University of Southampton

Faculty of Environmental and Life Sciences

Developing a best practice approach to real time clinical gait analysis as part of a clinical musculoskeletal assessment in the treatment of non-neurological lower limb symptoms in adults

by

Paul David Harradine

Thesis for the degree of Doctor in Philosophy

July 2022

Supervisors: Prof Catherine Bowen, Dr Lucy Gates, Dr Cheryl Metcalf

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Abstract

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Introduction

The purpose of real time clinical gait analysis (RTCGA) is to aid in diagnosis of musculoskeletal (MSK) conditions, determine treatment goals and evaluate treatment outcomes. Clinicians are recommended to conduct RTCGA as part of a lower limb MSK non-neurological adult patient assessment. The timely and accurate use of such a diagnostic method, with the smallest possibility of a missed diagnosis or misdiagnosis, is crucial in the treatment of any disease or disorder. Despite this, there remains little MSK RTCGA evidence to support the methods by which to do so.

This PhD reflects a programme of work which was undertaken to develop a best practice RTCGA approach for adult non-neurological lower limb MSK injury. The research aim was to establish a best practice approach for RTCGA to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults.

Study Design

This doctoral thesis programme of work employed a mixed methods approach, involving a series of deductive quantitative investigations followed by inductive qualitative investigation.

Deductive quantitative investigation involved scoping of the RTCGA best practice approach via narrative literature review, a patient and public involvement and engagement (PPIE) exercise and preclinical testing. A systematic review was conducted to robustly establish available MSK RTCGA literature.

Inductive, qualitative investigation involved exploration of MSK podiatrists' views and experiences of RTCGA for an exemplar condition, posterior tibial tendon dysfunction (PTTD), using thematic analysis of semi-structured interviews. Findings supplied the foundation by which preliminary clinical recommendations for a MSK RTCGA best practice approach were created.

Results

A preliminary objective RTCGA instrument was created. Scenario testing for face validity demonstrated this preliminary RTCGA instrument would not detect kinematic changes following intervention, and an additional immediate intervention RTCGA instrument was developed. The resultant preliminary RTCGA instrument, which was then subject to preclinical testing, consisted of 2 sections, the RTCGA instrument score and the RTCGA immediate intervention score.

Preclinical investigations demonstrated difficulties in the ability to test the preliminary RTCGA instrument for both reliability and validity.

Literature review and searches from narrative, systematic and PPIE investigations found a lack of high-level evidence and guidance for the use of RTCGA and the development of RTCGA best practice approaches.

In total, 6 substantial problems were encountered associated with the creation of an objective quantifiable instrument as a RTCGA best practice approach. These were a lack of existing RTCGA knowledge; developer bias; the necessity to

include shod gait assessment; a lack of normative kinematic data; the length and complexity of the preliminary RTCGA instrument and an inability to transiently alter kinematics and obtain valid data for testing. These issues deemed the continued development of an objective quantifiable RTCGA instrument to be counterproductive.

To understand the conundrum that an objective quantifiable RTCGA was not feasible yet is an approach suggested for use by clinicians (notably podiatrists) as an embedded component of their practice, the exploration of MSK clinician views and experiences of RTCGA was sought prior to attempting any further development. The resultant exploratory qualitative investigation confirmed that use of RTCGA was valued by MSK podiatrists, but that no consistent systematic approach for RTCGA was available.

Based upon these findings, a set of 4 core recommendations are proposed as a preliminary best practice RTCGA approach when assessing and treating adult PTTD (the GAIT assessment). These are:

Get a diagnosis (recommendation 1). RTCGA should be conducted after a provisional clinical PTTD diagnosis has been proposed.

Assess walking (recommendation 2). RTCGA should be used to aid in clinical diagnosis of adult patients with PTTD. Assessment should include a) essential kinematic observations, and b) dynamic presentation of pain.

Intervene and assess (recommendation 3). RTCGA should be performed after a clinical intervention, such as the fitting of foot orthoses or footwear, to observe any kinematic changes. If fitting foot orthoses, it should also be used to assess for patient perceived comfort.

Teach using clinical experience (recommendation 4). RTCGA education should be addressed through an experiential approach, such as small group practical teaching and clinical mentoring.

Conclusion

The research undertaken in this doctoral thesis programme of work is the first to apply development frameworks and methods in the attempt to establish a mechanism to record gait and gait changes within a MSK clinical setting, without the aid of computerised or video recording technology. A preliminary RTCGA best practice approach has been produced that supplies guidance for MSK podiatrists, in the form of the GAIT assessment, to aid in the clinical treatment and assessment of PTTD. However, the pathway to achieving a robust clinical practice guideline requires more work.

The lack of objective kinematic data for this field was a significant barrier to investigating and improving reliability and validity of RTCGA observations. RTCGA, as an aid in the diagnosis and treatment of MSK injury, is arguably a high-level skill associated with professional specialisation. It follows, therefore, that such a skill would be supported by objectivity and standardisation of practice, yet the lack of normative data for RTCGA continues to act as a barrier to this. A new approach in which RTCGA is focussed on the patient symptoms and evidence based observation is proposed.

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Research Thesis: Declaration of Authorship

Print name: Paul Harradine

Title of thesis: Developing a best practice approach to real time clinical gait analysis as part of a clinical musculoskeletal assessment in the treatment of non-neurological lower limb symptoms in adults

I declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;

2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;

3. Where I have consulted the published work of others, this is always clearly attributed;

4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;

5. I have acknowledged all main sources of help;

6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;

7. Parts of this work have been published as:

Harradine, P., Gates, L. and Bowen, C. (2018a) 'If it doesn't work, why do we still do it? The continuing use of subtalar joint neutral theory in the face of overpowering critical research', *Journal of Orthopaedic and Sports Physical Therapy*, 48(3), pp. 130-132.

Harradine, P., Gates, L. and Bowen, C. (2018b) 'Real time non-instrumented clinical gait analysis as part of a clinical musculoskeletal assessment in the treatment of lower limb symptoms in adults: A systematic review', *Gait and Posture*, 62, pp. 135-139.

Harradine, P. *et al*. (2021) 'Podiatrists' views and experiences of using real time clinical gait analysis in the assessment and treatment of posterior tibial tendon dysfunction', *Journal of Foot and Ankle Research*, 14(1), pp. 1-10.

Signature: Date:

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I would like to gratefully acknowledge the contribution of all participants, without whom this research would not have been possible.

I would also like to thank my friends and colleagues who have listened and supported me through what must have appeared to be endless discussions and explorations regarding gait analysis. I would particularly like to thank Lawrence Bevan for his support and insight.

Lastly, I would like to dedicate my thesis to my wife Beth, our seven children, and my ever-loving family.

Abbreviations

2D	Two dimensional
3D	Three Dimensional
AGREE II	Appraisal of Guidelines for Research and Evaluation II
CASP	Critical Appraisal Skills Programme
CGA	Clinical Gait Analysis
CTV	Central Tendency Value
CKC	Closed Kinetic Chain
FPI-6	Foot Posture Six Index
GA	Gait Analysis
GHORT	Gait Homunculus Observed Relation Tabular
IMFAA	International Musculoskeletal Foot and Ankle Assessment
JFAR	Journal of Foot and Ankle Research
JOSPT	Journal of Orthopaedic and Sports Physiotherapy
MSK	Musculoskeletal
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OKC	Open Kinetic Chain
PICO	Patient Intervention Comparison and Outcome
PP	Private practice

PPIE	Patient and Public Involvement and Engagement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PTTD	Posterior Tibial Tendon Dysfunction
RCT	Randomised controlled trial
RIP	Rearfoot Inversion Pattern
REP	Rearfoot Eversion Pattern
RTCGA	Real Time Clinical Gait Analysis
SD	Standard Deviation
SPF	Sagittal Plane Facilitation
SRV	Standardised Reference Value
SRVP	Standardised Reference Value Pattern
SSV	Symptom Specific Value
STJ	Subtalar Joint
STJN	Subtalar Joint Neutral
TS	Tissue Stress
UK	United Kingdom
US	United States

Chapter 1 Document introduction

1.1 Introduction

This document is submitted in consideration of a PhD degree at the School of Health Sciences, Faculty of Environmental and Life Sciences, University of Southampton.

The research presented is aimed to create a best practice approach to be used in the assessment of gait, and the inherent problems and issues in doing so. The thesis chapters present a review of published literature, and the research methods, findings, discussions and conclusions of this work. This includes proposed clinical recommendations (the GAIT assessment) to be used by musculoskeletal (MSK) podiatrists in the diagnosis and treatment of adults based on an exemplar condition of posterior tibial tendon dysfunction (PTTD).

The study originates from issues encountered while conducting and teaching gait analysis (GA) in a clinical setting. I have worked as a clinical MSK podiatrist in many settings since 1994, including National Health Service (NHS) podiatry clinics, NHS physiotherapy clinics, NHS orthopaedic triage and rheumatology centres. I have also worked in numerous private physiotherapy clinics and private hospitals before establishing ‘The Podiatry Centre’ as the base for my clinical work and orthosis manufacture in 2004. Along with the MSK clinical caseload, I worked as a lecturer in MSK undergraduate podiatry for 2 years at the University of Southampton and continue to teach postgraduate students independently and for private healthcare education provision companies.

Performing and teaching GA has always been challenging due to the lack of detailed literature, as well as the practical and academic mix of the skill itself. Although feeling confident in my clinical approach, understanding my process and being able to convey and teach it to students and colleagues created considerable problems. As evidence-based practice became embedded in podiatry in the 2000s, these difficulties intensified due to the lack of evidence in terms of the validity, reliability, or clinical value or standardisation of any GA method.

I worked with, and designed, numerous GA approaches in an attempt to address the issues facing my practice and MSK GA education. However, without access to academic guidance and research technology, these attempts may be seen retrospectively to be incomplete and prone to bias. Although not intentional, such bias is retrospectively apparent and influenced previous GA approaches in several ways. Confirmation bias resulted in the seeking out of information that supported my beliefs, highlighting areas that mattered to the approach I used in my clinics to the possible detriment of others. Cultural bias, also known as implicit bias, effected the origins of my baseline thinking. Through this doctoral thesis programme of work, I have reviewed, reflected and evaluated a greater extent of beliefs and theories relating to foot function and real time clinical gait analysis (RTCGA), not only from existing literature but also via original knowledge obtained from research completed as part of this thesis. This programme of work led to the development of clinical recommendations as an attempt to provide a best practice RTCGA approach within recognised scientific frameworks and increased awareness and scrutiny of potential bias.

1.2 Thesis structure and overall approach

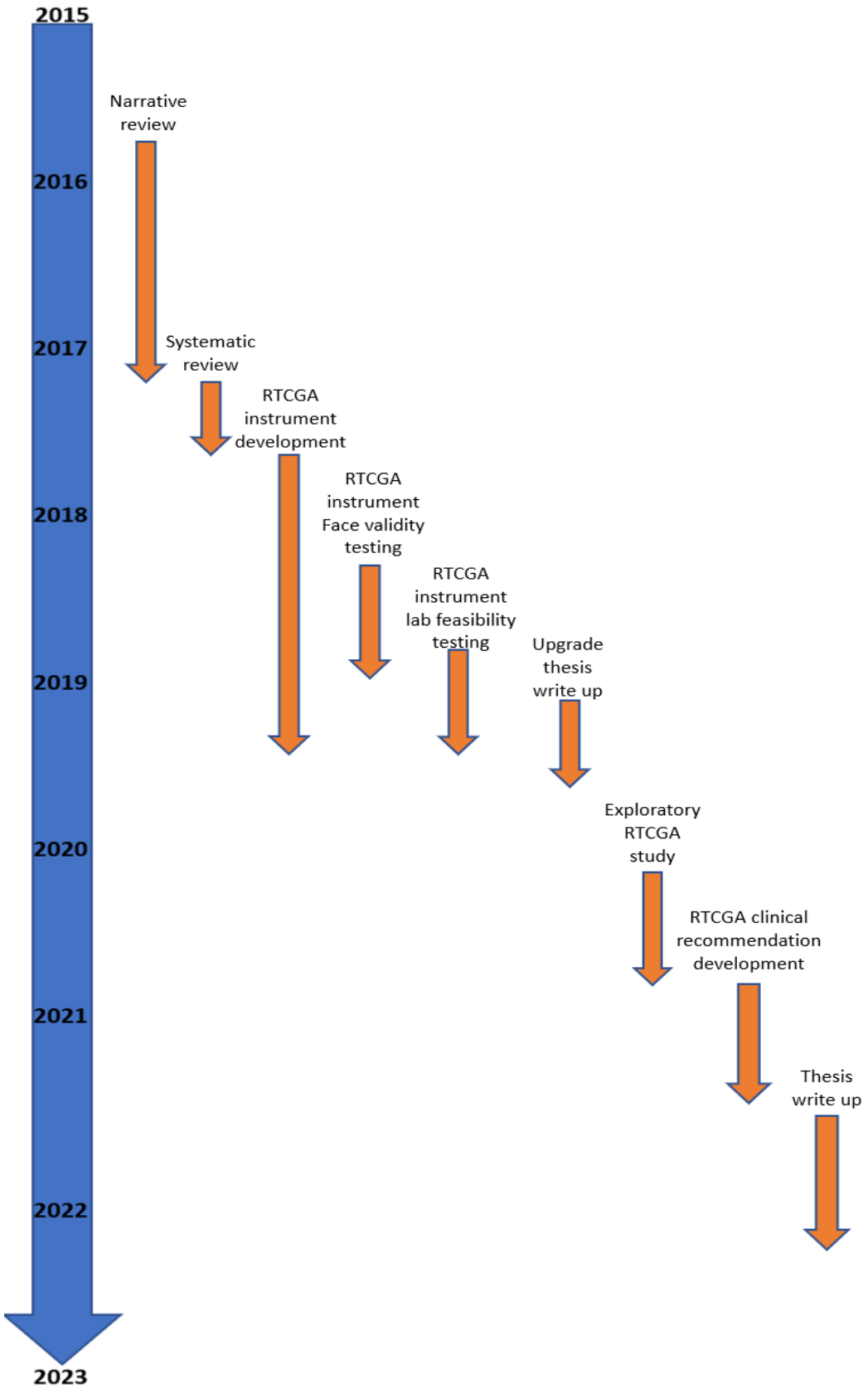
This doctoral thesis is divided into 11 chapters with 6 interrelated stages. Each stage relates to the development and process of answering the research question, and although relating to thesis chapters, are not bound numerically to them (Table 1.1, Chapter 1, page 3). Development has been iterative, with each stage directing and influencing the next.

Table 1.1 - Summary of thesis chapters, stages and associated publications

Chapter	Stage	Publication
1 Document Introduction	N/A	N/A
2 Thesis Background	N/A	(Harradine, Gates and Bowen, 2018a)
3 Narrative review	1	N/A
4 Systematic review	2	(Harradine, Gates and Bowen, 2018b)
5 Development of a quantifiable RTCGA instrument	3	N/A
6 Preclinical testing of face validity, reliability and concurrent validity	4	N/A
7 Exploration of MSK podiatrists' views and experiences of RTCGA	5	(Harradine *et al.*, 2021)
8 Development of a RTCGA clinical practice guideline	6	N/A
9 Discussion	N/A	N/A
10 Conclusion	N/A	N/A
11 Proposal for further work	N/A	N/A

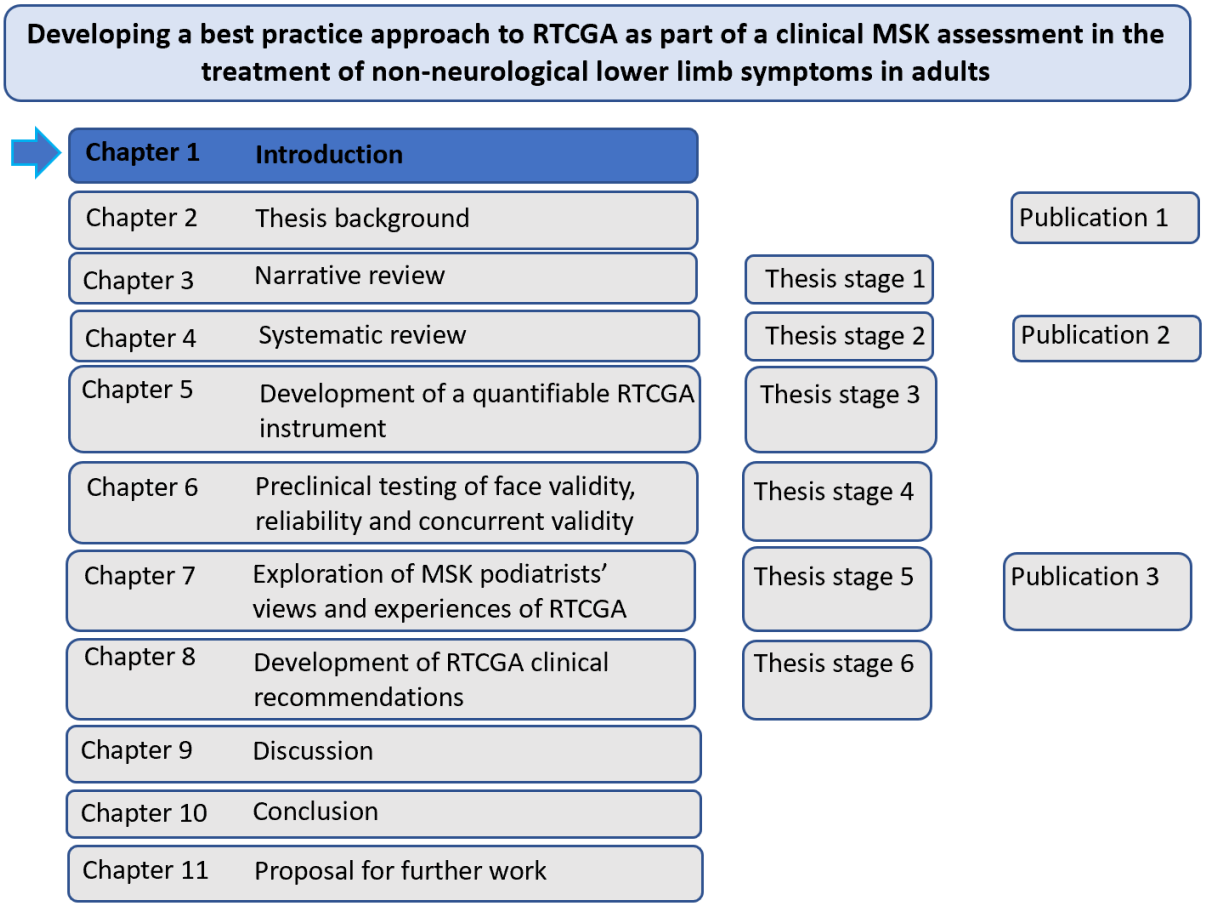
The chronological order and duration of work undertaken in relation to the 6 thesis stages is demonstrated in Figure 1.1, page 4.

Figure 1.1 – The chronological order and duration of work undertaken in relation to the 6 thesis stages



Each chapter begins with a diagrammatic overview of the thesis demonstrating the chapter within the context of the doctoral programme of work. Chapter 1 is demonstrated in Figure 1.2.

Figure 1.2 Doctoral thesis overview demonstrating Chapter 1 within the context of the programme of work



The iterative approach resulted in progressive adaptations to the programme of work, and as a result a range of differing methods and philosophical approaches were employed.

At outset it was anticipated the narrative review (stage 1) would confirm and detail the GA evidence gap already posited by the clinical and educational experience of thesis author. A systematic review (stage 2) would then supply sufficient literature and knowledge to confirm and address this evidence gap via the development (stage 3) and testing (stage 4) of a preliminary RTCGA instrument. If successful, a quantitative RTCGA instrument could then be presented as a best practice

approach for general clinical use and undergo further diagnostic tool assessment and analysis. These predicted stages would be iterative and pragmatic in their philosophical stance. The approach would be deductive, testing current theory, and use quantitative statistics to test for reliability and validity of the objective RTCGA instrument observations.

The anticipated progression and outcome of stages 1-4 did not happen (see Chapters 3-6, pages 29-124). Although the narrative review did establish an evidence gap in relation to GA and RTCGA (stage 1), the systematic review failed to find any robust knowledge with which to develop and then test a quantitative RTCGA instrument (stage 2). Instead, to address this evidence gap, health measure and diagnostic tool creation frameworks were used in the 'de-novo' development of a quantitative RTCGA instrument (stage 3). A lack of normative kinematic data presented difficulties for this stage, and suggestions made to overcome this issue (the use of standardised reverence values (SRVs)) were found to be unsatisfactory. Face validity testing the RTCGA instrument (stage 4) found flaws in its ability to detect small kinematic changes, and further multiple observations were included to satisfy conceptual development aims. This resulted in a lengthy and complicated RTCGA instrument. Laboratory based feasibility studies into RTCGA instrument reliability and validity testing (stage 4) produced unsatisfactory and unexpected outcomes when attempting to record and transiently alter healthy subject kinematics. As difficulties arose, no previous knowledge, literature or expertise was available to aid in overcoming these dead-end situations. At the conclusion of stage 4, a preliminary conclusion was drawn based upon the research findings. It was not possible to create an objective quantifiable RTCGA instrument for use as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults.

Although an important finding by itself, this preliminary conclusion did not concur with narrative review results on the use of GA. RTCGA was noted as frequently recommended and a supposedly useful MSK clinical assessment method, and yet no robust guidance or methods for its undertaking were available. Following 3 years of research, the programme of work was no closer to providing an answer or solution to this conundrum. The resultant frustration was solidified during the

MPhil / PhD upgrade viva, where examiners agreed that although the conducted work was satisfactory to upgrade, the stage 1-4 methodology would not be suitable to further address the established evidence gap. These stages had successfully demonstrated a lack of RTCGA knowledge which prevented the development and testing of an objective quantitative RTCGA best practice approach.

The following 3 months included an intense period of discussions with supervisors and the invitation and addition of a 3rd supervisor external to podiatry with engineering and commercial experience (Dr Cheryl Metcalf). It was anticipated a supervisor with qualitative knowledge and experience in different fields of outcome measure design and publication would be helpful in establishing further investigations into the RTCGA evidence gap. While accepting the importance of the composite results of stages 1-4, the experience of needing to start again was difficult. After 3 years of research, it was not possible to determine the incidence, reasons or process of RTCGA clinical use.

Stages 5 and 6 (Chapters 7 and 8, pages 125-158) were subsequently undertaken to address this lack of literature and knowledge surrounding the worth, use and methods of adult non-neurological MSK RTCGA. The results of stages 1-4 were not insuperable, but a change in approach was required, moving from quantitative to qualitative research approaches. By incorporating both methods, the overall methodology became a mixed methods approach. Stage progression was still iterate and the philosophical standing pragmatic, dealing with the practical rather than theoretical considerations of RTCGA. However, the approach became inductive, building a theory rather than testing one.

Stage 5 included semi-structured interviews with national MSK podiatrists to explore views, experiences and methods relating to RTCGA. Findings demonstrated RTCGA was valuable to these MSK podiatrists and that a consistent systematic approach for RTCGA that was repeatable would be beneficial. Based upon available literature and acquired knowledge, the creation of clinical recommendations as a best practice approach was therefore proposed.

Stage 6 was the development and definition of the GAIT assessment. The GAIT assessment is a core set of clinical recommendations for RTCGA devised from the previous stages and presented as the preliminary RTCGA best practice approach for PTTD. Developed to be helpful in the diagnosis and treatment of PTTD, their quality is limited due to a lack of recommendation detail arising from a remaining evidence gap. Further work is suggested.

Ontological and Epistemological position

With the mixed methods approach and the personal development concurrent with using both quantitative (stages 1-4) and qualitative methods (stages 5-6), the thesis authors ontological position developed during this programme of work from a realist to a critical realist standing. This change demonstrates a change in ontological stance of the thesis author and of the programme of work. It accepts that although there may be a knowable process of RTCGA, it's research and so presentation is dependent upon accessible subjective and socially located knowledge (Madill, Jordan and Shirley, 2000).

A contextualist epistemological stance is maintained throughout the thesis, where it is held that a RTCGA best practice approach is largely achievable, but it is acknowledged that the emerging knowledge is influenced by the context of the research and the researchers positions (Madill, Jordan and Shirley, 2000; Braun and Clarke, 2013)

Thesis Chapters

Chapter 1: description of the personal and professional development attained during the PhD process. Thesis structure and overall approach.

Chapter 2: overview of GA focused on its use in adult MSK non-neurological lower limb injury and clinics.

Chapter 3: stage 1- the narrative literature review of a best practice approach for RTCGA.

Chapter 4: stage 2- the systematic review of RTCGA of adult non-neurological lower limb injury.

Chapter 5: stage 3- the development of a quantifiable RTCGA instrument

Chapter 6: stage 4- the preclinical testing of the quantifiable RTCGA instrument. This stage led to the acceptance of the inability to design a quantitative objective approach to RTCGA with current knowledge and evidence.

Chapter 7: stage 5- the exploration of MSK podiatrists' views and experiences of RTCGA in the assessment and treatment of patients with PTTD.

Chapter 8: stage 6- the creation of the GAIT assessment, a core set of RTCGA recommendations for adults with PTTD.

Chapter 9: critical discussion in relation to the study findings, methods, and contribution to the existing body of knowledge.

Chapter 10: thesis conclusion.

Chapter 11: proposal for further work.

1.3 Personal and Professional Development

Over the last seven years I have applied a variety of educational methods and strategies to support my progress through the PhD process. The interim findings of the programme of work necessitated a change from quantitative to qualitative methodology. Unlike the quantitative approach, I had little previous experience in this field. This change in methodical direction was the largest personal developmental challenge of my PhD journey. The acquisition of new skills and knowledge to overcome this and other barriers encountered at different stages of the process have been achieved via various strategies. These include supervisory meetings, supervisor communication, meetings with statisticians and librarians, quantitative and qualitative training sessions, attending presentations, expansive reading and communicating with colleagues and peers.

Supervisor meetings were both face-to-face and later (due to Covid-19 restrictions) via Zoom remote conferencing. These meetings provided essential guidance to ensure the research study progressed in a meaningful direction. They also provided feedback and encouragement with regards to personal development and future requirements.

Face-to-face and remote meetings have been conducted with statisticians for quantitative research training and librarians with regards to ensuring the rigour of the literature reviews. I have completed online (LinkedIn Learning) NVivo training and attended lessons on “research paradigms”, “introduction to RCTs”, “making the most of supervision”, “critical appraisal”, “preparing a research proposal”, “SPSS statistics”, “research governance” and “research ethics”. This training increased my knowledge and confidence in conducting research and allowed me to explore differing research methods and approaches.

The PhD format followed has 3 mandatory milestones to be completed and reviewed. Milestone one was completed in April 2016 and focused upon establishing the need, development and use of a novel GA method in a clinical setting. The second milestone was completed in January 2017 and discussed the findings of the narrative review in relation to the current evidence on adult RTCGA conducted within the clinical MSK setting. The third milestone was scoping of a preliminary RTCGA instrument, with research methods for its testing, in relation to findings from the systematic review. It was completed in June 2017. The 3 milestones developed into the final aim to develop an instrument or tool to address the gap in knowledge and practice in relation to RTCGA.

The proposed programme of work was presented at the Primary Care and Public Health Conference, Birmingham NEC, on the 16th of May 2018 via a podium presentation and the systematic review presented via a poster presentation at the 2019 College of Podiatry annual conference. In addition, the findings and development of this research have formed an integral part of post-graduate lectures delivered under the title of “Assessment of the Foot in Relation to Gait Dysfunction and Injury”. I have presented this lecture to multidisciplinary groups more than forty times over the last 6 years. These smaller post graduate courses (most commonly to approximately 16 MSK clinicians of various professions)

permitted in-depth conversations and questioning the views and experiences of GA. These presentations have been invaluable in obtaining peer feedback and advice relating to the research study from peers and colleagues.

During this research study I was approached by the editor of the Journal of Orthopaedic and Sports Physiotherapy (JOSPT) to write an editorial regarding foot assessment and theory. This was undertaken as part of the doctoral process and increased knowledge regarding the limitation of current foot function theory in relation to gait. “If It Doesn't Work, Why Do We Still Do It? The Continuing Use of Subtalar Joint Neutral Theory in the Face of Overpowering Critical Research” was published in 2018 (Harradine, Gates and Bowen, 2018a). The conclusion and feedback from this paper reinforced the argument that an approach more valid to GA than a kinematic prediction from static assessment would be beneficial for patient care.

The stage 2 systematic review, “Real time non-instrumented clinical gait analysis as part of a clinical musculoskeletal assessment in the treatment of lower limb symptoms in adults: A systematic review”, was published in Gait and Posture in 2018 (Harradine, Gates and Bowen, 2018b). The stage 5 qualitative investigation into RTCGA “Podiatrists’ views and experiences of using real time clinical gait analysis in the assessment and treatment of posterior tibial tendon dysfunction”, was published in the Journal of Foot and Ankle Research (JFAR) in 2021 (Harradine *et al.*, 2021).

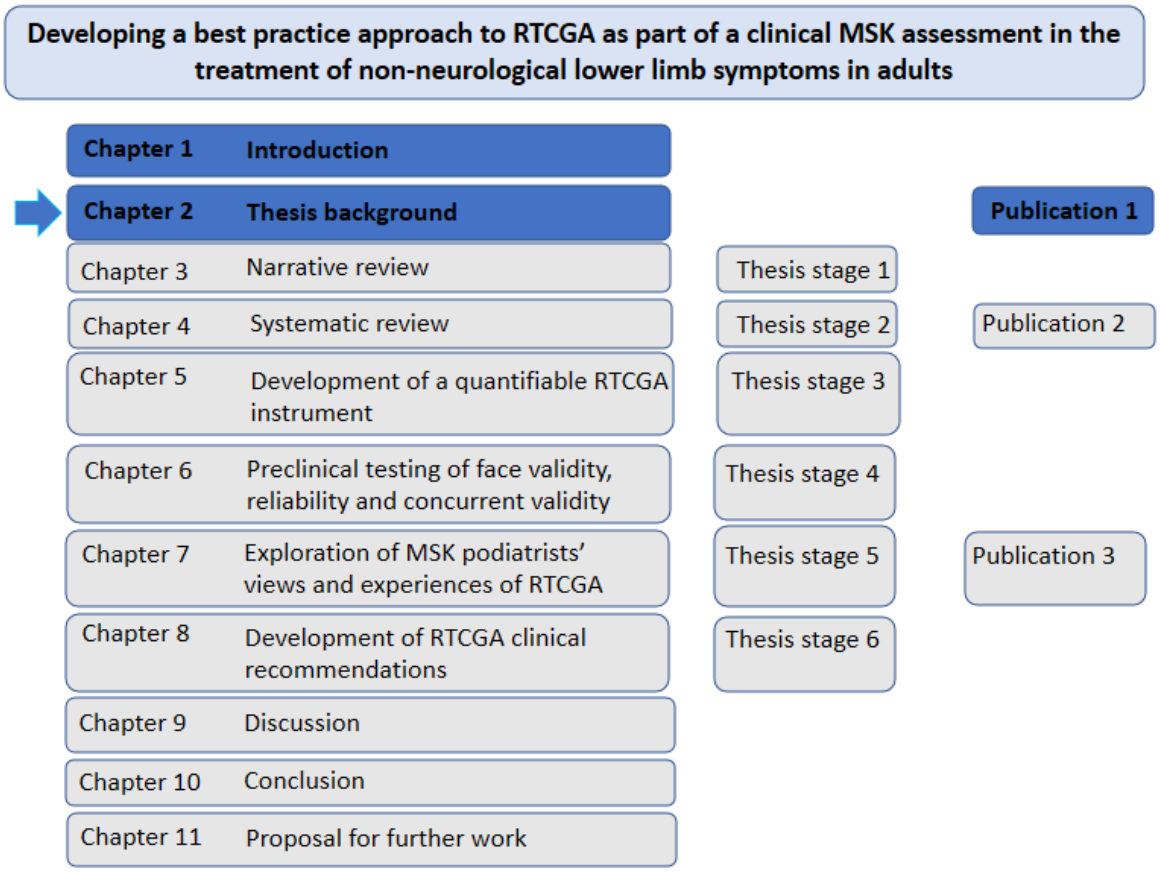
The timeline of the PhD candidature is presented in appendix A (page 187). The following chapters will introduce and provide a rationale for designing a best practice RTCGA approach to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults by initially examining current literature available on gait and GA.

Chapter 2 Thesis background

2.1 Introduction

This chapter explores and defines gait, GA and the core concepts central to this research in the development of a best practice approach to RTCGA. Figure 2.1 demonstrates Chapter 2 within an overview of the doctoral thesis.

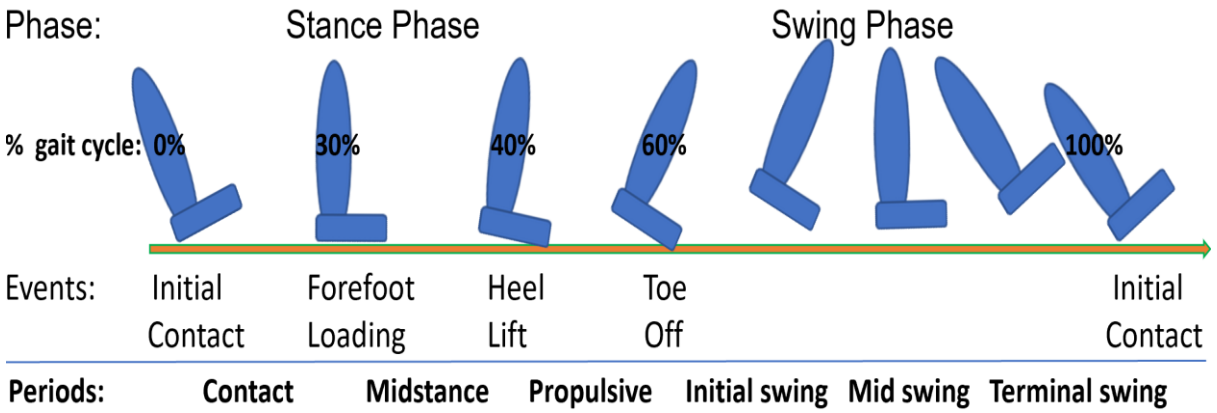
Figure 2.1. Doctoral thesis overview demonstrating Chapter 2 within the context of the programme of work



2.2 Gait analysis

Gait may be defined as the manner or style of walking (Perry, 1992; Levine, Richards and Whittle, 2012b). It consists of a cycle of repetitive stance and swing phase events which are subdivided in relation to the floor contact positions and timing (Figure 2.2, Chapter 2, page 14).

Figure 2.2. A diagrammatic example of the gait cycle, adapted from Neumann (2017) and Perry and Burnfield (2010b)



Prior to introducing the background of GA in relation to the assessment and treatment of injury, it is beneficial to define and review some of the common terminology surrounding the subject.

GA has been defined as the procedures involved in the assessment of gait disturbances to aid in the diagnosis, treatment and monitoring of diseases or disorders (Whittle, 1996; Levine, Richards and Whittle, 2012b; Baker *et al.*, 2016).

Clinical gait analysis (CGA) has been defined as the process of recording and interpreting biomechanical measurements of walking using computerised or video instrumentation to support clinical decision-making (Whittle, 1996; Baker *et al.*, 2016).

The definition offered for CGA may be misleading to the clinician working in a therapeutic setting. CGA could be interpreted to mean GA ‘pertaining to a clinic’. However, the word ‘clinical’ has several meanings, including (Collins, 2006; Waite, 2012):

• Relating to the observation and treatment of actual patients rather than theoretical or laboratory studies.

or

• Objective and efficient; coolly analytical and devoid of emotion.

Whittle (1996) was the first to offer a definition of CGA, stating CGA consists of video / recorded examination, measurement of gait parameters, kinematic analysis, kinetic measurement and electromyography. As a biomechanist specialising in gait, it may therefore not be surprising that his use of the word ‘clinical’ would represent ‘objective and efficient; coolly analytical and devoid of emotion’, rather than solely ‘relating to the observation and treatment of actual patients’.

Most clinicians working in MSK clinics are generally assumed to have limited access to the instrumentation and time requirements required for this definition of CGA (Coutts, 1999; Toro, Nester and Farren, 2003; Narayanan, 2007; Baker and Hart, 2013).The term CGA therefore does not reflect the assessment undertaken in the majority of MSK clinics or centres, but as highlighted soon after Whittle’s (1996) definition, is more associated with assessments conducted in specialised gait laboratories (Davis, 1997; Coutts, 1999).

The main factor determining GA to become CGA is not the presence of the clinical situation (the assessment of a patient), but instead the utilisation of analysis and playback instrumentation and technology. Previously GA conducted without the use of instrumentation or technology has been classed as “visual” or “observational” GA, but this definition has been muddied by authors using or suggesting the use of video recording as observational or visual GA (Brunnekreef *et al.*, 2005; Levine, Richards and Whittle, 2012b; Adams and Cerny, 2018).

