OR IR OR infrared therapy OR laser OR laser therapy OR ice OR cold therapy OR ice massage OR ice pack OR contrast bath OR cryotherapy

15. 4 AND 14

16. Posture OR balance OR traction

17. 4 AND 16

18. Education OR educational intervention OR patient education OR self-management OR self-management program OR neck school OR whiplash school

19. 4 AND 18

20. Behaviour approach* OR behaviour therapy* OR behaviour treatment* OR cognitive behaviour OR cognitive therapy* OR cognitive treatment* OR cognitive behaviour approach* OR cognitive behaviour therapy* OR psychological approach* OR psychological aspect*

21. 4 AND 20

2.2.3 Trial selection

After searching, the two independent researchers evaluated identified studies for eligibility by screening 1] title and abstract, then 2] full texts, grading each study as eligible/not eligible/might be eligible at each stage (Furlan et al., 2009a). Included studies were agreed by the two reviewers. The third reviewer (a methodological expert)

mediated in cases of disagreement. Due to the language limitations of all reviewers and suitability for the assessment of risk of bias within individual trials, only full text studies in English were included.

2.2.4 Data collection process

Data were extracted by the first researcher (the lead researcher) and checked by a second. Trial authors were contacted for additional data when data were missing or ambiguous as evaluated by the first researcher.

2.2.5 Data items

Trial authors, countries, study design, stage of whiplash patients, WAD classification, sample size, interventions, study setting, power calculations, outcome measures, follow-up period, loss to follow-up, intention to treat and main results were extracted for each trial. Data relating to key outcome measures including pain, disability, function, patient satisfaction, social impact and physical impairment based on the International Classification of Functioning, Disability and Health were extracted (WHO, 2001).

2.2.6 Risk of bias (RoB) in individual trials

The Cochrane RoB assessment tool is the standard tool for assessing RoB in RCTs (Moher et al., 2009a, Higgins et al., 2011a, Higgins et al., 2011c). It was developed by statisticians, epidemiologists and review authors using a rigorous methodology (Higgins et al., 2011b). This tool was utilised to assess the internal validity/ROB. Training in use of the Cochrane RoB assessment tool and a pilot of RoB

assessment were carried out by the two reviewers in order to give an opportunity for both reviewers to become familiar with the assessment form and construct the skills for RoB assessment. Then, the two reviewers evaluated the RoB for each included trial independently. The third reviewer mediated in cases of disagreement following discussion. Each RoB component was reported in terms of unclear, low or high risk of bias in tabular form (Higgins et al., 2011a, Higgins et al., 2011c, Rushton et al., 2011). The Kappa measure of agreement (Cohen, 1968) was utilised to assess the agreement between the two reviewers using SPSS version 21.

2.2.7 Summary measures

Risk of bias assessment was carried out based on the *Cochrane Handbook* (Higgins and Green, 2011, Higgins et al., 2011a, Higgins et al., 2011c). Quantitative data analysis was conducted in situations of comparability of interventions, outcome measures and assessment points across trials. Meta-analyses compared effect sizes with random effects as the primary analyses (Borenstein et al., 2010) and were conducted using STATA software version 12. The level of evidence was considered in line with the Grading of Recommendations Assessment, Development and Evaluation system (GRADE) (Guyatt et al., 2008).

2.2.8 Synthesis of results

The characteristics (e.g. country, sample size, grade of WAD, study design, interventions, outcome measures and follow-up period) and results of individual trials were summarised in a table. The standardised mean difference (SMD) and standard error of SMD were calculated to prepare for meta-analyses owing to the different outcome (e.g. VAS and NRS for assessing pain intensity) and different units of measure

(e.g. 10-VAS and 100-VAS) across included trials (Sedgwick and Marston, 2013). Meta-analyses were conducted based on the comparability of interventions, outcome measures and assessment points across trials using random effects model to increase statistical power (Borenstein et al., 2010) and eliminate underlying heterogeneity in terms of the differences of the subjects or interventions (e.g. age and the number of treatment sessions) and methodological diversity (e.g. blinding and concealment of allocation) among included trials. In reality, it would be very difficult to have a homogeneity in which fixed effects model is appropriate to perform a meta-analysis. The results of meta-analyses were tabulated in a table and graphically demonstrated in forest plots. Summary statistics including pooled estimate, 95% confident interval (CI), p-value and heterogeneity (I^2) were also tabulated.

2.2.9 Risk of bias across trials

RoB assessment across trials was tabulated in line with Rushton et al. (2011). The criteria of judgement for overall RoB followed recommendations in the *Cochrane Handbook* for assessing risk of bias in included trials (Higgins et al., 2011c). The level of evidence was evaluated by considerations of the overall potential risk of bias according to GRADE (Guyatt et al., 2008). If sufficient trials were included (≥10) it was intended to assess publication bias using Funnel plots (Schmid et al., 1998, Lau et al., 2006). Finally, the level of heterogeneity (I^2) was assessed in terms of percentage to demonstrate the credibility of each meta-analysis (Deeks et al., 2011).

2.3 Results

2.3.1 Trial selection

Fifteen RCTs (n = 1676 participants) across nine counties (Australia, Austria, Canada, Germany, Ireland, Italy, the Netherlands, Norway and Sweden) were included (Foley-Nolan et al., 1992, Borchgrevink et al., 1998, Bonk et al., 2000, Rosenfeld et al., 2003, Schnabel et al., 2004, Ferrari et al., 2005, Aigner et al., 2006, Dehner et al., 2006, Scholten-Peeters et al., 2006, Vassiliou et al., 2006, Ottosson et al., 2007, Dehner et al., 2009, Picelli et al., 2011, Conforti and Fachinetti, 2013, Jull et al., 2013). The process of study selection is detailed in **Figure 2.1**.

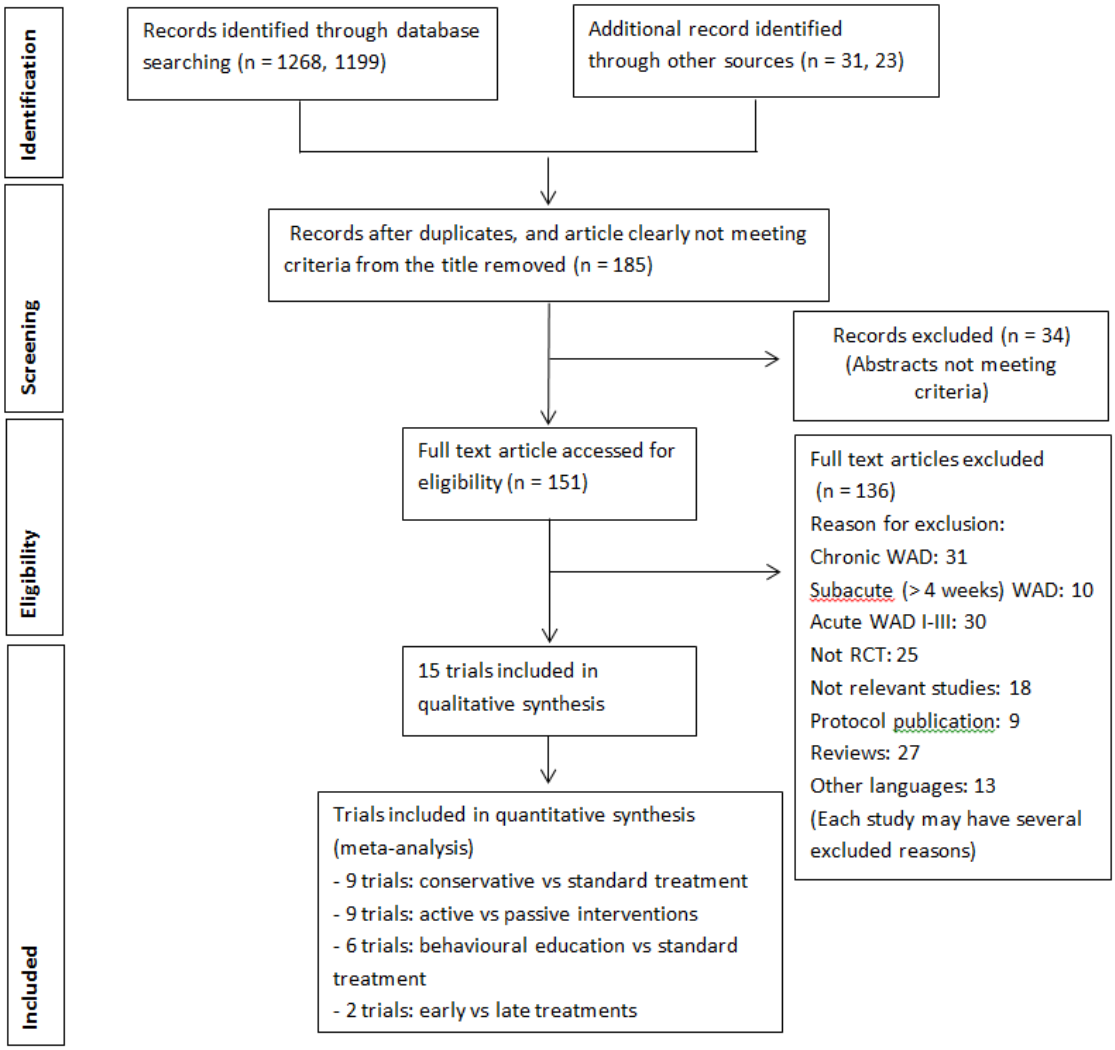

Figure 2.1: Study selection flow diagram (Moher et al., 2009).

2.3.2 Trial characteristics

Trial characteristics are summarised in **Table 2.2**. A range of conservative treatments were employed across included trials (see **Table 2.2** for details of interventions). WADII and WAD 0–II were studied through four trials in each grade and WAD I–II was studied through seven trials. All included trials were designed in a parallel single-blind (n = 9), unblinded (n = 3) and no mention of blinding (n = 3) RCT. Intervention comparison in the included individual trials can be grouped in terms of:

- conservative [any non-invasive intervention] versus standard/control (nine RCTs, n = 1182 participants) (Foley-Nolan et al., 1992, Borchgrevink et al., 1998, Bonk et al., 2000, Rosenfeld et al., 2003, Schnabel et al., 2004, Ferrari et al., 2005, Aigner et al., 2006, Vassiliou et al., 2006, Ottosson et al., 2007),
- active [activities from health professional suggestions to improve symptoms or reduce suffering from illness] versus passive [any intervention that uses other people, equipment or other things to reduce symptoms or illness] (nine RCTs, n = 1145 participants) (Borchgrevink et al., 1998, Bonk et al., 2000, Rosenfeld et al., 2003, Schnabel et al., 2004, Scholten-Peeters et al., 2006, Vassiliou et al., 2006, Ottosson et al., 2007, Dehner et al., 2009, Picelli et al., 2011),
- behavioural [strategies to promote useful behaviour to improve symptoms or reduce illness] versus standard/control (six RCTs, n = 987 participants) (Borchgrevink et al., 1998, Bonk et al., 2000, Schnabel et al., 2004, Ferrari et al., 2005, Vassiliou et al., 2006, Ottosson et al., 2007),
- and early [< one week] versus late [> two weeks] (two RCTs, n = 172 participants) (Rosenfeld et al., 2003, Dehner et al., 2006).

Outcome measures in individual trials varied in both subjective and objective aspects such as pain intensity (VAS or NRS), days of sick leave, IES, NDI, CROM, PPT, PFActS-C, GHQ 28, HPT, CPT, SF-36, TSK, PCI, SMFA, cervical proprioception, craniocervical flexor test, vasoconstrictor response, balance, functional recovery (VAS) and medications. Also, the follow-up period for the included trials ranged from 2 to 156 weeks.

Table 2.2: Summary of results from the 15 included individual trials

Studies	Countries	N	WAD	Design	Intervention 1	Intervention 2	Intervention 3	Outcome Measures	Follow-up Period	Main Results
Aigner et al. (2006)	Austria	53	II	Parallel RCT with single blind	Collar and laser acupuncture	Collar and placebo laser acupuncture	-	- CROM - Subjective symptoms (neck pain, dizziness, paresthesia and tinnitus) - Sick leave	3 weeks (Clinically) 8–12 months (Postal)	No significant difference between interventions in all outcome measures
Bonk et al. (2000)	Germany	147	0–II	Parallel RCT	Active therapy (active mobilisation and exercise)	Collar therapy	Control	- Subjective symptoms such as pain, stiffness - CROM	3 months	No significant difference between interventions at 3 months
Borchgrevink et al. (1998)	Norway	201	0–II	Parallel RCT with single blind	Act as usual	Immobilisati-on	-	- Subjective symptoms using questionnaire - Pain (VAS) - CROM - Shoulder movement - Sick leave	6 months	I1>I2 significant improvement in neck pain ($p<0.01$), pain during daily activities ($p<0.05$), headaches ($p<0.01$), painful regions ($p<0.01$), and memory and concentration problems ($p<0.001$) at 6 months. ROM of neck and shoulder did not differ between interventions.

Table 2.2: Continued

Studies	Countries	N	WAD	Design	Intervention 1	Intervention 2	Intervention 3	Outcome Measures	Follow-up Period	Main Results
Conforti and Fachinetti (2013)	Italy	135	I–II	Parallel RCT with single blind	HPLT	PT (manual therapy, passive and active exercise)	-	- Pain (VAS) - The date of return to work	6 weeks	I1>I2 significantly improved in both pain (p=0.005) and the date of return to work (p<0.001)
Dehner et al. (2006)	Germany	70	II	Parallel RCT	2 days with collar + standard PT after 1 week	10 days with collar + standard PT after 1 week	-	- Pain (VAS) - Disability (VAS) - CROM	6 months	No significant difference between interventions in all outcome measures
Dehner et al. (2009)	Germany	90	II	Parallel RCT	Active physical therapy	Passive physical therapy	Act as usual	- Pain (VAS) - CROM - Period of disability/ sickness costs	2 months	- Pain improvement: I1>I2>I3 significantly - CROM: I1=I2=I3 - Period of disability: I1=I2<I3
Ferrari et al. (2005)	Canada	112	I–II	Parallel RCT with single blind	Education pamphlet	Control group	-	- The number of recoveries	3 months	No significant difference between interventions

Table 2.2: Continued

Studies	Countries	N	WAD	Design	Intervention 1	Intervention 2	Intervention 3	Outcome Measures	Follow-up Period	Main Results
Foley-Nolan et al. (1992)	Ireland	40	0–II	Parallel RCT with single blind	PEMT + collar + active exercise	Placebo + collar + active exercise	-	- Pain (VAS) - CROM - Number of analgesics	3 months	I1>I 2 significant improvement in terms of pain (VAS) at 2 and 4 weeks but no significance at 12 weeks. For the CROM, I1>I2 significantly at 3 months ($p<0.001$).
Jull et al. (2013)	Australia	101	II	Parallel RCT with single blind	Multiprofess-ional intervention	Usual care	-	- Pain (VAS) - NDI - IES - PFActS-C - GHQ 28 - CROM - Craniocervical flexor test - Balance - Cervical proprioception - PPT - HPT - CPT - Sympathetic vasoconstrictor response - Types and dosage of medications	12 months	No significant difference between interventions in all outcome measures but the recovery of pain and disability between baseline, 6 and 12 months has significant differences in both interventions.

Table 2.2: Continued

Studies	Countries	N	WAD	Design	Intervention 1	Intervention 2	Intervention 3	Outcome Measures	Follow-up Period	Main Results
Ottosson et al. (2007)	Sweden	127	I-II	Parallel RCT with unblind	Educational programme + self-care (exercise for relaxation and postural control)	Standard Rx. (basic medications)	-	- Self-reported recovery - SF-36 - SMFA - Pain and mental distress (VAS) - Sick leave	12 months	I1>I2 significantly in terms of self-reported recovery ($p<0.03$) but no significant difference in other outcomes between interventions
Picelli et al. (2011)	Italy	18	I-II	Parallel RCT with single blind	Neck fascia manipulation	Neck mobilisation exercise + stretching	-	- CROM - Pain (VAS) - NDI - PPT	2 weeks	CROM: I1>I2 significantly ($p<0.01$) but other outcome measures, no significant differences between interventions.
Rosenfeld et al. (2003) [Rosenfeld et al. (2006) reporting same trial]	Sweden	102	0-II	Parallel RCT with single blind	Active mobilisation within 96 hours	Standard Rx. (rest, collar and gradual self-mobil) within 96 hrs	-	- Pain (VAS) - CROM - Sick leave	3 years	Pain and sick leave I1<I2 significantly ($p<0.05$) but no significance in CROM ($p=0.06–0.08$)
				Parallel RCT with single blind	Active mobilisation 14 days	Standard Rx. (rest, collar and gradual self-mobil) 14 days				
Schnabel et al. (2004)	Germany	200	I-II	Parallel RCT with un-blind	Mobilisation exercise	Collar therapy	-	- Pain (VAS) - Disability (VAS)	6 weeks	I1>I2 significantly in improving pain and disability ($p<0.05$)

Table 2.2: Continued

Studies	Countries	N	WAD	Design	Intervention 1	Intervention 2	Intervention 3	Outcome Measures	Follow-up Period	Main Results
Scholten-Peeters et al. (2006)	Netherlands	80	I–II	Parallel RCT with single blind	Education and exercise by PTs	Education by GPs	-	- Pain (VAS) - Functional recovery (VAS) - SF-36 - CROM - TSK - PCI - NDI - Disability in housekeeping and social activities (VAS)	13 months	At 12 weeks, I1>I2 significantly for CROM improvement but in long term I2>I1 significantly in terms of functional recovery, coping and physical functioning.
Verhagen et al. (2007)	Germany	200	I–II	Parallel RCT with unblind	PT + active exercise	Standard Rx (drugs + soft collar)	-	- Pain and disability (NRS) - Number of days with oral medication - The period of soft collar	6 months	I1>I2 significantly improved in terms of pain intensity and disability. Other outcomes had been reported but not compared using statistic procedure.

CPT: Cold Pain Threshold, CROM: Cervical Range of Motion, GHQ 28: General Health Questionnaire, HPLT: High-Power Laser Therapy, HPT: Hot Pain Threshold, I: Intervention, IES: Impact of Events Scale, NDI: Neck Disability Index, NRS: Numeric Rating Scale, PCI: Pain Coping Inventory, PFActS-C: Pictorial Fear of Activity Scale-Cervical, PPT: Pressure Pain Threshold, PT: Physiotherapy, RCT: Randomised Controlled Trial, Rx: Treatment, SMFA: Short Musculoskeletal Function Assessment, SF-36: Functional Health Status (Short Form 36), TSK: Tampa Scale for Kinesiophobia, VAS: Visual Analogue Scale

2.3.3 Risk of bias within and across trials

Agreement on RoB assessment between the two reviewers was very good (Kappa 0.87) (Peat, 2001). The RoB of individual trials is detailed in **Table 2.3**. All trials were assessed as high RoB for a range of reasons including: inadequate allocation concealment, selective outcome reporting, no intention to treat analysis, no specification of primary outcome, no specification of primary end point, no reporting of statistical analysis, no reporting of reasons for dropout, difference in loss to follow-up between groups, and no reporting of some outcome measures and/or information.

Table 2.3: Summary of risk of bias assessment from 15 included individual trials

Studies	Components of risk of bias							Summary of risk of bias	Overall RoB	Comments, high-risk components
	1	2	3	4	5a	5b	6			
Aigner et al. (2006)	U	U	U	L	H	H	H	High (3) Unclear (3) Low (1)	H	Three high components: 5a, 5b, 6 5a: No primary outcomes pre-specified 5b: No primary outcomes pre-specified 6: No primary end point specified No ITT reported
Bonk et al. (2000)	U	U	H	L	H	N/A	H	High (3) Unclear (2) Low (1) N/A (1)	H	Three high components: 3, 5a, 6 3: Unblind assessors 5a: No primary outcomes pre-specified 6: No primary end point specified No ITT reported
Borchgrevink et al. (1998)	U	U	L	H	U	N/A	H	High (2) Unclear (3) Low (1) N/A (1)	H	Two high components: 4, 6 4: Loss of follow-up >16 without stating from which group 6: No primary end point specified No ITT reported
Conforti and Fachinetti (2013)	U	U	L	L	H	N/A	H	High (2) Unclear (2) Low (2) N/A (1)	H	Two high components: 5a, 6 5a: No primary outcomes pre-specified 6: No primary end point specified No ITT reported No statistical analysis reported
Dehner et al. (2006)	L	L	U	L	H	N/A	H	High (2) Unclear (1) Low (3) N/A (1)	H	Two high components: 5a, 6 5a: No primary outcomes pre-specified 6: No primary end point specified No ITT reported

Table 2.3: Continued

Studies	Components of risk of bias							Summary of risk of bias	Overall RoB	Comments, high-risk components
	1	2	3	4	5a	5b	6			
Dehner et al. (2009)	L	L	U	U	H	N/A	H	High (2) Unclear (2) Low (2) N/A (1)	H	Two high components: 5a, 6 5a: No primary outcomes pre-specified 6: No primary end point specified No ITT reported
Foley-Nolan et al. (1992)	U	U	U	L	H	N/A	H	High (2) Unclear (3) Low (1) N/A (1)	H	Two high components: 5a, 6 5a: No primary outcomes pre-specified 6: No primary end point specified No ITT reported
Jull et al. (2013)	L	L	L	U	L	L	H	High (1) Unclear (1) Low (5)	H	One high component: 6 No ITT Pain (VAS) is reported with significant difference between groups at baseline
Ottosson et al. (2007)	L	L	H	L	N/A	L	H	High (2) Low (4) N/A (1)	H	Two high components: 3, 6 3: Unblind 6: No primary end point specified
Picelli et al. (2011)	L	U	L	L	H	N/A	H	High (2) Unclear (2) Low (3) N/A (1)	H	Two high components: 5a, 6 5a: P-value was not reported in NDI and PPT 6: No primary end point specified No ITT
Rosenfeld et al. (2003) [Rosenfeld et al. (2006) reporting same trial]	L	L	L	H	H	H	H	High (4) Low (3)	H	Four high components: 4, 5a, 5b, 6 4: Dropout difference between groups 5a: No primary outcomes pre-specified 5b: No primary outcomes pre-specified Reporting sick leave but have not stated it 6: No primary end point specified No ITT

Table 2.3: Continued

Studies	Components of risk of bias							Summary of risk of bias	Overall RoB	Comments, high-risk components
	1	2	3	4	5a	5b	6			
Schnabel et al. (2004)	U	U	U	H	H	N/A	H	High (3) Unclear (3) N/A (1)	H	Three high components: 4, 5a, 6 4: Loss of follow-up: A=36%, B=15% 5a: No primary outcomes pre-specified 6: No primary end point specified No ITT
Scholten-Peeters et al. (2006) [Scholten-Peeters et al. (2003) trial protocol]	L	L	L	L	L	L	H	High (1) Low (6)	H	One high component: 6 No primary end point specified
Vassiliou et al. (2006)	L	L	L	L	L	N/A	H	High (1) Low (4) N/A (5)	H	One high component: 6 6: No primary end point specified

1=Sequence generation, 2=Allocation concealment, 3=Blinding of participants, personnel and assessors, 4=Incomplete outcome data, 5a=Selecting outcome reporting (short term), 5b=Selecting outcome reporting (long term), 6=Other potential threats to validity, L=Low risk of bias, H=High risk of bias, U=Unclear risk of bias, N/A=Not applicable

2.3.4 Results of individual trials

The results of included trials demonstrated either significant or non-significant differences between intervention comparisons (**Table 2.2**). Five included trials reported no significant differences in all outcome measures between the intervention arms (Bonk et al., 2000, Ferrari et al., 2005, Aigner et al., 2006, Dehner et al., 2006, Jull et al., 2013). Another ten included trials reported significant differences between interventions in some outcome measures at some assessment points. Better improvements in pain and CROM in the experimental arm were illustrated by six (Foley-Nolan et al., 1992, Borchgrevink et al., 1998, Schnabel et al., 2004, Rosenfeld et al., 2006, Vassiliou et al., 2006, Conforti and Fachinetti, 2013) and three trials (Scholten-Peeters et al., 2006, Dehner et al., 2009, Picelli et al., 2011), respectively. Two trials found that the amount of sick leave in the experimental arm was lower than in the control arm (Rosenfeld et al., 2006, Conforti and Fachinetti, 2013). Finally, one trial indicated that the self-reported recovery scores in the experimental arm were better than in the control arm (Ottosson et al., 2007).

Based on an analysis of the comparability of interventions, outcome measures and assessment points across trials, meta-analyses were possible on four intervention comparisons, for three outcome measures (pain, CROM and sick leave). A summary of the meta-analyses is detailed in **Table 2.4**. Unfortunately, as the number of trials in each meta-analysis was less than 10, evaluation of publication bias using Funnel plots was not helpful.

Table 2.4: Summary of meta-analyses

Meta-analyses	Assessment points	Included trials	Sample size	I^2 (%)	Pooled estimate (95% Confidence Interval)	p-value
Conservative vs standard/control interventions		**9**	**1182**			
Pain intensity (VAS)		7	833			
	at ≤ 3 months	4	618	70.0	-5.35 (-12.90, 2.19)	0.164
	at 6 months	4	466	63.8	-11.76 (-20.14, -3.38)	0.005*
	at 1–3 years	3	215	0.0	-14.31 (-25.44, -3.19)	0.012*
CROM in sagittal plane		3	266			
	at 6 months	3	266	10.9	2.78 (-3.61, 9.17)	0.394
	at 3 years	2	88	60.5	9.95 (-7.78, 27.69)	0.271
CROM in coronal plane		5	413			
	at ≤ 3 months	2	147	64.2	0.35 (-5.78, 6.48)	0.911
	at 6 months	3	266	0.0	2.26 (-1.89, 6.42)	0.285
	at 3 years	2	88	64.1	5.58 (-5.83, 16.99)	0.338
CROM in horizontal plane		5	413			
	at ≤ 3 months	2	147	0.0	3.01 (0.43, 5.60)	0.022*
	at 6 months	3	266	55.1	-3.78 (-16.04, 8.48)	0.545
	at 3 years	2	88	19.0	4.85 (-6.80, 16.51)	0.415
Sick leave (days)		4	265	0.0	-17.59 (-39.02, 3.83)	0.107
Active vs passive interventions		**9**	**1145**			
Pain intensity (VAS)		8	943			
	at ≤ 3 months	5	728	76.3	-2.22 (-10.51, 6.07)	0.599
	at 6 months	5	546	56.9	-10.21 (-17.19, -3.23)	0.004*
	at 1–3 years	4	295	0.0	-18.24 (-26.39, -10.08)	< 0.001*
CROM in sagittal plane		5	364			
	at ≤ 3 months	2	98	80.6	-4.52 (-17.73, 8.69)	0.452
	at 6 months	4	346	0.0	3.37 (-1.69, 8.44)	0.192
	at 3 years	2	88	60.5	9.95 (-7.78, 27.69)	0.271
CROM in coronal plane		6	461			
	at ≤ 3 months	3	195	82.2	-0.40 (-6.94, 6.15)	0.905

Table 2.4: Continued

Meta-analyses	Assessment points	Included trials	Sample size	I^2 (%)	Pooled estimate (95% Confidence Interval)	p-value
	at 6 months	4	346	0.0	2.43 (-1.13, 5.99)	0.180
	at 3 years	2	88	64.1	5.58 (-5.83, 16.99)	0.338
CROM in horizontal plane		6	461			
	at ≤ 3 months	3	195	85.2	1.70 (-8.96, 12.35)	0.755
	at 6 months	4	346	69.4	0.76 (-11.28, 12.81)	0.892
	at 3 years	2	88	19.0	4.85 (-6.80, 16.51)	0.415
Sick leave (days)		3	215	0.0	-17.59 (-39.02, 3.83)	0.107
Behavioural vs standard/control interventions		**6**	**987**			
Pain intensity (VAS)		4	705			
	at 6 weeks	3	578	70.0	-5.35 (-12.90, 2.19)	0.164
	at 6 months	3	505	44.2	-8.46 (-15.37, -1.55)	0.016*
CROM in coronal plane	at 3–6 months	2	275	0.0	2.65 (0.93, 4.38)	0.003*
CROM in horizontal plane	at 3–6 months	2	275	0.0	2.94 (0.43, 5.46)	0.027*
Early vs late interventions		**2**	**172**			
Pain intensity (VAS)		2	172			
	at 6 months	2	172	79.2	-3.77 (-25.74, 18.21)	0.737
	at 3 years			0.0	-1.33 (-12.51, 9.85)	0.816
CROM in sagittal plane						
	at 6 months			51.3	1.93 (-13.16, 17.02)	0.802
	at 3 years	1 (2 sub-studies)	88	60.5	6.34 (-11.35, 24.04)	0.482
CROM in coronal plane						
	at 6 months			27.0	-1.01 (-8.93, 6.92)	0.803
	at 3 years			64.0	-1.49 (-12.95, 9.96)	0.799
CROM in horizontal plane						
	at 6 months			75.9	3.32 (-20.66, 27.31)	0.786
	at 3 years			19.1	7.69 (-4.86, 20.25)	0.230
Sick leave (days)				0.0	7.51 (-13.37, 28.40)	0.481

***** *Statistical significance ($p < 0.05$)*

2.3.5 Synthesis of results

Conservative intervention was more significantly effective for pain reduction than standard/control intervention at six months (-11.76, 95% CI: -20.14 to -3.38, p = 0.005, I^2 = 63.8%) and one to three years (-14.31, -25.44 to -3.19, p = 0.012, I^2 = 0.0%) (**Figure 2.2**). Moreover, conservative intervention was superior to the standard/control intervention for improvement of cervical mobility in the horizontal plane at ≤ three months significantly (3.01, 0.43 to 5.60, p = 0.022, I^2 = 0.0%) (**Figure 2.3**). However, there were no significant differences between interventions for pain reduction at ≤ three months, other follow-up periods in the horizontal plane of CROM, or any follow-up periods in terms of other planes of CROM, including the number of days of sick leave.

An example of detailed interpretation of the meta-analyses of the conservative intervention is that the conservative intervention was significantly more effective than the standard/control intervention for pain reduction (VAS) by 11.76 (-20.14 to -3.38, p = 0.005) at six months and 14.31 (-25.44 to -3.19, p = 0.012) at one to three years. Furthermore, it was significantly more effective in increasing the CROM by 3.01° (0.43 to 5.60, p = 0.022) than the standard/control intervention at ≤ three months.

Active intervention was more significantly effective than passive intervention for pain reduction at six months (-10.21, -17.19 to -3.23, p = 0.004, I^2 = 56.9%) and one to three years (-18.24, -26.39 to -10.08, p < 0.001, I^2 = 0.0%) (**Figure 2.4**). However, there was no significant difference in pain reduction at ≤ three months. Also, improvement of cervical mobility and days of sick leave were not significantly different between interventions.

Behavioural intervention was more significantly effective for pain reduction at six months (-8.46, -15.37 to -1.55, p = 0.016, I^2 = 44.2%) (**Figure 2.5**) and improvement

of cervical mobility in the coronal (2.65, 0.93 to 4.38, p = 0.003, I^2 = 0.0%) and horizontal planes (2.94, 0.43 to 5.46, p = 0.027, I^2 = 0.0%) at three to six months than the standard/control intervention (**Figure 2.6**). However, there was no significant difference between interventions for pain reduction at six weeks.

There were no significant differences between early and late interventions for pain reduction, CROM and days of sick leave in any follow-up period (**Table 2.4**).

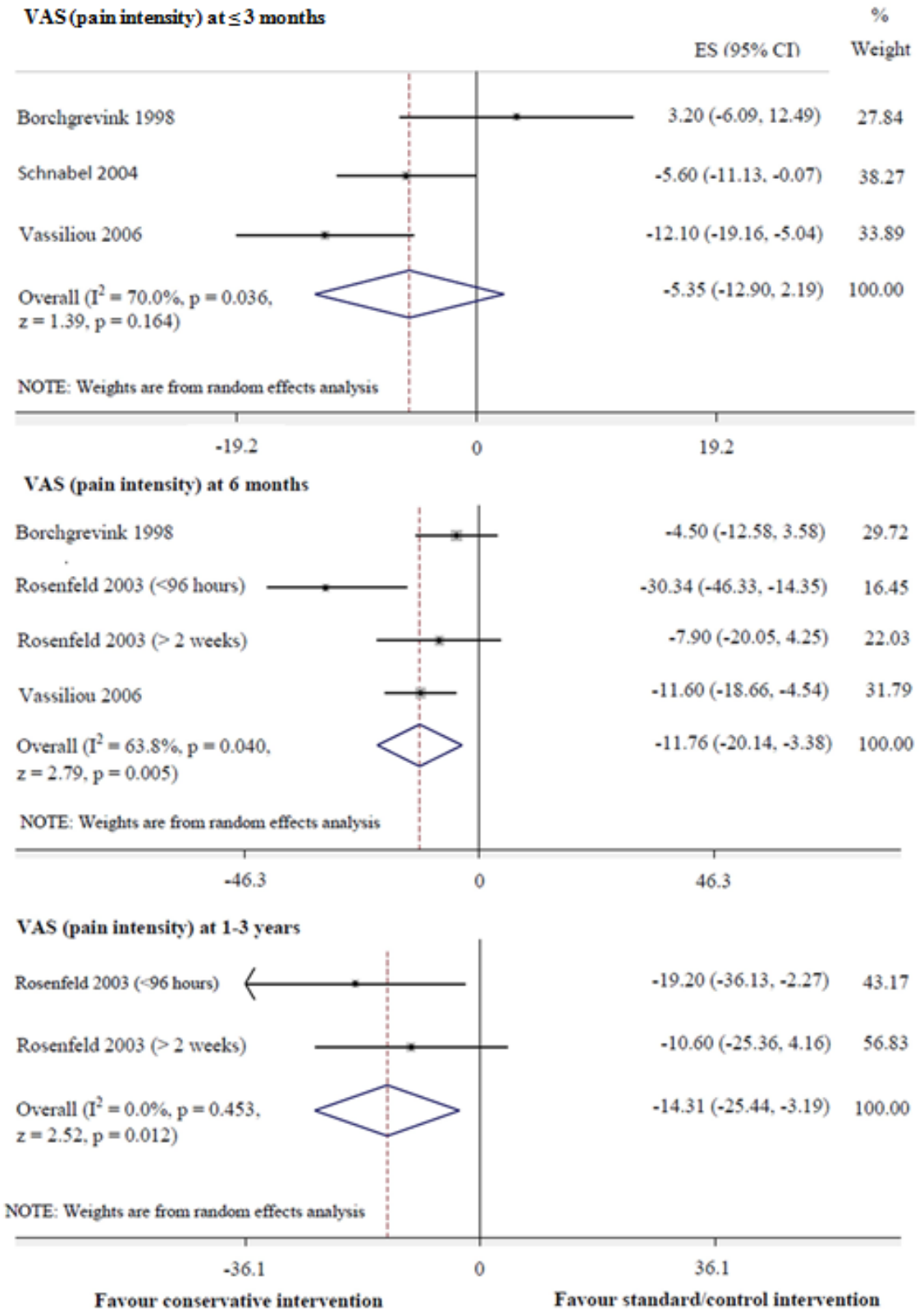

Figure 2.2: Conservative versus standard/control interventions for VAS (pain intensity).

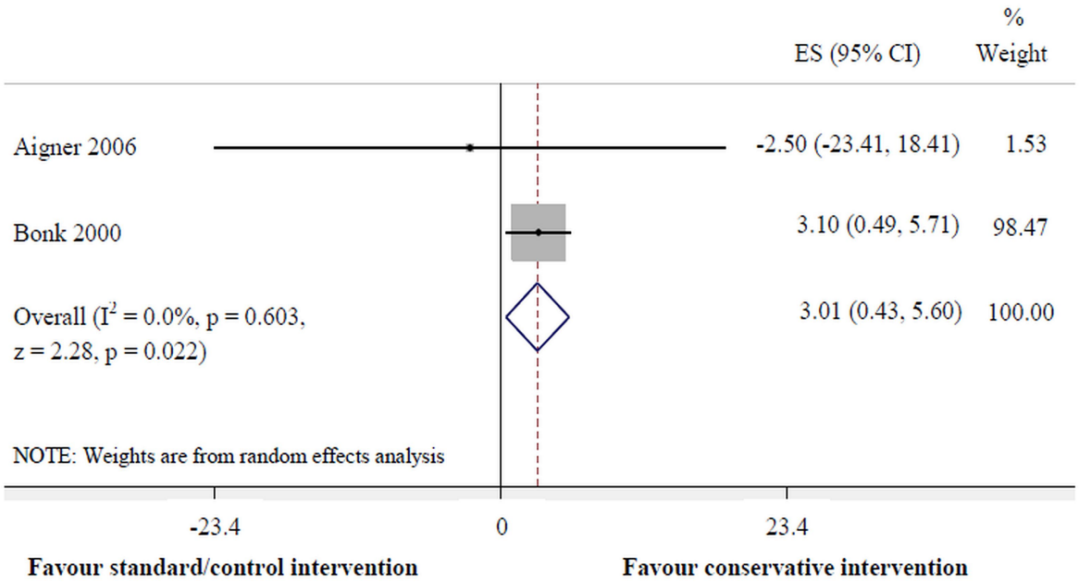

Figure 2.3: Conservative versus standard/control intervention for cervical horizontal movement at ≤ three months.

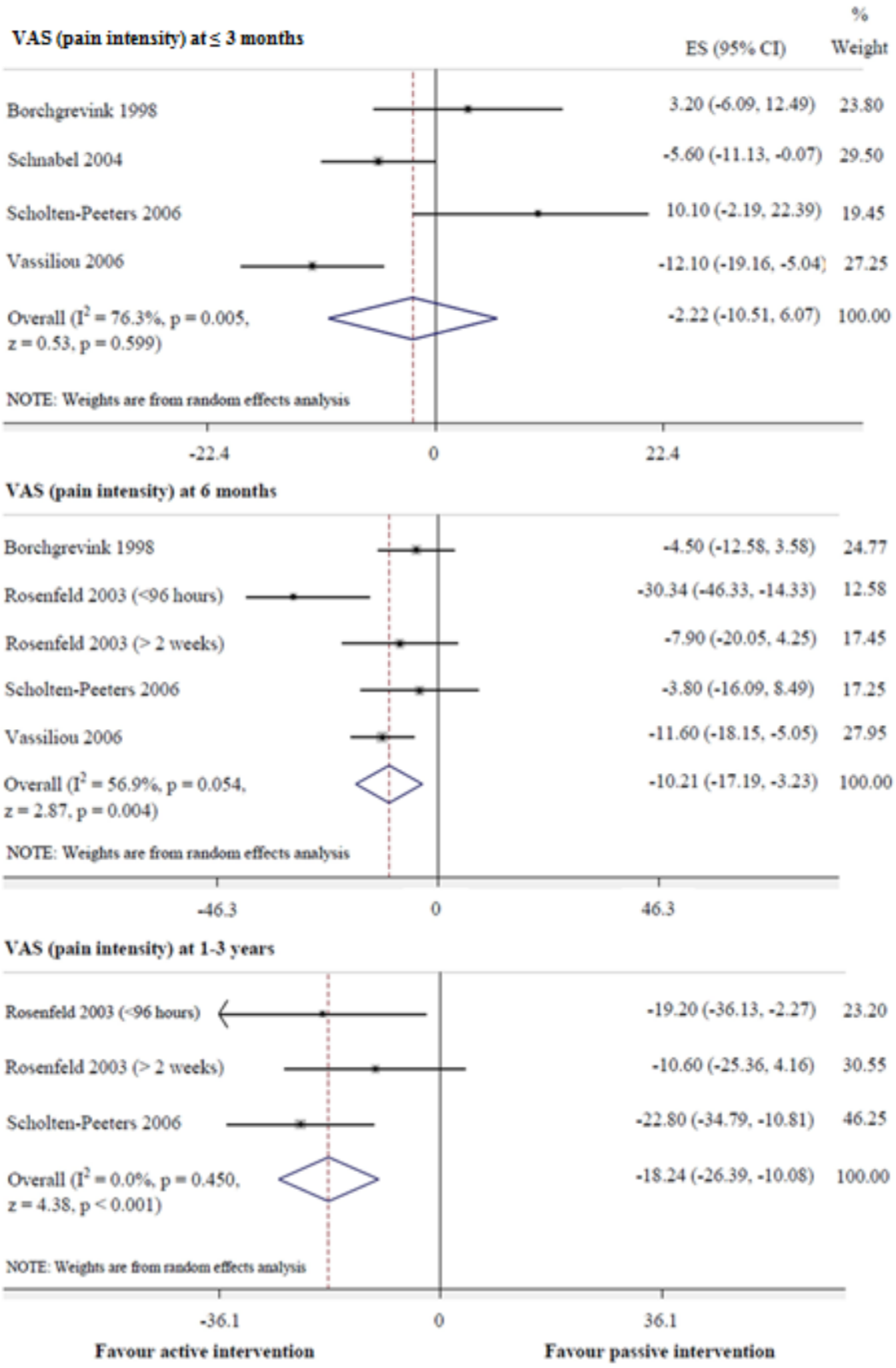

Figure 2.4: Active versus passive interventions for VAS (pain intensity).

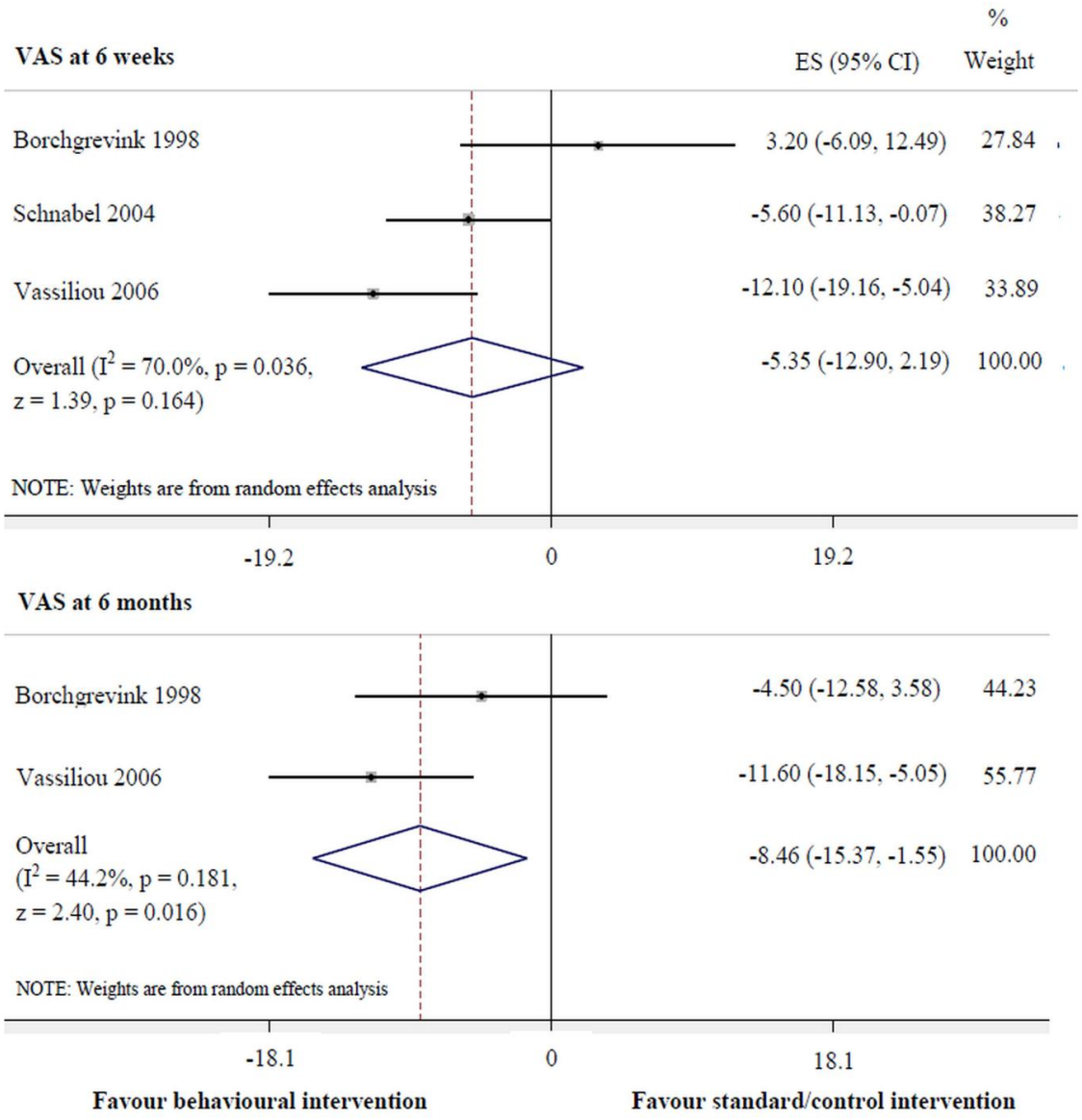

Figure 2.5: Behavioural versus standard/control interventions for VAS (pain intensity).

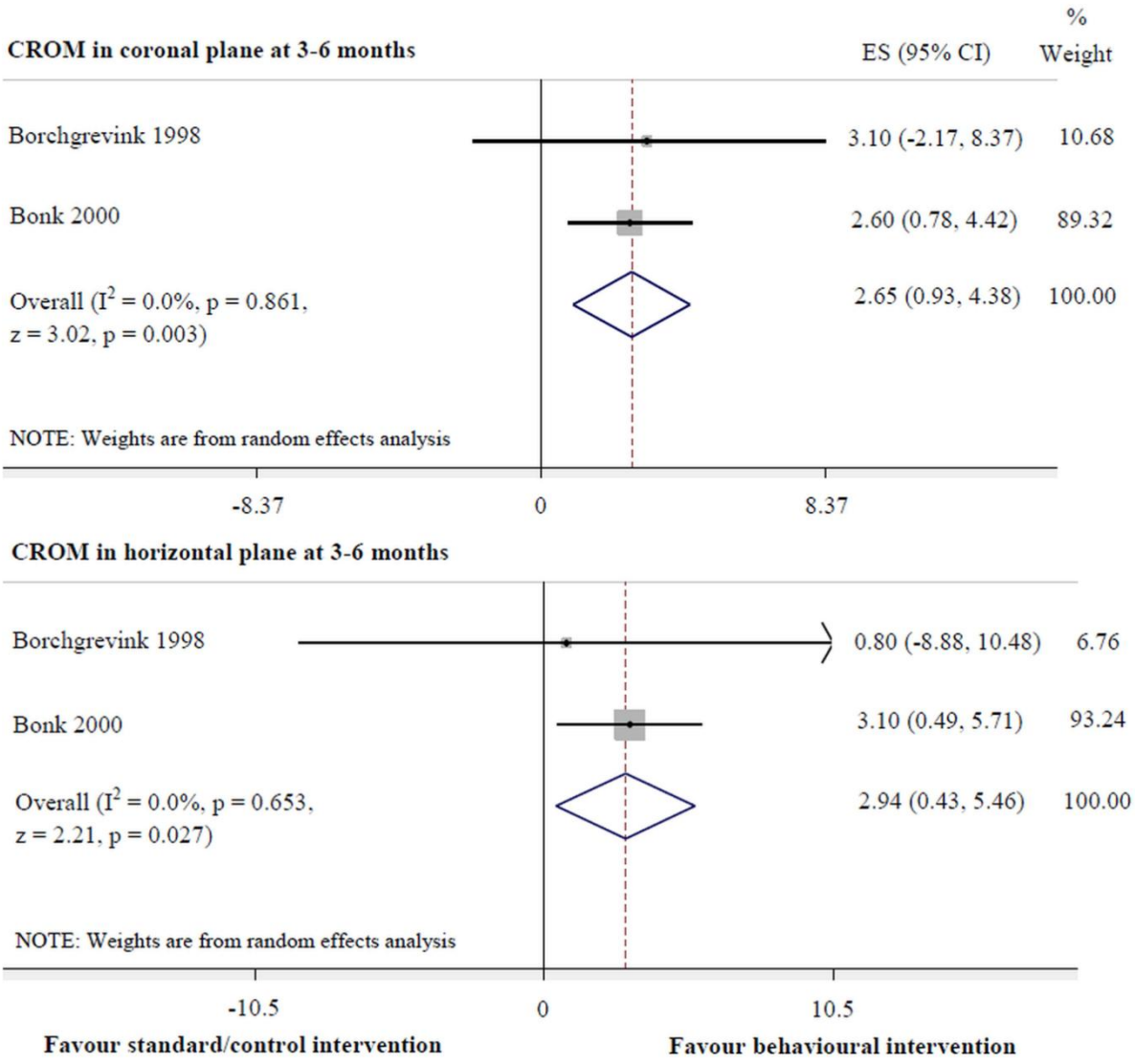

Figure 2.6: Behavioural versus standard/control interventions for cervical movement.

2.4 Discussion

2.4.1 Summary of evidence

Fifteen RCTs with high RoB were included. Some trials (Foley-Nolan et al., 1992, Borchgrevink et al., 1998, Bonk et al., 2000) may have a high risk of bias owing to poor reporting as they were published prior to the CONSORT reporting guidelines (Begg et al., 1996, Moher et al., 2001). Although trial reporting in terms of primary outcome, sample size calculation, random sequence generation and allocation

concealment significantly improved between 2000 and 2006 (Hopewell et al., 2010), the quality of reporting blinding, and descriptions of approach, exclusion, treatment and missing data, are still frequently inadequate (Glasziou et al., 2008, Abraha and Montedori, 2010, Hopewell et al., 2010), contributing in 2010 to the revised CONSORT statement (Moher et al., 2010, Schulz et al., 2010). In this systematic review, only three trials were published after 2010 (Picelli et al., 2011, Conforti and Fachinetti, 2013, Jull et al., 2013). Due to the high RoB across all trials, confidence in findings is reduced.

The meta-analyses findings are more powerful and reliable than those stemming from individual trials because of minimised biases from the individual trials by an increase generalisability (Walker et al., 2008). The results of the meta-analyses were influenced by individual trials demonstrating conflicting conclusions. For example (**Figure 2.2**), the meta-analysis demonstrated that conservative intervention was more effective than standard/control intervention for long-term pain reduction, despite some trials reporting negative findings (Rosenfeld et al., 2003, Ottosson et al., 2007). Another example is that some individual trials (Schnabel et al., 2004, Vassiliou et al., 2006, Dehner et al., 2009) found the active intervention was more effective for pain alleviation than the passive intervention in the short-term, whereas there was no effect demonstrated in the meta-analysis (**Figure 2.4**).

The level of heterogeneity was evaluated to determine the credibility of the evidence (Deeks et al., 2011). For example, in the meta-analyses demonstrating an effect for pain reduction at six months, the heterogeneity ranged from moderate (I^2 = 44.2%, behavioural intervention) to substantial (I^2 = 63.8%, conservative intervention; I^2 = 56.9%, active intervention). Thus, the credibility of the conservative, active and behavioural interventions for pain reduction at six months was acceptable compared

with standard/control, passive and standard/control interventions, respectively. However, the other significant differences between interventions using meta-analysis (conservative > standard/control for pain reduction at one to three years and CROM improvement in the horizontal plane at ≤ three months, active > passive for pain reduction at one to three years, and behavioural > standard/control for CROM improvement in coronal and horizontal planes at three to six months) did not have any heterogeneity ($I^2 = 0$) (**Table 2.4**).

Although this systematic review identified some interventions demonstrating an effect, the size of the effect was not clinically significant in all situations. The minimal clinically important differences (MCID) in patients with neck pain for the improvement of pain intensity (VAS) and CROM are at least 20 millimetres (Oostendorp et al., 2013) and 10˚ (de Koning et al., 2008), respectively.

The findings of this systematic review revealed that conservative intervention (non-invasive treatment inclusive of both physical and psychological components such as active mobilisation exercise, manual techniques, physical agents, multimodal therapy, behavioural approaches and education, except for drug therapy) may be a useful intervention for acute WADII management in terms of pain reduction in the medium (95% CI: -20.14 to -3.38, p = 0.005, $I^2 = 63.8\%$) to long term (95%CI: -25.44 to -3.19, p = 0.012, $I^2 = 0.0\%$), and improvement of cervical mobility in the horizontal plane in the short term (95%CI: 0.43 to 5.60, p = 0.022, $I^2 = 0.0\%$) compared with standard/control intervention.

Interestingly, the findings of this systematic review also suggested that two potential useful interventions for acute WADII management were worthy of further consideration. Firstly, active intervention (involving range of movement, mobilising

exercises, and strengthening of the neck and scapular muscles) was shown to be a useful intervention for pain reduction in the medium (95%CI: -17.19 to -3.23, p = 0.004) to long term (95%CI: -26.39 to -10.08, p = <0.001). Secondly, behavioural intervention (e.g. act as usual, education and self-care including regular exercise) may be effective for pain reduction in the medium term (95%CI: -15.37 to -1.55, p = 0.016) and improvement in cervical mobility in the coronal (95%CI: 0.93 to 4.38, p = 0.003) and horizontal planes (95%CI: 0.43 to 5.46, p = 0.027) in the short to medium term. The combination of the two interventions into an Active Behavioural Physiotherapy Intervention (ABPI) may potentially be an effective strategy for managing acute WADII.

Although clinical WAD guidelines (Moore et al., 2005, TRACsa, 2008, Jagnoor et al., 2014) have recommended both active (e.g. active exercises or staying active) and passive (e.g. manual therapy, electrotherapy and thermotherapy) interventions, the strong recommendations of these guidelines (active exercises, staying active and education) are along the same lines as the findings of this review (e.g. active and behavioural interventions). Furthermore, active intervention was supported by the systematic review of Rushton et al. (2011). However, there were many limitations (e.g. quality of evidence) to the current evidence and limited success of WAD management is still reported (Aigner et al., 2006, Dehner et al., 2006, Scholten-Peeters et al., 2006, Vassiliou et al., 2006, Ottosson et al., 2007, Dehner et al., 2009, Conforti and Fachinetti, 2013, Jull et al., 2013, Lamb et al., 2013, Michaleff et al., 2014), leading to the position of being unable to conclude what intervention is the best for acute WADII management. The, to date, inadequate consideration of a behavioural approach to interventions may have contributed to inadequate success of acute WADII management.

Therefore, an effective intervention for the management of WADII, particularly in the acute stage, is still required to prevent the development of chronicity.

2.4.2 Strengths

This review's strengths are its design and specific focus on acute WADII using a predefined protocol and attention to potential sources of bias such as: a minimisation of errors from searching, using two independent reviewers, decreased publication bias through searching both published and unpublished trials, assessment of RoB using two independent reviewers, and data extraction using two reviewers.

2.4.3 Limitations

This study's limitations include the small number of trials identified and their high RoB. Furthermore, effectiveness in terms of the outcome of NDI, which is a key outcome measure in whiplash patients (Miettinen et al., 2004, Merrick and Stalnacke, 2010, Walton et al., 2013) with high validity and reliability (MacDermid et al., 2009), could not be evaluated in a meta-analysis due to an insufficient number of trials utilising this measure. This is despite the NDI being recommended as an outcome measure for monitoring whiplash patients (Walton et al., 2013).

Furthermore, this systematic review did not include only WADII trials but WAD 0-II or I-II trials were also included to ensure that all trials recruiting a WADII population were reflected in the analyses. Only four trials focused solely on patients with WADII (Aigner et al., 2006, Dehner et al., 2006, Dehner et al., 2009, Jull et al., 2013). The inclusion of other trails which related to WADII can increase the statistical

power or generalisability in conducting a meta-analysis. However, the credibility in the specification of WADII was reduced.

According to GRADE (Guyatt et al., 2008), the evidence included in this review is low/very low (low in conservative and active interventions, very low in behavioural intervention) due to the limitations of this systematic review (e.g. high risk of bias in all included trials, low number of included trials in each meta-analysis, inability to evaluate publication bias in all meta-analyses, low heterogeneity in some meta-analyses, no archiving of MCID in all meta-analyses, and inability to synthesise findings for an important outcome measure (NDI). Consequently, an adequately powered, low risk of bias and well-reported trial to evaluate the effectiveness of acute WADII management is warranted to enable confidence in evidence for clinical practitioners, health policymakers and researchers.