There is therefore a need to differentiate between GA conducted without the use of CGA technology and that which is conducted with it. For this doctoral thesis programme of work the following refinement of terminology will be used, and the argument for these definitions was published by the thesis author in 2018 (Harradine, Gates and Bowen, 2018b) (Section 4.4.2, Chapter 4, page 52)

- Clinical Gait Analysis (CGA). Includes all GA conducted or evaluated using computerised or video recording and equipment. Examples include foot pressure analysis and video analysis.

- Real Time Clinical Gait Analysis (RTCGA). Pertains solely to GA visually assessed and concluded upon without computerised or recorded aid.

2.3 Walking

"Walking is a man's best medicine" – Hippocrates. 460 BC - 370 BC

Walking is an important component to healthy living and undertaken in varying amounts throughout the world. In a study utilizing smart phone step count technology across 111 countries, Althoff *et al.* (2017) reported average free-adult daily walking steps ranged from 3,500 in Indonesia to just under 7,000 steps in Hong Kong. The average daily steps across all 111 countries was 4961, with the United Kingdom (UK) above this average at 5,444 steps a day.

Within the UK and the United States (US), walking is the most common form of physical activity (NICE, 2012; CDC, 2013; Campbell *et al.*, 2018; Irvine *et al.*, 2020). Being unable to walk decreases a person's ability to be physically active, as well as limiting their walking transport capability for travelling to work or performing errands (Law, 1999; Pollard and Wagnild, 2017). Han *et al.* (2021), citing 14 papers from the US, UK, Europe, Australia and Iran, state an inability to perform walking activity to be linked to social isolation, psychological distress, an increased risk of chronic diseases such as diabetes and heart disease, and higher levels of cognitive impairment in older adults. Conversely, physical activity, such as walking, has been stated to reduce all-cause mortality and delivers important

prevention and treatment benefits for many different physical and psychological conditions (Bull *et al.*, 2020; WHO, 2020)

With the established health benefits of walking, healthcare initiatives have been undertaken to increase walking activity both in the UK and abroad (Varney, Brannan and Aaltonen, 2014; Adams *et al.*, 2017; Salbach *et al.*, 2019; Freak-Poli *et al.*, 2020; Irvine *et al.*, 2020). Within the UK, walking has been targeted as a chosen activity to improve the nation's health due to its accessibility and acceptability (Brannan *et al.*, 2017; Johnson, 2020). Brannan *et al*. (2017) cite the example that if 1 in 10 of the 7 million people aged 40-60 years in lower socioeconomic groups would perform 10 minutes of walking per day, it would prevent 251 yearly deaths and achieve an economic saving of £310 million per year.

2.4 Foot problems and walking

Although the benefits of walking are well established, the ability to walk can be restricted due to environmental, physical or psychological issues (Thomas *et al.*, 2011; Hunter, Ball and Sarmiento, 2018; Ward *et al.*, 2018; Salbach *et al.*, 2019; Alshehri *et al.*, 2021). Foot pain is a common example of such a physical issue, with a general population prevalence in the UK, USA, Europe and Australia ranging from 13 to 36% (Garrow, Silman and Macfarlane, 2004; Hill *et al.*, 2008; Mølgaard, Lundbye-Christensen and Simonsen, 2010; Thomas *et al.*, 2011; Gill *et al.*, 2016; Wranker, Rennemark and Berglund, 2016; Finney *et al.*, 2017; Gates *et al.*, 2019; Keenan *et al.*, 2019).

Foot pain is associated with impaired foot function, reduced health-related quality-of-life and disability (Katsambas *et al.*, 2005; Peat *et al.*, 2006; Hill *et al.*, 2008; Mickle, Munro and Steele, 2011). It has been specifically related to the reduced ability to walk. A UK based study of 16,222 adults over 55 years old found that the presence of foot pain increased the risk of having difficulty to walk by 2-fold (Keenan *et al.*, 2019). It was concluded that not only are foot problems in the over 55 age group extremely prevalent, but they also have a considerable impact on functional abilities such as walking. Although foot pain is recognised as being more common in older people (Dunn *et al.*, 2004; Thomas *et al.*, 2011; Gates *et*

al., 2019), it has also been shown to be highly prevalent among younger adults (Hill *et al.*, 2008).

Other lower limb joint pains also impair walking, and these joint pains are noted to occur individually or in combination (Keenan *et al.*, 2006; Finney *et al.*, 2017; Keenan *et al.*, 2019). Keenan *et al*. (2019) found that the only lower limb pain more common than foot pain was knee pain. Foot pain was present in 184.33 per 1000 study participants, while knee pain was present in 220.33 per 1000. More globally, knee pain has been found to affect approximately 25% of adults, the effect of which has been noted to limit mobility and impair quality of life (Nguyen *et al.*, 2011; Cui *et al.*, 2020). Keenan *et al.* (2019) report if both knee and foot pain are present, the most common of the multiple site pain presentations they observed, there is a 14-fold increase in the risk of walking difficulty.

Other foot conditions may also limit walking. Much of the GA literature relating to RTCGA exists relative to the assessment of paediatric gait problems, such as cerebral palsy. The gait of children with or without neurological disorders differs from adults and is often assessed in more specialised paediatric clinics (Van Hamme et al., 2015; Gor-García-Fogeda et al., 2016; Guffey et al., 2016). The assessment of paediatric gait is therefore omitted from the PhD thesis investigations. In addition, in the adult population neurological disorders may also limit walking, and observational GA (RTCGA) scales and measures have been developed for these specific disorders (Ridao-Fernández, Pinero-Pinto and Chamorro-Moriana, 2019). Again, these patients would present with specific gait problems differing from those in adult MSK clinics and are most often assessed in specialised neurology clinics. These patient groups are therefore also omitted from the PhD thesis investigations. The PhD thesis focus is the assessment of adult MSK lower limb symptoms without neurological conditions.

People with lower limb MSK pain may seek, or be referred for, consultation with professions such as podiatry, who assess and treat injuries related to the foot, gait and the lower limb. Adequate foot function is essential for healthy walking (Harradine and Bevan, 2009; Kuo and Donelan, 2010; Perry and Burnfield, 2010b), meaning podiatrists' opinions are often sought for minimising pain related to walking. MSK foot pain has been noted as being one of the primary reasons for

the utilisation of podiatry services in the UK (Hendry *et al.*, 2019). RTCGA is one of the most widely used clinical assessments available in MSK lower limb clinics (Payne and Bird, 2012). It has been called a fundamental skill for podiatrists (Southerland, 1996) and is a core subject in the UK podiatric medicine curriculum for undergraduate podiatry students (The College of Podiatry, 2016). A Royal College of Podiatry MSK lead has recently stated, in relation to establishing a MSK skill development framework that (italics added for emphasis) “Podiatrists already understand anatomy, *pathological gait*, clinical testing, and many of the other aptitudes that are the essential foundation to developing their MSK capabilities further.” (Cowley, Branthwaite and Halstead-Rastrick, 2021). Podiatrists have been using in-shoe appliances such as insoles and footwear modifications employing various theories and therapies to assess and treat gait-related symptoms since the profession began in the 18th century (Lee, 2001). For these reasons, much of the emphasis of this thesis will be upon podiatry as a profession, although an interdisciplinary approach is taken to all available research and literature upon the subject of GA.

2.5 Podiatry and GA: A historical perspective

In recent history (since the 1970s) 3 theories have become established in the podiatric literature in relation to treating gait-related lower-quadrant symptoms; the subtalar joint neutral (STJN) theory, tissue stress (TS) theory and sagittal plane facilitation (SPF) theory make up the most accepted approaches to the foot in relation to gait and gait dysfunction (Payne, 1998; Harradine and Bevan, 2009; Harradine, Gates and Bowen, 2018a).

Of these available approaches, STJN theory is the one most commonly used by podiatrists in daily practice, education and orthosis treatment (Landorf, Keenan and Rushworth, 2001; Harradine and Bevan, 2009; Jarvis *et al.*, 2017; Menz *et al.*, 2017). The main pioneer of this theory was Dr Merton Root (Lee, 2001), and it has been labelled “The Foot Morphology Theory”, “The Subtalar Joint Neutral Theory” or simply “Rootian Theory” / “Root Model” (Harradine, Bevan and Carter, 2006; Hawke *et al.*, 2008; Harradine and Bevan, 2009; Jarvis *et al.*, 2017; Harradine, Gates and Bowen, 2018a). Throughout the late 1950s and early 1960s Dr Root reported conducting hundreds of ‘biomechanical assessments’ and began

to understand the importance of the subtalar joint (STJ) from which he defined its 'neutral' position. From here, he created a classification of foot morphology, e.g., forefoot valgus, and linked this to foot function in gait (Root, Orien and Weed, 1971;1977; Root, 1981).

The main premise of STJN theory is that foot shape and position – when non-weightbearing or in standing – will predict motion and function of the foot and lower limb in gait (Harradine and Bevan, 2009; Jarvis *et al.*, 2017). No method of assessment for this dynamic normal or abnormal foot function is supplied by the STJN theory authors, and it is unclear if GA is even recommended as part of a STJN theory patient assessment. Rather, the underpinning principle of static measurement predicting dynamic function is used to provide a treatment rationale (Anthony, 1990; Michaud, 1993). These core concepts of the STJN theory have been challenged due to issues with poor assessment method reliability (Menz, 1995; Harradine and Bevan, 2009; Jarvis *et al.*, 2012; Harradine, Gates and Bowen, 2018a) and limited external validity (Jarvis *et al.*, 2017). STJN theory does provide a definition of normal gait, stating the foot passes through a STJN position at certain times of the gait cycle. CGA laboratory research has shown the validity of this claim to be poor, with the STJ of pain free young adults never passing through STJN in the stance phase of gait (McPoil and Cornwall, 1994; Pierrynowski and Smith, 1996).

The most popular alternatives to STJN theory are the TS theory and SPF theory (Payne, 1998; Harradine and Bevan, 2009; Harradine, Gates and Bowen, 2018a), and variances in definitions of normal and abnormal between all 3 theories have been noted and compared in the literature previously by the thesis author (Harradine, Bevan and Carter, 2003a; Harradine and Bevan, 2009). These are summarised in Table 2.1 (page 21).

Table 2.1 – Theoretical differences between current foot function theories (Harradine and Bevan, 2009).

	STJN Theory	SPF Theory	TS Theory
Criteria for Normalcy	The STJ passes through neutral at key stages of the gait cycle	The foot functions as a pivot, allowing adequate hip extension and a correct posture	The foot functions in a way that does not result in abnormal tissue stress and injury

Although there are fundamental differences to each theory relating to patient's assessment in relation to theoretical normalcy (Harradine and Bevan, 2009), all 3 have a commonality: none advocate or specifically detail the use of GA. One paper relating to the use of CGA is available for SPF theory (Dananberg and Guiliano, 1999). This paper does not describe or explain the methods or procedures of use of CGA equipment, only that it was used to aid in foot orthosis prescription. The primary clinical assessment for SPF theory remains static testing, using non-weightbearing tests for a functional hallux limitus or ankle equinus to predict changes to gait (Dananberg, 1986;1993;1999). To date, research upon static measures have been shown to demonstrate mostly weak or no correlation to foot kinematics in gait, including 1st metatarsophalangeal joint and ankle joint range of motion (Halstead and Redmond, 2006; Buldt *et al.*, 2015; Paterson *et al.*, 2015; Jarvis *et al.*, 2017; Behling and Nigg, 2020).

GA is thought to aid diagnosis, determine treatment goals, and to evaluate treatment outcomes (Rose, 1983; Coutts, 1999; Brunnekreef *et al.*, 2005; Levine, Richards and Whittle, 2012b; Baker *et al.*, 2016). It seems surprising that many clinicians rely on STJN, TS or SPF theories, which not only lack guidance upon GA but are also flawed by relying on specific poorly reliable and possibly invalid static foot assessments to predict how a patient will walk.

The critical issues with poor reliability and validity have led to conjecture surrounding the reasons for ongoing use and popularity of STJN theory, and these speculations were addressed as the first publication undertaken during this

doctoral programme of work (Harradine, Gates and Bowen, 2018a). This paper explored the continued use of established foot assessment theory in the face of overpowering critical research. The conclusion and feedback from this publication reinforced the argument that an approach more valid to GA than a kinematic prediction from static assessment would be beneficial for patient care. This paper is included in the following section, section 2.6.

Section 2.6. If it doesn't work, why do we still do it?

2.6.1 Introduction

The most effective method to asses foot function and create custom foot orthoses has been questioned and, whilst disagreements exist (Hawke *et al.*, 2008; Harradine and Bevan, 2009; Williams *et al.*, 2016), available literature continues to point to Dr Root's theory as being the most prevalently utilized (Landorf, Keenan and Rushworth, 2001; Menz *et al.*, 2017). Concurrently the worth of Dr Root's STJN theory has been challenged due to issues with poor reliability (Menz, 1995; Landorf, Keenan and Rushworth, 2001; Harradine and Bevan, 2009; Jarvis *et al.*, 2012), and more recently, limited external validity (Jarvis *et al.*, 2017). Inaccuracies in the interpretation and application of Dr Root's theories have also been proposed (Lee, 2001). This critical research spans decades and it begs the question as to why clinicians that evaluate and treat lower limb conditions still continue to utilise such a controversial approach.

This section briefly but critically reviews the main clinical areas of the STJN theory and concludes with a possible explanation and concerns for its ongoing use. To support this view, the following will be discussed: 1) historical inaccuracies, 2) challenges with reliability and 3) concerns with validity.

2.6.2 Historical inaccuracies

Placing the foot into STJN is used in several underpinning areas of the STJN theory. These include assessment of the non-weightbearing rearfoot to leg angle, measurement of forefoot to rearfoot position and the position in which casts for foot orthoses prescription are taken (Root, Orien and Weed, 1971;1977; Root, 1981; Lee, 2001).

The process by which Dr Root's method of foot assessment is researched and utilised is worthy of historical scrutiny. In a historical review of Dr Root's work by Lee (Lee, 2001) it becomes apparent that the main method employed to find STJN in the literature is not the one initially proposed by Dr Root and his co-workers. All research which has continually criticised reliability and more recently the validity of the STJN theory appear to find STJN by palpating the head of the talus and moving the STJ until articular margin congruency with the navicular is determined. This method was not proposed by Dr Root, but rather Wernick and Langer in 1971 (Wernick and Langer, 1971). Dr Root never endorsed this method (Lee, 2001). Instead, Dr Root proposed that:

Open Kinetic Chain (OKC) STJN Position

- A dell of the arc of motion of the STJ is notable when moving from the pronated to a supinated position. The position of this dell is STJN (Lee, 2001).
- Using bisection lines and calculating the total STJ range of motion. From there a 2:1 (inversion:eversion) ratio is applied. Moving the Calcaneum 2/3 from its maximally inverted position would detect the STJN. This method was published in 1971 (Root, Orien and Weed, 1971).
- If performed correctly, Dr Root proposed that both the procedures noted above would find the same position of STJN (Lee, 2001).

The OKC dell of motion position of STJN does not appear to have been formally published prior to Lee (Lee, 2001), and the reference for this work is quoted as "ML Root, personal communications, 1999". This assessment is stated to have been presented in seminars and graduate lectures through the 1950s and 60s (Lee, 2001). However, the lack of formal documentation or publication may explain the dearth of research and apparent use of this examination technique.

Closed Kinetic Chain (CKC) STJN Position

Pronate and supinate the foot in bipedal stance until (Root, Orien and Weed, 1971):

- There is palpable congruency of the STJ
- Visual concavity of the lateral surface of the foot to the leg is apparent
- A straight line is visible in the area of the calcaneocuboid joint
- When these 3 observations were noted, STJN was achieved in stance and the rearfoot to ground angle recorded.

Why the CKC methodology is discarded in lieu of the talar margin palpation method proposed by Wernick and Langer (Wernick and Langer, 1971) appears less clear. The use of palpation of the talonavicular joint (in OKC and CKC) to determine STJ congruency (and so STJN) is anatomically a different position to that proposed by Dr Root and his co-workers.

Applying the STJN theory to foot orthoses prescription demonstrates further possible historical inaccuracies. Dr Root may have been developing foot orthoses in his clinical practice (Root, 1981) but no descriptive text on custom orthoses prescription or manufacture was ever made available. Authors have cited Dr Root in their own texts and literature on foot orthoses prescription, often using terminology such as Rootian or Modified Rootian foot orthoses (Anthony, 1990; Michaud, 1993). It may be unwise to assume that Dr Root would agree with the interpretation of his work. Dr Root and his co-workers gave us a theory, in a time without 3D video GA and computerised plantar pressure examination, by which they believed we could ideally detect ‘normal’ and ‘abnormal’ foot function. They did not follow this up with any literature relating to the application of this theory to orthoses prescription.

2.6.3 Challenges with reliability

All available research on the reliability of STJN measurements have been found to be mostly moderate (Intra-tester) to poor (inter-tester) (Picciano, Rowlands and Worrell, 1993; Menz, 1995; Harradine and Bevan, 2009; Jarvis *et al.*, 2012), including joint positions and recommended bisection line placement on the leg

and foot. With regards to orthoses, the most common interpretation of the STJN theory requires a cast or impression of the foot to be taken in a non-weightbearing STJN (Root, 1981; Anthony, 1990; Michaud, 1993; Lee, 2001), resulting in a 'neutral negative cast' of the foot. The shape of the neutral cast is of upmost importance, as it is essential to capture the correct forefoot-to-rearfoot alignment. Without beginning to introduce issues with orthosis manufacture and casting reliability, the problems with STJN position reliability immediately seem to undermine this method.

2.6.4 Concerns with validity

A recent article (Jarvis *et al.*, 2017) has soundly questioned the validity of the foot morphology observations in Dr Root's STJN theory relating to gait. In this only paper of its kind, none of the static examinations advocated in Dr Root's STJN theory related to altered foot kinematics. Areas investigated included the STJN position and also the first ray position and forefoot to rearfoot angle. This is of prime importance when attempting to relate the STJN position to foot orthoses impression casting and prescription. Jarvis *et al.* (2017) concluded that both the poor reliability and validity of these underpinning STJN theory cornerstones mean "the Root *et al*. description of foot function and the associated assessment protocol are not a sound basis for clinical evaluation of the foot nor orthotic prescription."

2.6.5 If it doesn't work, why is it still done?

In the light of this uncertainty into the reliability, validity and historical accuracy of the STJN theory, it is appropriate to propose that its use in MSK lower limb clinics should be re-evaluated. However, despite the issues noted above, the outcome of the use of foot orthoses based broadly upon this theory appears positive (Hawke *et al.*, 2008). The most recent Cochrane Library review on the efficacy of custom foot orthoses (Hawke *et al.*, 2008) concluded there is a gold level of evidence for painful pes cavus and a silver level of evidence for foot pain in plantar fasciitis, rheumatoid arthritis and hallux valgus. Seven of the included 11 articles stated STJN as the position from which negative cast impressions were taken. It appears the STJN theory has become an accepted 'clinical fiction', an approach

where although clinicians are not measuring or assessing what they propose, and the theory may not describe reality, the net outcome is positive (Payne, 2000). In other words, the process which leads to treatment may work, but not in a way that the critical issues and theoretical failings actually matter.

It is possible the explanation of the continued use of the STJN theory is that alternative foot based theories also lack large population investigations to assess their clinical relevance, and also suffer from observer reliability and theoretical validity concerns (Harradine, Bevan and Carter, 2003b; Harradine and Bevan, 2009). Why should clinicians change their approach if there is no proven theory with a workable clinical assessment and treatment methodology to adopt? Kuhn (1970) proposed that the rejection of one accepted theory (or 'paradigm') will only occur when a critical mass of anomalies have arisen, and when a rival paradigm with greater problem solving capabilities has appeared. Using this model, the lack of rejection of the STJN theory may be due to the accepted anomalies not yet reaching a critical level, the lack of adequate rival theories, or both.

It has been suggested that different fields of science have different processes by which they progress and develop (Godfrey-Smith, 2021). Lakatos (1970) and Laudan (1978) both describe a different hypothetical method by which a field can progress and accept new theories without the total rejection of previous concepts or models. Instead, scientists working within a field may have access to numerous competing theories, a situation that was specifically excluded by Kuhn (1970). Some of these theories may be very general with elements budding off and joining emerging or existing theories, without the need for a fundamental change of core beliefs (Godfrey-Smith, 2021). It may even be beneficial to continue working with a theory even though the field no longer truly believes in its fundamental core values (Laudan, 1978). This approach has already been suggested to be more relevant to podiatric biomechanics than that proposed by Kuhn (Mathieson, 2001).

However, it is important to recognise the anomalies in Dr Root's STJN theory, as the acceptance of the fiction as fact results in practitioner resistance to change and an inability to look outside of established theory. Kuhn (1970), Lakatos (1970) and Laudan (1978) supply a range of philosophical processes within science by which a field can progress, but none recommend ignoring the results of scientific

exploration. Such a situation could lead to stagnation and slow development of possibly more effective alternative ideas. With ongoing theoretical uncertainty in relation to the foot and MSK injuries, it may benefit the practitioner to be inclusive of all theories within the framework of best evidence rather than dogmatic or exclusive to historical fictional models.

2.7 Podiatry and GA: where are we now?

Although STJN, TS and SPF theories do not supply specific or detailed recommendations for performing RTCGA or CGA, they do not actually exclude it. To suggest RTCGA or CGA is not conducted by podiatrists who use static tests from STJN, TS or SPF theory directly conflicts with the clinical experience of the thesis author. During the authors employment as a clinical lead NHS MSK specialist chairing a county-wide MSK podiatry interest group between 1998 and 2004, RTCGA rather than CGA was often discussed. RTCGA was conducted in all clinics and for most patients. In addition, post graduate GA lecturing conducted by the thesis author from 1995 to present has included conversing with colleagues and peers regarding their approach to GA. Again, RTCGA is continually stated to be commonly undertaken when assessing non-neurological lower limb MSK injury.

Although the experience of the thesis author alone may not be a fair representation of the global use of RTCGA, it does concur with the frequent recommended use of RTCGA in the literature. RTCGA has been cited to be one of the most widely-used clinical assessments available to podiatrists (Payne and Bird, 2012) and should be a fundamental skill for podiatrists (Southerland, 1996), as well as being the most versatile method of assessing gait (Levine, Richards and Whittle, 2012b). In a 4-round multidisciplinary delphi study aimed to identify a core set of objective MSK foot and ankle assessment measures, GA was recommended for both clinical and research-based applications (Gates, Bowen and Arden, 2015). Almost two-thirds of the expert steering committee (11 of the 17 participants) were from the podiatry profession. This high percentage of steering committee podiatrists supports the perceived value of podiatry expertise in this field, and also results in greater podiatric input and podiatry relevance in the creation of such measures.

Therefore, it appears although STJN, TS or SPF are being employed for static analysis, RTCGA is also being used as an adjunct to the assessment to aid in MSK patient diagnosis and treatment. Stating the use of theories such as the STJN theory by MSK podiatrists does not mean GA is not being conducted. However, the actual prevalence, methods, and reasons of use of GA among MSK podiatrists is not known.

2.8 Conclusion

Walking is an important physical activity for health and wellbeing, with global initiatives being undertaken to increase the general populations regular walking. However, lower limb pain, and specifically foot pain, has a high prevalence in the adult general population and is a limiting factor to walking ability.

Due to the high prevalence of foot pain, and the foot being an important part of walking, podiatrists are often consulted in relation to gait related lower limb MSK pain. The most common theories used by podiatrists relating to foot pain and function do not appear to include any detailed instruction or recommendation relating to GA, in contrast to the frequent recommendation for GA to be included as part of the assessment of lower limb MSK injury. It is proposed that these foot function theories, which place emphasis on static measures as an indication of gait, do not actually exclude the use of GA. GA is likely being used as an adjunct to the assessment to aid in MSK patient diagnosis and treatment. Further review and analysis of GA is required to investigate its use, worth and role as part of a MSK assessment of lower limb injuries.

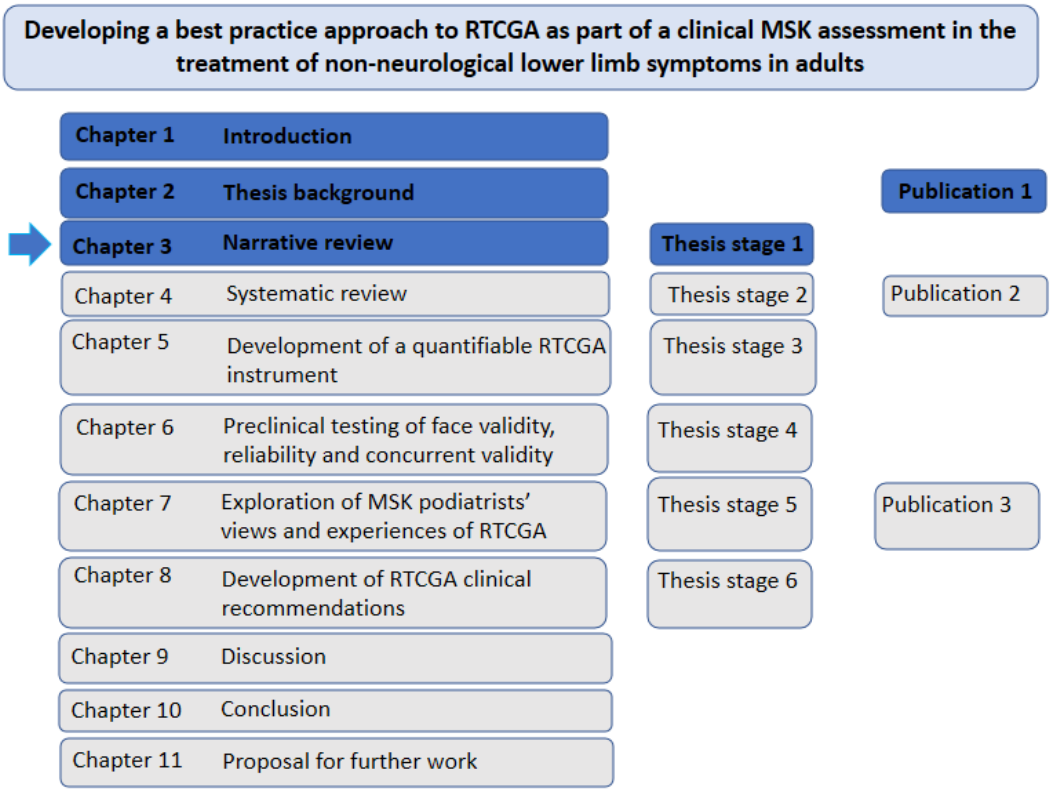
Chapter 3 Narrative Review

3.1 Introduction

Narrative reviews supply a summary and critique of a body of literature and then draw conclusions about the topic in question (MacLure, 2005; Boland, Cherry and Dickson, 2014). The primary purpose of this type of review is to provide a background of understanding of current knowledge and highlighting areas which require further work (Cronin, Ryan and Coughlan, 2008).

A narrative review of GA literature was undertaken as the initial part of this programme of work. The completion of a patient and public involvement and engagement (PPIE) exercise was also conducted to 'sense check' that findings from the narrative literature review were representative and compatible with opinions from podiatric MSK practice. Figure 3.1 demonstrates Chapter 3 within an overview of the doctoral thesis.

Figure 3.1. Doctoral thesis overview demonstrating Chapter 3 within the context of the programme of work



3.2 Pre-narrative review thesis aim and question

- Research Aim

To establish a best practice approach for GA to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults.

- Research Question

Is it possible to develop a best practice GA approach to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults.

- Research Hypothesis

It is possible to develop a best practice GA approach to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults.

3.3 Narrative review methodology

Narrative reviews have no standardised methodology consensus (Boland, Cherry and Dickson, 2014; Ferrari, 2015). Instead, a generalised framework has been proposed and followed for this programme of work (Green, Johnson and Adams, 2006; Ferrari, 2015). This framework includes a literature search detailing databases, keywords and inclusion / exclusion criteria, the recognition of key concepts with discussion in relation to the research question, and a conclusion related to the research design.

3.4 Literature Search

The literature search was conducted to identify references for GA in a sample with lower limb MSK injury. The data search was conducted on in November 2015 by one reviewer (PH). Databases included were the DelphiS, AMED, CINAHL and MEDLINE. The Boolean operator ‘AND’ was used to combine terms and the Boolean operator ‘OR’ was used to link synonyms. The Boolean operator ‘NOT’ was employed to exclude key terms. Keywords were gait, musculoskeletal,

walking, foot, ankle, knee, hip, analysis, assessment, examination and observation. Exclusion criteria were that of animal studies and the GA of running or backward walking.

If other than English language papers were found, translation would have been considered.

3.5 Results

Results of the narrative review are presented as 3 key concepts (sections 3.5.1 to 3.5.3).

3.5.1 Key Concept 1. GA, RTCGA and CGA

GA has been defined as the procedures involved in the assessment of gait disturbances to aid in the diagnosis, therapeutic intervention and monitoring of diseases or disorders (Whittle, 1996; Levine, Richards and Whittle, 2012b; Baker et al., 2016). Levine, Richards and Whittle (2012a) describe GA methods as being on a continuum, ranging from that conducted “in the absence of technological aids” (RTCGA) at one extreme to GA conducted with the use of “complicated” and “expensive equipment” (CGA) at the other.

The principal domains of GA focus on the kinematics (the description of movement without concern for underpinning forces) and kinetics (the study of forces and their effect on motion) (Perry and Burnfield, 2010a; Baker and Hart, 2013; Adams and Cerny, 2018). A variety of technological aids are available to aid in the CGA of kinematic and kinetic assessment. For kinematic analysis these include 2D and 3D camera-based systems (with or without active marker tracking), electrogoniometers and accelerometers. For kinetic analysis these include force platforms, pressure mats, force sensor systems and in-shoe devices. (Coutts, 1999; Perry and Burnfield, 2010a; Levine, Richards and Whittle, 2012a; Payne and Bird, 2012). By contrast, RTCGA is limited to kinematic assessment only. It is not possible to measure force, and so kinetics, without technological aid (Baker, 2007; Baker *et al.*, 2016; Adams and Cerny, 2018).

CGA is generally thought to be more clinically efficacious for patient care than RTCGA with the ability of CGA to quantifiably document observations with reliable instrumentation being the recurrent theme for this assumption (Perry, 1992; Coutts, 1999; Adams and Cerny, 2018). This proposed benefit of CGA is yet to be proven for non-neurological lower limb adult MSK injury. In a systematic review performed by Wren *et al*. (2011) and updated in 2020 (Wren *et al.*, 2020), it was concluded that a "small number of studies" (9 in total) clearly demonstrate the efficacy of CGA in relation to changing and reinforcing therapeutic intervention decisions, as well as the potential to improve patient outcomes and increase clinician confidence. None of these papers were concerned with adult MSK lower limb injuries, but rather neurological, paediatric or amputee samples. Findings should therefore not be translated to MSK patient populations. These findings align with those of an earlier review study by Baker *et al.* (2016), who concluded that the principal clinical domains for CGA should link to those for which research on its use is available: cerebral palsy, stroke, traumatic brain injury and lower limb amputation.

Toro, Nester and Farren (2003) investigated the status of NHS physiotherapy GA of children and adults within the UK via a questionnaire. Their findings showed that although RTCGA made up a major aspect of physiotherapy outpatients practice, there was no systematic use of a standardised GA instrument or recognised approach or protocol. Participants felt that a future standardised approach or guideline would be helpful, but only if it fitted into their current clinical restrictions, such as appointment durations. The addition of CGA technology was not seen as important. Although CGA technology has been available since before the date of this publication, the paper is nearly 20 years old. Since 2003 there has been a rapid development in video recording and playback mediums, such as those available on smart phones, tablets and laptops. This increased use of, and access to, technology may mean these results from 2003, in relation to technology and CGA, may not be a fair representation on the attitudes of UK outpatient NHS physiotherapists today.

The frequency of CGA or RTCGA use is unknown. However, it is generally assumed most clinicians do not routinely have access to or conduct CGA. The

reasons for this have been suggested as insufficient supporting MSK evidence, but also due to the lack of access to technology, time, financial reimbursement and training (Krebs, Edelstein and Fishman, 1985; Coutts, 1999; Toro, Nester and Farren, 2003; Narayanan, 2007; Wren *et al*., 2011; Baker and Hart, 2013; Baker *et al*., 2016). Baker *et al.* (2016) note the core essential CGA instrumentation to consist of a 3D kinematic tracking system with multicomponent force platforms and dynamic electromyography. They also suggest a CGA appointment duration of 2 hours. It is difficult to imagine many podiatrists, or any other MSK clinicians, having access routinely to this level of equipment or time. Unlike CGA, RTCGA requires no technological or instrumentation aids, and can be conducted quickly and possibly within the duration and context of a routine MSK patient appointment.

RTCGA will therefore be the focus GA method for this thesis, due to the universal ease of performing RTCGA, the perceived higher use of RTCGA compared with CGA, and the podiatry specific recommendation for learning and performing RTCGA (see section 2.4, Chapter 2, pages 17-19).

3.5.2 Key concept 2. RTCGA as a diagnostic process

The overall aims of GA include the aiding of diagnoses, determining intervention, setting intervention goals and evaluating treatment outcomes (Rose, 1983; Coutts, 1999; Brunnekreef *et al.*, 2005; Levine, Richards and Whittle, 2012b). GA is therefore classed within the available literature as a diagnostic assessment method both in terms of aiding diagnosis and treatment of a disease or disorder and in recognising gait changes after interventions. These overall aims stand true for both CGA and RTCGA.

The timely and accurate use of a diagnostic method, with the smallest possibility of a missed diagnosis or misdiagnosis, is crucial in the treatment of any disease or disorder (Schiff *et al.*, 2009; Singh, 2014). As previously discussed, CGA is recommended only to be of use in the diagnosis and treatment of cerebral palsy, stroke, traumatic brain injury and lower limb amputation (Baker *et al.*, 2016; Wren *et al.*, 2020). These conditions are specific, with particular gait changes and treatment interventions identified for each disorder. The diseases and disorders

that RTCGA may be employed as a diagnostic procedure or method in an adult non-neurological MSK setting are yet unknown. However, the use of RTCGA as a diagnostic procedure to aid in the evaluation and treatment of MSK injuries has merit. For example, greater rearfoot eversion angles have been linked to PTTD and patellofemoral pain syndrome (Houck *et al.*, 2009; Barton *et al.*, 2012). RTCGA could be used to observe greater rearfoot eversion as part of establishment of the clinical diagnosis, aid in the choice of intervention to reduce rearfoot eversion, and then to evaluate if treatments to reduce the rearfoot eversion have been successful. RTCGA requires no expensive or complicated equipment, is relatively quick to perform compared to CGA, already has a perceived high incidence of use, and has podiatry specific recommendations in place for its education and undertaking.

Reliability and validity are concepts that have a positive connotation in relation to diagnostic measurements and observations. For any procedure to be characterised as reliable and valid is to be described in positive terms (Carmines and Zeller, 1979). A third psychometric property used to assess the usefulness of a functional gait measures in clinical decision making is responsiveness (Adams and Cerny, 2018).

Validity may be defined as the extent to which any measuring instrument or tool measures what it is intended to measure for the purpose for which it is being used, while reliability concerns the degree to which results are consistent across repeated measurements (Carmines and Zeller, 1979; Heale and Twycross, 2015). Responsiveness of GA measures may be expressed in terms of minimal clinically significant change, which represents the smallest change of score in an outcome measure that a patient would perceive as beneficial (Beninato, Fernandes and Plummer, 2014; Bohannon and Glenney, 2014; Adams and Cerny, 2018). No research in relation to the reliability, validity or responsiveness of adult non-neurological MSK RTCGA was forthcoming.

The need for outcome measures in MSK podiatry was reported by the thesis author in 2001 (Harradine and Jarrett, 2001), and there are several foot pain measures available to assess patient perceived outcomes (Muller and Roddy, 2009; van der Zwaard *et al*., 2014). However, specific kinematic outcome

measures in relation to therapeutic interventions, such as orthoses, are not available. Being able to observe and record functional gait outcomes using RTCGA would allow the appraisal of interventions, not only to ensure treatment has been effective but also decrease the possibility of doing harm.

3.5.3 Key concept 3. Developing a RTCGA best practice approach

A best practice approach in health care should be directive, evidence-based, and quality-focused (Nelson, 2014). It is the concept by which evidence is synthesised either as an evidence base or in the form of clinical recommendations and guidance for patient care (Perleth, Jakubowski and Busse, 2001). Currently, no adult non-neurological best practice approach for RTCGA was available. There is a practical challenge with making multiple real time kinematic observations during stance phases of short durations. Perry and Burnfield (2010a) note that RTCGA may be more suited to noting gross, rather than subtle, gait abnormality. However, they go on to state a systematic RTCGA approach may aid in the recognition of “highly significant” and “more subtle” deviations. A RTCGA best practice approach would include guidance and recommendations for clinical practice to help diagnose and manage gait related MSK injury. It would address the current evidence gap between the common literature-based recommendation to conduct RTCGA and the lack of knowledge and guidance relating to its use.

Development of a RTCGA best practice approach would aid in the diagnosis and treatment of gait related injury. In addition, it could create the potential for generation of new knowledge within this field in the advancement of clinical practice. It is essential that to move the field forward, research into the validity and reliability of RTCGA is performed within a framework of creating a method which will be able to be utilised in adult non-neurological lower limb MSK clinics.

3.6 Narrative review conclusion

RTCGA is more applicable to podiatrists’ lower limb MSK clinics than CGA.

An evidence gap exists, where RTCGA is commonly recommended as a beneficial MSK diagnostic and management approach, but actual methods and uses of it remain unknown.

By developing a RTCGA best practice approach, an instrument could be created to aid patient assessment, treatment and outcome assessment.

3.7 PPIE exercise

Although narrative reviews are valuable in relation to clarification and insight (Boell and Cecez-Kecmanovic, 2014), they risk possible exclusion of data due to the lack of systematic methodology and “cherry picking” (bias) to bolster a particular perspective or belief (Boland, Cherry and Dickson, 2014; Whitty, 2015; Greenhalgh, Thorne and Malterud, 2018). The completion of PPIE exercise with podiatrists was therefore conducted to ‘sense check’ that findings from the narrative literature review were representative and compatible with opinions from podiatric MSK practice. PPIE has been stated to be of benefit to research by providing additional viewpoints to that of researchers, and ensuring research is relevant and meets the needs of service users and those who supply care for them (Boaz, Biri and McKevitt, 2016; ReACH, 2021).

A pragmatic approach was taken to engage a homogenous sample of participants. Opportunistic sampling was used to recruit from delegates attending the Primary Care and Public Health Conference, Birmingham NEC, in May 2018. The Primary Care and Public Health Conference is stated to be the UK’s leading event for podiatrists and many other NHS and private clinicians working in primary and community care (HCPC, 2018; StirlingEventsLtd, 2022). A conference track relating to lower limb MSK took place upon the morning of May 16th, including lectures upon leg length difference assessment, metatarsalgia with plantar plate injury and assessment of the developing flat foot. I was asked to participate on this track, with a podium presentation on RTCGA. Due to the combination of a MSK lower limb orientated collection of podium presentations and the attendance of podiatrists, it was anticipated that MSK podiatrists with an interest in GA would be in attendance.

In total, nine MSK podiatrists verbally consented to participate in an engagement conversation and for information from the conversation to be used to inform future research. Conversations were conducted individually in a set-aside quiet but

public area within the conference venue. A semi-structured approach was undertaken, with the following 2 questions being asked:

> Question 1 - What literature would you suggest I review in relation to developing a best practice approach to RTCGA for adult non-neurological lower limb MSK injury?
>
> Question 2 - What information and guidance would you expect from guiding literature in relation to RTCGA for adults with non-neurological lower limb MSK injury?

Answers and opinions were written manually and autonomously at the time of the engagement exercise.

From the 9 MSK podiatrists who participated, 4 literature sources were identified which were suggested to be useful (Question 1). These are presented in alphabetical order below:

1. Levine D, Richards J, Whittle M. (2012) ‘Methods of gait analysis’, in Levine D, Richards J, Whittle M (ed.) *Whittle’s gait analysis*. 5th edn. Edinburgh: Churchill Livingstone, pp.83-112
2. Payne, C. and Bird, A. (2012) 'Methods of analysing gait’, in Yates, B. (ed.) *Merriman’s assessment of the lower limb.* 3rd edn. London: Churchill Livingstone, pp. 308-20
3. Perry, J. and Burnfield, J.M. (2010) ‘Gait analysis systems’, in Perry, J and Burnfield, J.M. (Ed.) *Gait analysis. Normal and pathological function.* 2nd edn. Thorofare NJ: Slack Inc. pp. 403-406
4. Southerland, C. (1996) 'Gait evaluation in clinical biomechanics', in Valmassey, R. (ed.) *Clinical biomechanics of the lower extremity*. St Louis: Mosby, pp. 149–179

All 4 of these suggested texts are educational opinions published as chapters within books. None claim to be clinical guidelines, and none contain any research or investigations conducted by the authors in relation to their chapters aims. It would therefore be inappropriate to appraise the worth of their content using

methods suited to evaluating these approaches, such as the Critical Appraisal Skills Programme (CASP) appraisal tool system (Nadelson and Nadelson, 2014; CASP, 2017) or the Appraisal of Guidelines for Research and Evaluation II (AGREE II) guideline appraisal tool (Brouwers *et al.*, 2010). Instead, as part of the PPIE, podiatrists were asked what they felt would be expected from informative texts relating to RTCGA (Question 2). This pragmatic approach provided 9 suggestions by which the 4 suggested chapters could be reviewed for information pertained as useful in the design of a RTCGA best practice approach. These are presented in no particular order:

1. Development strategies or evidence underpinning recommended RTCGA methods.
2. Reasons and opinions for performing RTCGA.
3. RTCGA observable measures.
4. An adequate description of RTCGA observable measures.
5. RTCGA method for observations.
6. RTCGA observation interpretation.
7. Reliability of RTCGA methods.
8. Validity of RTCGA methods.
9. Citations of the proposed RTCGA method (or method update with research).

No further information upon the frequency of each recommendation within the sample was recorded, and volunteers were not questioned in relation to the weighting or importance of each suggestion. However, these findings permit the appraisal of each of the recommended chapters via reviewing each of the texts in relation to presence of information and guidance expected from the interviewed MSK podiatrists.

Findings of the review of recommended texts using these 9 suggested guidance and information criteria are demonstrated in Table 3.1 (page 39). If information was missing, this is demonstrated as a cross. If information was available, this is presented with a tick and findings summarised.

Table 3.1: Findings from RTCGA literature suggested by MSK podiatrists

	Southerland (1995)	Perry and Burnfield (2010)	Levine *et al*. (2012)	Payne and Bird (2012)
1) Development strategies or evidence underpinning recommended RTCGA methods and use are described.	X	X	X	X
2) Reasons and opinions for performing RTCGA.	X	✓ RTCGA is used to aid in decision making regarding which CGA equipment to use.	X	✓ RTCGA Provides an overall impression of gait and can be used to aid patient care
3) RTCGA observable measures.	✓ Presented as the Gait Homunculus Observed Relation Tabular (GHORT)	✓ Presented as the Full Body Observational Gait Analysis Form	✓ Presented as a list of 17 observations	✓ Presented as list of 26 observations for 'practical observational gait analysis'
4) Description of observable measures.	✓ 11observations are described, although descriptions are vague in relation to anatomical markers	X	X	X

5)RTCGA method for observations	X	X	X	X
6) RTCGA observation interpretation	X	X	X	X
7) Reliability of RTCGA methods	X	X	X	X
8) Validity of RTCGA methods	X	X	X	X
9) Future citations of the proposed RTCGA method (or method update)	X	X	X	X

Although all recommended texts supply suggested forms or lists of observations to be included in RTCGA, they all lack development background, substantive instructions for use, any assessment of reliability or validity and guidance on how findings should be interpreted. No literature regarding further update, research or use of the 4 approaches was found. This is consistent with the narrative review, in which approaches or protocols for RTCGA were not evident (sections 3.5.1 and 3.5.2, pages 31-35). It appears the authors of these chapters have instead presented a clinical author opinion which, although offers some insights, is low level evidence (Burns, Rohrich and Chung, 2011). The benefit or knowledge these texts offer to either performing or understanding RTCGA, or the further development of a RTCGA best practice approach, is limited.

This PPIE was not undertaken to be exhaustive in obtaining knowledge relating RTCGA literature and guidance, but instead to ensure findings from the narrative literature review were not unrepresentative of MSK podiatrists views and experiences. This PPIE was small, with no demographic details noted. Although

conducted at a national conference, delegates may have been from a small geographical area. The level of MSK podiatrist experience was not recorded. These results may therefore not be representative of all UK based MSK podiatrists. However, this PPIE provided reassurance that literature relevant to the RTCGA process has been considered. In addition, by consulting MSK podiatrists' external to this doctoral thesis programme of work, the engagement exercise reduced the influence of early-stage researcher confirmation bias upon development of a RTCGA best practice approach.

3.8 Chapter conclusion

Insights gained from this chapter have exposed that the methods, reasons, and use of RTCGA as a diagnostic procedure in the assessment and treatment of MSK non-neurological lower limb injury appear relatively unknown.

When performing GA, RTCGA is suggested to be more applicable to podiatrists' lower limb MSK clinics than CGA. Whilst the focus of this thesis will be upon RTCGA, the population use of RTCGA or CGA is unknown.

An evidence gap exists, where RTCGA is commonly recommended as a beneficial MSK diagnostic and management approach, but actual methods and uses of it remain unknown. It was therefore anticipated that by developing a RTCGA best practice approach, an instrument could be created to aid patient assessment, treatment and outcomes.

3.9 Post-narrative review thesis aim and question

The evidence gap relating to RTCGA was concluded to be more clinically valid to address than CGA. The narrative review resulted in a refinement to the research question, with RTCGA being the focus GA method for this doctoral thesis programme of work.

- Research Aim

To establish a best practice approach for RTCGA to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults.

- Research Question

Is it possible to develop a best practice RTCGA approach to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults.

- Research Hypothesis

It is possible to develop a best practice RTCGA approach to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults.

3.10 How stage 1 informed stage 2

Streiner, Norman and Cairney (2015) note that "...instruments rarely spring up fully grown from the brows of their developers". Instead, they are usually based upon what others have previously deemed to be important, relevant or discriminating. Stage 1 refined the research question and by doing so permitted a refined scope for a systematic review relating to RTCGA. A systematic review for methods and procedures of RTCGA in adult MSK patients was therefore undertaken to supply a robust appreciation of available RTCGA knowledge (stage 2). It was anticipated that literature to aid in the development of a best practice approach to adult MSK RTCGA could be obtained.

Chapter 4 Systematic review

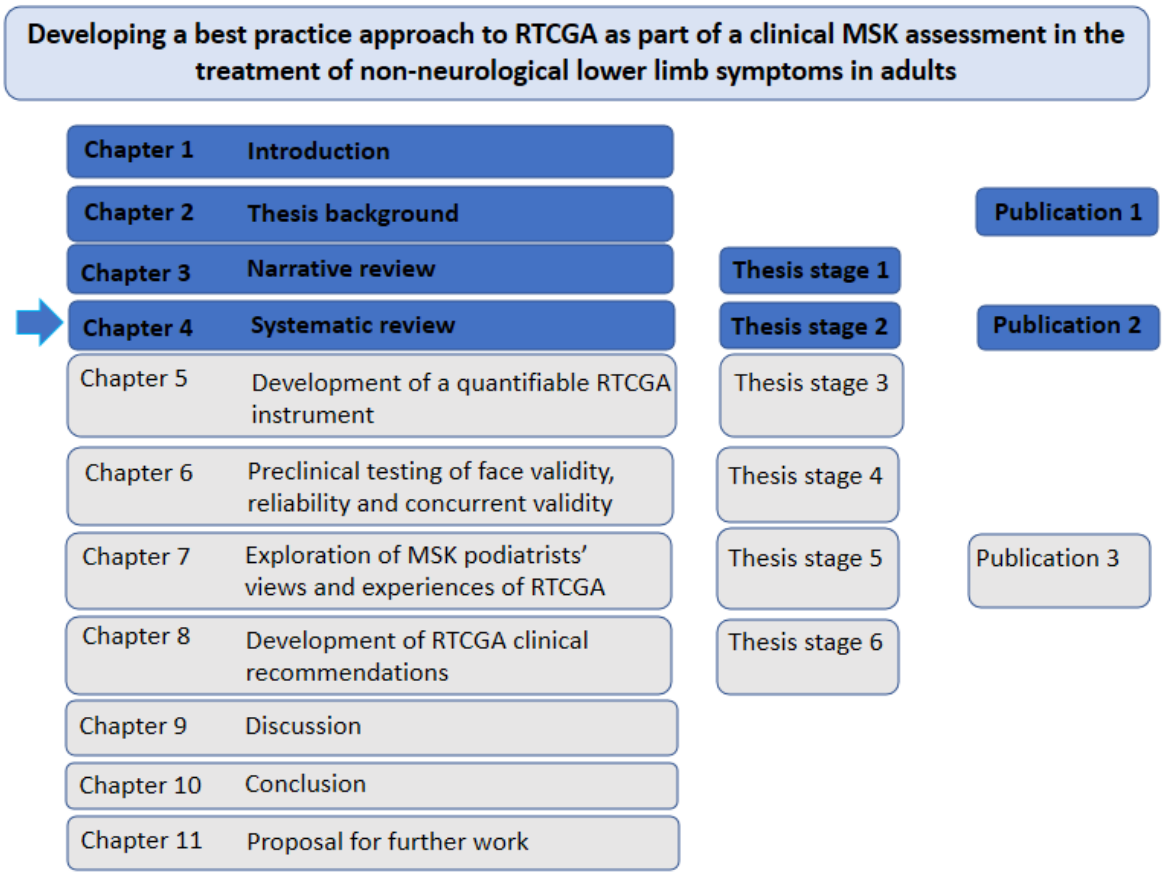
4.1 Introduction

Literature pertaining to RTCGA and adult non-neurological lower limb MSK injury was systematically reviewed. The aim of this systematic review was to evaluate and summarise the methods of RTCGA used in adult non-neurological MSK clinics treating the lower limb. It was hoped from these findings a protocol of best practice in a clinical setting could be established and also provide a foundation for further work and investigation if required.

This systematic review was published and makes up the second publication within this doctoral thesis programme of work (Harradine, Gates and Bowen, 2018b).

Figure 4.1 demonstrates Chapter 4 within an overview of the doctoral thesis.

Figure 4.1 – Doctoral thesis overview demonstrating Chapter 5 within the context of the programme of work



4.2 Methods

4.2.1 Search Strategy

Search criteria for the systematic review were identified using the Patient, Intervention, Comparison and Outcome (PICO) statement (Table 4.1)

Table 4.1. Description of the components of PICO in the systematic review (Harradine, Gates and Bowen, 2018b)

P	Adults with non-neurological lower limb MSK symptoms
I	Any kind of RTCGA of walking gait, used alone or in combination with other assessment methods, in the treatment of adult non-neurological lower limb symptoms
C	The comparison could be no GA, different forms of RTCGA, CGA or repeated measures of RTCGA
O	Reliability and validity of RTCGA, clinical efficacy of RTCGA in aiding the diagnosis and treatment of MSK injury in adult non-neurological lower limb injury.

The literature search was conducted to identify references for RTCGA in a symptomatic lower limb MSK adult sample with no neurological or amputation related injury or disorder. The data search was conducted on the 18th February 2017 by one reviewer (PH) and databases included were the DelphiS, AMED, CINAHL and MEDLINE. The Boolean operator ‘AND’ was used to combine terms and the Boolean operator ‘OR’ was used to link synonyms. The Boolean operator ‘NOT’ was employed to exclude key terms.

Overall search limitations were applied only to that of human participants. No historic date to results was set, as it was thought that older research (when technology was less readily available) may still hold valid results. If other than English language papers were found, translation would have been considered. Terms to exclude studies utilising computerised analysis or recording or playback equipment were not excluded at this stage. This is due to the possibility of such

technology being used to research the validity of RTCGA. This database search methodology is shown in Figure 4.2.

Figure 4.2 – Database search. Conducted 18th February 2017

1. Gait and walking
2. Analy* OR eval* OR assessment
3. 1 AND 2
4. Observation* OR visual OR live OR “Real Time”
5. 3 AND 4
6. 5 AND adult
7. 6 NOT child* NOT paediatr* NOT pediatr*
8. 7 NOT stroke NOT cerebr* NOT CVA
9. 8 NOT amput* NOT “muscular dystrophy” NOT sclerosis NOT “brain injury” NOT “spinal cord injury” NOT Alzheimer* NOT neuropath NOT neurological NOT parkinson*
10. “lower limb” OR “lower extremit*” OR foot OR ankle OR shin OR leg OR knee OR thigh OR hip
11. 9 AND 10
12. Musculoskeletal OR orthopaedic* OR orthopaedic* OR therap* OR physiotherap* OR podiatr* OR rehab* OR outpatient* OR doc*
13. 11 AND 12
14. Injur* OR pain* or symptom* or trauma*
15. 13 AND 14

Hand searches of bibliographic references identified additional publications. Grey literature refers to publications on any format not controlled by commercial publishers nor necessarily peer reviewed. Grey literature was included based on an initial search using the terms gait, walking and locomotion and rerun in conjunction with the terms analysis, assessment, or examination to ensure the search had captured all relevant sources.

4.2.2 Selection Criteria

Study inclusion and exclusion criteria used to determine articles included in this review are shown in Table 4.2.

Table 4.2 – Search inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Articles investigating visual un-instrumented walking GA as part of a clinical MSK assessment in the treatment of lower limb symptoms	Methods dependent on the use of computerised analysis or recording and playback equipment*
Adults	Assessments specific to amputation or neurological injury or disorder
	Paediatric patients

*****Studies using the above techniques are excluded unless used for validation of RTCGA

Potentially relevant articles were subject to abstract screening. The data extraction task was completed by hand. If deemed suitable, full text screening was then undertaken. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist criteria (Moher *et al.*, 2009) was used to extract data from identified literature.

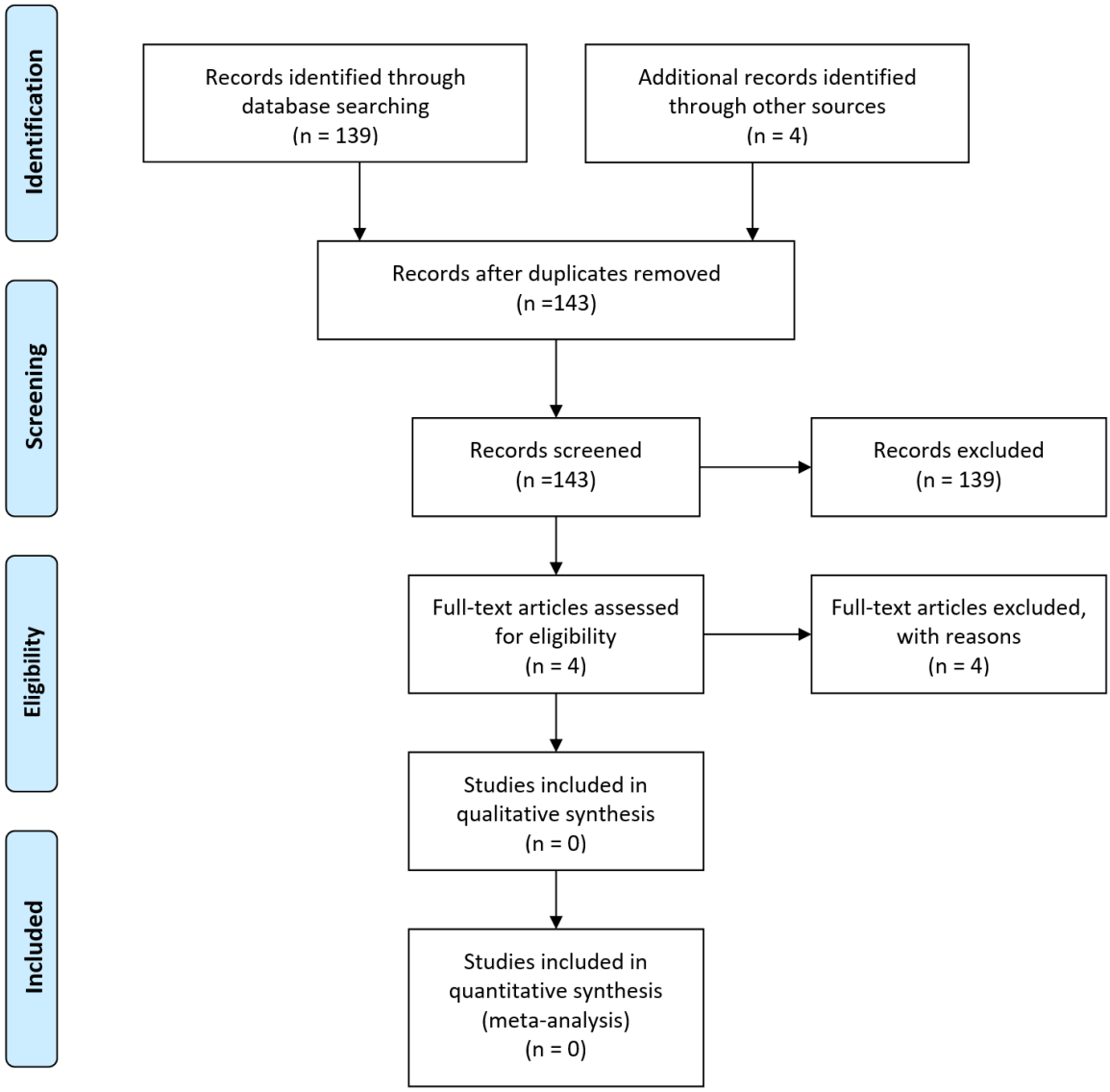
4.2.3 Quality assessment

The CASP tool was used to evaluate the included papers. The CASP tools are succinct and effectively cover the areas needed for critical appraisal of evidence (Nadelson and Nadelson, 2014). Specific CASP checklists have been developed for reviews of randomized controlled trials, systematic reviews, qualitative, case control, diagnostic, cohort, economic designs, and clinical prediction rule (CASP, 2017). CASP diagnostic test checklists were completed for each included paper (appendix B, page 188)

4.3 Results

Papers were evaluated for inclusion following the PRISMA flow chart, shown in Figure 4.3.

Figure 4.3 – Search results demonstrated within the PRISMA flowchart



A total of 143 papers were identified as a result of the literature search. 139 were identified via electronic literature sources (DelphiS, AMED, CINAHL and MEDLINE) and 4 were from the grey literature or hand searches of bibliographic references. All of these 143 went directly to abstract screening, from which 139 were excluded for not meeting the selection criteria. The primary reason for exclusion was the use of CGA with no relation to validation of RTCGA. There was

also a crossover with other exclusion criteria such as less common neurological disorders and also less common locomotion assessment such as walking backwards.

It was proposed the 4 remaining papers may relate to the research question and were worthy of full-text assessment for eligibility.

4.3.1 The gait arms legs and spine (GALS) assessment tool

2 of the remaining 4 articles related to the Gait Arms Legs and Spine (GALS) MSK assessment tool, one a validity study (Beattie *et al.*, 2008) and the other focusing on sensitivity and specificity of the tool (Beattie, MacIntyre and Cividino, 2012).

The GALS was developed to assist in the detection of MSK abnormalities after Doherty *et al*. (1990), in a review of 200 patients in a non-acute hospital setting, found assessment of the locomotor system was frequently absent during medical clerking. It is used by consultants, general practitioners and primary healthcare professions (Beattie *et al.*, 2008). RTCGA is the initial part of the physical assessment, but this is only 1 of 12 areas of examination and only 3 of the 29 total features assessed. The tool combines scores of separate assessments of the arm, legs and spine and so not specifically in relation to the lower limb or gait. Gait is assessed for symmetry and smoothness of movement, stride length and mechanics and ability to turn ‘normally’ and quickly. If or when an abnormality is observed, the health care professional records the result as ‘abnormal’ and then can note later the location and type of abnormality (Beattie *et al.*, 2008; Beattie, MacIntyre and Cividino, 2012). There is no guidance on a uniform or validated method to categorise these ‘abnormal’ findings further. No research or guidance is available into the details recorded clinically under the category of “abnormal”.

Validity was assessed for primary care use by comparing GALS tool scoring of family physicians with that of Rheumatologists. The coefficient of agreement (estimated Kappa) for the composite GALS score was 0.3675. The individual coefficient of agreement for the gait section was slightly higher at 0.49. This still

may be classed as only a moderate agreement between both groups (Landis and Koch, 1977).

In a following paper utilising the GALS MSK assessment tool, Beattie, MacIntye and Cividino (2012) state family physicians and nurse practitioners appeared able to employ the GALS examination to screen for possible signs of rheumatoid arthritis. Only the composite score was assessed, with no individual analysis of sections such as GA.

4.3.2 Author designed assessment tool

Brunnekreef *et al*. (2005) published a paper on a structured GA form used in the 'observational gait analysis' of patients with orthopaedic disorders. Although the study used videotaped analysis it was included as the abstract extrapolated upon the reliability of 'Visual Gait Analysis'. It was therefore possible that the videotape element of analysis was used to assess the validity of a form used for RTCGA.

This was not the case. From this paper it is unclear as to whether the form is designed to be used for RTCGA, or just to aid in interpretation of CGA, but there was no comparison or evaluation of RTCGA.

The samples included were taken from videotapes of patients who were referred for gait treatment to an orthopaedic clinic and were assessed using freeze frame and slow-motion. Raters were allowed to watch the patient as many times as they wished. This can therefore be classed as CGA rather than RTCGA. The authors concluded their form had inter-rater reliability (ICC values) among experienced and inexperienced raters of 0.42 and 0.40 respectively.

4.3.3 Clinical Education Paper

A paper on gait and posture assessment for general practitioners working with MSK injuries was published by Sweeting and Mock in 2007 (Sweeting and Mock, 2007). They propose 18 areas a general practitioner should assess during GA, with no reference to detailed methodology, reliability, or validity of any of these observations. The title and abstract is inappropriate to the content of the paper. The articles objectives, within the abstract, include assessment of gait and visual

scanning of abnormal gait. The methods for neither are presented with the main text.

4.4 Systematic review discussion

4.4.1 Lack of research

This review has found a lack of a standardised or systematic method of RTCGA in adults with a lower limb MSK injury.

The GALS MSK tool may be classed as ‘simplistic’ in its assessment of gait. In Beattie *et al*. 2008 paper (Beattie *et al.*, 2008), 9 out of the 10 patients who were classed as having an ‘abnormal gait’ were referred on for further gait investigation or assessment. It may be argued that GALS is more a tool used to identify the need for further referral for GA rather than a GA method itself. Brunnekreef *et al.* (2005) studied the reliability of their own ‘orthopaedic gait analysis form’. The observed 30 patients had been classed by the authors at inclusion as showing an undefined ‘mild to severe’ gait deviation. This sampling bias towards more obvious gait abnormality reduces the ability to withdraw data relevant to a general MSK clinic. It is also unclear from the paper if Brunnekreef *et al.* (2005) recommend their orthopaedic GA form to be used without the presence of recorded playback facility. Although no comments are directly related to this, they do conclude that “structured visual gait observation” is moderately reliable. If only this level of reliability was demonstrated while using a sampling bias of moderate to severe gait abnormality and assessed using video playback with freeze frame and pause capacity, it seems fair to conclude that even if findings could be migrated to RTCGA in a general lower limb MSK clinic then results would be poor.

On the basis of these results, it is difficult to predict the value, worth or even viability of including RTCGA in an MSK assessment. Coutts in 1999 (Coutts, 1999) stated “currently observational analysis on its own is insufficiently reliable to be clinically acceptable”. Eighteen years later and there appears to be no further work available to change this conclusion. We do not even know the proportion of clinicians using RTCGA, why they use it, how they are undertaking it or in which situations.

Whether there is still a clinical worth in conducting RTCGA therefore remains highly controversial. To date, there is only evidence of categorisation of RTCGA patterns by researchers in the physical therapy and surgical communities for neurological disorders such as cerebral palsy, stroke or Parkinson's disease (Toro, Nester and Farren, 2007; Roggendorf *et al.*, 2012). Each of these assessment tools utilises observing gait markers which link to a particular gait dysfunction related to the specific disease process. Even in more specifically researched areas such as stroke patients, Toro, Nester and Farren (2007) state a critical issue is the lack of a standardised method of gait classification. With this lack of research it would be expected that opinions on the use of RTCGA would remain balanced, but some authors still state that RTCGA is not only a powerful investigative tool, but even comparable to an X-ray or blood test (Sweeting and Mock, 2007). Stating such a high level of worth, with no apparent evidence base, appears unfounded and potentially misleading to MSK clinicians.

The lack of research in an area of assessment with common clinical recommendation and possible use may be seen as both surprising and relatively alarming. Abnormal gait has been cited by many as the cause of MSK lower limb injury and yet there appears no reliable or systematic method by which the majority of clinicians can assess for it. It also leads to questions in relation to treatments which are used to improve gait dysfunction by clinicians without access to CGA. Without being able to ascertain the worth of RTCGA, can changes from treatments such as foot orthoses, footwear advice, taping and muscle balance correction be considered measurable in their outcomes? If improvement to gait is a goal to a treatment (while also ensuring treatment has no adverse effects and is not detrimental to gait), then it would seem compelling to consider such practices questionable at the least. Greater access to CGA for all clinicians may be a method to improve patient assessment and outcomes. However, although opinion and limited publications appear to state that CGA is more beneficial than RTCGA, this has yet to be determined within the general symptomatic adult MSK population. With no research or evidence based guidelines on RTCGA, there simply is no current method for the CGA to be compared against in this sample group.

4.4.2 Terminology

This systematic review has highlighted the possible confusion in terminology used with describing the assessment of gait in a therapeutic clinical setting, agreeing with the need to clarify terminology introduced in section 2.2 (Chapter 2, pages 13-16). The authors propose the use of 'Real Time Clinical Gait Analysis' to specifically relate to the assessment of gait conducted live in health professional's clinics, without the use of any recording, play back or computerised equipment. The term 'Clinical Gait Analysis' has already been coined to describe GA conducted with the use of recording and evaluation technology. This acceptance of differing terminology may help reduce some of the issues experienced within this search. Brunnekreef *et al.* (2005) used the terms observational GA, videotaped observational GA and visual gait observation without clear definition or separation. 'Visual gait analysis' has been used elsewhere to mean GA conducted without technological aid (Wren *et al.*, 2011). It was unclear if the Brunnekreef *et al.* (2005) abstract, using the term 'structural visual gait observation', related to its title of videotaped observational GA or a conclusion obtained from this upon RTCGA, hence the papers inclusion.

4.4.3 Further work

With such findings, it seems reasonable for explication of these results to include recommendations for further work. Further referral for more in-depth analysis of gait is noted as an outcome in GALS research (Beattie *et al.*, 2008) and it is unclear if referral pathways in areas such as the NHS would have access to CGA. Development of an adult MSK RTCGA instrument or protocol could be useful for clinical practice. If types or 'patterns' of gait can be recognised, then linking this to injury, aetiology, treatment and outcomes would be beneficial. The requirement for an easy-to-use RTCGA tool amongst physiotherapists working in the NHS has already been suggested (Toro, Nester and Farren, 2003). Prior to the design of such a best practice approach, investigations into the current use or requirements of RTCGA within the variety of lower limb MSK clinics needs to be established. A systematic approach has recently lead to the development and proposal of the International Musculoskeletal Foot and Ankle Assessment (IMFAA) (Gates, Bowen and Arden, 2015). Such a method now needs to be employed for RTCGA.

A RTCGA best practice approach could be a worthy instrument for all clinicians treating adult lower limb MSK injury relating to gait dysfunction. These clinicians will have varied professional backgrounds and experience levels as well as working in multitudes of clinical settings. It is therefore essential that before further and possibly misleading information regarding RTCGA is passed onto MSK clinicians, the research into the validity, sensitivity and reliability of any RTCGA tool is assessed and presented with a balanced and clinically valid perspective.

4.5 Systematic review conclusion

This study has found a significant lack of justification into the use of RTCGA of adults with lower limb injury in MSK clinics. Although CGA may be more efficacious, it is assumed the methods by which this is conducted are not available for the majority of clinicians working with this patient group. A protocol for best practice could not be developed from this search. Further possible evolution in the role of RTCGA is proposed, but without additional guidance the current use of RTCGA as a part of this specific patient group analysis appears dubious at the very least.

4.6 Post systematic review of the literature

Four years have elapsed between the date of the systematic review search (February 2017) and the writing of this thesis. To ensure no recent relevant publications had been excluded, the search was repeated in February 2021. One additional text had become available relevant to the search parameters:

Adams, J. and Cerny, K. (2018) *Observational gait analysis: a visual guide*. Thorofare, NJ: Slack Incorporated

Following identification this publication was screened for eligibility in a similar fashion to the others in the systematic review, using CASP appraisal guidance and a PRISMA approach to inclusion.

The majority of Adams and Cerny (2018) is concerned with neurological disorders and falls / instability / elderly GA. Although content may be valuable for these

patient presentations, it's relevance to the creation of a best practice approach the MSK RTCGA is therefore reduced.

The authors present a new assessment method, an author-designed observational GA form (the 'JAKC Observational Gait Analysis' form). This is a tick box assessment form listing a variety of gait deviations which link closely to neurological gait dysfunction, such as clawing of toes and the extensor knee thrust. However, the associated instructional text for the JAKC form states that "videotape" of the patient's gait should be conducted. It appears the JAKC form is not designed for RTCGA, but instead as a tool by which to observe and record CGA findings. The process is presented under a new term of "observational clinical gait analysis". Although a definition of this term is not supplied, it does appear to support the notion that the JAKC approach is intended to aid observation of CGA technology findings, rather than RTCGA.

This aim for the use of the JAKC approach is further supported by the instructional videos which accompany the text. In these the example gait deviations are presented with a graph and a large 3D skeleton (such as that collected from CGA 3D data), but a small thumbnail of the actual participant walking (with no focus on the anatomical segment in question). It is difficult from these example resource videos to observe the actual anatomical segment being explained, but instead is easier to see the CGA representation.

There is no data or opinion on the reliability or validity supplied for the JAKC form by the authors. A literature database search (DelphiS, AMED, CINAHL and MEDLINE) of the terms "JAKC", "JAKC Observational gait analysis form", "Adams Cerny form" and "Adams Cerny observational gait analysis form" was conducted in July 2021 to search for any further research or opinion on this approach. No further literature was forthcoming from this search.

The JAKC form appears to have been designed primarily for use with neurological gait presentations and to be completed as an observational aid for CGA. It has no author presented data or opinion on its validity or reliability, and since publication no further notation or research upon this approach appears to have been published. Although the JAKC may be useful in the observation of CGA and in

patients with neurological type disorders, this text does not change the published systematic review findings in relation to both the lack of RTCGA guiding literature and recommendations for further work.

4.7 Discussion

In Chapters 3 and 4 (pages 29-56) an extensive review of the literature relating to RTCGA and adult MSK lower limb injury was presented.

Results demonstrate that currently there is no established RTCGA best practice approach or instrument for MSK adult lower limb injury. These findings agree with a 2019 systematic review of observational gait assessment scales which did not exclude neurological abnormality (Ridao-Fernández, Pinero-Pinto and Chamorro-Moriana, 2019), that "…researchers have dwelt on the analysis of gait on neurological pathologies but not on musculoskeletal injuries".

An evidence gap therefore exists, where MSK podiatrists may be advised to conduct RTCGA and may be doing so, but the best practice methods or procedures are at the level of clinical opinion with little underpinning robust evidence. If a best practice approach could be established, recommendations for clinical practice to help manage gait-related injury and reduce the use of unnecessary, ineffective or harmful interventions may be obtained. It had been anticipated a best practice approach to RTCGA could be developed or the development aided from the appraisal of the existing literature. However, the lack of robust evidence meant no previous work was available from which guidance could not imported or expounded to make best practice frameworks or even initial recommendations for establishing a best practice approach.

4.8 Conclusion

The systematic review of literature relating to RTCGA for adult MSK lower limb injury demonstrated a significant lack of robust evidence. This lack of evidence meant the construction of clinical guidance based upon previous work was not possible, and a different approach was therefore required.