2.5 Conclusions

This rigorous systematic review found that conservative management may be useful for acute WADII management for pain reduction and improvement in cervical movement. The findings of meta-analyses indicated that conservative and active interventions may be useful for pain reduction in acute WADII management in the medium to long term compared with the standard/control and passive intervention, respectively. Additionally, an improvement in cervical movement in the horizontal plane in the short term could be promoted by the employment of a conservative intervention. The employment of a behavioural intervention (e.g. act as usual, education and self-care including regular exercise) may be an effective treatment in reducing pain and improving cervical mobility in patients with acute WADII in the short to medium term compared with the

standard/control intervention. Finally, there was no significant difference between early (< one week) and late (> two weeks) interventions. Although the strong recommendation of useful interventions from clinical WAD guidelines and the findings in this review support each other with regard to WAD management, the limitations of this review have reduced confidence in the findings. Additionally, the limited success of WAD management is still reported. Therefore, an effective intervention for WAD management, especially in the acute stage, is still required to prevent the development of chronicity. The combination of an active physiotherapy and behavioural intervention herein termed 'Active Behavioural Physiotherapy Intervention (ABPI)' may be a useful strategy for managing patients with acute WADII.

Chapter summary

This chapter summarises the systematic review and meta-analysis of RCTs and evaluates the current conservative management of acute WADII. A key finding is that the combination of active and behavioural components into an ABPI may be a potential effective intervention for the management of acute WADII. Development of an ABPI was therefore planned using a robust methodology addressing the limitations identified in this systematic review. The development of the ABPI is detailed in the next chapter. This systematic review was published in PLoS ONE in 2015 (Wiangkham et al., 2015b) and orally presented at the World Confederation for Physical Therapy (WCPT) Congress 2015 in Singapore (Wiangkham et al., 2015a).

CHAPTER 3

Development of an Active Behavioural Physiotherapy Intervention (ABPI) for Acute WADII Management: A modified Delphi study

Abstract

This chapter provides a range of underlying principles and treatment components of an ABPI for managing patients with acute WADII. A modified Delphi study was conducted to use expert opinion to achieve consensus of the principles/components of the ABPI. International researchers and UK clinical whiplash experts participated in a three-round online survey using a combination of fixed-choice and open questions to increase the reliability and validity of the study. Experts suggested and agreed the underlying principles (e.g. returning to normal function as soon as possible, pain management, encouragement of self-management, and reducing fear avoidance and anxiety) and treatment components of the ABPI from both physical (e.g. postural control, exercises for stability and mobility) and psychological (e.g. education, advice to act as usual, reassurance, cognitive behavioural therapy and self-management) perspectives for the management of acute WADII. This study was published in BMJ Open 2016.

3.1 Background

Findings from the current systematic review and meta-analysis of RCTs (**Chapter 2**) evaluating the conservative management of acute WADII (Wiangkham et al., 2015b) demonstrated that active physiotherapy (activities suggested by a health professional to improve symptoms or reduce suffering from illness) was more effective

for pain reduction than passive intervention (any intervention that uses other people, equipment or other things to reduce symptoms or illness) at six months (95%CI: -17.19 to -3.23, $p = 0.004$) and one to three years (-26.39 to -10.08, $p < 0.001$). Furthermore, behavioural intervention (strategies to promote useful behaviour to improve symptoms and reduce illness) was more effective for pain reduction at six months (-15.37 to -1.55, $p = 0.016$) and improvement in cervical movement in the frontal (0.93 to 4.38, $p = 0.003$) and transverse planes (0.43 to 5.46, $p = 0.027$) at three to six months than standard/control intervention. The combination of active physiotherapy and a behavioural intervention in an ABPI, may therefore be an optimised and effective intervention for managing acute WADII and preventing chronicity (Wiangkham et al., 2015b). Unfortunately, the existing evidence was inadequate for enabling description and delivery of an ABPI as no previous research has considered a combined intervention in the management of acute WADII patients (four trials in our systematic review evaluated a behavioural but not combined intervention). The ABPI was therefore developed using a rigorous expert consensus method (namely, a modified Delphi study).

3.2 Methodology

3.2.1 Objective

To develop an Active Behavioural Physiotherapy Intervention (ABPI) for managing acute whiplash-associated disorder (WAD) II.

3.2.2 Design

The Delphi method is a standard, common and simple method of developing interventions in health care (Murphy et al., 1998). It has been defined as a "method for the systematic collection and aggregation of informed judgement from a group of

experts on specific questions or issues", p.131 (Reid, 1993). It is a low-cost, flexible and simple procedure aimed at gaining information independently and privately from a large number of people (Murphy et al., 1998). There are several further advantages to the Delphi method, such as anonymity, no socio-psychological pressure on the panellists and a higher response rate (von der Gracht, 2012). Although the nominal group technique can stimulate the interactions between panellists to develop an intervention, conducting the technique is difficult owing to the necessity of a meeting date, incurring high costs and potentially a low response rate. This would have been particularly difficult as the perspective of international researchers was very appropriate to this study. Another disadvantage of the technique is that a panellist with a high position can influence other panellists. Thus, the development of the ABPI for acute WADII management was conducted by a modified Delphi method.

In order to create an intervention for acute WADII management using the existing evidence to construct proposed underlying principles and treatment components and then develop the principles/components, a modified Delphi study was therefore performed according to a pre-specified protocol. Existing evidence and the views of research and clinical whiplash experts were considered with a view to defining and providing the underlying principles and the treatment components of an ABPI intervention for the management of patients with acute WADII.

It was anticipated that this study would consist of three rounds (Rushton and Moore, 2010, Rankin et al., 2012, Rushton et al., 2014b). LimeSurvey was used to collect data for the convenience of both researchers and participants. A five-point Likert scale evaluated the level of agreement throughout. Any underlying principles and

treatment components that did not achieve the consensus criteria were removed. The process of intervention development is summarised in **Figure 3.1**.

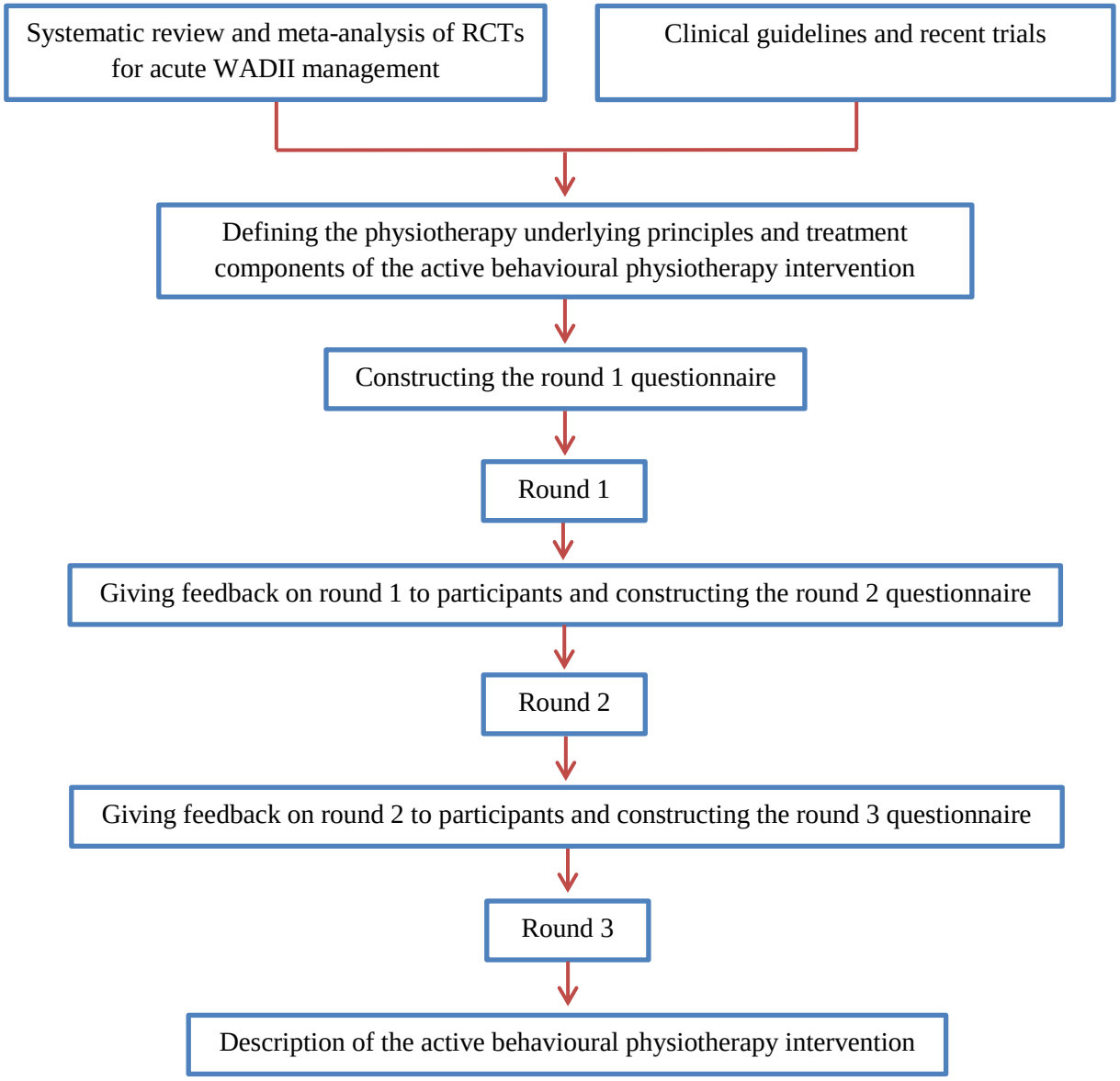

Figure 3.1: Diagram of the method of intervention development.

3.2.3 Purposive sample

In order to secure a diverse group of whiplash experts (i.e. those working in this area from a research, private physiotherapy or postgraduate clinical (predominantly UK National Health Service (NHS)) perspective, 97 (n = 40, 13 and 44, respectively) potential participants were targeted for recruitment from three groups:

1. International research whiplash experts who had published at least two articles in a peer-reviewed journal regarding WAD within the last 10 years.

2. UK private physiotherapists from the West Midlands region in the UK, who had experience in treating WAD for at least two years. In the UK context, insurance companies frequently refer WADII patients to private physiotherapy clinics. Therefore, it was important to include physiotherapists working in the private sector.

3. Postgraduate musculoskeletal physiotherapy students studying at the University of Birmingham in the UK, who had experience in treating WAD for at least two years. Additionally, they must have completed the cervical management component of their programme. Most of the recruited students worked for the NHS.

All groups of participants can be considered as experts informing the management of WAD based on their different experiences. The eligible experts were invited to participate via e-mail, which included a participant information sheet (**Appendix 7**) and consent form (**Appendix 8**). They were requested to sign and send back the consent form via post or scanned e-mail, depending on their preference, within four weeks. It was intended to recruit ten participants in each group to enable equal representation of the three groups and a feasible number of participants. Previous work has suggested that approximately 30 participants are appropriate in a Delphi study to enable consensus (Dionne et al., 2008, Fisher et al., 2010, Schutt et al., 2010).

3.2.4 Active Behavioural Physiotherapy Intervention (ABPI)

3.2.4.1 Underlying principles of the ABPI

The potential underlying principles of the ABPI were derived from the systematic review, clinical guidelines and recent trials. They included returning to normal function as soon as possible, returning to normal movement as soon as possible, pain management, reducing post-traumatic stress, reducing fear avoidance and anxiety, increasing confidence in exercises of the neck and shoulders, preventing future recurrent symptoms, encouraging self-management, returning to work and social activities as soon as possible, returning to pre-injury quality of life and facilitating personal motivation for adopting a healthy lifestyle.

3.2.4.2 Treatment components of the ABPI

The potential treatment components of the ABPI were derived from the systematic review, clinical guidelines and examination of recent trials. Components were then grouped according to their focus/emphasis:

Behavioural components

The proposed behavioural components of the ABPI consisted of cognitive behavioural therapy, whiplash education, act-as-usual advice, reassurance, postural control and education, introduction of relaxation techniques and promotion of self-management.

Physiotherapy components

The proposed physiotherapy components of the ABPI comprised active mobilisation exercises, stabilisation exercises including deep neck flexor muscles, mobilisation with movement techniques (Mulligan), stretching exercises, mobility exercises, progressive exercises for strengthening, postural stabilisation, sensorimotor

exercises (kinaesthetic sense, balance and eye movement) and breathing exercises. Passive interventions such as manual therapy and physical agents (e.g. electrotherapy and thermotherapy) were also included in this component. A passive intervention may be employed for pain relief and improvement of cervical mobility based on a physiotherapist's clinical reasoning.

Other treatments

The proposed 'other treatment component' comprised multimodal therapy and physical activity.

3.2.5 The modified Delphi method

After receiving responses from people who signed and returned the consent form, an e-mail was sent to the participants containing a link to the e-mail hosted on LimeSurvey. All of the participants' background information, including age, gender, country of origin, country of current habitation/work, highest qualification, current occupation, professional background and working period in WAD, was collected. Participants were invited to provide their level of agreement for each principle and component. Additionally, an open question was provided in each section in order to explore any principles/components that may have been overlooked. Any additional underlying principles and treatment components that were suggested by at least one participant were added into the underlying principles and the treatment components of the ABPI in order to evaluate participants' agreement with the suggestion in the next round. Furthermore, an open question was provided in the last section of the questionnaire to invite any further general comments or suggestions from the participants. In each round,

a reminder was sent to participants in the second and fourth week after the LimeSurvey link was sent.

Round 1

The purposes of round 1 were as follows:

1. To evaluate the level of agreement of the participants with the underlying principles identified from guidelines and recent trials.
2. To explore whether any underlying principles of the ABPI for acute WADII management were missing.
3. To evaluate the level of agreement of the participants with the proposed behavioural and physiotherapy components of the ABPI.
4. To explore whether any behavioural or physiotherapy components of the ABPI were missing.

Feedback on round 1 was provided to the participants in the form of summary tables (**Table 3.1**: participants' backgrounds, **Table 3.2**: underlying principles and **Table 3.3**: treatment components).

Round 2

The purposes of round 2 were as follows:

1. To evaluate the level of agreement of the participants with the underlying principles identified from round 1 data analysis of the ABPI.
2. To explore whether any underlying principles of the ABPI for acute WADII management were still missing.

3. To evaluate the level of agreement of the participants with the proposed behavioural and physiotherapy components identified from round 1 data analysis of the ABPI.
4. To explore whether any important components of the ABPI were still missing.

Feedback on round 2 was provided to the participants in the form of summary tables (**Table 3.2**: underlying principles and **Table 3.3**: treatment components).

Round 3

The purposes of round 3 were as follows:

1. To evaluate the level of agreement of the participants with the underlying principles identified from round 2 data analysis of the ABPI.
2. To rank the importance of the underlying principles identified from round 2 data analysis of the ABPI.
3. To evaluate the level of agreement of the participants with the proposed behavioural and physiotherapy components identified from round 2 data analysis of the ABPI.
4. To evaluate the feasibility of the underlying principles and the proposed components identified from round 2 data analysis of the ABPI being delivered in clinical practice.

Feedback on round 3 was not provided to the participants. The objective of this round was to make further clarifications of the underlying principles and components of the ABPI (Hsu and Sandford, 2007). Furthermore, the participants were asked to rank the underlying principles and suggest how to deliver the components of the ABPI in practice as a multicomponent intervention.

3.2.6 Data management

Individual feedback was anonymised to maintain participants' privacy. The personal information of participants was kept safely from any third party. All data were securely stored on a password-protected computer during the study. Only members of the research team could access the information. After completing the study, all data will be kept securely for ten years at the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, UK, before being securely destroyed.

3.2.7 Data analysis

The five-point Likert scale (higher values mean higher importance) is an ordinal scale (Allen and Seaman, 2007, Norman, 2010). Descriptive statistics, including median, interquartile range (IQR), quartile and percentage of agreement, were used to assess consensus in each round. Consensus was defined as follows and was progressed in each round to ensure strong resulting consensus in the final round.

Round 1: *criteria of consensus*

- Median ≥ 3
- Third quartile (Q3) ≥ 4
- Percentage of agreement $\geq 50\%$

Round 2: *criteria of consensus*

- Median ≥ 3.5
- Third quartile (Q3) ≥ 4
- IQR ≤ 2
- Percentage of agreement $\geq 60\%$ (Brown et al., 2005, Rushton et al., 2014b)

Round 3: *criteria of consensus*

- Median ≥ 4 (Rushton et al., 2014b)
- IQR ≤ 1 (Rayens and Hahn, 2000)
- Percentage of agreement ≥ 70% (Brown et al., 2005, Rushton et al., 2014b)

All quantitative data were analysed using IBM SPSS version 22. Qualitative data were extracted both deductively (to identify themes) and inductively (to identify additional themes) (Ayala and Elder, 2011, Bos et al., 2013). The importance of the underlying principles was ranked using scoring procedures.

Ethical approval

Ethical approval was granted by the University of Birmingham's Ethical Committee ***(ERN_ 14-1339)*** (**Appendix 3**).

3.3 Results

3.3.1 Participants

Thirty-six invited potential participants (11 researchers, 13 UK private physiotherapists and 12 UK postgraduate musculoskeletal physiotherapy students) signed and returned the consent form (participation rate = 37%). For round 1, 32 participants across eight countries (Australia, Finland, Greece, India, the Netherlands, Norway, Sweden and the UK) returned the questionnaire (16 males/16 females, response rate = 89%, mean age ± SD = 36.03 ± 13.22 years). There were no missing data in round 1. The details of participants' backgrounds are presented in **Table 3.1**. The qualifications and occupations of the participants were diverse. All but one participant had a background

in physiotherapy. Most participants had experience of treating whiplash patients at least two years.

Table 3.1: Participants' backgrounds

Characteristics	Participants (no)	Percentage of participants (%)
Highest qualification		
• Doctor of Philosophy	10	31.25
• Master degree	4	12.50
• Bachelor degree	18	56.25
Current occupation		
• Professor	3	9.38
• Associated professor	2	6.25
• Senior lecturer	1	3.13
• Assistant professor	0	0
• Lecturer	2	6.25
• Researcher in university	2	6.25
• Clinical practitioner in hospital	1	3.13
• Clinical practitioner in private sector	10	31.25
• Postgraduate musculoskeletal physiotherapy student	11	34.38
Professional background		
• Physiotherapy	31	96.88
• Other: sociology and insurance medicine	1	3.13
Whiplash experience (years)		
• < 2	6	18.75
• 2–5	11	34.38
• 6–10	5	15.63
• 11–15	3	9.38
• 16–20	3	9.38
• > 20	4	12.50

3.3.2 Underlying principles of the ABPI

The results of rounds 1, 2 and 3 for underlying principles are summarised in **Table 3.2**.

- In round 1, all underlying principles of the ABPI reached the consensus criteria. Furthermore, 'identify and manage sleep deprivations' was a new principle suggested.
- In round 2, there were 28 participants (78% of the original respondents) with no missing data. All underlying principles in this round achieved the consensus criteria with no additional suggestions.
- In round 3, there were 27 participants (75% of the original respondents) with no missing data. The agreement and the rank of the importance of the underlying principles are presented in **Table 3.2**. 'Prevent future recurrent symptoms' and 'identify and manage sleep deprivations' did not meet the consensus criteria with respect to the IQR. However, these underlying principles were included in the ABPI because their median and percentage of agreement were high.

Table 3.2: Results of rounds 1, 2 and 3 for underlying principles of the ABPI

5 = very important, 4 = important, 3 = no opinion, 2 = not important, 1 = not at all important

Underlying principles	Round 1			Round 2			Round 3			
	Median	**IQR (Q1, Q3)**	**% (no) of agreement**	**Median**	**IQR (Q1, Q3)**	**% (no) of agreement**	**Median**	**IQR (Q1, Q3)**	**% (no) of agreement**	**Rank**
Return to normal function as soon as possible	5	0.75 (4.25, 5.00)	100.00	5	0.00 (5.00, 5.00)	100.00	5	0 (5, 5)	100.00	1
Return to normal movement as soon as possible	5	1.00 (4.00, 5.00)	96.88	5	1.00 (4.00, 5.00)	100.00	5	1 (4, 5)	100.00	5
Pain management	5	1.00 (4.00, 5.00)	96.88	5	1.00 (4.00, 5.00)	96.43	5	1 (4, 5)	92.59	2
Reduce post-traumatic stress	4	1.00 (4.00, 5.00)	81.25	4	1.00 (4.00, 5.00)	85.71	4	1 (4, 5)	77.78	8
Reduce fear avoidance and anxiety	5	1.00 (4.00, 5.00)	93.75	5	1.00 (4.00, 5.00)	96.43	5	1 (4, 5)	96.30	4
Increase confidence in exercises of the neck and shoulders	5	1.00 (4.00, 5.00)	93.75	5	1.00 (4.00, 5.00)	96.43	5	1 (4, 5)	96.30	7
Prevent future recurrent symptoms	4	2.00 (3.00, 5.00)	71.88	4	1.50 (3.25, 4.75)	75.00	4	2* (3,5)	74.07	11
Encourage self-management	5	1.00 (4.00, 5.00)	96.88	5	0.00 (5.00, 5.00)	96.43	5	0 (5, 5)	100.00	3
Return to work and social activities as soon as possible	5	0.75 (4.25, 5.00)	100.00	4	1.00 (4.00, 5.00)	100.00	5	1 (4, 5)	100.00	6
Return to pre-injury quality of life	4.5	1.00 (4.00, 5.00)	100.00	5	1.00 (4.00, 5.00)	100.00	4	1 (4, 5)	85.19	10
Facilitate personal motivation for healthy lifestyle	4	1.00 (3.00, 4.00)	71.88	4	1.00 (3.00, 4.00)	75.00	4	0 (4, 4)	77.78	12
Other please detail	Identify and manage sleep deprivations (provided by n = 1 participant)			4	0.00 (4.00, 4.00)	85.71	4	2* (3, 5)	74.07	9

Did not meet consensus criteria

3.3.3 Treatment components of the ABPI

The results of rounds 1 and 2 for the treatment components of the ABPI are presented in **Table 3.3**. In round 1, the following treatment components did not achieve the consensus criteria and were removed in the round 2 questionnaire: mobilisation with movement techniques (Mulligan), joint manipulation, Transcutaneous Electrical Nerve Stimulation (TENS), Percutaneous Electrical Nerve Stimulation (PENS), Microcurrent Electrical Nerve Stimulation (MENS), electrical stimulation, interferential current, diadynamic current, high-voltage galvanic current, electromagnetic therapy, laser therapy, ultrasound, short-wave diathermy, shock wave diathermy, infrared light, microwave and mechanical traction. However, stabilisation exercises, including deep neck extensor muscles, neural mobilisation, muscle energy techniques, acupuncture and dry needling, were suggested and added to treatment components in the round 2 questionnaire.

In round 2, breathing exercises, muscle energy techniques, cryotherapy, acupuncture and dry needling were removed for round 3 according to the consensus criteria. Mental imagery (a cognitive technique) was proposed and added to the questionnaire in round 3 to test the level of agreement for its inclusion.

Table 3.3: Results of rounds 1 and 2 for treatment components of the ABPI

5 = very important, 4 = important, 3 = no opinion, 2 = not important, 1 = not at all important

Treatment components	Round 1			Round 2		
1. Behavioural treatment components	**Median**	**IQR (Q1, Q3)**	**% (no) of agreement**	**Median**	**IQR (Q1, Q3)**	**% (no) of agreement**
Cognitive behavioural therapy	4	1.00 (3.00, 4.00)	62.50	4	1.00 (4.00, 5.00)	85.71
Whiplash education	5	1.00 (4.00, 5.00)	93.75	5	1.00 (4.00, 5.00)	96.43
Advice to act as usual	5	1.00 (4.00, 5.00)	90.62	5	1.00 (4.00, 5.00)	89.29
Reassurance	5	1.00 (4.00, 5.00)	96.88	5	1.00 (4.00, 5.00)	100.00
Postural control and education	4	0.75 (4.00, 4.75)	87.50	4.5	1.00 (4.00, 5.00)	85.71
Relaxation techniques	4	1.00 (3.00, 4.00)	65.62	4	0.75 (3.25, 4.00)	75.00
Self-management	5	0.75 (4.25, 5.00)	96.88	5	0.00 (5.00, 5.00)	100.00
Other please detail	No other treatment components were provided by participants			Mental imagery (a cognitive technique) (provided by n = 1 participant)		
2. Physiotherapy treatment components						
Exercise and mobilisation therapy						
Mobilisation with movement techniques (Mulligan)	3	2.00 (2.00, 4.00)	40.62*			
Active mobilisation exercises including cervical protraction-retraction	4	1.75 (3.25, 5.00)	75.00	4	1.00 (4.00, 5.00)	85.71
Stabilisation exercises including deep neck flexor muscles	4	1.00 (4.00, 5.00)	87.50	4	1.00 (4.00, 5.00)	82.14
Stretching exercises	4	2.00 (2.00, 4.00)	62.50	4	1.00 (3.00, 4.00)	67.86
Mobility exercises	4	1.00 (4.00, 5.00)	100.00	4	1.00 (4.00, 5.00)	100.00
Progressive exercises for strengthening	4	1.75 (3.25, 5.00)	75.00	4	0.00 (4.00, 4.00)	85.71
Postural stabilisation	4	0.75 (4.00, 4.75)	81.25	4	1.75 (3.25, 5.00)	75.00
Sensorimotor exercises (kinaesthetic sense, balance and eye movement)	4	2.00 (3.00, 5.00)	62.50	4	1.00 (3.00, 4.00)	71.43

Table 3.3: Continued

Treatment components	Round 1			Round 2		
Exercise and mobilisation therapy (continued)	**Median**	**IQR (Q1, Q3)**	**% (no) of agreement**	**Median**	**IQR (Q1, Q3)**	**% (no) of agreement**
Breathing exercises	3.5	1.00 (3.00, 4.00)	50.00	3‡	1.00 (3.00, 4.00)	46.43‡
Other please detail	Stabilisation exercises including deep neck extensor muscles (provided by n = 2 participants)			4	1.00 (4.00, 5.00)	82.14
Manual therapy						
Joint mobilisation	4	2.75 (2.25, 5.00)	65.62	4	1.75 (3.00, 4.75)	71.43
Massage or soft tissue mobilisation/manipulation	4	1.00 (3.00, 4.00)	62.50	4	2.00 (3.00, 5.00)	71.43
Joint manipulation	3	1.00 (2.00, 3.00)*	21.88*			
Other please detail	• Neural mobilisation (provided by n = 2 participants) • Muscle energy techniques (provided by n = 1 participant)			4 3‡	1.00 (3.00, 4.00) 2.00 (2.00, 4.00)	67.86 28.57‡
Physical agents						
Transcutaneous Electrical Nerve Stimulation (TENS)	2*	2.00 (1.00, 3.00) *	12.50*			
Percutaneous Electrical Nerve Stimulation (PENS)	1*	1.00 (1.00, 2.00) *	0.00*			
Microcurrent Electrical Nerve Stimulation (MENS)	1*	1.00 (1.00, 2.00) *	0.00*			
Electrical stimulation	1*	1.75 (1.00, 2.75) *	3.13*			
Interferential current	1*	1.00 (1.00, 2.00) *	0.00*			
Diadynamic current	1*	1.00 (1.00, 2.00) *	0.00*			
High-voltage galvanic current	1*	0.75 (1.00, 1.75) *	0.00*			
Electromagnetic therapy	1*	1.00 (1.00, 2.00) *	0.00*			

Table 3.3: Continued

Treatment components	Round 1			Round 2		
Physical agents (continued)	**Median**	**IQR (Q1, Q3)**	**% (no) of agreement**	**Median**	**IQR (Q1, Q3)**	**% (no) of agreement**
Laser therapy	1*	1.00 (1.00, 2.00) *	0.00*			
Ultrasound	1*	1.00 (1.00, 2.00) *	6.25*			
Short-wave diathermy	1*	0.75 (1.00, 1.75) *	0.00*			
Shock wave diathermy	1*	0.75 (1.00, 1.75) *	0.00*			
Infared right	1*	1.00 (1.00, 2.00) *	0.00*			
Microwave	1*	1.00 (1.00, 2.00) *	0.00*			
Cryotherapy	3.5	2.00 (2.00, 4.00)	50.00	3‡	2.00 (2.00, 4.00)	35.71‡
Heat	4	1.00 (3.00, 4.00)	68.75	4	1.00 (3.00, 4.00)	71.43
Mechanical traction	2*	2.00 (1.00, 3.00) *	12.50*			
Other please detail	No other treatment components were provided by participants					
3. Other						
Multimodal therapy	4	1.00 (3.00, 4.00)	59.38	4	0.75 (3.25, 4.00)	75.00
Physical activity such as aerobic and fitness	4	1.00 (4.00, 5.00)	87.50	4	0.00 (4.00, 4.00)	82.14
Other please detail	• Acupuncture (provided by n = 1 participant) • Dry needling (provided by n = 1 participant)			3‡ 2‡	1.00 (2.00, 3.00)‡ 1.00 (2.00, 3.00)‡	14.29‡ 7.14‡

**Did not meet consensus criteria for round 1, ‡ did not meet consensus criteria for round 2*

Table 3.4 presents the results from round 3 for the treatment components. Relaxation techniques, mental imagery, active mobilisation exercises, stretching exercises, sensorimotor exercises, joint mobilisation, massage, neural mobilisation, heat and multimodal therapy did not meet the consensus criteria. However, active mobilisation exercises, including cervical protraction-retraction and multimodal therapy, were included in the ABPI due to the observed high median score and percentage of agreement.

Table 3.4: Results of round 3 for treatment components of the ABPI

1. Behavioural treatment components	**Median**	**IQR (Q1, Q3)**	**% (no) of agreement**
Self-management	5	0 (5, 5)	100.00
Advice to act as usual	5	1 (4, 5)	100.00
Whiplash education	5	1 (4, 5)	92.59
Reassurance	5	1 (4, 5)	92.59
Cognitive behavioural therapy	4	1 (4, 5)	81.48
Postural control and education	4	1 (4, 5)	81.48
Relaxation techniques	4	1 (3, 4)	55.56*
Mental imagery (a cognitive technique)	3*	0 (3, 3)	22.22*
Applying these behavioural treatment components in practice for individual patients: • Education for pain management and reducing psychological stress • Self-management • Self-efficacy • Multimodal treatment strategies • As part of physiotherapy programme			
2. Physiotherapy treatment components			
Exercise and mobilisation therapy			
Stabilisation exercises including deep neck extensor muscles	5	1 (4, 5)	77.78
Mobility exercises	4	1 (4, 5)	88.89
Progressive exercises for strengthening	4	1 (4, 5)	81.48
Postural stabilisation	4	1 (4, 5)	81.48

Table 3.4: Continued

2. Physiotherapy treatment components	Median	IQR (Q1, Q3)	% (no) of agreement
Exercise and mobilisation therapy (continued)			
Stabilisation exercises including deep neck flexor muscles	4	1 (4, 5)	81.48
Active mobilisation exercises including cervical protraction-retraction	4	2 (3, 5)*	74.07
Stretching exercises	4	1 (3, 4)	59.26*
Sensorimotor exercises (kinaesthetic sense, balance and eye movement)	4	1 (3, 4)	62.96*
Manual therapy			
Joint mobilisation	4	2 (3, 5)*	62.96*
Massage or soft tissue mobilisation/manipulation	4	1 (3, 4)	55.56*
Neural mobilisation	3*	1 (3, 4)	48.15*
Physical agents			
Heat	3*	2 (2, 4)*	44.44*
Applying these physiotherapy treatment components in practice for individual patients • Apply as part of clinical reasoning process relevant for each individual patient • Self-management using exercise therapy			
3. Other			
Multimodal therapy	4	2 (3, 5)*	74.07
Physical activity such as aerobic and fitness	4	1 (3, 4)	70.37
Applying these other possible treatment components in practice for individual patients • Multimodal therapy, e.g. referring to a GP for analgesia or other professionals as required • Adding aerobic exercise as part of the home programme			

***Did not meet consensus criteria for round 3*

3.4 Discussion

This modified Delphi study explored the opinions of international research whiplash experts, UK private physiotherapists and UK postgraduate musculoskeletal physiotherapy students regarding acute WADII management. The response rate in the final round was 75% from the consenting respondents, which is quite high compared

with previous studies (Carnes et al., 2010, Rushton et al., 2014b). This study provided open questions in each section including the last section (for general comments or suggestions) in order to allow panellists to comment and express their views, to enable greater ecological validity of the results (McDonnell et al., 1996).

In managing acute WADII, it is interesting to consider the following underlying principles: returning to normal function as soon as possible, pain management, encouragement of self-management, reducing fear avoidance and anxiety, returning to normal movement as soon as possible, returning to work and social activities as soon as possible, and increasing confidence in exercises involving the neck and shoulders, which were rated highly and ranked one to seven among the important underlying principles. These underlying principles can assist individual physiotherapists in setting goals to manage their patients. However, other underlying principles could be considered based on an individual patient's particular problems.

The findings suggest a range of behavioural and physiotherapy treatment components of the ABPI in managing patients with acute WADII. The current acute WAD guidelines generally suggest reassurance and staying active, including education, pharmacotherapy, and active and passive (low level of evidence) physiotherapy (Moore et al., 2005, TRACsa, 2008, Jagnoor et al., 2014). However, the consensus reached in this study highlights a specified range of both behavioural intervention (e.g. education, advice to act as usual, reassurance, postural control with education, cognitive behavioural therapy and self-management) and active physiotherapy interventions (e.g. exercises for stability and mobility) which are potentially effective intervention components in managing patients with acute WADII. Furthermore, the suggestion of multimodal therapy and the promotion of physical activities were also provided by the

participants. However, the Jull et al.'s trial (2013) reported that there was no significant difference between multimodal therapy and usual care in several outcomes (i.e. pain, NDI, CROM, IES, PFActS-C, GHQ 28, PPT, craniocervical flexor test, cervical proprioception, balance, HPT, CPT, sympathetic vasoconstrictor response, and types and dosage of medications).

According to the WAD literature, patients with WADII commonly face both physical (e.g. pain and disability) and psychological (e.g. fear of movement, anxiety and depression) problems (Sterling et al., 2005, Sterling and Chadwick, 2010, Buitenhuis and de Jong, 2011, Nijs et al., 2011). The findings of this study regarding suggested treatment components addressed both physical and psychological problems and suggest that the development of a multicomponent ABPI may assist physiotherapists in managing their WAD patients. However, minimal information from participants regarding how to deliver the components of the ABPI in practice was provided, and in particular no underpinning psychological theory was proposed to inform the structure and nature of the intervention.

Self-efficacy, as defined by Bandura (1995), p.2, is "*the belief in one's capabilities to organise and execute the courses of action required to manage prospective situations*". In essence, self-efficacy is task-specific self-confidence and this psychological construct plays a key role in Bandura's social cognitive theory (Lee et al., 2014b, Schwarzer et al., 2015). In the rehabilitation context, self-efficacy judgements correlate with quality of life and general health status and functioning as reflected in both psychological (e.g. anxiety, depression and fear of movement) and physical (e.g. pain and physical function) aspects (Borsbo et al., 2010, Barlow, 2013). Consequently, the enhancement of self-efficacy, which also was recommended by some whiplash

experts to apply as part of the behavioural component of the ABPI **(Table 3.4)**, may work in managing both physical and psychological problems for patients with acute WADII. Interestingly, the self-efficacy beliefs are more important determinants of disability than fear avoidance beliefs in patients with musculoskeletal pain (Denison et al., 2004). Furthermore, the enhancement of self-efficacy can reduce anxiety and depression (Borsbo et al., 2010). Therefore, the self-efficacy theoretical concept will be used to develop (underpin and deliver) the ABPI for the management of acute WADII in the next chapter.

Strengths

This study is the first to present the principles and treatment components of an ABPI, which were initially identified from the currently rigorous systematic review evaluating the effectiveness of acute WADII management (Wiangkham et al., 2015b). The principles and treatment components were developed by a robust methodology using fixed-choice and open questions presented in an online survey to increase the reliability and validity of the study through critical judgements of international research and local clinical whiplash experts. Then, a theoretical perspective was applied to consolidate the emerging principles and components and suggest processes of behavioural change, developing the ABPI further as a complex intervention in line with the Medical Research Council Framework of Complex Interventions (Craig et al., 2008) which suggests the process of developing and evaluating a complex intervention. The reason for using this framework is that physiotherapy is a complex intervention owing to the degree of flexibility or tailoring of the intervention permitted (Craig et al., 2008).

Limitations

The study had a low recruitment rate with 37% agreeing to participate from the sample of invited experts (36/97 potential participants). This was anticipated and the aim to recruit n = 30 participants was achieved. Although there were 40 eligible international WAD researchers, only 11 (27.5%) consented to participate. Interestingly, the main reason for them declining to participate was that they work with chronic WAD patients (n = 6). It was the same situation for recruiting postgraduate musculoskeletal physiotherapy students (12/44 participated). Even though most of them worked in the NHS, a lot of them had never treated whiplash patients. Among researchers and students who explained their reasons for not participating there was therefore no obvious risk of bias owing to a potential participant's decision to participate. In contrast and unsurprisingly, the recruitment rate in the private sector was high (13/13 respondents) as this is where most whiplash patients are treated in the UK. This narrow professional involvement could be considered a limitation, but in the UK context, WADII patients are most commonly managed by physiotherapists. It should also be noted that six out of all the participants had experience working with whiplash patients for less than two years. These participants could be researchers.

To make it more convenient for the participants, this study involved the administration of an electronic questionnaire, leading to a lack of interaction and discussion among panellists. However, the number of rounds provided within the Delphi method provided an opportunity for panellists to make further clarifications and to review the findings based on the respondents from the total sample of participants. Using open questions to increase the ecological validity may have less generalisability to the whole field of musculoskeletal practitioners.

3.5 Conclusions

Experts suggested and agreed the underlying principles (e.g. returning to normal function as soon as possible, pain management, encouragement of self-management, and reducing fear avoidance and anxiety) and treatment components of the ABPI in both physical (e.g. postural control, exercises for stability and mobility) and psychological (e.g. education, advice to act as usual, reassurance, cognitive behavioural therapy and self-management) perspectives for the management of acute WADII. Owing to a lack of identification of any theory to underpin the ABPI and its delivery in physiotherapy practice, the ABPI was further developed using social cognitive theory and centred on self-efficacy enhancement (Bandura, 1977) as a result of the physiotherapy intervention.

Chapter summary

This chapter presents a range of underlying principles and treatment components in both physical and psychological aspects for acute WADII management by international research and local clinical whiplash experts over three rounds of the modified Delphi method. Although this study provided underlying principles and more varied behavioural interventions for acute WADII management than clinical guidelines, a psychological theory is required to underpin and deliver the ABPI to physiotherapy practice in line with the Medical Research Council Framework of Complex Interventions (Craig et al., 2008). The potentially useful theory is a social cognitive theory focusing on self-efficacy enhancement. The process of completing the developing the ABPI as a complex intervention is presented in **Chapter 4**.

CHAPTER 4

Development of the ABPI for Acute WADII Management Using Social Cognitive Theory Focusing on Self-efficacy Enhancement

Abstract

This chapter provides the detail of the development of the ABPI as a complex intervention in line with the Medical Research Council Framework of Complex Interventions. A social cognitive theory focusing on self-efficacy enhancement was used to underpin and deliver the ABPI for the management of acute WADII. The relationship between self-efficacy, pain, physical function and psychological stress are discussed in this chapter. Concept, phases (understanding, maturity, stamina and coping) and examples of the ABPI including the sources of self-efficacy enhancement (performance accomplishment, verbal persuasion and physiological/emotional states) and goal setting strategy are provided.

4.1 Background

Whiplash patients have both physical and psychological impairments (Sterling et al., 2005, Buitenhuis and de Jong, 2011, Myran et al., 2011, Nijs et al., 2011, Barnsley, 2013, Sterling, 2014). Establishing a management strategy to address both perspectives is challenging. The current evidence indicates that up to 60% of whiplash patients develop chronicity with ~30% experience moderate to severe pain and disability (Sterling et al., 2004, Merrick and Stalnacke, 2010, Jull et al., 2011b, Sterling, 2014). An effective intervention for acute WADII management is therefore required to prevent acute WADII patients from progressing to chronicity. According to a report on physical

and psychological problems among patients with WAD (Sterling et al., 2005, Sterling and Chadwick, 2010, Myran et al., 2011, Nijs et al., 2011, Buitenhuis and de Jong, 2011, Sterling, 2014), treating both perspectives at the same time may be an effective strategy for acute WADII management (Wiangkham et al., 2015b).

An Active Behavioural Physiotherapy Intervention (ABPI), identified from the currently rigorous systematic review and meta-analysis of RCTs evaluating conservative management for acute WADII (Wiangkham et al., 2015a, Wiangkham et al., 2015b), may be a potentially effective intervention in managing patients with acute WADII. The results suggested that a combination of both active physiotherapy [more effective than passive intervention at six months (95% CI: -17.19 to -3.23) and one to three years (-26.39 to -10.08)] and a behavioural approach [more effective than standard/control intervention for pain reduction at six months (-15.37 to -1.55) and improvement in cervical movement in the coronal (0.93 to 4.38) and horizontal (0.43 to 5.46) planes at three to six months] was warranted. However, the existing evidence was inadequate to create a complex intervention. The ABPI was therefore developed through the use of a modified Delphi method to define and provide underlying principles and treatment components, using international research and UK clinical whiplash experts (Wiangkham et al., 2016b). Unfortunately, the results of the modified Delphi study did not clearly support any theory for underpinning and delivering the ABPI in physiotherapy practice. Thus, key concepts and tenets from a strongly supportive theory was explored to provide a conceptual basis for an ABPI for the management of acute WADII patients in line with the Medical Research Council framework for developing complex interventions (Craig et al., 2008). The ABPI was developed as a complex

physiotherapy intervention in order to address both physical and psychological problems for acute WADII management.

A range of psychological theories (e.g. cognitive-behavioural therapy, acceptance and commitment therapy, self-efficacy) have been used in musculoskeletal management (e.g. low back pain and neck pain) (Morley et al., 1999, Wicksell et al., 2008, Lamb et al., 2010, Ludvigsson et al., 2015). Although cognitive-behavioural therapy was investigated in acute WADII, there were no significant differences when compared to usual care (Jull et al., 2013). Another possible theory of the acceptance and commitment therapy has never investigated in the acute WAD population, and based on existing research may be appropriate to apply in the chronic WAD rather than in the acute stage (Wicksell et al., 2008, Wicksell et al., 2010). According to the WAD and the musculoskeletal literature, the most appropriate theory for the management of acute WADII is self-efficacy enhancement (a part of social cognitive theory) which was also suggested as a relevant strategy to apply as part of the behavioural component of the ABPI by some whiplash experts from the modified Delphi study (Wiangkham et al., 2016b).

As proposed by Bandura (Bandura, 1977), social cognitive theory has been applied in various fields, including psychology, education and health care, to encourage appropriate behaviours by increasing level of self-confidence (Bandura, 1977, Bandura, 1994, Lee et al., 2014b, Schwarzer et al., 2015). A key concept within social cognitive theory is self-efficacy or "*people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives*" (Bandura, 1994, p.71). Within the physiotherapy literature, increasing self-efficacy is a strategy used to manage musculoskeletal patients (Thomeé, 2007,

Williamson et al., 2008, Barlow, 2013, Ludvigsson et al., 2015). Previous research has found that self-efficacy judgements correlate with the quality of life and health of patients with respect to both physical (e.g. pain and physical functions) and psychological (e.g. anxiety and depression) perspectives (Borsbo et al., 2010, Barlow, 2013) in a rehabilitation context. Increasing the level of self-efficacy is therefore an interesting principle for underpinning the ABPI to manage patients with acute WADII.

For whiplash patients, an RCT investigating a home exercise programme in 59 patients with acute WAD found that the initial level of self-efficacy was positively correlated with the recovery of WAD patients (Soderlund et al., 2000). Self-efficacy mediated the relationship between coping and disability, which was reported by a prospective study of WAD patients (Soderlund and Lindberg, 2002). Furthermore, self-efficacy was found to hold positive implications for disability, quality of life and general health in a cross-sectional study of 433 chronic pain patients (including patients with spinal cord injury-related pain, chronic WAD patients and fibromyalgia patients). More specifically, work by Borsbo and colleagues (2010) explored the relationship between self-efficacy judgements in these patient groups and physical function and psychological variables (e.g. pain, depression, anxiety, catastrophising, disability, quality of life and reported health) (Borsbo et al., 2010). The findings were that self-efficacy correlated negatively with pain and positively with quality of life and general health (Borsbo et al., 2010).

Drawing from this literature, the ABPI was therefore further developed based on social cognitive theory (Bandura, 1977) to include self-efficacy enhancement as an underpinning component of physiotherapy management for preventing acute WADII patients from progressing to chronicity. The enhancement of self-efficacy stems from

targeting four sources of self-efficacy in terms of performance accomplishments, verbal persuasion, vicarious experience and physiological/emotional states. This chapter details the theory informing the overall developed complex ABPI, strategy to deliver the ABPI and the task specific components of delivery of the ABPI. Finally, the concept, phases and examples of the ABPI were provided to prepare for training the physiotherapists in the experimental arm in the phase II trial.

4.2 Relationships among self-efficacy, pain, physical function and psychological stress

Self-efficacy, pain, physical function and psychological stress are intimately related. Previous work on WAD adopting an RCT (Soderlund et al., 2000, Wicksell et al., 2010), prospective cohort (Soderlund and Lindberg, 2002) or cross-sectional (Borsbo et al., 2010) design found that a change in one component can alter another (**Figure 4.1**). The relationship between each component is further discussed below.

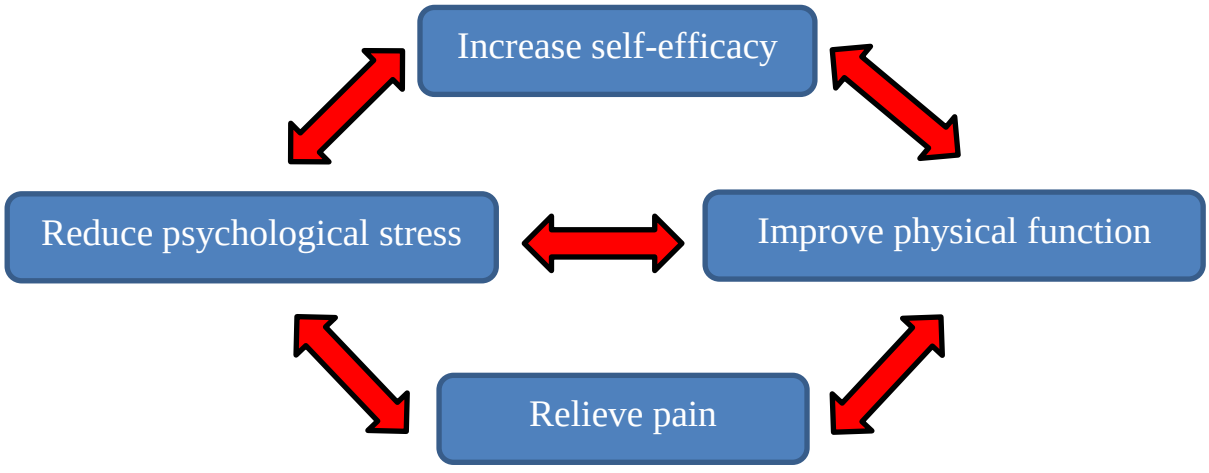

Figure 4.1: Relationship among self-efficacy, pain, physical function and psychological stress.

4.2.1 Self-efficacy and psychological stress

Previous work has indicated that increased self-efficacy can reduce psychological stress (e.g. reported symptoms of anxiety and depression) (Borsbo et al., 2010). However, the relationship between these two concepts appears to be reciprocal. A reduction in psychological stress will further increase self-efficacy (Bandura, 1977). Self-efficacy is therefore negatively correlated with psychological stress.

4.2.2 Self-efficacy and physical function

In the WAD literature, previous research has revealed a positive relationship between self-efficacy and physical function (Wicksell et al., 2010). Patients' confidence to engage in exercise and lifestyle physical activities can be promoted by a self-efficacy enhancing strategy (Marcus et al., 1992), thereby leading to subsequent improvements in physical function (Soderlund and Lindberg, 2002, Borsbo et al., 2010). Soderlund and Lindberg (2002) found that the direct effect of exercise self-efficacy corresponded to a reduction in the levels of disability experienced by whiplash patients from 97% to 93% and 67% at baseline, 6- and 12-month follow-ups, respectively. Additionally, if patients see progress in their physical function, their self-efficacy is expected to further increase (Bandura and Locke, 2003, French et al., 2014).

4.2.3 Psychological stress and physical function

Physical function increases when manifestations of psychological stress (e.g. anxiety and depression) are reduced (Borsbo et al., 2010, Wicksell et al., 2010). For example, reducing anxiety and depression can increase adherence to a neck and shoulder exercise programme, leading to improved cervical mobility and functions

(Asmundson et al., 2013). Also, if patients see a progression in neck movement and overall functioning, their psychological stress will be reduced (Bandura and Locke, 2003). In other words, there is a negative correlation between psychological stress and physical function (Wicksell et al., 2010).

4.2.4 Psychological stress and pain

Psychological stress has been found to correlate positively with pain (Leeuw et al., 2007, Borsbo et al., 2010). Reduction in psychological stress such as anxiety and fear avoidance could reduce pain (Leeuw et al., 2007, Borsbo et al., 2010). According to the International Association for the Study of Pain (IASP), pain is a subjective symptom related to physical and psychological factors depending on emotional experience associated with actual or potential tissue damage (IASP, 2014). With pain reduction, psychological stress could be further reduced (Bandura and Locke, 2003).

4.2.5 Physical function and pain

Physical function has been found to correlate negatively with pain (Soderlund et al., 2000, Gheldof et al., 2006, Leeuw et al., 2007). Pain can reduce physical function (Soderlund et al., 2000, Gheldof et al., 2006, Leeuw et al., 2007). For example, patients with acute WAD do not want to move their neck because it is painful. Therefore, relieving pain may be a good strategy prior to promoting an exercise programme, leading to improvement in physical function. As patients start to realise the benefits to their physical function, continuing with their prescribed exercises can lead to further pain reduction (Bandura and Locke, 2003, Schnabel et al., 2004, Rosenfeld et al., 2006, Vassiliou et al., 2006, Dehner et al., 2009).

4.3 Development of the concept of the ABPI for accelerating acute WADII recovery

Self-efficacy is an important factor in regard to behavioural change and maintenance of the new behaviour (Strecher et al., 1986, Marcus et al., 1992, French et al., 2014). For example, the study of Marcus et al. (1992) examining the relationship between stage of readiness to change and self-efficacy in exercising found that people who had little confidence in their capability to exercise started and regularly participated in physical activity. Findings from a systematic review indicated that self-efficacy can assist patients with heart failure in initiating and maintaining exercise interventions, leading to accelerating heart failure recovery (Rajati et al., 2014). Research has also indicated that self-efficacy may be a useful element in promoting active intervention and self-management (Strecher et al., 1986, Marcus et al., 1992, Chappuis and Soltermann, 2008, French et al., 2014), which are relevant to successful behavioural change.

According to recent whiplash studies, the enhancement of self-efficacy is a functional mediator in reducing disability in patients with acute WAD (Soderlund et al., 2000, Soderlund and Lindberg, 2002). Based on the work of Soderlund and colleagues (Soderlund and Lindberg, 2002) and other above-mentioned studies indicating the importance of self-efficacy judgements to successful physiotherapy outcomes (e.g. disability and pain), the concept of self-efficacy (and its assumed antecedents in Bandura's social cognitive theory) to underpin the ABPI may assist in accelerating normal movement and function of the neck and shoulder in acute WADII patients, in order to prevent patients from progressing to chronicity. By considerations of the potential benefits of increasing self-efficacy and its relationships to physical function, psychological stress and pain, the enhancement of self-efficacy should be fundamental

in managing and encouraging the appropriate behaviours in patients with acute WADII (Michie et al., 2011).

Figure 4.2 presents the development of the ABPI for acute WADII management considering both empirical (results from the modified Delphi study) (Wiangkham et al., 2016b) and theoretical (social cognitive theory central to self-efficacy enhancement) (Bandura, 1977) perspectives. The concept of the ABPI was generated by the underlying principles resulting from the modified Delphi study and the enhancement of self-efficacy concept. Then, the concept and the treatment components resulting from the modified Delphi study were considered to create the phases of the ABPI.

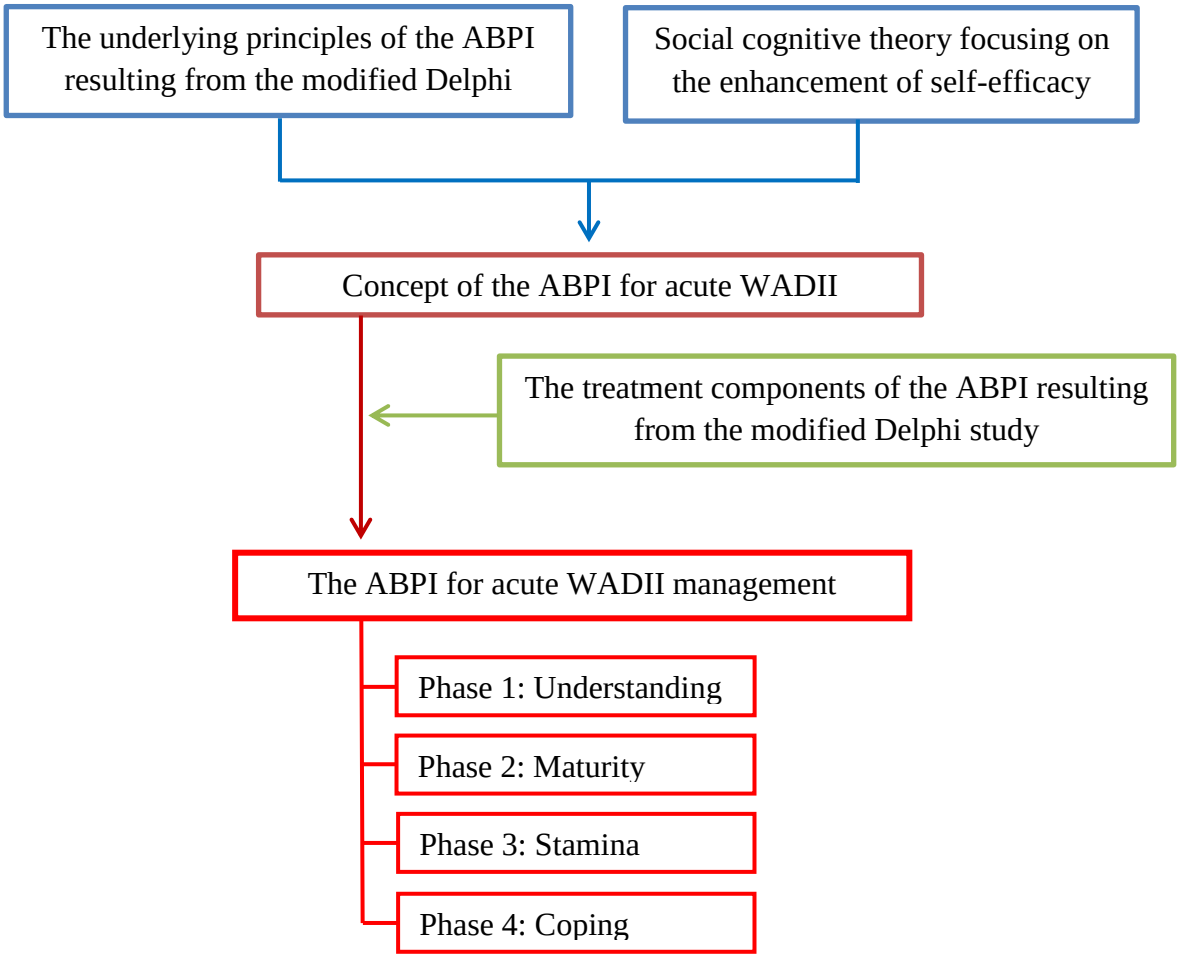

Figure 4.2: Flow diagram of the development of an ABPI for acute WADII in line with the Medical Research Council Framework of Complex Interventions.