4.9 How stage 2 informed stage 3

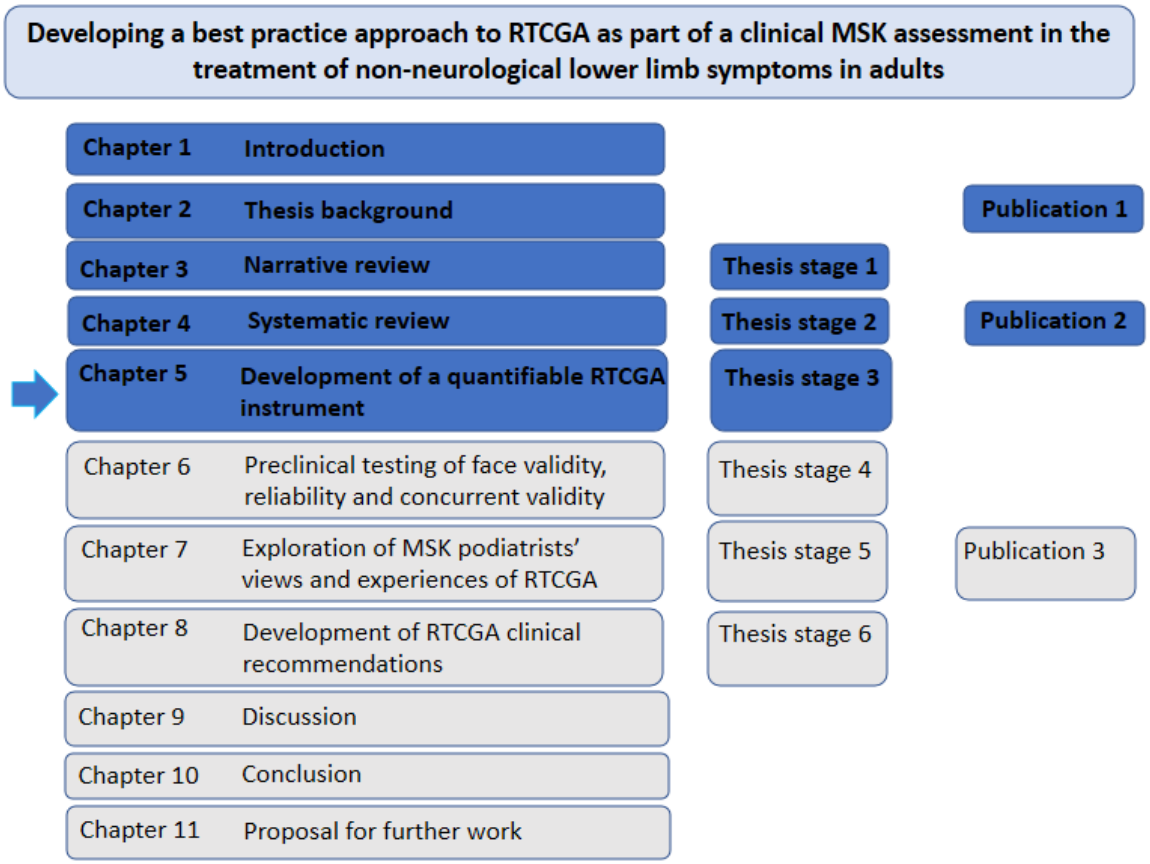
The systematic review (stage 2) found a lack of robust underpinning RTCGA evidence for the creation of a RTCGA best practice approach. This lack of knowledge was not only in relation to the measures and observations which should make up RTCGA, but also with regards to use and application of RTCGA within MSK clinics. With the lack of guiding literature by which to create a RTCGA best practice approach, a different development approach was required (stage 3).

Chapter 5 Development of a quantifiable RTCGA instrument

5.1 Introduction

Figure 5.1 demonstrates Chapter 5 within an overview of the doctoral thesis.

Figure 5.1. Doctoral thesis overview demonstrating Chapter 5 within the context of the programme of work



A thorough review of existing MSK RTCGA literature found a significant lack of robust or guiding RTCGA literature required to create a RTCGA best practice approach (stages 1 and 2).

Ideally, a RTCGA best practice approach should be developed by adopting and/or adapting other suitable high-quality internationally peer reviewed methods or procedures (NICE, 2015; Streiner, Norman and Cairney, 2015). In the absence of

significant literature and no known guidance relating to RTCGA approaches that could be adapted for clinical use, it was attempted to establish a framework by which a future RTCGA best practice approach could be developed ‘de novo’.

5.2 Review of developmental methods

In relation to MSK injury, approaches to best practice in areas other than RTCGA have been conducted previously and largely presented as clinical guidelines or recommendations (Lin *et al.*, 2018; Lin *et al.*, 2020). The quality of such guidelines has been noted to be variable, but mostly low (Lin *et al.*, 2020).

In a 2020 systematic review focusing on the most prevalent areas of MSK injury (lower back, hip and knee arthritis and shoulder injury), 11 higher quality MSK guidelines have been noted (Lin *et al.*, 2020). The majority of these included ‘physical examination’, such as joint positions, to assist in the diagnosis or classification of MSK disorders. Three of these guidelines were created via adherence to National Institute for Health and Care Excellence (NICE) guideline development recommendations (NICE, 2014;2016; Van Wambeke *et al.*, 2017) and the remaining 8 via systematic review and expert consensus (Fernandes *et al.*, 2013; Hopman *et al.*, 2013; Côté *et al.*, 2016; Globe *et al.*, 2016). However, the ‘physical examination’ recommendation made up only one element of the best practice clinical guidance of all approaches, with other aspects such as imaging, psychosocial factor assessment and health screening making up other recommendations (Lin *et al.*, 2020). These guidelines are therefore not developed as an objective measure or scale, as required with RTCGA, but instead as a collection of recommended and tested diagnostic and treatment modalities. This method may therefore not be applicable to RTCGA development.

Similar to the high-quality guidelines noted by Lin *et al.* (2020), Gates *et al*., (2015) used systematic review and expert opinion to develop the IMFAA. A collection of 20 core foot and ankle assessment measures was established via a systematic review followed by an expert consensus Delphi process. It was proposed that this combination of assessments would meet the requirements of foot and ankle screening but does require further investigation for the reliability and validity of included measures (Gates, Bowen and Arden, 2015). Like the

higher quality MSK guidelines incorporating physical examination noted by Lin *et al.*, (2020), the IMFAA is not intended as a measure itself, but more a collection of selected measures or assessments. For example, the observation of gait parameters is highly recommended as one of the IMFAA assessments, but the methods or measures associated with this GA are not detailed. Although this approach highlights the perceived importance of GA, it does not aid in the GA process itself. RTCGA is a physical examination in the form of observation of movement and position, stated to be of use in aiding diagnosis and intervention (Rose, 1983; Coutts, 1999; Brunnekreef *et al.*, 2005; Levine, Richards and Whittle, 2012). A RTCGA best practice approach would therefore require the establishment of the explicit observations and measures most efficacious in aiding the assessment and treatment of MSK injury, with specific development strategies required for the creation of such an objective instrument.

One of the highly recommended measures included in the IMFAA is the foot posture six index (FPI-6) (Gates, Bowen and Arden, 2015). The FPI-6 is cited within literature to be a validated and reliable clinical method for the systematic clinical examination of static foot posture (Keenan *et al.*, 2007; Reilly *et al.*, 2009; Aquino *et al.*, 2018; Carrasco *et al.*, 2021; Carroll *et al.*, 2021). The FPI-6 consists of 6 aspects of static, bilateral weight-bearing foot posture: observation of calcaneal position, arch height, number of visible toes, talonavicular bulge, supra- and infra- malleolar concavity, and palpation of the talar head. Apart from palpation of the talar head, these measures are real time and visual. Foot posture is scored from -12 (a very supinated foot) to +12 (a very pronated foot) (Redmond, Crosbie and Ouvrier, 2006). As a diagnostic tool it is therefore able to establish not only if foot posture is pronated or supinated, but also indicate the extent of which. Theoretically if there is a change in foot posture over time, the FPI-6 would detect this also. The FPI-6 is therefore a collection of real time observational postural measures, similar to the requirement of multiple joint observations in RTCGA, which has been subjected to testing for validity and reliability.

Other static foot posture measures have been developed, and there are three which have been validated against the considered ‘gold standard’ of radiographic angular measurements (Buldt *et al.*, 2015). These measures are the dorsal arch

height ratio (McPoil *et al.*, 2008), the arch index (Cavanagh and Rodgers, 1987) and the normalised navicular height truncated (Evans *et al.*, 2003). However, rather than visual observational measures, these approaches require a combination of footprints, measurement platforms, measuring aids (such as digital callipers) and formulative calculations (often requiring technological aid) (Cavanagh and Rodgers, 1987; Williams and McClay, 2000; Evans *et al.*, 2003; McPoil *et al.*, 2008; Buldt *et al.*, 2015). These measures are therefore not real time, and their development may be more closely comparable to CGA methods than RTCGA approaches.

The FPI-6 most closely matches the developmental requirements of the RTCGA instrument, and the FPI-6 creation process was therefore investigated as the primary method of creating an objective RTCGA instrument.

A variety of possible descriptive terms for an objective RTCGA best practice approach were considered during these stages of the development process. These included RTCGA ‘procedure’, ‘method’, ‘tool’, ‘system’, ‘scheme’, technique’ and ‘instrument’. To reduce possible confusion surrounding this superfluous variation of mostly interchangeable terms, the phrase ‘RTCGA instrument’ was adopted at this stage.

5.3 Review of the FPI-6 developmental method

Although no developmental framework was documented in the creation of the FPI-6 (Redmond, 1998), retrospectively the process appears to align with the diagnostic and health measure instrument development methods initially proposed by Davis (1996) and later published in greater detail by Streiner, Norman and Cairney (2015). This process consists of 5 steps:

1) Recognise preliminary conceptual aims

2) Generate items

3) Select a scoring system

4) Develop the items

5) Employ testing of the new measure

For step 5 of the process, employing testing of a new measure, Gluud and Gluud (2005) provide further guidance for such research and testing of proposed diagnostic approaches. This additional guidance consisted of 4 phases to be specifically employed in the evaluation and development of diagnostics and measures used in medicine, such as a RTCGA instrument. These phases are:

Phase 1 - Establish a normal range in a healthy population.

Phase 2 - Establish measures of diagnostic accuracy such as validity and reliability.

Phase 3 - Employ randomised trials to determine patient benefits from testing.

Phase 4 - Implement large continuous surveillance studies to identify effect.

Colli *et al.* (2014), in a paper which included the lead author Christian Gluud from the 2005 paper (Gluud and Gluud, 2005), updated the 4 phases and added an additional earlier Phase:

Phase 0 – Establish the reliability and validity (preclinical phase)

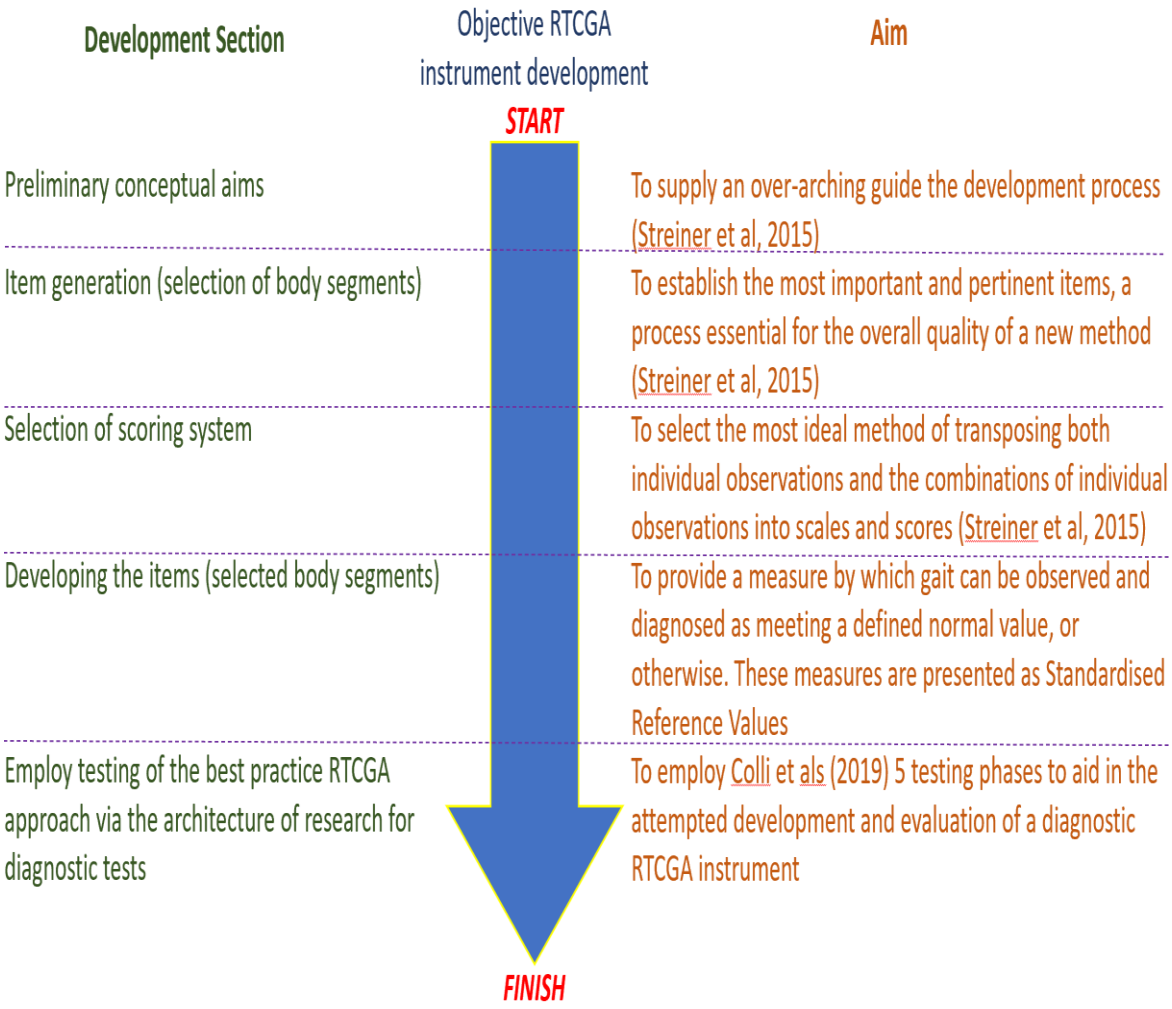
These phases, along with their suggested forms of testing, are summarised in Table 5.1 (pages 62).

Table 5.1. The phases of the architecture of diagnostic research and methods of testing seen in each Phase (adapted from Colli *et al.*, 2014)

Phase	Description	Method of testing examples
0	Establish the reliability and validity (preclinical phase)	Face validity studies and small sample studies of healthy or diseased persons
1	Establish a normal range in a healthy population	Case series of healthy individuals
2	Establish measures of diagnostic accuracy such as validity and reliability	Patient control, cross-sectional or randomised controlled trial (RCT) depending upon the disorder or disease in question
3	Employ randomised trials to determine patient benefits from testing	RCT
4	Implement large continuous surveillance studies to identify effect	RCT or cohort depending upon the disorder or disease in question

A summary of the proposed development strategy for the creation of a RTCGA instrument, centred upon the process to create the FPI-6, is presented in Figure 5.2 (page 63).

Figure 5.2. A summary of the development strategy for the creation of a RTCGA instrument



Each of these development sections are described in further detail in sections 5.3.1 to 5.4 (Chapter 5, pages 63-91).

5.3.1 Preliminary conceptual aims

Before establishing the contents of a RTCGA best practice approach, preliminary conceptual decisions were required to be established by which to guide the development process (Davis, 1996; Streiner, Norman and Cairney, 2015). With the lack of previous guiding literature, the proposed RTCGA concepts are designed based upon literature relating to GA purpose and use. As such, 3 pragmatic preliminary concepts are proposed to be required for RTCGA:

1. It provides an accurate diagnosis of abnormal gait.

The accuracy of information or measurements is their quality of being true or correct, even in small details. A RTCGA approach should accurately differentiate between a normal and abnormal gait observation. If abnormal gait observations can be accurately measured or recorded, then the RTCGA method could be useful in relation to stated aims of GA aiding clinical diagnosis and determining treatment goals (Rose, 1983; Coutts, 1999; Brunnekreef *et al.*, 2005; Levine, Richards and Whittle, 2012b).

2. It provides an accurate assessment of gait changes following intervention.

In addition to aiding diagnosis and determining treatment goals, an overall aim of GA is to evaluate treatment outcomes (Rose, 1983; Coutts, 1999; Brunnekreef *et al.*, 2005; Levine, Richards and Whittle, 2012b). To be able to accurately detect changes in gait following a therapeutic intervention is therefore a requirement for RTCGA.

3. It is relatively short and simple to complete.

The only previous research relating to practitioner requirements in relation to a GA method or procedure was conducted via a survey to outpatient physiotherapists in 2003 (Toro, Nester and Farren, 2003). The conclusion was that any future method would need to be concise and easy to use, and that these values were more important to the participants than the accuracy of the method. In addition to these findings, it may be assumed that a RTCGA approach that was simple to complete and did not require a large additional amount of time or resources would obtain better uptake and use than one which was not.

A RTCGA best practice approach should therefore include a set of objective observed tests designed to evaluate and diagnose a patient’s gait, not only before treatment but also after, in the most concise and simple approach possible.

5.3.2 Item generation (selection of body segments)

Following concept identification, item generation via selection and construction is the next step in the creation of a new measure or instrument. The selection of the most important and pertinent items is essential for the overall quality of the new method (Davis, 1996; Streiner, Norman and Cairney, 2015).

Items for a RTCGA instrument are the observations deemed to be most important for the evaluation of normal or abnormal gait kinematics. A best practice rationale for the kinematic observations to be included in the RTCGA instrument is therefore required. As with the design of conceptual aims, the lack of guiding literature prevented the employment or use of previously established selection criteria for kinematic RTCGA observations. A pragmatic approach was employed, based upon available literature relating to gait and RTCGA.

For a kinematic observation to be justifiably included in a RTCGA instrument, 4 main criteria are proposed:

1) To be an important anatomical area in the process of gait in a healthy population.

2) To have available kinematic healthy adult population data.

3) To have clinical relevance to the MSK clinician.

4) To be observable.

Each of the 4 ideal criteria are explained in greater detail below, and then in specific relation to the justification of item generation / selection of kinematic observations.

1) To be an important anatomical area in the process of gait in a healthy population

Some body segments may be more important to the process of a gait cycle than others. For example, in midstance the position of the hand may theoretically be less important to the gait process than the position of the hip.

To propose a hierarchy of anatomical importance for body segments in gait, an understanding of the gait process and functional bodily requirements in healthy adults is required.

Kuo and Donelan (2010) provide a critical analysis and thorough description of the available theories of gait principles in a healthy population. They present both the 'six determinants of gait' and 'inverted pendulum' theories before proposing a modification to the 'inverted pendulum theory' which they call the 'dynamic walking approach'. Initially they cite research which discredits the 'six determinants of gait' paradigm and recommend this theory is no longer taught or clinically employed. Then, through the dynamic walking approach, they describe the essential principles of lower limb motion and function required for what they class as a 'healthy gait'. For a gait to be 'healthy', they propose the requirements for it not only to be characteristic of gait found in a healthy symptom-free population, but also for it to be metabolically efficient and stable.

Dynamic walking theory describes the stance leg as behaving like an inverted pendulum, thereby allowing for gait to be metabolically efficient. The stance limb 'pendulum' conserves mechanical energy, requiring little work to produce motion along an arc (the stance phase). A corollary to the inverted pendulum stance limb is the pendulum like motion of the swing limb. The same conservation of mechanical energy is therefore applied to the swing limb, meaning little work is required to move it. McGreer (1990) proposed that the entire gait cycle can be largely produced through the ballistic motion of the 2 coupled pendulums of the swing and stance limb.

However, the main failing attributed by Kuo and Donelan (2010) in the unmodified inverted pendulum theory is the inability to explain how the body continues to progress while both feet are on the floor during initial and terminal stance phases (and so a pendulum is not swinging). In addition, the foot undertaking contact phase is applying a posterior (or breaking) force to walking progression, which would need to be countered by an anterior (or accelerating) force to maintain gait velocity. The dynamic walking model uses energy return from an extending hip (causing a loaded stretch in the anterior hip anatomy), stored energy in the calf / Achilles complex (for push off) and knee flexion at contact (providing anterior

force while reducing impact shock) as 3 methods by which anterior force negates the posterior force of heel contact. These 3 methods preserve progression velocity and momentum while both feet are on the floor, and thereby permit efficient and stable gait (Kuo and Donelan, 2010).

Kuo and Donelan (2010) recognise the foot as a complicated and essential structure for their theory to work. They describe the foot having to work as a "section of a wheel" in the stance phase for the limb to function as an inverted pendulum. No further explanation is forthcoming on the methods employed by the foot to act as a "section of a wheel". However, this analogy appears to directly agree with other authors who have also recognised the requirement of the foot to allow the limb to 'swing' above it. These authors have provided more detail to the foot's function in gait and aligned the function more with a system of "rockers" rather than a "wheel section" (Dananberg, 2000; Harradine and Bevan, 2009; Perry and Burnfield, 2010b). The rocker system is timed with frontal plane motion of the rearfoot, allowing internal and external leg rotation to occur via pronation and supination at the STJ respectively (Khamis and Yizhar, 2007; Souza *et al.*, 2010; Tateuchi, Wada and Ichihashi, 2011; Resende *et al.*, 2015; Koshino *et al.*, 2017).

More anatomically proximal in the understanding of the gait process, Gracovetsky (1987), Vleeming *et al.* (2007) and Yizhar *et al*. (2009) highlight the importance of spinal and upper limb motion in dynamic efficiency (often when combined called the 'spinal engine', Gracovetsky (1997)). This links well with Kuo and Donelan's (2010) lower limb requirements for a healthy gait. They propose that through arm swing and the myofascial attachments from the upper to lower limbs, gait efficiency is improved. Such theoretical benefit to efficiency is supported by research, with walking requiring up to 12 percent more metabolic energy without arm swing (Collins, Adamczyk and Kuo, 2009).

Using the dynamic walking theory, rocker foot-based models and the spinal engine model it is possible to begin to propose segments of the human body for which assessment in gait would be more important. These segments would need to function theoretically in a way which would promote efficiency and stability

within the dynamic walking model, and so be justified to be included in a RTCGA instrument.

2) To have available kinematic healthy adult population data.

For a segment to be included, kinematic values from a healthy population should be available. These kinematic values would need to be of a gold standard, for example those obtained from the 3D type kinematic systems such as Vicon (Vicon Motion Systems Ltd UK) (Windolf, Götzen and Morlock, 2008). This CGA kinematic research data allows a distinction to be made between gait patterns seen as normal in the healthy population, and those that are not.

The comparison of these research based normal values to the proposed theoretical normal values is therefore required. For example, Kuo and Donelan (2010) suggest that the knee should be almost extended in midstance for gait to be efficient and stable. If CGA knee kinematics in healthy populations find this not to be the case, a compromise would either need to be made to the theory, the assessment, or the segment would need to be possibly neglected. If enough data presented demonstrating a difference between the CGA kinematic literature and the gait model proposed by Kuo and Donelan (2010) this may lead to the rejection of the theory as a valid and useful basis by which to create a RTCGA instrument.

When reviewing the available CGA kinematic normative data, only a relatively small amount of research is apparent. A true normative kinematic value in a healthy population is therefore not possible to achieve. Instead, a central tendency value (CTV) may be useful. Central tendency is defined as “the statistical measure that identifies a single value as representative of an entire distribution” (Gravetter and Wallnau, 2000). It aims to provide a description of the entire data as the single value that is most typical and / or representative of the collected data.

The arithmetic mean is the most commonly used measure of a CTV (Manikandan, 2011). It is computed by adding all the values in the data set divided by the number of observations and it is this method that was applied to calculate the kinematic CTV for each RTCGA instrument segment. The use of single value,

rather than a mean with a standard deviation (SD) range, was employed at this stage to aid in simplicity for diagnostic method development.

3) Have clinical relevance to the MSK clinician

For inclusion an observation should have a clinically relevant link to any known MSK lower limb injury or abnormality. The use of kinematic CTVs alone does not allow for the inclusion of observations based upon this premise. If recognised kinematics known to link to injury have been established, observations for them are therefore important to include. For example, knee hyperextension in midstance has been linked to chronic posterior capsular knee injury (Teran-Yengle *et al.*, 2011). As a contrast, position of the wrist in gait has not been linked to any MSK injury at all. The knee in midstance is therefore more valid to be assessed in the RTCGA instrument compared to the wrist. The detection of knee hyperextension in midstance is a clinically relevant inclusion. A symptom specific value (SSV) is therefore be taken into account when justifying segments and kinematic values relating to a theoretically healthy gait. As both the CTVs and SSVs are important, the term Standardised Reference Value (SRV) is used to explore and amalgamate both kinematic observations obtained from the central tendency calculations and MSK symptom specific gait patterns. It would then be theoretically possible to aim to develop a method by which RTCGA can diagnose if a gait pattern matches the SRV or does not.

4) Be an observable body segment

For an area to be assessed, its movement in relation to another segment or the ground needs to be observable to the clinician. For example, knee extension is observable in relation to movement of the tibia and femur. However, although arch lowering and raising is a recognised kinematic finding in gait in a healthy population, the observation is obstructed with the patient wearing shoes. Areas which are observable should take precedence over segments that are not.

5.3.3 Selection of the scoring system

Appropriate scoring permits the most ideal assessment of both individual observations and the combinations of individual observations into scales and scores. If possible, the avoidance of differential weighting of items has been recommended as this theoretically decreases instrument error and simplifies its use and completion (Streiner, Norman and Cairney, 2015). Therefore, scoping explored the simplest possible options initially for the RTCGA instrument. Each kinematic observation can be deemed important as any other, requiring no weighting of observations. A simple scoring scale of 0 or +1 is therefore suitable for each kinematic observation, allowing the clinician to simply note if the section being observed met the SRV (and so scored 0) or not (and scored 1).

5.3.4 Developing the selected body segments

Six observable body segments are reasonable proposals for inclusion: 1) Feet 2) Ankles 3) Knees 4) Hips 5) Back and Pelvis and 6) Upper Limbs. These anatomical segments, and kinematic observational measures from them, are the items for the RTCGA instrument. Each item is presented below and justified in terms of theoretical requirement for gait in the healthy adult population, available CGA kinematic data, MSK clinical relevance and being an observable body segment. As previously stated, it is important to keep measures to a theoretical minimum to create the most simple and easy to use instrument as possible.

5.3.4a The foot

Theoretical importance to gait in the healthy population

The theoretical requirement of foot function in the healthy population requires a complex combination of both frontal and sagittal plane motion in the stance phase.

In the frontal plane, the rearfoot has been proposed to evert and then invert (Root, Orien and Weed, 1977; Perry and Burnfield, 2010b). This motion is seen as a perquisite for normal lower limb and spinal motion as it couples with leg internal and then external rotation (Perry and Burnfield, 2010b). Although the normal

direction and timing of motion is noted, the normative rearfoot to leg angles are not supplied.

Kinematic ranges in the healthy population

The foot's theoretical frontal plane direction of motion agrees with the available kinematic data. The rearfoot does evert and then inverts through the stance phase in healthy adults. Eversion occurs for the first 50-60% of the stance phase, followed by inversion (Wright, Desai and Henderson, 1964; McPoil and Cornwall, 1996; Leardini *et al.*, 2007; Campbell *et al.*, 2016). The calcaneal eversion and inversion is often quoted as a direct representation of subtalar joint (STJ) pronation and supination (Root, Orien and Weed, 1977; McPoil and Cornwall, 1996; Horwood and Chockalingam, 2017). A rearfoot coupling also exists in the kinematic literature between rearfoot pronation and supination and lower limb internal and external rotation (Khamis and Yizhar, 2007; Souza *et al.*, 2010; Tateuchi, Wada and Ichihashi, 2011; Resende *et al.*, 2015; Koshino *et al.*, 2017)

The mean kinematic value of maximum rearfoot eversion to the leg ranges in research between 5-6 degrees (Youberg *et al.*, 2005; Cornwall and McPoil, 2009; Chuter, 2010; Levinger *et al.*, 2013; Zhang, Paquette and Zhang, 2013). The CGA methods used to assess for this position were both electromagnetic motion analysis (Youberg *et al.*, 2005; Cornwall and McPoil, 2009) and 3D motion analysis (Chuter, 2010; Levinger *et al.*, 2013; Zhang, Paquette and Zhang, 2013). A CTV of 5 degrees eversion was calculated from all data.

Clinical relevance to the MSK clinician

Frontal plane motion and position of the foot has been linked to many lower limb injuries. In a review aimed at better understanding foot pronation, Horwood and Chockalingham (2017) linked increased rearfoot eversion to pronation, and pronation via a literature review to injuries such as plantar fasciitis, PTTD and patellofemoral pain syndrome. Decreased rearfoot eversion is not described in the literature as a detrimental finding until it becomes severe. A varus calcaneus (a rearfoot inverted to the leg) has been cited as a risk factor in recurrent ankle injuries (Van Bergeyk, Van Younger and Van Carson, 2002; Fraser *et al.*, 2019)

and also peroneal tendonitis (Valmassy, 1996). As less than 0 degrees (a varus calcaneus) in midstance is proposed to be a risk to injury, this SSV could be included as the minimum value of inversion in midstance. Amalgamating such clinical relevance into the kinematic ranges in a healthy population allows the creation of SRVs in the design of a RTCGA method.

Be an observable body segment

Normal daily footwear covers the foot, meaning direct observation of foot movements is not possible. To date all walking kinematic foot studies have either been barefoot, or assumed that motion of the shoe reflects in-shoe foot motion (McCulloch, Brunt and Vander Linden, 1993; Eng and Pierrynowski, 1994). This assumption has no confirming research.

One study has used sandals to assess the effect of footwear (different sole firmness) on foot kinematics in walking (Morio *et al.*, 2009). Using a sandal allowed the placement of reflective markers required for 3D analysis to be placed directly on the foot, rather than the shoe. Morio *et al*. (2009) reported a significant decrease in rearfoot eversion when their sample walked in soft sandals compared to barefoot, and again with firm sandals compared to soft sandals and barefoot. This reduction in eversion may also occur in shoe type footwear, but the effect of the shoe upper on foot function (a sandal has no upper) has not been established. Transposing effects of sandals to shoes may therefore be misleading.

Future technological advances in computerised GA may enable the better understanding of the effects of shoes on foot kinematics. An example of this is dynamic radiographic GA technology, where the shoe can simply be ‘seen through’ and ignored. Such studies are becoming available, but as yet these methods of researching kinematics have looked at the effect of footwear while running only (Anselmo *et al.*, 2018).

With recognition of the issue surrounding footwear and RTCGA, there are 3 options regarding the use of the foot segment in a RTCGA instrument. These are to: 1) limit the RTCGA instrument to barefoot assessment, 2) remove the foot as a

segment to be observed, or 3) loosely consolidate shoe motion to an indicator of foot motion and by doing so accept possible inherent errors in this segment.

Limiting the RTCGA instrument to barefoot analysis greatly reduces its clinical worth and validity in mostly shod populations (such as the UK and the vast majority of the northern hemisphere). Many of our treatments include the changing of footwear or the adding of orthoses to footwear. As it is normal to wear shoes, designing a RTCGA instrument solely for use in a barefoot population appears counter intuitive. Ideally, a RTCGA instrument would be applicable to both a barefoot and shod assessment.

The possibility to exclude the foot segment altogether would reduce the worth of the instrument due to the previously stated theoretical and clinical relevance of the foot in gait. Its function appears pivotal, and so assessment of its function could not be removed without needing to re-evaluate the total worth of creating a RTCGA instrument.

The option to include the foot segment while shod allows this important region to be assessed while keeping the RTCGA instrument clinically valid to the population in which it will likely be used. However, including a shod shoe segment would require the acceptance of possible error and the need for a change in terminology to highlight this. If used when the patient is shod, the RTCGA instrument would not be assessing foot position or motion, but instead shoe position and motion. The shoe movement would be seen as an indicator of foot motion or position, rather than a true assessment of it. Terminology changes associated with this acceptance would be to cease using the term “rearfoot motion” to describe shoe motion and replace it with “rearshoe motion”. In addition, in the ankle segment the dorsiflexion of the foot in relation to the leg is not being assessed, but the dorsiflexion of the plantar aspect of the shoe in relation to the leg. Terminology change here would be from “ankle dorsiflexion” to “shoe to leg dorsiflexion” when the patient is assessed shod. Different assessment forms would need to be utilised noting either “rearfoot” (for barefoot observations”) or “rearshoe” (for shod observations). For ease in presentation, examples and figures supplied in this chapter and related appendices are demonstrated as a shod observation and so state “rearshoe”.

Although including the shoe motion segment in the creation of a RTCGA instrument appears to have greater clinical face validity than either excluding the foot or testing barefoot, it does raise other issues which need to be recognised. The most important is that there is considerably less CGA kinematic data of healthy adults in shoes to use as the gold standard for normal data. All previous 3D kinematic or dynamic radiographic data has been conducted on barefoot samples, running samples or in Sandals (Morio *et al.*, 2009; Bishop, Hillier and Thewlis, 2017; Anselmo *et al.*, 2018). This means we have no established shod normal kinematic range in a healthy population from which to create a CTV and so diagnose normal or abnormal rearshoe motion or position.

For the foot segment a pragmatic solution is to use the barefoot kinematic rearfoot data to represent the rearshoe data until further research becomes available to establish the validity of this assumed correlation. That said, it has to be acknowledged there is potential for decreased validity for detection of gait patterns which do not follow the kinematic foot position and motion determined in the barefoot healthy population. This decision was taken with a view to reassess the foot's inclusion later in the development process following further testing.

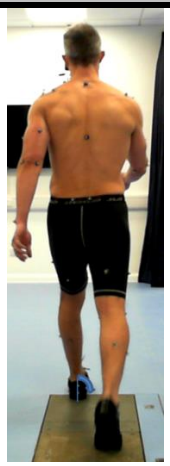
SRVs

Relating to the proposed SRVs, a RTCGA instrument would therefore need to:

- Detect any rearfoot / rearshoe inversion at heel strike
- Detect a lack of rearfoot / rearshoe inversion prior to heel lift and through propulsion.
- Detect maximum rearfoot / rearshoe eversion to the leg of angles greater than 5 degrees.
- Detect an inverted rearfoot / rearshoe to leg angle during midstance.

Visual description and examples of the foot SRVs are shown in Figure 5.3.1 (page 75)

Figure 5.3.1. Visual description and example of the foot SRVs. © University of Southampton.

Body Segment	Observation perspective	Observation	Observation example	Amplitude (in degrees) or direction of motion used as the SRV
Foot	Posterior	Contact period rearshoe direction of motion		**Eversion.** The direction of the arrow in the observation diagram is in the direction of eversion. Motion is observed of the shoe to the leg. If this motion occurs in the contact phase (as it did in this example shown by the arrow), it satisfies the SRV.
	Posterior	Rearfoot maximum eversion		**5 or less.** A maximum shoe to leg eversion in stance phase of 5 degrees of less is the SRV. The example is below 5 degrees, and so satisfies the SRV.

	Posterior	Midstance maximum rearshoe inversion		**Less than 0.** During midstance the SRV is any shoe to leg inversion angle less than 0 degrees. The example is 2.9 degrees everted, and so satisfies the SRV.
	Posterior	Rearshoe direction of motion after contact period		**Inversion before toe off.** The direction of motion of the arrow in the example is in the direction of inversion. Motion is observed of the shoe to the leg. If this motion occurs after the contact period (as it did in this example shown by the arrow), it satisfies the SRV.

5.3.4b The ankle

Theoretical importance to gait in the healthy population

For a theoretically healthy gait, as described by the dynamic walking inverted pendulum model (Kuo and Donelan, 2010), the ankle works as a rocker (the second rocker, (Harradine and Bevan (2009)) in the sagittal plane. The second rocker allows the stance limb to pass above the weightbearing foot, and so work as an inverted pendulum. The range of motion theoretically proposed as normal is 10 degrees of maximum dorsiflexion (Root, Orien and Weed, 1977; Levine, Richards and Whittle, 2012b) occurring in midstance.

Kinematic ranges in the healthy population

The kinematic normal found in healthy subjects ranges from 6 degrees to 14 degrees (Kadaba, Ramakrishnan and Wootten, 1990; Zhang, Paquette and Zhang, 2013; Kwon, Son and Lee, 2015; Gatt *et al.*, 2017; Jarvis *et al.*, 2017). The CTV of these 5 papers is 10 degrees. This matches with the theoretical required value. However, Zhang *et al.* (2013) found a statistically greater stance phase maximal dorsiflexion angle in shod compared to barefoot. The barefoot sample demonstrated maximum dorsiflexion angles at a mean of 6.1 degrees, while the same sample shod in trainers (with holes cut in to allow 3D marker placement) demonstrated a mean of 11.3 degrees. The shod value is almost double the barefoot value, but still close to the 10-degree amount found from the average of 3D kinematic studies barefoot. As only one study is available regarding the effects of footwear on maximal ankle dorsiflexion, it is unwise to explicate this finding to all footwear or samples. Until further research is available, the theoretical and barefoot CTV of 10 degrees should be used as the SRV.

Clinical relevance to the MSK clinician

A lack of ankle dorsiflexion in gait has been linked to MSK conditions such as plantar fasciitis (Patel and DiGiovanni, 2011; Monteagudo *et al.*, 2018) and metatarsalgia (Chahal, Davies and Blundell, 2020; Amaha, 2021). Range of motion greater than the CTV found in the average population is not linked to common injury and so not required to be included in the diagnostic RTCGA instrument.

Be an observable body segment

Ankle dorsiflexion is the angle made in the direction of flexion between the lateral aspect of the foot (base of the calcaneus to the 5th metatarsophalangeal joint) and the fibula. Although shorts or leggings permit the observation of the lateral aspect of the leg, the foot is obscured by a shoe. Ankle dorsiflexion of the foot in relation to the leg is not being assessed, but rather the dorsiflexion of the plantar aspect of the shoe in relation to the leg. However, its clinical relevance and theoretical importance (functioning as the 2nd rocker and by doing so allowing normal

pendular lower limb motion) is high. This point is similar to the previous section justifying the inclusion of assessment of the foot, even though it is obscured to true assessment by footwear also. Terminology change here would be required to highlight this accepted observational challenge to validity, changing “ankle dorsiflexion” to “shoe to leg dorsiflexion” when assessed shod.

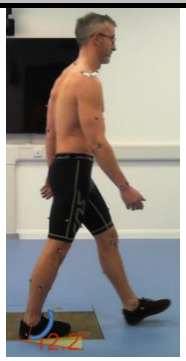
SRV

Relating to the proposed SRV, a RTCGA instrument would therefore need to:

- Be able to detect a maximal foot / shoe to leg dorsiflexion in midstance of less than 10 degrees.

Visual description and example of the ankle SRV is shown in Figure 5.3.2.

Figure 5.3.2. Visual description and example of the ankle SRV. © University of Southampton.

Body Segment	Observation perspective	Observation	Observation example	Amplitude (in degrees) or direction of motion used as the SRV
Ankle	Lateral	Maximum Shoe to leg dorsiflexion angle		**10 or more.** During midstance the SRV is maximum dorsiflexion of 10 degrees or more. This angle is taken as the shoe dorsiflexion angle from 90 degrees to the leg. The example is over 10 degrees dorsiflexed, and so satisfies the SRV.

5.3.4c The knee

Theoretical importance to gait in the healthy population

An extended, or nearly extended, knee in midstance is noted within the dynamic walking model of gait to aid in walking efficiency and stability (Kuo and Donelan, 2010).

Transverse plane motion of the knee and lower limb is essential for normal lumbopelvic motion in gait and is coupled with rearfoot pronation and supination (Harradine, Bevan and Carter, 2006; Harradine and Bevan, 2009; Perry and Burnfield, 2010b; Souza *et al.*, 2016). The theoretical amount of this rotation is not presented in the literature, rather the direction of motion which is internal at contact and external through midstance and propulsion.

Kinematic ranges in the healthy population

Kozanek *et al.* (2009) used a dual fluoroscopic imaging technique to study tibiofemoral kinematics during walking gait. Agreeing with previous authors (Lafortune *et al.*, 1992), they concluded the predominant motion of the knee during the stance phase of gait occurred in the sagittal plane. The knee was extended at heel strike, flexed during loading response and reached the first flexion peak of about 8° during early midstance. Thereafter, the knee begins to extend until about 40% of stance phase and remains in slight hyperextension (average 3.5°) throughout midstance.

3D analysis of the knee in the sagittal plane in symptom free subjects demonstrates slightly more flexion at midstance, with the mean ranging from 2 degrees (Kwon, Son and Lee, 2015) up to 8 degrees (Eitzen *et al.*, 2012). Kadaba et al (1990) found mean maximum extension at midstance to be 4 degrees flexed. The main difference between assessment criteria (fluoroscopic imaging compared to 3D analysis) is important, with 3D kinematics using a Vicon based system finding the knees to be slightly flexed (to varying degrees) while fluoroscopic imaging demonstrated hyperextension in midstance (Kwon, Son and Lee, 2015). A RTCGA instrument is more akin to 3D skin placement methods than fluoroscopic imaging, and it may be presumed that the variation in findings

although worth noting, is not excessively large. Both methods concur with theoretical requirements that the knee is either fully or nearly fully extended during midstance. The CTV is 3 degrees flexed. However, sagittal plane analysis also needs to be assessed in terms of too much motion and hyperextension. As with the foot, where too much or too little motion needs to be assessed, the same is required with the knee. Hyperextension in midstance is not seen as a normal finding in terms of theory or 3D kinematic data (Perry, 1992; Kuo and Donelan, 2010; Kwon, Son and Lee, 2015).

Transverse plane direction of motion literature agrees with theory. 3D kinematic studies report during the contact phase the knee internally rotates, followed by gradual external rotation during midstance, with the knee externally rotated during late stance and swing in the normal population (Kadaba, Ramakrishnan and Wootten, 1990; Lafortune *et al.*, 1992; Nester, 2000; Souza *et al.*, 2010; Barton *et al.*, 2012; Koshino *et al.*, 2017).

Clinical relevance to the MSK clinician

Motion linked to injury in the sagittal plane of the knee is noted in both hyperextension (extension past 0 degrees) and a lack of extension (noted from previous data to be a knee flexed greater than 3 degrees in midstance). Hyperextension of the knee is linked to injury and symptoms such as increased stress to the posterior capsule of the knee joint, anterior cruciate ligament and the anterior compartment of the tibiofemoral joint (Teran-Yengle *et al.*, 2011). Increased knee flexion in midstance is linked to patellofemoral pain (Fox *et al.*, 2018).

From a transverse plane perspective, prolonged internal rotation knee during midstance has also been linked to patellofemoral pain syndrome (Powers, 2003; Mirzaie *et al.*, 2016).

Be an observable body segment

The knee is fully observable in the frontal and sagittal plane via the use of shorts or leggings.

SRVs

Relating to the proposed SRVs, a RTCGA instrument would therefore need to:

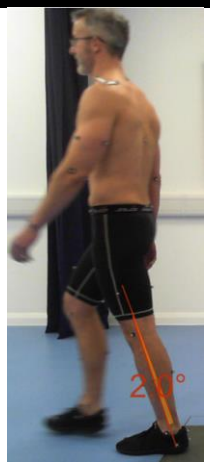
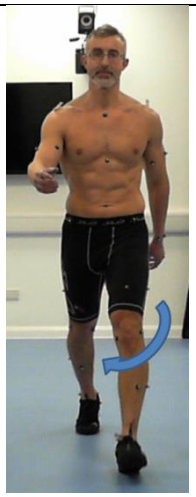
- Detect a lack of sagittal plane midstance knee extension of less than 3 degrees.

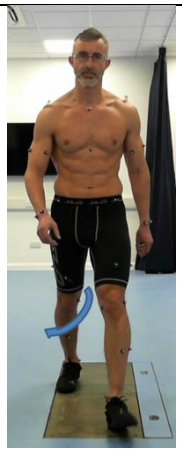
- Detect sagittal plane midstance hyperextension.

- Detect transverse plane internal (contact phase) and then external knee rotation (following contact phase) timing.

Visual description and examples of the knee SRVs are shown in Figure 5.3.3 (page 82)

Figure 5.3.3. Visual description and example of knee SRVs. © University of Southampton.

Body Segment	Observation perspective	Observation	Observation example	Amplitude (in degrees) or direction of motion used as the SRV
Knee	Lateral	Maximum flexion and midstance		**3 degrees or less for maximum flexion. 1 degree or more of hyperextension.** The angle is taken between the leg and the thigh. The maximum knee extension in midstance is 2 degrees. This is not hyperextended or flexed beyond 3 degrees. The satisfies the SRVs of both maximum flexion and hyperextension.
	Lateral	Hyperextension in stance phase		
	Anterior	Contact period knee direction of motion		**Internal rotation.** The direction of motion of the arrow in the example is in the direction of internal rotation. If this motion occurs in the contact phase (as it did in this example as shown by the arrow), it satisfies the SRV.

	Anterior	Midstance and propulsive period direction of motion		**External rotation.** The direction of motion of the arrow in the example is in the direction of external rotation. If this motion occurs following the contact phase (as it did in this example as shown by the arrow), it satisfies the SRV.

5.3.4d The hip

Theoretical importance to gait in the healthy population

Sagittal plane motion in the stance phase begins with the hip flexed and then extending 15 degrees (Perry and Burnfield, 2010b). Hip extension is an essential element of the inverted pendulum action which described healthy gait in the dynamic walking model (Kuo and Donelan, 2010) with its importance cited by many authors who utilise inverted pendulum theory (Dananberg, 1993; Harradine, Bevan and Carter, 2006; Harradine and Bevan, 2009; Perry and Burnfield, 2010b).

Unlike knee hyperextension, there is no theory or symptom specific literature relating excessive hip extension. It appears hyperextension is either anatomically not possible or not detrimental to an efficient and stable gait.

Kinematic ranges in the healthy population

From a kinematic perspective, using 3D analysis, the total sagittal plane range of motion has been found to be around 40 degrees, with CTV maximum extension (measured between the femur and the pelvis) of these studies being 15 degrees (Bergmann *et al.*, 2001; Eitzen *et al.*, 2012; Foucher *et al.*, 2012; Kumar *et al.*, 2015; Kwon, Son and Lee, 2015; Bennett, Fleenor and Weinhandl, 2018; MacRae

et al., 2018). This agrees with theoretical data in both range and amplitude of motion.

Clinical Relevance to the MSK clinician

An inability of the hip to extend in gait has been linked to MSK injury including mechanical orientated LBP (Dananberg and Guiliano, 1999; Lee, 2011), Ilio-psoas overuse injury (Harradine, Bevan and Carter, 2006), neck pain (Lee *et al.*, 2013) and patellofemoral pain (Hamstra-Wright *et al.*, 2017).

Be an observable body segment

The hip is fully observable in the frontal and sagittal plane with the use of lycra shorts or leggings.

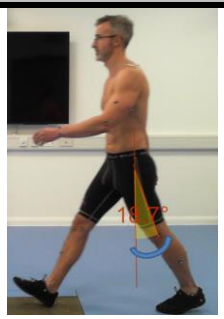
SRV

Relating to the proposed SRV, a RTCGA instrument would therefore need to:

- Detect a lack of 15 degrees of total hip extension during the stance phase.

Visual description and example of the hip SRV is shown in Figure 5.3.4 (page 85).

Figure 5.3.4. Visual description and example of the hip SRV. © University of Southampton.

Body Segment	Observation perspective	Observation	Observation example	Amplitude (in degrees) or direction of motion used as the SRV
Hip	Lateral	Maximum contact period extension		**15 or more.** During stance phase the SRV is a maximum of 15 degrees or more. This angle is made between the thigh and pelvis. The example is greater than 15 degrees, and so satisfies the SRV.

5.3.4e The back and pelvis

Theoretical importance to gait in the healthy population

Pelvic drop, or tilt, is one component of the more complex motion of pelvic rotation (Vleeming, Mooney and Stoeckart, 2007). Pelvic rotation is part of the spinal engine (Gracovetsky and Iacono, 1987; Gracovetsky, 1988; Gracovetsky, 1997) and therefore seen as part of efficiency for gait in healthy subjects. The amount of pelvic drop is not presented by these authors, however Perry and Burnfield (2010b) propose this range of motion in normal individuals to be a 5 degrees "drop" (lateral inclination in the frontal plane) away from the weightbearing limb.

Kinematic ranges in the healthy population

Callaghan *et al*. (1999), conducted analysis using eletrogoniometers on 5 healthy subjects to quantify movement of the lumbar spine in walking. Frontal plane motion showed lateral flexion to the contralateral side (i.e., at right heel contact, left lateral flexion of the spine). The lumbar spine laterally flexed following heel contact to the maximum value at toe off. A wide variation in range of motion was

present in just 5 subjects. However, all participants exhibited the same pattern which matches that theoretically proposed.

Later 3D kinematic studies during walking have demonstrated the same general lateroflexion on each side per cycle in the frontal plane (Feipel *et al.*, 2001; Lamoth *et al.*, 2002; Ceccato *et al.*, 2009; Kulmala *et al.*, 2017; Crossley *et al.*, 2018). The pelvic drop CTV of these studies is 5 degrees, agreeing with the amount theoretically proposed by Perry and Burnfield (2010b).

Clinical relevance to the MSK clinician

Although some amount of motion is seen as aiding efficiency in the gait of a healthy population, clinical emphasis is placed upon high values of frontal plane pelvic stance phase motion in relation to injury and abnormal foot function (Carter, Harradine and Bevan, 2003; Leetun *et al.*, 2004; Snyder *et al.*, 2009; Souza *et al.*, 2010; Chuter and de Jonge, 2012; Souza *et al.*, 2016). However, too little motion may also be an indicator of a lack of engagement of the spinal engine, causing a detrimental effect of the efficiency and stability of gait (Vleeming, Mooney and Stoeckart, 2007).

For this reason, both too much and too little pelvic drop needs to be included in the instrument development. For the purpose of instrument design, angles above 5 degrees are seen as excessive, but those less than 0 degrees may demonstrate a lack of spinal engine in gait and are recommended to be included.

Be an observable body segment

The pelvis and lower back are able to be observed with the patient wearing just shorts or shorts with additional clothing that permits observation of the lower back.

SRVs

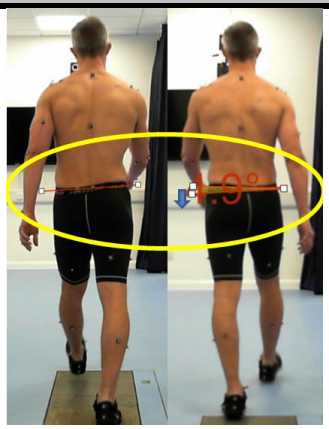
Relating to the proposed SRVs, a RTCGA instrument would therefore need to:

- Detect frontal plane pelvic drop away from the weight bearing limb of greater than 5 degrees

- Detect frontal plane pelvic drop away from the weight bearing limb of less than 0 degrees

Visual description and examples of the back and pelvis SRV is shown in Figure 5.3.5.

Figure 5.3.5. Visual description and example of back and pelvis SRV. © University of Southampton.

Body Segment	Observation perspective	Observation	Observation example	Amplitude (in degrees) or direction of motion used as the SRV
Back and Pelvis	Posterior	Maximum stance phase lateral pelvic tilt		**1 to 5 degrees.** The pelvic drop in the frontal plane is the total amount of drop from one stance phase to the other. This should be between 1 and 5 degrees in total. The example is in this range, and so satisfies the SRV.

5.3.4f The upper limb

Theoretical importance to gait in the healthy population

Meyns *et al.* (2013) concluded in a narrative literature review that arm swing should be seen as an integral part of human bipedal gait, and that arm swinging during normal bipedal gait most likely serves to reduce energy expenditure. Other authors have noted fascial attachments of the upper to lower limb and theorise on these working together to increase efficiency and stability of gait (Gracovetsky,

1988; DeRosa and Porterfield, 2007; Vleeming, Mooney and Stoeckart, 2007; Ortega, Fehlman and Farley, 2008; Yizhar *et al.*, 2009). These theoretical proposals and findings link well to Kuo and Donelan's (2010) requirements for gait in a healthy population.

Kinematic ranges in the healthy population

It has been commented that most modelling studies on gait seem to ignore arm swing altogether (Pieter, Brujin and Duysens, 2013), resulting in a relative lack of research based arm swing values to utilise for the RTCGA instrument design. Studies that are available agree on the timing of motion. The arm at the shoulder flexes and extends during each stride. Maximum extension is reached during ipsilateral heel contact, and peak flexion occurs with contralateral initial contact (Murray, Sepic and Barnard, 1967). Although noting considerable variation occurs amongst individuals, Perry and Burnfield (2010) quote Murray, Sepic and Barnards (1967) previous work that during moderate walking speed the average sagittal plane arc of motion is 32 degrees. Of this total 32 degrees range of motion, 24 degrees is flexion and 8 degrees extension. More recent studies, using more valid and reliable 3D kinematic data collection methods, have concluded a larger range of motion existing in healthy adults. The total range of motion ranged between a mean of 46 degrees (Plate *et al.*, 2015) and 50 degrees (Mirelman *et al.*, 2015). Of this total amplitude, there is slightly increased extension compared to flexion. Using the more recent studies, the extension CTV is 26 degrees, and flexion 22 degrees. Faster walking increases the total arc of motion (Murray, Sepic and Barnard, 1967; Hejrati *et al.*, 2016), but is not relevant to this study.

Clinical relevance to the MSK clinician

Although there is research showing a link between a decreased arm swing and lower back pain, no differentiation between cause and effect have been made in such studies (Huang *et al.*, 2011). It is therefore possible that lower back pain causes a decrease in arm swing, or vice versa. However, although there are no available direct papers demonstrating reduced arm swing to be an aetiological cause of MSK symptoms, its importance as an indicator of the spinal engine and in providing an efficient and stable gait warrants its inclusion.

As with hip extension, there does not appear to be a link with a range of motion in excess of the CTV being detrimental to gait efficiency, or stability or linking to symptoms. A range of above the amount noted below is therefore not included as an assessment criterion in the RTCGA instrument.

Be an observable body segment

The arms are able to be observed with the patient wearing just shorts or shorts with an item of clothing which permits observation of the shoulder and arms.

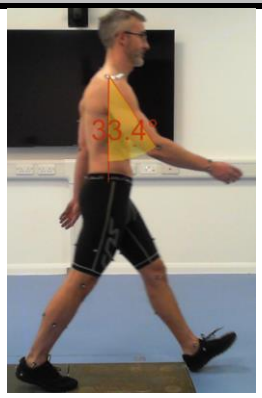
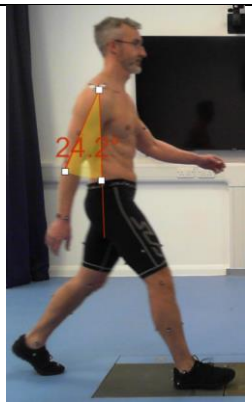
SRVs

Relating to the proposed SRVs, a RTCGA instrument would therefore need to:

- Detect a lack of arm flexion of 22 degrees
- Detect a lack of arm extension of 26 degrees

Visual description and examples of the upper limb SRVs are shown in Figure 5.3.6 (page 90).

Figure 5.3.6. Visual description and example of the upper limb SRVs. © University of Southampton.

Body Segment	Observation perspective	Observation	Observation example	Amplitude (in degrees) or direction of motion used as the SRV
Arm	Lateral	Maximum stance phase extension		**26 or more**. During stance phase the SRV is an angle into extension of 26 degrees or more. The angle is made between the upper arm (humerus proximally to the elbow joint) and the midline of the body . The example is greater than 26 degrees, and so satisfies the SRV.
	Lateral	Maximum stance phase flexion		**20 or more**. During stance phase the SRV is an angle into flexion of 20 degrees or more. The angle is made between the upper arm (humerus proximally to the elbow joint) and the midline of the body . The example is greater than 20 degrees, and so satisfies the SRV.

5.4 The preliminary RTCGA instrument

The SRVs used in the design of the RTCGA instrument are summarised in Table 5.2 (page 92). As stated previously, the use of CTVs as a single value is recommended rather than a mean with a SD range. The reason for this approach is for simplicity in the instrument development and also for clinicians using the instrument. Using one figure allows an uncomplicated observation for clinicians to view, and an easier scoring system. The observation would either match the CTV number or would not.

Table 5.2. Summary of Standardised Reference Values (SRVs)

Body segment	Plane of motion	Direction of motion	Observation	Amplitude (in degrees) or direction of motion used as the SRV
1) Feet (section 5.3.4a)	Frontal	Eversion or Inversion	Contact period rearfoot / rearshoe direction of motion	Eversion
	Frontal	Eversion	Rearfoot / rearshoe maximum eversion	5 or less
	Frontal	Inversion	Midstance maximum rearfoot / rearshoe inversion	Less than 0
	Frontal	Eversion or Inversion	Rearfoot / rearshoe direction of motion after contact phase	Inversion before toe off
2) Ankles (section 5.3.4b)	Sagittal	Dorsiflexion	Maximum Foot / Shoe to leg dorsiflexion angle	10 or more
3) Knees (section 5.3.4c)	Sagittal	Flexion	Maximum flexion at midstance	3 degrees or less
	Sagittal	Extension	Hyperextension in stance phase	1 degree or more
	Transverse	Internal or external rotation	Contact period knee direction of motion	Internal rotation
	Transverse	Internal or External rotation	Midstance and propulsive period direction of motion	External rotation before toe off

4) Hips (section 5.3.4d)	Sagittal	Extension	Maximum stance phase extension	15 or more
5) Back and Pelvis (section 5.3.4e)	Frontal	Lateral Rotation	Maximum stance phase lateral pelvic tilt	1 to 5 degrees
6) Upper limbs (section 5.3.4f)	Sagittal	Extension	Maximum stance phase extension	26 or more
	Sagittal	Flexion	Maximum stance phase flexion	20 or more

Using proposed SRVs (Table 5.2, Chapter 5, page 92), 13 observations were included in the preliminary RTCGA instrument. These were taken from 6 anatomical segments: the foot, ankle, knee, hip, back and pelvis and upper limbs.

A simple scoring scale of 0 or +1 was employed as per the conceptual design (section 5.3.3, Chapter 5, page 70). This would allow the clinician to note if the section being observed met the SRV (and so scored 0) or not (and scored 1). Scores are added, giving a scale of gait dysfunction, but leaving this approach conceptually and arithmetically simple (Streiner, Norman and Cairney, 2015).

At the end of each body segment the items are added for both left and right separately, and then left and right combined. A combined total of 0 would again indicate that the SRVs in all sections had been observed, and this would be classed as a standardised reference value pattern (SRVP) of gait.

SRVPs can therefore be calculated for each body segment individually. In addition, all segments can then be added bilaterally or for the left and right side individually to supply a total score for each side or combined. A score of 0 would demonstrate gait matches the SRVP. The larger the number, the less the gait being observed matches the SRVP, and so larger the gait dysfunction. The scale is different for each body segment due to the variation in number of items. For

example, the maximum score of a gait pattern not matching the SRVP for the foot on each side is +4, while the ankle is +1. For the total combined score of all segments the scale would range from 0 (where all observations match their SRVs and gait demonstrates the SRVP) to + 26 (where no observations match their SRV and gait is as far removed as possible to the SRVP). It would be theoretically possible to review the individual scores to establish the body segments which score the highest, and so those least matching their SRVs

Figure 5.4.1 (page 95) shows the preliminary RTCGA instrument scoring protocol, and Figure 5.4.2 (page 96) shows the preliminary RTCGA instrument scoring table by which to complete and scale the assessment. For ease in presentation, “rearshoe observations” are noted rather than the barefoot “rearfoot observation”, but the scoring system for either is the same.

Figure 5.4.1. The preliminary RTCGA instrument scoring protocol

Foot Segment	**Grading**		**RTCGA score**
	Observation	**Scoring**	
1)Contact period rearshoe motion	Eversion	0	0 to +1
	Inversion	1	
2)Maximum rearshoe eversion	Less than 5 degrees	0	0 to +1
	5 degrees or greater	1	
3)Midstance maximum rearshoe inversion	Less than 1 degree	0	0 to +1
	1 degree or greater	1	
4)Rearshoe inversion after contact phase	Inversion	0	0 to +1
	No inversion	1	
Ankle Segment	**Grading**		**RTCGA score**
	Observation	**Scoring**	
5)Midstance shoe to leg dorsiflexion	10 degrees or more	0	0 to +1
	Less than 10 degrees	1	
Knee Segment	**Grading**		**RTCGA score**
	Observation	**Scoring**	
6)Midstance maximum extension	Flexed by 3 degrees or less	0	0 to +1
	Flexed by 4 degrees or more	1	
7)Midstance knee hyperextension	Not extended greater than 0 degrees	0	0 to +1
	Extended greater than 0 degrees	1	
8)Rotation at contact	Internal	0	0 to +1
	External	1	
9)Late stance phase rotation	External	0	0 to +1
	No external	1	
Hip Segment	**Grading**		**RTCGA score**
	Observation	**Scoring**	
10) Maximum extension	15 degrees or more	0	0 to +1
	Less than 15 degrees	1	
Back and pelvis segment	**Grading**		**RTCGA score**
	Observation	**Scoring**	
11) Pelvic drop	1 to 5 degrees	0	0 to +1
	Less than 1 or greater than 5 degrees	1	
Upper limb segment	**Grading**		**RTCGA score**
	Observation	**Scoring**	
12) Arm swing flexion	20 degrees or greater flexion	0	0 to +1
	Less than 20 degrees flexion	1	
13) Arm swing extension	26 degrees or greater extension	0	0 to +1
	Less than 26 degrees	1	

Figure 5.4.2. The preliminary RTCGA instrument scoring sheet

Observation segment	**RTCGA instrument score**	
	Left	**Right**
Foot		
1) Contact period rearshoe motion		
2) Maximum rearshoe eversion		
3) Midstance maximum rearshoe inversion		
4) Rearshoe inversion from midstance		
Shoe observation total		
Shoe observation total combined		
Ankle		
5) Shoe to leg dorsiflexion		
Shoe to leg observation total combined		
Knee		
6) Knee extension		
7) Knee hyperextension		
8) Rotation at contact period		
9) Rotation after contact period		
Knee observation total		
Knee observation total combined		
Hip		
10) Hip extension		
Hip observation total combined		
Back and pelvis		
11) Pelvic drop		
Back and pelvis observation total combined		
Upper limb		
12) Arm flexion		
13) Arm extension		
Upper limb observation total		
Upper limb observation total combined		
SIDE TOTAL		
COMBINED TOTAL		

5.5 Discussion

Due to the ‘de novo’ approach required in the development of a RTCGA best practice approach, it was essential to comprehensively review progression during the iterate stages of this doctoral thesis programme of work. Without previous or established literature or guidelines by which to compare development, ‘sense checking’ reviews are critical to ensure progress and direction fulfils conceptual aims and methodological objectives. Concerns were raised as a result of this

review of development of the preliminary RTCGA instrument as outlined in this chapter, and these are discussed in turn within the following section (5.5.1).

5.5.1 Concerns regarding preliminary RTCGA instrument development

A lack of existing RTCGA knowledge

Anatomical significance was stated to be considered important in item generation (section 5.3.2, Chapter 5, pages 65-70), but there was no available robust literature to inform which observations should be deemed as anatomically important. It is not known if the proposed anatomical scope of assessment of the foot, ankle, knee, hip, pelvis and arms is important or relevant for all MSK podiatrists and for all lower limb MSK conditions. Although theoretical reasoning was applied to item generation, the included areas were decided and finalised by the PhD candidate alone. Observations deemed important by one MSK podiatrist could be a poor representation of what the MSK podiatry profession as a whole would class as important. Possible developer bias is discussed individually later in this chapter (‘Developer bias’, page 98).

Symptoms were also proposed to play an important role in anatomical segment selection. For example, knee hyperextension in midstance has been linked to chronic posterior capsular knee injury (Teran-Yengle *et al.*, 2011). As a contrast, motion of the arm in gait has not been linked to knee pain, but both are part of the RTCGA instrument. If a patient presented with posterior knee pain, it is not known if a MSK podiatrist would assess the foot, ankle, knee, hip, pelvis and back and upper limb. They may choose just to observe the knee in midstance. This option is not supplied in the RTCGA instrument, and it is not known if a MSK podiatrist would therefore find this instrument relevant to their practice or possibly too complicated or cumbersome to complete. Furthermore, working with the same example, it is not known if MSK podiatrists are aware of the link between hyperextension in gait and chronic posterior capsular knee injury. There may be other RTCGA observations they find more predictive and useful for chronic posterior knee injury.

This lack of awareness of RTCGA MSK requirements and procedures represents a significant gap in our knowledge when creating a RTCGA instrument. It was concluded the RTCGA instrument as it stands was not an adequate representation of a best practice approach for MSK podiatrists due to the assumptions made by the developer in the absence of guiding RTCGA literature and knowledge.

Developer bias

Bias is the preconceived notion of something, based on information we have, perceive to have, or lack (Smith and Noble, 2014).

The RTCGA instrument developer (the thesis author) is an experienced MSK podiatrist. Having prescribed more than 10,000 pairs of custom foot orthoses and performing their own strategy for RTCGA routinely at assessment, fitting and reviews, they have performed RTCGA more than 30,000 times. This may lead to confirmation bias, the seeking out of information or developing ideas that support something already believed, cueing into areas that matter to that one approach and dismissing things that do not (Klayman, 1995; Smith and Noble, 2014). This in turn can lead to the “ostrich effect”, where a subject seeks to avoid information or ideas that may disprove their original point, beliefs or practice. Cultural bias, also known as implicit bias, may also be present. The PhD candidate is a podiatrist with the associated professional approach, attitude and culture that can affect the origins of the baseline thinking (Chapman, Kaatz and Carnes, 2013; Smith and Noble, 2014) compared to other professions who perform RTCGA. If the RTCGA instrument is intended to be used by MSK podiatrists only, this cultural bias may be thought to be less important. However, there may be other approaches to RTCGA from other professions which, if included, could improve the instrument.

Without knowledge of current RTCGA practice or guiding literature, the bias inherent in a single author development approach was recognised. Such bias would have led to the inclusion of observations possibly not important to a RTCGA instrument, and the exclusion of those that were.

Inclusion and stated importance of shod gait

For an area to be assessed, the anatomical kinematic observation was deemed essential (section 5.3.2, Chapter 5, pages 65-70). However, direct observation of the foot in a shoe is not possible. Foot kinematics cannot be observed with the patient wearing shoes (which is normal for the majority of the northern hemisphere population). To date all kinematic foot studies have either been barefoot or assumed that motion of the shoe reflects in-shoe foot motion (McCulloch, Brunt and Vander Linden, 1993; Eng and Pierrynowski, 1994; Arnold and Bishop, 2013). This assumption, which was adopted for the purpose of this instrument design also, has no confirming research. A review regarding quantifying foot kinematics inside athletic footwear concluded the opposite; that it is inappropriate to rely on external shoe motion to infer in-shoe foot motion (Arnold and Bishop, 2013).

Future technological advances in CGA may enable the better understanding of the effects of shoes on foot kinematics. An example of this is dynamic radiographic GA technology, where the shoe can simply be ‘seen through’ and ignored. Such studies are becoming available, but as yet these methods of researching kinematics have looked at the effect of footwear while running only (Anselmo *et al.*, 2018). This study concluded frontal plane rearfoot motion was considerably more than observed footwear motion.

The option of limiting the RTCGA instrument to barefoot analysis would greatly reduce its validity in mostly shod populations (such as the UK). In addition, many of our treatments include the changing of footwear or the adding of orthoses to footwear. The possibility to exclude the foot segment altogether would also reduce the validity of the assessment due to the previously stated theoretical and clinical importance of the foot in gait. Accepting inherent errors means to accept poor assessment validity. None of these outcomes appear satisfactory, and the approach to this taken by MSK podiatrists while performing RTCGA is unknown. It was therefore concluded that without further technology to understand how the foot and different shoes work together, that the RTCGA instrument did not represent a valid method of foot measures.

Lack of kinematic normative data

Gluud and Gluud (2005) suggest that when establishing normal data the sample must be large enough to examine the potential influence of characteristics such as sex, age, time of day, physical activity, and exposure to drugs. Characteristics which have an influence on gait include age, weight, opioid use, race, time of the day and between day variability, walking speed and gender (Byrne *et al.*, 2002; Chehab, Andriacchi and Favre, 2017; Horst *et al.*, 2017; Henriksen *et al.*, 2019; Wilson *et al.*, 2019; Hill *et al.*, 2020).

The foot segment can be used as an example to demonstrate the difficulties in establishing normative data values. The largest amount of normative foot kinematic data relative to the proposed RTCGA instrument relates to frontal plane motion of the rearfoot in relation to the leg. Four studies regarding this in healthy individuals are available (Youberg *et al.*, 2005; Cornwall and McPoil, 2009; Chuter, 2010; Zhang, Paquette and Zhang, 2013)

Youberg *et al*. (2005) recruited 40 individuals (20 men and 20 women) aged 23 to 44 years (mean ± SD, 28.5 ± 5.3,). The subjects had a mean ± SD body mass 72.9 ± 13.5 kg.

Cornwall and McPoil (2009) studied 279 individuals (119 men and 160 women) aged 18 to 45 years (mean ± SD, 27 ± 4.2 years). The participants had a mean ± SD body mass of 70.2 ± 12.8 kg.

Chuter *et al.* (2010) used a sample of 20 male and 20 female participants but separated these into 2 gender balanced groups depending on a normal or pronated FPI-6 score. Mean age for the study group was age 32.4 yrs (SD ± 4.7 yrs) and mean weight 69.5kg (SD ± 4.1 kg). Only data for the right foot was included.

Zhang, Paquette and Zhang (2013) recruited 10 healthy male participants aged 25.8 ± 4.83 years and 76.4 ± 7.19 kg weight.

Summarising the above, our available rearfoot motion normative data appears to be available only from one age range (young adults). Weight is moderately

variable between studies, but no details are available to differentiate between the findings of ages or weight of the recruits to relate to rearfoot motion findings. There is no mention of sample ethnicity or the time-of-day data was collected. It is doubtful if the above would be adequate to meet Gluud and Gluud's (2005) requirements to establish healthy sample normal data being inclusive of all possible influential characteristics. We appear to have no data at all regarding older adults.

These studies also are only conducted barefoot. There exists no normal data repository for foot walking kinematics shod. This is not surprising as footwear design and choice has multiple variations. For example, foot kinematic measurements may not be the same in a slipper as it is in walking shoes. If a patient gets heel pain in both (while out walking or around the home) then GA may be valid in both, but the normal kinematic values to compare observations to is not known. If knowledge of the foot movement inside a shoe was known, then a rule of thumb may theoretically be applied. However, all previous 3D kinematic or dynamic radiographic data has been conducted on barefoot samples, running samples or in Sandals (Morio *et al.*, 2009; Chuter, 2010; Bishop, Hillier and Thewlis, 2017; Anselmo *et al.*, 2018).

Moissenent *et al.* (2019), published after stage 1 thesis development, found that there is not enough normal value data for CGA to quantify and record the magnitude of deviations from. Put another way, there is not enough normal kinematic data from which to diagnose abnormal kinematic data. They concluded the development of a normal data repository would require a vast amount of resources and time which are not forthcoming. True normal kinematic values in a healthy population are therefore not available, meaning there are no established CTVs and so no way to propose further SRVs. The development process used for RTCGA instrument depended upon these values to diagnose normal or abnormal kinematics. In the absence of this data, this process is flawed.

Horst *et al.* (2017) have also concluded a further fundamental issue with GA. They contest that gait changes throughout the day, and that the idea that gait patterns that are assumed to be near constant over time needs to be reconsidered. If a system is continuously changing by itself, then what is normal for that system is

also changing throughout the day. There may therefore be more variables to normative kinematic data than was previously assumed. They conclude that GA has to be reconsidered in the context of these findings, not only towards being more individualised but also towards situational diagnosis, therapy and evaluation of treatment effects (Horst *et al.*, 2017; Horst, Mildner and Schöllhorn, 2017). In addition, intervention outcomes may not be that at all, but just a natural variation in gait.

The premise therefore that a diagnostic instrument could be made to detect a normal or abnormal RTCGA observation, or if an observation following an intervention was closer or further from the normal gait pattern, is currently flawed. There appears no substantive literature upon which to establish normal values, and any changes to a gait observation not immediately observed may just be part of a natural variation found in walking.

Complexity of the instrument

An initial preliminary conceptual decision was for the RTCGA instrument to be relatively short and simple to complete (section 5.3.1, Chapter 5, pages 63-65). The RTCGA instrument has 26 observations to undertake, with 11 sums of scores to complete and interpret. It is fair to assume that this is not simple or short to complete, but whether this is complex to a point to deter use by MSK podiatrists is not known.

5.6 Conclusion

Although this chapter has pragmatically created a RTCGA instrument as a method by which to provide a best practice approach, this process has multiple flaws and causes for concern. The following advances in knowledge are required to address the concerns relating to achieving the conceptual aims of the RTCGA instrument:

1) A large interdisciplinary development group to reduce one-author and one-profession bias. One profession could still be highlighted as an aim for the RTCGA instrument, but knowledge from other professions that undertake RTCGA should not be avoided.

2) Knowledge on current RTCGA methods. This information was not available from literature, and original research to establish the use and methods of RTCGA would need to be undertaken.

3) A kinematic normal values data repository. This would permit the creation of SRVs and enable the diagnosis of gait as normal or abnormal. In addition, it would allow the diagnosis of gait patterns becoming closer to or further from the SRVs following intervention. However, inter-day variations in kinematics would need to also be acknowledged.

4) Research to establish if foot kinematics can be inferred from shoe kinematics.

5) Expert opinion on the complexity and length of the RTCGA instrument, and if this would be a barrier to its clinical implementation.

5.7 How stage 3 informed stage 4

There is a lack of guiding literature and evidence for the development of a RTCGA best practice approach. Stage 3 explored the methods by which a RTCGA best approach could be developed ‘de novo’, resulting in the creation of a preliminary objective RTCGA instrument. Following the creation of the RTCGA instrument (stage 3), preclinical phase 0 testing (see Table 5.1, Chapter 5, page 62) was required to establish the validity and reliability of this new approach (stage 4).