4.4 Concept of the ABPI for acute WADII management

This concept was designed to guide physiotherapists in managing patients with acute WADII by considering the underlying principles of the ABPI resulting from the modified Delphi study (Wiangkham et al., 2016b) and the enhancement of self-efficacy concept (Bandura, 1977, Borsbo et al., 2010, Barlow, 2013). All underlying principles were grouped and then designed in a potential sequence for the management of patients with acute WADII. The final goal of management or the overarching outcome of treatment is to return to normal movement and function as soon as possible, ranked as the most important underlying principle resulting from the modified Delphi study (Wiangkham et al., 2016b). Additionally, there were several main subgoals (further underlying principles from the Delphi study) that should be identified (e.g. reducing psychological stress, increasing confidence in exercises, pain reduction, improvement in cervical stability and mobility, returning to quality of life, and returning to social and work activities) to help WADII patients in reaching the final goal. The metaphor here is 'climbing a mountain', which is why the model was designed in a triangular shape (**Figure 4.3**). There are four steps to the concept of the ABPI for the management of acute WADII.

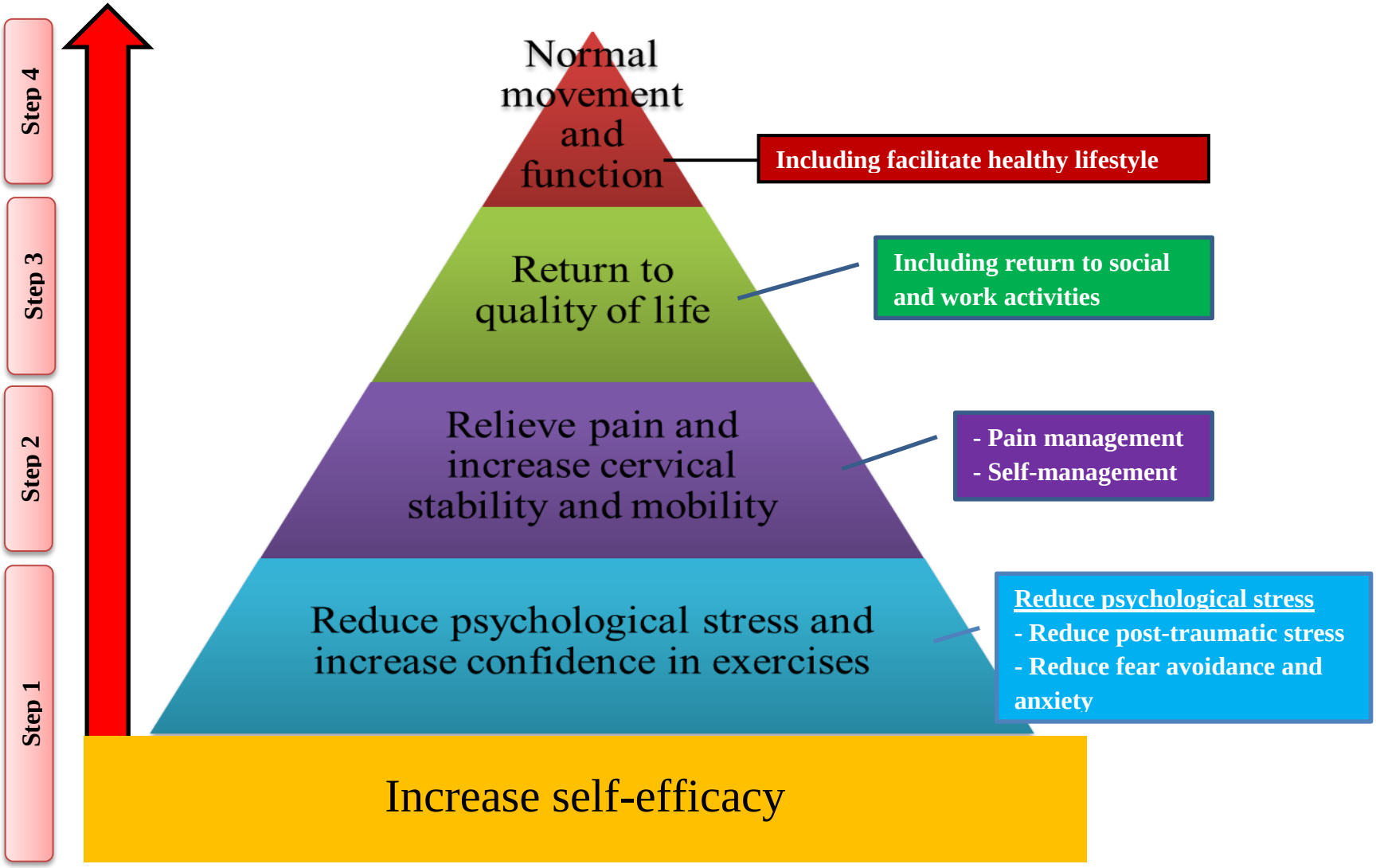

Figure 4.3: Concept of the ABPI for acute WADII management.

Step 1 – Enhancing the level of self-efficacy in exercises and reducing psychological stress (e.g. anxiety, depression and fear of movement) is the first step in the concept of the ABPI. Borsbo et al. (2010) and Barlow (2013) found that an increase in self-efficacy can decrease psychological stress and enhance confidence in exercises, leading to improvement in physical function.

Step 2 – After reduction of psychological stress, pain reduction and improvement in cervical stability and mobility are primarily targeted. Borsbo et al. (2010) found that pain is relieved when psychological stress is reduced. Consequently, patients with acute WADII may be easily managed and an exercise programme promoted after pain reduction. In this step, exercises are principally promoted in order to accelerate recovery. Several WAD studies found that cervical exercises can reduce pain and disability (Schnabel et al., 2004, Rosenfeld et al., 2006, Vassiliou et al., 2006, Dehner et al., 2009).

Step 3 – Restoring patients' quality of life including returning to work and social activities is promoted in order to encourage patients back to their normal life. Furthermore, patients are encouraged to continue their home exercises and self-management in order to improve their physical function.

Step 4 – Reaching normal movement and function is the aim of this step. Furthermore, patients will be supported in becoming people with a healthy lifestyle by continuing exercises and physical activities in the long term in order to prevent the

recurrence of symptoms. The physiotherapist will suggest some sources for further education regarding a healthy lifestyle.

For the management of acute WADII, an approach of enhancing or maintaining the level of self-efficacy is employed within each visit (treatment session), managed by physiotherapists throughout the rehabilitation process in order to reduce/prevent psychological problems, to promote self-management and to confidence in exercises/physiotherapy programmes.

4.5 Self-efficacy enhancement

According to Bandura (Bandura, 1977), the improvement of self-efficacy can be stimulated by four sources (**Figure 4.4**).

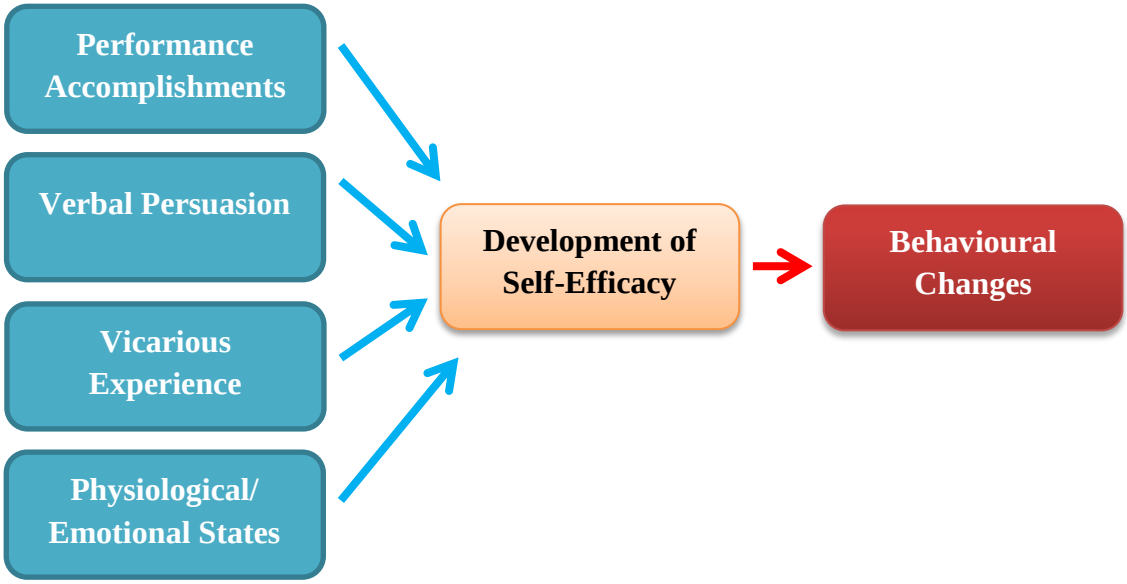

Figure 4.4: Sources for development of self-efficacy.

4.5.1 Performance accomplishments or past performance

The most influential factor in the development of self-efficacy is performance accomplishment, which is past performance based on personal experiences (Bandura and Locke, 2003). In principle, if people do something well, their self-efficacy will increase. Moreover, experiencing positive consequences of an activity can facilitate further activity (Parschau et al., 2013). In physiotherapy practice, physiotherapists design goals/tasks (e.g. exercise or a home programme) from easy to difficult levels to avoid unnecessary anxiety (Doerfler and Aron, 1995). If the patients succeed a goal or task, they will be more confident to complete further goals/tasks (Bandura and Locke, 2003). The physiotherapists use the benefits of positive experiences and accomplishments in indicating their patients to increase the level of self-efficacy. When patients are unsuccessful, physiotherapists guide them to accomplish the goal/task. However, physiotherapists and their patients reset a goal/task when the goal/task is too difficult or unrealistic.

4.5.2 Verbal persuasion

Self-efficacy can be developed by verbal persuasion (Bandura, 1977). Verbal encouragement or positive feedback can stimulate people to improve their self-efficacy while verbal discouragement or negative feedback can reduce their self-efficacy (Ilies et al., 2010). Soderlund and Sterling (2016), conducted an RCT to examine the effect of verbal persuasion on self-efficacy in individuals with chronic neck pain and healthy controls, found that a short verbal persuasion seems to be a useful strategy for increasing the self-efficacy level. Unfortunately, their study has some limitations in terms of using short verbal manipulation, the small sample size and the heterogeneity of

the target participants (including both traumatic and non-traumatic chronic neck pain). However, one sentence of instruction can influence therapeutic outcomes in acupuncture significantly (Lee et al., 2014a). In physiotherapy practice, physiotherapists should use verbal encouragement to guide/provide feedback and challenge patients to increase their self-efficacy, leading to successful goals/tasks (Bandura and Locke, 2003). For acute WADII management using the ABPI, verbal persuasion is used independently by physiotherapists to enhance the level of self-efficacy for their patients.

4.5.3 Vicarious (observational) experience or modelling

Vicarious experience, occasionally recognised as modelling, is observing a person in completing a task (Bandura, 1977). The model should have as similar characteristics (e.g. in age, sex and condition) as possible to the observer. The self-efficacy of the observer will increase when witnessing a similar model obtain a successful outcome for a task or goal (Goubert et al., 2011). The self-efficacy of the observer will reduce if they see the model fail. Currently, video modelling is an option for increasing the self-efficacy level. A meta-analysis of video modelling for children and adolescents with autism spectrum disorders reported that video modelling is an effective strategy in improving social-communication skills, physical function and behavioural function (Bellini and Akullian, 2007).

Unfortunately, this source of self-efficacy enhancement is not practically suitable for WADII patients within the private setting. Firstly, video modelling is an expenditure for the management, and would not be advantageous for business reasons (e.g. costs of building the model and compact discs (CDs)) and cost-effectiveness. Secondly, most WADII patients are workers who may not want to spend a lot of time

watching a video every day and then exercising, particularly after getting back to work. Finally, an active intervention or exercise programme prescribed by physiotherapists, varies from visit to visit depending on a patient's condition as management is progressed. Normally, physiotherapists demonstrate and check the accuracy of exercise/home programmes before assigning them to their patients. Thus, vicarious experience is not directly used in the complex ABPI for acute WADII management.

4.5.4 Physiological and emotional states

Physiological and emotional states may influence an individual's capability and self-efficacy (Bandura, 1977). People who perceive a physiological response to be negative will experience an increase in psychological stress. This will reduce self-efficacy. An example within physiotherapy may be the presence of non-painful "cracking" sensation or sound during neck movement. A patient's perception that this is negative may increase anxiety or fear of movement, leading to a reduction in the level of self-efficacy in neck exercises. A physiotherapist may educate patients regarding the cracking sound to reduce anxiety and fear of movement to increase self-efficacy in exercises. Furthermore, an introduction of breathing/progressive muscle relaxation exercises can reduce psychological stress (Feldman et al., 2010). These strategies can also reduce muscle tension, leading to relief of muscle pathology (e.g. muscle guarding/spasm) and improvement in cervical movement/function (Toivanen et al., 1993, Burns and Wells, 2006). The designing of tasks/goals in each step of the ABPI concept should consider patients' health conditions from both physiological and emotional perspectives.

4.6 Goal-setting concept for acute WADII management

Goal setting has been utilised to monitor and/or increase the enhancement of self-efficacy (Locke and Latham, 2002). It is consistent with the major source of self-efficacy, namely performance accomplishment or past experience, because patients can see how they achieve a goal/task and realise task accomplishment when goal setting is done effectively. Goal setting is also a key element of self-management (Locke and Latham, 2002) that has been recommended by panellists from the modified Delphi study (Wiangkham et al., 2016b). Goal setting is a valid, reliable and practical strategy for constructing motivation (Locke and Latham, 2002). It leads to increased effort to complete activities/tasks and, as a result can lead to increased personal performance (Locke and Latham, 2002, Ilies et al., 2010, Winton and Kane, 2016). An important benefit of goal setting is the acceleration of task completion (Locke and Latham, 2002). In managing acute WADII patients, physiotherapists can apply verbal persuasion to guide and provide feedback to their patients to achieve each goal. When patients see their improvement, performance accomplishments or past performance will play their part in further increasing patients' confidence (Bandura, 1993, Bandura and Locke, 2003). Then, patients can manage their symptoms daily based on their physiotherapists' suggestions and home programmes. Hence, the concept of goal-setting is important in monitoring patients with acute WADII.

Diagram of goal setting for acute WADII management

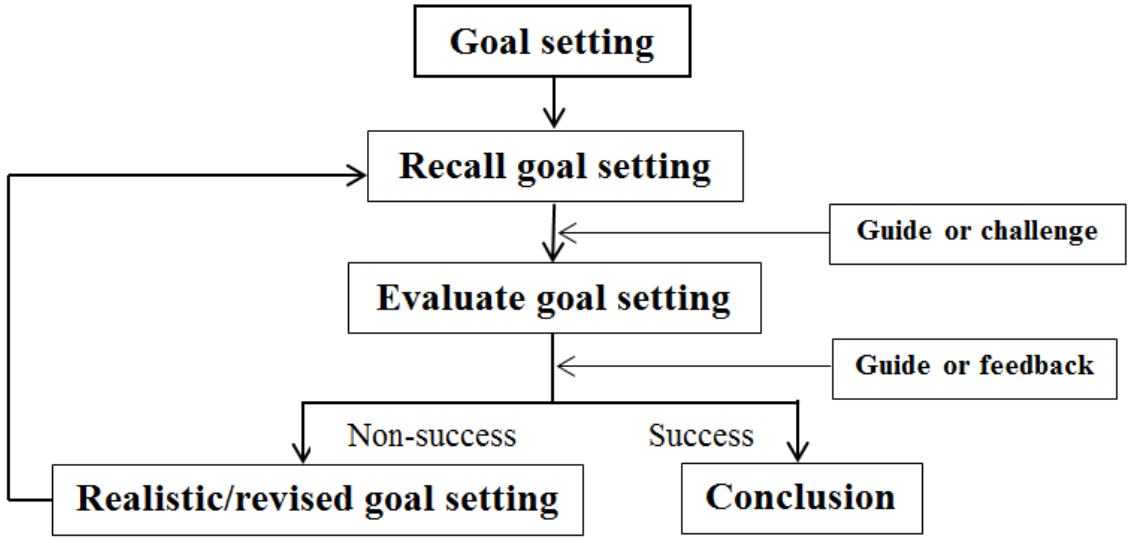

Figure 4.5: Goal-setting concept for acute WADII management adapted from Thomee (2007).

Figure 4.5 outlines the process of using goal setting.

- Firstly, a goal will be set and then patients will be reminded of that goal. In physiotherapy practice, goals of treatment will be designed by physiotherapists and their patients to reduce barriers (e.g. expectation and direction of treatment) based on the concept of the ABPI for acute WADII management (**Figure 4.3**).
- Secondly, physiotherapists will guide or challenge their patients to achieve the goal with home programmes prior to evaluation during the next visit. For example, the physiotherapists may instruct a patient to do gentle cervical exercises to maintain/increase neck movement/function and reduce pain in the first visit, and the goal, including adhering to the physiotherapy programme, will be evaluated during the next visit.
- Finally, after the goal evaluation, feedback will be provided to the patients. If the patients achieved the goal, physiotherapists will give positive feedback to

increase the level of self-efficacy. Physiotherapists can guide their patients to try again when they cannot achieve the goal at the first time of asking. However, the goal can be revised by the physiotherapists and their patients if they think that the goal is too difficult or inappropriate for patients' conditions prior to reminding them of the goal for another cycle.

4.7 The ABPI for acute WADII management

The ABPI for acute WADII management was designed based on the concept of the ABPI and the enhancement of self-efficacy theoretical concept. **Figure 4.6** presents the four phases of the ABPI: understanding, maturity, stamina and coping. The phases were developed from the steps of the concept of the ABPI. Each phase consists of task specific self-efficacy interventions individual to each patient and their presentation. The exercises/tasks in the beginning phase will be easier and became harder or more complicated in later phases to avoid overanxiety based on the enhancement of self-efficacy theoretical concept (Doerfler and Aron, 1995). Three sources of self-efficacy will be utilised in each phase and visit depending on their suitability in order to further increase confidence in self-management and exercises.

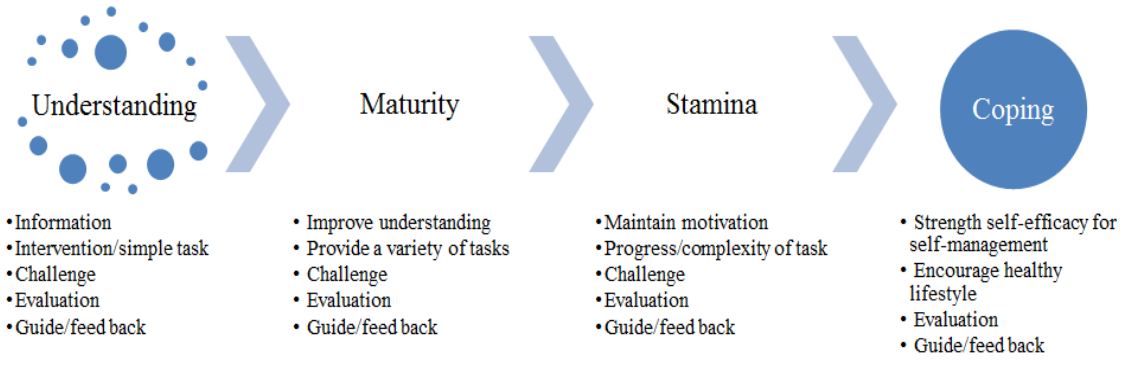

Figure 4.6: The phases of the ABPI for acute WADII management adapted from Thomee (2007).

4.7.1 Phase 1 – Understanding

Strategy: To provide general information regarding simple whiplash pathology, pain management and self-management, and promote gentle exercises. Ottosson et al. (2007) found that the number of acute WADII patients who received general information about WAD and information about how to manage themselves recovered was higher than in the control group. Both groups received the same standard medical treatment (Ottosson et al., 2007). Furthermore, the enhancement of self-efficacy level will be used to underpin the education in reducing/preventing psychological problems (e.g. overanxiety and fear avoidance) and increasing confidence in exercises (Soderlund and Lindberg, 2002, Borsbo et al., 2010).

Aim: To reduce psychological stress and increase confidence in exercises through education and by increasing the level of self-efficacy.

Goals:

- To educate patients regarding whiplash and increase the level of self-efficacy with a view to reducing/preventing psychological problems and improving confidence in exercises

- To initiate gentle exercises aimed at maintaining/improving cervical stability and mobility

- To promote self-management both psychological and physical aspects

Practice:

- Initially, acute WADII patients will be educated by physiotherapists regarding simple whiplash pathology, pain management and self-management. Additionally, verbal persuasion will be carried out aimed at increasing the level of self-efficacy in order to reduce/prevent psychological

problems (e.g. anxiety, depression and fear avoidance) and to motivate patients to start gentle exercises. For example, patients can be informed that their symptoms are completely normal and would improve if they adhered to a physiotherapy programme. In this phase, some patients may find it difficult to do some activities (e.g. staying in their car or driving). However, physiotherapists can use the three sources of self-efficacy to make them more confident in order to reduce fear avoidance.

- Simple gentle exercises will be promoted for a home programme in order to improve cervical stability and mobility. For example, physiotherapists may assign isometric neck exercises in all degrees of freedom and cervical range of motion (CROM) exercises with pain-free range of motion (ROM) for an initial home programme.
- Self-management will be promoted in both psychological (e.g. stress management and relaxation techniques) and physical (e.g. pain reduction and physical functions) aspects. The patients will be educated about how to manage their pain and symptoms by their physiotherapists.
- Interventions such as manual therapy and other modalities can be prescribed based on the physiotherapists' clinical reasoning. During each visit, the physiotherapists will evaluate goals and give feedback or guide the patients on how to achieve them.

4.7.2 Phase 2 – Maturity

Strategy: The second phase requires the physiotherapists to improve the patients' understanding of whiplash pathology and self-management strategies. Normally, the patients meet their physiotherapists in one visit for 30 minutes a week. However, the patients have 24 hours a day, seven days a week to manage their problems. A self-management and home programme is therefore required to accelerate recovery. In this phase, a variety of exercises will be highlighted to improve cervical stability and mobility.

Aim: To improve cervical stability and mobility

Goals:

- To increase self-efficacy level to reduce psychological stress (when patients still need to), and further increase confidence in exercises and self-management
- To improve cervical stability and mobility through exercises
- To promote self-management of pain and physical functions (psychological management when patients need it, e.g. fear avoidance)

Practice:

- The level of self-efficacy will be raised to further increase confidence in performing the exercises and self-management (reduce psychological stress when patients need to) using the three sources:
    - Performance accomplishment

      For example, physiotherapists can refer to patients' symptoms (e.g. pain, CROM and fear avoidance), which are improved from the previous visit in order to enhance the level of self-efficacy in a physiotherapy programme and through patients' self-management.

- Verbal persuasion

  Physiotherapists can give further education or feedback to their patients. The most important is that physiotherapists challenge/build motivation for their patients to continue exercises and self-management.

- Physiological/emotional states

  Patients will improve their emotional states through a good relationship with their physiotherapists. For instance, physiotherapists explain the presence of non-painful "cracking" during neck movement exercises.

- Exercises/home programmes for cervical stability and mobility

  Physiotherapists will design an exercise programme aimed at the improvement of cervical stability and mobility (e.g. resisted neck and shoulder exercises, active ROM and mobilisation exercises).

- Self-management of pain and physical functions

  Physiotherapists will suggest how patients should manage their symptoms and how to improve physical functions in terms of a home programme.

- Other physiotherapy programmes based on clinical reasoning

4.7.3 Phase 3–Stamina

Strategy: Progressive cervical exercises key to this phase in order to restore patients' quality of life. The confidence and motivation of patients in relation to exercise programmes and self-management will be increased/maintained through the use of three sources of self-efficacy enhancement by physiotherapists.

Aim: To restore quality of life

Goals:

- To increase/maintain self-efficacy to give patients confidence in exercises and self-management

- Progressive exercises for cervical stability and mobility

- To promote self-management with a view to improving physical functions and restoring quality of life

Practice:

- The confidence of patients in exercise programmes and self-management will be increased/maintained through the use of three sources of self-efficacy enhancement by physiotherapists. For instance, when the patients see their progression, their confidence in self-management and exercises will rise. Moreover, physiotherapists can encourage patients to do things in the right way and to keep going, leading to a further increase in the patients' efficacy.
- More complex exercises/home programmes (e.g. strengthening and range of motion exercises) will be designed to improve cervical functions and to restore normal movement and function. By getting close to normal, patients should be able to regain their quality of life.
- Self-management for improving physical functions and restoring quality of life (e.g. fully getting back to their working with few problems and confidence in driving their car and other physical activities)
- Other physiotherapy programmes based on clinical reasoning

4.7.4 Phase 4 - Coping

Strategy: In this phase, patients should have a sufficiently strong level of self-efficacy for self-management and performing exercises. Furthermore, a healthy lifestyle will be promoted in order to prevent the recurrence of symptoms and to create healthy people.

Aim: To return to normal movement and function

Goals:

- To maintain/increase the level of self-efficacy in terms of self-management and exercises

- To promote self-management with a view to improving physical functions

- To facilitate the long-term goal of a healthy lifestyle

Practice:

- Patients will be encouraged to maintain/increase self-efficacy for self-management and exercises. The patients in this phase should have strength at the self-efficacy level.
- Exercises and a home programme (e.g. strengthening and ROM exercises including physical activities) will be designed to help patients regain normal movement and functions.
- Self-management for physical functions (e.g. working or driving without any limitation).
- In facilitating a healthy lifestyle, physiotherapists will stimulate their patients to be healthy people and then encourage them to undertake self-education.

The number of treatment sessions in each phase will vary depending on an individual patient's presentation and problems based on physiotherapist's justification. The recommendation is for between one and three visits in each phase. At each visit, physiotherapists will evaluate their patients and then categorise them into an appropriate phase prior to planning suitable treatment using their clinical reasoning. The management will be flexible based on the individual patient presentation in line with the recommendation of the Medical Research Council Framework of Complex Intervention (Craig et al., 2008).

Table 4.1 presents a summary of the ABPI in terms of phases, strategies, goals and interventions regarding management in patients with acute WADII.

Table 4.1: Active Behavioural Physiotherapy Intervention (ABPI) for acute WADII management

Phases	Strategies	Goals	Interventions
1) Understanding	• Information • Intervention/simple task • Challenge • Evaluation • Guide/feed back	• Increase self-efficacy to reduce psychological stress and increase confidence in exercises through education • Initiate gentle exercise to maintain/improve neck stability and mobility • Promote self-management for psychological and physical management	• Increase self-efficacy using verbal persuasion provided by physiotherapists with the aim of reducing psychological stress and increasing confidence in exercises through whiplash education (e.g. simple whiplash pathology, pain management and self-management with benefits of exercises) • Initiate gentle exercises and home programmes including challenges for neck stability and mobility exercises (e.g. isometric neck exercises, chin in and active CROM without pain) • Promote self-management to include both psychological (e.g. stress management and relaxation techniques) and physical (e.g. pain reduction and physical functions) aspects • Other physiotherapy programmes based on clinical reasoning
2) Maturity	• Improve understanding • Provide a variety of tasks • Challenge • Evaluation • Guide/feed back	• Increase self-efficacy to reduce psychological stress and further increase confidence in exercises • Exercises for neck and shoulder stability and mobility • Promote self-management of pain and physical functions	• Increase self-efficacy (reduce psychological stress and improve confidence in performing exercises) o Performance accomplishment (e.g. relieve pain, increase CROM and fear avoidance o Verbal persuasion (e.g. further whiplash education/feedback when patients need it, continue exercises with challenges) o Increase emotional stages with good relationship • Exercises/home programmes including challenges for neck and shoulder stability and mobility exercises (e.g. resisted neck and shoulder, and active ROM or mobilisation exercises) • Promote self-management of pain and physical functions (psychological management when patients need it) • Other physiotherapy programmes based on clinical reasoning

3) Stamina	• Maintain motivation • Progress/complexity of task • Challenge • Evaluation • Guide/feed back	• Increase/maintain self-efficacy to create confidence in self-management and exercises • Progressive exercises for stability and mobility • Promote self-management of physical functions	• Increase/maintain self-efficacy for self-management and exercises o Performance accomplishment (e.g. relieve pain, increase CROM and improve physical functions) o Verbal persuasion (e.g. guide/feed back, continue exercises with challenges) o Increase/maintain emotional stages with good relationship • Progressive exercises/home programmes including challenges for strengthening and ROM exercises • Promote self-management of physical functions • Other physiotherapy programmes based on clinical reasoning
4) Coping	• Strength self-efficacy for self-management • Encourage healthy lifestyle • Evaluation • Guide/feed back	• Maintain/increase self-efficacy for self-management and exercises • Promote self-management of physical functions • Facilitate long-term goal of healthy lifestyle	• Maintain/increase self-efficacy o Performance accomplishment (e.g. physical functions) o Verbal persuasion (e.g. guide/feedback, continue exercises with challenge to be a healthy lifestyle person) o Increase/maintain emotional stages with good relationship • Home programmes for strengthening and ROM exercises including physical activities to help patients regain normal movement and function • Promote self-management of physical functions • Facilitate the adoption/maintenance of a healthy lifestyle • Other physiotherapy programmes based on clinical reasoning

Note: *The management of each stage can be modified by physiotherapists depending on clinical reasoning.*

4.8 An example of the ABPI for acute WADII management

Phase 1

Goals:

- Whiplash education and increasing self-efficacy level for reducing/preventing psychological problems and improving confidence in exercises
- To initiate gentle exercises for maintaining/improving cervical stability and mobility
- To promote self-management both psychological and physical

Practice:

- Individual examination, both subjective and objective examinations (10 mins)
- Interventions (15 mins)
    - Whiplash education (e.g. simple whiplash pathology, pain management and self-management) to reduce/prevent psychological stress
    - Increasing self-efficacy using verbal persuasion to reduce/prevent psychological stress and improve confidence in exercises
    - Promotion of initiate gentle exercises/home programmes including challenges for cervical stability and mobility exercises (e.g. isometric neck exercises, chin in and active CROM with pain-free ROM)
    - Self-management in both psychological (e.g. stress management, relaxation techniques) and physical (e.g. pain reduction and physical functions) aspects

- Other physiotherapy programmes based on clinical reasoning

- Assessment (5 mins): Self-efficacy evaluation using 0–10 point Numerical Rating Scale (NRS) (0 = I cannot do, 10 = I am certain I can do) for completing exercise/home programmes, other assessments (e.g. pain intensity, CROM or NDI)
- Plan: next visit

Chapter summary

This chapter demonstrates how the ABPI was developed as a complex physiotherapy intervention based on empirical and theoretical evidence in line with the Medical Research Council Framework of Complex Interventions (Craig et al., 2008). The results from the modified Delphi study were combined with social cognitive theory focusing on the enhancement of level of self-efficacy (using three sources: performance accomplishments, verbal persuasion, and physiological/emotional states), which was found as a potentially useful and suitable theory to underpin and deliver the ABPI to physiotherapy practice. The description of the ABPI was provided in terms of the concept, phases and examples for managing patients with acute WADII. The phases of the ABPI consisted of understanding, maturity, stamina and coping. Goal setting, which correlates with the enhancement of self-efficacy (link to performance accomplishment), was used to monitor patients in order to accelerate goal completion. Next stage, the ABPI will be evaluated for the feasibility and acceptability in managing patients with acute WADII in the physiotherapy practice.

CHAPTER 5

Methodology for a Pilot and Feasibility Trial of the ABPI in a Private Insurance Setting

Abstract

This chapter provides the methodology of a pilot and feasibility trial of the ABPI for acute WADII management in a private insurance setting. The trial consisted of two phases: 1] an external cluster randomised, double blind (assessor and participants), parallel two-arm (ABPI versus standard physiotherapy) pilot and feasibility trial to evaluate procedures and feasibility of the ABPI; and 2] an embedded exploratory qualitative study to explore the acceptability of the ABPI to physiotherapists (all physiotherapists in the ABPI arm) and participants (n = 20 in the ABPI arm) of the trial using semi-structured interviews and a focus group, respectively. In phase I, six private physiotherapy clinics were recruited and cluster randomised either to the ABPI (n = 3) or standard physiotherapy (n = 3) arms by a computer-generated randomisation sequence. It was planned to recruit sixty participants (30 each arm) and evaluate at baseline and three months post baseline. The planned primary outcome measure was the Neck Disability Index. Data were analysed and summarised based on a pre-specified quantitative synthesis to evaluate eligibility, recruitment and follow-up rates. In the qualitative phase II, thematic analysis was used both deductively (to identify themes) and inductively (to identify additional themes). Any adverse/ serious adverse event was recorded and reported throughout the trial. The trial steering and data monitoring committee was established to monitor the trial. This trial protocol is registered ISRCTN84528320 and published in BMJ Open 2016.

5.1 Background

The ABPI was identified from the currently rigorous systematic review and meta-analysis of RCTs evaluating the conservative management for acute WADII (Wiangkham et al., 2015a, Wiangkham et al., 2015b) as a potential effective strategy (Wiangkham et al., 2015b). The existing evidence was inadequate to generate an intervention for managing patients with acute WADII. Therefore, the ABPI was developed using empirical (a modified Delphi study by international whiplash researchers, UK private physiotherapists and UK postgraduate musculoskeletal physiotherapy students) (Wiangkham et al., 2016b) and theoretical (social cognitive theory focusing on self-efficacy enhancement) perspectives (Bandura, 1977) in line with the Medical Research Council Framework of Complex Interventions (Craig et al., 2008). Having developed the intervention through a rigorous process, it is now important to explore the feasibility of delivering the intervention in preparation for a future definitive cluster randomised trial.

In the UK, a substantial proportion of patients with WADII are managed within the private sector. Since 2008, the number of UK whiplash claims from road traffic accidents is around 450,000–550,000 people (Ellman et al., 2013). In 2012–2013, the number of UK whiplash claims from road traffic accidents was 476,938 people (The-House-of-Commons, 2013). Given the increase in the cost of claims from £7 to £14 billion over the past decade (Mooney, 2012), the economic burden may be caused by the number of chronic WAD patients who are reported to represent up to 60% of WAD patients (Jull et al., 2011b, Sterling, 2014). Therefore, the delivery of the ABPI for the management of patients with acute WADII needs to take place in the private setting.

5.2 Aims and objectives

To evaluate the procedures, feasibility and acceptability of the ABPI in managing acute WADII within the UK insurance private sector to inform the design and sample size requirements for a future definitive RCT.

5.2.1 Primary objectives

- To evaluate the feasibility of procedures for a cluster randomised controlled trial (i.e. randomisation, recruitment, collecting data, trial management and follow-up) (Lancaster et al., 2004, Arain et al., 2010, Thabane et al., 2010, Whitehead et al., 2014)
- To explore the acceptability of the ABPI (Arain et al., 2010)
- To evaluate recruitment rates, refusal rates and adherence of participants in the private sector in the UK (Arain et al., 2010, Thabane et al., 2010)
- To evaluate the loss of follow-up of participants in the private sector in the UK (Arain et al., 2010, Whitehead et al., 2014)

5.2.2 Secondary objectives

- To estimate the required sample size for a clustered definitive trial (Gould, 1995, Coffey and Muller, 2003, Arain et al., 2010, Thabane et al., 2010, Whitehead et al., 2014)
- To evaluate the feasibility of data collection for cost-effectiveness analysis (Arain et al., 2010)

5.3 Methods

This trial was conducted according to a predefined protocol (Wiangkham et al., 2016a) and subsequent deviations were reported in order to minimise potential biases. It followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines to ensure sufficient transparency for protocols of clinical trials (Chan et al., 2013). Research methods and reporting were in accordance with the CONSORT 2010 statement: extension to cluster randomised trials (Campbell et al., 2012) for phase I and COnsolidated criteria for REporting Qualitative research (COREQ): a 32-item checklist for interviews and focus groups (Tong et al., 2007) for phase II.

5.3.1 Trial design

There are two phases to this trial.

Phase I: An external pilot and feasibility trial of a cluster randomised double-blind (assessor and participants) parallel two-arm design, comparing the ABPI with standard physiotherapy management, was conducted to evaluate the procedures and feasibility of the ABPI. Six private physiotherapy clinics in the West Midlands, UK were recruited. There are many advantages to cluster randomisation in terms of administrative convenience (Edwards et al., 1999), including obtaining the cooperation of investigators, ethical considerations (Edwards et al., 1999), enhancing participant compliance, reducing treatment contamination (Wyatt et al., 1998, Edwards et al., 1999, Siebers et al., 2009, Campbell et al., 2012), participant blinding (Campbell et al., 2012) and logistical conveniences (Edwards et al., 1999). However, the required sample size in a cluster RCT is larger than that of an ordinary RCT (Teerenstra et al., 2012).

Six private physiotherapy clinics (Birmingham City, Great Barr, Moseley, Solihull, Sutton Coldfield and West Bromwich) were invited to sign consent forms (**Appendix 9**) (cluster-level consent) prior to cluster randomisation (Campbell et al., 2012). Following randomisation, consecutive potential participants, referred by an insurance company, were screened and recruited by a clinical administrator by telephone to book an initial recruitment appointment. The participant information sheet (**Appendix 10**) and consent form (**Appendix 11**) were sent via e-mail/post to interested patients to give them the opportunity to read them in advance of the appointment. During the appointment, the recruiting physiotherapist discussed any issues relating to the trial, confirmed eligibility and obtained written consent (individual-level consent). After giving informed written consent, the participants were assessed on all outcome measures by a blinded assessor using standardised instruments with established measurement properties. Assessments were made at baseline (following recruitment and consent) and at three months post baseline. All outcome assessments were independent of treatment sessions and treatment clinics to ensure that the assessor was blinded to treatment allocation. The assessor was a physiotherapist familiar with the outcome measures, and blinded to reduce potential biases. The assessor was not able to access the booking system and participants' information while the participants did not know which intervention arm they were allocated to in order to ensure that both the assessor and participants were blinded. At the end of the three-month follow-up for each participant, the assessor was asked 'what intervention the patient had received' and the participants were asked which intervention arm they had been allocated to evaluate the blinding. Two assessment centres (Moseley and Sutton Coldfield clinics) central to all clinics enabled convenient attendance for participants. The participants received a reminder

two days prior to the baseline assessment and three-month follow-up. Providing a reason for participants' withdrawal was voluntary. On the consent form, the participants were asked to confirm whether they would like their data removed or kept in the trial in the case they decided to withdraw from the trial (**Appendix 11**).

Phase II: After the completion of the external pilot and feasibility trial (Wiangkham et al., 2016a), an embedded qualitative study was conducted to explore the acceptability of the ABPI for participants and physiotherapists, and to explore how trial procedures and processes worked in practice (Graham et al., 2014). The qualitative study employed two methods, namely semi-structured individual interviews for physiotherapists and a focus group for participants. Potential participants in both methods were invited via e-mail, including an attached participant information sheet (**Appendices 12** and **13** for the individual interviews and focus group, respectively) and consent form (**Appendices 14** and **15** for the individual interviews and focus group, respectively). Prior to performing individual interviews and the focus group, the participants received an opportunity to ask questions in order to decide whether they wished to complete the consent form. After they had returned the consent form, demographic characteristics of the participants such as age, gender, occupation and ethnicity were collected and reported (Tong et al., 2007). The interviewer, moderator and facilitator were independent of the trial interventions, physiotherapy clinics and insurance companies to ensure confidential discussion and avoid potential biases. Transcripts were returned to participants for any comment and clarification (De Cocker et al., 2015). The interviewer for individual interviews and the moderator for the focus

group were trained to enhance their qualitative skills prior to conducting an interview. In this trial, the interviewer and moderator was the same person.

Personal characteristics of research team

- Taweewat Wiangkham (male): MRes AHR, BSc PT (Hons), Cert ICH GCP, MTPTC. Doctoral Researcher (the lead researcher)
- Alison Rushton (female): EdD, MSc, Grad Dip Phys, Cert Ed, Dip TP, FCSP, HCPC, FHEA, FMACP. Senior Lecturer in Physiotherapy and Academic Lead Physiotherapy (the lead supervisor)
- Joan Duda (female): PhD, MSc, BA. Professor of Sport and Exercise Psychology (secondary supervisor)
- Sayeed Haque (male): PhD, MSc, BSc (Hons), FRSS. Senior Lecturer in Medical Statistics (territory supervisor)

Individual interviews for physiotherapists in the experimental arm

Three physiotherapists who delivered the ABPI (at the beginning there were four physiotherapists who delivered the ABPI to physiotherapy practice but one of them stopped treating whiplash injury owing to receiving a new position and responsibility in the same private physiotherapy company) were invited to an individual face-to-face interview by the lead researcher using a semi-structured interview technique (Graham et al., 2014, Stow et al., 2015). Each interview, which lasted no more than one hour and took place at the physiotherapists' clinics, explored the opinions and attitudes (e.g. experiences, perceptions and barriers of using the ABPI), acceptance and recording of the ABPI in managing acute WADII. Furthermore, perceptions of the similarities and

differences between standard physiotherapy and the ABPI were examined. Topic guides (**Table 5.1**) for individual interviews were tested by the lead researcher twice prior to implementation. All interviews were noted, audio digitally recorded and transcribed by the lead researcher.

Table 5.1: Individual interview theme for the physiotherapists in the ABPI arm

Themes	Questions

1	***Opinions and attitudes regarding the new intervention***
	
	1.1 Physiotherapists' experiences and perceptions
	
	- What is your **perception about using the ABPI** for treating your patients?
	- What do you think about the **concept of the ABPI**?
	  o Increase self-efficacy
	  o Reduce psychological stress and increase confidence in exercises
	  o Relieve pain and increase stability and mobility of neck
	  o Restore quality of life
	  o Normal movement and function
	- Do you think the enhancement of **self-efficacy** is useful for the management of acute WADII? Why or why not?
	  o Performance accomplishment
	  o Verbal persuasion
	  o Physiological/emotional states
	- What do you think about the **phases of the ABPI** and how they work?
	  o Understanding
	  o Maturity
	  o Stamina
	  o Coping
	  o Note: which one takes more time than other phases (how many sessions)
	  o The average of treatment sessions
	- What do you think about using **goal setting** for managing patients with acute WADII?
	- What is the **benefit of the ABPI** in your opinion and experience?
	- Does the **ABPI work equally well** with your patients? How?

	- How does **self-management** work with your patients?
	- How do you encourage your patients to have a **healthy lifestyle**?
	- How do you encourage your patients to carry out self-education?
	
	1.2 Barriers
	- How did you feel when you used the **ABPI for the first time**?
	- Have you **felt confident** in using the ABPI since the training day? How?
	- What helped you to be confident in using the ABPI?
	  o Training day
	  o Individual training
	- Did you have any **obstruction** in using the ABPI for treating your patients? How?
	
	With prompts for detail and elaboration of points

2	***Similarities and differences between the standard physiotherapy and the ABPI***
	- What are the **similarities and differences** between standard physiotherapy and the ABPI?
	- **Which intervention do you feel may be more helpful** in managing your patients? Why?
	  o **Private sector**
	  o **NHS**
	
	With prompts for detail and elaboration of points

3	***Acceptance of the new intervention*** - **Do you think the ABPI is an effective intervention** for acute WADII management? Why? Or why not? How does it work? - Do you think the ABPI should be used in managing acute WADII in **general**? Why? - Would you like to **change/modify** the ABPI? If so how? With prompts for detail and elaboration of points
4	***Recording*** - How do you feel about the treatment recording? - What are the difficulties with recording in this study? With prompts for detail and elaboration of points

Focus group for participants in the experimental arm

All participants who received the ABPI and completed three months of follow-up post baseline assessment (face-to-face assessment or telephone assessment) were invited via e-mail to participate in a focus group (modified from the protocol of Wiangkham et al. (2016a) due to the difficulty of the recruitment). The focus group is a standard and common procedure for evaluating the acceptability of an intervention (Ayala and Elder, 2011, De Cocker et al., 2015, Stow et al., 2015). There are several advantages to focus groups, including reduced costs compared with one-to-one interviews, plus the fact that focus groups are conducive to tapping in to variability in attitudes and opinions due to the interaction facilitated, and provide a comfortable forum for the expression of individual and collective points of view (Sim, 1998).

A reminder e-mail regarding the date, time and location of the interview was sent to the participants one day prior to the focus group. The focus group interview/discussion lasted for approximately 1.5 hours, was held at the university and was led by an expert facilitator (the lead supervisor) with a moderator (the lead researcher) to observe group interaction/dynamics and record the main themes of the discussion. An important reason for using an expert facilitator is to obtain sufficient quality of the data and to avoid potential biases (e.g. consistency bias and dominant respondent bias) (Sim, 1998). The focus group topic guide included the intervention that the participants received, the opinions and attitudes of the participants about the intervention, how the participants accepted the intervention, and if and how behaviour has changed. After giving their consent, the focus group commenced by agreeing 'ground rules' for the group including not discussing the content of the group interview outside of the session. The facilitator started with an introduction to the study and

organised questions ranging from general to specific related to interesting topics (**Table 5.2**). The focus group was observed, noted and digitally audio-recorded by the lead researcher. The transcription was provided by a company specialised in transcription service. The participants' names were not linked to any information in the reporting of findings from the group discussion, and findings were reported for the whole group rather than for individual participants. After the focus group, the moderator and facilitator discussed the main findings and unexpected outcomes (De Cocker et al., 2015).

Table 5.2: Focus group theme for the participants in the ABPI arm

Themes	Questions
1	***Intervention*** - What was the treatment that you **received** from your physiotherapist? - What did you like or dislike? - How did your physiotherapist **approach** you from the first visit to discharge? - What was the **home programme** that you were recommended by your physiotherapist from the first visit to discharge? What did you feel (like/dislike)? Easy/hard? - How did your physiotherapist suggest you **manage your symptoms** from the first visit to discharge? What did you feel (like/dislike)? Easy/hard? With prompts for detail and elaboration of points
2	***Opinions and attitudes regarding the new intervention*** - Do you think the treatment that you received was **useful**? Why? Or why not? - What is your **expectation** for your treatment? - Would you suggest anything in your treatment be **changed or modified**? - Was there **anything missing** from your treatment?

	With prompts for detail and elaboration of points
3	***Acceptance of the new intervention*** - How did you **feel after receiving** the treatment? - Do you **accept the treatment** that your physiotherapist gave to you? Why? - What is/are the **benefit**(s) of the treatment that you received from your physiotherapist? - Do you think the treatment should be used for acute WADII management in **general**? Why? Or why not? With prompts for detail and elaboration of points
4	***Behavioural changes*** - Did you notice any **differences in your lifestyle** after receiving the treatment? If yes, how? If no, why not? - After going through this treatment, have you committed to adopting a **healthy lifestyle**? If yes, how? If not, why not? With prompts for detail and elaboration of points

5.3.2 Participants

Participants were recruited from six UK private physiotherapy clinics. Demographic characteristics, including age, gender, accident history, present drugs and information regarding WAD symptoms, were noted by the blinded assessor at the baseline assessment. The participants in this trial can normally claim all expenditures regarding their treatment sessions from their insurance company. The trial paid for all participants' journeys at baseline and three-month follow-up that were additional contact points.

5.3.2.1 Eligibility criteria for clusters

Private clinics in the West Midlands, UK. Preliminary data had identified that each clinic had at least two patients presenting with acute WADII each month.

5.3.2.2 Inclusion criteria

Participants aged 18–70 years presenting with WAD grade II [neck complaint and musculoskeletal sign(s)] (Spitzer et al., 1995) from a road traffic accident within the previous four weeks (Sterling and Kenardy, 2006, TRACsa, 2008, Jull et al., 2013, Sterling, 2014, Jagnoor et al., 2014, Wiangkham et al., 2015b).

5.3.2.3 Exclusion criteria

Signs and symptoms of upper cervical instability (Tough et al., 2010), cervical artery dysfunction (Rushton et al., 2014a), suspected serious spinal pathology, open wounds, active inflammatory arthritis, tumours, infection of the skin and soft tissue, bleeding disorders or using anticoagulant medication (Tough et al., 2010), any current or previous treatment from any other third party, presenting with any serious injuries of other areas of the body resulting from the accident, history of cervical surgery (Crawford et al., 2004), previous symptomatic degenerative diseases of the cervical spine within six months before the road traffic accident (Rosenfeld et al., 2000), previous history of whiplash or other neck pain (Jull et al., 2013), alcohol abuse (Rosenfeld et al., 2000, Rosenfeld et al., 2003), dementia (Rosenfeld et al., 2000, Rosenfeld et al., 2003), serious mental diseases (Rosenfeld et al., 2000, Rosenfeld et al., 2003), psychiatric diseases (Richter et al., 2004, Lamb et al., 2007), and/or non-English speaking and reading.

5.3.3 Interventions

Interventions were described based on the Template for Intervention Description and Replication (TIDieR) (Hoffmann et al., 2014). Participants in both intervention arms attended face-to-face physiotherapy sessions lasting for up to 30 minutes once a week in a private physiotherapy clinic. The number of treatment sessions varied between six and eight sessions based on the individual physiotherapist's assessment. All physiotherapists in both intervention arms had a minimum of a bachelor degree in physiotherapy with two years of post-registration experience, and were registered with the Health and Care Professions Council (HCPC). To evaluate the fidelity of the ABPI, a summary of treatment sessions was systematically collected and sessions were randomly observed by the lead researcher. This enabled monitoring and feedback regarding the intervention to the treating physiotherapist.

5.3.3.1 Standard physiotherapy intervention

Patients were managed according to current practice reflecting the recommendations provided in the clinical whiplash guidelines (Moore et al., 2005, TRACsa, 2008, Jagnoor et al., 2014). Physiotherapy interventions such as reassurance, education, manual therapy, exercise therapy and physical agents, including a home programme of exercises, were part of management depending on the individual physiotherapist's clinical reasoning for the individual patient. The treating physiotherapists selected appropriate interventions based on examination findings and clinical reasoning (Rushton et al., 2014a).

5.3.3.2 Active Behavioural Physiotherapy Intervention (ABPI)

The specific details of this intervention, including the underlying principles (e.g. returning to normal function/movement as soon as possible, encouraging self-management, and reducing fear avoidance and anxiety) and the specific treatment components in both physical (e.g. exercise programmes for stability and mobility) and psychological (e.g. cognitive behavioural therapy, whiplash education, advice to act as usual, reassurance, self-management, and postural control and education) aspects, were developed by international research and local clinical whiplash experts through a modified Delphi method (Wiangkham et al., 2016b). Taking into consideration both empirical and theoretical perspectives in line with the Medical Research Council Framework of Complex Interventions (Craig et al., 2008), social cognitive theory (with a particular focus on self-efficacy enhancement) was used to underpin the ABPI to manage patients with acute WADII (Bandura, 1977, Thomeé, 2007).

The ABPI for acute WADII management consisted of four phases in terms of the promotion of understanding, maturity, stamina and coping. The number of treatment sessions in each phase varied depending on individual patients' conditions based on the physiotherapist's justification. The recommendation was approximately one to three visits in each phase. Further details about the ABPI were provided in **Chapter 4.**

The training of physiotherapists in the experimental arm to deliver the ABPI was delivered in advance of data collection. The training consisted of a group tutorial and workshop followed by individual training sessions to construct the concept of how to design the intervention and how to manage patients with WADII using the ABPI programme based on the findings of the patient history and physical examination data, and evidence-informed clinical reasoning (Rushton et al., 2014a). The physiotherapists

had four weeks to practise their skills embedded in the ABPI in managing patients with acute WADII prior to participants' recruitment. They were randomly observed by the lead researcher every week before starting the participant recruitment and every month during data collection. Feedback was provided throughout the trial.

5.3.4 Outcomes

All outcome measures were collected by the blinded assessor using the data-collection form (**Appendix 16**).

5.3.4.1 Primary outcome measure

The Neck Disability Index (NDI) is a patient-reported outcome measure and a valid, reliable and responsive tool in assessing pain and disability of the neck in both acute and chronic conditions (Vernon and Mior, 1991, Pietrobon et al., 2002, Vernon, 2008, MacDermid et al., 2009). The NDI is a self-administered questionnaire that includes ten sections focusing on functional activities such as pain intensity, personal care, lifting, reading, headache, concentration, work, driving, sleeping and recreation (Vernon and Mior, 1991). Each section is scored from zero to five, with five representing the greatest disability. The sum is calculated to indicate the participant's perceived level of disability (Vernon and Mior, 1991). The NDI is a robust predictor of outcome for acute WAD (Walton et al., 2013) and is recommended for monitoring patients with WAD by several clinical guidelines, including the NHS Library, New South Wales Motor Accidents Authority, British Columbia Physiotherapy Association, Royal Dutch Society for Physical Therapy and the South Australian Centre for Trauma and Injury (TRACsa, 2008, Vernon, 2008, Jagnoor et al., 2014). Consequently, several

previous whiplash intervention trials have used the NDI as the primary outcome (Jull et al., 2013, Lamb et al., 2013, Sterling et al., 2015).

5.3.4.2 Secondary outcome measures

Visual Analogue Scale (VAS) for pain intensity

The most common complaint in patients with WAD is pain (Holm et al., 2008). Pain was measured using a 0 mm (no pain) to 100 mm (worst possible pain) Visual Analogue Scale (VAS) (Huskisson, 1974), which is a simple and preferred tool for assessing pain intensity, with high validity and reliability in evaluating acute pain (Bijur et al., 2001, Myles and Urquhart, 2005, Price et al., 2008). The identification of initial pain intensity using the VAS has been found to be an important prognostic factor in predicting poor recovery in patients with acute WAD (Hendriks et al., 2005, Walton et al., 2013).

Cervical Range of Motion (CROM)

Decreasing cervical mobility is a common finding in patients with WADII (Stovner, 1996). Cervical range of motion (CROM) is highly sensitive and can be specifically tested for discrimination between asymptomatic and symptomatic whiplash (Dall'Alba et al., 2001) and for handicap prediction of acute whiplash injury (Kasch et al., 2001). In this trial, the CROM was measured using the cervical range of motion device (Hole et al., 1995). The cervical range of motion device is a highly valid and reliable device in measuring CROM and was attached to the head (Malmstrom et al., 2003, Williams et al., 2010, Williams et al., 2012). The participant sat on a comfortable chair with both hips and knees flexed to 90º. CROM measurements were recorded three

times in each movement direction. The mean of the three measurements was used for data analysis.

Pressure Pain Threshold (PPT)

Pressure pain threshold (PPT) was measured using minimal pressure force to identify the threshold of stimulating pain (Vanderweeen et al., 1996). Patients with WAD frequently reported central hyperexcitability in both acute (≤ one month) (Sterling et al., 2003, Sterling et al., 2004, Fernandez-Perez et al., 2012) and chronic stages (Stone et al., 2013). The investigation of PPT at remote pain-free muscles suggests that a component of hypersensitivity in patients with WAD may come from central sensitisation (Carroll et al., 2008). A digital pressure algometer is a highly valid and reliable instrument, and was used to detect the sensitivity of symptomatic areas and distal pain-free areas (Kinser et al., 2009, Walton et al., 2011). The speed of applied force was 30 kPa/s (Fernandez-Perez et al., 2012). The participants were required to press a button when their sensation changed from pressure to perceived pain (Fernandez-Perez et al., 2012). PPT was assessed at the insertion of the levator scapulae (Fernandez-Perez et al., 2012) and the upper one-third of the tibialis anterior muscle (Walton et al., 2011) on both sides, three times each side, with an interval of one minute between each test (Kardouni et al., 2015, Walton et al., 2014). The mean of the three measurements was used for data analysis. The starting position of the assessment was comfortable upright sitting with hip and knee flex at 90º for the levator scapulae and supine lying with the knee of an assessed side flex at 90º for the tibialis anterior.

Impact of Events Scale (IES)

The Impact of Event Scale (IES) is a valid and reliable 15-item questionnaire assessing current stress and indicating the symptoms of post-traumatic stress (Horowitz et al., 1979, Zilberg et al., 1982, Sundin and Horowitz, 2002) that may contribute to a high risk of persistent symptoms (Richter et al., 2004, Sterling et al., 2005, Buitenhuis et al., 2006, Asmundson and Katz, 2008). The IES has been recommended by some clinical whiplash guidelines for monitoring whiplash management (TRACsa, 2008, Jagnoor et al., 2014).

Fear Avoidance Beliefs Questionnaire (FABQ)

The physical disability of patients with WAD can be influenced by fear avoidance beliefs and associated behaviours following whiplash injury (Pedler and Sterling, 2011, Vernon et al., 2011, Kamper et al., 2012). Patients with dysfunctional illness beliefs need to have these addressed to prevent chronicity (Buitenhuis and de Jong, 2011). The Fear Avoidance Beliefs Questionnaire (FABQ) is a 16-item valid and reliable tool administered to patients with neck pain (Cleland et al., 2008), to assess their perceptions of the impact of physical activity and work on their levels of pain and disability.

EuroQol-5 Dimensions (EQ-5D)

The EQ-5D is a valid and reliable self-report quality of life (QoL) questionnaire (Haywood et al., 2005). It is recommended as a useful tool for measuring generic QoL in order to provide information for cost-effectiveness analysis (Rabin and Charro, 2001). The EQ-5D has been translated into many languages (Luo et al., 2013). For the whiplash literature, the EQ-5D was used to provide information for cost-effectiveness analysis in one large RCT (Lamb et al., 2013).

5.3.5 Assessment of outcome

Blinded assessment of outcomes took place at baseline and at three months post baseline. After three months, the whiplash patients who continued with symptoms and problems were defined as chronic (TRACsa, 2008, Sterling, 2014). In a future definitive trial, the primary endpoint will be three months and the number of recovered WADII patients within three months will be evaluated. Longer-term follow-up is also planned for one year. Participants who did not attend the three-month follow-up assessment were contacted by telephone and asked if they would like to make a new appointment. If they could not make a new appointment, they were asked by the blinded assessor to complete the NDI via telephone interview, a process which has established reliability and validity (Hallal et al., 2010). Additionally, EuroQol-5 Dimensions (EQ-5D), which was reliable for telephone assessment (McPhail et al., 2009), was also completed via telephone assessment.

5.3.6 Feasibility of cost-effectiveness analysis

Direct and indirect medical costs were collected to assess the feasibility of data collection for the planned cost-effectiveness analysis in the definitive trial. Participants received a diary pocket book (**Appendix 17**) to record any activities related to whiplash management such as using medication and consulting other health professionals, along with any costs they incurred, days of sick leave and benefits claimed that related to whiplash management. On the first page of the diary pocket book, general information about the participants (e.g. post code, work status and income) was collected. Costs related to physiotherapy management were collected from the physiotherapy clinics. Training costs of physiotherapists in the experimental ABPI arm were also recorded.

5.3.7 Sample size

As this was a pilot and feasibility trial, a power calculation was not required (Arain et al., 2010). Although establishing targeted sample sizes for pilot/feasibility trials is controversial, it was planned to recruit 60 participants (30 per arm) in order to provide sufficient power of parameters for designing an adequate power randomised controlled trial (Hertzog, 2008). Data from the physiotherapy clinics provided evidence of n = 18 eligible participants available per month across the six private physiotherapy clinics. The recruitment rate of this trial was considered adequate if at least 50% of eligible participants were recruited. Based on this estimate, it was planned to take six to seven months for participant recruitment with a three-month follow-up.

5.3.8 Randomisation

To minimise selection bias at the cluster level, a computer-generated randomisation programme was used by the lead researcher to randomise six private physiotherapy clinics into two groups: standard physiotherapy intervention (n = 3 clinics: Birmingham City, Great Barr and Sutton Coldfield) and the ABPI (n = 3 clinics: Moseley, Solihull and West Bromwich). The allocation was concealed prior to assignment. Only the lead researcher was involved in this process. Cluster randomisation was implemented before participants were recruited.

5.3.9 Data analysis

Phase I: Data were analysed and summarised based on a pre-specified quantitative synthesis to evaluate eligibility, recruitment and follow-up rates. Quantitative data were analysed using IBM SPSS version 22. Descriptive statistics assessed the feasibility of the ABPI for acute WADII management based on the nature

of the pilot and feasibility trial to inform the design of a future definitive trial (see **Table 5.3**) (Thabane et al., 2010). The participants who received other treatments from the initial randomised treatment allocation were not disregarded in the trial and their data were included in intention-to-treat analyses. The primary endpoint of this trial was evaluation of the NDI at three-month follow up. Evaluation of the dropout rate of participants was a criterion to confirm the primary endpoint. The intracluster correlation coefficient (ICC) was also calculated in order to prepare information for sample size calculation within a clustered definitive trial. The analysis and findings of the quantitative data were discussed with the research team at each stage and AWIS steering and data monitoring committee in the meetings.

Phase II: Each individual interview and focus group was transcribed. All transcripts were read several times before the lead researcher made notes and codes. QRS NVivo 10 was employed to identify themes regarding the acceptability of the ABPI to physiotherapists and participants, and how trial procedures and processes worked in practice (Corbin and Strauss, 1990, Hsieh and Shannon, 2005). All data were analysed both deductively (to identify themes) and inductively (to identify additional themes) in line with thematic analysis (Ayala and Elder, 2011, Bos et al., 2013). Preliminary codes were repetitively developed and grouped by the lead researcher using the software, diagrams and tables to finalise themes and subthemes. The analysis and findings emanating from the qualitative data were discussed with the research team at each stage and AWIS steering and data monitoring committee at the end. The mapping and interpretation of the data were used to explore and explain relevant patterns. The

interpretation of qualitative data was carried out in parallel with the quantitative findings.

In the focus group, a key aim of the analysis was to identify any emerging group consensus regarding attitudes toward and experiences of the ABPI (Kitzinger, 1995). The participants' names were not linked to any information in the reporting of findings from the group discussion, and findings were reported for the whole group rather than for individual participants.

Upon completion of the pilot and feasibility trial, the following possible decisions were considered by evaluating the feasibility criteria (**Table 5.3**) for conducting the definitive trial (Thabane et al., 2010):

- Stop if the main trial is not possible or valuable
- Continue but modify the protocol if the main trial is possible and valuable
- Continue without modifications but monitor closely if the main trial is possible and valuable with close monitoring
- Continue without modifications if the main trial is possible and valuable.

Table 5.3: Feasibility assessment criteria

Objectives	Criteria of success
To evaluate the feasibility of procedures (e.g. randomisation, recruitment, collecting data, management and follow-up) (Lancaster et al., 2004, Arain et al., 2010, Thabane et al., 2010, Whitehead et al., 2014)	The trial was considered feasible if it could be run smoothly without serious problems or obstructions that were capable of stopping the study (Lancaster et al., 2004, Thabane et al., 2010)
To investigate the acceptability of the developed intervention (Arain et al., 2010)	The trial was considered feasible if a majority of the physiotherapists and patients found the developed intervention acceptable
To evaluate recruitment rates, refusal rates, retention and adherence of participants in the private sector in the UK (Arain et al., 2010, Thabane et al., 2010)	The trial was considered feasible if ○ ≥ 50% of eligible patients were recruited ○ at least three participants a week per intervention arm were recruited ○ the participants adhere to the physiotherapy programme (e.g. performing tasks/activities and/or exercises based on their physiotherapists' suggestions or prescriptions)
To evaluate dropout rates of participants in the private sector in the UK (Arain et al., 2010, Whitehead et al., 2014)	The trial was considered feasible if ≤ 20% of all recruited participants dropped out
To estimate the required sample for a definitive trial (Gould, 1995, Coffey and Muller, 2003, Arain et al., 2010, Thabane et al., 2010, Whitehead et al., 2014)	The trial was considered feasible if the sample size (the number of targeted participants) for a future phase III definitive trial was feasible to achieve based upon recruitment data
To evaluate the feasibility of data collection for cost-effectiveness analysis (Arain et al., 2010)	The trial was considered feasible if the following components of the cost-effective analysis could be collected with minimal

	missing data (≤ 10%): o General information (e.g. current work status and salary) o Direct medical costs ▪ Medical costs (e.g. physiotherapy, general practice and complementary medicine) ▪ Resource uses (e.g. diagnosis tests) o Indirect medical costs ▪ Participant journey costs ▪ Training costs for physiotherapists in the experimental arm

5.3.10 Trial management and monitoring

The trial was managed by the Trial Management Group consisting of the lead researcher and the supervisor team. The trial combined the Trial Steering Committee and the Data Monitoring Committee functions in line with the nature of the pilot and feasibility trial into the Acute Whiplash Injury Study (AWIS) Steering Group, consisting of an independent chair, an external member, the lead supervisor, a statistical expert, a physiotherapist, a WADII patient and the lead researcher. The AWIS Steering Group met at the start of recruitment (**Appendices 18** and **19**), after three months of recruitment (**Appendices 20** and **21**) and at the completion of data collection (**Appendices 22** and **23**). The lead researcher was qualified in Good Clinical Practice [an achievement from the International Conference on Harmonisation of Good Clinical Practice (ICH GCP), certificate number: 33951-36-41796].

5.3.11 Adverse events

Adverse events in this trial were considered to be of low risk. Firstly, WADII [neck complaint and musculoskeletal sign(s)] is not normally a cause of serious adverse events (Lamb et al., 2013, Michaleff et al., 2014). Secondly, both the ABPI and standard physiotherapy interventions were conservative treatments without existing reporting of serious adverse events (Lamb et al., 2013, Michaleff et al., 2014). Consequently, patients are unlikely to receive any serious harm from either intervention. Generally, only minor adverse events are likely to occur after the physiotherapy intervention. The most common adverse event for the physiotherapy intervention is muscle soreness, which commonly recovers within one or two days (King and Anderson, 2010).

5.3.12 Serious adverse events

This trial had a very low risk of serious adverse events in terms of patient pathology, treatment nature and treatment management. Participants were evaluated by a physiotherapist prior to seeking consent to ensure that the participants were classified as WADII [presented with only musculoskeletal signs, without any neurological signs] to meet the eligibility criteria, thereby excluding patients with high severity WAD. All physiotherapists in this trial managed their patients based on the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT) cervical framework (Rushton et al., 2014a), which provides a framework for clinical reasoning to avoid the risk of any adverse events regarding vascularity and instability of the neck from physical therapy intervention. However, progressive symptoms within three days and being admitted to the hospital due to whiplash problems were reported for serious

adverse events. If any serious adverse events occurred, patients were able to continue with the trial when their symptoms were resolved.

5.3.13 Procedures for reporting adverse and serious adverse events

An adverse event reporting form was provided to all clinics. When a participant experienced any unpleasant symptoms, they were asked to report them to their physiotherapist. The physiotherapist reported any event to the lead researcher within 24 hours. Then, the lead researcher reported to the AWIS Steering Committee within 24 hours to enable analysis of the event and any required action. Although this trial might have a low risk of adverse events, any sign(s) and/or symptom(s) that would cause life-threatening situations, inpatient hospitalisation and significant disability (e.g. inability to work) might occur. Any unexpected serious adverse events were immediately reported with a written form and verbal contact by the physiotherapists to the lead researcher. After that, the lead researcher reported to the AWIS Steering Committee immediately.

5.3.14 Research governance

The trial maintained research governance by using the principles of the Research Governance Framework for Health and Social Care.

5.3.15 Data management

All information collected about and from the participants has been kept safely from any third party to maintain the participants' privacy. All collected documents have been stored in a secure place. All electronic data have also been confidentially stored in

a password-protected computer. Data can only be accessed by members of the research team. The findings will be submitted for publication to medical journals and presented at conferences and local seminars. The trial will only be published in a completely unattributable format or at an aggregate level in order to ensure that no participant can be identified. After completing the trial and publications, all data will be securely destroyed after being kept securely for ten years at the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham.

5.3.16 Ethical and R&D considerations

NHS ethical approval and R&D approval were not required as the trial sites were outside of the UK National Health Service. The insurance/private clinics did not require any other regulatory approval. Support for the trial was put in place by the private clinics and the insurance companies. Ethical approval was provided by the University of Birmingham's Ethics Committee *(ERN_15-0542)* (**Appendix 6**).

Chapter summary

This chapter presents the methodology of the pilot and feasibility trial of the ABPI for acute WADII management in a private insurance setting. The methodology comprised two parallel phases. Phase 1 was an external pilot and feasibility cluster randomised, double-blind (assessor and participants), parallel two-arm (ABPI vs standard physiotherapy) clinical trial to evaluate procedures and feasibility. Six private physiotherapy clinics were recruited and cluster-randomised by a computer-generated randomisation sequence. Sixty participants (30 in each arm) were targeted for recruitment and assessed at baseline and at three-month follow-up post baseline. The

NDI was planned for the primary outcome measure. Phase 2 was an embedded qualitative study using semi-structured in-depth interviews (all physiotherapists in the ABPI arm) and a focus group (all participants who received the ABPI). Descriptive analysis was used to analyse the quantitative data to evaluate the feasibility of the ABPI. Qualitative data was coded and analysed deductively (to identify themes) and inductively (to identify additional themes) in line with thematic analysis to explore the acceptability of the ABPI. The results of the external pilot and feasibility trial (phase I of the methodology) are presented in the next chapter. The findings of the embedded qualitative study (Phase II) are reported in **Chapter 7**.

CHAPTER 6

External Cluster Randomised Double-blind Pilot and Feasibility Trial of the ABPI in a Private Insurance Setting: Results from phase I

Abstract

This chapter presents the quantitative results of an external cluster randomised double-blind, parallel two-arm pilot and feasibility trial of the ABPI in a private insurance setting (phase I of the methodology detailed in **Chapter 5**). This trial was conducted to evaluate the procedures and feasibility of the implementation of the ABPI for acute WADII management. Twenty-eight participants (20 in the ABPI and 8 in the standard physiotherapy arm) were recruited from 240 potential participants. The results are descriptively reported in line with the nature of a pilot and feasibility trial. Furthermore, the related information for cost-effectiveness analysis, sample size calculation, serious adverse events and blinding evaluation are also reported in this chapter. Interestingly, the findings suggest that the ABPI is a potentially effective intervention for preventing patients with acute WADII transitioning to chronicity by consideration of the NDI ≤ 4 (19/20 participants for the ABPI and 1/6 for the standard physiotherapy arm). The considerations in planning for a future phase III definitive trial will be discussed in **Chapter 8**.

6.1 Participant recruitment

Patients were recruited between 06/11/2015 and 01/07/2016 and were followed up for a three-month period across six private physiotherapy clinics. The trial was stopped by the consensus of the AWIS Trial Steering and Data Monitoring Committee owing to the

timescale, budget and the reduction of the number of referrals (**Appendix 21**). Two hundred and forty (136 in the ABPI arm and 104 in the standard physiotherapy arm) potential participants were assessed for eligibility by administrators who were trained to screen and classify patients with acute WADII. Twenty-seven in the ABPI arm and 13 in the standard physiotherapy arm eligible participants were booked to attend initial assessment in order to confirm eligibility, provide consent and enable baseline assessment data to be collected. Unfortunately, seven eligible participants from the ABPI arm and five eligible participants from the standard physiotherapy arm could not attend this initial appointment. Their reasons are provided in **Table 6.1**. Therefore, 28 out of 40 eligible patients with acute WADII gave their consent and were entered into the trial (20/27 [74.07%] in the ABPI arm and 8/13 [61.54%] in the standard physiotherapy arm). The CONSORT diagram (**Figure 6.1**) presents participant progression through the trial.

Table 6.1: Eligible patients interested in participating but unable to attend recruitment

Category of reasons	ABPI arm (n = 7)			Standard physiotherapy arm (n = 5)		
	WB	ML	SH	GB	BC	SC
Travel issues to assessment centres	3	-	-	1	1	-
Work commitment	-	1	2	-	-	2
Booking patients would like to reschedule but unable to book an initial assessment within 4 weeks post injury	-	-	1	-	-	1

WB = West Bromwich, ML = Moseley, SH = Solihull, GB = Great Barr, BC = Birmingham City, SC = Sutton Coldfield

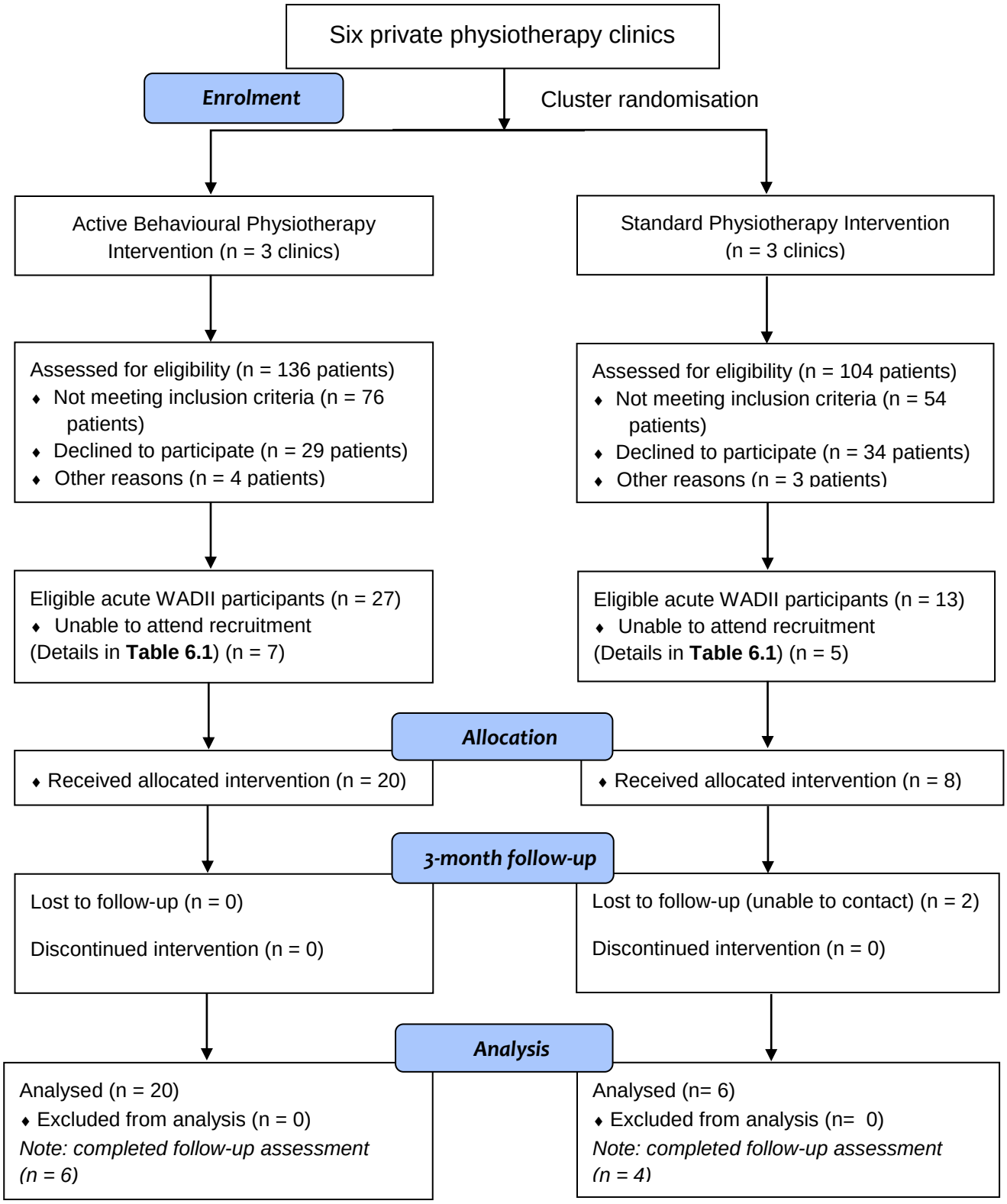

Figure 6.1: CONSORT flow diagram (adapted from CONSORT 2010).

Participant recruitment was temporarily stopped for the Christmas and New Year holiday from 12th December 2015 to 4th January 2016 owing to exceptional and unforeseen circumstances. Specifically, recruitment was curtailed due to the liquidation (from 5th January 2016 to 13th March 2016) of the private physiotherapy company that ran the clinics. Fortunately, in March 2016, one insurance company offered to take over the private physiotherapy company. Following a series of complex negotiations, recruitment was recommenced after a break of three months. Recruitment was initially slow as the new company became established and administrator illness was resolved. The new administrator was trained to screen and identify eligible participants.

Table 6.2 provides the issues affecting participants' decisions to not participate in this trial. There were three main categories of reasons in terms of ineligibility, declining and other reasons. Reasons for patients' ineligibility included: 'post four weeks after road traffic accident', 'serious symptom(s) in other regions of the body besides the neck', 'having treatment with another clinic', 'history of cervical surgery' and 'non-English speaking'. Reasons for potential participants declining included: 'did not want to participate' and 'work commitment'. Other reasons included: 'unable to book initial assessment within four weeks' and 'did not want to travel to assessment centre (different physiotherapy clinic)'.

Table 6.2: Issues affecting participants' decision to not participate (based on administration data)

Category of reasons	ABPI (n = 109)	Standard PT (n = 91)
○ Reasons for ineligibility (obtained from clinical admin team)		
○ Post four weeks after road traffic accident	54	42
○ Serious symptoms in other regions	10	6
○ Having treatment with another clinic	8	4
○ History of cervical surgery	3	2
○ Non-English speaking	1	-
○ Reasons for declining (obtained from patients by clinical admin team)		
○ Did not want to participate	10	12
○ Work commitments	19	22
○ Other reasons		
○ Unable to book initial assessment within four weeks	2	1
○ Did not want to travel to assessment centre (different Physio 1st clinic)	2	2

6.2 Baseline data

6.2.1 Characteristics of participants by intervention arm

The median age of participants was 38.00 (range 22 to 70, IQR: 21.50) years. **Table 6.3** presents the baseline participants' characteristics by intervention arm. The median ages of participants in the ABPI and standard physiotherapy arm were 34.00 (IQR = 16.00, range: 22 to70) and 50.50 (IQR = 18.75, range: 26 to 70), respectively. More males were recruited to the ABPI arm than females (17:3), whereas there were more females than males in the standard physiotherapy arm (2:6). White British was the most common ethnic group represented in both arms.

Table 6.3: Baseline participants' characteristics by intervention arm

Demographic category	ABPI (n = 20)	Standard physiotherapy (n = 8)
Age (range, median (IQR))	22 to 70, 34.00 (16.00)	26 to 70, 50.50 (18.75)
Gender (male:female)	17:3	2:6
Ethnic group	White (n = 9) Asian (n = 7) Chinese or other (n = 2) Black (n = 1) Mixed (n = 1)	White (n = 6) Asian (n = 1) Chinese or other (n = 1)

6.2.2 Characteristics of physiotherapists by intervention arm

Table 6.4 presents characteristics of physiotherapists by intervention arm. The median ages of physiotherapists in the ABPI and standard physiotherapy arms were 27 (IQR = 0, range: 23 to 31) and 28 (IQR = 0, range: 26 to 30) years, respectively. All physiotherapists in the ABPI arm were male. Two Britons qualified with bachelor degrees in physiotherapy and one Greek qualified with a master degree in advanced musculoskeletal physiotherapy delivered the ABPI. One Briton (male) and one Greek (female) qualified with bachelor degrees in physiotherapy and one Greek (male) qualified with a master degree in advanced musculoskeletal physiotherapy delivered the standard physiotherapy. The physiotherapists' duration of experience post qualification was the same in both arms, with a median of three (IQR = 0, range of the ABPI arm: 2 to 4, range of the standard physiotherapy: 2 to 6) years.

Table 6.4: **Characteristics of physiotherapists by intervention arm**

Categories	ABPI (n = 3)	Standard physiotherapy (n = 3)
Age (years) Median (IQR) Range	27.00 (0.00) 23 to 31	28.00 (0.00) 26 to 30
Gender male:female	3:0	2:1
Ethnicity (n =)	British (2) Greek (1)	British (1) Greek (2)
Physiotherapy qualification (n =)	Bachelor (2) Master (1)	Bachelor (2) Master (1)
Physiotherapy years of experience, Median (IQR) Range	3.00 (0.00) 2 to 4	3.00 (0.00) 2 to 6

6.3 Numbers analysed

For each group, all participants were analysed based on their original assigned intervention arms (**Figure 6.1:** CONSORT diagram). There were no missing data.

6.4 Outcomes and estimation

6.4.1 Primary and secondary outcome measures

Primary and secondary outcome measures at baseline and three months are descriptively presented in **Table 6.5**. The figures show that most outcomes (e.g. NDI, VAS (pain intensity), IES, EQ-5D VAS, CROM and PPT) at baseline suggest differences between the intervention arms. These differences could however be caused by the substantial difference of the number of participants in each intervention arm. The differences at baseline could also impact on the recovery of the participants. However, further statistical comparisons cannot be performed owing to the pilot and feasibility trial nature of this trial (Eldridge et al., 2016). It is therefore difficult to conclude whether the differences are significant or not.

At three months, scores on the NDI, VAS (pain intensity), IES, FABQ, and EQ-5D total and subscales were reduced in both trial arms. The only exception was the usual activities subscale of the EQ-5D, where no difference was observed between baseline and three-month follow-up scores in the standard physiotherapy arm. The EQ-5D VAS scores in both trial arms were improved at three months compared with baseline. Similarly, physical assessments (all planes of CROM and PPT of the levator scapulae and tibialis anterior muscles) were improved in both intervention arms.

At the three-month follow-up by intervention arm, the NDI, VAS (pain intensity), IES, ED-5D (total and all subscales) were reduced in the ABPI arm more than in the standard physiotherapy arm. However, the standard physiotherapy arm had a lower score in the FABQ than in the ABPI. The scores of EQ-5D VAS and physical assessments in the ABPI arm were improved more than the standard physiotherapy arm, with the exception of sagittal cervical movement.

The median of difference in each outcome measure is descriptively provided in **Table 6.5 and 6.6**. The NDI, VAS (pain intensity) and EQ-5D total and all subscales in the ABPI arm were reduced more than the standard physiotherapy arm. Moreover, the EQ-5D VAS, CROM all directions and PPT bilaterally for both the levator scapulae and tibialis anterior muscles (except for the left tibialis anterior muscle, which was more improved in the standard physiotherapy arm than in the ABPI arm) were more improved in the ABPI arm when contrasted to the standard physiotherapy arm. However, the psychological outcome measures (IES and FABQ) were reduced more in the standard physiotherapy arm than in the ABPI arm.

At three months post baseline, 19/20 (95%) participants in the ABPI arm were fully recovered (NDI ≤ 4) (Vernon and Mior, 1991, Pool et al., 2007, MacDermid et al., 2009, Jull et al., 2013, Sterling, 2014). In the standard physiotherapy arm, one out of the six participants (~17%) was fully recovered.

Table 6.5: Primary and secondary outcome measures at baseline and three-month follow-up

Outcome measures	ABPI			Standard physiotherapy		
	Baseline (n = 20) Median (IQR)	**3-month Median (IQR)**	**Median of difference (IQR)**	**Baseline (n = 8) Median (IQR)**	**3-month Median (IQR)**	**Median of difference (IQR)**
NDI	17.50 (18.00)	1.00 (2.75) *n=20*	16.50 (17.25)	21.50 (15.50)	8.00 (8.75) *n=6*	6.50 (12.50)
VAS	55.50 (29.50)	3.50 (8.25) *n=6*	48.50 (37.25)	47.00 (31.25)	14.50 (14.75) *n=4*	37.00 (49.75)
IES	29.50 (31.75)	7.50 (30.50) *n=6*	13.50 (22.00)	48.00 (32.25)	26.00 (49.75) *n=4*	24.00 (36.50)
FABQ	60.00 (25.00)	38.00 (19.24) *n=6*	9.50 (33.00)	61.50 (22.25)	25.50 (19.75) *n=4*	22.00 (31.00)
EQ-5D total	11.00 (5.50)	6.00 (1.75)	5.50 (4.75)	10.50 (7.00)	8.50 (4.50)	2.00 (3.00)
Mobility	2.00 (2.00)	1.00 (0.00)	1.00 (1.75)	2.50 (1.75)	1.00 (1.25)	0.50 (1.25)
Self-care	2.00 (1.75)	1.00 (0.00)	1.00 (1.00)	2.00 (0.75)	1.00 (1.00)	0.00 (0.25)
Usual activities	3.00 (1.75)	1.00 (0.00)	1.50 (1.00)	2.00 (1.00)	2.00 (0.25)	0.00 (0.25)
Pain/discomfort	3.00 (0.75)	1.00 (1.00)	2.00 (1.00)	3.00 (1.75)	2.00 (0.50)	0.00 (1.00)
Anxiety/depression	2.00 (2.00)	1.00 (0.00)	1.00 (1.00)	2.50 (1.00)	1.50 (2.50)	0.00 (2.25)
EQ-5D VAS	57.50 (32.50)	98.50 (8.00) *n=20*	27.00 (24.75)	67.50 (45.50)	75.50 (34.75) *n=6*	-2.00 (19.00)
CROM		*n=6*			*n=4*	
Flexion	22.50 (7.67)	46.50 (15.50)	27.67 (14.00)	29.00 (13.24)	47.00 (25.34)	17.34 (21.01)
Extension	22.83 (17.58)	36.50 (30.50)	21.17 (23.59)	19.83 (24.83)	46.33 (24.50)	14.83 (35.33)
Lt. rotation	29.67 (18.33)	54.00 (16.08)	22.00 (28.42)	40.67 (25.01)	49.67 (24.50)	-1.00 (26.00)
Rt. rotation	30.67 (17.83)	53.34 (25.17)	32.00 (26.91)	36.34 (22.16)	45.00 (17.34)	4.34 (12.00)
Lt. lateral flexion	22.34 (13.33)	34.17 (8.67)	11.50 (16.58)	26.00 (12.83)	26.67 (12.67)	1.17 (13.25)
Rt. lateral flexion	22.67 (11.84)	36.50 (10.75)	11.17 (15.50)	22.17 (10.84)	29.34 (8.42)	6.67 (8.08)

Table 6.5: Continued

Outcome measures	ABPI			Standard physiotherapy		
	Baseline (n = 20) Median (IQR)	**3-month Median (IQR)**	**Median of difference (IQR)**	**Baseline (n = 8) Median (IQR)**	**3-month Median (IQR)**	**Median of difference (IQR)**
PPT		*n=6*			*n=4*	
Lt. levator scapulae	74.67 (71.75)	168.67 (180.66)	90.33 (110.99)	58.67 (36.66)	109.34 (71.08)	63.67 (79.67)
Rt. levator scapulae	71.50 (69.66)	197.17 (157.50)	121.50 (118.33)	77.17 (44.00)	134.00 (67.59)	49.67 (83.09)
Lt. tibialis anterior	106.17 (101.08)	223.17 (228.33)	49.84 (129.75)	103.17 (41.08)	168.00 (233.42)	72.67 (192.42)
Rt. tibialis anterior	90.17 (110.34)	211.84 (233.50)	101.01 (105.00)	88.50 (24.51)	163.67 (181.91)	86.00 (160.58)

The trial was unable to collect the secondary outcome measures (except for EQ-5D) where follow-up measurements were taken over the telephone. **Table 6.6** presents secondary outcome measures for participants who attended face-to-face the three-month follow-up assessment. The median scores at three-month follow-up and median of difference for each outcome measure did not change but minimal differences were observed in the median of the baseline scores between **Table 6.5** and **Table 6.6**. These differences are most likely due to variability in the difference of the number of sample sizes.

By considering the difference in the baseline median scores between all participants (**Table 6.5**) and those who attended three-month follow-up face-to-face (**Table 6.6**), the baseline median scores of the latter group in VAS (pain intensity) [median from 55.50 (29.50) (**Table 6.5**) to 58.00 (33.00) (**Table 6.6**)] and PPT of the left levator scapulae [74.67 (71.75) to 75.00 (121.84)] and bilaterally of the tibialis anterior muscles [left 106.17 (101.08) to 124.67 (128.42), right 90.17 (110.34) to 110.67 (157.58)] in the ABPI arm were increased compared with the median baseline of all participants, similarly to the VAS (pain intensity) [47.00 (31.25) to 54.50 (48.00)], IES [48.00 (32.25) to 50.00 (13.25)], CROM extension [19.83 (24.83) to 28.83 (22.51)], transverse cervical movement [left 40.67 (25.01) to 45.34 (11.17); right 36.34 (22.16) to 41.00 (22.67)], left lateral cervical flexion [26.00 (12.83) to 26.67 (3.41)] and PPT of the right levator scapulae muscle [77.17 (44.00) to 79.83 (33.00)] in the standard physiotherapy arm.

However, the baseline median scores of participants who attended face-to-face three-month follow-up in response to the IES [29.50 (31.75) to 25.50 (26.25)], FABQ [60.00 (25.00) to 53.00 (30.00)], CROM all directions [flexion 22.50 (7.67) to 22.33

(9.26), extension 22.83 (17.58) to 18.00 (29.58), left rotation 29.67 (18.33) to 29.00 (21.34), right rotation 30.67 (17.83) to 16.17 (24.67), left lateral flexion 22.34 (13.33) to 21.00 (20.17), right lateral flexion 22.67 (11.84) to 20.33 (21.75)] and PPT of the right levator scapulae muscle [71.50 (69.66) to 69.84 (204.92)] in the ABPI arm and FABQ [61.50 (22.25) to 59.00 (29.75)], CROM flexion [29.00 (13.24) to 26.17 (13.67)], PPT of the left levator scapulae [58.67 (36.66) to 58.50 (32.92)] and bilaterally of the tibialis anterior muscles [left 103.17 (41.08) to 102.67 (61.33), right 88.50 (24.51) to 81.50 (25.34)] in the standard physiotherapy arm were reduced when contrasted to the median baseline of all participants. Only the right cervical lateral flexion shared the same median score (22.17) across these two comparative groups. Within the subgroup of participants who provided face-to-face assessment at the three-month follow-up, five out of six (~83%) participants in the ABPI arm were fully recovered (NDI $\leq$ 4) (Vernon and Mior, 1991, Pool et al., 2007, MacDermid et al., 2009, Jull et al., 2013, Sterling, 2014). In the standard physiotherapy, no (0/4) participants were found to be fully recovered (NDI $\leq$ 4).

Table 6.6: Secondary outcome measures at baseline and three-month follow-up of attending face-to-face follow-up participants

Outcome measures	ABPI			Standard physiotherapy		
	Baseline (n = 6) Median (IQR)	3-month (n = 6) Median (IQR)	Median of difference (IQR)	Baseline (n = 4) Median (IQR)	3-month (n = 4) Median (IQR)	Median of difference (IQR)
VAS	58.00 (33.00)	3.50 (8.25)	48.50 (37.25)	54.50 (48.00)	14.50 (14.75)	37.00 (49.75)
IES	25.50 (26.25)	7.50 (30.50)	13.50 (22.00)	50.00 (13.25)	26.00 (49.75)	24.00 (36.50)
FABQ	53.00 (30.00)	38.00 (19.24)	9.50 (33.00)	59.00 (29.75)	25.50 (19.75)	22.00 (31.00)
CROM						
Flexion	22.33 (9.26)	46.50 (15.50)	27.67 (14.00)	26.17 (13.67)	47.00 (25.34)	17.34 (21.01)
Extension	18.00 (29.58)	36.50 (30.50)	21.17 (23.59)	28.83 (22.51)	46.33 (24.50)	14.83 (35.33)
Lt. rotation	29.00 (21.34)	54.00 (16.08)	22.00 (28.42)	45.34 (11.17)	49.67 (24.50)	-1.00 (26.00)
Rt. rotation	16.17 (24.67)	53.34 (25.17)	32.00 (26.91)	41.00 (22.67)	45.00 (17.34)	4.34 (12.00)
Lt. lateral flexion	21.00 (20.17)	34.17 (8.67)	11.50 (16.58)	26.67 (3.41)	26.67 (12.67)	1.17 (13.25)
Rt. lateral flexion	20.33 (21.75)	36.50 (10.75)	11.17 (15.50)	22.17 (16.00)	29.34 (8.42)	6.67 (8.08)
PPT						
Lt. levator scapulae	75.00 (121.84)	168.67 (180.66)	90.33 (110.99)	58.50 (32.92)	109.34 (71.08)	63.67 (79.67)
Rt. levator scapulae	69.84 (204.92)	197.17 (157.50)	121.50 (118.33)	79.83 (33.00)	134.00 (67.59)	49.67 (83.09)
Lt. tibialis anterior	124.67 (128.42)	223.17 (228.33)	49.84 (129.75)	102.67 (61.33)	168.00 (233.42)	72.67 (192.42)
Rt. tibialis anterior	110.67 (157.58)	211.84 (233.50)	101.01 (105.00)	81.50 (25.34)	163.67 (181.91)	86.00 (160.58)

6.4.2 Information regarding cost-effectiveness

Table 6.7 provides information about the cost-effectiveness of the two treatment arms, and illustrates that the number of treatment sessions and physiotherapy management costs in the ABPI arm were lower than in the standard physiotherapy arm. However, the physiotherapists in the ABPI were trained to deliver the intervention, which cost approximately £200.

Table 6.7: Cost-effectiveness information

Categories	**ABPI (n = 20)**	**Standard physiotherapy (n = 8)**
Treatment sessions (median, IQR)	4.00 (4.00)	6.00 (4.50)
Physiotherapy costs (median, IQR)	£ 90.00 (70.00)	£ 120.00 (75.00)
Physiotherapists' training costs	£200	-

Table 6.8 presents the information from the participants' diary pocket books. Only two participants in the ABPI arm returned their diary pocket book. Both participants were employed and one had an annual income of £10,000 to £19,999 and the other £30,000 to £39,999. Sick leave payment was provided by their employer in each case. One participant left her work for nine days while taking some medication. She visited her general practitioner (GP) three times and paid £16.80 for the medication. None of the participants in the standard physiotherapy arm returned their diary pocket book.

Table 6.8: Information from participants' diary pocket books

Categories	Participant 1	Participant 2
Current work status	Employed	Employed
Annual incomes	£10,000–£19,999	£ 30,000–£39,999
Employer's sick pay	Yes	Yes
The amount of sick leave	9 days	-
Taking medications	Analgesics 83 tablets Relaxants 15 tablets	-
Visit with general practitioner (GP)	3	-
Drug costs	£16.80	-

6.4.3 Coefficient of intracluster correlation (ICC) and sample size calculation for a cluster RCT

One of the important aims of conducting a pilot and feasibility trial is calculating the required sample size for a future definitive trial. In accordance with the pilot and feasibility trial, ICC was calculated to inform the design effect or inflation factor prior to calculation of the sample size for a cluster RCT.

- ICC or ρ was calculated based on the following equation:

$$\text{ICC or } \rho = \frac{s_b^2}{(s_b^2 + s_w^2)}$$

$$= \frac{(16.574)}{(16.574) + (25.367+3.116)}$$

$$= 0.368$$

Note: *S_b^2 = variance between clusters and S_w^2 = variance within clusters of the NDI based on the findings of this pilot and feasibility trial*

- Design effect (DE) or inflation factor was calculated based on the following equation: DE = 1+((m-1)*ICC)

  = 1+ ((10-1)*0.368)

  = 1+3.312

  = 4.312

  Note: *m = cluster size*

- Individual RCT sample size calculation was calculated based on the following equation:

Individual sample size calculation = $f(\alpha, \mathrm{P})\frac{2\sigma^2}{(\mu_1-\mu_2)^2}$

= f(0.05, 90%)* [(2*(16.574)/(4)^2]

= 10.5*(33.148/16)

= 21.75 ~ 22 patients per arm

Note: *Power =90%, significance level = 0.05, difference of NDI = 4*

The difference NDI = 4 can potentially differentiate between no (complete recovery NDI ≤ 4) and mild disability (NDI = 5-14) based on the results of this pilot and feasibility trial (NDI = 1 at three-month follow-up in the ABPI) (Vernon and Mior, 1991). Additionally, the cut-off point of the NDI ≤ 4 also is supported by the study of Pool et al. (2007) for patients with non-specific neck pain. However, the minimal clinically important difference (MCID) can also be used to inform the sample size. However, the MCID of the NDI is quite variable, for example, ≥ 8 for neck surgery

(Carreon et al., 2010) and 11 for non-specific neck pain (Pool et al., 2007) affecting its value.

- The sample size under cluster RCT = DE*individual sample size

  = 4.312*44

  = ~ 190 patients

Based on an estimation of loss to follow-up of 20%, the required sample size for a definitive cluster RCT is 238 patients. Therefore, the required number of clusters is ~24 physiotherapy clinics based on the cluster size (m = 10).

Table 6.9 provides a range of optional sample sizes for a cluster RCT by changing cluster size and difference of NDI scores. The calculations demonstrate that the sample size correlates positively with the cluster size and negatively with the difference of NDI. Actually, the sample size correlates positively with the power (β**)** and negatively with significance level (α). Although β = 80% can be accepted in some trials, β = 90% is recommended in order to increase the quality of the study and confidence in the findings. The calculations illustrate the importance of considering the different options in conducting a future definitive trial because different parameters of the sample size calculation will inform very different pragmatic choices for a cluster RCT regarding number of participants and physiotherapy clinics. For example, a difference in the sample size of a cluster RCT between n =120 (the difference in NDI = five) and n = 190 (the difference in NDI = four) at a cluster size of ten will lead to a difference in seven regarding the number of required physiotherapy clinics (n = 12 and 19, respectively).

Table 6.9: Optional sample size for a cluster randomised controlled trial by changing cluster size and difference of NDI

Cluster size	A = 0.05, β = 90%, Difference of NDI = 8 Individual SS =12	A = 0.05, β = 90%, Difference of NDI = 7 Individual SS =14	A = 0.05, β = 90%, Difference of NDI = 6 Individual SS =20	A = 0.05, β = 90%, Difference of NDI = 5 Individual SS =28	A = 0.05, β = 90%, Difference of NDI = 4 Individual SS =44
10 DE = 4.312	SS = 52 patients	SS = 60 patients	SS = 86 patients	SS = 120 patients	SS = 190 patients
20 DE = 7.992	SS = 96 patients	SS = 112 patients	SS = 160 patients	SS = 224 patients	SS = 352 patients
30 DE = 11.672	SS = 140 patients	SS = 164 patients	SS = 234 patients	SS = 326 patients	SS = 514 patients
40 DE = 15.352	SS = 184 patients	SS = 214 patients	SS = 308 patients	SS = 430 patients	SS = 676 patients
50 DE = 19.032	SS = 228 patients	SS = 266 patients	SS = 380 patients	SS = 532 patients	SS = 838 patients

SS = sample size, DE = design effect or inflation factor, α = significance level, β = power

6.4.4 Serious adverse events

No serious adverse event was reported in this trial.

6.4.5 Blinding evaluation

The views of both participants and assessor were evaluated at three-month follow-up in regard to the effectiveness of blinding of this trial. We found that neither the participants (who attended face-to-face three-month follow-up) nor the assessor knew what intervention arm each participant was allocated to in the trial.

Chapter summary

Although the number of recruited participants did not reach the targeted sample size (n = 30 in each arm), the findings suggested that the ABPI is a potentially effective intervention for preventing patients with acute WADII from progressing to chronicity (NDI $\leq$ 4; 19/20 for the ABPI arm and 1/6 for the standard physiotherapy arm). As this is a pilot and feasibility trial, results were descriptively reported. We can see that the results in the ABPI arm appear to be more positive than results in the standard physiotherapy in terms of scores in the NDI, VAS, EQ-5D, CROM and PPT whereas responses to the IES and FABQ in the standard physiotherapy appear to be more positive than results in the ABPI arm. According to the limited information from the cost-effectiveness analysis, the number of treatment sessions and physiotherapy costs were less than in the standard physiotherapy. The findings of the embedded exploratory qualitative study (phase II of the methodology) regarding the acceptability of the ABPI for physiotherapists (semi-structured in-depth interviews) and patients (a focus group) are provided in the next chapter.

CHAPTER 7

Acceptability of the ABPI to Physiotherapists and Patients with WAD II: Findings from the embedded qualitative study (phase II)

Abstract

The chapter presents the findings of the embedded qualitative study (phase II of the protocol detailed in **Chapter 5**) that explored the acceptability of the ABPI to physiotherapists and patients with WADII. After completion of the external pilot and feasibility trial, individual semi-structured interviews and a focus group were conducted to explore all physiotherapists' (n=3) and patients' (n=20) perceptions, respectively. Participants' (physiotherapists and patients) characteristics and the findings (presented as themes, subthemes and quotes) are presented. The findings illustrated that the ABPI can be acceptable to physiotherapists and patients with WADII. However, the focus group has a substantial limitation owing to only one patient participating.

7.1 Individual semi-structured interviews

Three male physiotherapists (median age 27 (IQR = 0.00) years, range: 23 to 31) were interviewed in their clinics (**Appendices 24** to **26** for the transcripts). Two of them were qualified with a bachelor degree in physiotherapy, and were of British background. The third was qualified to masters level with an MSc in Advanced Musculoskeletal Physiotherapy, and was of Greek background. The median of physiotherapy experience

was three years (IQR = 0.00, range: 2 to 4). **Table 7.1** presents the characteristics of individual physiotherapists.

Table 7.1 Characteristics of individual physiotherapists

Characteristics	Physio A	Physio B	Physio C
Age	27	23	31
Ethnicity	Greek	British	British
Physiotherapy qualification	Master	Bachelor	Bachelor
Physiotherapy experience	3 years	2 years	4 years

Themes and subthemes are diagrammatically summarised in **Figure 7.1**. Quotations for each theme and subtheme were tabulated **(Tables 7.2–7.5)**. The text provides narrative summaries of the emergent themes and refers to the tables for illustrative quotations from participants. Within the individual semi-structured interviews with the three physiotherapists who delivered the ABPI, details were obtained with regard to the ABPI contents, barriers to usage, distinctiveness and acceptance.

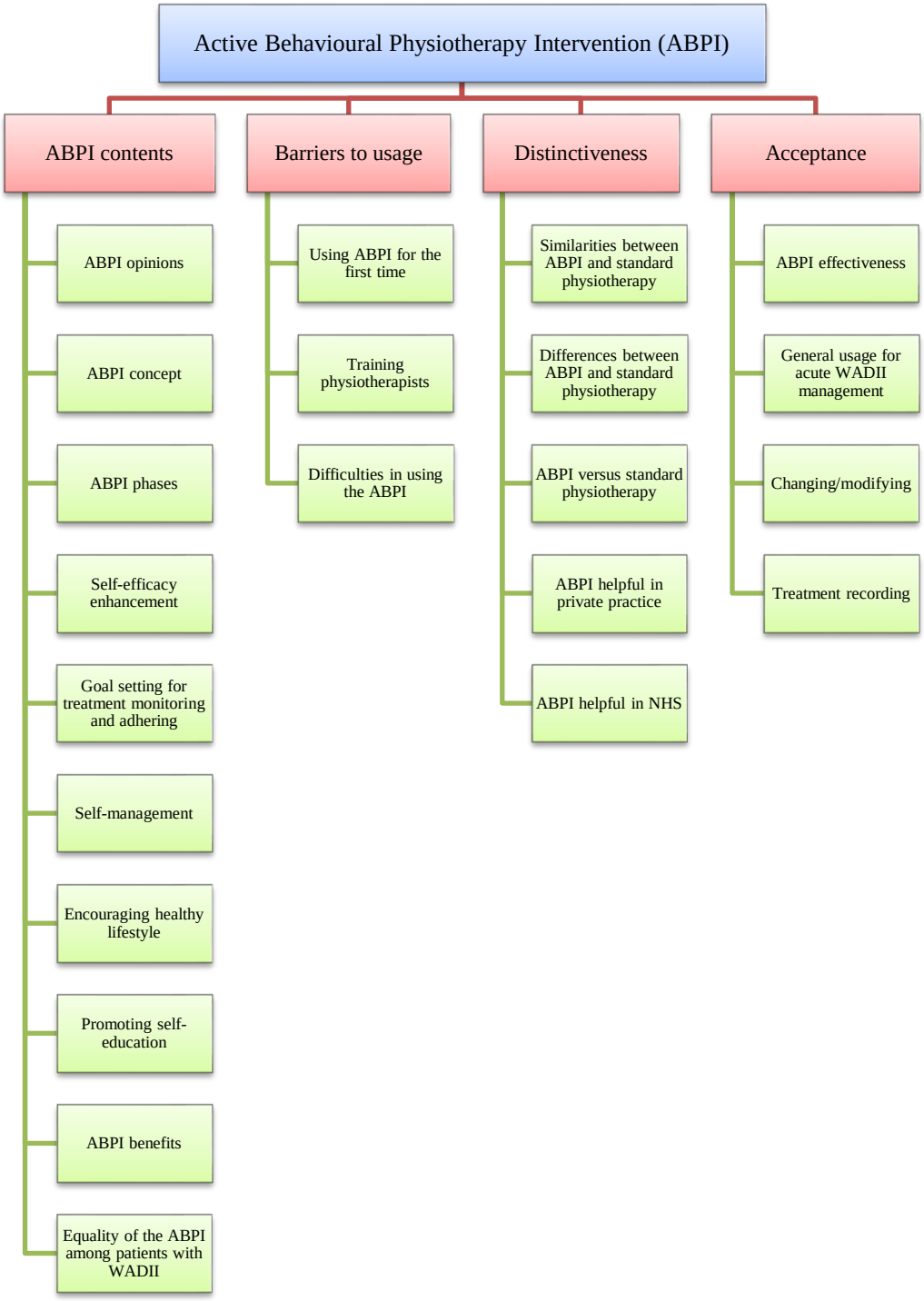

Figure 7.1: Physiotherapists' perceptions, experiences, opinions and attitudes regarding the ABPI.

7.1.1 Theme 1 – ABPI contents (Table 7.2)

ABPI opinions (subtheme 1)

All physiotherapists who delivered the ABPI thought that it was a useful intervention for managing acute WADII patients. The ABPI helped them in exploring and managing patients with acute WADII in regard to both physical and psychological issues (physiotherapist A, **Table 7.2**, **subtheme 1**). Physiotherapists usually focus on physical impairment and trying to reduce pain and improve physical function. Using the ABPI, patients' opinions, feelings and whatever they would like to achieve through physiotherapy were quantified/objectified to guide physiotherapists in managing their patients (physiotherapist B, **Table 7.2**, **subtheme 1**). Physiotherapist C described the ABPI as being good for people who were not confident about their recovery (**Table 7.2**, **subtheme 1**). Therefore, it can be seen that the ABPI can help physiotherapists to understand and be aware of patients' concerns and/or how patients are feeling about managing their problems.

ABPI concept (subtheme 2)

All of the physiotherapists felt that the ABPI was based on logical concepts and provided a clear pathway with easy-to-recognise stages for managing patients with WADII (**Table 7.2**, **subtheme 2**). Using the enhancement of self-efficacy to complete the targeted goal/task motivated patients to stay active and adhere to their treatment programme (**Table 7.2**, **subtheme 2**). The ABPI was described as "*a good flexible framework for physiotherapists*" by physiotherapist B (**Table 7.2**, **subtheme 2**). Physiotherapist A said: "*the ABPI tried to guide patients to be better using two different ways (physical and psychological) at the same time*" (**Table 7.2**, **subtheme 2**). The concept of the ABPI, based on the enhancement of self-efficacy and logical steps of management, was therefore felt to

be useful for physiotherapists in managing patients with acute WADII in regard to both physical and psychological challenges at the same time.

ABPI phases (subtheme 3)

All physiotherapists thought that the ABPI had logical phases in terms of understanding, maturity, stamina and coping. They found that most treatment sessions were used in the understanding phase rather than other phases (**Table 7.2**, **subtheme 3**). Physiotherapist A said: "*I had to decide how much knowledge I should give to patients in each visit based on individual conditions*" (**Table 7.2**, **subtheme 3**). Physiotherapist C found that the understanding phase was very important at the beginning (**Table 7.2**, **subtheme 3**). After the understanding phase (the reduction of psychological stress and barriers between practitioners and patients), the physiotherapists felt that their patients went through the other phases very quickly (physiotherapists A and B, **Table 7.2**, **subtheme 3**).

Self-efficacy enhancement (subtheme 4)

All physiotherapists found that the enhancement of self-efficacy was useful for the management of acute WADII (**Table 7.2**, **subtheme 4**). Physiotherapist B said: "*self-efficacy had a massive role in recovery*" (**Table 7.2**, **subtheme 4**). Physiotherapist A found that "*ABPI helped patients to get more and more self-efficacy*". Consequently, patients were much more adhered to the physiotherapy treatment (physiotherapist C, **Table 7.2**, **subtheme 4**). Performance accomplishment, emotional state and verbal persuasion were mentioned as the most powerful sources for the enhancement of self-efficacy level by physiotherapists C, B and A, respectively (**Table 7.2**, **subtheme 4**).

Goal setting for treatment monitoring and adhering (subtheme 5)

Goal setting was deemed to be a useful strategy in managing patients with acute WADII. Physiotherapist A said: "*goal setting or targeting helps the directions of the treatment*" (**Table 7.2**, **subtheme 5**). Goal setting was also helpful for patients in enhancing their self-efficacy level (physiotherapists A and C) and adhering to physiotherapy programmes (all physiotherapists, **Table 7.2**, **subtheme 5**). Moreover, it was a good strategy for reminding physiotherapists what their patients needed to achieve and reminding patients what they needed to do in their home programmes, and both were reported to lead to more positive results (all physiotherapists, **Table 7.2**, **subtheme 5**).

Self-management (subtheme 6)

The ABPI had a substantial positive impact on self-management. All physiotherapists gave home exercise programmes/tasks to their patients (**Table 7.2**, **subtheme 6**). The physiotherapists demonstrated some examples of their patients' home exercise programme in the clinic to make sure that their patients implemented exercises correctly when in their home (physiotherapist A, **Table 7.2**, **subtheme 6**). All physiotherapists said it was important to motivate patients to self-manage appropriately (e.g. in terms of exercising, controlling pain and increasing their confidence in some activities outside of the clinic) because they saw their patients once or twice a week (**Table 7.2**, **subtheme 6**). Hence, they perceived that self-management was an important element for a more rapid and complete recovery.

Encouraging healthy lifestyle (subtheme 7)

The encouragement of a heathy lifestyle was perceived to be a good strategy to promote long-term positive outcomes. Sometimes patients did not want to move their head and neck after whiplash injury. All the physiotherapists involved in this trial tried to encourage their patients to adopt a healthy lifestyle by using advice and education (**Table 7.2**, **subtheme 7**). Physiotherapist B said he took patients in to the gym and did some exercises with them, while providing some knowledge about pain and exercises (**Table 7.2**, **subtheme 7**). Physiotherapist C suggested that the promotion of a healthy lifestyle should be considered for each individual patient (**Table 7.2**, **subtheme 7**). Motivating patients to take part in some active activities was felt to be a good strategy (physiotherapist A, **Table 7.2**, **subtheme 7**) because once the patients had seen the benefits, they were more likely to continue to stay active and engage in other healthy behaviours.

Promoting self-education (subtheme 8)

There were several strategies to promote self-education for a long-term healthy lifestyle. Twitter, YouTube, articles and websites were perceived as being useful in educating patients with WADII (physiotherapists B and C, **Table 7.2**, **subtheme 8**). However, the physiotherapists felt that some sources should be checked in order to guide the patients in the right direction with accurate information (physiotherapist C, **Table 7.2**, **subtheme 8**). The physiotherapists suggested that they might give certain information (e.g. suggesting some good-quality articles or websites) at the beginning about how to adopt a healthier lifestyle to facilitate their patients to continue with self-education (physiotherapists B and C, **Table 7.2**, **subtheme 8**). For example, physiotherapist C demonstrated and described symmetrical exercises including giving feedback and

explaining the benefits to encourage exercises and healthy behaviours (**Table 7.2**, **subtheme 8**). Physiotherapist A found that his patients continued with their self-education after they saw the benefits of staying active or maintaining a healthy lifestyle (**Table 7.2**, **subtheme 8**).