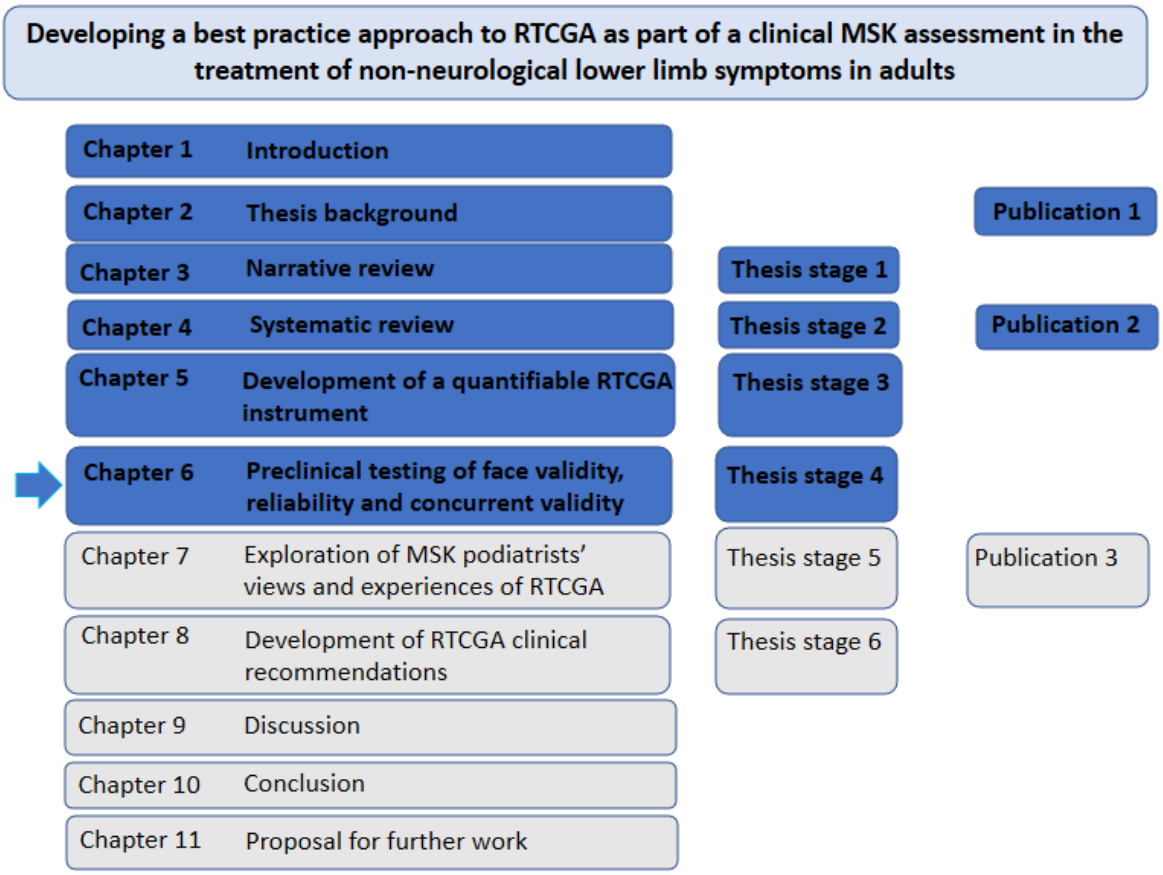
Chapter 6 Preclinical testing of face validity, reliability and concurrent validity

6.1 Introduction

Chapter 5 resulted in the creation of the preliminary objective quantifiable RTCGA instrument as a best practice approach to RTCGA, using development frameworks from Streiner, Normal and Cairney (2015) and Colli *et al*. (2014). Continuing to employ the same development methods, this RTCGA instrument next required preclinical testing to begin the process of establishing the validity and reliability of the new approach (see Figure 5.2, Chapter 5, page 63). The RTCGA instrument was created 'de novo' due to the lack of significant or robust guiding literature. This was also true with regards to the methods of testing for the RTCGA instrument. No guiding or informative literature upon testing was available. Gait laboratory based feasibility experiments to determine what could and could not be successfully tested were therefore undertaken.

This chapter describes stage 4; face validity and gait laboratory-based investigations. During this step, amendments to the RTCGA instrument were attempted to address problems which arose during face validity testing. This amendment consisted of the creation of a RTCGA immediate intervention score. Development of the total RTCGA instrument therefore continued within stage 4, as demonstrated chronologically in Figure 1.1 (page 4). This further RTCGA instrument development is introduced briefly within the chapter, and in complete form for further information as appendix C (pages 204-210). Figure 6.1 (page 106) demonstrates Chapter 6 within the context of an overview of the doctoral thesis.

Figure 6.1 – Doctoral thesis overview demonstrating Chapter 6 within the context of the programme of work



6.2 Preclinical testing of the preliminary RTCGA instrument

The preliminary objective RTCGA instrument presented in section 5.4 (Chapter 5, pages 91-96) was developed via the use of frameworks and approaches to determine the items and methods of observation which should be included in a best practice approach.

Following the development strategy outlined in Figure 5.2 (page 63), the next developmental step was to test the RTCGA instrument for both validity and reliability (preclinical).

Without available pre-existing evidence and guidance on testing of RTCGA procedures, it was initially important to assess the viability of available testing methods. This would in turn direct the content of the RTCGA instrument, as

measures and methods which could not undergo the scrutiny of recommended testing could not be included within the final approach.

Two preclinical testing methods were assessed, face validity via the implementation of scenario testing (sections 6.2.1 and 6.2.2, Chapter 6, pages 107-11), and reliability and validity testing by gait laboratory-based investigations (sections 6.2.3 and 6.2.4, Chapter 6, pages 111-120). These make up phase 0 of the 5 phases of diagnostic instrument testing (Colli *et al.*, 2014), the preclinical assessment of validity and reliability (Table 5.1, Chapter 5, page 62).

6.2.1 Testing face validity of the preliminary RTCGA instrument

Face validity was studied via scenario testing. Face validity may be defined as whether, on the face of it, the instrument appears to be assessing the desired qualities (Streiner, Norman and Cairney, 2015). The desired qualities of the preliminary RTCGA instrument have been established previously within the conceptual aims. These were that the best practice approach would provide an accurate diagnosis of abnormal gait, provide an accurate diagnosis of gait changes following intervention, and be relatively short and simple to complete (section 5.3.1, Chapter 5, pages 63-65).

With the lack of evidence by which to predict the range, success or outcome of any testing method, face validity testing was conducted in-house. In-house testing allows greater control of the process while obtaining quick responses with minimal set up and recruitment concerns (Elragal and El Kommos, 2012). Any required changes in testing methods or the RTCGA instrument could therefore be applied quickly with minimal economic consequence.

Face validity was determined by testing the RTCGA instrument around fictional clinical scenarios. Scenario testing, which is most frequently used for testing software, uses hypothetical stories to help work through a problem to test a process or system. It highlights requirement-related, or conceptual aim related, issues (Kaner, 2003). The premise of this method is to avoid step-by-step testing instructions with expected results and instead replace them with a narrative giving

freedom to the tester while confining the scope of the test (Crispin and Gregory, 2009).

Kaner (2003) states the following 5 requirements are necessary for a scenario to be beneficial:

1. The test is based on a theoretical story.

2. The story is motivating.

3. The story is credible and would likely occur in the real world.

4. The story involves a complex use of the process or system or a complex set of data.

5. The test results are easy to evaluate. This is valuable for all tests but is especially important for scenarios because they are complex.

Fictional scenarios were created based on these 5 requirements, to represent a range of MSK lower limb gait patterns and presentations:

The following scenarios were used:

I. Excessive pronation related gait patterns.

Gait patterns associated with a bilateral increased rearfoot eversion pattern (REP) were used (see Table C1, appendix C, page 204). Observations applied were rearfoot and rearshoe eversion angles of greater than 5 degrees and a lack of both rearfoot inversion and external knee rotation following the contact period (see SRVs, Table 5.2, Chapter 5, pages 92).

II. Excessive supination related gait patterns.

Gait patterns associated with a bilateral increased rearfoot inversion pattern (RIP) were used (see Table C1, appendix C, page 204). Observations applied were rearfoot and shoe inversion at contact phase, rearfoot inversion of 1 degree or

greater, and internal knee rotation during the contact period (see SRVs, Table 5.2, Chapter 5, pages 92).

III. Gait patterns associated with a lack of joint motion at the ankle, knee, hip, back and pelvis and upper limbs.

Observation scenarios were used where bilaterally all motions were less than those noted within the SRVs (Table 5.2, Chapter 5, page 92)

IV. Gait patterns associated with excessive joint motion at the knee, hip and back and pelvis.

Observation scenarios were used where bilaterally all motions were greater than those noted within the SRVs (Table 5.2, Chapter 5, page 92)

V. Small positive (closer to the SRV) and negative (further from the SRV) changes in gait kinematics following therapeutic intervention for scenarios I. to IV.

Scenarios I. to IV. were repeated following the intervention designed to decrease pronation or supination and / or increase or decrease joint motion.

VI. Large positive (closer to the SRV) and negative (further from the SRV) changes in gait kinematics following therapeutic intervention for scenarios I. to IV.

Scenarios I. to IV. were repeated following the intervention designed to decrease pronation or supination and / or increase or decrease joint motion.

Combinations of presentations of kinematic observations and intervention outcomes were then completed to obtain motivating and credible testing scenarios (Kaner, 2003). This process was completed in-house by the thesis author. A preliminary RTCGA instrument scoring sheet (Figure 5.4.2, Chapter 5, page 96) was completed for each of the scenarios and an assessment made on whether

the results met the RTCGA instrument conceptual aims. An example of the combined presentation scenario testing is presented as appendix D (pages 211-223).

As demonstrated by the example in appendix D (pages 211-223), the preliminary RTCGA instrument responded well to scenario testing for the observation and scoring to diagnose gait kinematics that deviated from the SRVs in the scenarios used.

However, in intervention scenarios the instrument failed to detect and score positive kinematic changes unless it was of a magnitude to represent the SRV. Large or small negative kinematic changes were only noted if they crossed the SRV. In addition, if the observation was already outside of the SRV, and the intervention made the kinematic observation further from the SRV, this did not alter the score.

Therefore, although the preliminary objective RTCGA instrument met the first conceptual aim of providing an accurate diagnosis of abnormal gait, it failed to provide an accurate diagnosis of gait changes following intervention. Further development of the preliminary RTCGA instrument was required to increase the ability of the approach to accurately detect and measure changes, positive or negative, following therapeutic intervention.

The testing of face validity employing scenario testing, appeared successful.

6.2.2 The development and face validity testing of the preliminary RTCGA instrument immediate intervention score

The development and investigation of an immediate intervention element of the RTCGA instrument were undertaken to detect for kinematic changes following intervention.

Following this amendment, the preliminary RTCGA instrument consisted of 2 sections, the first a score in relation to SRVs (the previously described RTCGA instrument score, see section 5.4, Chapter 5, pages 91-96) and the second to detect changes in gait following intervention (the RTCGA instrument immediate

intervention score). This development and additional section is included as appendix C (pages 204-211).

The RTCGA instrument immediate intervention score was run through the same multiple theoretical clinical case scenarios as the preliminary RTCGA instrument (see section 6.2.1, Chapter 6, pages 107-110).

The RTCGA instrument immediate intervention score worked well for the theoretical scoring of immediate kinematic changes following therapeutic intervention, as demonstrated by an example in appendix E (pages 223-235). Both small and large changes resulted in a change to scoring.

Face validity testing of the preliminary RTCGA instrument and immediate intervention score appeared satisfactory in relation to providing an accurate diagnosis of abnormal gait and an accurate diagnosis of gait changes following intervention. At this stage it became apparent that the developing RTCGA instrument may not be adequately meeting the third of the conceptual aims, for the best practice approach to be relatively short and simple to complete. This is discussed further within this chapter discussion (section 6.3.1, Chapter 6, page 121).

6.2.3 Reliability and validity testing

The preclinical reliability and concurrent validity testing of the preliminary RTCGA instrument made up part of the developmental framework phase 0 testing. This chronologically overlapped with the preclinical testing of face validity (see sections 6.2.1 and 6.2.2, Chapter 6, pages 107-111).

Reliability and validity are concepts that have a positive connotation in relation to measurements and observations. For any procedure to be characterised as reliable and valid is to be described in positive terms (Carmines and Zeller, 1979). A third psychometric property used to assess the usefulness of a functional measure in clinical decision making is responsiveness (Adams and Cerny, 2018).

Validity may be defined as the extent to which any measuring instrument or tool measures what it is intended to measure for the purpose for which it is being

used. Reliability concerns the degree to which results are consistent across repeated measurements (Carmines and Zeller, 1979; Heale and Twycross, 2015).

RTCGA instrument preclinical testing is concerned with criterion related validity, defined as the extent to which a measure is related to an outcome. Criterion validity involves the correlation between the test and criterion variables. It compares the test results with other results (the criteria) already held to be valid (Heale and Twycross, 2015). For this study it was proposed to compare the expert observer's RTCGA instrument scores (the test variables) with the 3D Vicon system (Vicon Motion Systems Ltd UK) obtained scores (the criterion variables). A high level of criterion validity would demonstrate expert clinicians could use the RTCGA instrument and be reasonably confident that the specific gait patterns or changes they are scoring would be similar to that obtained by a 3D Vicon system analysis.

Within this type of validity there are 2 sub-groups, predictive validity (the comparison by which the test predicts what it is supposed to predict) and concurrent validity (the comparison between the measure in question and an outcome assessed at the same time) (Carmines and Zeller, 1979; Twycross and Shields, 2004). When used in clinic, for the RTCGA instrument to have worth, it would need to measure or score what the clinician is seeing at that time. The research for this stage of design and testing is therefore looking to assess the criterion related concurrent validity of the RTCGA instrument and its individual components.

Same-tester (intra-tester) and different tester (inter-tester) reliability would be investigated as part of preclinical RTCGA instrument testing. A high level of intra-tester reliability would demonstrate a clinician could repeatedly use the RTCGA instrument and be confident of similar results. For inter-tester reliability, a high level of agreement would lead to confidence that the RTCGA instrument result from one clinician would be similar to other clinicians.

Responsiveness of GA measures may be expressed in terms of minimal clinically significant difference (Adams and Cerny, 2018). This property would be

investigated as part of phase 2 clinical testing, and so is not included at this preliminary phase 0 (see Table 5.1, Chapter 5, page 62).

This phase 0 testing served 2 purposes. Firstly, to test the preliminary RTCGA measures for reliability and validity, and by doing so further evaluate what measures would be best included or require excluding from the final RTCGA instrument. There is a practical challenge with making multiple kinematic observations during stance phases of short durations. Perry and Burnfield (2010a) note that RTCGA may be more suited to noting gross, rather than subtle, gait abnormality. However, they go on to state a systematic RTCGA approach (such as the RTCGA instrument) may aid in the recognition of “highly significant” and “more subtle” deviations. Currently the validity and reliability of MSK RTCGA observations, large or small, is unknown (see section 3.5.2, Chapter 3, page 33).

Secondly, phase 0 testing was required to explore the viability of testing methods. With a lack of literature surrounding previous RTCGA development and testing, methods used would be without prior founding research. If observations or approaches within the preliminary RTCGA demonstrated difficulty to test, then these areas would be less likely to be included within the RTCGA instrument.

Reliability and concurrent validity were proposed to be judged using a repeated measures design employing clinically representative kinematic presentations and variations. Using modified insoles, the aim was to impose an abnormal kinematic pattern of gait on a healthy participant. This would allow assessment of both healthy individual gait without the insoles and a transiently induced abnormal kinematic gait pattern with them. Insoles which would reduce the ability of the hip and knee to extend and increase the REP (see appendix C, pages 204-211) of gait were used.

Lower and upper limb kinematics relevant to the RTCGA instrument (foot, ankle, knee, hip, back and pelvis and upper limb) were measured using the 3D Vicon system. The 3D Vicon system is recognised as the gold standard system for GA, in terms of both validity and reliability of data collected, and is used to establish concurrent validity of new GA systems (Barker *et al.*, 2006; Windolf, Götzen and Morlock, 2008; Tanaka *et al.*, 2018; Albert *et al.*, 2020; Ota *et al.*, 2021). For this

3D motion capture, passive reflective markers were attached to the study participants' lower limbs, lower back, upper limbs and the study plimsoll. During this process both sagittal and frontal plane webcam recordings were taken using Dartfish 2D Motion Capture Analysis (Dartfish Ltd, Switzerland). Dartfish 2D Motion Capture Analysis was used for simple video capture only, and chosen for its previous use in GA research (Borel, Schneider and Newman, 2011; Nantsupawat *et al.*, 2015)

RTCGA instrument scores from expert MSK podiatrists from 2D recordings would then be compared between themselves (intra-tester reliability), each other (inter-tester reliability) and to gold standard measurements obtained from a 3D Vicon system (concurrent validity).

Before progressing to the point of recruiting expert MSK podiatrists to observe and score walking participants, a review of the methods and the Vicon system 3D data collected was undertaken.

Ethics committee approval was obtained on 5/11/18 (reference: 41636). Volunteers were recruited via poster presentations (see appendices F and G, pages 236 and 237), were supplied with participant information sheets (appendix H, pages 238-244) and completed participation consent forms (appendix I, pages 244-247). Three healthy volunteers were recruited.

Volunteer characteristics are shown in Table 6.1.

Table 6.1. Volunteer characteristics

Volunteer	Gender	Age	BMI
1	Female	43	19.1
2	Male	39	24.3
3	Male	32	26.0

The insoles had a stiff 3mm polypropylene base with a lateral 8-degree rearfoot post (Figures 6.2.1 and 6.2.2, page 115). The polypropylene was covered by 1mm EVA to prevent the foot slipping which may cause discomfort. Identical pairs were

used. Similar insoles have been demonstrated to decrease sagittal plane lower limb motion and increase rearfoot eversion (Hall and Nester, 2004; Shaw *et al.*, 2018), and both these changes in motion have theoretically been linked to a concomitant decrease in knee extension (Harradine, Bevan and Carter, 2006).

Figure 6.2.1. A stiff insole made from 3mm polypropylene base material with an 8-degree lateral rearfoot hemi post. © University of Southampton.

Figure 6.2.2. The same insole with an inclinometer smart phone app demonstrating the 8-degree lateral rearfoot wedging. © University of Southampton.

Participants wore a plimsoll with an outer sole of uniform-hardness and simple cross-section and walked upon a 12 metre walkway with an 8 metre length capture zone. The study participants walked at a self-selected speed. 3 walks were completed for each condition and data averaged.

Preliminary results were analysed to assess changes in gait with each of the insole conditions. No consistently significant or expected kinematic changes observed using the 3D Vicon system, in any of the test conditions, were found. Any changes which did occur did not move kinematic results from matching a SRV to being outside the SRVP. In addition, although volunteers were healthy and symptom free, kinematics at times did not match SRVs prior to insole intervention.

These results are demonstrated in Figures 6.3.1 to 6.4.3 using examples of rearshoe to leg and sagittal plane knee and hip kinematics. The first 60% (approximate stance phase length) is discussed. For the purpose of the graphs the term “insole” and “orthotic” are used interchangeably.

Figures 6.3.1, 6.3.2 and 6.3.3 (pages 116-117) demonstrate the right rearshoe, knee and hip for one volunteer respectively. The right rearshoe did demonstrate greater eversion through the stance phase, but not to a point where it became greater than the SRV of 5 degrees everted. The right knee kinematics remained within the SRVs, with a slight increase in flexion with the insole only apparent at the terminal stance phase. This change would not be scored within the preliminary RTCGA instrument as it does not relate to the SRVs. The right hip closely followed the SRVs but with the insole there was a small decrease in stance phase total extension. This change appears to be small but may possibly cross the SRV of 15 degrees of extension.

Figure 6.3.1 Right rearshoe to leg motion

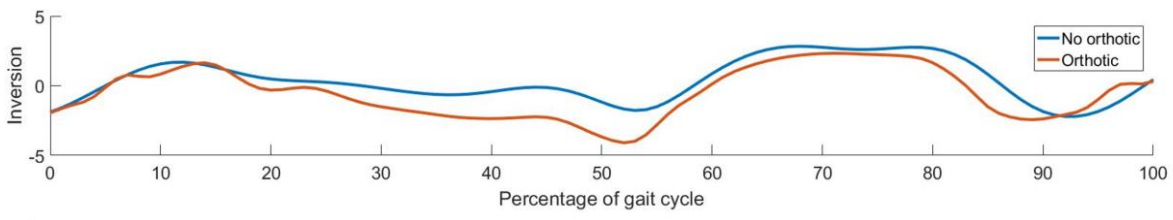


Figure 6.3.2. Right sagittal plane knee motion

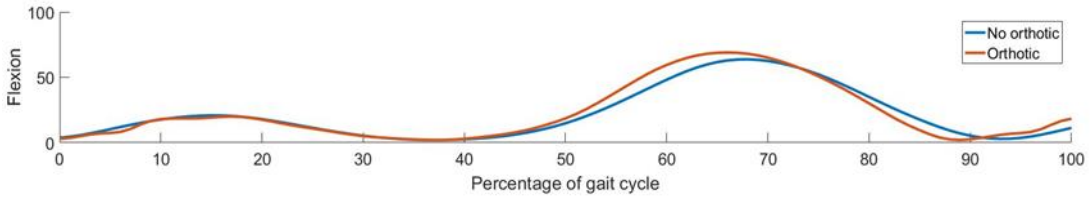
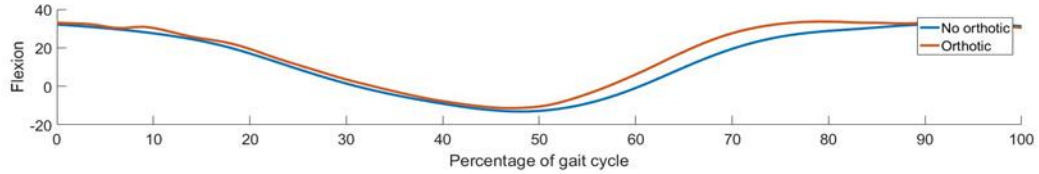


Figure 6.3.3. Right sagittal plane hip motion



Figures 6.4.1, 6.4.2 and 6.4.3 (pages 117-118) demonstrate the left rearshoe, knee and hip for a different volunteer. Without the insole, the rearshoe demonstrated inversion at contact. With the insole there was brief inversion, but then eversion. The insole condition represented the SRV more closely than the none-insole condition. Maximum rearshoe eversion is slightly greater without the insole. The left knee extended (hyperextended) greater than the SRV both with and without the insole, but less so with the insole. The insole pattern therefore matched SRVs more closely. Similar hip extension and flexion with or without the insole occurred. The timing of this motion did change, with maximum hip flexion and extension occurring later in the gait cycle without the insoles. An unexpected finding was the left hip began flexed and then extended with the insole (a more normal pattern), while the none-insole hip began at 0 degrees and then flexed. In this case it appears the insole data matched normative kinematics more closely than the non-insole data. However, none of these hip changes would have altered the RTCGA score, as there was no change to maximum hip extension.

Figure 6.4.1 left rearshoe to leg motion

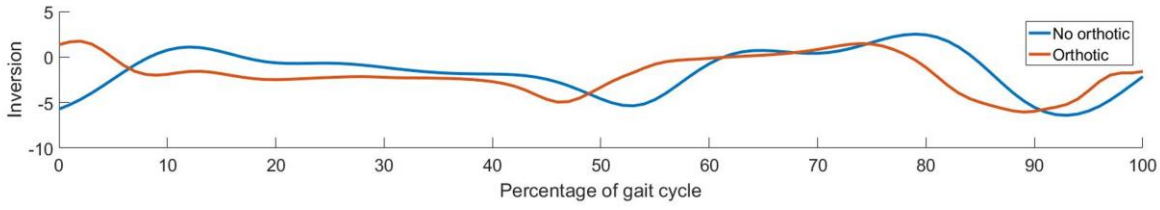


Figure 6.4.2. Left knee sagittal plane motion

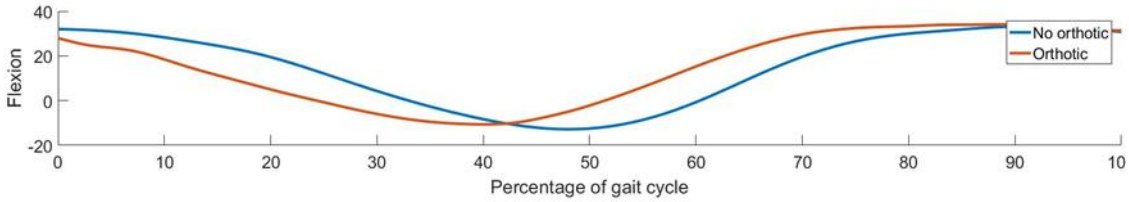
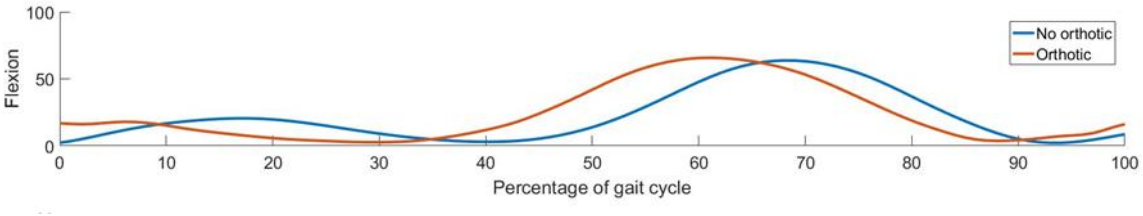


Figure 6.4.3. Left hip sagittal plane motion



In addition to the concerns regarding the attempt to impose adequate changes volunteer kinematics, several serious methodological issues also arose with regards to the 2D webcam data. Firstly, it was noted the validity of the observation relating to a clinical comparison was reduced as the subjects had anatomical markers on then. This would theoretically aid in the observation of the subjects by allowing greater visualisation of segments. Secondly, the on-screen observation of a patient walking was very small with no focus on sections observed. It permitted no movement of the observer to obtain a closer or better view of segments as the subject walked past or towards them. 2D webcams were placed at the end of the walkway (for the frontal plane observation) and to the side (for sagittal plane observation). The sagittal plane observation was required to be at a distance from the walkway to capture a complete gait cycle and the entire walking participant (head to toe). The validity of comparing on-screen assessments to that conducted real time in a clinic was therefore highlighted as a concern, and methods by which to reduce this issue proposed. Lastly, using Dartfish playback technology, it was possible to play insole and no insole walking conditions side-by-side on the same screen to permit immediate visual comparison. The data was also able to be paused and slow-motion playback utilised. This process was conducted to assess for the changes in gait that could be observed on the 2D images. Although the small and inconsistent kinematic variations were later noted

from evaluation of 3D Vicon data, no visible changes were apparent on the 2D observations. It was therefore deemed very unlikely that podiatrists watching the 2D gait videos without the ability to make side-by-side comparisons and slow or pause the images would be able to do so either. A method by which to make larger, more consistent changes to gait was therefore required.

These studies demonstrated the proposed methods by which to test reliability and concurrent validity required revising. The attempted changes to address these issues are described in the next section (section 6.2.4. Chapter 6, pages 119-120).

6.2.4 Amended reliability and concurrent validity testing

To negate the requirement of insoles to make clinically significant changes to gait it was proposed to assess if one person (the thesis author) could “act out” gait patterns which did not match the SRVs. It was anticipated that by intentionally walking in set patterns that kinematic changes would be both predictable and of a magnitude to permit testing.

To address the issue of the validity of still 2D webcam recording playback as a representation of RTCGA observations, an experiment with moving the 2D cameras into different positions during data collection was proposed. It was intended that several positioning options should be made available for future MSK podiatrist observers of the video to choose, thereby increasing the validity of these 2D recordings. The position MSK clinicians use in terms of GA procedures is unknown, and so a variety of webcam positions were planned to be recorded. 2D webcams were attempted to be positioned by the side of the walkway at a 45-degree angle in the transverse plane, to capture data of combined sagittal and frontal plane observations. In the sagittal plane, camera positions more adjacent to the walkway set at both higher and lower levels were attempted to permit closer scrutiny of the upper or lower body quadrant respectively. Frontal plane images would be captured as before.

Ethical committee approval for the required amendments was received on 23/01/19 (41636.A1).

The suggested moving and multiple positions of the 2D camera caused direct obstruction of the 3D Vicon camera data collection. Proposed variations in 2D camera position to increase the validity of recorded observations in relation of in-clinic RTCGA was not possible.

3D Vicon data of the acted variations to kinematics was collected but not analysed due to the above incomplete data collection with obscuring from the 2D camera placement.

Due to the failure of the amended 2D video capture to supply valid data for validity and reliability testing without possible obstruction of 3D capture, further methodology changes appeared to be required. However, at this time a review and “sense checking” of the outcomes of development to this point was conducted. These are discussed further as a whole in the following section, 6.3.

6.3 Discussion

Stages 1-4 developed a preliminary approach as an objective quantifiable RTCGA instrument. This consisted of a collection of observed measures designed to evaluate and diagnose a patient’s gait, not only before treatment but also after, in the most concise and simple manner (section 5.3.1, Chapter 5, pages 63-65). This development was conducted via the framework and strategies proposed earlier in the same chapter (section 5.2, Chapter 2, pages 58-60).

At the final phase of stage 4, further appraisal of the process to this point was initiated. Many areas of the testing process from this chapter caused concern relating to the ability of the objective RTCGA instrument to fulfil its conceptual aims.

These concerns are discussed under 2 headings, firstly the amendment of the RTCGA instrument following the assessment of face validity. Secondly, the methods by which preclinical reliability and concurrent validity were investigated.

6.3.1 Concerns regarding preliminary RTCGA instrument face validity testing outcomes

Through face validity studies as part of Phase 0 testing (Colli *et al.*, 2014), this preliminary RTCGA instrument was amended to include the RTCGA instrument immediate intervention score (appendix C, pages 204-211). This inclusion raised further concerns with regards to the RTCGA instrument meeting the conceptual aims of being relatively short and simple to complete (section 5.3.1, Chapter 5, pages 63-65). The RTCGA instrument, following inclusion of the immediate intervention score, now has at least 20 observations to complete each side with selections of different forms with differing observations depending on findings from the initial RTCGA score. This added level of complexity would further distance the RTCGA instrument from its conceptual requirement to be simple or short to complete.

6.3.2 Concerns regarding the methods by which preclinical reliability and concurrent validity were investigated.

Methods by which to transiently alter kinematics

Insole-imposed test conditions did not produce significant or predicted changes to gait detectable by the 3D Vicon system. Gait kinematic patterns which did or did not match the SRVs were essential to progress the investigation of reliability and validity of the RTCGA instrument.

These results suggest the initial data collection was not suitable for Phase 0 testing (preclinical reliability and validity) of the RTCGA instrument. As this testing is essential for further development, understanding and rectifying the possible reasons for the failure to collect adequate data needed to be considered.

When reviewing the literature, the changes to gait with either a stiff sole or lateral rearfoot wedging, although stated to be either statistically significant (Hall and Nester, 2004) or “large” (Shaw *et al.*, 2018), were possibly not of the magnitude or reliability that is required for this study. The mean difference in rearfoot eversion reported from the 7 papers included by Shaw *et al.* (2018) was less than 0.5 degrees, with studies reporting both greater and lesser amounts of eversion with

lateral rearfoot posting. Hall and Nester (2004) supply no quantifiable data on the decrease in hip extension in their paper, but instead present results in the form of graphs. It appears from these graphs the reduction in hip extension, although stated to be statistically significant, is less than 1 degree. It is unclear if all results were in the same direction. The insole type used to transiently change gait may therefore not only make changes too small to be reliably predictable in a 3 person sample, but the variability in change in direction of motion was not taken into consideration.

Although the combination of lateral posting to increase rearfoot eversion and a stiff sole to decrease the foot's ability to pivot may have theoretically predictive outcomes (greater rearfoot eversion and less hip and knee extension), there is no kinematic data to support this. Based on this lack of data, it was instead proposed that acting out of different kinematic patterns would be attempted. Although data collection for this study was incomplete, there appears no pre-existing data regarding past attempts to produce such kinematic presentations.

Obtaining 2D data similar to clinical observation

Several issues also arose with regards to the 2D webcam images. Validity of the observation relating to a clinical comparison was reduced as the subjects had anatomical markers on then. This would theoretically aid in the observation of the subjects by allowing greater visualisation of segments. In addition, the on-screen observation of a patient walking was small with no focus on sections observed. It permitted no movement of the observer to obtain a closer or better view of segments as the subject walked past or towards them.

6.4 Conclusion

The following advancements would be required to address these concerns which arose during the feasibility studies:

1) A recognised method by which kinematics can be altered to permit representative testing before and after intervention.

2) New technology to permit 3D Vicon assessment to be conducted without skin markers.

3) Cameras to permit independent movement and focusing on selected segments to reproduce clinician assessment for greater validity. Playback options would need to be individual and varied depending on the view required.

4) Technology to permit (3) without blocking or obstructing Vicon 3D cameras.

6.5 How stages 1-4 informed following stages

At the outset of this programme of work it was anticipated that a narrative review (stage 1) would confirm and detail the GA evidence gap already posited by the clinical and educational experience of thesis author (See section 1.1, Chapter 1, page 1). A systematic review (stage 2) would then supply sufficient literature and knowledge to confirm and address this evidence gap via the development (stage 3) and testing (stage 4) of a preliminary RTCGA instrument. If successful, a quantitative RTCGA instrument could then be presented as a best practice approach for general clinical use and undergo further diagnostic tool assessment and analysis. These predicted stages would be iterative and pragmatic in their philosophical stance. The approach would be deductive, testing current theory, and use quantitative statistics to test for reliability and validity of the objective RTCGA instrument observations.

This anticipated progression and outcome of stages 1-4 did not happen. Although the narrative review did establish an evidence gap in relation to GA and RTCGA (stage 1, Chapter 3, pages 29-42), the systematic review failed to find any robust knowledge with which to develop and then test a quantitative RTCGA instrument (stage 2, Chapter 4, pages 43-56). Instead, to address this evidence gap, health measure and diagnostic tool creation frameworks were used in the ‘de-novo’ development of a quantitative RTCGA instrument (stage 3, Chapter 5, pages 57-104), and preclinical testing of validity and reliability attempted (stage 4, Chapter 6, pages 105-124).

Six currently insurmountable issues arose during the development and testing stages of an objective RTCGA instrument (stages 3 and 4):

1) A lack of existing RTCGA knowledge.

2) Substantial exposure to developer bias.

3) The necessity to include shod gait assessment.

4) A lack of kinematic normative data.

5) The final complexity of the instrument.

6) An inability to transiently alter kinematics and obtain valid 2D data for testing.

Stages 1-4 did therefore not produce a positive outcome for these attempted developmental methods and strategies; however, it was an essential and successful evaluation of the legitimate processes available for the creation of a RTCGA best practice approach. At the conclusion of stage 4, a preliminary conclusion to the research question (section 3.9, Chapter 3, pages 41-42) can be drawn based upon the research findings to this point. It was not possible to create an objective quantifiable RTCGA instrument for use as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults.

Although an important finding by itself, this preliminary conclusion did not concur with narrative review results on the use of GA. RTCGA was noted as frequently recommended and a supposedly useful MSK clinical assessment method (see sections 3.5.1 and 3.5.2, Chapter 3, pages 31-35). Yet, no robust guidance or methods for its undertaking are available and methods to develop an objective approach encountered a collection of insurmountable obstacles.

The following stage (stage 5, Chapter 7, pages 125-144) was subsequently undertaken to address the lack of literature and knowledge surrounding the worth, use and methods of adult non-neurological MSK RTCGA.

Chapter 7 The exploration of MSK podiatrists' views and experiences of RTCGA

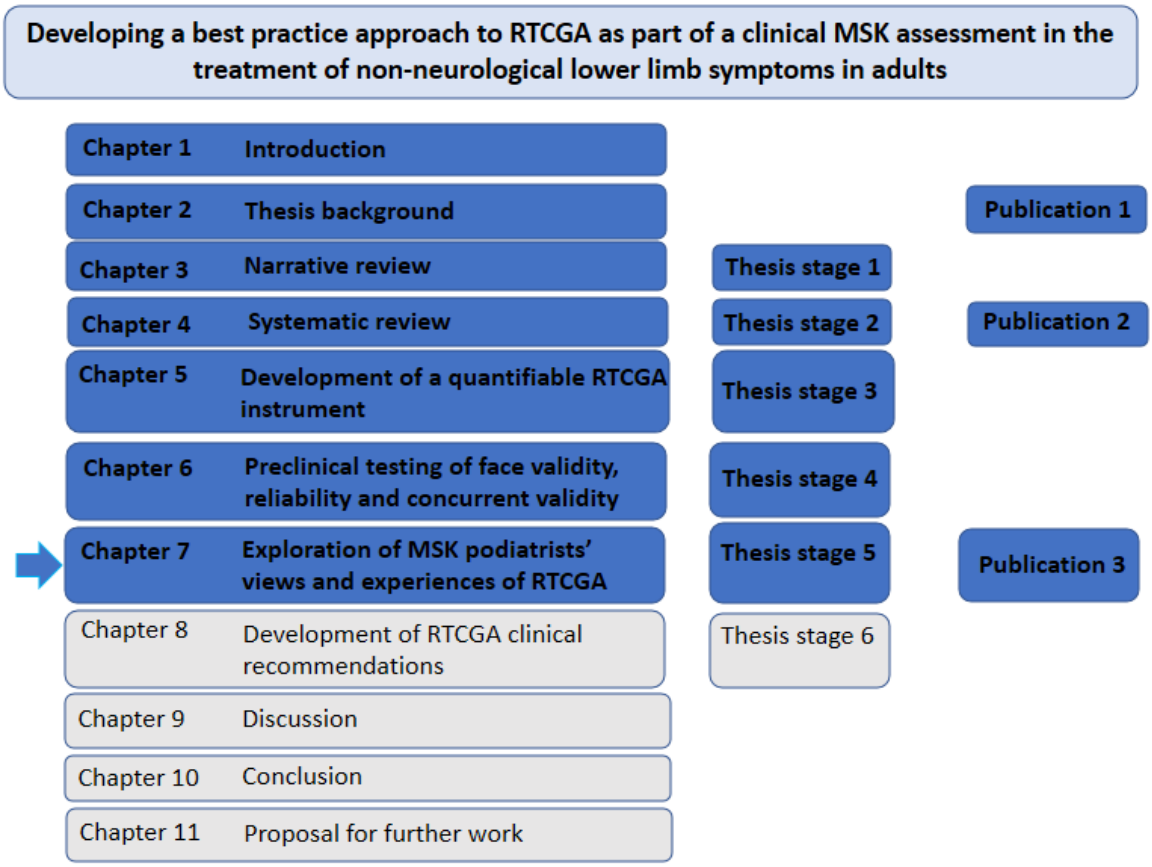
7.1 Introduction

The previous chapters revealed a gap in knowledge regarding the clinical aims, objectives and methods of RTCGA. An attempt to create an objective RTCGA instrument to address this evidence gap met currently insurmountable methodological obstacles. The results of stages 1-4 were not insuperable, but a change in approach was required, moving from quantitative to qualitative research approaches. By incorporating both methods, it was at this stage (stage 5) the overall programme of work methodology became a mixed methods approach. Stage progression is still iterate and the philosophical standing pragmatic, dealing with the practical rather than theoretical considerations of RTCGA. However, the approach became inductive, building a theory rather than testing one.