ABPI benefits (subtheme 9)

The ABPI helped physiotherapists to explore and treat both the physical and psychological issues and challenges faced by their patients in order to manage them towards making a full recovery (**Table 7.2**, **subtheme 9**). Normally, physiotherapists focus on only physical problems (physiotherapists A and C, **Table 7.2**, **subtheme 9**). For example, physiotherapist C mentioned that "*sometimes, without the ABPI, physio will make movement better, just make muscles feel more relaxed*" (**Table 7.2**, **subtheme 9**). The ABPI encouraged physiotherapists to look more widely at both the physical and psychological aspects. Some physiotherapists expressed the feeling that the ABPI broadened their practice, e.g.: "*I get to know more things that I never thought about them...I never thought we could use these kinds of things in our daily practice*" (physiotherapist A, **Table 7.2**, **subtheme 9**) and "*It is something which I didn't see early in my career...it took me wider*" (physiotherapist B, **Table 7.2**, **subtheme 9**). One perceived advantage of the ABPI was that it helped physiotherapists to be aware of what their patients wanted and what they should do (physiotherapists B and C, **Table 7.2**, **subtheme 9**). Once the patients had achieved their expectation, it was felt that they would continue to change their behaviours based on their physiotherapists' suggestions to be healthier if they were not active people (physiotherapist A, **Table 7.2**, **subtheme 8**). If someone was already active, they might maintain their motivation and continue to be active following their injury and

treatment. Therefore, it was perceived that the ABPI can drive patients with WADII to adopt and maintain a healthy lifestyle as a long-term goal.

Equality of the ABPI among patients with WADII (subtheme 10)

The physiotherapists perceived that the ABPI can work for all patients with WADII (**Table 7.2**, **subtheme 10**). However, the speed of recovery using the ABPI was perceived to vary depending on the individual patients (physiotherapist B, **Table 7.2**, **subtheme 10**)**.** Physiotherapist C said: "*the ABPI was brilliant for people who weren't very confident in getting back to normal*" (**Table 7.2**, **subtheme 10**). Physiotherapist C felt that the ABPI did not have a big impact on people who were already active and wanted to get back to being active quickly (**Table 7.2**, **subtheme 10**).

Table 7.2: Theme 1 – ABPI contents by physiotherapists

Subthemes	*Quotations*	Interviewee
1. ABPI opinions	*"It was quite helpful to use the ABPI with my patients. The ABPI helps me to understand and how to explore and manage patients' problems in both physical (e.g. neck, lower back) and psychological (e.g. fear avoidance, anxiety and depression)."*	A
	"I think ABPI is definitively a good strategy/intervention as it allows us to quantify/objectify the subjective opinions of patients and how their feelings before the management…As physios we tend to use things such as pain as a scale measurement. This has made me focus on function more."	B
	"I think that the biggest part is that the ABPI is brilliant for people who aren't very confident in getting back to normal."	C
2. ABPI concept	*"We do not only focus on physical management (e.g. reducing pain or increasing ROM) but we have to focus on and think what is going on in patients' minds…As physiotherapists, we know that the main goals are pain and disability. However, patients may think their main goals are driving, going back to work or going back to the gym. Setting goals and then trying to achieve each goal using the enhancement of the level of self-efficacy was useful for acute WADII management…The ABPI tries to guide patients to be better using two different ways (i.e. physical and psychological) at the same time. It is logical in managing WADII patients…The ABPI tries to motivate the patients to stay active by using psychological strategies to make patients confident about completing each goal/task."*	A
	"I think the ABPI is a good concept and logical strategy… The ABPI system is a clear pathway with easy-to-recognise stages… It is a good flexible framework to use for physiotherapists…If we can push them to do functional tasks and return to previous activities, their confidence will skyrocket and naturally pain/awareness of symptoms is likely to fade."	B

	"I think the ABPI concept has logical steps, especially with whiplash injury. We try to convince them to move and realise there will be pain. It is the right thing to do, which is always the first step for me…I think it puts some more emphasis on themselves to go away and do it. I think it is worth it (ABPI) is motivational technique not just you know not only beneficial treatment WAD but make them some more logical to carry out treatment as well."	C
3. ABPI Phases	*"The phases of the ABPI in terms of understanding, maturity, stamina and coping are quite logical to follow in managing patients with acute WADII. At the beginning, it seems to be that there was a lot of information to educate patients. I had to decide how much knowledge I should give to patients in each visit based on individual conditions…The number of treatment sessions was used in understanding and maturity phases rather than stamina and coping phases. After the psychological factors were reduced, physical functions were improved easily…No more than three sessions in each phase. The average treatment sessions for the understanding and maturity phases were one or two sessions."*	A
	"I think there are good phases…The number of sessions in each phase is so variable among the patients. Well! As a physio, you get a lot of patients who are nervous and they will be at the understanding phase for a lot longer."	B
	"I feel the understanding phase is certainly very very important initially. For my treating people, I think initially that the understanding part can be the longest time sometimes, often. And then I would say move out to maturity and they can quite quickly go to stamina and straightaway they go into coping…it (ABPI) is all my such a right ball moment for a lot of patients."	C
4. Self-efficacy enhancement	*"…the enhancement of the level of self-efficacy was useful for acute WADII management…I think that verbal persuasion (e.g. making patients understand whiplash injury, how this would affect their life, building their motivation and bringing them back to everyday routine) is the most important source…After patients see the benefits in each assessment, they get more and more the level of self-efficacy…the ABPI helps patients to get more and more self-efficacy."*	A

	"In my experience, the patients' emotional state will have a large impact on recovery following WADII. Once I have built a rapport with the patient and we have a level of trust, verbal persuasion can be useful. Then, if we're pushing them to do something, they're doing a task to get performance accomplishment then it is brilliant...In summary, I think self-efficacy has a massive role in recovery."	B
	"Yes, definitely (the self-efficacy enhancement is useful for acute WADII management). I think it is a really good way to measure how they feel…Their home mood is a lot more positive…I think when we break down to small jumps or goals and keep achieving it will make them feel much better. They will be a lot more compliant with the treatment because they can see the improvement. I would say performance accomplishment is the most effective for the self-efficacy enhancement…you know the verbal persuasion is good maybe as a physiotherapist suspect, how good physiotherapist you are. But for them, I think what they see, what they feel, they set themselves a target and then they achieve it. I think straightaway it is a lot more possible for them."	C
5. Goal setting for treatment monitoring and adhering	*"The goal or target helps the directions for the treatment…Setting goals and then trying to achieve each goal using the enhancement of the level of self-efficacy was useful for acute WADII management…For example, one patient had a problem with his driving. His goal was to try to gain confidence in driving. The first time his self-efficacy in driving was 5/10. The second time, his self-efficacy was 6/10. The most important thing was that the patient felt more and more confident in his driving and physiotherapy programme. We can see that goal setting is helpful to enhance the level of self-efficacy and comply with the physiotherapy programme…When patients see the benefits of the treatment, the treatment progression can move quickly."*	A
	"It (goal setting) is the key. Earlier in my career, I would tend to see patients and would set goals but never really look at them again until the last session once we are going to discharge. You can lose track of where you are, what you're heading towards. As I have developed as a physio, I always keep the patients' goal in my mind and focus my treatment on achieving patient goals…it (goal setting) keeps the patients focused on what they want to	B

	achieve. It tends to get the patient to be more positive about their rehabilitation, their achievement and their goals. They are a lot happier with how they're progressing on their own, a lot more cognitive about treatment and their general progress is faster."	
	"…it (goal setting) is a lot more effective than me just saying your movement is 10% better to them, it doesn't really mean anything. When they say now, I am able to lift, this is work as well and it is not aggravating. That is much more beneficial for them…I think when we break down to small jumps or goals and keep achieving it will make them feel much better. They will be a lot more compliant with the treatment because they can see the improvement…Goal setting is helpful to enhance self-efficacy, especially performance accomplishment. If you set them a target and say let's get you back into swimming, for example. They got a goal, you gonna do two lanes maybe something very simple. When they do that it doesn't make it worse and anything feel better. Then they would apply that to other things such as their job…Although we set goals for them, I often hear they may say I also do this and try to do this, this and this. They understand the concept very quickly and then apply it by themselves to multiple tasks. They start to use the technique by themselves, it is really really good."	C
6. Self-management	*"It was quite important. After the patients leave the clinic, they have to practise a lot. In the clinic, we did some examples to make sure that the patients did it correctly. The self-management was quite beneficial for patients because they had to practise it daily. They had to know how to exercise, control pain and increase their confidence in some activities (e.g. driving). The ABPI was helpful for self-management."*	A
	"I found if we continually push and explain that active is always better than passive. Patients tend to be happier with self-management if you have done this. For the first day of whiplash patients, I normally highlight I can give you a temporary benefit, but if you want to get permanent benefits and quicker, you are going to do your exercises at home. This is the key thing. As long as from the first session we do that they tend to be very happy."	B
	"They will have big impacts on their recovery if they do the right things at home. I think that was brilliant about the ABPI. I think it does raise their awareness of what they need to do on	C

	a daily basis at home for their self-management. It puts a lot more on it for them. I feel they do take a lot more responsibility for it. Especially set in goals that they want to achieve, it is not necessarily the case that we want them to achieve them. They feel a lot more about hitting their targets. That is very good self-management and I will say motivation to keep doing the right things at home…We see them maybe once a week sometimes twice a week. They should really do the right thing every single day."	
7. Encouraging healthy lifestyle	*"After the whiplash, people did not want to move their head so much. Thus, I encouraged them to move and stay active. At the beginning, some symptoms might be aggravated but in the long term it was quite helpful."*	A
	"We have to try to make a difference to patients' lifestyle. For some patients, it will work. So, for a lot of them, it tends to be the things like weight loss not exercises. I will often get them into the gym with me. We can practise so they know they are going to be fine. If I can't get them to want to change, it could reflect on myself as a practitioner…I usually encourage my patients and say 'exercise is the best medicine'…You typically get a bit older patients, maybe 60 to 70, who think, Oh! I'm too old to exercise. Our doctor said I shouldn't do sport anymore or I shouldn't do anything on my knees anymore. We can remind them in a positive encouraging manner. Actually, we've come a long way from when they are probably told that and we go with the complete approach that often something tends to save them. I don't give you a tablet but I fix all your problems. The close thing that we have, and you can look at any textbooks and ask any doctors, is exercise. I think that one thing which I tend to find is a good rapport to try to encourage patients…If the patients say I am not sure I can go to the gym, I will get them to the gym and straightaway with me and go to do exercises and will talk about pain they may have."	B
	"I suppose some patients are very good at taking on the advice. I found it sometimes is difficult. Sometimes, some people may feel they are criticised in some ways. It can be a difficult area to talk to some people. I think most people are quite happy to receive the advice, often they ask for some advice about a healthy lifestyle from us…For them what they need to do is just improve what they can already do. I think it is a lot more beneficial rather	C

	than compare themselves with other people. As long as they can increase what they should do, they will be better for it. I think it is good in that way to be more specific to each patient."	
8. Promoting self-education	*"I tried to motivate my patients to be healthy people, stay active and get back to their everyday routine. After they saw some benefits, they continued finding some information by themselves."*	A
	"Different patients will have different understanding and levels of interest. Some might try, I'm gonna go home and then they're gonna trust your words. They're gonna read research around them. When you identify those patients to our routine and then find the way to motivate them, I found the really good resources I often use are Twitter or YouTube…I give them access to some world leaders, put it into English terms not physio medical terms. I would then encourage them to view resources. I also build up as I am doing some symmetrical exercises. I explain how that works and I give them consistent feedback about what I am doing. It is not just a case of our physio gives me an exercise, I got to do it. It is a case of our physio gives an exercise because it will help A, B, and C…Sports people are the easiest job in the world to treat. They want to know everything about their body and how to improve. So, I typically see a lot of bodybuilders, e.g. weightlifters. You can introduce a bit of bone and you know they will come back with everything about that topic because they feel it will help them to improve. This makes adherence to treatment much easier."	B
	"I do sometimes make patients aware to always check sources you get information from because there are a lot of conflicts and opinions. Some of them found it in anywhere, it is very much opinion based. ..The best thing that we do, we try to direct them to certain articles and websites which are of good quality. ..We are more than happy for them to want to do that. It is important to try to guide them in the right direction, right information for them."	C
9. ABPI benefits	*"I get to know the patients a little bit better. I get to know more about patients' problems both physical and psychological. We have to manage both perspectives, not only just physical symptoms in order to make patients better or completely recover…it (ABPI) is*	A

	helpful in managing patients with acute WADII. The ABPI helps me to explore patients' background, physical and psychological problems. Also, the ABPI guides how to sort out patients' problems in both perspectives. The combination between physiotherapy and psychological strategy is really helpful…I get to know more things that I never thought about them. I never thought we could use these kinds of things in our daily practice."	
	"APBI does make the therapist constantly rethink where the patient is in rehab and adjust treatment strategies accordingly. Just allow more objectivity in using more outcome measures, always positive for physiotherapy…I like the ABPI. It has helped me as a physio. It is something which I didn't see early in my career. It took me wider. When the first time, I cannot treat it to what I want it. Forget about the goals during the treatment. It really makes you focus on that patient's goals and within treatment what physiotherapists should be."	B
	"I think it (ABPI) fits quite well into WAD treatment sessions …I think it gives me a little bit more responsibility for what patients need to do. Sometimes, without the ABPI, the physio will make movement better, make muscles feel more relaxed. Patients do not really take in their ownership. Sometimes, they will say to me, I don't know if I am getting better, I am hoping you can tell me. You know when they use the ABPI what is happening, they take more responsibility for whether they get better or not…Using the ABPI, using self-efficacy, they can see themselves that they are improving rather than me just saying to them, yes, you move your head slightly more now, you got 70% movement rather than 50%. So, it is a lot more helpful for them. It is a lot more applicable for them."	C
10. Equality of the ABPI among patients with WADII	*"The ABPI is quite straightforward to understand and follow for the patients. I found that the ABPI worked in all my patients."*	A
	"At the moment, although I do a lot of verbal persuasion, I get them to do certain tasks to perform the performance accomplishment stage. They will then go sit in their car and you can do the visualisation exercises as soon as the car approaching them, they go straight back to the first phase. It takes a lot longer to break down that barrier…You get some patients to pass through very quickly. ...They absorb absolutely everything you say. Next	B

	time you see them, they will be in the coping phase. You discharge them. I think it very much depends on individual patients."	
	"I think that the biggest part is that the ABPI is brilliant for people who aren't very confident in getting back to normal. They feel they need to rest, they feel they need to keep still and not move it and it will be healed, that is very much their opinion…you also get some patients who come in and suffer a lot. They are really active and wanna get better in a week. They push themselves really really hard. It (ABPI) can still be effective but you can try to rein in the goals a little bit. It (ABPI) is not gonna have as big impacts on them as you would do on the people who are less confident in movement...I just say I think the people who will benefit the most are the people who are a lot more apprehensive about doing formal movement and whatever."	C

7.1.2 Theme 2 – Barriers to usage (Table 7.3)

Using the ABPI for the first time (subtheme 1)

When using it for the first time, all physiotherapists felt it was a little difficult to deliver the ABPI to patients with acute WADII (**Table 7.3**, **subtheme 1**). Two of them were confident about delivering the ABPI within the next treatment session (physiotherapists B and C, **Table 7.3**, **subtheme 1**) and another physiotherapist was confident after using the ABPI two to three times (physiotherapist A, **Table 7.3**, **subtheme 1**).

Training physiotherapists (subtheme 2)

Both the training day and individual follow-up training were perceived as being helpful in delivering the ABPI to patients with acute WADII. Physiotherapist A said he was confident about delivering the ABPI after the training day by adapting his everyday practice (**Table 7.3**, **subtheme 2**). Semi-confidence in delivering the ABPI after the training day was indicated by physiotherapists B and C (**Table 7.3**, **subtheme 2**). Both of them preferred the individual training to the training day. Finally, all physiotherapists thought a combination of both a training day and individual follow-up was best in training a physiotherapist to deliver the ABPI (**Table 7.3**, **subtheme 2**).

Difficulties in using the ABPI (subtheme 3)

None of the physiotherapists reported any difficulties in using the ABPI (**Table 7.3**, **subtheme 3**). However, there were some concerns in terms of it being time-consuming to address initial barriers between physiotherapists and their patients (physiotherapist A, **Table 7.3**, **subtheme 3**). This was particularly thought to be the case for patients who had psychological disorders (physiotherapist B, **Table 7.3**, **subtheme 3**), and some patients

who also had pain and discomfort in different areas of the body (e.g. neck and back) (physiotherapist C, **Table 7.3**, **subtheme 3**).

Table 7.3: Theme 2 – Barriers to ABPI usage by physiotherapists

Subthemes	*Quotations*	Interviewee
1. Using ABPI for the first time	*"It was a little bit difficult to adapt and know about the ABPI at the beginning. After using the ABPI two or three times, it was quite helpful and quite easy and straightforward. Probably, I need a little bit more time as I am a foreigner. However, apart from that I was quite happy to use the ABPI."*	A
	"Panic! I think it likes it when you do anything new. It is a brand-new system where I've got to categorise patients. I thought to myself what if I got this wrong, how would I know what the problem was, am I doing this right and so on. After the first session, I quickly recovered my feeling and I did gain confidence."	B
	"I found it a little bit difficult initially. But again, the more you use it, just like anything it becomes second nature, it is quite quick. It doesn't take very long to get a little bit more experience. It doesn't take long to go through…I think sometimes, I have some difficulties from my point of view recording exactly what stages they are in. You think in one stage, one point, when you talk to them a little bit more, you know they may be in a different stage but yes! I mean that's all part of the process. The more I use it as a physio the better I become as well."	C
2. Training physiotherapists	*"I have been confident in using the ABPI since the training day. On that day, you are provided with a lot of information and guidance on which way physiotherapists should focus on. According to the information, I had adapted for my everyday practice at the beginning. Then, I was ready to continue…Both the training day and individual training were helpful. I cannot really say that one is superior to another."*	A
	"I was semi-confident about the training at the head office. Probably, the way I learn, I am not someone who can sit and be told this is how you can do that, and absorb it, I have to do it to learn (active learner)…For me, individual training would be more powerful. I don't think there is a problem with the training day strategy. If I've just been sent a document to	B

	look up online and then has you come in, I wouldn't know much what I am doing. If I just have the training day and then go, I probably wouldn't really know too much about what we were doing. For me, the individual training is better. I would like to be observed and I would like to be questioned. However, I can see the value in both."	
	"Again initially, I wasn't confident….Sometimes, I have found it difficult to try to break down some tasks initially…I think you do need both are best. If I had to say which one is better, I would probably say individual training slightly. But I still think both, I would say probably 60:40 per cent. I think both are definitely important."	C
3. Difficulties in using the ABPI	*"It was not difficult to use at all. Only at the beginning, I spent a little bit of time understanding structures and following your concepts, examples and case studies. After understanding the concept, I was ready to go…I worry a little bit more about it being time-consuming because it was difficult to get an answer from patients at the beginning. I need to spend one or two sessions building trust between physio and patients. And then exploration in patients will be easier."*	A
	"Not really to be honest. I already highlighted earlier the patient who I felt was inappropriate for APBI. I hope your results will show otherwise, but I don't think that I have any patient who really struggled to go through the stages."	B
	"As I said, the only thing that I found difficult is two different injuries."	C

7.1.3 Theme 3 – Distinctiveness (Table 7.4)

Similarities and differences between ABPI and standard physiotherapy

All physiotherapists thought that the similarity between the ABPI and the standard physiotherapy was that both interventions addressed physical problems (**Table 7.4**, **subtheme 1**). However, the ABPI helped physiotherapists to be aware of psychological challenges (e.g. fear avoidance, anxiety and depression) being faced by their patients (all physiotherapists, **Table 7.4**, **subtheme 2**). Furthermore, the responsibility for WAD recovery was taken by the patients who received the ABPI. This was different to the patients receiving the standard physiotherapy (physiotherapist C, **Table 7.4**, **subtheme 2**). Physiotherapists therefore perceived that the ABPI covered the patients' treatment both from physical and psychological perspectives, including motivating patients to take part in their recovery.

ABPI versus standard physiotherapy for managing patients with acute WADII

The ABPI was perceived as being more helpful in managing patients with acute WADII than standard physiotherapy (all physiotherapists, **Table 7.4**, **subtheme 2**). The ABPI was not only helpful in the private sector, but all physiotherapists thought that it could also be useful in the National Health Service (NHS) (**Table 7.4**, **subthemes 3–4**). However, the physiotherapists interviewed emphasised the importance of training, in that all physiotherapists should be trained to deliver the ABPI (physiotherapist B, **Table 7.4**, **subtheme 4**).

Table 7.4: Theme 3 – Distinctiveness of the ABPI by physiotherapists

Subthemes	*Quotations*	Interviewee
1. Similarities between ABPI and standard physiotherapy	*"We take care of patients for physical problems (e.g. pain reduction, increasing ROM and strengthening) based on physiotherapy clinical reasoning."*	A
	"The similarity definitely is you're encouraging them and helping them to function and continue monitoring improvement which guides your rehabilitation planning."	B
	"I think the similarities are that as physios, we try to motivate patients to exercise at home and do certain tasks but you can quantify a lot better with the ABPI."	C
2. Differences between ABPI and standard physiotherapy	*"The ABPI tries to guide patients to be better using two different ways (e.g. physical and psychological) at the same time. This is how the ABPI is different from the standard physiotherapy…The ABPI tries to motivate the patients to stay active by using psychological strategies to make patients confident about completing each goal/task…Learning about patients' background, exploring the patients a little bit more. Don't see the patients, only pain, ROM and strengthening, but explore some limitations in other aspects such as fear avoidance, anxiety and depression."*	A
	"…obviously! it (ABPI) makes me think a lot more about the psychological state, one thing I just haven't thought about before in as much detail is the effect of anxiety."	B
	"Probably, the difference I think is someone who comes in and has standard physio and has the ABPI. If you have standard physio, you might think you gonna get fixed by the physio, with the ABPI you (patient) take a lot more responsibility yourselves and have a lot more that way."	C
3. ABPI versus standard physiotherapy	*"Definitely the ABPI. This is because the ABPI takes care of both physical and psychological problems at the same time. It's two in one."*	A

	"ABPI definitive helps. I am hoping there will be more research into it."	B
	"From the experience that I have, I would probably say just on the limited number of people, probably say ABPI...It is better than just standard physiotherapy."	C
4. Helpful in private	*"…, it (ABPI) is quite helpful, easy and straightforward to use the ABPI for acute WADII management."*	A
	"ABPI definitive helps… I have definitely incorporated the approach into my regular practice and had beneficial results."	B
	"The ABPI is helpful for physios in the private sector. They still need to do a lot of work to get better outcomes. For me, using the ABPI does really help them with that."	C
5. Helpful in NHS	*"… you or someone can give them the guidelines that they should follow. I think it would be very beneficial even in the NHS."*	A
	"If you train the physios in the NHS, there is no reason why physios in the NHS should not be able to use the ABPI and the ABPI will work in the NHS as well."	B
	"I do think it works in the NHS definitely. It would be even more beneficial."	C

7.1.4 Theme 4 – Acceptance (Table 7.5)

ABPI effectiveness (subtheme 1)

All physiotherapists thought that the ABPI was an effective intervention in managing patients with acute WADII in order to prevent chronicity (**Table 7.5**, **subtheme 1**). The reasons were different across the physiotherapists. Physiotherapist A thought staying active and goal setting were helpful strategies (**Table 7.5**, **subtheme 1**). That the ABPI helped physiotherapists to focus on what the patients wanted to achieve was the reason provided by physiotherapist B for why the ABPI was effective (**Table 7.5**, **subtheme 1**). Physiotherapist C said that the improvement in a patient's level of understanding and self-efficacy enhancement which generated motivation were substantial reasons for why the ABPI was successful in acute WADII management (**Table 7.5**, **subtheme 1**).

General usage of the ABPI for acute WADII management (subtheme 2)

All physiotherapists thought that the ABPI could be used for acute WADII management in both the private and NHS sectors (**Table 7.4**, **subthemes 3–4 and Table 7.5**, **subtheme 2**). However, the physiotherapists believed that training in delivering the ABPI was important (physiotherapist B, **Table 7.5**, **subtheme 2**). Currently, two of the physiotherapists are continuing to use the ABPI in their daily practice (physiotherapists B and C, **Table 7.5**, **subtheme 2**) and one of them has applied the principles of the ABPI to other pathologies in different regions (physiotherapist C, **Table 7.5**, **subtheme 2**).

Changing or modifying (subtheme 3)

None of the physiotherapists had any idea about changing or modifying the ABPI (**Table 7.5**, **subtheme 3**). They stated that the ABPI framework worked for their routine practice (physiotherapists B and C, **Table 7.5**, **subtheme 3**). However, physiotherapist A commented: "*I think make it a little bit simple if it is possible*" (**Table 7.5**, **subtheme 3**). However, he did not have any issues or problems with how the ABPI was implemented in the present research (physiotherapist A, **Table 7.5**, **subtheme 3**).

Treatment recording (subtheme 4)

None of the physiotherapists found any problem with treatment recording (**Table 7.5**, **subtheme 4**). The recording took one or two minutes more than their normal patient records (physiotherapist B, **Table 7.5**, **subtheme 4**). However, physiotherapist A suggested that it would be easier to record if the ABPI was simpler (previously, he mentioned making ABPI a little simpler if it was possible) (**Table 7.5**, **subtheme 4**). In contrast, physiotherapist C thought that the treatment recording of the ABPI did not make further work for him but it was quite useful and suitable for his physiotherapy company (**Table 7.5**, **subtheme 4**).

Table 7.5: Theme 4 – Acceptance of the ABPI by physiotherapists

Subthemes	*Quotations*	Interviewee
1. ABPI effectiveness	*"Yes, definitely. The ABPI is quite useful to prevent chronicity because it tries to motivate patients to stay active and whatever. Finding a goal and trying to reach the goal is a helpful strategy. I found that the ABPI is very very beneficial."*	A
	"I think it is. As I said, I feel it is good at objectifying subjective findings allowing physios to have a better structure to their management plan. It allows us to focus on what the patient wants to achieve, not what we want them to achieve."	B
	"I do think it is effective. I think the reason for it is because their level of understanding is a lot greater when you go through set ways. I really think using self-efficacy, I think it generates motivation for them. I think that is one of the most important things really…I more use it as a physio that is better than I became as well. I think generally it has been good. I think it is able to give a little bit more success with the recovery in certain patients definitely. Probably sometimes before, I wouldn't have much success, I found it is quite rewarding to do it that way definitely."	C
2. General usage for acute WADII management	*"Yes, why not! This is because it is helpful in managing patients with acute WADII. The ABPI helps me to explore patients' background, physical and psychological problems. Also, the ABPI guides how to sort out patients' problems in both perspectives. The combination between physiotherapy and psychological strategy is really helpful…The ABPI can be used in both the private sector and the NHS."*	A
	"Yes, if the phyios are trained…I have definitely incorporated the approach into my regular practice and had beneficial results."	B
	"From my experience, it has been effective for every patient that I have used it on so far. So, I say definitely. The other good point I think is it doesn't take any more time… ABPI is studying with pure research for whiplash. I think use it across the board. You	C

	can apply it to anything…But at the same time to understand the study purpose, you need to start up with one particular pathology or injury. But I definitely think so and I have already used it in other areas as well because I do see the value in it."	
3. Changing/modifying	*"No, I don't think so. I think make it a little bit simpler if it is possible. I don't know. Even at this stage in this research, it was quite straightforward. I cannot see any issue."*	A
	"…the system works for me. So, I haven't really thought about changing it."	B
	"Nothing. I can't really think of anything particularly."	C
4. Treatment recording	*"It was a little bit time-consuming, that's why I suggested you make it a little bit easier. If you make it easier, I think it will be easier to make notes and this will help you in recording a little bit more…There is no difficulty in recording in this study."*	A
	"…the extra things we had to record made it slow initially. Once you get used to it or additional stuff that you may want to include, it will take one or two minutes extra. I don't have any problem with that."	B
	"We recorded in a SOAP note and also in extra treatment boxes which come up to us, we have to note down what interventions were used in the ABPI. I think I don't have work on different system of we got certain patient measurement system that we used on so…I think in my feel in the private sector in how it works in particularly my company, I found it very straightforward and easy to do… It might take a fraction longer maybe. You write a few more lines. I would take 30 seconds longer maybe at the most. So, I wouldn't say it has been particularly any more difficult really."	C

7.2 Focus group

All (n = 20) participants in the ABPI arm were contacted by e-mail, text and telephone in order to recruit them for a focus group. Only n = 3 participants verbally agreed to participate in the focus group. The reasons for not participating varied among the participants. The most common reason (n = 13) for participants not participating was that they had work commitments even though the focus group was timed for 7.00 pm. Two participants could not be contacted. One participant did not have anyone to cover her children and one participant had already booked a holiday.

When the focus group was conducted, only one participant (male, aged 70 years) took part. Two participants who had verbally agreed to participate could not attend on the day owing to work commitments. The principles of the focus group were modified into an interview format for the one patient. The aim of the focus group/interview was to explore patients' perceptions, experiences, opinions and attitudes regarding the ABPI (**Appendix 27** for the transcript). The identified themes and subthemes are diagrammatically summarised in **Figure 7.2** and tabulated with quotations in **Table 7.6**.

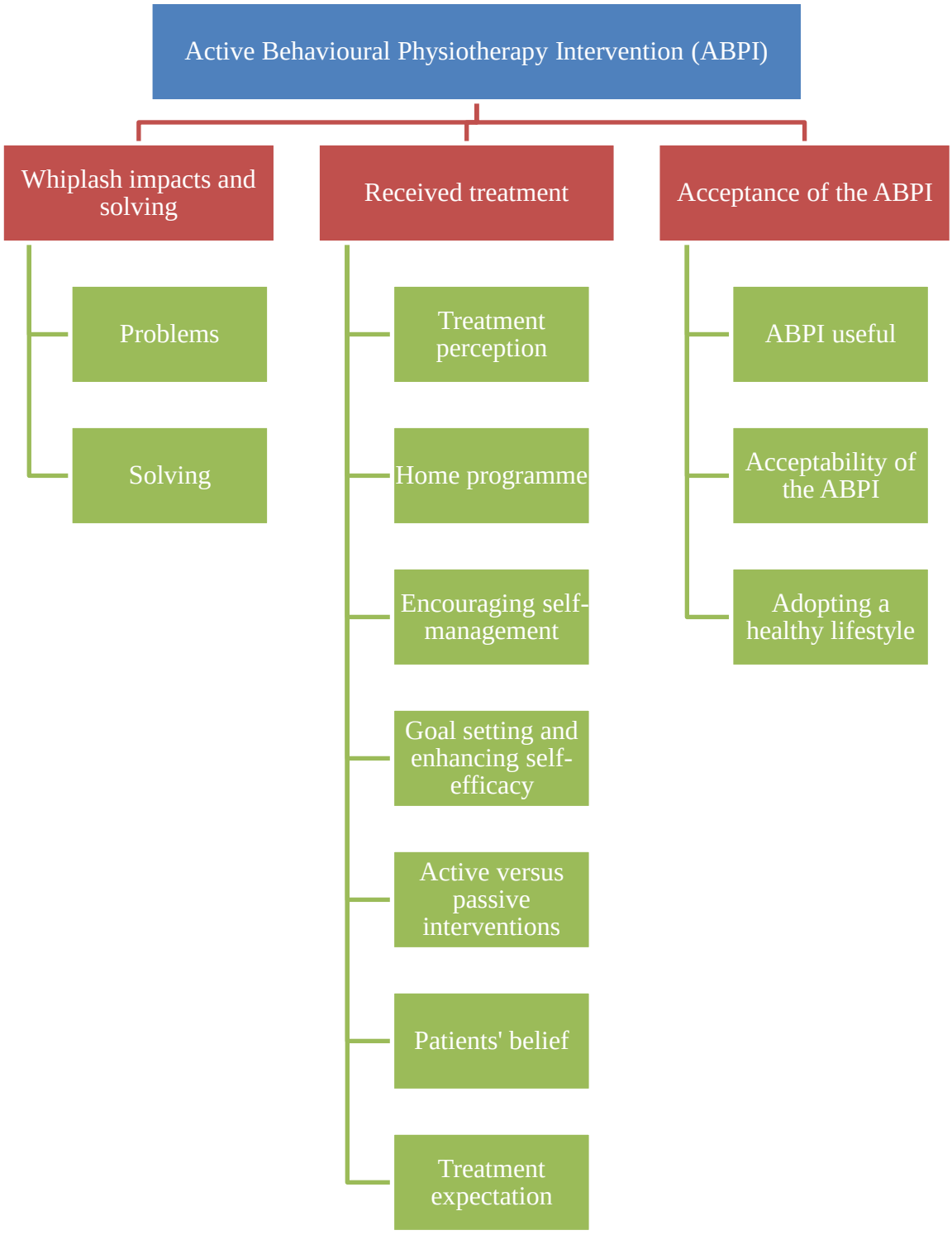

Figure 7.2: Participant's perceptions, experiences, opinions and attitudes regarding the ABPI.

7.2.1 Theme 1 – Whiplash impact and solving

The participant reported both physical (e.g. limited neck movement) and psychological (e.g. fear avoidance and anxiety regarding being hit by other cars from behind) problems following the injury (**Table 7.6**, **subtheme 1**). The participant had attempted to find strategies to solve his problems. For example, he used mirrors a lot more for looking behind his car rather than turning his head (**Table 7.6**, **subtheme 2**). Moreover, the participant tried to continue driving until he reduced his fear of doing so in line with his physiotherapist's suggestion (**Table 7.6**, **subtheme 2**).

7.2.2 Theme 2 – Received treatment

The participant described that he received prescriptions for exercises and a home programme that involved moving his neck in various directions and repeating it several times twice a day (**Table 7.6**, **subtheme 1 and 2**). His physiotherapist had tried to encourage him to perform self-management (**Table 7.6**, **subtheme 3**). For instance, the physiotherapist suggested that the participant should continue driving **(Table 7.6**, **theme 1**, **subtheme 2)**. From his explanation, it appeared that his physiotherapist had tried to use goal setting to manage the rehabilitation and recovery of the participant (**Table 7.6**, **subtheme 4**).

The participant also received a neck massage in the last three sessions (**Table 7.6**, **subtheme 1**). He liked the massage (**Table 7.6**, **subtheme 6**) and he felt that his recovery might have been quicker if he had had hands-on physiotherapy at the beginning (**Table 7.6**, **subtheme 7**). However, the participant thought that the management he had received was

helpful (**Table 7.6**, **subtheme 8**) and he trusted his physiotherapist to manage his problems (**Table 7.6**, **subthemes 7 and 8**).

7.2.3 Theme 3 – Acceptability

The participant did not have any problem with his neck a couple of weeks after physiotherapy treatment was complete (**Table 7.6**, **subtheme 1**). During his physiotherapy treatment, he did whatever his physiotherapist suggested (e.g. driving) or prescribed (e.g. neck exercises) (**Table 7.6**, **subthemes 1 and 2**; **Table 7.6**, **theme 1**, **subtheme 4**). Moreover, an obvious indication that the participant accepted the ABPI was that he had advocated the treatment he had received to his son (**Table 7.6**, **subtheme 2**). Additionally, the participant said he accepted what his physiotherapist prescribed and was happy with his neck (**Table 7.6**, **subtheme 2**). With regard to adopting a healthy lifestyle, the participant usually walked for two or three hours in Worcester, Leamington and other places (**Table 7.6**, **subtheme 3**).

Table 7.6: Perceptions, experiences, opinions and attitudes of the participant in the ABPI arm

Theme	Subtheme	*Quotations*
1. Whiplash impacts and solving	1. Problems	*"…it stopped me doing a lot of things you know…it was difficult to turn my head to see what was behind without turning my whole body… I was actually very wary of cars behind me and I was a little bit unsure of driving insofar as I kept having this flashback of the car hitting me you know and not being able to do anything about it."*
	2. Solving	*"…I use my mirrors a lot more … he (the physiotherapist) said if you keep driving it should be okay…I knew that if I stopped driving I probably wouldn't have got back into the car."*
2. Received treatment	1. Treatment perception	*"Mostly movement of my neck in various directions and that was repeated in several ways. Also I had a neck massage in the last three sessions I was there, which I thought didn't help at the time but a couple of days later it felt good."*
	2. Home programme	*"Movement more than anything else, different positions of my neck, doing multiples of ten exercises on each movement and doing that probably twice a day."*
	3. Encouraging self-management	*"...physiotherapist was encouraging self-management obviously to get my neck moving…I didn't have any real thoughts about that but whatever he did it worked."*
	4. Goal setting and enhancing self-efficacy	*"...he (the physiotherapist) was asking me questions about how I felt and how the exercises coming along and was I finding them difficult or easy, and he recorded everything that I said on his laptop, so I assumed that he helped me progress through it."*
	5. Active versus passive	*"I think I would have liked more hands-on physiotherapy initially, but I don't know whether that was relevant at the time, but the massage on my neck seemed to improve my situation….the exercises were a bit of a chore to do."*

	6. Patient's belief	*"…three weeks in fact that the massage came in and I felt that the physio was doing me good, but not my own exercises with my neck. I could be wrong of course, but that's how I felt…Well looking back on that I still feel the same that if I'd had hands on right away it might have gone a bit quicker you know…I mean I just supposed that the physiotherapist knew what he was doing. Maybe he was being gentle to start with and easing me into massage, I don't know, I'm not sure about that."*
	7. Treatment expectation	*"I got what I thought was right…I mean leave it to the professionals you know, I mean I'm no expert on anything like that, so I have no thoughts on those matters."*
3. Acceptability of the ABPI	1. ABPI useful	*"After I had finished physiotherapy, I still had aches in my neck, but after a couple of weeks they disappeared and to date I'm still okay, I've got no problems with my neck, which surprised me really you know…there were so many different movements of my head and neck. But I persevered and I did it at least once a day and I'm sure it showed improvement….my neck is probably 90% of what it used to be."*
	2. Acceptability	*"Sometimes I skipped it because of other commitments, but in the main I did the exercises during the day…I recommended (treatment that I had) to my son because he was with me…I thought that maybe I should have had the massages to start with, but I'm not a physiotherapist so I accepted what he prescribed…I'm quite happy with my neck."*
	3. Adopting a healthy lifestyle	*"I mean weekends I might be in Worcester, Leamington or other places and I'll walk for about two or three hours."*

Chapter summary

Drawing from individual semi-structured interviews, this chapter presents the perceptions, experiences, opinions and attitudes of both physiotherapists (n = 3) and one participant who were involved in the ABPI arm. Although the recruitment to the focus group for the patients was not successful (and thus why, in reality, an individual semi-structured interview was conducted for the one patient), the results presented in this chapter have demonstrated that both the physiotherapists and the participant found the ABPI can be acceptable. This view was particularly expressed by the physiotherapists. The physiotherapists decribed how the ABPI worked with their patients with acute WADII. Two of them described how they have gone on to use the ABPI in their daily practice for other patient presentations. The participant described that he adhered to the treatment programme, and was quite happy with his neck and tends to adopt active activities (e.g. walking). The findings from both quantitative (**Chapter 6**) and qualitative (**Chapter 7**) studies are discussed in the next chapter.

CHAPTER 8

Discussion for the Pilot and Feasibility Trial

Abstract

Chapters 6 and **7** presented the results of an external cluster randomised pilot and feasibility trial of an ABPI in a private insurance setting and an embedded exploratory qualitative study of the acceptability of the ABPI intervention to physiotherapists and a patient with WADII, respectively. **Chapter 6** demonstrated that conducting the ABPI for acute WADII management is feasible in terms of the procedures (e.g. randomisation, recruitment, data collection, trial management and follow-up) and feasibility of the intervention (e.g. tendency to be an effective intervention in preventing chronicity). Furthermore, **Chapter 7** illustrated that the ABPI was acceptable to both physiotherapists and patients. This chapter discusses the findings from **Chapters 6** (e.g. participant recruitment, baseline characteristics of participants, characteristics of physiotherapists, outcomes and estimation, and information about cost-effectiveness analysis) and **7** (e.g. acceptability for physiotherapists, acceptability for participants and keys to potential effectiveness of the ABPI for acute WADII management). Furthermore, strengths and limitations of the pilot and feasibility trial are also discussed. Finally, the criteria of the considerations for a future definitive trial are provided.

8.1 An external cluster randomised double-blind pilot and feasibility trial of the ABPI

8.1.1 Participant recruitment

According to the trial protocol (Wiangkham et al., 2016a), 30 participants were required in each intervention arm. Trial recruitment was planned for six to seven months and follow-up assessment for another three months. This was based on early feasibility data supporting the recruitment of at least 50% of eligible participants (n = 18) available per month across six private physiotherapy clinics (Wiangkham et al., 2016a, p. 9). The trial started in November 2015 and recruitment should therefore have been finished by May 2016.

Due to the unexpected liquidation of the private physiotherapy company, the trial was temporarily halted from 12th December 2015 to 13th March 2016. Fortunately, an insurance company took over the private physiotherapy company and after considerable negotiation agreed to continue the trial. To ensure the fidelity of the ABPI delivery after the temporary stop, all physiotherapists in the ABPI arm of the trial were retrained. The trial recruitment period was extended to 1st July 2016 under the oversight of the AWIS Steering and Data Monitoring Committee (**Appendix 21**). As a consequence of the unexpected liquidation of the private physiotherapy company, issues involving administrators (e.g. sickness and leaving without informing other people when recruiting potential participants) and a low participant recruitment rate (e.g. travel issues, work commitments and inability to book reschedule for an initial assessment within four weeks) were key issues when recruitment recommenced. The reasons for stopping recruitment in July were the timescale related to the PhD funding and student

visa, a reduction in the number of referrals with the new company and limitations of the trial budget (**Appendix 21**).

Issues leading to participants not participating in this trial were provided in **Chapter 6**. A key reason was that some participants did not want to travel to a different physiotherapy clinic for the assessments (two optional clinics). Although the closing time of one assessment centre was 9.00 pm on Fridays and another centre was used on Saturdays in order to be flexible around work commitments, several potential participants declined due to their own work-related constraints. This would be an important issue to address for a future definitive trial. It would be ideal to have an assessor in each clinic to enable the baseline assessment to take place local to each clinic prior to the first treatment session. That would then stop the patient needing to make the separate journey for the assessment. Another key consideration that affected recruitment was the takeover of the clinics by one insurance company, as this meant that the other insurance companies did not want to continue to refer their clients. These issues illustrate the complexities of the private physiotherapy sector**.**

In **Figure 6.1** (CONSORT diagram) and **Table 6.5**, the number of participants between the intervention arms at baseline (20 in the ABPI and eight in standard physiotherapy) and three-month follow-up (20 in the ABPI and six in standard physiotherapy) was substantially different. One cause was inequality in the number of referrals in the two arms (136 in the ABPI and 104 in standard physiotherapy). Additionally, the number of participants declining to participate was higher in the standard physiotherapy than in the ABPI arm (**Table 6.2**). Consequently, the eligible (n = 13) and recruited (n = 8) participants in the standard physiotherapy was fewer than in the ABPI arm (n = 27 eligible and n = 20 recruited participants). In a cluster design, the

number of referrals may be an influencing factor in recruiting the number of eligible and recruited participants in each arm. In this trial, the research team attempted to minimise the difference of the number of referrals between intervention arms using two levels of randomisation. Larger-size physiotherapy clinics were randomly divided into two groups by a computer-generated randomisation sequence and then the smaller clinics were randomly allocated based on provided information. Unfortunately, the numbers of eligible and recruited participants between the intervention arms were still substantially different. In a future study, the number of referrals between the intervention arms should be as equal as possible in order to equalise to the extent possible the recruitment rate between the intervention arms.

8.1.2 Baseline characteristics of participants

The median age in each intervention arm was substantially different (34 [IQR = 16.00] years in the ABPI arm and 50.50 [IQR = 18.75] years in the standard physiotherapy arm). This may have been a factor that explained the differences seen descriptively in recovery between the two arms (ABPI arm 19/20 = 95% (95% CI: 76.4% to 99.1%); standard physiotherapy arm 1/6 = 16.7% (95% CI: 3.0% to 56.4%). However, one meta-analysis of prognostic factors for persistent WAD made a comparison between older and younger age (n = 12 individual trials with 2,347 participants) and found that older age (≥ 50–55 years old) was not a significant factor (OR = 1.00, 95%CI: 0.97 to 1.04) for the risk of persistent pain and disability (Walton et al., 2013).

Additionally, the proportion of males and females was different across the two arms (there were more males than females in the ABPI arm and vice versa in the

standard physiotherapy arm). The influence of gender is supported by systematic review and meta-analysis data (Walton et al., 2013), which found that females significantly tended to have more persistent problems than males (OR = 1.64, 95%CI: 1.27 to 2.12, n = 14 individual trials with 4,128 participants). However, analysis of the odds ratio suggests that the difference in the proportions of participants with persistent symptoms between genders was low.

There was also a difference regarding ethnic group across the trial arms, although this appeared to have no impact on the trial results (the majority of participants in both arms were white British). There were seven and one participants of Asian background in the ABPI and standard physiotherapy arms, respectively. Differences in the number of Asian participants in the two arms may be influenced by the geographical locations of the clinics that they were recruited from. Different locations in the UK (even through in the same city) present the difference in the proportion of ethnic groups (e.g. white British and Asian) (Barry et al., 2015, Curtis et al., 2016). In terms of Asian background, this ethnic group may influence the proportion of fully recovered participants in this trial. However, all Asian participants in the ABPI were fully recovered whereas one Asian in the standard physiotherapy was not. Only one non-completely recovered (NDI = 7) participant in the ABPI arm and one completely recovered (NDI = 3) participant in the standard physiotherapy arm were White British. In this trial, no conclusion can be drawn regarding the influence of ethnic group due to the limited sample size. In the WAD literature, the prevalence of WAD has been substantially reported in Western countries. The people's beliefs on WAD recovery in each country may be a factor of WAD recovery. However, laypersons' beliefs in WAD

recovery between Singapore and Australia were not different but the prevalence of chronic WAD in both countries is different (Ng et al., 2013).

Finally, most outcomes (i.e. NDI, VAS (pain intensity), IES, EQ-5D VAS, CROM and PPT) at baseline seem to be different between the intervention arms. These could have an impact in interpreting the recovery of the participants at the three-month follow-up. According to the nature of the pilot and feasibility trial (Thabane et al., 2010, Eldridge et al., 2016), a statistical comparison cannot be implemented. Therefore, it cannot be concluded whether the differences are significant or not. For the interpretation of the possible treatment effects of the ABPI for the management of acute WADII, the median of difference between baseline and three-month follow-up in each outcome was provided in **Table 6.5 and 6.6** in order to minimise biases.

8.1.3 Characteristics of physiotherapists

Chapter 6 pointed out that the physiotherapy qualifications (two bachelors and one master in each group) and duration of work experience post qualification (median = 3 years in each group) were consistent across intervention arms. Additionally, physiotherapists' characteristics in terms of age (ABPI median = 27 years, standard physiotherapy median = 28 years), gender (male:female 3:0 ABPI, 2:1 standard physiotherapy) and ethnicity (British:Greek 2:1 ABPI and 1:2 standard physiotherapy) were similar across intervention arms, and were therefore unlikely to have had an impact on results. One cross-sectional study (n = 356 physiotherapists) had previously found that the duration of work experience post qualification and level of qualification positively correlated with the level of knowledge in managing musculoskeletal conditions (Childs et al., 2005). In the future trial, the duration of work experience post

physiotherapy qualification and level of qualification of physiotherapists in both intervention arms should be standardised as far as possible by considerations these factors prior to randomisation in order to avoid a potential bias when examining the trial findings.

8.1.4 Outcomes and estimation

In accordance with what is expected for a pilot and feasibility trial (Thabane et al., 2010), the results in this trial were descriptively reported without investigating statistical significance. The outcome measures in this trial were evaluated from patient reported (NDI, VAS pain intensity, IES and FABQ) and physical (CROM and PPT) measures. The measurement included physical (NDI, VAS pain intensity, CROM and PPT) and psychological (IES and FABQ) outcome measures which cover the problems of patients with WADII (Sterling and Chadwick, 2010, Myran et al., 2011, Barnsley, 2013, Sterling, 2014). Interestingly, the VAS pain intensity and PPT, which have been used in whiplash trials (Jull et al., 2013, Michaleff et al., 2014), can be classified as a mix type between physical and psychological perspectives because pain involves both physical and psychological factors (e.g. emotion and tissue damage) (IASP, 2014) Furthermore, quality of life and general health status for the patients was measured using EQ-5D (Haywood et al., 2005).

Taking into consideration each outcome measure at three-month follow-up, the participants in the ABPI arm seemed to experience improved recovery compared to the standard physiotherapy arm in terms of NDI, VAS (pain intensity), IES, EQ-5D total and some subscales (e.g. usual activities, pain/discomfort and anxiety/depression) including the EQ-5D VAS, CROM in transverse and coronal planes, and PPT bilaterally

of the levator scapulae and tibialis anterior muscles (**Tables 6.5** and **6.6**). However, the participants in the standard physiotherapy arm showed better results in responses to the FABQ and in terms of sagittal cervical movement. Critically, the better results in two (two of six directions of CROM and one secondary outcome measure) of seven outcome measures of the standard physiotherapy cannot compete with the ABPI, which had better results in several outcome measures, both primary and secondary.

The potential advantage of the ABPI can also be seen upon analysis of the median of difference for each outcome measure. In **Tables 6.5** and **6.6**, the participants who received the ABPI demonstrated greater improvement in all outcome measures than the participants who received the standard physiotherapy. The exceptions were IES, FABQ and PPT on the left tibialis anterior muscle, which demonstrated better improvement in the standard physiotherapy arm than the ABPI arm. Furthermore, the median of difference of the planned primary outcome measure (NDI) between baseline and three-month follow-up reach the minimal clinically important difference (MCID) in the ABPI arm (NDI $\geq$ 8) (Pool et al., 2007, Carreon et al., 2010), whereas in the standard physiotherapy arm it did not . The final evidence to support why the ABPI may be an effective intervention in managing patients with acute WADII to prevent chronicity is the number of completely recovered participants at three-month follow-up when considering a cut off of NDI $\leq$ 4 (Vernon and Mior, 1991, Sterling et al., 2006, Pool et al., 2007, MacDermid et al., 2009, Sterling, 2014). In this trial, the number of fully recovered participants at three-month follow-up was 19/20 (95%) in the ABPI arm and 1/6 (~17%) in the standard physiotherapy arm. The results suggested that the ABPI may be an effective intervention for the management of acute WADII in preventing chronicity when contrasted to the standard physiotherapy.

It should be noted that the ABPI did not show the potential improvement in the psychological outcome measures (e.g. IES and FABQ) rather than the standard physiotherapy. However, the small sample size and the substantial difference of the number of participants between the intervention arms cannot draw the confident conclusion regarding the effectiveness of the ABPI in psychological aspect.

The loss to follow-up in this trial was low, although the majority of participants were young males who tended to drop out more than older males and females (Carstensen et al., 2015). In the ABPI, there was no loss to follow-up whereas two (25%) participants in the standard physiotherapy were lost to follow-up. Thus, the overall loss to follow-up in this trial was low at ~7% at three-month follow-up and indeed less than what has been observed in the previous pilot trials related to the management of WAD based on the currently provided evidence (> 16% at six-week follow-up) (Ask et al., 2009, Tough et al., 2010). A useful strategy for ensuring low loss to follow-up was telephone follow-up, which is valid and reliable (Hallal et al., 2010).

Due to using a telephone follow-up assessment, all physical assessments and some self-reported outcome measures were not assessed owing to the nature of telephone follow-up assessment (for physical assessments), bearing in mind the assessment and validity and reliability in assessing each outcome measure via telephone (for other outcome measures). In regard to the evaluation of pain intensity in future research, the numerical rating scale (NRS) is valid verbal assessment of pain intensity (Bijur et al., 2003). The NRS should be used as an outcome measure when assessing pain intensity via telephone rather than the VAS. Using the telephone in assessing a participant for a long time may lead to an issue of withdrawal or loss to follow-up.

However, if the future definitive trial needs to collect some physical assessment, home follow-up would be an option.

8.1.5 Information about cost-effectiveness analysis

In this trial, the number of treatment sessions and costs of physiotherapy management in the ABPI arm were lower than those in the standard physiotherapy arm, even though the physiotherapist training costs were included (**Table 6.7**). Consequently, the ABPI may have the potential to reduce the costs of WADII management. However, the diary pocket book (**Appendix 17**), which was used to record the relevant information for cost-effectiveness analysis, was returned by only two participants (both from the ABPI arm) (**Table 6.8**). Hence, the comparison between the interventions in other relevant factors for cost-effectiveness analysis (e.g. other health professional costs and medication) cannot be performed. In this trial, the majority of participants were young males (**Table 6.3**). In the whiplash literature, young males tend to take less responsibility in the trial (Carstensen et al., 2015). Therefore, it would not be a good idea to give them a form and expect them to return it. In a future definitive trial, collaborating with an insurance company or a physiotherapy company and setting up an electronic system that would record any relevant information for cost-effectiveness analysis may potentially be a useful strategy.

8.2 An embedded exploratory qualitative study on the acceptability of the ABPI

The findings from the embedded exploratory qualitative study (**Chapter 7**) supported the external pilot and feasibility trial (**Chapters 5** and **6**) and described how the ABPI can be successful in managing patients with acute WADII with regard to the prevention

of the development of chronicity. Both physiotherapists and patients found the ABPI can be acceptable for managing acute WADII (**Chapter 7**).

8.2.1 Acceptability for physiotherapists

With respect to the new intervention, the acceptability of practitioners is an important issue in considering the developed intervention through general practice. Without acceptability for the practitioner, the developed intervention may be ignored in reality. In this trial, the findings from the individual semi-structured in-depth interviews illustrated that all the elements of the ABPI can be acceptable to the physiotherapists (**Chapter 7**). Furthermore, the physiotherapists felt that the ABPI can be applied to other areas and different pathologies. Owing to the benefits of the ABPI in managing patients, some physiotherapists mentioned that they had used the ABPI for their daily practice after the completion of this trial. Finally, they thought that the ABPI cannot be useful only in the private sector but it could also work in the National Health Service. Therefore, it is obvious that the ABPI can be used in general practice for acute WADII management after proving to be an effective intervention in the definitive trial.

8.2.2 Acceptability for participants

The ABPI cannot be acceptable only to physiotherapists but also to the participant who received the intervention and attended the focus group (**Chapter 7**). The ABPI also motivated him to adhere to the physiotherapy programme and adopt an active lifestyle. However, the participant believed that massage was the key factor in his neck recovery and it would have been good if he could have received massage earlier. He preferred massage to exercises similarly to the majority (~87%) of patients with

neck pain who expected that their neck pain would be significantly improved by massage (Bishop et al., 2013). The study (involving n = 140 participants) of Bishop et al. (2013) found that the patients' expectations substantially influenced clinical outcome measures. For example, the number of recoveries among the patients who did not expect complete pain relief was lower than the patients expected at six months (odds ratio [OR] = 0.19, 95%CI: 0.05 to 0.70). Interestingly, patients who believed in the efficacy of completing prescribed exercises increased their odds of success at six months (OR = 11.4, 95%CI: 1.70 to 74.70) (Bishop et al., 2013), which is good if the physiotherapists can persuade their patients to believe in exercises.

However, in this pilot and feasibility trial, the participant emphasised that he was not an expert and that he accepted whatever his physiotherapist prescribed (e.g. home exercises) or suggested (e.g. behaviours/tasks). The participant's opinion is similar to 91% of people in Quebec City, Canada who had trusted physiotherapists in managing musculoskeletal disorders in primary care in an electronic survey study (n = 513) (Desjardins-Charbonneau et al., 2016). It should be noted that the participant who was interviewed was one of the fully recovered participants. Another indication regarding the acceptability of the ABPI is that the participant suggested the intervention to his son (his son was with him in the car at the time of the accident). Thus, we can see that the participant accepted the ABPI, leading him to adhere to the physiotherapy programme and making a complete recovery.

8.3 Keys to potential effectiveness of the ABPI for acute WADII management

The potential value of the ABPI for acute WADII management in this trial may be contributed by three strategic elements in terms of self-efficacy enhancement, exploring patients' expectations and self-management.

8.3.1 Self-efficacy enhancement for acute WADII management

The qualitative study (**Chapter 7**) illustrated that the ABPI motivated patients to stay active and complete their goals/tasks based on the social cognitive theory focusing on self-efficacy enhancement (Bandura, 1977 and physiotherapists A and C, theme 1, subtheme 2). Enhancement of the level of self-efficacy is a key element in encouraging patients with WADII to stay active and is consistent with the physiotherapy programme being focused on self-management. A previous qualitative study investigating patients with acute WAD (Williamson et al., 2015a) found that some patients thought that pain was damaging further tissues and exercises were not helpful. An increased level of self-efficacy (Bandura, 1977) using three sources (i.e. performance accomplishment, verbal persuasion and physiological/emotional states) can change their beliefs and behaviours. After the patients had seen their progression, the level of self-efficacy was not only enhanced but also improved adherence to the physiotherapy programme and self-management (Bandura and Locke, 2003, physiotherapists A and C, theme 1, subtheme 2) may lead to successful WAD management. Previous research also indicated that the enhancement of self-efficacy is a functional mediator in reducing disability in patients with acute WAD (Soderlund et al., 2000, Soderlund and Lindberg, 2002). Therefore, self-efficacy is an influencing factor of WAD recovery.

Enhancement of self-efficacy can improve psychological stress, pain and physical function. The literature review in **Chapter 4** identified that the level of self-

efficacy is associated with psychological stress, physical function and pain. Borsbo et al. (2010) found that an increase of self-efficacy can reduce psychological stress (e.g. fear avoidance, anxiety and depression). Once psychological stress has been reduced, pain can be relieved (Leeuw et al., 2007, Borsbo et al., 2010). Then, physical function can be improved easily after pain reduction (Wicksell et al., 2010). In addition, the enhancement of self-efficacy can increase confidence in completing the prescribed exercises and engaging in recommended physical activities, leading to an improvement in physical function (Soderlund and Lindberg, 2002, Borsbo et al., 2010).

Performance accomplishment, verbal persuasion and physiological/emotional states were mentioned as the most powerful strategies in enhancing the level of self-efficacy by physiotherapists C, A and B, respectively, although Bandura and Locke (2003) stated that the most powerful factor in the development of self-efficacy is performance accomplishment. The different opinions among physiotherapists may come from their experiences. However, performance accomplishment is suggested by theory as the most powerful source of the self-efficacy enhancement (Bandura, 1977, Bandura and Locke, 2003), was informed in the training day. Therefore, trainers should emphasise the most powerful source for the enhancement of the level of self-efficacy to physiotherapists in future training before a definitive trial and then evaluate the opinions of the physiotherapists for the most powerful sources in enhancing self-efficacy after the definitive trial for wider generalisability.

8.3.2 Exploring patients' expectations

The ABPI guided physiotherapists to explore what their patients wanted to achieve and how to manage them (**Table 7.2**). By exploring the expectations or beliefs of the patients, some inappropriate beliefs can be identified. This exploration provides an opportunity for physiotherapists to educate or give appropriate and accurate information. Then any barriers between the views of physiotherapists and patients would be reduced. As a result, we would expect that patients would adhere to the physiotherapy programme more readily, thus leading to more positive results. The findings of a neck pain study supported this mechanism that the expectations of patients' recovery have a positive association with their recovery (Bishop et al., 2013). Consequently, appropriate expectations can drive patients to recover straightforwardly and quickly. Therefore, the exploration of patients' expectations and education with precise and useful information for the physiotherapy management and self-management may be a factor impacting the effectiveness of the ABPI.

8.3.3 Self-management for acute WADII management

Normally, physiotherapists meet their patients once or twice a week with each visit lasting for 30 minutes (physiotherapist C, **Table 7.2**, **theme 1**, **subtheme 6**). Self-management is therefore useful in managing patients due to the time limitation of physiotherapy. It is important that the patients can manage their symptoms and adhere to the physiotherapy programme appropriately. After that, their recovery can progress very fast (Bandura and Locke, 2003). This benefit of self-management has been confirmed by all the physiotherapists who delivered the ABPI (**Chapter 7**). However, physiotherapists should make sure that their patients perform their exercises or other

tasks properly and indicating the correct postural control, by checking before assignment. Rechecking of the home programme at the next visit was a strategy to ensure that the patients adhered to their prescription or treatment programme. Another benefit of self-management was the reduction of management costs (Boyers et al., 2013).

8.4 Strengths of the pilot and feasibility trial

The ABPI is a novel potential effective intervention for the management of acute WADII bearing in mind the number of fully recovered participants (NDI ≤ 4) (Vernon and Mior, 1991, Sterling et al., 2006, MacDermid et al., 2009, Sterling, 2014) at three-month follow-up. The findings of this trial can be considered reliable due to the high quality of the methodology used in terms of:

- Conducting and reporting in accordance with the CONSORT 2010 statement: extension to cluster randomised trial (Campbell et al., 2012) and COnsolidated criteria for REporting Qualitative research (COREQ): a 32-item checklist for interviews and focus groups (Tong et al., 2007) for phases I and II, respectively.
- A cluster RCT in order to avoid treatment contamination, increasing participant compliance (Siebers et al., 2009, Campbell et al., 2012), participant blinding (Campbell et al., 2012), and logical and administrative convenience (Edwards et al., 1999).
- A double-blind design to reduce potential biases. The effectiveness of blinding assessor and participants was evaluated at three-month follow-up by asking

which intervention arm each participant was allocated to. The results demonstrated that neither assessor nor participants knew about this information.

- Using an independent assessor (an independent postgraduate physiotherapist) and training the assessor in both validity and reliability in all outcome measures prior to conducting the trial, leading to obtaining highly reliable results.
- Incorporating both quantitative and qualitative methods (O'Cathain et al., 2013, O'Cathain et al., 2015) to address all perspectives of the pilot and feasibility trial. The findings of both studies supported each other to confirm that the ABPI has a high chance of being an effective intervention for acute WADII management.
- Precision and fidelity in delivering the ABPI to physiotherapy practice (e.g. setting one training day and four weeks for the individual training, systematic treatment recording and random observation of physiotherapists in the ABPI arm every month).
- Using a trial steering and data monitoring committee to increase the quality of the trial (e.g. providing suggestions to enhance obtaining high-quality data, providing optional information for experts to deal with any problems, and patient safety). Eldridge et al. (2016) suggested that the quality of data collection for phase II trial is an important issue to consider for a future definitive trial.
- Using an experienced interviewer (the lead researcher: training and piloting for improving his qualitative skills and developing topic guide prior to implementing definitive individual semi-structured interviews) for the semi-structured interviews and an experienced facilitator (the lead supervisor) for the

focus group to manage the dynamics of group discussion, leading to an increase in precise information for data collection (Petty et al., 2012).

- Using open, closed, general and specific questions in a qualitative study to receive key information from physiotherapists and participants regarding the acceptability of the ABPI (Ayala and Elder, 2011).
- Enhancing the trustworthiness of the qualitative findings by discussing data-analysis with the supervisory team in each stage.

Moreover, the ABPI was acceptable to both physiotherapists and the participants bearing in mind the findings of the embedded qualitative study (**Chapter 7**). The overall loss to follow-up in this trial was low with no dropout in the ABPI arm of the external pilot and feasibility trial (**Chapter 6**). Furthermore, the ABPI would contribute by reducing the costs of WAD management (lower number of treatment sessions and cheaper costs of physiotherapy management than for the standard physiotherapy). Finally, this trial is the first implementation regarding WAD management in the UK private insurance setting which is a difficult sector in conducting a research. Consequently, the elaborate factors in investigating a research regarding WAD in the UK private insurance setting were informed to consider for the definitive trial.

8.5 Limitations of the pilot and feasibility trial

8.5.1 Trial limitations

This trial was stopped by the consensus of the AWIS Trial Steering and Data Monitoring Committee (e.g. due to the timescale, the budget and the low number of referrals), even though the trial did not reach the target sample size predominantly due to the unexpected liquidation of the private physiotherapy company. Furthermore, the

numbers of eligible and recruited participants between the intervention arms were substantially different due to the inequality of the number of referrals and eligible participants in each arm which would reflect from the cluster randomisation and the geography of physiotherapy clinics. Although the telephone follow-up assessment was a useful strategy to reduce the loss to follow-up, some outcome measures (e.g. VAS, CROM, PPT, IES and FABQ) cannot be assessed due to the nature of telephone assessment including the validity and reliability in assessing via telephone.

In this trial, the level of education (less than post-secondary), headache at inception and low back pain at baseline were not collected from the participants. However, these factors are significant predictors of persistent WAD (Walton et al., 2013). Therefore, in a future definitive trial, it is advised that such information be collected and monitored with an eye toward predicting the recovery of patients with acute WADII.

At the beginning, it was planned that a diary pocket book would be used to record any activities related to whiplash management such as using medication and consulting other health professionals, along with any costs, days of sick leave and benefits claimed that relate to whiplash management. Also, it was planned that the diary pocket book would be used to collect general participant information such as postcode, work status and annual income. After completion of the trial, only two participants returned their diary pocket book. It is obvious from this trial that the diary pocket book did not work in regard to collecting information for a cost-effectiveness analysis.

Finally, this trial did not use the CONSORT statement: extension to randomised pilot and feasibility trials (Eldridge et al., 2016) because the CONSORT was published

after the completion of this trial. However, this trial had addressed all recommendation issues of the CONSORT.

8.5.2 Language barriers

Language limitations may have been an issue in interviewing and delivering the ABPI in English (Mikkonen et al., 2016). Although the interviewer (the lead researcher) was trained and did some pilots regarding semi-structured individual interviews to enhance his qualitative skills and to develop the topic guide, the limitations of English being a second language may have been a factor contributing to information missing. In this trial, one of the physiotherapists was a Greek and English was his second language. He wanted more times (two to three times) than the British physiotherapists (once) for ABPI practice to gain confidence in delivery. Thus, the ABPI may be a little bit difficult for physiotherapists for whom English is a second language, when the training is in English including managing patients in the UK. However, he was happy in delivering the ABPI in this trial.

8.5.3 Non-success of participant recruitment for the focus group

A substantial limitation of the planned focus group was that only one participant attended this event although all participants were invited. The focus group thus became a semi-structured interview. Consequently, inadequate information was collected (e.g. approach of the physiotherapist and specific details regarding self-management). Thus, the confidence in findings is reduced. A higher number of participants may be better for recalling and obtaining information from a number of participants via the focus group (Kitzinger, 1995, Ayala and Elder, 2011). The recommendation regarding the

appropriate number of participants in a focus group is six to ten participants (Petty et al., 2012).

8.6 Considerations for a future definitive trial

Table 8.1 details the criteria of the considerations for a future definitive trial. An adequately powered cluster RCT of a future definitive trial can be deemed feasible by modifying some issues and considerations raised in the present pilot and feasibility trial.

Table 8.1: Considerations for a future definitive trial

Objectives	Criteria for success	Considerations
To evaluate the feasibility of procedures (e.g. randomisation, recruitment, collecting data, management and follow-up) ○ Randomisation ○ Recruitment	The trial would be considered feasible if it was run smoothly without serious problems or obstructions that were able to stop the study.	All research procedures were feasible but the following issues should be considered: ○ No issue regarding the randomisation (i.e. no report regarding participants' disagreement with treatment allocation) including data from qualitative study. ○ Ideally, double blinding should be kept in order to maintain the quality of the trial but more assessors need to be provided for every clinic in order to reduce the risk factor of journey issues (patients did not want to travel to other physiotherapy clinics) if a future trial is to be sufficiently funded. ○ Increase the number of recruited physiotherapy clinics/insurance companies in order to increase the recruitment rate.

○ Collecting data		○ Although no issue from semi-structured physiotherapists' interviews, the participant recruitment of the focus group did not work in this trial. In the future trial, semi-structured interview or telephone interview may be considered for exploring the participants' perceptions. ○ An increase in the number of assessors may be considered. Setting assessment centres did not work in this trial due to participants' journey issues. Assessors should be provided in each clinic. ○ Information for cost-effectiveness analysis should be considered in another way (set up an electronic system by collaborating with an insurance company or a physiotherapy company in order to record rather than giving a diary pocket book to participants). ○ Collecting level of education (less than post-secondary), headache at inception and low

○ Management ○ Follow-up		back pain, which are the significant predictors of persistent WAD. ○ No difficulty with the management for the quantitative study. ○ Face-to-face follow-up may be an issue because participants get back to their normal life and they may not want to come to a clinic owing to their work commitments. Telephone follow-up may be an interesting option for a future trial.
To investigate the acceptability of the developed intervention	The trial would be considered feasible if the physiotherapists and the patients found the developed intervention acceptable.	Qualitative data found that all physiotherapists from the individual semi-structured interviews and the patient from the focus group accepted the ABPI. Furthermore, there was no dropout of participants in the ABPI arm at three-month follow-up.
To evaluate recruitment rates, refusal rates, retention and adherence to participants in the private sector in the UK	The trial would be considered feasible if ○ ≥ 50% of eligible patients were recruited	Overall, the trial was feasible if ○ 70% of eligible patients were recruited

	○ At least three participants a week per intervention arm were recruited ○ ≥ 80% of all recruited participants completed the follow-up at three months ○ There was adherence to the physiotherapy programme.	○ An average of one (1.27) person was recruited per week (excluding temporary stopping of the trial). This point was an issue to modify in the future trial. An increase in the number of recruited physiotherapy clinics may be an option. ○ ~93% of recruited participants completed three-month follow-up ○ A qualitative study found that the participants adhered to their physiotherapy programme (mentioned by both physiotherapists and patients)
To evaluate dropout rates of participants in the private sector in the UK	The trial would be considered feasible if ≤ 20% of all recruited participants dropped out	2/8 (25%) participants were lost to follow-up at three months. Therefore, the overall dropout in this trial was ~7%.
To estimate the required sample for a definitive trial	The trial would be considered feasible if it was feasible to achieve the sample size for a cluster RCT based upon	The required sample size for a cluster RCT is 238 patients using 24 physiotherapy clinics based on power = 90%, significance level = 0.05, difference

	recruitment data	of NDI = 4 and cluster size = 10.
To evaluate the feasibility of data collection for cost-effectiveness analysis	The trial would be considered feasible if the following components of the cost-effective analysis were collected with minimal missing data: o General information (e.g. current work status and salary) o Direct medical costs ▪ Medical costs (e.g. physiotherapy, general practice and complementary medicine) ▪ Resource uses (e.g. diagnosis tests) o Indirect medical costs ▪ Participant journey costs ▪ Training costs for physiotherapists in the experimental arm	Only two participants returned their diary pocket book. Another strategy for collecting information for cost-effectiveness analysis should be considered in another way for a future trial. Setting up an electronic recording system by collaborating with an insurance company or a physiotherapy company may be a good option in order to collect relevant information.

Based on the findings of this trial, the future definitive trial with adequate power and low risk of bias is now required to evaluate the effectiveness of the ABPI for the management of acute WADII. However, in going forward the trial protocol requires some minor modifications. The sample size of the definitive trial would be 238 participants (power = 90%, significance level = 0.05, difference of NDI = 4 and cluster size = 10) which would require 24 private physiotherapy clinics. The protocol for this trial will be carried forward with those key components (e.g. cluster randomisation, parallel two-arm and double-blind) within it to ensure that the definitive trial is low risk of bias.

The process will be the same with the protocol (Wiangkham et al., 2016a). However, the following issues will be modified for the definitive trial. Firstly, the number of private physiotherapy clinics with related insurance companies will be recruited to 24 clinics. Twenty-four assessors will be employed and provided in all clinics (one assessor per clinic). The potential participants will attend the recruitment process and baseline assessment prior to their first treatment session in the same day without waiting longer than 15 minutes in order to reduce the number of their journey and time. VAS will be replaced by NRS to assess the pain intensity of the participants. At three-month follow-up assessment (primary endpoint), the participants will have three options: attending the face-to-face assessment in the clinic, requesting an assessor to their houses or assessing via telephone. Additionally, 12-month follow-up will be used to assess the participants for the long term using the telephone follow-up. Based on 1.27 participants were recruited per week per intervention arm in this trial, the recruitment will take around ~94 weeks for the future definitive trial. However, the number of physiotherapy clinics in the future definitive trial is higher than this trial four

times. The recruitment period of the definitive trial may reduce to ~24 weeks with one year for the follow-up.

Secondly, direct and indirect medical costs will be collected by setting an electronic system with private physiotherapy companies and/or insurance companies in order to perform the cost-effectiveness analysis comparing between the intervention arms.

Thirdly, level of education, headache at inception and low back pain, which are the significant predictors of persistent WAD (Walton et al., 2013) will be collected at baseline assessment in order to analyse correlation between relevant factors and WADII recovery.

A part of the definitive trial, an embedded qualitative study will be valuable to extend the preliminary data in order to further explore the acceptability of the ABPI to physiotherapists and patients. The modification is the telephone semi-structured interviews will be used to explore the patients' perceptions replacing the focus group. Twenty patients will be targeted for the telephone interview.

Chapter summary

This chapter presented discussions of findings stemming from and issues raised throughout this pilot and feasibility trial for both quantitative and qualitative studies. The findings of this trial indicated that the ABPI is feasible (e.g. procedures, sample size and modified collection of data for cost-effectiveness analysis) and valuable (higher proportion of completely recovered participants, fewer treatment sessions, and cheaper physiotherapy management costs than the standard physiotherapy including acceptability from physiotherapists and patients) in terms of conducting a future

definitive trial in order to evaluate the effectiveness of the ABPI for the management of acute WADII and the efficacy of the ABPI for preventing chronic problems. However, some issues of the protocol (Wiangkham et al., 2016a) should be modified in terms of increasing the number of physiotherapy clinics/insurance companies, enhancing the number of assessors and a strategy to follow up (if the research is adequately funded), collecting relevant information for cost-effectiveness analysis by setting up an electronic system, collecting further information on potentially significant predictors of persistent WAD, procedures of follow-up assessment (e.g. at baseline, three month and one year) and using telephone semi-structured interview replacing the focus group to explore the acceptability of the ABPI from the patients in order to make a future definitive trial robust. The next chapter presents a general discussion regarding the multiphase PhD project.

CHAPTER 9

General Discussion and Conclusions of the Multiphase Project

Abstract

This chapter summarises the evidence and presents a general discussion and conclusions regarding the development and evaluation of the ABPI for acute WADII management throughout a multiphase PhD project (systematic review and meta-analysis, modified Delphi study with development of the ABPI using social cognitive theory central to self-efficacy enhancement, and a pilot and feasibility trial).

9.1 Strengths of this multiphase project

This rigorous multiphase project has produced the ABPI which is a novel physiotherapy intervention with a potential effectiveness in managing patients with acute WADII to prevent the development of chronicity effectively.

9.1.1 Developing and evaluating the ABPI using a rigorous process

The ABPI was identified and developed using a precise, rigorous and transparent methodology with a pre-specified protocol in all studies. First, a rigorous systematic review and meta-analysis of RCTs (Wiangkham et al., 2015b) was conducted using gold standard methods (Furlan et al., 2009b, Higgins et al., 2011b) and reporting (Moher et al., 2009b) to summarise what we know about the potentially effective conservative intervention in the acute stage of WADII, the most common classification of WAD (at least 70% patients) managed by physiotherapists (Sterling, 2004a, Williamson et al., 2015b). The systematic review and meta-analysis of RCTs has been mentioned as the most powerful and lowest risk of bias research design (Sackett et

al., 1996). The systematic review found that the combination of active physiotherapy and a behavioural intervention (ABPI) may be a useful strategy for acute WADII management.

Then, the ABPI was developed using a modified Delphi method, which is a standard, low-cost, flexible and simple method of developing an intervention in health care through expert consensus (Murphy et al., 1998) to generate underlying principles and specific treatment components for acute WADII management by a diverse group of whiplash experts. To increase the reliability and validity of the study, fixed-choice (to evaluate the level of agreement in each item) and open (to provide an opportunity for all panellists to comment and expresses their opinions in each section and the last section for general comments and suggestions) questions were used in an online survey in all three rounds (McDonnell et al., 1996). Furthermore, the consensus criteria were increased more and more in each round (Wiangkham et al., 2016b).

The ABPI was developed as a complex physiotherapy intervention for acute WADII management. However, the results of the modified Delphi study did not provide any useful theory to underpin the ABPI. Thus, the ABPI was further developed by combining the results of the modified Delphi study (Wiangkham et al., 2016b) and a social cognitive theory focusing on the enhancement of self-efficacy (Bandura, 1977) in order to underpin and deliver the ABPI to physiotherapy practice in line with the Medical Research Council Framework of Complex Interventions (Craig et al., 2008). The concept, phases and examples of the ABPI, including a strategy for enhancing the level of self-efficacy and monitoring patients with WADII, were provided for physiotherapists prior to phase II trial. Taking into consideration the accuracy and fidelity in delivering the ABPI, the physiotherapists in the ABPI arm were trained

through a training day (lecturing and group discussing for three hours) and individual training (observing their practice, giving feedback and discussing any issues regarding the ABPI for four weeks). Then, the physiotherapists were randomly observed every month. The fidelity of intervention delivery is an important process in conducting a trial to obtain reliable results.

Finally, the rigorous protocol and reporting of the pilot and feasibility trial by conducting both quantitative and qualitative studies were a strength of this multiphase project, leading to high reliability of the findings (Wiangkham et al., 2016a). For example, the research methods and reporting were in accordance with the CONSORT 2010 statement: extension to cluster randomised trial (Campbell et al., 2012) and COnsolidated criteria for REporting Qualitative research (COREQ): a 32-item checklist for interviews and focus groups (Tong et al., 2007) for phases I and II, respectively.

The ABPI is feasible (**Table 8.1**) and valuable (higher proportion of completely recovered participants, fewer treatment sessions and cheaper physiotherapy management costs, compared with the standard physiotherapy) in conducting a future definitive trial. Additionally, it can be acceptable from both physiotherapists and participants who received the ABPI. Remarkably, the number of completely recovered participants (NDI $\leq$ 4) was 19/20 (95%) participants in the ABPI arm and 1/6 (~17%) participants in the standard physiotherapy arm. **Figure 9.1** presents a diagram of the development of the ABPI for acute WADII management.

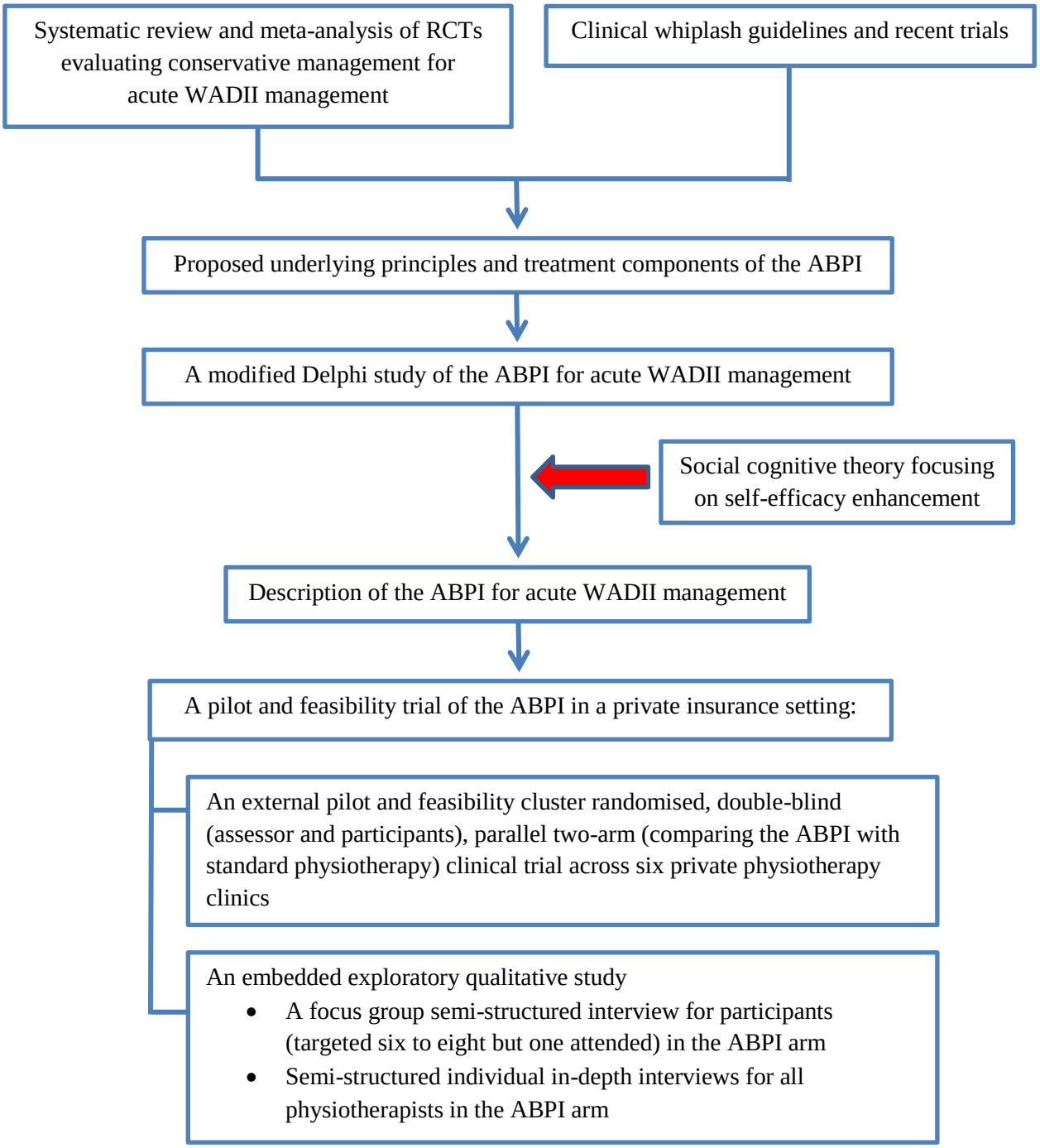

Figure 9.1: Summary flow diagram of the development of an Active Behavioural Physiotherapy Intervention (ABPI) for acute whiplash-associated disorder (WAD) II.

9.1.2 ABPI covering both physical and psychological management

The analysis of the existing literature have highlighted the key limitations of WAD management may be caused by inadequate addressing psychological problems of the patients. The ABPI was developed for the management of acute WADII in both physical and psychological aspects using both empirical (Wiangkham et al., 2015b, Wiangkham et al., 2016b) and theoretical (Bandura, 1977, Thomeé, 2007, Barlow, 2013, Ludvigsson et al., 2015) evidence. Consequently, the ABPI is a potentially effective intervention for acute WADII management in order to prevent the development of chronicity.

9.1.3 Changing direction of current thinking for acute WADII management

The overall strategy of the ABPI for acute WADII management is encouraging appropriate behaviours with adhering to physiotherapy programme. Using the behavioural approach/intervention as a part of the ABPI is similar direction of the current health care management (Press et al., 2016). Press et al. (2016) have mentioned that behavioural approach/intervention is an effective strategy to improve patient outcomes in health care management. The direction of the ABPI for the acute WADII management had been identified since the systematic review (Wiangkham et al., 2015b) which found that the combination of active physiotherapy and behavioural intervention may be a useful strategy prior to developing using both empirical (Wiangkham et al., 2016b) and theoretical (Bandura, 1977, Thomeé, 2007, Barlow, 2013) evidence.

Keating et al. (2016) (published abstract) reported the low level of self-efficacy in patients with acute WAD I-III in an Irish setting. Consequently, self-efficacy enhancement seems to be an appropriate strategy to manage patients with acute WAD.

However, the trial was small (n = 18) and a larger sample size is required to confirm their findings. According the above information and the findings of the pilot and feasibility trial (**Chapter 6** and **7**), the ABPI can be therefore effective for acute WADII management. It seems that both active physiotherapy and behavioural intervention (e.g. self-efficacy enhancement) may be important elements in managing patients with acute WADII.

9.1.4 Potential benefits of the ABPI for acute WADII management

According to the findings of the pilot and feasibility trial (**Chapter 6** and **7**), the ABPI has been demonstrated as a potentially effective intervention for acute WADII management to prevent chronicity. As WADII is the most common classification of whiplash, if it can be proved that the ABPI is an effective intervention, this will make a substantial difference to the high number of patients and related organisations (e.g. insurance companies, the NHS, patients' companies or workplaces). They will obtain a lot of benefits (e.g. returning to health-related quality of life of patients quicker than the current management, decreasing the costs of WAD management, reducing the number of days of sick leave and restoring the quality of employees at work). It can be seen that an effective intervention is useful for patients' quality of life and economics at individual, national and international levels.

9.1.5 First investigation of WAD research in a private insurance sector

Although the substantial proportion of patients with WAD in the UK is managed in the private insurance sector, there is no research regarding WAD management in this sector. This would be the difficulties (e.g. concerning business issues and involving

several organisations) in implementing a research in this sector. This project is the first research investigation regarding WAD management in the UK private insurance setting. Therefore, the related issues for conducting a research into WAD within this sector were explored to enable other preparations for the future definitive trial.

9.2 Limitations of this multiphase project

Each study forming part of the thesis has explored in depth its specific limitations. The overall key limitations of this multiphase project come from the pilot and feasibility trial in terms of not reaching the targeted sample size, very low response rate for collecting information for cost-effectiveness analysis and very low recruitment rate for the focus group. Owing to the PhD time scale and research budget, it was not possible to complete the definitive trial as part of the PhD. Phase III definitive trial is therefore now required to evaluate the effectiveness of the ABPI in managing patients with acute WADII.

9.3 Conclusions

This rigorous multiphase project was conducted to develop and evaluate a complex intervention for managing patients with acute WADII in order to prevent the development of chronicity. Over the past decade, up to 60% of patients with WAD have developed chronic problems and 30% have experienced moderate to severe pain and disability. An effective intervention for the management of acute WAD is required, especially WADII, which is reported to represent at least 70% among WAD patients.

The recently published systematic review and meta-analysis of RCTs evaluating the effectiveness of the conservative management of acute WADII (Wiangkham et al.,

2015b) found that active intervention was more effective than passive intervention for pain reduction at six months (95%CI: -17.19 to -3.23, p = 0.004) and one to three years (-26.39 to -10.08, p < 0.001). Additionally, behavioural intervention was superior to standard/control intervention for pain alleviation at six months (-15.37 to -1.55, p = 0.016) and improvement in cervical movement in the coronal (0.93 to 4.38, p = 0.003) and horizontal (0.43 to 5.46, p = 0.027) planes at three to six months. Thus, the combination of active physiotherapy and a behavioural intervention (ABPI) may be a useful strategy for acute WADII management.

The ABPI was developed through expert consensus from international research and UK clinical whiplash experts using a modified Delphi study to provide the underlying principles and specific treatment components for acute WADII management (Wiangkham et al., 2016b). A key finding from the Delphi study was that there was no underlying theory to support delivery of the ABPI. In line with the Medical Research Council Framework of Complex Interventions (Craig et al., 2008), the ABPI was further developed using social cognitive theory focusing on the enhancement of self-efficacy (Bandura, 1977). The concept, phases and examples of the ABPI including a strategy of self-efficacy enhancement and monitoring patients with acute WADII were created and provided for physiotherapists in the ABPI arm prior to the phase II trial.

A cluster randomised pilot and feasibility trial of the ABPI was conducted according to a predefined protocol (Wiangkham et al., 2016a) in a private insurance setting to evaluate the procedures, feasibility and acceptability of the ABPI for acute WADII management. The trial consisted of two parallel phases: 1] an external pilot and feasibility cluster randomised, double-blind (assessor and participants), parallel two-arm (ABPI versus standard physiotherapy) clinical trial to evaluate procedures and

feasibility; 2] an embedded exploratory qualitative study using semi-structured individual in-depth interviews (all physiotherapists in the ABPI arm) and a focus group (one participant attended having targeted six to eight participants) to explore the acceptability of the ABPI. The results confirm that the ABPI is feasible (**Table 8.1**) and valuable (higher proportion of completely recovered participants, fewer treatment sessions and cheaper physiotherapy management costs) in conducting a future definitive trial. Additionally, it can be acceptable from both physiotherapists and participants who received the ABPI. Remarkably, the number of completely recovered participants (NDI ≤ 4) was 19/20 (95%) participants in the ABPI arm and 1/6 (~17%) participants in the standard physiotherapy arm. Therefore, it is now important to conduct the definitive trial with minor modifications to evaluate the effectiveness of the ABPI for acute WADII management.

APPENDICES

Appendix 1: The effectiveness of conservative management for acute whiplash-associated disorder (WAD) II: a systematic review and meta-analysis of randomised controlled trials (published in PLoS ONE)

http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0133415

Appendix 2: Effectiveness of conservative management for acute whiplash-associated disorder (WAD) II: a systematic review and meta-analysis of randomised controlled trials (abstract published in Physiotherapy)

http://www.sciencedirect.com/science/article/pii/S0031940615016727

Appendix 3: Ethical approval of the modified Delphi study of the ABPI for acute WADII management

Appendix 4: Development of an active behavioural physiotherapy intervention (ABPI) for acute whiplash-associated disorder (WAD) II management: a modified Delphi study (published in BMJ Open)

http://bmjopen.bmj.com/content/6/9/e011764.full

Appendix 5: Ethical approval of the cluster randomised pilot and feasibility of the ABPI for acute WADII management

Appendix 6: Acute Whiplash Injury Study (AWIS): a protocol for a cluster randomised pilot and feasibility trial of an Active Behavioural Physiotherapy Intervention in an insurance private setting

http://bmjopen.bmj.com/content/6/7/e011336.info

Appendix 7: Participant information sheet for the development of the ABPI for acute WADII management: a modified Delphi study

Participant Information Sheet

The Development of Active Behavioural Physiotherapy Intervention for Acute Whiplash Associated Disorder (WAD) II Management

Whiplash Associated Disorder (WAD) is a neck injury usually from a road traffic accident. The annual UK incidence of WAD is approximately 300,000. The annual economic cost related to WAD is estimated as $3.9 billion in the US and €10 billion in Europe with the cost of insurance claims having risen from £7 to £14 billion in a decade. This reflects a considerable financial burden internationally. 93% patients can be classified as WADII [neck problem and musculoskeletal problems e.g. limited movement], and are commonly managed by physiotherapy. Patients experience both physical and psychological problems.

40-60% patients go on to experience chronic symptoms, with moderate to severe levels of pain and disability. Effective management of WADII in the acute stage is therefore important to prevent chronicity. At present we are unclear regarding what is effective management. Therefore, for the first part of this PhD a systematic review was conducted to summarise what we know about effective management in the acute stage.

The systematic review found that active physiotherapy (focus on returning to activity and function/work) was effective for pain reduction, and that behavioural intervention (focus on pain management and patient taking responsibility for recovery) was effective for pain reduction and improvement of neck movement. In order to prevent chronicity, the combination of active physiotherapy and behavioural intervention called the 'active behavioural physiotherapy intervention' may be a useful strategy to manage acute WADII.

In this study, the underlying principles and the components of the active behavioural physiotherapy intervention will be developed using a modified Delphi method. The final part of the PhD will then be a randomised cluster pilot trial using the developed intervention.

What is the purpose of this study?

The aim of this project is to define the underlying principles and the components of an active behavioural physiotherapy intervention for acute whiplash associated disorder (WAD) II management.

Do I have to take part?

Your participation is voluntary. We believe that you are able to make an important contribution to this project. You do not have to respond to our request if you do not want to participate. We are asking you to take part in this project because you meet our inclusion criteria for one of our three included groups of participants:

1. Active researcher in the field who have published at least 2 articles regarding WAD within the previous 10 years.
2. Physiotherapists working in private practice in the UK who have experience in treating WAD for at least 2 years.
3. Postgraduate students registered on the MSc Advanced Manipulative Physiotherapy programme (University of Birmingham) who have at least 2 years' experience of treating WAD.

We believe that your background enables you to provide useful and important information to inform our development of an optimal active behavioural physiotherapy intervention for acute WADII management.

What will I do if I take part?

We would like you to read this information sheet, sign the consent form and send it back via post or e-mail within 2 weeks. If you have any questions when you read through the consent form please email me your questions. After we receive your consent form, we will confirm your participation.

We are anticipating 3 rounds for this study. The link to the electronic questionnaire for round 1 will be sent to you via e-mail. Round 1 will ask you to rate the importance of the underlying principles and the proposed components of the active behavioural physiotherapy intervention. The underlying principles and proposed components are derived from our systematic review, clinical guidelines and recent trials. You will also be invited to add in any principles and/or components that you feel are missing. You will be asked to complete the questionnaire within 4 weeks and will receive a reminder after 2 and 4 weeks.

In round 2, you will receive summary feedback on round 1 and will be asked again to rate the importance of the underlying principles and the proposed components of the active behavioural physiotherapy intervention agreed as important from round 1.

In the final round, you will receive summary feedback on round 2 and will be asked to rate both the importance and feasibility of the components of the active behavioural physiotherapy intervention agreed as important from round 2.

What are the possible disadvantages and risk of taking part?

The study does require some of your time. You will be required to answer 3 rounds of the survey via SurveyMonkey. It is anticipated that each round will take 10-30 minutes.

What are the possible benefits of taking part?

Although there are no personal benefits for your participation in this study, your information can contribute to acute WADII management and future studies. There are many substantial benefits when the active behavioural physiotherapy intervention is able to manage acute WADII effectively. Firstly, a vast number of WADII patients can return to their quality of life quickly due to prevent chronicity effectively. Furthermore, direct and indirect medical costs will be declined to manage acute WADII management. Finally, socioeconomic burden from WADII problems will be reduced in both individual and national levels in terms of earning capacity and productivity changes due to days of sick leave and ability of work.

Will my taking part in the study be kept confidential?

All responses to our questionnaire and information provided by you will be anonymised and securely stored in a password protected computer during study. Your computer IP address will not be saved. After completion of this study, all information will be confidentially kept for 10 years at School of Sport, Exercise and Rehabilitation Sciences, at the University of Birmingham before being securely destroyed. Data can only be accessed by the researcher and his supervisors. In order to ensure that no participant can be identified, information emanating from this study will only be published in a completely unattributable format or at an aggregate level.

Can I withdraw from the study after it has started?

You can withdraw your participation in the study at any time by emailing the researcher, without any implications. In this event, we will send you an email confirming that you have been withdrawn. After that you will not be contacted anymore about this project. Any data collected prior to your withdrawal from the study will be included in the data analysis.

What will happen to the results of the research study?

The results of this study will enable us to take the developed intervention forwards into a feasibility trial. The findings from this study will be submitted for publication to a peer reviewed journal and will be presented at conferences and local seminars.

Who is organising the research?

This project is being undertaken as part of a PhD in the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, United Kingdom.

Please do not hesitate to contact us if further information is required.

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Mobile
E-mail:

or

Dr Alison Rushton

Lead Supervisor
Academic Lead Physiotherapy
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Birmingham
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UK
Tel
Email

Appendix 8: Consent form for the development of the ABPI for acute WADII management: a modified Delphi study

CONSENT FORM

Title of Project:

The development of active behavioural physiotherapy intervention for acute Whiplash Associated Disorder (WAD) II management

Name of Researcher:

Taweewat Wiangkham

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated _____ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw from the study by sending e-mail to the researcher. I understand that I would then receive an e-mail confirming my withdrawal, and I understand that any data collected prior to my withdrawal will be included in the data analysis. ☐

3. I would like to receive feedback about the findings of this study. ☐

4. I understand that any information will be used anonymously and I will not be identified in and reports, publications or presentations related to this work. ☐

5. I would like to take part in the above study. ☐

Name of Participant	Date	Signature

Appendix 9: Consent form of the pilot and feasibility trial for the private physiotherapy/ insurance company

CONSENT FORM

Title of Project:

Acute Whiplash Injury Study (AWIS): a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy intervention for acute Whiplash Associated Disorder (WAD) II management in an insurance private setting

Name of Researcher:

Taweewat Wiangkham

Please tick all boxes

1. I confirm that I have read and understand the protocol of the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw from the study by sending e-mail with a reason(s) to the researcher. I understand that I would then receive an e-mail confirming my withdrawal. ☐
3. I am happy for our patients to be included as part of this study. ☐
4. I am happy for our physiotherapists to participate in this study. ☐

Director of ……..	Date	Signature
Name of Researcher	Date	Signature

Appendix 10: Participant information sheet for the external cluster randomised double-blind, parallel two-arm (ABPI versus standard physiotherapy) pilot and feasibility trial (phase I)

Participant Information Sheet

Acute Whiplash Injury Study: a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy treatment for acute Whiplash Associated Disorder (WAD) II management in an insurance private setting

Whiplash Associated Disorder is a neck injury usually from a road traffic accident. More people are affected by whiplash each year and it can lead to pain and disability. Therefore, it is important for a physiotherapist to prevent chronicity by using effective management in the acute stage. The evidence so far suggests that a combination of active and behavioural treatment programme when the patient is still acute, may be a useful strategy to manage Whiplash Associated Disorder.

We have developed an active behavioural physiotherapy treatment programme using international experts that we plan to use in a large clinical trial to see if it works.

What is the purpose of this trial?

To evaluate procedures, feasibility and acceptability of the active behavioural physiotherapy treatment for acute Whiplash Associated Disorder.

Do I have to take part?

It is entirely up to you. We believe that you can make a great difference by taking part in this trial. You do not have to participate if you do not want to. We are asking you to take part in this trial because you meet our inclusion criteria:

1. Your age is between 18-70 years old.
2. Your neck problems were caused by a road traffic accident within the last four weeks.
3. Your neck problems are classified as whiplash associated disorder.

We really believe that your participation will greatly help us to see how the active behavioural physiotherapy treatment works. This will help a lot of patients with acute Whiplash Associated Disorder to preventing chronicity.

What will I do if I take part?

We would like you to read this information sheet, sign the consent form and bring it to your first visit. If you have any questions when you read through the consent form please ask the physiotherapist.

After signing the consent form, you will be assessed by another physiotherapist for key clinical outcome measures. The process of assessment will take about 30 minutes. Then, you will receive your physiotherapy treatment programme. We will make another appointment with you to assess clinical outcome measures at 3 months after the first assessment. This follow-up assessment will also take about 30 minutes.

What are the possible disadvantages and risk of taking part?

You will be treated using either the developed active behavioural physiotherapy treatment or standard physiotherapy treatment. Both are a form of conservative treatment without any serious problem. Sometimes, you may feel muscle soreness from a physiotherapy treatment, but it will recover within 48 hours. You will be required to visit an assessing physiotherapist 2 times, when the project starts and 3 months later. Each visit will take about 30 minutes. You will be supported for journey costs.

What are the possible benefits of taking part?

You will receive physiotherapy treatment as part of this study. Some patients will receive current standard care and others will receive an active behavioural physiotherapy treatment. We are interested in whether one treatment is better than the other to improve management of patients with Whiplash Associated Disorder and to prevent chronic problems. If we can prevent chronic problems, patients can return to their quality of life, direct and indirect medical costs will be reduced.

Will my taking part in the study be kept confidential?

All information regarding each participant will be kept safely from any third party to keep the participants' privacy. All collected documents will be stored in a secure place. The electronic information will be stored in a password protected computer during study. After completion of this trial, all information will be confidentially kept for 10 years at the School of Sport, Exercise and Rehabilitation

Sciences, University of Birmingham, before being securely destroyed. Data can only be seen by the primary researcher and his supervisors. To make sure that no participant can be identified, information emanating from this trial will only be published in a completely unattributable format or at an aggregate level.

Can I withdraw from the study after it has started?

You can withdraw your participation in the trial at any time up to 3 months after you signed the consent form agreeing to take part, by emailing the primary researcher with your reason(s), without any consequence. Providing a reason is voluntary but not required. In this event, we will send you an email confirming that you have been withdrawn. After that you will not be contacted anymore about this trial. Any data collected prior to your withdrawal will also be deleted.

What will happen to the results of the research study?

The results of this trial will enable us to evaluate the findings to inform a future large trial involving a large number of patients. The findings from this trial will be submitted for publication to a medical journal and will be presented at conferences and local seminars.

Who is organising the research?

This project is being undertaken as part of a PhD in the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, United Kingdom.

Please do not hesitate to contact us if further information is required.

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Email:

Appendix 11: Consent form for the external cluster randomised double-blind, parallel two-arm (ABPI versus standard physiotherapy) pilot and feasibility trial (phase I)

CONSENT FORM

Title of Project:

Acute Whiplash Injury Study (AWIS): a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy intervention for acute Whiplash Associated Disorder (WAD) II management in an insurance private setting

Name of Researcher:

Taweewat Wiangkham

Please tick all boxes

1. I confirm that I have read and understand the information sheet dated _____ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw from the study by sending e-mail with a reason(s) to the researcher. I understand that I would then receive an e-mail confirming my withdrawal ☐
3. I understand that I will be assessed by an assessor for clinical outcome measurements at the initial physiotherapy appointment (baseline) and at a 3-month follow-up assessment. ☐
4. I understand that I will not be identified in any reports, publications or presentations related to this work. ☐
5. I would like to take part in the above study. ☐
6. When you withdraw in this study, would you like us to remove your data. **Yes** ☐ **No** ☐

Name of Participant	Date	Signature

E-mail:

Telephone:

Name of Researcher	Date	Signature

Appendix 12: Participant information sheet for the embedded qualitative study (phase II): semi-structured interviews

Participant Information Sheet

Semi-structure Interview

Acute Whiplash Injury Study: a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy intervention for acute Whiplash Associated Disorder (WAD) II management in an insurance private setting

Whiplash Associated Disorder is a neck injury usually from a road traffic accident. More people are affected by whiplash each year and it can lead to pain and disability. Therefore, it is important for a physiotherapist to prevent chronicity by using effective management in the acute stage. The evidence so far suggests that a combination of active and behavioural treatment programme when the patient is still acute, may be a useful strategy to manage Whiplash Associated Disorder.

We have developed an active behavioural physiotherapy treatment programme using international experts that we plan to use in a large clinical trial to see if it works.

What is the purpose of this study?

To evaluate acceptability of the active behavioural physiotherapy intervention for acute WADII management within the insurance/private sector

Do I have to take part?

Your participation is voluntary. We believe that you are able to make an important contribution to this project. You do not have to respond to our request if you do not want to participate. We are asking you to take part in this project because you are a physiotherapist who used the developed intervention in managing patients with acute WADII. We really believe that your participations will substantially assist us to see how the active behavioural physiotherapy worked. This would lead to help the vast number of patients with acute WADII in preventing chronicity.

What will I do if I take part?

We would like you to read this information sheet, sign the consent form and give it back to a researcher in the interviewed day. If you have any questions when you read through the consent form please ask the interviewer. The interview will take your time around 10-20 minutes.

What are the possible disadvantages and risk of taking part?

The interview will take your time around 10-20 minutes. Your opinions and any conservation in this interview will be anonymous. So, you cannot be identified.

What are the possible benefits of taking part?

Although there are no personal benefits for your taking part in this interview, your participation can contribute to acute WADII management and future studies. As you are a physiotherapist who used the developed intervention, your experiences and opinions are a valuable factor to evaluate the acceptability of the active behavioural physiotherapy intervention which is developed by whiplash experts across the world. Your experiences and opinions will help us to explore the strengths and weaknesses of the developed intervention in order to consider for the future definitive trial.

Will my taking part in the study be kept confidential?

Your personal information will be kept safely from any third party stored to maintain the participants' privacy. All collected documents will be stored in a secure place. The electronic information will be confidentially stored in a password protected computer during study. After completion of the interview, all information will be confidentially kept for 10 years at the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, before being securely destroyed. Data can only be accessed by the primary researcher and his supervisors. In order to ensure that no participant can be identified, information emanating from the interview will only be published in a completely unattributable format or at an aggregate level.

Can I withdraw from the study after it has started?

Your participation is voluntary and that you are free to withdraw anytime.

What will happen to the results of the research study?

The results of this interview will enable us to evaluate the acceptability of the active behavioural physiotherapy intervention which is an important factor for considering the future definitive trial. The findings from this trial will be submitted for publication to a peer reviewed journal and will be presented at conferences and local seminars.

Who is organising the research?

This project is being undertaken as part of a PhD in the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, United Kingdom.

Please do not hesitate to contact us if further information is required.

Taweewat Wiangkham

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School of Sport, Exercise and Rehabilitation Sciences
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UK
Tel:
Email:

Appendix 13: Participant information sheet for the embedded qualitative study (phase II): a focus group

Participant Information Sheet

Focus Group

Acute Whiplash Injury Study: a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy intervention for acute Whiplash Associated Disorder (WAD) II management in an insurance private setting

Whiplash Associated Disorder is a neck injury usually from a road traffic accident. More people are affected by whiplash each year and it can lead to pain and disability. Therefore, it is important for a physiotherapist to prevent chronicity by using effective management in the acute stage. The evidence so far suggests that a combination of active and behavioural treatment programme when the patient is still acute, may be a useful strategy to manage Whiplash Associated Disorder.

We have developed an active behavioural physiotherapy treatment programme using international experts that we plan to use in a large clinical trial to see if it works.

What is the purpose of this study?

To evaluate acceptability of the active behavioural physiotherapy intervention for acute WADII management within the insurance/private sector

Do I have to take part?

It is entirely up to you. We believe that you can make a great difference by taking part in this project. You do not have to participate if you do not want to. We are asking you to take part in this project because you are a participation in the experimental group. We really believe that your participation will greatly help us to see how the active behavioural physiotherapy is. This will help a lot of patients with acute WADII in preventing chronicity.

What will I do if I take part?

We would like you to read this information sheet, sign the consent form and bring it to the interviewed day. If you have any questions when you read through the consent form please ask us. The group interview will take your time around an hour. Please do not worry if you forget to bring the consent form to the interviewed day. We will provide it for you.

What are the possible disadvantages and risk of taking part?

The group interview will take your time around an hour. Your opinions and any conversation in this interview cannot be anonymous because of the nature of a group discussion. However, your information and the conversation in the group discussion will be kept safely from any third party and will therefore be confidential.

What are the possible benefits of taking part?

Your journey costs will be supported. Although there are no personal benefits for your taking part in this interview, your participation can contribute to acute WADII management and future studies. In this interview, the acceptability of the active behavioural physiotherapy intervention will be evaluated to see how it worked. Your experiences and opinions are a valuable factor to evaluate the acceptability of the active behavioural physiotherapy intervention which is developed by whiplash experts across the world. Your experiences and opinions will help us to explore the strengths and weaknesses of the developed intervention in order to consider for the future definitive trial.

Will my taking part in the study be kept confidential?

According to the nature of a group discussion, anonymity within this setting cannot be assured. However, confidentiality of the information about you and your conversation in the group discussion will be kept safely from any third party to keep your information confidential. The group interview will commence by agreeing 'ground rules' for the group that will include not discussing the content of the group interview outside of the session. Your name will not be linked to any information in the reporting of findings from the group discussion, and findings will be reported for the whole group rather than for individual participants. All collected documents will be stored in a secure place. The electronic information will be stored in a password protected computer during study. After completion of this interview, all information will be confidentially kept for 10 years at the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, before being securely destroyed. Data can only be seen by the primary researcher and his supervisors. To make sure that no participant can be identified, information emanating from this trial will only be published in a completely unattributable format or at an aggregate level.

Can I withdraw from the study after it has started?

You cannot withdraw your participation during the interview.

What will happen to the results of the research study?

The results of this interview will enable us to evaluate the acceptability of the active behavioural physiotherapy intervention which is an important factor for considering the main trial. The findings from this trial will be submitted for publication to a peer reviewed journal and will be presented at conferences and local seminars.

Who is organising the research?

This project is being undertaken as part of a PhD in the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, United Kingdom.

Please do not hesitate to contact us if further information is required.

Taweewat Wiangkham

Doctoral Researcher
School of Sport, Exercise and Rehabilitation Sciences
University of Birmingham
B15 2TT
Mobile:
E-mail:

Dr Alison Rushton

Lead Supervisor
Academic Lead Physiotherapy
School of Sport, Exercise and Rehabilitation Sciences
University of Birmingham
B15 2TT
Tel:
Email:

Appendix 14: Consent form for the embedded qualitative study (phase II): semi-structured interviews

CONSENT FORM

Title of Project:
Acute Whiplash Injury Study: a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy intervention for acute Whiplash Associated Disorder (WAD) II management in an insurance private setting

[Semi-structured interview for the physiotherapists in the experimental arm]

Name of Researcher:
Taweewat Wiangkham

Please tick all boxes

1. I confirm that I have read and understand the information sheet dated _____ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw anytime. ☐
3. I understand that I will be individually interviewed by a researcher using a semi-structured interview. ☐
4. I understand that I will not be identified in any reports, publications or presentations related to this work. ☐
5. I would like to take part in the above study. ☐

Name of Participant	Date	Signature

E-mail:

Telephone:

Name of Researcher	Date	Signature

Appendix 15: Consent form for the embedded qualitative study (phase II): the focus group

CONSENT FORM

Title of Project:

Acute Whiplash Injury Study: a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy intervention for acute Whiplash Associated Disorder (WAD) II management in an insurance private setting

[For the participants of focus group]

Name of Researcher:

Taweewat Wiangkham

Please tick all boxes

1. I confirm that I have read and understand the information sheet dated _____ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary. However, I cannot withdraw from the study during the interview because of the limitation of a group discussion setting. ☐
3. I understand that I will be interviewed using focus group technique. The anonymity within a focus group setting cannot be made because of the nature of a group discussion. ☐
4. I understand that I will not be identified in any reports, publications or presentations related to this work. ☐
5. I would like to take part in the above study. ☐

Name of Participant	Date	Signature

E-mail:

Telephone:

Name of Researcher	Date	Signature

Appendix 16: Data collection form for the external pilot and feasibility trial

Participant Data Collection Form

Acute Whiplash Injury Study (AWIS): a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy intervention for acute Whiplash Associated Disorder (WAD) II management in an insurance private setting

Date: ...../...../.....

Physiotherapy Clinic: .....

Participant Data:

First name: ..... **Surname:**.....

Gender: ☐ Male ☐ Female **Date of birth:** ...../...../.....

Date of motor vehicle accidents: ...../...../.....

To which of this ethic groups do you consider you belong (✓)?