To increase the understanding and use of RTCGA, thematic analysis applied to semi-structured interviews was conducted to explore MSK podiatrists' views and experiences of RTCGA for patients with PTTD. Improving knowledge of MSK podiatrists' views and experiences of RTCGA increases understanding of the reasons why, and methods by which, it is performed. An increase in knowledge may lead to further recommendations to aid the RTCGA process. The aim of this study is to provide unique insights into some MSK podiatrists' use and opinions of RTCGA, using PTTD as an exemplar common adult condition for which RTCGA is used.

Figure 7.1 demonstrates Chapter 7 within an overview of the doctoral thesis (page 126).

Figure 7.1. Doctoral thesis overview demonstrating Chapter 7 within the context of the programme of work



This exploratory study was published and makes up the third publication within this doctoral thesis programme of work (Harradine *et al.*, 2021).

7.2 Method

7.2.1 Study design

This study has a descriptive phenomenological philosophical underpinning, using a qualitative methodology, featuring semi-structured in-depth one to one interviews to explore MSK podiatrists' use and opinions of RTCGA in patients with PTTD.

This study was carried out in full accordance with the Declaration of Helsinki on ethical principles. Ethical committee approval was granted by the University of Southampton Ethics and Research Governance Committee (Reference: 55599).

7.2.2 Participants

MSK podiatrists were recruited for this study. MSK Podiatry is an area of expertise within the podiatry profession. However, there exists no professional definition of a MSK podiatrist, and no specific qualification required to treat an adult MSK caseload in podiatry. Within this study MSK podiatrists were defined following Vernon's definition of expertise (Vernon, 2009), as podiatrists with at least 5 years of MSK experience and consulting at least weekly with patients with lower limb MSK injuries. Sample size was determined following the recommendation by Braun and Clark (Braun and Clarke, 2013); a purposive sample of 30 MSK podiatrists was identified.

Participants were recruited using a specialist Facebook group (MSK:UK) following permission from the group administrator. A message briefly outlining the study was posted, inviting potential volunteers to contact the thesis author via email (appendix J, page 247). A snowballing strategy through word-of-mouth was used to increase recruitment. All subsequent volunteers were sent an email with the participant information sheet, consent form and demographics form (appendices K – M, pages 248-256). All participants provided written informed consent

Recruitment strategy employed a purposive sampling framework to include podiatrists with at least 5 years clinical experience in treating MSK patients, weekly consultations with adult patients with lower limb injury, access to a computer with Skype and an email address for correspondence. To prevent any financial or corporate bias in relation to GA equipment podiatrists with affiliations or involvement in any organisation or entity with any financial interest in CGA equipment were excluded.

The research team, consisting of the PhD thesis author and supervisors, agreed a priori to cease data collection if data saturation occurred before 30 interviews, such that saturation refers to a point were additional interview data fails to generate new information (Glaser and Strauss, 1967; Morse, 1995; Sandelowski, 1995; Francis *et al.*, 2010).

7.2.3 MSK condition of focus

PTTD was selected as a focus condition in this study. As a common adult MSK foot and ankle problem treated by podiatrists (Durrant, Chockalingam and Hashmi, 2011; Richie, 2020), it was determined likely that MSK podiatrists would have a good awareness of the condition including diagnostic and treatment approaches. Although data of prevalence is limited (Gómez-Jurado, Juárez-Jiménez and Munuera-Martínez, 2021), incidence has been reported to be 3% of all women over the age of 40 and 10% of adults over 65 (Johnson and Strom, 1989; Kohls-Gatzoulis *et al.*, 2009). Foot orthoses are frequently recommended as non-operative treatment (Wapner and Chao, 1999; Kohls-Gatzoulis *et al.*, 2004; Trnka, 2004; Bluman, Title and Myerson, 2007; Kulig *et al.*, 2009) with a recent systematic review concluding the use of orthotic treatment may be effective in reducing pain in early PTTD stages (Gómez-Jurado, Juárez-Jiménez and Munuera-Martínez, 2021). In addition, changes in kinematics (increased rearfoot eversion, forefoot abduction and arch lowering) are predictable and documented (Rattanaprasert *et al.*, 1999; Tome *et al.*, 2006; Ness *et al.*, 2008; Houck *et al.*, 2009; Richie, 2020). It is therefore a condition that MSK podiatrists will both be aware of, and most likely be using RTCGA, at all stages of the patient treatment pathway.

7.2.4 Interviews

A semi-structured interview method was used to obtain rich and detailed data about individual experiences and perspectives of RTCGA (Morse, 1995). Using this method responses are determined to a greater extent by the participant; issues important to them, but not specifically included on the interview guide, can be explored (Hammersley and Atkinson, 2019). Interview questions were developed and approved by all authors. The interview guide is included as appendix N, (pages 257-258).

Interviews were conducted by the thesis author via Skype from the researcher's and participants' homes or places of work. This method of online face-to-face interviewing is more convenient for participants while still enabling observation of verbal and non-verbal cues (Janghorban, Roudsari and Taghipour, 2014). It has been suggested that there is little difference in the data quality between online

and face-to-face interviews, further supporting the use of online remote interviews (Weller, 2017; Robinson, Shin and Gangadharan, 2021). Transcription was completed within 48 hours of the interview, permitting ongoing assessment for saturation.

7.2.5 Pilot study

The first 3 interviews were included in a pilot study; used for reflection and to ensure the technology and methodology was appropriate, and the information obtained was adequate.

No change to methodology was required, therefore these first 3 interviews were also included in the main data analysis.

7.2.6 Data analysis

Data was transcribed by the thesis author using orthographic transcription (Jefferson, 2004) and video files deleted. Completed transcripts were imported into a data analysis package (N-Vivo 2020).

Following transcription, an inductive approach to thematic analysis of the data was undertaken (Braun and Clarke, 2013). The codes, themes and interpretations of data were discussed and agreed within the research team. Respondent validity was then sought, with summarised data being reviewed by 3 participants to ensure results accurately reflected their intents and meanings (Guest, MacQueen and Namey, 2012).

7.3 Results

Interviews were conducted between March and August 2020. Interview duration ranged from 11 minutes and 52 seconds to 39 minutes and 9 seconds, with a mean duration of 19 minutes and 9 seconds. Saturation occurred at the 29th interview, when incoming data for the last 3 interviews produced no further new information (Guest, MacQueen and Namey, 2012). No participants withdrew from the study.

Twenty-nine participants were therefore included in the study. All were based in the UK and practitioners in MSK podiatry with a range of characteristics described in detail in Table 7.1 (page 130).

Table 7.1 – Participant characteristics

Participant	Year Qualified	Weekly MSK caseload (% of hours worked)	Weekly MSK caseload (hours)	Weekly MSK caseload (Number of patients seen)	Duration of MSK Speciality (Years)	Private practice (PP) / NHS ratio	Additional Qualifications
1	2010	30	15	18	9	100% PP	None
2	1994	100	45	70	25	80% NHS 20% PP	MSc Theory of Podiatric Surgery
3	2009	100	32	45	7	100% NHS	MSc Podiatry
4	2000	80	28	40	18	100% PP	None
5	2000	80	25	40	18	100% PP	None
6	2009	100	38	50	11	95% NHS 5% PP	MSc Theory of Podiatric Surgery
7	2010	60	20	40	9	40% NHS 60% PP	None
8	2003	80	30	30	16	100% PP	None
9	2008	100	37.5	32	10	50% NHS 50% PP	MSc MSK studies (lower limb)
10	1999	100	24	36	12	100% NHS	MSc Clinical Biomechanics
11	1992	50	30	35	20	40% NHS 60% PP	PG Cert

12	1999	75	20	30	15	75% NHS 25% PP	MSc Theory of Podiatric Surgery
13	2014	25	8	10	5	100% NHS	MSc
14	2005	70	25	20	10	20% NHS 80% PP	MSc
15	2001	75	30	22	17	100% NHS	MSc Clinical Biomechanics
16	1994	90	45	40	25	100% PP	MSc Podiatry
17	1992	40	12	25	28	100% PP	None
18	1988	10	4	5	32	100% NHS	None
19	1987	25	10	10	30	100% PP	None
20	1996	20	6	4	20	100% PP	None
21	2009	30	6	7	11	100% PP	PG Dip
22	1990	100	35	60	30	100% NHS	MSc Clinical Biomechanics
23	2007	80	22	32	13	100% PP	None
24	2002	100	19	28	15	100% NHS	None
25	1991	50	17.5	16	30	100% PP	PhD
26	2003	15	3	3	13	100% PP	None
27	2003	80	28	28	17	10% NHS 90% PP	None

28	2003	100	25	30	15	100% PP	MSc Sports Podiatry
29	1995	98	35	80	25	100% PP	PG Dip Biomechanics
Average	2000	68	23	31	17	62%PP 38%NHS	NA

The 3 participants contacted for respondent validity confirmed the study results accurately reflected their intents and meanings.

Five key themes were identified using thematic analysis: 1) RTCGA method; 2) Working with RTCGA; 3) RTCGA uses; 4) What could aid RTCGA?; 5) How RTCGA skills are acquired. An abridged summary, with excerpts of data drawn from the transcripts, is presented below. Non-verbal utterances (e.g., er, erm), repeated words and thinking pauses have been removed to improve the reading process. A Word cloud, to demonstrate word frequency, is presented as appendix O (page 259).

7.3.1 Theme 1: RTCGA method

This theme explains RTCGA methods and procedures. This includes not only the physical observation itself, but also how the findings are documented.

All participants reported performing RTCGA at some time, even if they also had access to equipment or technology to perform CGA, however the processes employed varied between participants. Commonly the RTCGA process begins when the patient walks into the clinic, allowing an observation thought to be more valid as a relaxed unobserved gait pattern.

"So when I do gait analysis to start with I always collect the patient from the waiting room so I look at how they get up, how they walk back to the clinic because that is a little bit of a walk and they get in front of me and that's usually quite good because although they've got their shoes on they're not self-conscious" (Int 15).

When the process of RTCGA is performed and the patient is aware of the observation, participants reported that they will assess their patient walk in the best environment they have available to them. This appears rather opportunistic, with clinics, doorways and corridors being used, depending on room and the confidentiality of the setting. The procedure, in terms of how long patients walk, podiatrist position, method of observations and if they walk barefoot or shod first, varied between participants.

"And they will walk to and fro from me either in a hallway, corridor, room, waiting area. Wherever is free hopefully not observed by other people" (Int 2).

The timing of when RTCGA was performed during a patient assessment showed no common trend across the participants. Dynamic observations occurred before or after static analysis. In addition, there emerged no common order to which specific observations were conducted.

"So, I just get a patient to get up and just start walking. I use a short space. Probably be about three meters that's about the length of the corridor and I'll just say to the patients nice and relaxed and can you just walk back and forward at your own constant pace and that's it really. I tend to try to be kind of systematic in what I'm doing. I'll always look at the foot straight away and then I'll tend to work my way up and have a look at the knee position if I can get their trouser legs above their knee" (Int 14).

"I generally will ask the patient to leave their shoes on when they arrive and ask them to walk up and down. I'll note what I'm seeing. I'll then ask the patient to sit down and go through the problem in a bit more depth and then I'll go unshod" (Int 17).

CGA, utilising technology and equipment, was used occasionally. The most frequent equipment utilised being 2D recordings analysed using computer software. Participants who used this method reported that it was used after RTCGA had been conducted.

"I generally watch them walking usually across a room first. I feel you get more from that than from anything else. If there's something in particular I want to get in more detail, I would then video them. Occasionally you can't video them because

their mobility isn't good enough. And if I wanted to show them something I would also video them" (Int 8).

Participants varied in their account of their method or structure employed when documenting RTCGA findings. Grading systems were most commonly used, the most prevalent being to grade motion or positions via a 4-point scale of none, small, medium or large.

"Yeah I'd generally go small, medium, large. Generally on grading scales I use a three point or a five point grading. I don't see the point of getting too much finer than that" (Int 23).

"Large, medium or small or none, yeah" (Int 15)

There is a high amount of variability in the RTCGA observations. For barefoot RTCGA there were a total of 132 different observations noted across the participants, 82 of which were individual (observed by only one of the participants interviewed). Only 4 observations occurred commonly (rearfoot to leg, medial bulge, forefoot abduction and the arch). Shod assessment, occurring either with or without orthoses at either assessment or review, demonstrated less total variation of observations across participants. 62 shod observations were stated, less than half of those used for barefoot RTCGA. Again, there is a high amount of observations individuality, with 43 of 63 observations noted only to occur once across participants. Only 2 observations were noted commonly: the medial bulge (most frequent) and the rearfoot to leg angle (less frequent). These 2 observations were also noted in the barefoot RTCGA observations, but when barefoot, the rearfoot to leg presented as a more common trend than the medial bulge observation.

"No. You clearly aren't. You're looking at the shoe. But then what I'm tending to look for is that kind of splay of the shoe to the medial side. The kind of bulging out on the medial side." (Int 20).

7.3.2 Theme 2: Working with RTCGA

This theme explores how participants work with RTCGA for PTTD in the environment of a lack of formal instruction (Chapter 4, pages 43-56) (Harradine, Gates and Bowen, 2018b).

Even though all participants used RTCGA in the assessment of patients with PTTD, there was a common acceptance that quantitative objective measurements were not possible and that the process was a subjective one.

"It's more you just write what you see there's not really a structure to it you get when you follow a system it's really kind of what you see. It's very subjective" (Int 13).

Participants valued RTCGA in clinical decision making. When a RTCGA outcome was discussed, such as a decrease in rearfoot eversion or reduction in the medial bulge, participants would use this result to guide further treatment. For example, if a patient's symptoms had not improved but their RTCGA demonstrated a positive change, the participant stated that they would often refer on for further imaging. If asked if they trust their RTCGA, the answer was yes.

"Yeah I probably am" (Int 2).

"That is what I do currently yes" (Int 3).

The majority of participants highlighted a lack of established normative kinematic data to use in relation to RTCGA. Instead, observations were performed in relation to the presenting symptom.

"I don't know what normal or abnormal is" (Int 4).

"I certainly wouldn't be using a zero degree you know the calc being completely vertical to the tibial. I don't tend to use a reference point. The idea that for me is just to try to reduce that stress, reduce that calcaneal eversion. More obviously you're reducing force more. But I don't use a reference point to try to get it up to no" (Int 14).

Participants did consider footwear a limitation to conducting RTCGA. Observing shod walking was seen as a restricted observation, and indication of in-shoe foot function or a direct observation of footwear only.

"You might see certain markers or indicators. You might see sort of the medial heel counter or the upper you may see some movement there. But definitely you know barefoot you will see them, you'll get a much clearer view of that arch flattening" (Int 22).

If using observation of the shoe to infer in-shoe foot motion, the limitations of this approach were often acknowledged.

"We don't necessarily know what the foot's doing inside the shoe but if I don't see the shoe evert I assume that the foot's not everting anymore. I know now that isn't super accurate but then again it's best can we do clinically" (Int 28).

7.3.3 Theme 3: RTCGA uses

This theme describes different uses of RTCGA through stages of the patient treatment pathway.

Participants reported that RTCGA was most commonly used at assessment and foot orthoses fitting, and much less so at review. Participants used RTCGA to assess kinematics, which link to the symptom, but also to reproduce gait-related pain in the clinic to aid in the assessment and diagnosis of the injury.

"So, wanting to obviously look at the hip position, the knee positioning the foot positions seeing whether there was any abnormalities which you may be able to pick up on. Any limping, any pain." (Int 13).

Commonly RTCGA was used to assess kinematic outcomes after the provision of orthoses, both positive or negative, and to check footwear suitability.

"Again, I'm probably looking at the calcaneus seeing if that is, if the valgus is reduced, again if the talonavicular joint is less visible. Probably the main things with a shoe on I'd be looking at would be from behind sort of rearfoot to leg angle really" (Int 20).

"Yea, that would be barefoot really and then whatever I do and put in their footwear it's more or less just to see, is the shoes helping things. Is the particular footwear maybe not suitable and then you could advise the patient of that? I'm also seeing is it correctable by putting the patient in footwear, does it make a difference to the foot position that you can see as they walk along?" (Int 7).

"Just to make sure we aren't causing any other complications" (Int 27).

RTCGA was occasionally stated as being invalid to assess kinematic changes with foot orthoses.

"I don't think I'll see as much with the shoe on" (Int 11).

"No. Because kinematics is a blunt instrument" (Int 25).

Following the fitting of orthoses, RTCGA was often used to check orthosis comfort. This trend was stronger than using RTCGA to assess for kinematic changes.

"To be honest as soon as I put the insoles in, I'm more looking for the comfort aspect. I don't really look to see if anything in gait is changed" (Int 14).

CGA was occasionally used for kinematic comparison at review appointments and to encourage patient engagement in treatment plans.

"They also see the technology analysis so they get to see their footscan images, they get to see the video gait analysis, you explain what's going on and you actually have a visual to back that up rather than just saying oh as I watched you walk there I can see X, Y and Z. So perhaps the patient involves themselves a wee bit more in treatment and gains more confidence in you as a practitioner with those visual aids there" (Int 7).

7.3.4 Theme 4: What could aid RTCGA?

This theme reports views on changes that may be beneficial to MSK podiatrists using RTCGA. It brings together possible clinical factors, which limit or restrict RTCGA.

When participants were asked what they believed the challenges and difficulties were regarding RTCGA, some suggested that a more standardised approach would be helpful.

"I suppose it would be quite nice to have a set, sort of not rules as such, but something to follow so you know, perhaps in different parts of gait, things to look out for. Kind of like the FPI [Foot Posture Six Index] I suppose" (Int 1).

"I would love to have one, that you know, we could all say every single podiatrist in the UK uses, a standardised one, but I'm not aware one exists. But it would be great if it did exist" (Int 7).

Occasionally specific areas of improvement such as measurement and documentation were suggested. In addition, while discussing the possible benefits of new approaches specific concerns were noted. These included any suggested changes not taking more time than currently available, fitting in with their current method and that it had undergone testing for validity and reliability.

"I'd use it as guidance. And if it worked and it fitted in and it was a good way to document something to get decent values that were easily understood and reliable between different podiatrists." (Int 19).

A lack of clinical space and time were noted as barriers to RTCGA.

"Well really just that you know when you're watching them walk down a corridor you can only see them from the front and behind so you're not getting a true look at the talonavicular bulging and the reduction of the arch profile you can only observe that when they're right in front of me so that's something that, as they closer to me, I'll angle myself and have a little sneaky peak. Whereas when you're looking from the front and back, all you're seeing is you're not getting a sagittal plane really because you're unable to see from the side, so I'd say that's my biggest limitation. You could always look at it as a time issue as well." (Int 14).

Use of gait assessment equipment or technology was suggested by the majority of participants. Both positive and negative opinions were present. It was not seen as a necessity.

"I wasn't convinced by a lot of it. That's my personal opinion and probably I'm shooting myself in the foot here but I think you can get very bogged down in things, machines telling you what should be wrong with that patient" (Int 10).

"Yes, well I guess in the NHS its very much the visual thing because we don't really have the facilities here to record the information and retain the information from the video analysis, but in my private practice I would use more the video analysis and the FScan read outs and information because at least that can be saved and documented and then you can come back to it after treatment" (Int 7)

7.3.5 Theme 5: How RTCGA skills are acquired

This theme relates to how participants have obtained their knowledge of the methods and reasons for performing RTCGA.

Most participants indicated that they acquired RTCGA skills via experience. Some also learnt from colleagues, post and undergraduate education, journals and books. However, the occasionally stated the use of literature and courses was expressed only in conjunction with experience.

"It's down to experience and it's down to knowing what I feel is normal based on what I've seen over the years and what I've assessed" (Int 18).

"I think over thirty years having to listen to many lectures and read many papers and seen many patients I've collated lots of sort of little pearls of wisdom from many different practitioners and I use that to really give me my full understanding of the injured area, patients function, and where the patient wants to be and how I can get them there." (Int 17).

7.4 Discussion

The results of this study provide unique insight into these MSK podiatrists experience and opinions of RTCGA (focusing on PTTD as the exemplar). Five themes emerged as 1) RTCGA method; 2) Working with RTCGA; 3) RTCGA uses; 4) What could aid RTCGA?; 5) How RTCGA skills are acquired.

Participants in this study used RTCGA in the assessment and treatment of PTTD, in accordance with recommendations that GA forms part of a general or lower limb MSK adult patient assessment (Rose, 1983; Southerland, 1996; Whittle, 1996; Norris, 1998; Coutts, 1999; Curran and Dananberg, 2005; Baker, 2007; Levine, Richards and Whittle, 2012b; Payne and Bird, 2012). It was evident that their observations of gait included kinematic scrutiny combined with patient-perceived experiences such as pain and orthosis comfort. In addition, the observation sequence was variable and normative reference values for gait were found to be generally unimportant.

The most common barefoot RTCGA observations performed were the rearfoot to leg angle, medial bulge, forefoot abduction and arch integrity. These kinematic observations are markers of pronation (Root, Orien and Weed, 1977), changes of which are acknowledged in PTTD (Rattanaprasert *et al.*, 1999; Tome *et al.*, 2006; Ness *et al.*, 2008; Houck *et al.*, 2009; Richie, 2020). Only 2 common RTCGA observations emerged relating to the shod context: the rearfoot to leg angle and

medial bulge. The main reason for this was explained by participants as the challenge in observing the foot when the shoe obstructs visualisation of the foot movements. These 2 observations within the shod context were however still used as markers of pronation, where assessing shoe kinematics was seen as a proxy marker of foot function. Conversely, findings suggest MSK podiatrists are aware of the limitation in validity of inferring in-shoe foot motion from footwear observation (Arnold and Bishop, 2013).

The 2 common shod observations (the rearfoot to leg angle and medial bulge) allowed participants to theoretically assess the immediate kinematic outcome of management strategies to modify pronation, such as at the fitting of foot orthoses. RTCGA was not used to assess kinematic outcomes over longer time periods, such as between appointments. Moving patients away from painful gait patterns was expressed as the primary rehabilitation objective by participants in this study. These observations and methods are in agreement with recommendations from other authors to reduce pronation as an aim of treatment for PTTD (Durrant, Chockalingam and Hashmi, 2011; Harradine *et al.*, 2011; Richie, 2020). The observations from participants in this study also highlighted a lack of clinically feasible and reliable normative kinematic data to use in relation to RTCGA and support the reasoning towards a focus on the presenting clinical symptoms rather than modification of risk factors for preventative approaches.

Although common kinematic observations emerged, a high amount of variation was also noted between participants in this study. A variety of anatomical landmarks, motions and terminology were described. This was not expressed as a problem and participants did not appear to be aware that their observations were often individualised. Documentation of RTCGA findings was also diverse, the most common method being to grade motion or positions via a 4-point scale of none, small, medium or large. The high number of variations in observations and documentation may be a result of RTCGA lacking structured and validated guidelines (Chapter 4, pages 43-56) (Harradine, Gates and Bowen, 2018b). Indeed, some participants suggested that a standardised approach would be helpful, indicating that future work should focus on development of national guidelines through expert consensus.

CGA - utilising technology and equipment - was used occasionally by participants in this study. The most frequent equipment reported was 2D recordings analysed through computer software. CGA equipment was not deemed as being essential to assess the gait of patients with PTTD, but the benefits for its use were expressed by some and countered by others. The negative opinions presented in this study are contrary to the positive emphasis on CGA found in literature, where it has been suggested that CGA is more efficacious, valid and reliable than RTCGA (Perry, 1992; Coutts, 1999; Wren *et al.*, 2011). The reason for the participant's differing opinions on the use of CGA were not specifically explored as part of this study. However, it could be in part explained by appropriateness of the clinical setting and a lack of time being cited as challenges and barriers to RTCGA. Likewise, there was a common acceptance that quantitative objective measurements were not possible and that the process was a subjective one. This is not surprising given the inadequacies of nationally agreed guidance for minimal RTCGA space and time requirements (Chapter 4, pages 43-56) (Harradine, Gates and Bowen, 2018b).

The final theme related to how RTCGA skills were acquired primarily through experience and occasionally via observing colleagues, courses and review of literature. Learning through experience, or 'experiential learning', is a well-established theory relating to teaching and skill acquisition (Beard and Wilson, 2018). Although it is acknowledged that practical skills can be taught with learner participation, the delivery of good experiential learning has become complex, possibly even 'super complex' (Barnett, 2000). Itin (1999) states the educators main role in experiential learning include selecting suitable experiences for the learner whilst posing problems, setting boundaries, supporting, insuring physical and emotional safety, guiding reflection and providing any necessary information. This may be difficult to perform in a large group or classroom environment. Instead RTCGA skill acquisition may be best suited to a small group or even a mentoring system. However, in the context of learning RTCGA the participants in this study often described their experience as the unique method by which they have acquired the skill or knowledge to perform RTCGA. They are not being purposely 'taught' a method from best practice nor is it evidence based. A potential explanation is the current lack of RTCGA research and literature

(Harradine, Gates and Bowen, 2018b), or that simply experiential learning is the best way to acquire skill in this area.

7.4.1 Potential strengths and limitations

This study is the first of its kind to investigate MSK podiatrists use and opinions of RTCGA.

That said, a number of limitations should be considered when interpreting the findings. Firstly, this study examined the perceptions of MSK podiatrists currently practising in the UK. Results may not, therefore, be representative of MSK podiatrists from other countries or to other professions who perform RTCGA. In addition, other than being in the UK, geographical details of the participants are not known. It is possible different areas in the UK may have other uses and opinions on RTCGA not represented in this study.

Secondly, a purposive sample was used, where first responders were selected. It is not known if the range of participant characteristics (Table 7.1, page 130) is a fair representation of MSK podiatrists working in the UK. However, this method allowed for an efficient gathering of primary data regarding RTCGA.

Thirdly, the 1:1 interview process may lead to a lack of research breadth due to smaller sample sizes (when compared to, for example, a large-scale survey) (Braun and Clarke, 2013). These limitations reduce confidence that results can be generalisable as representative of all UK MSK podiatrists. Although saturation was reached within the study sample, demonstrating no new data may have been forthcoming with an increased sample size, generalisability was not the intention of this study. Rather it was to achieve in-depth insight from the purposively sampled participants. The 1:1 interview process allowed the collection of rich and detailed data with flexibility to pursue different areas or subjects as they arose. This is valuable with inductive research in circumstances such as this, where there is a lack of established literature and knowledge (Braun and Clarke, 2013).

Fourthly, information regarding the success of the different recruitment strategies to obtain participants was not collected. Volunteers were obtained via a specialist Facebook group (MSK:UK) or through a snowballing strategy via word-of-mouth. Awareness of the most efficient recruitment strategy may have been helpful for

researchers conducting comparable research. Finally, PTTD was used as focus condition in this investigation. This allows for confidence in relevance of findings to this condition but restricts the universal application of results to other MSK lower limb injuries. Relevance to general MSK podiatry caseloads is therefore limited. However, this study could be used as an exemplar model from which views and opinions on RTCGA and other lower limb conditions can the investigated.

7.4.2 Further recommendations

MSK podiatrists use RTCGA when treating adult PTTD as both an outcome measure and as an aid in decision making. This implies a perceived worth in conduction of RTCGA. Further research incorporating wider sampling and investigating other MSK lower limb conditions appears justified.

An improvement in clinical space and time is advocated to facilitate RTCGA. However, the actual amount of time and space required for RTCGA has not been established. It is recommended that minimum requirements are established in relation to the clinical environment and appointment durations best suited for RTCGA. Further suggestions of applying such minimum requirements to aid in RTCGA can then be advised.

The availability of a standardised approach would be seen as a positive aid to RTCGA and PTTD. It is recommended that the development of a standardised approach, such as the creation of clinical recommendations through expert consensus and stakeholder involvement, is undertaken (see Chapter 8, pages 145-158).

The findings of this study have provided unique insight into how these UK based MSK podiatrists utilise RTCGA in practice. A more comprehensive representation of the use of RTCGA may be achieved by further work as detailed in Chapter 11 (pages 183-186)

7.5 Conclusion

Findings from this study have provided a comprehensive view of how podiatry MSK clinicians utilise RTCGA within their practice. RTCGA is used regularly by MSK podiatrists as an outcome measure and to aid decision making when

assessing and treating adult PTTD. This implies a perceived worth in conducting RTCGA from a podiatric viewpoint. Observations were not merely kinematic, but also included patient perceived experiences, such as pain and orthosis comfort. Common kinematic observations emerged for both the barefoot and shod context. The main difficulty in performing RTCGA is restriction on clinical time and space, while a more systematic approach to RTCGA would be seen as helpful. RTCGA is a skill acquired through experience. Further work is recommended that focuses on development of national RTCGA guidance.

7.6 How stage 5 informed stage 6

Earlier attempts to develop an objective RTCGA instrument as a best practice approach failed due to the lack of robust guidance or literature (stages 1 - 4). However, the RTCGA evidence gap still existed. Stage 5 undertook a qualitative inductive approach to increase current understanding and use of RTCGA by MSK podiatrists in the UK.

Results from stage 5 highlighted that RTCGA does have clinical worth, and that further guidance for performing RTCGA would be beneficial. This exploratory study provided information regarding current RTCGA practice and ideal characteristics of future RTCGA guidance. From these findings the development of RTCGA clinical recommendations as a best practice approach to aid MSK podiatrists in the assessment and treatment of adult PTTD were attempted and form the next chapter (stage 6) of this doctoral thesis programme of work.

Chapter 8 The development of RTCGA clinical recommendations

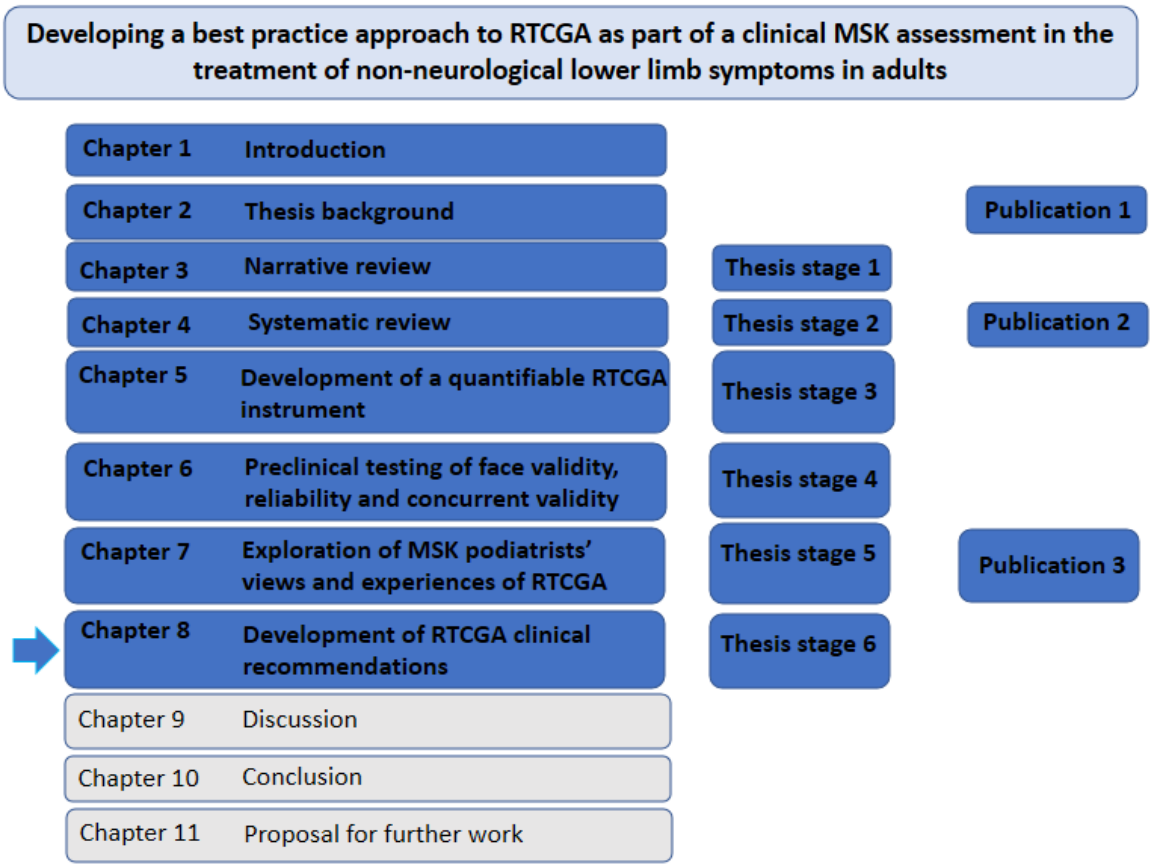
8.1 Introduction

Chapter 8 details the development and use of 4 core RTCGA clinical recommendations. Clinical recommendations are a recognised method by which evidence is synthesised to supply best practice approaches for patient care (Perleth, Jakubowski and Busse, 2001). A RTCGA best practice approach would include guidance and recommendations for clinical practice to help diagnose and manage gait related MSK injury. These 4 core recommendations, which are presented as an acronym to aid in clinical implementation (the GAIT assessment), supply unique guidance for MSK podiatrists to aid in the clinical treatment and assessment of an exemplar condition, PTTD.

However, the pathway to achieving a robust clinical practice guideline requires further work. Whilst the proposed GAIT 4 core recommendations do go some way to supporting consistency for clinical decision making, limitations are noted. A lack of existing RTCGA guidance and the inability to robustly test for the reliability and validity of RTCGA kinematic observations persists. With full acknowledgement of these limitations, Chapter 8 presents the GAIT assessment as a feasible MSK RTCGA best practice approach (stage 6), developed via insight from the doctoral thesis programme of work which can be strategically aligned with the NICE guidelines creation process of scoping, development and exploratory investigation stages (stages 1-5) (NICE, 2015).

Figure 8.1 (page 146) demonstrates Chapter 8 within an overview of the doctoral thesis.

Figure 8.1. Doctoral thesis overview demonstrating Chapter 8 within the context of the programme of work



8.2 Generation of recommendations

Assessment and interpretation of the available evidence and data collected in stages 1-5 was collated to generate clinical recommendations (Brouwers *et al.*, 2010; NICE, 2015). These stages follow the recommended clinical guidance development process of scoping (stages 1 and 2), development (stages 3 and 4), consultation (stage 5), recommendation development (stage 6) and ideally publication and dissemination (NICE, 2015).

The thesis author and supervisors participated in reviewing, revising, and agreeing all recommendations. This process consisted of inclusive independent review, with comments addressed and revised by the thesis author. Two group meetings (consisting of the thesis author and supervisors) were also undertaken to aid in establishing and ensuring agreement of all content.

Four core recommendations were developed based upon a rationale of the supporting evidence, creating the preliminary RTCGA clinical recommendations for adult PTTD. These recommendations are presented for the assessment and treatment of adult PTTD by MSK podiatrists based in the UK. An acronym, GAIT, is suggested as a clinical aid-memoire for the content and order of recommendations and detailed in section 8.3 (page 154).

8.2.1 Recommendation 1

RTCGA should be conducted after a provisional clinical PTTD diagnosis has been proposed.

Rationale

Common RTCGA observations have only been established in relation to PTTD (Harradine *et al.*, 2021). It is unknown if these same observations would be conducted for other adult MSK lower limb injuries. These RTCGA clinical recommendations should therefore be undertaken after a provisional diagnosis of PTTD has been made, after history taking, static assessment and any other required diagnostic clinical tests. RTCGA can then be used to aid in confirmation of PTTD diagnosis, establishing the condition severity and assessing treatment outcomes (section 7.3.3, Chapter 7, pages 136-137) (Harradine *et al.*, 2021).