White: ☐ British ☐ Other White background

Asian or Asian British: ☐ Bangladesh ☐ Indian ☐ Pakistani ☐ Other Asian background

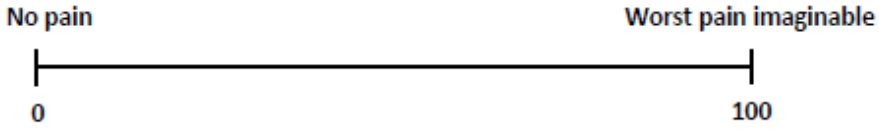
Black or Black British: ☐ Caribbean ☐ African ☐ Other Black background

Chinese or other ethnic group: ☐ Chinese ☐ Other

Mixed: ☐ White/ Black Caribbean ☐ White/ Black African

☐ White/ Asian ☐ Other Mixed Background

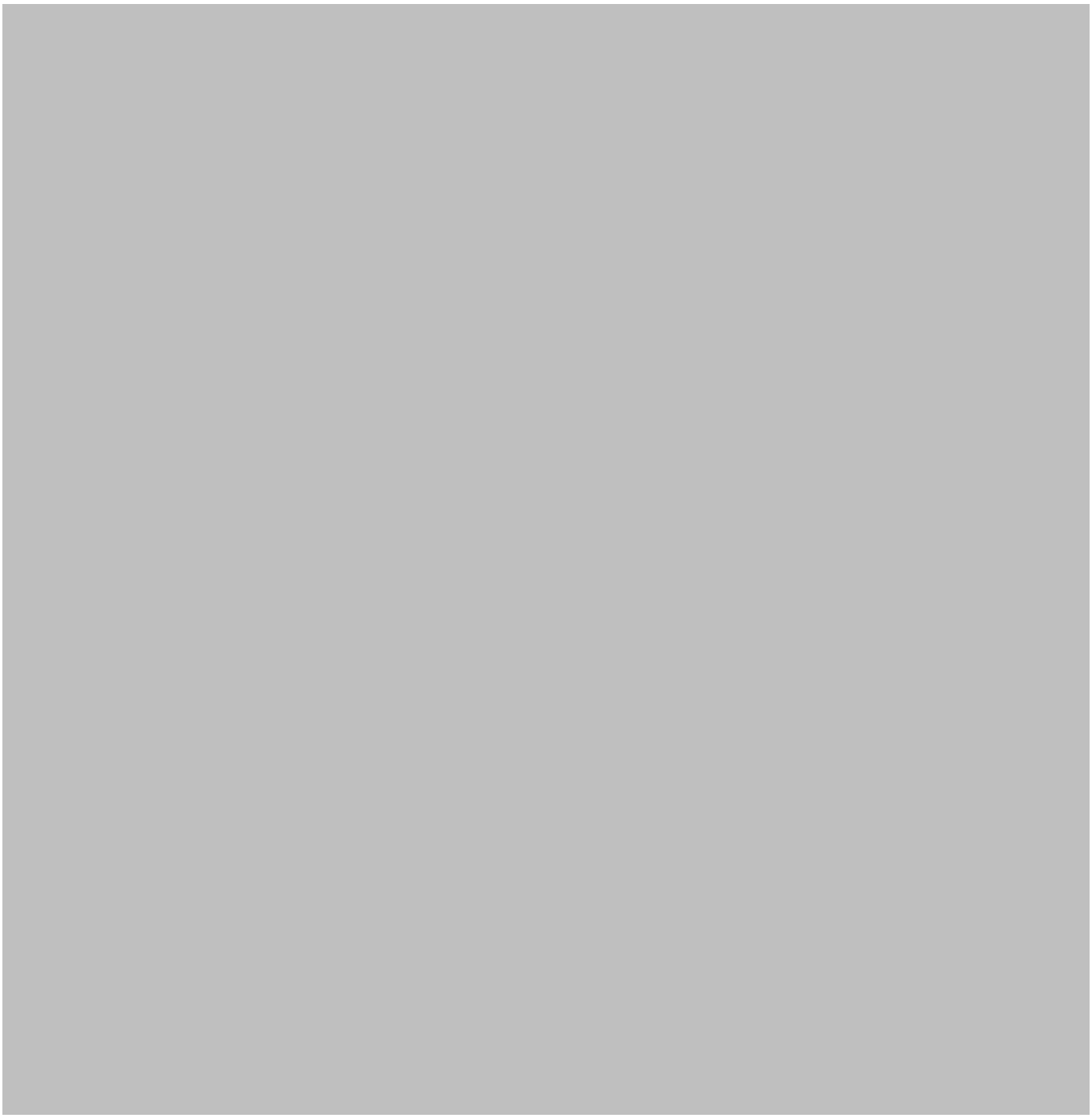
Visual Analogue Scale (VAS): Please mark (X) as your pain intensity today



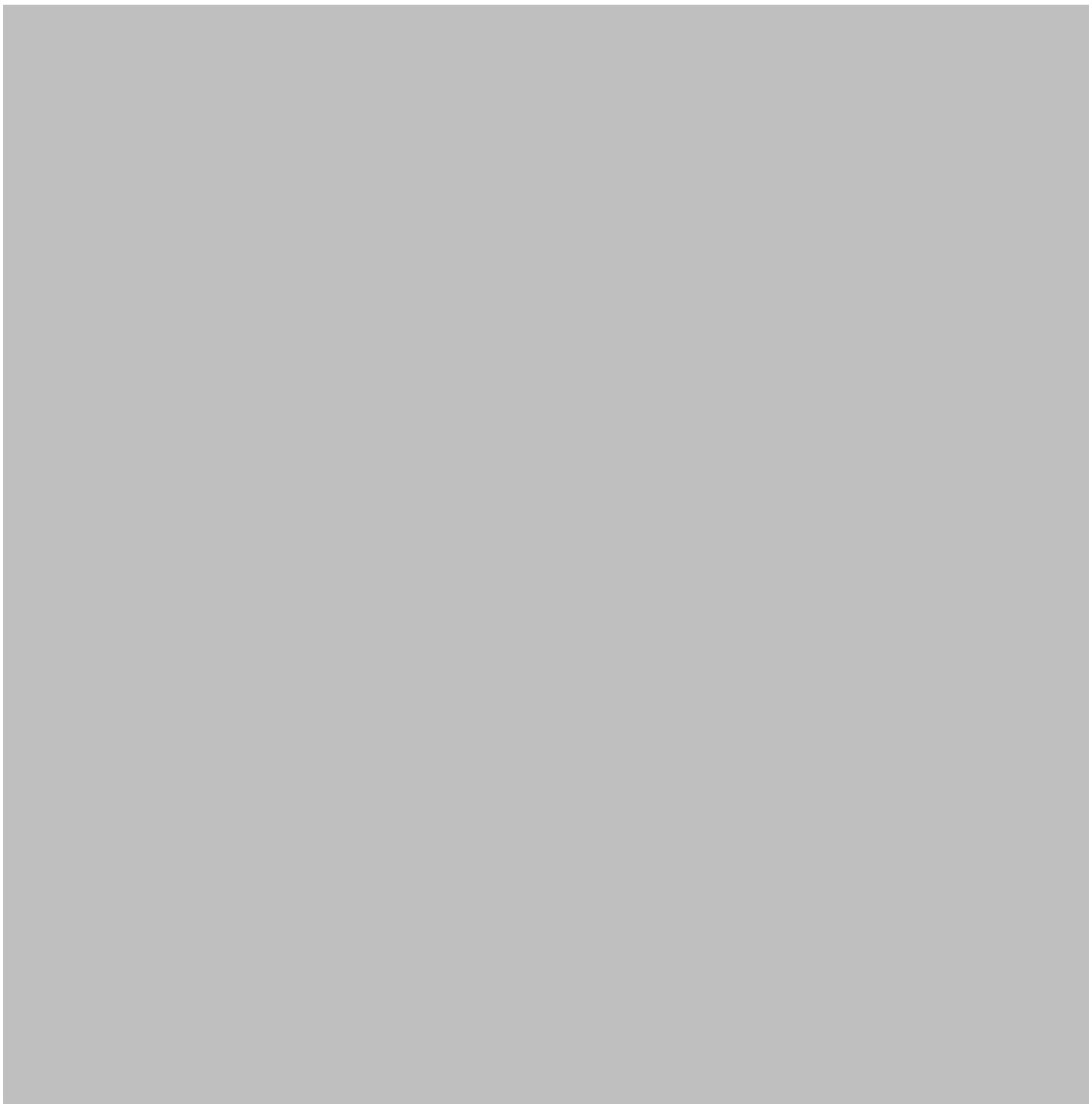
Neck Disability Index

Impact of Events Scale

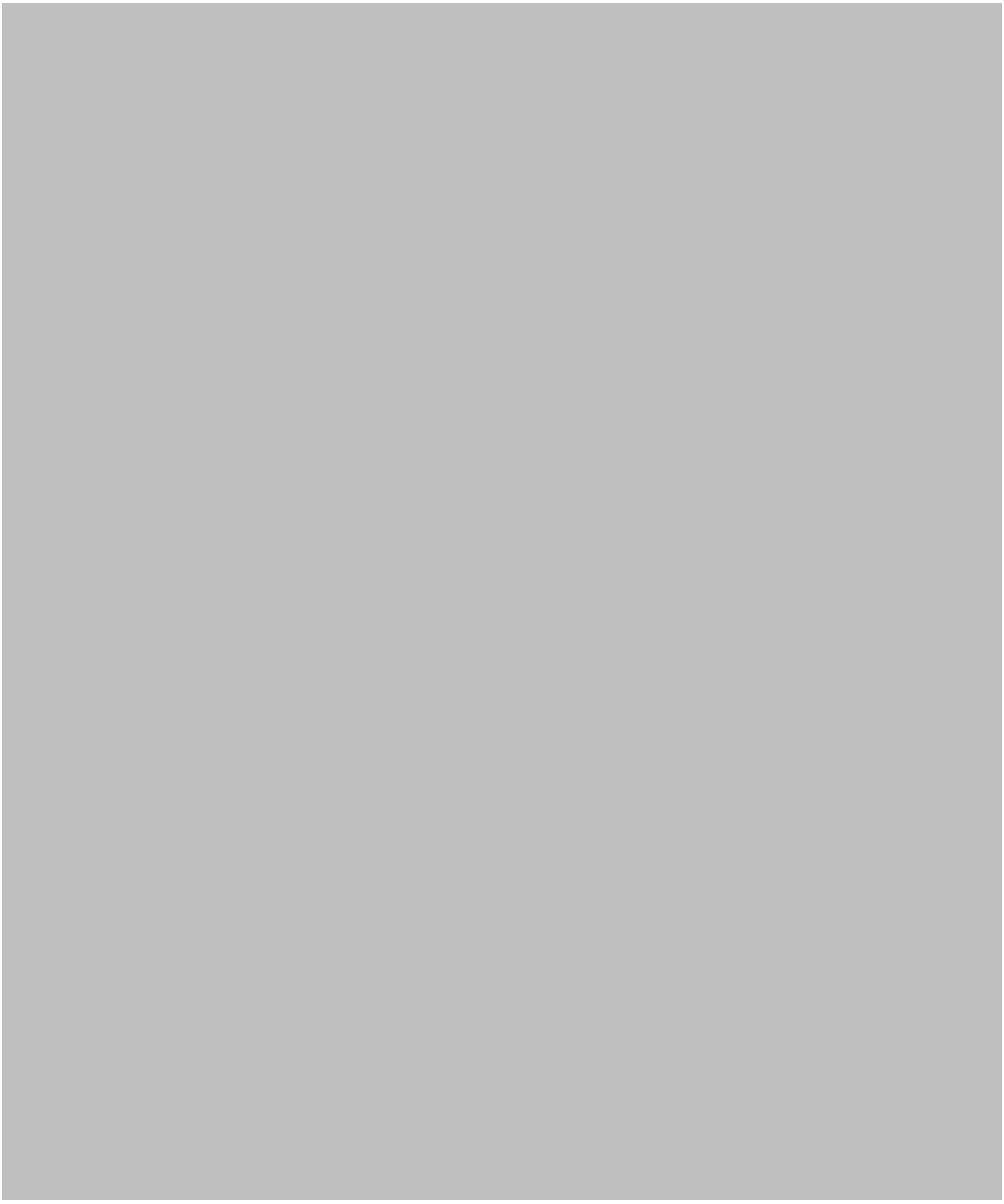
The following list is made by the comments of people after stress life events. Please tick (✓) each item, indicating how frequently these comments were true for you DURING THE PAST SEVEN DAYS. If they did not occur during that time, please mark the 'not at all' column.

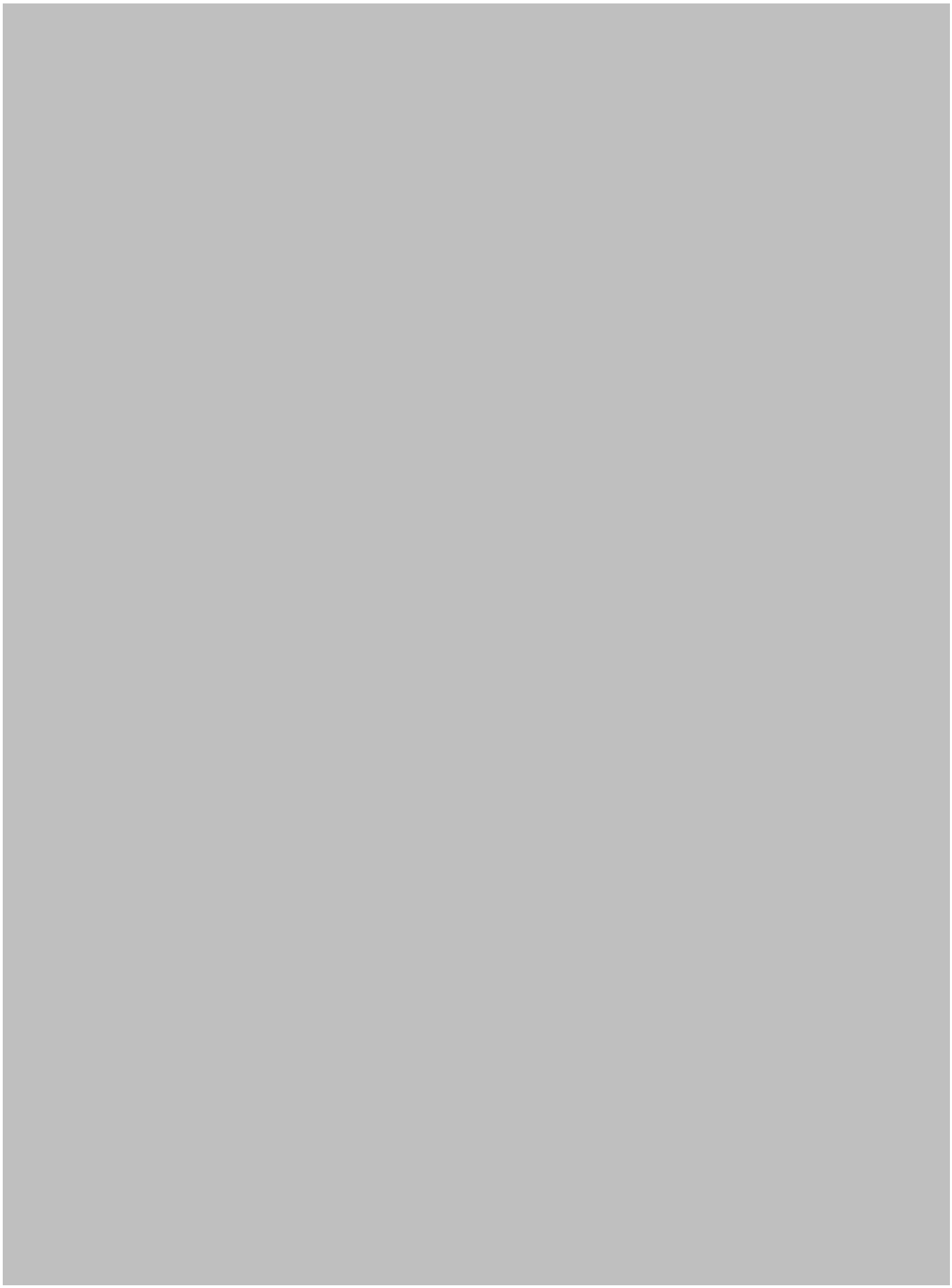


Fear-Avoidance Beliefs Questionnaire



Quality of Life EQ5D 5L (English version for UK)





For the Assessor

Cervical Range of Motion (CROM):

Directions	1 (degree)	2 (degree)	3 (degree)	Average (degree)
Flexion				
Extension				
Lt. Rotation				
Rt. Rotation				
Lt. Lateral flexion				
Rt. Lateral flexion				

Pressure Pain Threshold (PPT):

Muscles	1 (kPa)	2 (kPa)	3 (kPa)	Average (kPa)
Lt. Levator scapulae				
Rt. Levator scapulae				
Lt. Tibialis anterior				
Rt. Tibialis anterior				

Appendix 17: Diary pocket book for collecting relevant information of cost-effectiveness analysis

A Diary Pocket Book for Participants

Acute Whiplash Injury Study (AWIS): a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy intervention for acute Whiplash Associated Disorder (WAD) II management in an insurance private setting

Participant Information:

The following information helps us to explore the costs associated with your physiotherapy treatment. Please provide the following information.

Your Physiotherapy Clinic:.....

Post Code: .....

What is your current work status:	**Please indicate (✓) which income band your approximate annual household income would fall within:**
☐ Employed ☐ Self-employed ☐ Housewife/ husband ☐ Unemployed ☐ Carer ☐ Retired ☐ Student ☐ Other please detail.....	☐ < £10,000 ☐ £10,000-£19,999 ☐ £20,000-£29,999 ☐ £30,000-£39,999 ☐ £40,000-£49,999 ☐ £50,000-£59,999 ☐ £60,000-£69,999 ☐ £70,000 or above

Please choose a statement below that best describes your

Sick Pay / Benefits:

Are you currently receiving any of the following because of your neck problem:

Employer's sick pay	Yes ☐ No ☐
Statutory sick pay	Yes ☐ No ☐
Disability living allowance	Yes ☐ No ☐

Note: After your first visiting with your physiotherapist, please provide the number of sick leave, taking drug or meeting other health professionals. This information will help us to evaluate for cost effectiveness analysis.

Week 1:

Please provide the number of sick leave in this week..................... day(s)

Did you take any dugs for your neck problem? ☐ Yes ☐ No If YES, what kind of the drug? How many tablets? ☐ Analgesics _______tablets ☐ Relaxants _______tablets ☐ Other please detail .... _______tablets	
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../...........
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../...........
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../...........

Week 2:

Please provide the number of sick leave in this week........................ day(s)

Did you take any dugs for your neck problem? ☐ Yes ☐ No If YES, what kind of the drug? How many tablets? ☐ Analgesics _______tablets ☐ Relaxants _______tablets ☐ Other please detail .... _______tablets	
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../...........
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../...........
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../...........

Week 3:

Please provide the number of sick leave in this week...................... day(s)

<table>
<tr><td colspan="2">Did you take any dugs for your neck problem?
☐ Yes
☐ No

If YES, what kind of the drug? How many tablets?
☐ Analgesics _______tablets
☐ Relaxants _______tablets
☐ Other
please detail .... _______tablets</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
</table>

Week 4:

Please provide the number of sick leave in this week....................... day(s)

Did you take any dugs for your neck problem? ☐ Yes ☐ No If YES, what kind of the drug? How many tablets? ☐ Analgesics _______tablets ☐ Relaxants _______tablets ☐ Other please detail .... _______tablets	
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../..........
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../..........
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../..........

Week 5:

Please provide the number of sick leave in this week........................ day(s)

<table>
<tr><td colspan="2">Did you take any dugs for your neck problem?
☐ Yes
☐ No

If YES, what kind of the drug? How many tablets?
☐ Analgesics _______tablets
☐ Relaxants _______tablets
☐ Other
please detail .... _______tablets</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
</table>

Week 6:

Please provide the number of sick leave in this week…………………… day(s)

<table>
<tr><td colspan="2">Did you take any dugs for your neck problem?
☐ Yes
☐ No

If YES, what kind of the drug? How many tablets?
☐ Analgesics ______tablets
☐ Relaxants ______tablets
☐ Other
please detail ……………………………………………………… ______tablets</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail……………………………………………………</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£……………… Date: …../……/……….</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail……………………………………………………</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£……………… Date: …../……/……….</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail……………………………………………………</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£……………… Date: …../……/……….</td></tr>
</table>

Week 7:

Please provide the number of sick leave in this week...................... day(s)

<table>
<tr><td colspan="2">Did you take any dugs for your neck problem?
☐ Yes
☐ No

If YES, what kind of the drug? How many tablets?
☐ Analgesics _______tablets
☐ Relaxants _______tablets
☐ Other
please detail .... _______tablets</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail..</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail..</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail..</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
</table>

Week 8:

Please provide the number of sick leave in this week...................... day(s)

Did you take any dugs for your neck problem? ☐ Yes ☐ No If YES, what kind of the drug? How many tablets? ☐ Analgesics _______tablets ☐ Relaxants _______tablets ☐ Other please detail .... _______tablets	
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../...........
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../...........
Other health professional that you have seen this week for your neck problem: ☐ General Practitioner (GP) ☐ Other physiotherapist ☐ Osteopath ☐ Chiropractor ☐ Other Please detail..	**Did you have to pay?** ☐ No ☐ Yes If yes, please provide how much you paid? £.................. **Date:** ...../....../...........

Week 9:

Please provide the number of sick leave in this week........................ day(s)

<table>
<tr><td colspan="2">Did you take any dugs for your neck problem?
☐ Yes
☐ No

If YES, what kind of the drug? How many tablets?
☐ Analgesics _______tablets
☐ Relaxants _______tablets
☐ Other
please detail .... _______tablets</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£................... Date: ...../....../...........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£................... Date: ...../....../...........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£................... Date: ...../....../...........</td></tr>
</table>

Week 10:

Please provide the number of sick leave in this week....................... day(s)

<table>
<tr><td colspan="2">Did you take any dugs for your neck problem?
☐ Yes
☐ No

If YES, what kind of the drug? How many tablets?
☐ Analgesics _______tablets
☐ Relaxants _______tablets
☐ Other
please detail .... _______tablets</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail..</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../...........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail..</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../...........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail..</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../...........</td></tr>
</table>

Week 11:

Please provide the number of sick leave in this week...................... day(s)

<table>
<tr><td colspan="2">Did you take any dugs for your neck problem?
☐ Yes
☐ No

If YES, what kind of the drug? How many tablets?
☐ Analgesics _______tablets
☐ Relaxants _______tablets
☐ Other
please detail .... _______tablets</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail..</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail..</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail..</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../..........</td></tr>
</table>

Week 12:

Please provide the number of sick leave in this week...................... day(s)

<table>
<tr><td colspan="2">Did you take any dugs for your neck problem?
☐ Yes
☐ No

If YES, what kind of the drug? How many tablets?
☐ Analgesics _______tablets
☐ Relaxants _______tablets
☐ Other
please detail .... _______tablets</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../...........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../...........</td></tr>
<tr><td>Other health professional that you have seen this week for your neck problem:
☐ General Practitioner (GP)
☐ Other physiotherapist
☐ Osteopath
☐ Chiropractor
☐ Other
Please detail...</td><td>Did you have to pay?
☐ No
☐ Yes

If yes, please provide how much you paid?

£.................. Date: ...../....../...........</td></tr>
</table>

Appendix 18: Acute Whiplash Injury Study (AWIS) trial steering and data-monitoring committee meeting 17th December 2015: agenda

AGENDA

AWIS Trial Steering Group and Data Monitoring Committee

Seminar room G86, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Edgbaston campus, B15 2TT

Meeting date	17th December 2015	**Chair**	Dr. Nicola Heneghan
Trial registration	ISRCTN84528320	**Member**	Dr. Esther Williamson Dr. Alison Rushton Dr. Sayeed Haque Simon Smith Jonathan Price Taweewat Wiangkham
Time	1-3 pm.		

1. Introduction and welcome	**TW**
2. Apologies	**TW**
3. Brief summary of the study	**TW**
4. Recruitment 06.11.15 to 12.12.15 • Recruitment summary • Introduced patients • CONSORT diagram • Expected versus actual recruitment *Note: A major issue is slow recruitment rate*	**TW**
5. Data quality • Baseline assessment	**TW**
6. Data • Demographic data • Primary and secondary outcome summary	**TW**
7. Withdrawals / violations • Withdrawals / violations and reasons	**TW**
8. Serious adverse events • Serious adverse events • Adverse events	**TW**
9. Any other business	**TW**
10. Date and time of next meeting	

Appendix 19: Acute Whiplash Injury Study (AWIS) trial steering and data-monitoring committee meeting 17th December 2015: minutes

MINUTES

AWIS Trial Steering Group and Data Monitoring Committee

Seminar room G86, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Edgbaston campus, B15 2TT

Thursday 17th December 2015 13:00-15:00 pm

	Responsible Person
1. WELCOME	**NH/TW**
Introduced committees Introduction Acute Whiplash Injury Study (AWIS) Aims of the AWIS committee	
2. ATTENDEES AND APOLOGIES	**NH/TW**
AWIS Attendees: Dr. Nicola Heneghan Dr. Esther Williamson Dr. Sayeed Haque Simon Smith Taweewat Wiangkham Apologies: Dr. Alison Rushton Jonathan Price Minutes taken by TW	

3. BRIEF SUMMARY OF THE STUDY AND DISCUSSION POINTS	**TW**
Acute Whiplash Injury Study (AWIS) protocol for a pilot and feasibility trial of the Active Behavioural Physiotherapy Intervention (ABPI) for acute Whiplash Associated Disorder (WAD) II management • A cluster randomised pilot and feasibility parallel two arms o Recruitment summary o Introduced patients o CONSORT diagram o Data quality (baseline assessment) o Data ▪ Demographic data ▪ Primary and secondary outcome summary o Expected versus actual recruitment (*Note: A major issue is slow recruitment rate)* ▪ Changing and training a new admin to improve the recruitment rate • An embedded qualitative study of the ABPI <u>Action points:</u> To develop participant information sheet (TW send the PIS to SS, complete) To set up an accurate data recording (TW and Jon, complete) Changing and training a new admin to improve the recruitment rate (TW and Jon, complete) To organise next meeting (TW, complete)	
4 SERIOUS ADVERSE EVENTS	**TW**
No serious adverse events were reported throughout the trial.	
5. ANY OTHER BUSINESS	**NH/TW**
NH and TW thanked everyone for attending and closed the meeting.	

Appendix 20: Acute Whiplash Injury Study (AWIS) trial steering and data-monitoring committee meeting 28th June 2016: agenda

AGENDA

AWIS Trial Steering Group and Data Monitoring Committee

Meeting room G5, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Edgbaston campus, B15 2TT

Meeting date	28th June 2016	**Chair**	Dr. Nicola Heneghan
Trial registration	ISRCTN84528320	**Member**	Dr. Esther Williamson Dr. Alison Rushton Dr. Sayeed Haque Simon Smith Jonathan Price Taweewat Wingkham
Time	11 am-1 pm.		

11. Welcome	**TW**
12. Attendees and apologies	**TW**
13. Minutes and action points from previous meeting a. TW to send PIS to Simon to getting feedback. Complete. b. TW to set up an accurate data recording. Complete.	
14. Recruitment 06.11.15 to 27.06.16 • Recruitment summary • CONSORT Diagram • Stopping recruitment	**TW**
15. Data quality • Baseline assessment • 3 months follow-up assessment	**TW**
16. Data • Demographic data • Primary and secondary outcome summary	**TW**
17. Withdrawals / violations • Withdrawals / violations and reasons	**TW**
18. Serious adverse events	**TW**
19. Any other business	**TW**
20. Date and time of next meeting	

Appendix 21: Acute Whiplash Injury Study (AWIS) trial steering and data-monitoring committee meeting 28th June 2016: minutes

MINUTES

AWIS Trial Steering Group and Data Monitoring Committee

Meeting room G5, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Edgbaston campus, B15 2TT

Thursday 28th June 2016 11:00-13:00

	Responsible Person
1. WELCOME	**NH/TW**
Aims of this meeting	
2. ATTENDEES AND APOLOGIES	**NH/TW**
AWIS Attendees: Dr. Nicola Heneghan Dr. Esther Williamson Dr. Alison Rushton Dr. Sayeed Haque Jonathan Price Taweewat Wiangkham Apologies: Simon Smith (Unable to contact him since last meeting although in telephone callings, text messages, left voice mails, and electronic mails) Minutes taken by TW	
3. BRIEF SUMMARY OF THE STUDY AND DISCUSSION POINTS	**TW**

Acute Whiplash Injury Study (AWIS): a pilot and feasibility trial of the Active Behavioural Physiotherapy Intervention (ABPI) for acute Whiplash Associated Disorder (WAD) II management
• A cluster randomised pilot and feasibility parallel two arms
  ○ Recruitment summary
  ○ CONSORT diagram
  ○ Data quality
  ○ Data with no missing data
  ▪ Demographic data
  ▪ Primary and secondary outcome summary	

▪ 3 months follow-up Some participants were assessed via telephone for NDI (primary outcome measure). These patients did not have time to attend the 3 months follow-up assessment because of their work. ▪ Withdrawal/ drop-out No withdrawal or drop-out o Expected versus actual recruitment o Stopping participant recruitment ▪ Time scale ▪ The reduction of the number of referrals (low referrals in summer) ▪ Trial budget ***Supported by AWIS committee discussion, the recruitment should be stopped.*** • An embedded qualitative study of the ABPI o Staying in the protocol ▪ Semi-structured interviews for physiotherapists in the experimental arm ▪ A focus group (6-8 participants) for patients in the experimental arm o Some suggestions by committees ▪ Using telephone interview when cannot do in face to face semi-structured interview or focus group ▪ When a focus group cannot be conducted, semi structured interview may be a good option • Future trial o After taking over the Physio 1st, solicitors control physiotherapists about the number of treatment session o Interview Jon to explore the current system of the Physio1st and the possible of the future definitive trial <u>Action points:</u> To stop trial recruitment (TW, complete) To organise next meeting (NH and TW, complete)	
4 SERIOUS ADVERSE EVENTS	**TW**
No serious adverse events were reported throughout the trial.	
6. ANY OTHER BUSINESS	**NH/TW**
NH and TW thanked everyone for attending and closed the meeting.	

ACUTE WHIPLASH INJURY STUDY (AWIS)

Trial Steering and Data Monitoring Committee
28th June 2016
Meeting room G5
School of Sport, Exercise and Rehabilitation Sciences
University of Birmingham

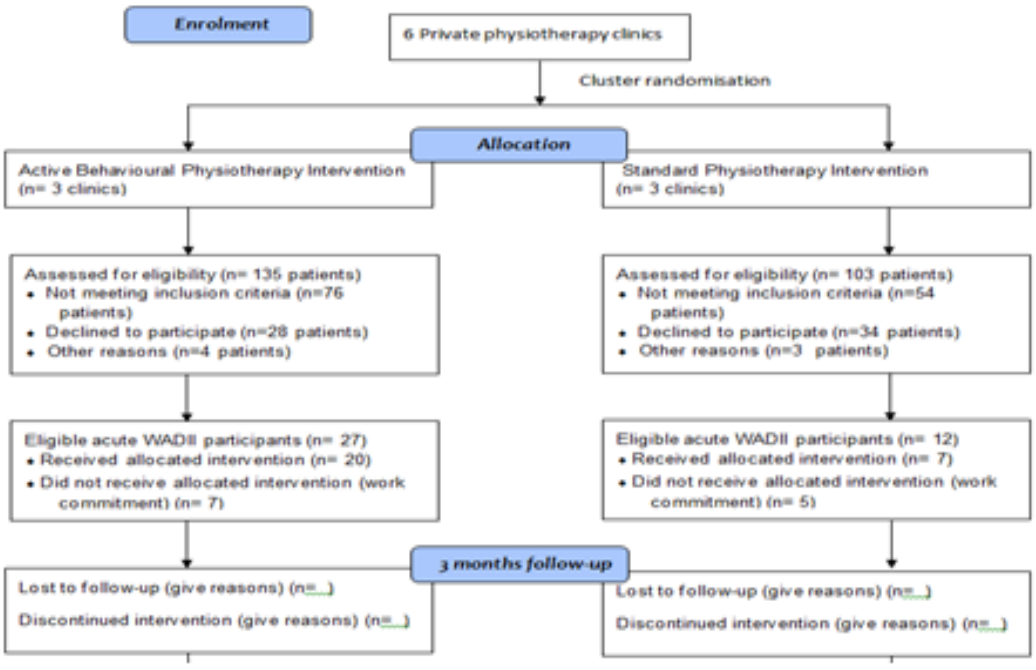
Recruitment details 6/11/2015-13/12/2015

- 4 participants
- 3 males for the experimental arm (all from Moseley clinic)
  - 1 completed 3 months follow-up by face to face
  - 3 completed 3 months follow-up via telephone
- 1 female for control arm (from Sutton Coldfield clinic)
  - Completed 3 months follow-up via telephone

Recruitment details 1/3/2016-26/6/2016

Clinics	ND referrals	Not meet criteria	Declined	Unable to book < 4 weeks	Online booking	Left message	Eligible pts	Participated	Completed 3 months F/U
West Brom	37	23	8				6	3 (50%)	1
Solihull	60	33	9		1	3	14	10 (71.43%)	
Moseley	38	18	10		2	1	7	4 (57.14%)	
Experimental arm	136	74	27		3	4	27	17 (62.96%)	1
Great Barr	36	20	14				2	2 (100%)	
Bham City	33	18	12			1	2	0 (0%)	
Sutton Coldfield	34	16	8	1		1	8	4 (50%)	1
Control arm	103	64	34	1	-	2	12	8 (60%)	1
Total	238	128	81	1	3	6	39	25 (58.97%)	2

CONSORT Diagram



Demographic data

- 27 Participants mean age 39.67 ± 13.91 years
  - 7 (25.9%) for standard PT (mean age 50.57 ± 13.66 years)
  - 20 (74.1%) for ABPI (mean age 35.85 ± 12.11 years)
- Gender

Intervention arm	Female	Male	Total
Standard PT	5	2	7
ABPI	3	17	20
Total	**8**	**19**	**27**

Demographic data

Intervention arm	British	Asian/ Asian British	Black/ Black British	Chinese or other	Mixed	Total
Standard PT	6	1	0	0	0	7
ABPI	9	7	1	2	1	20
Total	**15**	**8**	**1**	**2**	**1**	**27**

Baseline assessment

Outcome measures	Standard PT	ABPI
Pain intensity	47.00 (27.00)	55.50 (29.50)
NDI	23.00 (10.00)	17.50 (18.00)
IES	49.00 (41.00)	29.50 (31.75)
FABQ	64.00 (25.00)	60.00 (25.00)
EQ-5D	11.00 (8.00)	11.00 (5.50)
VAS_EQ-5D	60.00 (49.00)	57.50 (32.50)

Baseline assessment

CROM	Standard PT	ABPI
Flexion	26.00 (12.66)	22.50 (7.67)
Extension	19.33 (27.66)	22.83 (17.58)
Lt. rotation	40.00 (29.34)	29.67 (18.33)
Rt. Rotation	32.00 (25.33)	30.67 (17.83)
Lt. lateral flexion	25.67 (16.33)	22.34 (13.33)
Rt. Lateral flexion	24.67 (11.00)	22.67 (11.84)

Baseline assessment

PPT	Standard PT	ABPI
Lt. Levator Scapulae	67.33 (40.66)	74.67 (71.75)
Rt. Levator Scapulae	75.00 (48.67)	71.50 (69.66)
Lt. Tibialis Anterior	98.00 (46.00)	106.17 (101.08)
Rt. Tibialis Anterior	93.67 (26.00)	90.17 (110.34)

Note: no missing data for all baseline assessments

Three months F/U post baseline

- 6 participants completed 3 months F/U
  - 3 completed by face to face (2 males in ABPI, 1 female in control)
  - 3 completed by telephone (2 males in ABPI, 1 female in control)
- Gender

Intervention arm	Female	Male	Total
Standard PT	2	-	2
ABPI	-	4	4
Total	2	4	6

- All participants in the ABPI group were recovered according to NDI ≤ 4
- All participants in the control group were not recovered according to NDI ≥ 5

Three months F/U post baseline

Outcome measures	Standard PT	ABPI
NDI	8.50 ± 4.95 8.50 (0.00)	0.50 ± 0.58 0.50 (1.00)
Pain intensity		8.33 ± 14.43
IES		15.67 ± 17.16
FABQ		35.67 ± 10.02
EQ-5D		5.33 ± 0.58
Cx. Flexion		45.55 ± 3.28
Cx. Extension		44.33 ± 16.19
Cx. Lt. Rotation		53.00 ± 6.94
Cx. Rt. Rotation		51.11 ± 13.07
Cx. Lt. Lateral Flexion		28.11 ± 12.22
Cx. Rt. Lateral Flexion		32.56 ± 6.83

Three months F/U post baseline

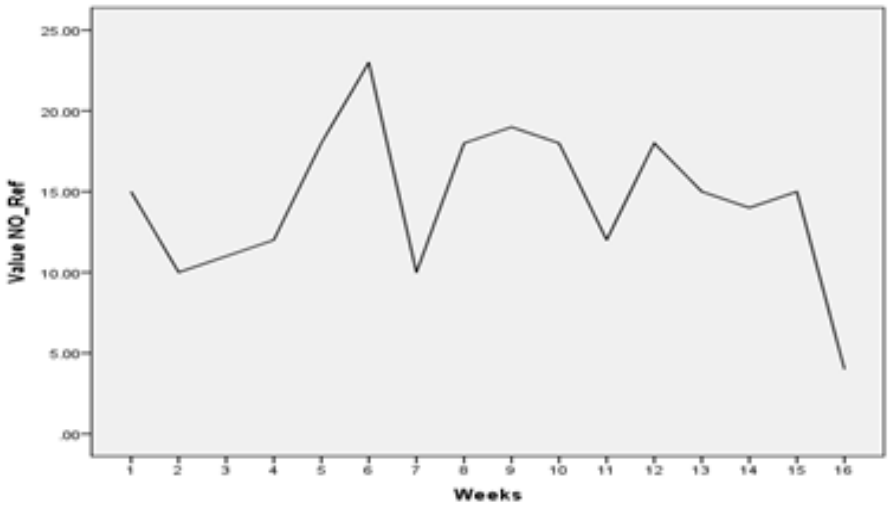
PPT	Standard PT	ABPI
Lt. Levator Scapulae		186.55 ± 47.26
Rt. Levator Scapulae		205.67 ± 50.86
Lt. Tibialis Anterior		275.22 ± 52.56
Rt. Tibialis Anterior		267.89 ± 70.17

Three months F/U post baseline

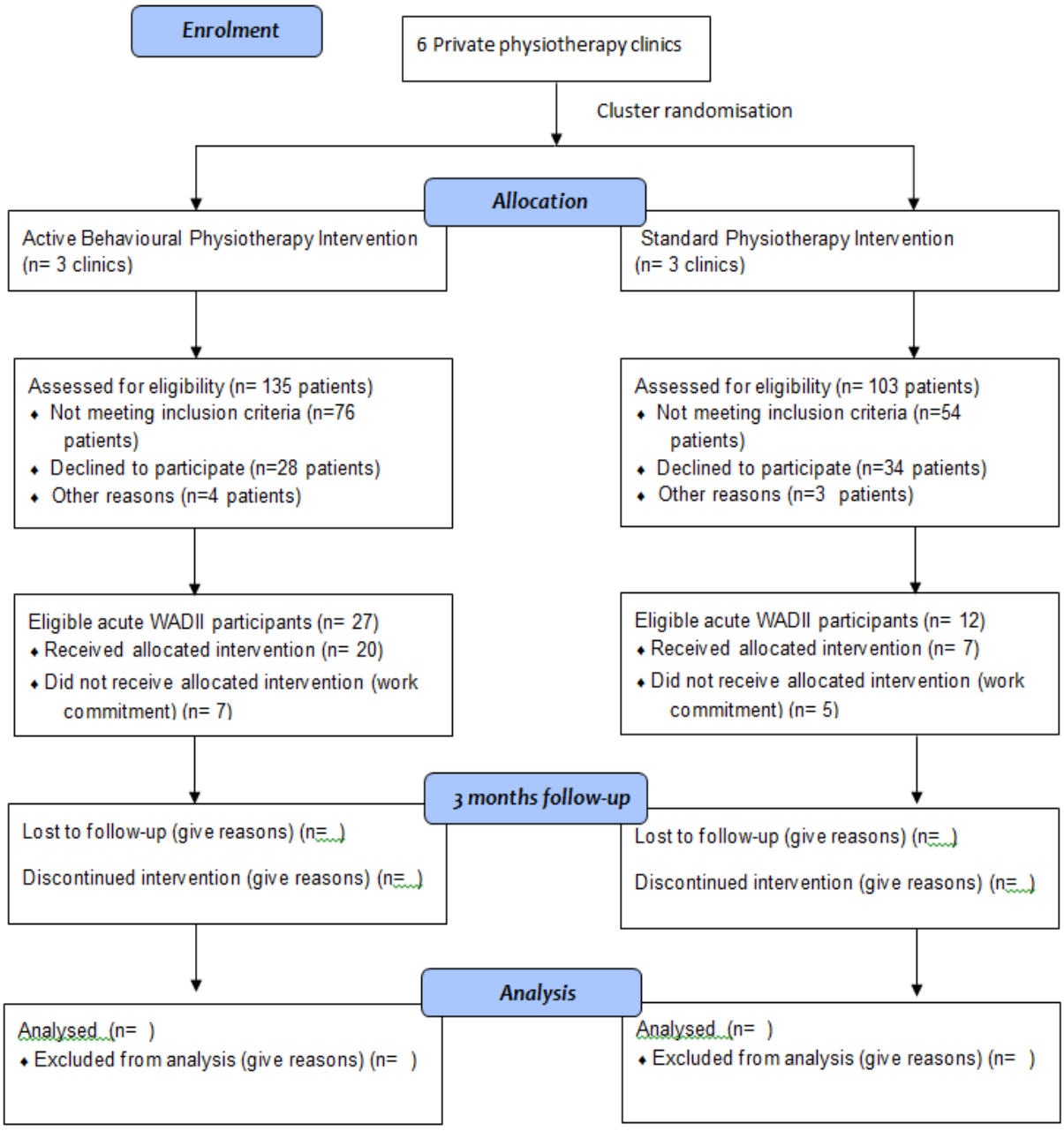
- No missing data
- No adverse/serious adverse events were reported

Discussion

- Stopping recruitment
  - The reduction of the number of referrals



CONSORT FLOW DIAGRAM



Acute Whiplash Injury Study (AWIS): Monitoring the pilot and feasibility trial of acute WADII management in an insurance private setting

- **Recording from 6th November 2015 to 20th December 2016**
  - Do not know how many patients were asked.
  - 13 eligible patients
  - 4 involved participants (1 full 3 months F/U and 3 telephone F/U)

- **Recording from 1st March 2016 to 6th March 2016**

Referrals (n)		**Not meet criteria**	**Eligible patients**		**recruited participants**		**Completed 3 months F/U**	
15		**15**	**0**		**0**		**0**	
Experimental	**Control**		**Experimental**	**Control**	**Experimental**	**Control**	**Experimental**	**Control**
10	5	- 9 pts post 4 weeks - 3 pts serious symptoms in other regions - 3 pts do not want to participate	-	-	-	-	-	-

- **Recording from 7th March 2016 to 13th March 2016**

Referrals (n)		**Not meet criteria**	**Eligible patients**		**recruited participants**		**Completed 3 months F/U**	
10		**10**	**0**		**0**		**0**	
Experimental	**Control**		**Experimental**	**Control**	**Experimental**	**Control**	**Experimental**	**Control**
8	2	- 7 pts post 4 weeks - 2 pts do not want to participate - 1 pt unable to book initial assessment within 4 weeks	-	-	-	-	-	-

- **Recording from 14th March 2016 to 20th March 2016**

Referrals (n)		Not meet criteria	Eligible patients		recruited participants		Completed 3 months F/U	
11		9	2		2		0	
Experimental	Control		Experimental	Control	Experimental	Control	Experimental	Control
6	5	- 6 pts post 4 weeks - 2 pt non-English speaking - 1 pt unable to book initial assessment within 4 weeks	1	1	1	1	-	-

- **Recording from 21st March 2016 to 27th March 2016**

Referrals (n)		Not meet criteria	Eligible patients		recruited participants		Completed 3 months F/U	
12		11	1		1		0	
Experimental	Control		Experimental	Control	Experimental	Control	Experimental	Control
5	7	- 4 pts post 4 weeks - 4 pts do not want to participate - 2 pts serious symptoms in other regions - 1 pt non-English speaking	-	1	-	1	-	-

- **Recording from 28th March 2016 to 3rd April 2016**

Referrals (n)		Not meet criteria	Eligible patients		recruited participants		Completed 3 months F/U	
18		14	4		2		0	
Experimental	Control		Experimental	Control	Experimental	Control	Experimental	Control
13	5	- 4 pts post 4 weeks - 6 pts do not want to participate - 2 pts unable to book initial assessment within 4 weeks - 1 pts serious symptoms in other regions - 1 pts non-English speaking	2	2	1	1	-	-

- **Recording from 4th April 2016 to 10th April 2016**

Referrals (n)		Not meet criteria	Eligible patients		recruited participants		Completed 3 months F/U	
23		22	1		1		0	
Experimental	Control		Experimental	Control	Experimental	Control	Experimental	Control
9	14	- 15 pts post 4 weeks - 5 pts do not want to participate - 1 pts unable to book initial assessment within 4 weeks - 1 pt non-English speaking	-	1	-	1	-	-

- **Recording from 11th April 2016 to 17th April 2016**

Referrals (n)		Not meet criteria	Eligible patients		Recruited participants		Completed 3 months F/U	
10		8	2		2			
Experimental	Control		Experimental	Control	Experimental	Control	Experimental	Control
3	7	- 4 pts post 4 weeks - 2 pts do not want to participate - 1 pt having treatment with another clinic - 1 pt non-English speaking	-	2	-	2	-	-

- **Recording from 18th April 2016 to 24th April 2016**

Referrals (n)		Not meet criteria	Eligible patients		Recruited participants		Completed 3 months F/U	
18		18	0		0			
Experimental	Control		Experimental	Control	Experimental	Control	Experimental	Control
11	7	- 10 pts post 4 weeks - 3 pts non-English speaking - 3 pts do not want to participate - 1 pt having treatment with another clinic - 1 pt unable to book initial assessment within 4 weeks	-	-	-	-	-	-

- **Recording from 25th April 2016 to 1st May 2016**

Referrals (n)		Not meet criteria	Eligible patients		Recruited participants		Completed 3 months F/U	
19		12	7		4			
Experimental	**Control**		**Experimental**	**Control**	**Experimental**	**Control**	**Experimental**	**Control**
15	4	- 6 pts post 4 weeks - 2 pts do not want to participate - 2 pts unable to book initial assessment within 4 weeks - 2 pts non-English speaking	7	-	4	-	-	-

- **Recording from 2nd May 2016 to 8th May 2016**

Referrals (n)		Not meet criteria	Eligible patients		Recruited participants		Completed 3 months F/U	
18		15	3		2			
Experimental	**Control**		**Experimental**	**Control**	**Experimental**	**Control**	**Experimental**	**Control**
11	7	- 5 pts post 4 weeks - 3 pts do not want to participate - 3 pts serious symptoms in other regions - 2 pts booking via bodycare without screening - 1 pt having treatment with another clinic - 1 pt unable to book initial assessment within 4 weeks	3	-	2	-	-	-

- **Recording from 9th May 2016 to 15th May 2016**

Referrals (n)		Not meet criteria	Eligible patients		Recruited participants		Completed 3 months F/U	
21		18	3		1			
Experimental	Control		Experimental	Control	Experimental	Control	Experimental	Control
12	9	- 6 pts post 4 weeks - 4 pts serious symptoms in other regions - 3 pts do not want to participate - 2 pts booking via bodycare without screening - 1 pt having treatment with another clinic - 1 pt unable to book initial assessment within 4 weeks - 1 pt history neck surgery	-	3	-	1	-	-

- **Recording from 16th May 2016 to 22nd May 2016**

Referrals (n)		Not meet criteria	Eligible patients		Recruited participants		Completed 3 months F/U	
18		13	5		4			
Experimental	Control		Experimental	Control	Experimental	Control	Experimental	Control
9	9	- 5 pts post 4 weeks - 2 pts serious symptoms in other regions - 2 pts do not want to participate - 2 pts booking via bodycare without screening - 2 pts non-English speaking	5	-	4	-	-	-

- **Recording from 23rd May 2016 to 29th May 2016**

Referrals (n)		Not meet criteria	Eligible patients		Recruited participants		Completed 3 months F/U	
15		8	7		6			
Experimental	**Control**		**Experimental**	**Control**	**Experimental**	**Control**	**Experimental**	**Control**
11	4	- 3 pts post 4 weeks - 2 pts do not want to participate - 2 pts serious symptoms in other regions - 1 pt non-English speaking	7	-	6	-	-	-

- **Recording from 30th May 2016 to 5th June 2016 : Admin on A/L**

- **Recording from 6th June 2016 to 12th June 2016**

Referrals (n)		Not meet criteria	Eligible patients		Recruited participants		Completed 3 months F/U	
14			3		1			
Experimental	**Control**		**Experimental**	**Control**	**Experimental**	**Control**	**Experimental**	**Control**
6	8	- 5 pts post 4 weeks - 2 pts serious symptoms in other regions - 7 pts left message or voicemail	1	2	1	-	-	-

- **Recording from 13th June 2016 to 19th June 2016**

Referrals (n)		Not meet criteria	Eligible patients		Recruited participants		Completed 3 months F/U	
12			-		-			
Experimental	**Control**		**Experimental**	**Control**	**Experimental**	**Control**	**Experimental**	**Control**
4	8	- 1 pt post 4 weeks - 9 pts left message or voicemail - 2 pts booking via online system without screening	-	-	-	-	-	-

- **Recording from 20th June 2016 to 26th June 2016**

Referrals (n)		Not meet criteria	Eligible patients		Recruited participants		Completed 3 months F/U	
4		3	1		1		2	
Experimental	**Control**		**Experimental**	**Control**	**Experimental**	**Control**	**Experimental**	**Control**
2	2	- 2 pts do not want to participate - 1 pt do not want to travel to assessment centre	1	-	1	-	1	1

Appendix 22: Acute Whiplash Injury Study (AWIS) trial steering and data-monitoring committee meeting 17th October 2016: agenda

AGENDA

AWIS Trial Steering Group and Data Monitoring Committee

Meeting room G5, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Edgbaston campus, B15 2TT

Meeting date	17th October 2016	**Chair**	Dr. Nicola Heneghan
Trial registration	ISRCTN84528320	**Member**	Dr. Esther Williamson Dr. Alison Rushton Dr. Sayeed Haque Simon Smith Jonathan Price Taweewat Wingkham
Time	1-2 pm.		

21. Welcome	**NH/TW**
22. Attendees and apologies	**TW**
23. Minutes and action points from the previous meeting	**TW**
24. Recruitment • Recruitment and follow-up summary CONSORT Diagram	**TW**
25. Data quality • Baseline assessment • 3 months follow-up assessment	**TW**
26. Data • Demographic data • Primary and secondary outcome summary	**TW**
27. Withdrawals / violations • Withdrawals / violations and reasons	**TW**
28. Serious adverse events	**TW**
29. Qualitative study • Semi-structured interviews for physiotherapists in the experimental arm • A focus group for participants in the experimental arm	**TW**
30. Any other business	**NH/TW**
31. Thank you all committees for their invaluable time and contributing in this trial	

Appendix 23: Acute Whiplash Injury Study (AWIS) trial steering and data-monitoring committee meeting 17th October 2016: minutes

MINUTES

AWIS Trial Steering Group and Data Monitoring Committee

Meeting room G5, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Edgbaston campus, B15 2TT

Thursday 17th October 2016 13:00-14:00

	Responsible Person
1. WELCOME	**NH/TW**
Aims of this meeting	
2. ATTENDEES AND APOLOGIES	**NH/TW**
AWIS Attendees: Dr. Nicola Heneghan Dr. Esther Williamson Dr. Alison Rushton Dr. Sayeed Haque Jonathan Price Taweewat Wiangkham Apologies: Simon Smith (Unable to contact him since last meeting although in telephone callings, text messages, left voice mails, and electronic mails) Minutes taken by TW	

3. BRIEF SUMMARY OF THE STUDY AND DISCUSSION POINTS	**TW**
Acute Whiplash Injury Study (AWIS): a pilot and feasibility trial of the Active Behavioural Physiotherapy Intervention (ABPI) for acute Whiplash Associated Disorder (WAD) II management • A cluster randomised pilot and feasibility parallel two arms o Recruitment and follow-up summary o CONSORT diagram o Data quality o Data with no missing data ▪ Demographic data ▪ Primary and secondary outcome summary ▪ Baseline and 3 months follow-up ▪ Withdrawal/ drop-out • An embedded qualitative study of the ABPI o Semi-structured interviews for physiotherapists in the experimental arm o Focus group for the participants in the experimental arm • Considerations for the future definitive trial	
4 SERIOUS ADVERSE EVENTS	**TW**
No serious adverse events were reported throughout the trial.	
7. ANY OTHER BUSINESS	**NH/TW**
NH and TW thanked everyone for their invaluable time and contributing in this trial.	

Appendix 24: Transcript of the semi-structured interview for physiotherapist A

An Embedded Qualitative Study of an Active Behavioural Physiotherapy Intervention (ABPI)

Semi-structured interview for physiotherapists in the ABPI arm

1st Interviewee on 28th July 2016

Moseley Clinic 5-6 pm.

1. Opinions and attitudes for an Active Behavioural Physiotherapy Intervention (ABPI)

1.1 Physiotherapists' experience and perceptions

T: What is your perception in using the ABPI for treating your patients?

I: It was quite helpful to use the ABPI in my patients. The ABPI helps me to understand and how to explore patients' problems in both physical (e.g. neck, lower back) and psychological (driving, getting to the gym). Then, I have to manage those problems.

T: What do you think about the concept of the ABPI

I: It was quite interesting. As I told you, we do not only focus on physical management (e.g. reduce pain or increase ROM) but we have to focus on and think what is going on about patients' mind. However, I concern a little bit more about time consuming because it was difficult to get an answer from patients at the beginning. I need to spend about 1-2 sessions to build trust between physio and patients. And then exploration in patients will be easier. I think that the concept of the ABPI is logical in managing WADII patients.

T: Do you think the enhancement of self-efficacy is useful for the management of acute WADII? Why or why not?

I: Yes, it was quite helpful. For physiotherapists, we know that the main goals are pain and disability. However, patients may think their main goals are driving, going back to work or going back to the gym. Setting a goal and then try to archive each goal using the enhancement the level of self-efficacy was useful for acute WADII management. I think that verbal persuasion (e.g. making patients understanding whiplash injury, how this would effect to their life, building their motivation and putting them back to everyday routine) is the most important source. However, I told you at the

beginning about time consuming. After patients see the benefits in each assessments, they got more and more the level of self-efficacy. After pain reduction, I found that the ABPI works very well.

T: What do you think about the phases of the ABPI and how they work? (5.51)

I: The phases of the ABPI in terms of understanding, maturity, stamina, and coping are quite logical to follow in managing patients with acute WADII. At the beginning, it seems to be there was a lot of information to educate patients. I had to decide how much knowledge that I should give to patients in each visit based on individual conditions. The average sessions for the overall management are 7-8 sessions per patient. No more than 3 sessions in each phase. The number of treatment sessions was used in understanding and maturity phases rather than stamina and coping phases. After the psychological factors were reduced, physical functions were improved easily. However, the 2 beginning phases need a bit more time than the 2 later phases. When patients see the benefits of the treatment, the treatment progression can go quickly. The average treatment sessions for the understanding and maturity phases were 1-2 sessions.

T: What do you think about goal setting for managing in patients with acute WADII? Why or why not? (8.25)

I: It was quite interesting and beneficial. The goal or target helps the directions for the treatment. We tried to reach each goal. After patients see their progression, their self-efficacy is enhanced more and more in each assessment. For example, one patient had problem about his driving. His goal was try to make confidence in driving. The first time his self-efficacy in driving was 5/10. In the second time, his self-efficacy was 6/10 and progress in each driving. The most important thing that the patient felt more and more confidence in his driving and physiotherapy programme. We can see that goal setting is helpful to enhance level of self-efficacy and comply in physiotherapy programme.

T: What is the benefit of the ABPI in your opinion and experience? (10.00)

I: I get to know the patients a little bit better. I get to know more about what patients' problems in both physical and psychological. We have to manage both perspectives, not only just physical symptoms in order to make patients better or completely recovery.

T: Did the ABPI work equal with your patients? How? (10.30)

I: Yes, it was quite equal. The ABPI is quite straightforward to understand and follow the patients. I found that the ABPI worked in all my patients.

T: How self-management work with your patients? (11.20)

I: It was quite important. After the patients go out from the clinic, they have to practice a lot. In the clinic, we did some examples to make sure that the patients do correctly. The self-management was quite beneficial for patients because they had to practice in daily. They had to know how to exercises, control pain and increase their confidence in some activities (e.g. driving). The ABPI was helpful for self-management. This is because the ABPI helped patients to get more and more self-efficacy.

T: How encouragement your patients to be a healthy lifestyle work among your patients? (12.30)

I: It was quite interesting topic. After the whiplash, people did not want to move their head so much. Thus, I encouraged them to move and stay active. At the beginning, some symptoms might be aggravated but in the long term it was quite helpful.

T: How you encourage self-education?

I: I tried to motivate my patients to be a healthy person, stay active and be back to everyday routine. After their saw some benefits, they continued finding some information by themselves.

1.2. Barriers

T: How did you feel when you used the ABPI at the first time? (13.40)

I: It was a little bit difficult to adapt and know about what exactly about the ABPI at the beginning. After using the ABPI 2-3 times, it was quite helpful and quite easy to straightforward. Probably, I need a little bit more time according to I am a foreigner. However, a part from that I was quite happy to use the ABPI.

T: Have you feel confidence in using the ABPI since the training day? How? (14.10)

I: Yes, I was confident in using the ABPI since the training day. In that day, you provided a lot of information and guide which way physiotherapists should focus on. According to the information, I had adapted for my everyday practice at the beginning. Then, I ready to continue.

T: What help you make confidence in suing the ABPI? Training day/individual training? (15.00)

I: Both training day and individual training were helpful. I cannot really say that one is superior to another. I get to know more things that I never thought about them. I

never think we can use these kinds of things in our daily practice. As a physiotherapist, we focus only pain, ROM, strengthening and stabilisation rather than exploration patients' background and their mind.

T: Did you have any obstruction in using the ABPI for treating your patients? How? (15.40)

I: It was not difficult to use at all. Only the beginning, I spent a little bit of time to understand structures and follow your concepts, examples, and case studies. After understanding the concept, I ready to go.

2. Similarities and differences between the standard physiotherapy and the ABPI

T: What are the similarities and differences between standard physiotherapy and the ABPI? (16.35)

I: Learning about patients' background, explore the patients a little bit more. Don't see the patients only pain, ROM, and strengthening but explore some limitations in other aspects such as fear avoidance, anxiety, and depression. The ABPI tries to make motivation of the patients to stay in active by using psychological strategy to make patients confidence to complete each goal/task. By staying in active, pain and stiffness were reduced, leading to improvement of physical function. The ABPI tries to guide patients to be better using 2 different ways (e.g. physical and psychological) at the same time. These are what the ABPI different from the standard physiotherapy.

The similarity is we definitively treated the patients. The patients felt better. We take care patients for physical problems (e.g. pain reduction, increase ROM and strengthening) based on physiotherapy clinical reasoning.

T: Which intervention do you feel may be more helpful in managing your patients? Why? Private/NHS? (18.10)

I: Definitively the ABPI. This is because the ABPI takes care both physical and psychological problems at the same time. It likes 2 in 1.

The ABPI can use in both private sector and NHS. In the private sector point of view, it is quite helpful, easy, and straightforward in using the ABPI for acute WADII management. In the NHS, you or someone can give them the guideline what they should follow. I think it would be very beneficial even through in NHS.

3. Acceptance of the ABPI

T: Do you think the ABPI is an effective intervention for acute WADII management? Why or why not? How it work?

I: Yes, definitively. The ABPI is quite useful to prevent chronicity because it tries to motivate patients to stay active and whatever. Finding a goal and try to reach the goal is a helpful strategy. I found that the ABPI is very very beneficial.

T: Do you think the ABPI should be used in managing acute WADII in general? Why? (23.20)

I: Yes, why not! This is because it is helpful in managing patients with acute WADII. The ABPI helps me to explore patients' background, physical and psychological problems. Also, the ABPI guides the way how to sort out patients' problems in both perspectives. The combination between physiotherapy and psychological strategy is really helpful.

T: Would you like to change/modify the ABPI? If so how? (23.45)

I: No, I don't think so. I think make it a little bit simple if it is possible. I don't know. Even on this stage in this research, it was quite straightforward. I cannot see any issue.

4. Recording

T: How do you feel about the treatment recording?

I: There was a little bit about time consuming that why I suggested you to make it a little bit easier. If you make it easier, I think it will be easier to put them down to the notes and this will help you in recording a little bit more.

T: What are difficulties with recording in this study? (25)

I: There is no difficulty in recording in this study. The only problem was how to get appropriate information from the patients. You have to build patients to trust you first and then try to explore them and find their problems. At the beginning, they did not want to open and tell you what their problems. This is a little bit challenging. But a part of that, no problem. In the beginning of this study, I felt a bit difficult to note it down but after understanding in depth and practice more, it was easier.

Appendix 25: Transcript of the semi-structured interview for physiotherapist B

An Embedded Qualitative Study of an Active Behavioural Physiotherapy Intervention (ABPI)

Semi-structured interview for physiotherapists in the ABPI arm

2nd Interviewee on 18th August 2016

Birmingham City Clinic 1-1.30 pm.

1. Opinions and attitudes for an Active Behavioural Physiotherapy Intervention (ABPI)

1.1 Physiotherapists' experience and perceptions

T: What is your perception in using the ABPI for treating your patients?

I: I think it is a good strategy to use. I think it is something that a lot of physiotherapists will subconsciously be using without knowing it already. So, I think it is a definitively good intervention as it allows us to quantify/objectify the subjective opinions of patients and how their feeling. And it does then allow you to refer the patients a lot easier highlighting improvements/saying here where you are now compared to day one. Now you're certainly so many much better, so many much better and really bring a part of attempt showed the improvement they can have something plus on to which a lot better for their life and pain for example. As physio's we tend to use things such as pain as a scale measurement. This has made me focus on function more so, i.e. it is more important that the patient focuses on the fact they can achieve a functional goal/task even if they do get a bit of pain.

T: What do you think about the concept of the ABPI (1.30)

I: Again, I think it is a good concept and I think it is something that many physiotherapists will be doing without thinking. So, it is a good concept and easy way to promote patient specific and function based outcome measures. I think the ABPI is a logical strategy as long as it is not a rigid strategy. So let say, I will be aiming to improve their confidence. If their confidence improvement, I'm not going to restrict the patients and limit their activities. Any activities they think all my symptoms improvement, my range of movement increasing although it is not where I want it to be yet, I want to try some more. I think we should allow flexibility in the system to allow them to push on as able as often increased function leads to reductions in symptoms. If we can push them to do functional tasks and return to previous activities, their confidence will sky rocket and naturally pain/awareness of symptoms is likely to fade. I

think it is just about recognise in the approach which type individual patients have that flexibility within the system to allow it.

T: Do you think the enhancement of self-efficacy is useful for the management of acute WADII? Why or why not? (3.30)

I: Yes. I definitively do think self-efficacy something that should be used because at the end of the day physiotherapist's role and/or psychologist's role when they take the patients as well is to restore function. We think we want to reduce pain and increase mobility that part of it but overall our goal is to get people back to doing what they want to do. Self efficacy is a good way to monitor this as it measures confidence in doing a task, so will incorporate a lot of other factors, such as pain, previous experience.

In my experience, the patients emotional state will have a large impact on recovery following WAD2. Once I have built a rapport with the patient and we have a level of trust, verbal persuasion can be useful. Then, if we're pushing them to do something, they're doing a task to get performance accomplishment then it is brilliant. However if we can get them to associate an activity with a positive emotional response its going to have much longer lasting and more beneficial effects. You're feeling good, feeling less pain, feeling happy about the task. Once this is the case the patient is likely to recovery quickly and be much more active in rehab. In summary, I think self efficacy has a massive role in recovery.

T: What do you think about the phases of the ABPI and how they work? (6.00)

I: I think there are good phases and I think the ABPI system is a clear pathway with easy to recognize stages. It is a good framework to use for physiotherapists. I think it does allow you with the instruction that you gave us. We then can look and take them to treatment appropriately. Within the system that flexibility where you don't have to pass through. It says 1 session or so on. You spend different times different sessions with different variations within patients.

The number of session in each phase is so variable on the patients. Well! As a physio, you get a lot of patients who are nervous and they will be at understanding phase for a lot longer. At the moment, although I do a lot of verbal persuasion, I get them to do certain tasks to perform performance accomplishment stage. They will then go sit in their car and you can do the visualisation exercises as soon as the car approaching them, they straight back to the first phase. It takes a lot longer to break down that barrier. Then, you can get the other subgroup. You got some patients to pass through very quickly. So, like 2 sessions need to stay averagely. Then, you get another

one who gets a bit worried. They absorbed absolutely everything you say. Next time, you see them, they will be at coping phase. You discharge them. I think it is very much depend on individual patients.

T: What do you think about goal setting for managing in patients with acute WADII? Why or why not? (8.50)

I: It is the key. Earlier in my career, I would tend to see patients and would set goals but never really look at them again until the last session once we are going to discharge. You can lose track of where you are, what you're heading towards. As I have developed as a physio, I always keep the patients goal in my mind and focus my treatment on achieving patient goals. I will continually ask e.g. you are going to get back to cycling 30 miles or something, how far you cycle now. Are we doing this is a hundred percent of your normal? Because then, it keeps the patients focus on what they want to achieve. It tends to get the patient to be more a positive about their rehabilitation, their achievement, and their goals. They are a lot of happier with how their progressing in their own, a lot more cognitive with treatment and general progress faster.

T: What is the benefit of the ABPI in your opinion and experience? (9.50)

I: I am someone who would use self-efficacy as part of my goal setting and routine treatment anyway. I would expect that a number of therapists will already include self efficacy as part of their routine patient management already. Although I use outcome measures to monitor major improvement, it gives me a safe set standard and what we can expect for different goal self-efficacy, it then makes me objective find. APBI does make the therapist constantly rethink where the patient is in rehab and adjust treatment strategies accordingly. Just allow that more objectivity in using more outcome measure always positive for physiotherapy.

T: Did the ABPI work equal with your patients? How? (10.50)

I: Mostly, however there is always some patients who won't fit in with the normal. They won't fit in and they just won't be progressing like we would normally see. They have preexisting conditions or problems. One patient is bring to mind; I am not sure you will include her in the final study but she would already have massive history of anxiety and used Birmingham Healthy Mind a lot. For me, she just wasn't progress using the ABPI. I referred to cognitive therapist. Just because although the ABPI is good, we have to recognise she would probably still out of my scope as a physiotherapist in terms of providing cognitive support. So, that is only an example I can give. However, the ABPI work equal in almost of my patients.

T: How self-management work with your patients? (12.00)

I: It depends on the patients. So, I think one skill physio one thing this does help you to do, you got to recognise where the patient is the one who is normally active and has very much of internal locus of control or where naturally have an external locus of control. They want me to come and fix rather than me gives them a tool to fix themselves. It is one of key things I actually do something why I tend to try get my patients to see me less often. I find if we continually push and explain that active always get them better than passive. Patients tend to be happier with self-management if you have done this. For the first day of whiplash patients, I normally highlight I can give you a temporary benefits, you want to get a permanently and quicker, you are going to do your exercises at home. This is the key thing. As long as from the first session, we do that they tend to be very happy.

T: How encouragement your patients to be a healthy lifestyle work among your patients? (13.10)

I: It depends. So, as a physio, we tend to use an every contact counts approach. We have to try to make a difference to patients' life style. For some patients, it will work. So, a lot of them, it tends to be the things like weight loss not exercises. I will often get them into the gym with me. We can practice they know they are going to be fine. If I can't get them to want to change, it could be reflected my-self as a practitioner. The patients have done somethings (e.g. smoking) 40-50 years. And they might say, yes! I know I should stop but it is too late now. Depends on what you try to archive about healthy lifestyle or you try to give up what you try to start.

I think building a rapport with the patients and consistency with the treatment. I usually encourage my patients and say 'exercise is the best medicine'. You typically get a bit older patients, may 60-70 older who think. Oh! I'm too old to exercise. Our doctor said I shouldn't do sport anymore or I shouldn't my knee anymore. We can remind them for a positive encouraging manner. Actually, we come a long way from when they are probably told that and we go with the complete approach that often something tend to safe them. I don't give you a tablet but I fix all your problems. The close thing that we have and you can look to any textbooks and ask any doctors is exercises. I think that one thing which I tend to find a good rapport to try to encourage patients. I always said I prefer active rather than passive approach. If the patients said I am not sure I can go to the gym, I will get them to the gym and straightaway with me and go to exercises and will talk about pain they may have.

T: How you encourage self-education? (15.40)

I: This is something you can always give to patients. Different patients will have different understanding and levels of interests. Some might try, I'm gonna go home and then they're gonna trust your words. They're gonna read research around them. When

you identify those patients to our routine and then find the way to motivate them, I found the really good resources I often use are twitter or Youtube. Because I am appreciate that I am not a world expert of pain mechanism, pain biology. However, I know I give them access them to some world leaders put it into English terms not physio medical terms. I would then encourage them to view resources. I also build up as I am doing something symmetrical exercises. I explain how that work and I give them consistent feedback what I am doing. It is not just a case of our physio give me an exercise, I got to do it. It is case of our physio give be an exercise because it will help A, B, and C. So on and so on. I think sports people are easiest job in the word to treat. They want to know everything about their body and how to improve. So, I typically see a lot of body builders e.g. weight lifting. You can introduce a bit of bone and you know they will comeback everything about that topic because they feel it will help them to improve. This makes adherence to treatment much easier

1.2. Barriers

T: How did you feel when you used the ABPI at the first time? (18.40)

I: Panic! I think it likes when you do anything new. It is a brand new system where I've got to categorise patients. I thought to myself what if I got this wrong, how I know, what is the problem, am I doing this right and so on. I know this is [redacted] research. After the first session, quickly to recovery my feeling and I did gain confidence.

T: Have you feel confidence in using the ABPI since the training day? How? (19.10)

I: I think I was semi-confidence on the training in the head office. Probably, the way I learn. I am not someone who can sit and be told this is how you can do that, and absorb it, I have to do it to learn (active learner). So, I probably 50-60 percent confidence after the training day. The training day was good but after I've seen a first few patients it makes a lot more and more confident. If I was unsure, I can go back and read everything that you gave me about the stages, examples of the treatment.

T: What help you make confidence in suing the ABPI? Training day/individual training? (20.30)

I: For me, individual training would be more powerful. I don't think there is a problem with the training day strategy. If I've just been sent a document to look up online and then has you come in, I wouldn't know much what I am doing. If I just have

the training day and then go, I probably wouldn't really know too much of what we were doing. For me, the individual training is better. I would like to be observed and I would like to be questioned. However, I can see the value in both.

T: Did you have any obstruction in using the ABPI for treating your patients? How? (21.15)

I: Not really to be honest. I already highlighted earlier. Regarding the patient who I felt was inappropriate for APBI. I hope your results will show otherwise, but I don't think that I have the patient who really struggled to go through the stages.

2. Similarities and differences between the standard physiotherapy and the ABPI

T: What are the similarities and differences between standard physiotherapy and the ABPI? (22.00)

I: I think this depends on the type physio you are really. As I said at the starting, I am someone who always use self-efficacy normally in my practice. I encourage patients: you can do this, can you do that, what level you are and so on. So, the similarity definitively is you're encouraging them and take them to their function and continue be monitoring improvement with guides your rehabilitation planning. I think that the main differences, obviously! it makes me think a lot more about the psychological state, one thing I just haven't thought about before in as much detail is the effect of anxiety.

T: Which intervention do you feel may be more helpful in managing your patients? Why? Private/NHS? (23.10)

I: ABPI definitive helps. I am sure going forward that will be more research into it. Probably, it will be combination between the ABPI and traditional physiotherapy to be honest. It's all about patient identification and getting the right strategy for the right patients. As I said, the ABPI is brilliant because it objectifies subjective findings. You look at a lot of leading physios treat about pain education, all are on the internet. They probably do the ABPI without knowing it and they don't objective findings in terms of different strategies, following principle as a part of their management. So, I think it is going to be mixed of both. I have definitely incorporated the approach into my regular practice and had beneficial results.

In my view, they should be no difference between private sector and NHS sector in terms of quality of care although people often expect better quality of physios in the private sector. I accept, working in the private sector probably allows me to see patients more regularly/sooner. I believe the NHS and private physios, you should get the

exactly same quality of physio, you should be adequately trained and provide the same quality of care. If you will train the physio in the NHS, there is no reason why physios in NHS should not be able to use the ABPI and the ABPI will work in the NHS as well.

3. Acceptance of the ABPI

T: Do you think the ABPI is an effective intervention for acute WADII management? Why or why not? How it work? (25.10)

I: I think it is. As I said, I feel it is good at objectifying subjective findings allowing physios to have a better structure to their plan of management. It allows us to focus on what the patient wants to achieve, not what we want them to achieve.

T: Do you think the ABPI should be used in managing acute WADII in general? Why? (26.00)

I: Yes, if the phyios will be trained. As I said, in the perfect world, there are no different physios in different companies, different environments such as NHS and private. In reality, there can be large variations in quality. As long as, we can sure that they are certain benchmark of practice, level practitioners who provide the ABPI. It is another a brilliant tool that is an outcome measure effectively to guide practice and it can be a very helpful tool.

T: Would you like to change/modify the ABPI? If so how? (26.50)

I: Umm! It is not something I am not giving too much thought to really. It is a system that works for me. Yes, the system works for me. So, I haven't really thought about change it because I haven't need too.

4. Recording

T: How do you feel about the treatment recording? (27.10)

I: It is good. For my patients in the experimental arm, the extra things we had to record made it slow initially. Once you get use it or additional stuff that you may want to include. It will take 1 or 2 minutes extra. I don't have any problem with that.

T: What are difficulties with recording in this study? (28)

I: It is the time management. If we think recently, the average physio session is 30 mins. Now, in the 30 mins you have to get the patient, it will take a few mins. You have to get a bit subjective and objective exams, 3-4 mins maybe. Then, the ABPI you

got a few extra questions another 2 mins. The actual provided treatment does not take any more time. I have done 20 mins treatment in average. After that I need to complete a note and a few minute for reminding home programmes.

General comments: I like the ABPI. It has helped me as a physio. It is something which I haven't seen early in my career. It took me a wider. When the first time, I cannot treat it to what I want it. Forget about the goals during the treatment. It really makes you focus on that patient's goals and within treatment what physiotherapists should be. Like I said earlier, we restore function. All physios want normalise and maximise function. APBI is a good outcome measure for helping guide the patient progressing in return to their normal function.

Appendix 26: Transcript of the semi-structured interview for physiotherapist C

An Embedded Qualitative Study of an Active Behavioural Physiotherapy Intervention (ABPI)

Semi-structured interview for physiotherapists in the ABPI arm

3rd Interviewee on 25th August 2016

West Bromwich Clinic 11.00-11.40 pm.

1. Opinions and attitudes for an Active Behavioural Physiotherapy Intervention (ABPI)

1.1 Physiotherapists' experience and perceptions

T: What is your perception in using the ABPI for treating your patients?

I: I found it certainly effective in some patients, particularly patients to very apprehensive initially to start move in the neck is quite difficult to get them to start move in and realise activity and it is the best thing for them. So, I found it very very effective for them certainly. I wouldn't say it is ineffective for patients who are happy to move already but they don't need as much. Definitively! beneficial for who are more inapprehensive definitively.

T: What do you think about the concept of the ABPI (1.00)

I: I think it fit in quite well into WAD treatment session very well. We do spend sometimes I have to use hands on treatment. It is very easy for us to be discussing with them and set goals and go away with them. I think we gonna record in each week, I think give them some more the reasons to go home and actually carry through rather than do it. Sometimes, patients that we advised them to do something, they might come back in a week and they haven't done it particularly. When we actually measure in each week and rise them rate in 10 how they feeling and coping with different aspects. I think it put some more emphasis on themselves to go away and do it. I think it is worth it is motivational technique not just you know not only beneficial treatment WAD but make them some more logical to carry out treatment as well.

I think the ABPI concept has a logical step, especially with whiplash injury. We try to convince to move and know gonna be pain and let them know. It is the right thing to do that is always the first step for me. It is a psychological stress that they worry because high level of pain sometimes associated with they often think they must be a serious pathology underlying. It just try to convince them you know that is not the case,

try to reduce self-stress down first of all. Obviously, you reduce fear stress and not gonna fear last tense and can feedback into the muscle spasm and different things. So, I think it is really important to address in those steps because it is definitively you know. If I tell them to straightaway to go straight to the end step, force them to move their neck as far as they can and say get back to do exactly what you do before that too much in the step. They won't really comply with their own treatment. They worry about giving the goals because they may see unrealistic. When you break it down to small steps, they just lead it each week, they can flow in often. They do scope by themselves as well. They will come away and say you know what I have been a little bit more active notice myself. It actually feels much better anyway. I think when they realise themselves rather than just me say it to themselves. I think they trust themselves more suppose in the way what they feel because they know how they feel. They trust that more than just going straight away I will be advised from phyio. Probably, met the first time to straightaway take on their worth what they should do, they gonna have their own feeling about it. Once start to try to think themselves, they found that beneficially.

T: Do you think the enhancement of self-efficacy is useful for the management of acute WADII? Why or why not? (4.40)

I: Yes, definitively. I think it is a really good way to measure how they feel. Often, if we comment and will said how do you feel to day? They gonna say it is still hurt and it is not necessary to gain better. I think when we use self-efficacy, it is a lot more effective for them because they will then come back myself know is better than what it was last week. Their home mood is a lot more positive. We ask them to be aware of it for them to just how they feel and they get an honest. A lot more specific to them as well it is not just me say, look at their ROM say 70% or 90%, we want 100%. It is something that very applicable to them. Might be the most important for them, might be their struggling to do part of their job, not be carried. They worry and might have some pressures work for that. We can said you are get in there and make to see themselves in their own assessment and it is a lot more effective than me just say your movement 10% better that to them, it is not really mean anything. When they say now, I am able to lift, this is work as well and it is not aggravate. That is much more beneficial for them.

I think the performance accomplishment are the most powerful for the self-efficacy enhancement personally. Again, I will go back, you know the verbal persuasion is good may be as a physiotherapist suspect, how good physiotherapist you are. But for them, I think what they see, what they feel, they set themselves about target and then they archive it. I think straightaway it is a lot more possibility to them. Initially, they may think I can't do anything, I can't move it. You just set them a goal may archive it, again motivation is a bit momentum as well. They can feel they will get better. They know they are not there yet but they know they will get there. I think when we break

down to small jumps or goals and keep archive. It will make them feel much better. They will be a lot more complied with the treatment because they can see the improvement. I would say performance accomplishment is the most effective for the self-efficacy enhancement.

T: What do you think about the phases of the ABPI and how they work? (7.50)

I: I feel the understanding phase is certainly very very important initially. For my treating people, I think initially that the understanding part can be the longest time sometimes, often. And then I feel would say move out to maturity and they can quite quickly go to stamina and straightaway they into coping. On the time scale, I would say the understanding phase is the longest period certainly. Probably, it is the hard I would say. I really do feel when treating whiplash, they is all my such a right ball moment for a lot of patients, they would say realise what they need to do and they realise a day. Again, it is a performance accomplishment. See they got better. They think oh! this is from we need to replicate. So, I think it is the most important part overall.

T: What do you think about goal setting for managing in patients with acute WADII? Why or why not? (9.10)

I: Again. Definitively, I think you need to set goals because a lot of WAD need to be done treating more is what they do at home definitively. So, it is very important they are go and orientate they got something to aim for. If they just at home, and they are not and just hope it. Often! They feel I will be gonna heal, as you know they are not really heal. Healing needs to take place about get in the move, it needs to be something active and it has been taken place. They do need to do that day in day out. They need to be consistent with what they do at home. If they haven't get a goal, I think they cannot hit that target. So, I think it is really important.

I think that goal setting is helpful to enhance self-efficacy, especially performance accomplishment. If you set them a target and say let get you back into swim for example. They got a goal, you gonna do two lanes maybe something very simple. When they do that it doesn't make it worse and anything feel better. They gonna straightaway they can take that away and apply that to other things such as job. They may say I have done it there what gonna do in this. Then, they can use it by themselves and they can apply to different areas by themselves. Although we set goals for them, I often heard they may say I also do in this and try to do this, this and this. They understand the concept very quickly and then apply by themselves to multiple tasks. They start use the technique by themselves, it is a really really good.

T: What is the benefit of the ABPI in your opinion and experience? (11.46)

I: Again, I think it is a lot more. I think it take me a little bit more responsibility for what patients need to do. Sometimes, without the ABPI, physio will make movement better, just muscle feel more relax. Patients do not really take in their honorship. Sometimes, they will say to me, I don't know I am getting better, I am hoping you can tell me. You know when use the ABPI what is happening, they take more responsibility they have been more whether they get better or not. Again, they realise, we ask them to set goal at home and ask them to do that. If they don't, it is a big part of the management. They realise they need to be doing a lot more. They take honorship of their own recovery. I think that is the key. We see them may be one a week sometimes twice a week. They should really do the right thing every single day. I think they do realise one a week use this technique. They are a lot more where and how important, they in row of recovery.

T: Did the ABPI work equal with your patients? How? (13.15)

I: I think that the biggest part is, the ABPI is brilliant for people who aren't very confident in get them back to normal. They feel they need to rest, they feel they need to keep still and not move it and it will be healed that very much of that opinion. For them, it works brilliant because it is very very effective. They get better by convince and set the goals to increase their activities. After you also get some patients who come in and very suffer. They might have a very heavy job. They still really lift incredibly heavy. They are really active and wanna get better in a week. They push themselves really really hard. It is still can be effective but you can try to range in the goals a little bit. I would say it is gonna be slowly less. It is not gonna have big impacts on them than you would do on the people who are less confident in movement. Is that make sense! I am not say it does not express at all. I just say I think the people who will have benefits from the most are everyone would be the people who are a lot more apprehensive about doing formal movement and whatever.

T: How self-management work with your patients? (14.30)

I: It is a very important part certainly. I mean we will leave them and they should do something often. Even the hands on treatment we do, yes! They cannot do that to their at home. I also give them some techniques, they can use self-massage, spinal vertebral and different things. Again, that should be more help them to realise. They are the main important thing on their recovery. They will have the big impacts on their recovery if they do the right in home. I think that was brilliant about the ABPI. I think it does raise their awareness of what they need to do on the day basis at home to their self-management. It puts a lot more on it for them. I feel they do take a lot more responsibility for it. Especially set in goals that they want to archive, it is not necessary that we want them to archive. They feel a lot more about their suppose, they will

motivate to do, they actually want to hit targets. That is a very good to self-management and I will say motivation to keep doing in the right things at home.

T: How encouragement your patients to be a healthy lifestyle work among your patients? (16.00)

I: I suppose some patients are very good taking on the advice. I found it sometimes is difficult. Sometimes, some people may feel, they are criticised in some ways. It can be a difficult area to talk to some people. I think most people are quite happy to receive the advice, often they ask about some advice about healthy lifestyle from us. Again, some people don't like doing a certain thing. Self-efficacy very much bring how their feel. They do not compare themselves with other people. They are not intimidated by other people who can long run or anything. For them what they need to do is just improve what they can already do. I think it is a lot more beneficial rather than compare themselves with other people. As long as they can increase what they should do, they will better for it. I think it is good in that way to make more specific to each patient.

T: How you encourage self-education? (17.30)

I: We got certain articles and videos these we can advise about pain management and different things like that. I suppose this might be a bad thing of my part. I do sometimes make patients aware always check sources you get information from because it is a lot of conflicts and opinions. Some of them found it in anywhere, it is very much opinion base. So, I said you have to be careful what you read and where do you take, is it the truth? Because it is so many conflicts and different things. We often try to give them certain videos to go and watch, or certain articles they can have a read which we feel the right way to treat. They are still self-education themselves, from the certain samples, something is necessary these will guide them. The best think that we do. We try to direct them to a certain articles and websites which have a good quality. You go on the internet you can find any sources of advice or anything. Some information can be updated as well. I think it is a definitively good thing if they want to educate themselves. This is show again they try to have their honourship which is really important. We are more than happy for them to want to do that. It is important to try to guide them in the right direction, right information for them.

1.2. Barriers

T: How did you feel when you used the ABPI at the first time? (19.30)

I: I found that some elements that we do already use in a degrees but not in a good way. It wasn't set out for them I suppose. This is what I think it is a really good way, they understand a lot better and set a way to do it. I found it a little bit difficult

initially. But again, more you use it, just like anything it becomes second next, it is quite quickly. It doesn't take very elongate to get a little bit more experiences. It doesn't take long to go through. The ideal time, we do any hands on treatment, we can talk through things at that points in time there. It fits in well with what we do already. I wouldn't say it takes really anymore time particularly. Yes, it is very beneficial for them, especially for certain patients it is really really beneficial for them. I think sometimes, I have a bit of difficulties from my point of view recording exactly what stages are in often. You think in one stage, one point, when you talk to them a little bit more, you know they may be in different stage but yes! I mean that all part of the process. I more use it as a physio that is better that I became as well. I think generally it has been good. I think it is able to a little bit more success with the recovery in certain patients definitively. Probably sometimes before, I wouldn't have much success, I found it is quit rewards in that way to do it definitively.

T: Have you feel confidence in using the ABPI since the training day? How? (21.20)

I: Yes! Again initially, I wasn't confident. Definitively, a lot more confidence now. I think some of the tricky part that I have was sometimes I try to break down. If they have n goals, often we always say what do you want to get back to. It might be say play football or it could be anything like that or ride my motorcycle. Sometimes, I have been a difficulty with try to break down some more a task initially. Probably, it is a big problem that I have. Again, they still gonna be something they want to archive. Is it make sense! Rather than just against something like thinking. Oh! Well he want to play football really but you say full ROM. So, say to them we need to get your movement back to you. It is not particularly prelim to them. It is not necessary, they gonna push on their own. So, try to break it down to small goal and motivate them. Sometimes, patients have been working initially, they have to come out from their work because it aggravates too much for them. So, goals have to move backward again and different points. So, that can be a difficult part, they feel like they move backward slightly. I mean you have that in anything and in any form of treatment you do you have that issue. It is not specific to the ABPI. Yes, I would say that is the hard part is trying to break it down to small jump.

T: What help you make confidence in suing the ABPI? Training day/individual training? (23.20)

I: The training day is really good and it was a full day. We have a lot of time to ask questions on what we unsure as well. It is a quite small group, I think it was good. At the same time, we have a plenty time to think through. That's all really good. All information we can go away with takes a bit more time to digest. Then, you contact us

and give opportunities to ask further questions even later days. We were advised to start use it, not just done in particular patients to the research but to start use it as well and recording certainly patients as well. We got more practice in that way. You came to observe me as well, make sure that you are happy with the way I was applying it. So, I might think I do it in the right way but maybe I wasn't. It is good that you came and observed me for a few patients. Give me a feedback I need it. So, the support is always really really good. Obviously, there were physios, we work together and can talk to e.g. Jon who is here as well. Yourself is always available. So, we have plenty of supports. If anything will have difficulties with, you can give more advice how to apply certain things.

I think sometimes one of difficulty that I have is the patients came in, especially for whiplash injury. Sometimes, they are suffering back pain as well at the same time. Sometimes, they may get quite better regarding neck symptoms, however, back cannot hold for a certain thing. For example, return back to full duty work for a long term goal for them, they may not quite better for the goal. They probably wouldn't be from regarding their neck injury or whiplash injury, may be the lower back symptoms hold them back a bit. So, I think applying ABPI to every region. ABPI is studying with pure research for whiplash. I think use it across the whole. You can apply it to anything. Maybe, if we done that, that would be easy I suppose. But the same time to understand the study purpose, you need to start up with one particular pathology or injury. But I definitively think and I already have used in other areas as well because I do see the values in it. That would be the only thing that I said.

I do think both training day and individual training are valuable because I think sometimes on individual training, you leave your questions as you, you away that you don't know. Is that make sense! Your lesson questions, you can see the potentially problems, you can answers them and perform with that. When you are in the group setting of a few of physios, they will ask sometimes physios would ask some questions. I initially haven't thought up. With them, you know that I wouldn't know that even then. So, that would be very beneficial as well. However, when it in individual, you do even more time. The individual training, you got a chance to actually see how to perform. Sometimes, how you think you perform and how you are, could be different. It is really really good to get it two to be as an effective as possible. I think you do need both are best. If I have to say which one is more, I would probably say individual training slightly more. But I still think both, I would say probably 60:40 percent. I think both are definitively important.

T: Did you have any obstruction in using the ABPI for treating your patients? How? (28.40)

I: Not anymore. No. As I said the only thing that I found with difficult is two different injuries. Not anymore. No.

2. Similarities and differences between the standard physiotherapy and the ABPI

T: What are the similarities and differences between standard physiotherapy and the ABPI? (29.10)

I: Standard physiotherapy is hands on techniques where the ABPI isn't. That is the differences. I think similarities are phyio, we try to motivate patients to exercises at home and certain tasks but you can quantify a lot better with the ABPI. So, I think it is very very effective in that way. It adds to what to try to archive because what can do at their home as well. So, I think it is a lot more about psychological effects. I think it is tackle a lot better. You advise them to do anyway with standard physio. It helps them to take more responsibility with it I think. They will understand in level a lot of higher as well what they need to do to make a full recovery. It is better than just standard physiotherapy. I think sometimes with standard physiotherapy, they become a little bit over rely on what we can do. They may think they come in each week to get fix. The ABPI approach is a lot more about what they can do. I think it is very good in that way. Probably, the difference I think is someone who comes in and has standard physio and has the ABPI. If you have standard phyio, you might think you gonna to get fix by physio, for the ABPI you take a lot more responsibility yourselves and have a lot more that way.

T: Which intervention do you feel may be more helpful in managing your patients? Why? Private/NHS? (31.30)

I: Normally, if patients come in and we do certain manual techniques. They will in some feel better I suppose. However, if they not do in the right thing at home, that will reduce. A lot patients who were recover quicker may be a better one, I suppose to say. From the patients I work with they all got better very quick. From what experiences that I have, I would probably say just on the limited people, probably say ABPI and that should go on small sample that I got currently. Yes! I probably say this point, yes may be ABPI, probably.

The ABPI is helpful for physios in the private sector. They still need to do a lot of work to get better outcome. For me, using the ABPI does really help them with that. So, I think definitively help. I think if anything is probably even more beneficial in the public sector. We quite look we can see people every week if they are not necessary do in what they should do at home. Then, we can help them a little bit more with hands on treatment we do whereas in NHS sometimes it can be 4 weeks. So, I think they know in

their goals be focus on them is more important for them. We are not there to counseling and remind them. They know what they need to do.

I do think it would in NHS definitively. They would be beneficial even more so, this is because probably, they do not probably have much contact time. Again, the fact is to get their level of understanding at first of all. It is more important.

I have never work in NHS. I did like a rotation for training about 6 weeks period. Probably, it has changed quite a bit now. I don't know too much but as I said I think I can't see why wouldn't be, just effective at all.

3. Acceptance of the ABPI

T: Do you think the ABPI is an effective intervention for acute WADII management? Why or why not? How it work? (35.10)

I: I do think it is effective. I think the reason for it is because their level of understand is a lot greater when you go through set way. I really think using self-efficacy I think it generates motivation for them. I think that is only one the most important thing really. As I said, I think I mention before often people come in, they just keep saying, it still hurt. They don't say whether is getting better or not. They just very very focus on pain that is very much they think about. They did not trust about task oriented or goal oriented. I just think it is still hurting. Using the ABPI, using self-efficacy, they can see themselves that they are improving rather than me just say to them, yes, you move your head slightly more now, you got 70% moving rather than 50%. So, it is a lot more helpful for them. It is a lot more applicable for them.

T: Do you think the ABPI should be used in managing acute WADII in general? Why? (36.20)

I: So again, I will say yes. I do find it has been an effective for the patients. We try to give several different forms of interventions when we treat. You got manual therapy, cryotherapy, thermotherapy, exercise therapy. You got different forms. Sometimes, certain one won't be effective. You still use and apply if they respond well, then you continue to use it. For my experiences, it has been effective for every patient that I use it on so far. So, I say definitively. The other good point I think is it doesn't take any more time. With treatment what you can only really do in hands on treatment or you can do exercise therapy. You have to one or the other in the timeframe where I feel you can use it at the same with doing another different technique as well. It doesn't take up any more time either. Yes! I think it is really effective.

T: Would you like to change/modify the ABPI? If so how? (37.40)

I: Nothing. I can't any really strict out of my head, no. No, I can't really think in anything particularly.

4. Recording

T: How do you feel about the treatment recording? (38.10)

I: So, we recorded in a SOAP note and also in extra treatment boxes which come up to us, we have to record down what interventions were used in the ABPI. I think I don't have work on different system of we got certain patient measurement system that we used on so, don't know how would work if it wouldn't be written SOAP notes. That would be only a different. I think in my feel in the private sector in how it works in particularly my company, I found it very straightforward and easy to do.

T: What are difficulties with recording in this study? (39.00)

I: It might take a fraction longer maybe. You write a few more lines. I would take 30 seconds longer maybe the most. So, I wouldn't say it has been particular any more difficult really. It is quite easy to record. It is very easy for us to relay back to the previous notes. We can see you know everything all in the same page. It is quite easy we can fit through. We can see the improvement since, you know reporting back to the patients, you know 2 weeks ago, you did slow now you here. So, that again just reinforces it for them. Yes, I think the way of setting up for us it has been quite easy and straightforward.

Appendix 27: Transcript of the focus group of participant in the ABPI arm

An Embedded Qualitative Study of an Active Behavioural Physiotherapy Intervention (ABPI)

Focus group for a participant in the ABPI arm

Focus group room of the School of Sport, Exercise and Rehabilitation Sciences

28th September 2016

19.00-20.00

F: So how long ago was it when you had your treatment?

I: Well the accident was the 9 May and it followed probably about two to three weeks after that, I'm not 100% sure.

F: Yeah.

I: And I had six consultations with the physiotherapist in [redacted].

F: Okay and thinking back about the treatments that you had, what did that treatment consist of, how would you describe that?

I: Mostly movement of my neck in various directions and that was repeated in several ways. Also I had a neck massage in the last three sessions I was there, which I thought didn't help at the time but a couple of days later it felt good.

F: Okay.

I: Eventually things seemed to improve but I was doing exercises at home anyway in between sessions and I had some whiplash, as I mentioned earlier, but that went during the course of the physiotherapy. But after I'd finished my six week session it came back with a vengeance and I've had that ever since, the whiplash, to date, which is obviously the 28 September.

F: And how long after you finished did that come back?

I: About a week later.

F: Okay and do you know what triggered that or…?

I: No not really, I thought I'd just got an ordinary back pain and it's like a knife sticking in me. Although I've got osteoarthritis, it was, I assumed was sciatica and just made my osteoarthritis a little bit more painful.

F: Yeah.

I: And that's been the case ever since.

F: Okay. And do you think that was connected to your whiplash and the neck pain initially or unconnected?

I: Well I've never had that before so I assumed that it was a contribution to it. Yeah so almost certainly that was the cause.

F: Okay and then going back to the problems you had following your whiplash with your neck, what happened to those symptoms when you finished physiotherapy?

I: It still carried on, I still had aches in my neck, but after a couple of weeks they disappeared and to date I'm still okay, I've got no problems with my neck, which surprised me really you know given the severity of the pain that I had early on.

F: Okay. So you sound quite pleased with your outcome.

I: Yes definitely, yes.

F: Yeah.

I: I think I would have liked more hands on physiotherapy initially, but I don't know whether that was relevant at the time, but the massage on my neck seemed to improve my situation.

F: Okay and you said the early part of that treatment was the exercise.

I: Yes.

F: Anything else about the early part of the treatment that you can remember?

I: Well only that it hurt and that the exercises were a bit of a chore to do. I felt that the physiotherapy part of it I was doing and nobody else, but it was only after a couple of weeks, three weeks in fact that the massage came in and I felt that the physio was doing me good, but not my own exercises with my neck. I could be wrong of course, but that's how I felt.

F: Okay, so it sounds as if you were looking for the hands on from the beginning of the treatment?

I: Yeah, yeah.

F: So was it a bit of a surprise that you were doing more exercises?

I: Yeah, yeah that I was sort of left to my own devices to exercise. I do know however, that that is all part and parcel of physiotherapy, that you do that yourself, but I wasn't so sure about my neck you know, because it's obviously a sensitive part of my body you know.

F: Yeah, yeah. So it was a surprise at the time but looking back on that, how do you feel about it looking back?

I: Well looking back on that I still feel the same that if I'd had hands on right away it might have gone a bit quicker you know.

F: Yeah.

I: But I can't be sure of that, it was just my feelings then and now.

F: Yeah okay. You've said already you were doing things at home, what did the physiotherapist have you doing at home?

I: Movement more than anything else, different positions of my neck, doing multiples of ten exercises on each movement and doing that probably twice a day.

F: Yeah.

I: Sometimes I skipped it because of other commitments, but in the main I done the exercises during the day.

F: Okay, and did they get easier over time or more difficult over time?

I: No I think it remained the same until I had the massage hands on.

F: Yeah.

I: But then again I had the sciatica but I didn't know whether it was sciatica and I still don't know whether it is sciatica, all I know is that I still get this jabbing pain in my back on certain movements. Apart from that I'm quite happy with my neck.

F: Okay. And had your sciatica started before you were discharged with your neck or…?

I: Yes.

F: Yeah, so it had started.

I: It had started yes and then it disappeared after a couple of weeks and of course I told the physio that it was fine, its gone, but once my six weeks had finished it seemed to come back with a vengeance and I thought perhaps I'd just jarred my back perhaps, the pain was down my legs as well. So again, I'm not absolutely sure it's to do with sciatica and hopefully this… I've got more physio for my sciatica, if that's what it is, and I start that this coming Friday and I've been booked in for an MRI scan at the [redacted] Hospital.

F: Okay. And then going back to those exercises that you were doing at home, I know you said they were overall hard.

I: Yeah.

F: Were there any exercises within that that were easier than others to do or were they all equally difficult?

I: Equally difficult.

F: Okay.

I: Not that I'd noticed that it was any different, I just closed my eyes and done the exercises you know.

F: Yeah. And were they difficult because it was painful or…?

I: Yes, yes that's about it yeah. Not unduly painful though but it was you know nonetheless a pain.

F: Yeah okay. And thinking about the treatment that you had, there were sort of two components to the treatment that you've described to me there, so there was that's hands off bit, where you were exercising.

I: Yes.

F: And then there was the massage bit which was a bit more hands on.

I: Yeah.

F: Is there any other breakdown of the different components of treatment or do you think it's fair to describe that it was in two phases?

I: Yeah it was in two phases definitely yeah.

F: Okay, and the point where you were discharged, how did that decision come about? So was that from the physiotherapist?

I: Yes it was, he just said you've got one more treatment.

F: Okay.

I: And that was it.

F: And did you feel that was around the right time to finish?

I: I wasn't 100% sure about that.

F: Yeah.

I: It was his decision based on what I had said to him about my neck and I guess he made the right decision at the right time.

F: Yeah, okay. And thinking back over that treatment – I think I know the answer to some of these ones already – but what did you like about the treatments?

I: Well that it was… I liked the hands on bit simply because I, although it hurt at the time, after a day or so it felt much better.

F: Yeah.

I: And I obviously looked forward to it again the following week but I wasn't sure that that's what was going to happen because he never told me.

F: Yeah.

I: And… but it did happen nonetheless for a further two weeks after that. And that felt good you know, I mean the massage was for about between seven and eight minutes, so it had obviously done some good you know.

F: And you said it made you feel better; in what way did it make you feel better?

I: Well that it was getting down to the actual problem of the whiplash, if that's what it was.

F: Yeah.

I: And I was pleased that it went the way it did.

F: Okay. And did the physiotherapist use any goal setting with you, so giving you targets of what you needed to achieve?

I: No not at all, no.

F: Okay. Was that perhaps because you did that yourself anyway?

I: Yeah probably, yeah. I mean if I couldn't have done the exercises I certainly would have told him.

F: Yeah.

I: But I was quite happy with what was happening and I told him that, okay I didn't have any movement yesterday; I didn't feel like it you know.

F: Yeah.

I: And yeah it feels good.

F: Okay. And during that time when you had the symptoms was there anything that you were struggling to get back to do at home or in your social life?

I: Well I was actually very wary of cars behind me and I was a little bit unsure of driving insofar that I kept having this flashback of the car hitting me you know and not being able to do anything about it. So I was always, and still am now, wary of what's behind me and how close they are you know.

F: And how did you get over that to get back in the car, so at what point did you drive?

I: Just by persevering, I mean I didn't stop driving, I made sure of that because I knew that if I stopped driving I probably wouldn't have got back into the car.

F: Yeah, it would be harder.

I: Yeah, so I got back into my car and I've driven ever since.

F: Okay, and did you talk your fears there through with the physiotherapist at all?

I: Yes I did, yeah I told him that I felt you know, very wary of what was around me whilst I was driving and in particular, when I was stopped at the traffic lights in case anybody came up and done the same thing.

F: Yeah.

I: So psychologically I guess, it had an effect on me.

F: And did the physiotherapist help you with trying to get around that and overcome that?

I: No, he just said if you… well he said if you keep driving it should be okay, but he didn't go into any detail about it.

F: Okay. And was there anything else that you'd had to stop doing or was difficult to do?

I: Well it was difficult to turn my head to see what was behind without turning my whole body.

F: Yeah.

I: That was a bit, just uncomfortable you know. And of course I use my mirrors a lot more now.

F: Yeah, that's when you realise you've got mirrors don't you when you can't move.

I: Yeah. But yeah generally I feel okay apart from the sciatica, which even my doctors don't understand.

F: Yeah okay. And thinking back, we were talking there about what you liked about the treatment, was there anything you didn't like about the treatment?

I: Not really, I mean the guy who was doing it was… he obviously knew what he was doing and he actually typed down all of his questions and my answers, so he was making notes of how I was at the time and the exercises that he'd given me, and also mentioned the sciatica, again if that's what it is, I don't know myself.

F: Yeah.

I: So on the whole I thought he was okay; he was very friendly, he was worried about his job because he was Greek, he thought he might have to go back to Greece.

F: Oh yes, yeah, not what they want to do at the moment is it.

I: Yeah, yeah that's right, so he went and had a holiday after I'd finished.

F: Okay.

I: So I don't know whether my physiotherapy was cut short [laughs].

F: Okay. And you've said that you think the massage definitely made a difference.

I: Definitely yeah.

F: What about the exercise component of the treatment?

I: I'm not sure about that, I mean I thought it was a chore at the time because there were so many different movements of my head and neck. But I persevered and I done it at least once a day and I'm sure it showed improvement.

F: Okay, and what the physiotherapist was doing there was encouraging you to self-manage obviously to get your neck moving.

I: Yes.

F: Do you think that made a difference, that approach made a difference?

I: I'm not sure about that, I didn't have any real thoughts about that but whatever he done it worked.

F: Okay. And as part of the visits can you remember the physiotherapist asking you questions or measuring how you were improving as time progressed?

I: I'm sure he was, yeah, he was asking me questions of how I felt and how were the exercises coming along and was I finding them, difficult or easy, and he recorded everything that I said on his laptop, so I assumed that he helped me progress through it.

F: Okay, and I'm wondering if you can remember the answers to know, sometimes as a patient yourself, you pick up the differences in improving, so this week you can turn this far, next week you may be able to turn…

I: No there was none of that, none of that.

F: Okay.

I: I did express that it was feeling a lot better you know.

F: Yeah.

I: But I didn't sort of say any particular movement helped you know.

F: Yeah okay. Anything else about the actual treatment that I haven't asked you about? Was there anything else that the physiotherapist did that we haven't talked through?

I: No I think he just pursued his regime of whiplash you know, which I assume was the right thing to do.

F: Okay and what about the explanation about what whiplash was, so how did you feel about that, so did you come away…

I: I didn't have an explanation.

F: Okay, okay.

I: I assumed that my allocated solicitors saw to that.

F: Okay.

I: And obviously the third party paid the bill so as far as I was concerned it was all booked for you you know.

F: Okay, okay. And what about the advice on what you should do to help yourself rather than the what not to do or… did you find that was easy to then take home?

I: Yeah I mean he said continue doing the exercises as and when you feel you need it. And I haven't felt the need to do them.

F: Okay.

I: My thoughts were much more on my back you know, lower back pain and legs and I sort of dismissed the whiplash. And I think psychologically that's helped me get over it by concentrating on something different like my back you know. How true that is I'm not sure.

F: Okay, it's an interesting thing to pick up on though.

P: Yeah diverting your mind to something else.

F: Yeah, yeah absolutely. And is there anything else that you'd expected as part of your treatment that didn't happen?

I: No I mean I got what I thought was right you know.

F: Yeah.

I: I mean leave it to the professionals you know, I mean I'm no expert on anything like that, so I have no thoughts on those matters.

F: Okay. And if you were chatting to one of your family, say one of your children or a friend, would you recommend the treatment that you had?

I: Sure, yeah, yeah, well I did, my son, I recommended my son because he was with me.

F: Oh okay.

I: And he was going to just let it go and hoo-ha'd it you know, and I said look you must sort it out.

F: Okay, and did he have treatment there or did he go somewhere else?

I: No he wouldn't go and have treatment. He lives in [redacted] so.

F: Oh okay.

I: So I left it to him and he just made an ordinary claim and they asked him if he wanted physio and he said no.

F: Okay.

I: But he's much stronger than I am and younger and fitter.

F: He's a bit younger, yeah; he has that advantage doesn't he.

I: Yes.

F: Okay and as part of the treatment did the physiotherapist talk about self-efficacy or your ability to achieve different milestones in your recovery?

I: No, no.

F: And is that something that you thought through yourself so did you pace your return to try and get back to doing everything as normal or are you someone who just goes for it?

I: No I just went through it and it's what I expected you know. I didn't expect to have a whole regime around it you know. To me it was something that happened and the sooner I forget it the better.

F: Yeah.

I: And I think that helped me having that kind of attitude.

F: Yeah, yeah I'd agree with that. And you were talking about how you were fearful of driving, understandably.

I: Yeah, yeah.

F: Were you fearful of anything else following the accident?

I: No it was just the worry of somebody hitting me and I didn't really want to go through that, I'm no spring chicken as you already know.

F: Only because I know you've got children [laughter]. So we've talked through the specifics of the treatment and what difference it made to the whiplash, are there any principles of that treatment that you've taken into… so where you've got the sciatica at the moment, is there anything you've taken across?

> I: Well I do sort of do some exercises whilst I'm in bed before I get up, you know like bringing my knees up as far as I can and I have a certain amount of difficulty insofar that I've got type 2 diabetes and my toes are semi sort of numb you know. And I also have a stent in my left leg, so I just accept what's going on and do what I can you know.

F: Yeah, and that approach of trying to keep moving, is that always there for you?

> I: Yes it is, yeah, I mean I walk, I mean weekends I might be in Worcester, Leamington or other places and I'll walk for about two or three hours.

F: Yeah.

> I: I mean I have a walking stick but I've never used it.

F: Okay, so there's a real independence within you.

> I: Well its something that I'm not going to give up easily walking you know.

F: Yeah.

> I: I mean if I sit down that's me finished, that's my outlook.

F: Yeah. And how do you think that influenced then your approach to the physiotherapy treatment of the whiplash? So if that's you already.

> I: Yeah it was just something that was stuck on the side if you like. I mean I wasn't paying for it and I knew something had to happen you know and I just went along with it.

F: Yeah.

> I: I mean I've had physio before on my back some years ago at [redacted] and I joined the classes there, I was quite good at what I was doing and I felt good after it, but I didn't do anything outstanding other than exercising you know and life goes on.

F: So do you think everyone would response in that way or do you think people are quite different?

I: Well I would like to think so, but there are people who will just sit down and say, well there's me you know and I'm not like that, I just get on with it.

F: Yeah.

I: I've already been stopped, you know I used to do a lot of hiking at one time and I don't do that anymore of course you know and I've got a disabled badge, a blue badge because of my problems. But it hasn't stopped me getting around you know.

F: Yeah, so you've had to adapt what you do.

I: Yeah.

F: But you've kept it going.

I: Yeah.

F: And when you had the whiplash injury initially did that limit your activity to start with or did you manage to keep that going?

I: Yes it did, yeah; it stopped me doing a lot of things you know. I just didn't feel like doing things at the time, but I said to myself you know, get up and start moving otherwise what will happen if you don't.

F: Yeah. So can you remember how long you had that feeling that it was hard to move?

I: Well it was only about half a dozen days, six or seven days, a week at the most.

F: Okay, and then you could get yourself going again.

I: Oh yeah, yeah.

F: Yeah okay. And is it easy to keep your activity going now?

I: Yeah like I say, I mean I drove to [redacted] and back on Monday, it's not a problem.

F: And anything from your neck that you're feeling now?

I: No my neck is probably 90% of what it used to be, its not totally you know, but then again I don't feel it because I don't think about it.

F: Yeah.

I: And the diversion to my back, my back's… I take co-codamol, which is quite a strong painkiller you know and even that, I'm supposed to take eight a day and I take two in the morning and that's it, I walk through it.

F: And have you just had to start taking those again because of your back?

I: No, I was on them before for my osteoarthritis.

F: Okay.

I: But it doesn't really make any difference to my sciatica, I still get those jabs if I make a wrong move and sometimes when I'm in the bathroom, I do shave now and again, if I bend unnecessarily I get a jab and I'm woo you know, that kind of thing, but it goes, its not with me all the time.

F: And the painkillers that you're taking have you taken them consistently through the whiplash and the sciatica?

I: Yes I have yeah.

F: Yeah, always at that same dose?

I: Yes, two tablets a day, 30 mg.

F: Okay so you didn't have to take that higher for the whiplash?

I: Well I wouldn't want to anyway because I know they can be addictive and if I can walk through it, what the hell.

F: Yeah okay. Anything that I haven't asked you that you think is relevant?

I: Not really.

F: So the only thing that I can think of just reflecting back on the treatment, we talked about those two phases of the active phase and then you had the passive treatments as part of that, just looking back on that, do you think that was the right way round, do you think that might have been better the other way round?

I: I'm not sure; I mean I just supposed that the physiotherapist knew what he was doing. Maybe he was being gentle to start with and easing me into massage, I don't know, I'm not sure about that.

F: So one of the reasons why he did that was to try have the education and the you being active and then you managing at the beginning.

I: I would have thought so, logically thinking that's probably how it happened, but I wasn't… I didn't think that way at the time.

F: Yeah.

I: I thought that maybe I should have had the massages to start with, but I'm not a physiotherapist so I accepted what he prescribed if you like.

F: Okay, and final reflection, do you think the treatment made any difference? So if you had had no treatment, what do you think would have happened?

I: Oh yes it's definitely made a difference yeah, particularly the massage.

F: Yeah.

I: I think if I'd have left it I'd have been in trouble.

F: Yeah.

I: And something else that was on my mind at the time, and we touched on it earlier, that a lot of people are claiming whiplash and they really haven't got it but they're claiming anyway, and I felt am I being put in that category you know. So there was a time when I thought you know what, do they think that I've been dishonest.

F: Okay.

I: But that phase passed because I knew in my own mind that it wasn't a falsehood.

F: And were you feeling that at the beginning of the treatment?

I: Yes, yes.

F: Okay and what triggered that, so do you think that was related to the type of treatment or the communication or…?

I: I think it was the fact that physiotherapy was ordered on my behalf, I wasn't asked.

F: Yeah, yeah.

I: But I suppose these solicitors have to make money somewhere.

F: Yeah, it's a funny system of doing it isn't it, it feels quite strange.

I: Yeah.

F: Okay so when you turned up for physiotherapy initially did you want it at that point or you weren't sure?

I: I knew I needed something and apparently it was the right thing to do you know, but like I said, I'm no expert on these things and at times like that you have to rely on other people to make those decisions for you you know, and I was quite happy to do that.

F: And you said about the six treatments, so you felt you'd come to the end of your treatment…

I: Yeah it was quite abrupt really.

F: Yeah, I just wanted to pick up on that. So why was it abrupt?

I: I don't know whether it was the fact that he was going on holiday and I did have a flavour of that at the time you know and I thought oh he's going on holiday, well is that it you know.

F: Okay.

I: And that was it.

F: Okay and it wasn't limited by the solicitor in any way?

I: No.

F: So you felt it was the physiotherapist that was stopping it at that point.

I: Yeah, yeah, yeah. Yeah he just, when I went in that last morning he said, this is your last session you know and I thought right.

F: Okay. And do you think that was based on what you were saying to him about how well you were doing or…?

I: I'm not sure actually, I mean maybe he was given a period of physiotherapy to dish out to me or dole out to me you know, maybe they said six weeks we'll pay for, nothing more, that could have been the third party insurance. So I'm not even sure about that because I was kept out of the equation.

F: Okay. Anything that you can think of that links into this that I haven't asked you?

I: Not really no.

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