8.2.2 Recommendation 2

RTCGA should be used to aid in clinical diagnosis of adult patients with PTTD. Assessment should include a) essential kinematic observations, and b) dynamic presentation of pain.

a) The following essential kinematic observations are recommended. These are not exclusive, and other kinematic observations can also be conducted.

Barefoot: Rearfoot to Leg Angle, Medial Bulge, Forefoot Abduction and Arch Height (Figures 8.2.1 to 8.2.4, pages 148-149).

Figure 8.2.1. Barefoot observation of the Rearfoot to Leg angle (highlighted by red lines). © University of Southampton.

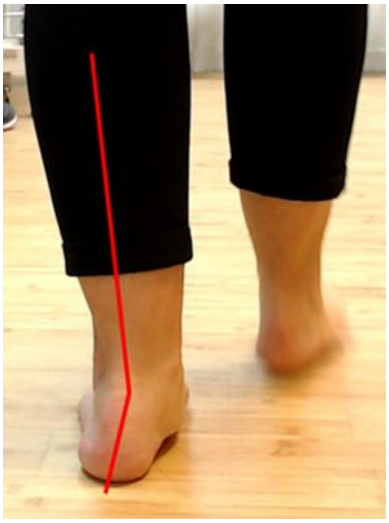


Figure 8.2.2. Barefoot observation of the Medial Bulge (area highlighted by red circle). © University of Southampton.

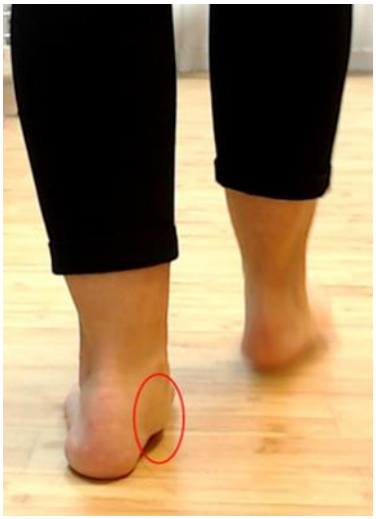


Figure 8.2.3. Barefoot observation of Forefoot Abduction (area highlighted by red circle). © University of Southampton.

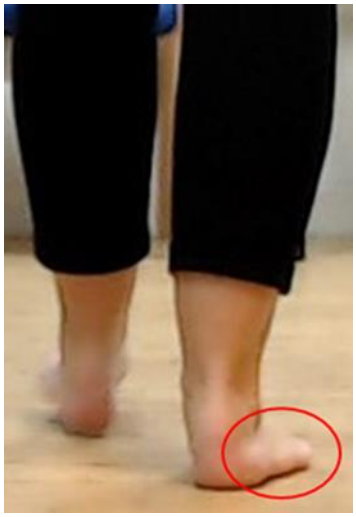


Figure 8.2.4 Barefoot observation of the Arch Height (area highlighted by red circle). © University of Southampton.

Shod: Rearfoot to Leg Angle and Medial Bulge (Figures 8.3.1 and 8.3.2)

Figure 8.3.1. Shod observation of the Medial Bulge (area highlighted by red circle). © University of Southampton.

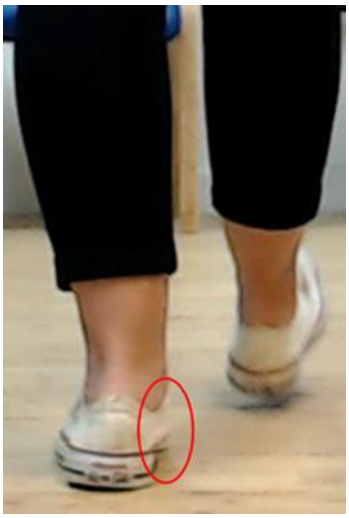
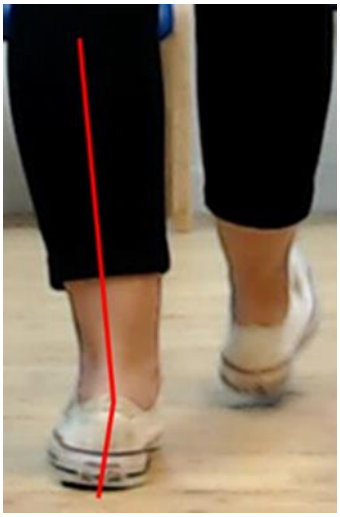


Figure 8.3.2. Shod observation of the Rearfoot to Leg angle (highlighted by red lines). © University of Southampton.



Kinematic observations should be graded based on your own experience using the following 4-point scale: 1) None, 2) Small, 3) Medium, or 4) Large

b) Pain in gait should be noted in terms of its anatomical position and severity. Medial foot and ankle pain in the approximate anatomical area of the posterior tibial tendon is diagnostic of PTTD.

Rationale

It has been established that MSK podiatrists use RTCGA to assess for specific kinematics associated with PTTD (section 7.3.1, Chapter 7, pages 132-134) (Harradine *et al.*, 2021). The most common barefoot kinematic observations performed by these MSK podiatrists, using the terminology most utilised, were rearfoot to leg angle, medial bulge, forefoot abduction and the arch height. Shod kinematic observations only demonstrated 2 commonly used observations: the medial bulge and rearfoot to leg angle (section 7.3.1, Chapter 7, pages 132-134) (Harradine *et al.*, 2021). Increased dynamic magnitudes of arch lowering, rearfoot to leg eversion angles, forefoot abduction and medial bulge are defined as diagnostic of PTTD (Rattanaprasert *et al.*, 1999; Tome *et al.*, 2006; Ness *et al.*, 2008; Houck *et al.*, 2009).

It has also been established that MSK podiatrists do not relate objective measurements (e.g., angles) to the scaling system they use, instead relying on experience to grade the observation (section 7.3.5, Chapter 7, pages 138-139) (Harradine *et al.*, 2021). The documentation of RTCGA kinematic observations was performed subjectively using a variety of scales and terms, the most common of which was a 4-point scale of none, small, medium, or large (section 7.3.1, Chapter 7, pages 132-134) (Harradine *et al.*, 2021). The documentation of patient notes should be comprehensible (HCPC, 2021) and this 4-point scale appears both straight forward and user friendly. However, there is no established method to categorise motions or positions into this scaling system, and it is therefore left to the MSK podiatrists clinical experience to judge this kinematic observation grading.

The high individuality of MSK podiatrist observations need to be considered. For barefoot RTCGA there were a total of 132 different observations noted across the participants, 82 of which were individual (observed by only one of the participants interviewed). A total of 62 different shod observations were stated, 43 of which were individual (section 7.3.1, Chapter 7, pages 132-134) (Harradine *et al.*, 2021). Recommending essential observations does not exclude further observations being taken, allowing MSK podiatrists to both include other personal preferences and to tailor their assessment for individual patient needs.

RTCGA was also used to reproduce gait related pain to aid in the assessment and diagnosis of the injury (section 7.3.3, Chapter 7, pages 136-137) (Harradine *et al.*, 2021). Pain experienced at the medial aspect of the foot and ankle during gait is consistent with a diagnosis of PTTD (Durrant, Chockalingam and Hashmi, 2011; Bubra *et al.*, 2015). The description of patient perceived pain while performing RTCGA is therefore recommended. The method MSK podiatrists employ to document or measure patient pain during gait is not known. Although it is recommended the placement and severity of the pain is noted, the precise methods by which this is documented is therefore left to MSK podiatrist choice.

8.2.3 Recommendation 3

RTCGA should be performed at the fitting of foot orthoses or footwear to observe any kinematic changes. If fitting foot orthoses, it should also be used to assess for patient perceived comfort.

Rationale

It is recommended shod assessment is performed before and after intervention designed to influence the essential kinematic observations. Kinematic changes can then be recorded. MSK podiatrists perform RTCGA to assess for positive or negative outcomes and thereby modify treatment options (section 7.3.3, Chapter 7, pages 136-137) (Harradine *et al.*, 2021). MSK podiatrists do not aim treatments to change essential kinematic observations to an objective normative value, instead they aim to reduce these in relation to the symptom, e.g., reducing the rearfoot eversion to reduce strain in the posterior tibial tendon (section 7.3.3, Chapter 7, pages 136-137) (Harradine *et al.*, 2021). Changes observed are recommended to be documented using the 4-point scale system as presented in recommendation 2; none, small, medium, or large.

Along with kinematic outcomes, MSK podiatrists use RTCGA to check for foot orthoses comfort (section 7.3.3, Chapter 7, pages 136-137) (Harradine *et al.*, 2021). Orthosis comfort is a patient perceived sensation. The method MSK podiatrists employ to document or measure patient perceived orthosis comfort is

not known. This method is therefore left unspecified and the precise methods by which this is documented is left to MSK podiatrist choice.

8.2.4 Recommendation 4

RTCGA education should be addressed through an experiential approach, such as small group practical teaching and clinical mentoring.

Rationale

MSK podiatrists stressed the importance of experience in learning and performing RTCGA (section 7.3.5 Chapter 7, pages 138-139) (Harradine *et al.*, 2021). RTCGA education needs to be focussed accordingly. Examples of experiential learning include small group practical teaching and clinical mentoring. Expecting to learn RTCGA from books or conferences may not be valid without the addition of clinical experience.

However, acquiring RTCGA skills via practical experience may have been employed due to the lack of guidance and literature from which to learn (Chapters 3-4, pages 29-56) (Harradine, Gates and Bowen, 2018b; Ridao-Fernández, Pinero-Pinto and Chamorro-Moriana, 2019; Harradine *et al.*, 2021). These RTCGA recommendations are novel and, in relation to adult PTTD, may supply information to aid educators to teach RTCGA skills in more varied educational and clinical settings than just the experiential environment.

8.3 The GAIT assessment

These 4 core recommendations create the preliminary RTCGA best practice approach to assist the MSK podiatrist assess and treat an exemplar condition, PTTD. The GAIT acronym, demonstrated below, can be used to aid in the dissemination and clinical implementation of these recommendations, supplying the clinician with a concise aide-memoir of RTCGA guidance for adult PTTD.

Get a diagnosis. RTCGA should be conducted after a provisional clinical PTTD diagnosis has been proposed (recommendation 1)

Assess walking. RTCGA should be used to aid in clinical diagnosis of adult patients with PTTD. Assessment should include a) essential kinematic observations, and b) dynamic presentation of pain (recommendation 2).

Intervene and assess. RTCGA should be performed after a clinical intervention, such as the fitting of foot orthoses or footwear, to observe any kinematic changes. If fitting foot orthoses, it should also be used to assess for patient perceived comfort (recommendation 3).

Teach using clinical experience. RTCGA education should be addressed through an experiential approach, such as small group practical teaching and clinical mentoring (recommendation 4).

8.4 Discussion

These 4 clinical recommendations are a proposed preliminary best practice approach to facilitate the RTCGA process in the assessment and treatment of adult PTTD (as an exemplar condition). Prior to this, following systematic review of the literature, no previous RTCGA guidance was found for any adult MSK non-neurological lower limb injury (Chapter 4, pages 43-56) (Harradine, Gates and Bowen, 2018b). The GAIT assessment therefore supplies unique guidance for continuity of practice for clinicians when performing RTCGA for the assessment and treatment of adult PTTD.

The scarcity of MSK and RTCGA clinical guidance is arguably a barrier to progressing the field toward intervention trials and highlights the importance of the development of MSK clinical guidance, such as the GAIT assessment, created with aid from established quality benchmarks and processes (Brouwers *et al.*, 2010; NICE, 2015). Edwards *et al.* (2017), in a systematic review of evidence for current recommendations concerning the management of foot health for people with chronic long-term conditions, found many of the current recommendations to be only related to the treatment and management of the diabetic foot. MSK guidance made up only 3 of the included 166 publications and were graded using the AGREE II tool as having moderate to low methodological quality (Edwards *et al.*, 2017).

The lack of previous RTCGA guidance makes it difficult to predict MSK podiatry uptake of new recommendations. Clinical barriers to RTCGA have been noted to be limitations to clinical time and space (See section 7.3.4, Chapter 7, pages 137-138) (Harradine *et al.*, 2021). Avoiding additional demands on these constraints theoretically should improve uptake. Using patient perceived, and core kinematic observations already commonly undertaken, reduces the need for additional resources. In addition, using observations that MSK podiatrists already perform allows for familiarity with the recommendations, possibly acting as a facilitator to uptake.

A survey-based study investigating the uptake of guidelines associated with rheumatoid arthritis related foot problems found most specialist rheumatology podiatrists do use recommended guidelines (Williams *et al.*, 2013). However, the uptake within non-specialised podiatrists was poor. As the recommendations relating to the rheumatoid foot were also intended for non-specialist podiatrists the lack of uptake in this group was a concern. However, these RTCGA recommendations are proposed for the use of MSK podiatrists (rather than non-specialist podiatrists) and so the uptake of recommendation use among a possibly comparable specialist podiatrist group is encouraging. The author will continue to progress this work through a dissemination strategy (See section 9.7, Chapter 9, pages 177-180) that will include ongoing publication and conference presentations of the GAIT assessment.

8.4.1 Potential strengths and limitations

Published RTCGA evidence as a source of data for these recommendations is scarce. Topics with limited evidence, such as RTCGA, have been stated to benefit most from the development of clinical guidance, due to the uncertainty and conflicting opinions inherent in such areas (Rosenfeld and Shiffman, 2009). This study may be seen as part of this clinical guidance development.

However, a lack of evidence in certain areas, for example, the methods by which MSK podiatrists grade patient perceived pain in recommendation 2 (section 8.2.2, Chapter 8, page 147-151), has resulted in deliberate vagueness in some recommendations. To aid clarity the reasons for writing deliberately vague recommendations are explained in recommendation rationales (Rosenfeld and Shiffman, 2009). Even with recognition, this absence of detail increases the risk of differing approaches, interpretations, and application of these clinical recommendations as a best practice approach.

The need for established observation reliability or validity has been stated by some as important guidance characteristics (section 7.3.4, Chapter 7, pages 137-138) (Harradine *et al.*, 2021). Ideally MSK podiatrists would have access to, or have resources to generate, population level normative kinematic data for quantitative comparison. However, this cannot be done without agreed measures to test, leading to a vicious circle which may prevent guidance development. It is essential to recognise that when generating new clinical guidance based on little clinical evidence, that whatever recommendations are provided are then tested for validity and reliability. This doctoral thesis programme of work recognises the lack of evidence (stages 1-4) (Harradine, Gates and Bowen, 2018b), provides insight to the continuation in use of RTCGA despite this lack of evidence (stage 5) (Harradine *et al.*, 2021), and generates core clinical recommendations (stage 6) based on this sequence of work ready for validation as the next step. The authors therefore recommend future research includes establishing normative population data for the essential kinematic observations and using such to investigate the validity and reliability of the processes within these core recommendations (see Chapter 11, pages 183-186).

Creating recommendations based on limited evidence also increases the possibility that the key areas may not be fair representations of requirements for all UK based MSK podiatrists. The only available study examined the perceptions of MSK podiatrists currently practising in the UK and only for PTTD (Chapter 7, pages 125-144) (Harradine *et al.*, 2021). These recommendations are therefore restricted in their application to MSK podiatrists based in the UK and PTTD. However, guidance supplied may be of interest to other professions involved in treating MSK conditions of the lower limb. RTCGA guidance provided from exploring the experiences of MSK podiatrists may be transferable and relevant to aid other professions performing RTCGA and for other lower limb MSK conditions.

Adult patients with PTTD are stakeholders in any clinical guidelines and recommendations, but the development process did not include their consultation. This omission increases the possibility of recommendation bias towards podiatrist requirements, to the detriment of patient requirements. In addition, although MSK podiatrist experiences and opinions were used to create these recommendations, their views on the completed process have yet to be sought. This again may bias the applicability of these recommendations.

8.5 Conclusion

Four core recommendations for the use of RTCGA in the assessment and treatment of adult patients with an exemplar condition, PTTD, are proposed as a best practice approach for continuity of practice for clinicians. As an aid-memoire, these are presented as the GAIT assessment. Although further research and development is essential, it is anticipated that these recommendations will aid current MSK practice and form the foundation of clinical guidance development, maximising progress towards improving PTTD patient outcomes. Potentially this GAIT approach offers a foundation model for RTCGA that, if given more focused and collaborative attention, provides additional insights to advance the field towards RTCGA instruments that are valid, reliable and repeatable.

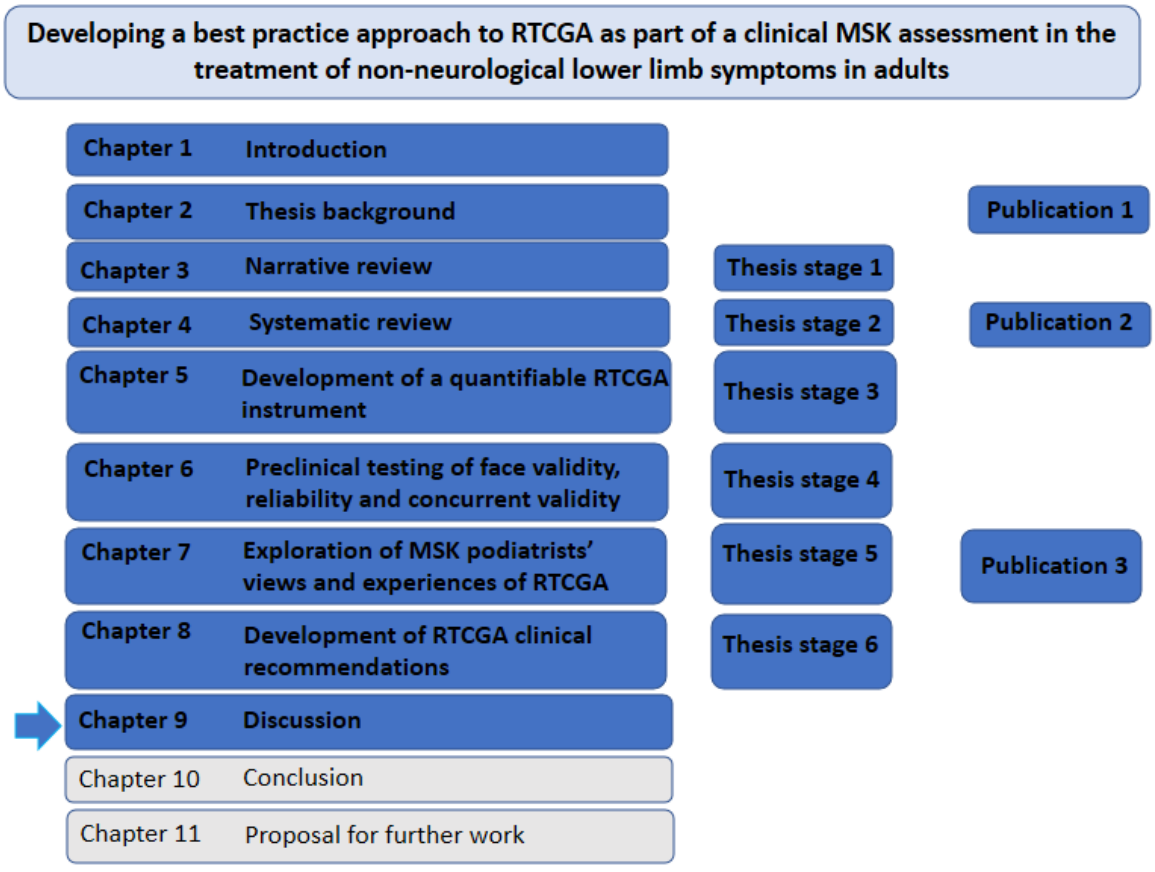
Chapter 9 Discussion

9.1 Introduction

In this chapter the research aim and question that directed the study and the findings generated from the 6 different research stages are reviewed.

Figure 9.1 demonstrates Chapter 9 within an overview of the doctoral thesis.

Figure 9.1. Doctoral thesis overview demonstrating Chapter 9 within the context of the programme of work



These research stages were developed via an iterate approach, with results from each stage informing and directing the next. This design by iteration led to significant changes and developments of the methods and approaches during the doctoral thesis programme of work. Stages 1-4 were studies of RTCGA methods and testing, including the development and consequent rejection of a quantitative objective RTCGA instrument in its initially considered form.

A systematic review was undertaken, stage 2, to robustly review all methods and procedures of RTCGA in adult non-neurological MSK patients. Following stages 1-4, uncertainty still existed with regards to the method by which a best practice approach could be developed. Stages 5 and 6 were undertaken to address the evidence gap established in stages 1-4 and became the inductive and qualitative investigation of RTCGA.

For clarity of process, the deductive stages (1-4) and inductive stages (5 and 6) are discussed separately in this chapter (sections 9.2 and 9.3 respectively, pages 161-168). The body of work is then discussed as a whole (sections 9.4 – 9.6, pages 168-177). A summary of the suggested future work is also presented. The chapter concludes with the potential benefits and implications to the profession of podiatry based on the development of a best practice approach.

9.1.1 Rationale

The study aim was to establish a best practice approach for RTCGA to be used as part of a clinical MSK assessment in the treatment of lower limb non-neurological symptoms in adults.

The overarching research question was therefore to establish if it was possible to develop such a best practice RTCGA approach to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults. Answering the overarching research question leads to 2 possibilities by which clinical practice may be improved:

Firstly, if it is possible to create a best practice approach to RTCGA this may benefit clinical practice by aiding MSK diagnosis and evaluating therapeutic intervention outcomes (Rose, 1983; Coutts, 1999; Brunnekreef *et al.*, 2005; Levine, Richards and Whittle, 2012b). The timely and accurate use of any diagnostic method, with the smallest possibility of a missed diagnosis or misdiagnosis, is crucial in the treatment of any disease or disorder (Schiff *et al.*, 2009; Singh, 2014). This in turn may prevent unnecessary, ineffective, or harmful interventions.

Secondly, a failure to develop a RTCGA best practice approach would have equally important clinical consequences. The systematic review of MSK RTCGA concluded that "…without additional guidance the current use of RTCGA as a part of this specific patient group analysis appears dubious at the very least." (section 4.5,Chapter 4, page 53) (Harradine, Gates and Bowen, 2018b). This agreed with similar previous sentiments expressed by Coutts (Coutts, 1999), that "…currently observational analysis (RTCGA) on its own is insufficiently reliable to be clinically acceptable". RTCGA may be an unnecessary, invalid and unreliable clinical investigation, the use of which could lead to needless, ineffective or harmful interventions. The inability to develop a best practice RTCGA approach would therefore have further consequences and recommendations for the use or otherwise of RTCGA in adult non-neurological MSK lower limb clinics.

9.2 Discussion of deductive stages 1 - 4

Literature reviews (stages 1 and 2) revealed no robust RTCGA guidance to aid in the creation of a RTCGA best practice approach. In the absence of evidence, it was initially proposed to establish an objective RTCGA instrument from scratch ('de novo') employing development (stage 3) and testing (stage 4) methods recognised for the creation of clinical guidance, diagnostic tools and health measures (Colli *et al.*, 2014; NICE, 2015; Streiner, Norman and Cairney, 2015). The resultant objective RTCGA instrument, devised to score RTCGA observations in relation to representative normative objective measures (the SRVs), failed to convincingly satisfy any of its conceptual aims. Following stage 4, this process was deemed unsuccessful for the development of a RTCGA best practice approach, and a different method adopted (stage 5).

However, a similar process to create an objective measure of static foot posture (the FPI-6), initially introduced for comparison and guidance in Chapter 5 (sections 5.2-5.3, pages 58-63), has yielded positive results in meeting its conceptual aims (Redmond, Crosbie and Ouvrier, 2006). The FPI-6 development strategy was similar to the preliminary RTCGA instrument development process. It consisted of developer derived measures / items from the literature, definition of a scoring system, undertaking an informal proof of concept evaluation and then testing for concurrent validity via comparison to a gold standard test and

laboratory testing with transiently imposed deviations of foot postures. This matches with the RTCGA instrument strategy to derive items / measures from available literature, select the scoring system and test for reliability and validity.

Although the overall strategy adopted by Redmond *et al.* (2006) was similar, the process compared to the current PhD resources differed significantly from the outset. Redmond *et al.* (2006) note 119 papers were identified as describing in adequate detail the clinical evaluation of foot posture. From this literature they were able to derive measures suitable for inclusion based on their self-proposed conceptual aim to be able to measure foot postural changes in each of the 3 body planes. By comparison, the comprehensive review of literature for RTCGA revealed no adequately robust or detailed guidance. It was not possible to derive measures from pre-existing literature. It was therefore concluded that the items and measures were to be created via deductive reasoning using conceptual aims and development strategies in relation to current knowledge on adult gait and MSK lower limb injuries.

The deductive RTCGA development process exposed the objective RTCGA instrument development to an increased risk of bias (section 5.5.1, Chapter 5, page 98). The measures and items were based upon the available literature on gait theory and lower limb symptoms, but not on previous RTCGA methods or instruments. Upon reflection, at this point, the measures and observations within an objective RTCGA instrument could have potentially been selected via the use of expert opinion using a consensus approach such as a Delphi or Nominal Group Technique. Such approaches assume that group judgments are more valid than individual judgments. Although these methods were not used in the development of the FPI-6, it has been used in the development of other best practice MSK approaches such as the IMFAA (Gates, Bowen and Arden, 2015).

As discussed in section 5.2 (Chapter 5, pages 58-60) group consensus was not conducted at development stages. The FPI-6 creation process closely matched the developmental requirements of the RTCGA instrument and was therefore investigated as the primary method of creating an objective RTCGA instrument. In addition, group consensus had largely been used in MSK assessment to establish agreement on collections of tested diagnostic and treatment modalities, rather

than the creation of objective measures or scales themselves. This appeared contrary to the development required for an objective RTCGA instrument. However, by obtaining group consensus a different RTCGA instrument may have been developed, less prone to bias and with greater consideration of items and procedures. It is not possible to predict the observations and measures which may have been included, or if the conceptual aims for RTCGA from experts would have differed from that proposed by the thesis author.

Testing of the selected RTCGA instrument items also lacked guiding evidence. FPI-6 development did test concurrent validity using comparison to an established method of obtained foot posture measurement (the arch index scores) and laboratory based static electromagnetic motion tracking (Redmond, Crosbie and Ouvrier, 2006). For RTCGA, no established method for which gold standard comparisons to be made existed. Laboratory based methods by which to test concurrent RTCGA validity failed due to both an inability to produce required variations in gait kinematics but also in the technology not being available by which essential data could be collected for testing.

The foundation for the RTCGA instrument approach was that there is a scientifically agreed normal gait, and if there is a normal gait then there must also be an abnormal gait. If the deviations from this normal gait can be observed and recorded, then an abnormal gait can be diagnosed. In addition, if interventions are provided to reduce this abnormal gait, then their outcome can be evaluated by observing if this has occurred. This general MSK approach could then be used for any and all MSK gait abnormality. Robust literature review and instrument development revealed a significant lack of normative data for the deductively selected kinematic RTCGA observations. For the FPI-6, Redmond *et al.* (2006) did not undertake their aim to establish a valid clinical tool to measure foot posture by using normative data. Instead, they used foot posture observations that would indicate either a pronated or supinated presentation. A score of 0 for any segment was not seen as normal, but rather as not demonstrating a pronated or supinated observation. A later study led by one developer of the FPI-6 revealed the normal FPI-6 score in their adult population sample not to be 0, but to be +4 (Redmond, Crane and Menz, 2008). This does not detract from the use of the FPI-6 as a

method by which to observe, score and record static foot posture. It simply means the foot posture score of +4 is representative as normal in their research sample.

Creating an objective scoring system which does not rely on normative values, such as that used in the FPI-6, is a possibility. Each body segment could be marked simply in range and magnitude of direction. For example, rather than saying a body segment will score greater the further away it is from its SRV / normative value, it may be possible to instead observe measures from a reference point of one segment being parallel to another. Using the rearshoe to leg item as an example, rather than scoring positively if the angle is greater than the SRV of 5 degrees everted, it could be possible instead to use angle measures from 0 being the rearshoe parallel to the leg. If it was up to 5 degrees everted from parallel this could score +1, and greater than 10 degrees everted could score +2. If it was up to 5 degrees inverted from parallel this could score -1, and greater than 10 degrees inverted could score -2.

However, there are problems with this approach. Unlike with the FPI-6 and the 119 informative papers at the developer's disposal, there is no established robust guidance on what magnitude of kinematics that should be scored as -2, -1, 0, +1 or +2. For the foot segment, footwear will still obscure the observation and there remains no method by which to increase or decrease kinematics at suggested anatomical segments for validity studies. The technological advances required by which to test reliability and validity are still not available.

It therefore appears that although future improvements in some areas of objective RTCGA instrument development are possible, the extent of current limitations would deem the benefit of these insufficient to obtaining a valid or reliable best practice approach. In addition, due to the absence of available representative normative kinematic data and the individual and inter-day variation of gait in healthy populations (Horst *et al.*, 2017; Horst, Mildner and Schöllhorn, 2017; Moissenet, Leboeuf and Armand, 2019), this doctoral thesis programme of work would recommend against basing the diagnosis of abnormality or benefits of treatment on normative values, theoretical or otherwise. Without further research to establish population representative normative kinematic data, the creation of

objective RTCGA observations reliant on normal and abnormal kinematics have an increased risk of poor validity, missed diagnosis and misdiagnosis.

9.3 Discussion of the inductive stages 5 and 6

The aim of this doctoral thesis programme of work was to establish a best practice approach for RTCGA to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults. If possible, this would then aid in the diagnosis and treatment of MSK patients.

Following the decision to reject the initial objective best practice approach to MSK RTCGA using methods discussed in section 9.2 (pages 161-165), an explorative study was undertaken with clinicians to increase the understanding of RTCGA in the assessment and treatment of adults with lower limb MSK injury (Harradine *et al.*, 2021). Results demonstrated that RTCGA was a frequently used procedure in clinical practice and that the attitude towards the need for further guidance via a RTCGA best practice approach was positive.

RTCGA clinical recommendations, now known as the GAIT assessment, were therefore developed from the results of scoping, development and the exploratory study into the use of RTCGA by MSK podiatrists. Due to the enormous range of potential MSK conditions assessed by clinicians, the lack of kinematic normative data, and the need to collect detailed interview data, the common and often debilitating focus condition of PTTD was chosen. Using an exemplar condition allowed for a more individualised approach to RTCGA in a symptom specific situation. This approach has been recommended previously as a solution to the lack of available large normative data repositories and the variability of normal gait observations (Horst *et al.*, 2017; Horst, Mildner and Schöllhorn, 2017).

Findings from the exploratory study are unique. This is the first known study to explore this topic of relevance to clinicians and researchers alike. Five themes emerged and were identified as 1) RTCGA Method; 2) Working with RTCGA; 3) RTCGA uses; 4) What could aid RTCGA?; 5) How RTCGA skills are acquired (Chapter 7, pages 125-144) (Harradine *et al.*, 2021). Clinical observations were not only kinematic, but also included patient perceived experiences such as pain

and orthosis comfort. The most common barefoot RTCGA observations performed were the rearfoot to leg angle, medial bulge, forefoot abduction and arch height. Documentation methods varied with a 4-point scale system to grade motion and position most often employed and decided via experience.

However, the use of experience by which to measure or grade RTCGA observations does raise serious concerns regarding the individuality of such experience for each podiatrist. This aspect requires further investigation as part of reliability and validity testing. There may be an underpinning observational experience common to all podiatrists for specific MSK conditions, meaning inter-tester reliability of observation grades could be satisfactory. However, this may not be the case. The recognition of experience as an important part in the RTCGA process guides future reliability and validity testing to investigate this method of measuring or scaling RTCGA observations.

This study does highlight a problem with the creation of clinical recommendations in the absence of substantive underpinning literature, as they depend on existing literature by which to be created. Without such literature, it may be plausible to reason against the development of clinical recommendations. If there's no literature, then there's no evidence apart from expert opinion. With no robust evidence, then there can be no robust best practice approach. However, topics with limited evidence, such as RTCGA, have been stated to benefit most from guidance development, due to the uncertainty and conflicting opinions inherent in their use (Rosenfeld and Shiffman, 2009). We have established that, for PTTD amongst UK podiatrists, RTCGA is frequently undertaken and for a variety of reasons other than just to observe kinematics. These findings are novel, not noted in literature elsewhere. Without such creation of knowledge and clinical recommendation development this primary approach to clinical best practice cannot be initiated.

The preliminary conceptual aims were for a RTCGA best practice approach to provide an accurate diagnosis of abnormal gait, provide an accurate assessment of gait changes following intervention and be relatively short and simple to complete (Section 5.3.1, Chapter 5, pages 63-65). These conceptual aims were created by the thesis author but are similar to the opinions on RTCGA uses for

PTTD from themes 1-4 in sections 7.3.1 to 7.3.4 (Chapter 7, pages 132-138) (Harradine *et al.*, 2021). This similarity is encouraging for the validity of this research study in relation to representing the general requirements of MSK podiatrists and RTCGA. The GAIT assessment presented in Chapter 8 (section 8.3, page 154) may not meet these conceptual aims without further research and development. The inability to produce detailed guidance based upon robust evidence means currently the recommendations may provide inaccurate or misleading results, and so do not fulfil the role of a best practice approach. At best the GAIT assessment may increase the knowledge in relation to PTTD RTCGA timing of use (recommendation 1), procedure (recommendations 2 and 3), and education (recommendation 4), and provide the initial step into the development of further clinical guidance (see Chapter 11, pages 183-186).

However, there remains a void of knowledge and evidence gap regarding the use of RTCGA for all other adult lower limb MSK conditions. Within the environment of this lack of RTCGA research, it may be beneficial to suggest the GAIT assessment for PTTD can be translated into other conditions. For example, the aim of all RTCGA may be to establish the known kinematic variations linked to the MSK condition in question, observe and grade them (currently based upon the clinicians' experience), and then note if these improve following intervention. RTCGA could still also be used to assess patient pain and orthoses comfort. Such an assumption is fraught with difficulty. Without further investigation into the perceived need for RTCGA clinical recommendations or guidance, including exploratory or consensus studies, the transferability of the approach for PTTD into all MSK lower limb conditions remains unknown. There may be a variety of different RTCGA approaches for a variety of different conditions, or there may be a common underpinning process for which PTTD may or may not be representative. Further clinical recommendation or guidance development and evaluation is required. Until then the clinical use and reasons of RTCGA in adult non-neurological lower limb MSK clinics for conditions other than PTTD remains unknown. MSK clinicians undertaking RTCGA for all conditions, including PTTD, should be aware of the limitations of this assessment method and undertake RTCGA with the understanding of such. RTCGA may be an unnecessary, invalid, and unreliable clinical investigation, the use of which could lead to unwarranted,

ineffective or harmful interventions as well as superfluous economic demands on services and patients.

9.4 Summary of the findings

Due to a significant lack of robust guiding literature, this PhD has attempted to develop an objective best practice RTCGA approach via a deductive reasoning approach. Using a clinical user led approach and laboratory testing procedures, a preliminary objective and quantifiable RTCGA instrument was first created and tested. This initial attempt to address the research aim was unsuccessful due to a lack of existing RTCGA literature and the inability to adequately perform preclinical testing. Following stages 1-4, this unsuccessful outcome led to an intermediatory result relating to the research question; it was not possible to develop an objective RTCGA approach to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults using this method.

Prior to stage 5, the evidence gap revealed in Chapter 3 still existed; that RTCGA is commonly recommended to be beneficial in MSK diagnosis and management, but actual methods and uses of it remain unknown. Due to the clear absence of evidence to support clinical reasoning, an exploratory study was undertaken to aid in the understanding of MSK podiatrists' attitudes towards and uses for RTCGA (stage 5). An exemplar symptom (PTTD), recognised as a condition that MSK podiatrists are both familiar with and likely be using RTCGA for, was chosen to aid in obtaining depth and detail from results in an area with limited existing evidence. It also guided the RTCGA approach away from being developed to evaluate all lower limb non-neurological MSK injury to instead being symptom specific, in this case PTTD. A more individualised and symptom specific approach to GA has been suggested to be desirable in the absence of population normative data (Horst *et al*., 2017; Horst, Mildner and Schöllhorn, 2017). Findings demonstrated that RTCGA was an important part of the clinical assessment, and that the MSK participants attitude towards a more standardised approach to RTCGA for PTTD was positive.

Using the available literature and clinicians view, of which the explorative study made up the most significant proportion (see Chapter 7, pages 125-144) (Harradine *et al.*, 2021), the GAIT assessment was developed as a preliminary RTCGA best practice approach (see Chapter 8, pages 145-158). This approach consists of 4 core recommendations, supplying initial and unique RTCGA guidance to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults. This doctoral thesis programme of work has provided profession specific guidance in an early form for a common and debilitating MSK condition (PTTD). However, this approach is limited not only in use to the exemplar condition of PTTD and to UK based MSK podiatrists, but also due to the lack of robust evidence and detail upon which the recommendations were formed. Relating this to the research aim, question and hypothesis, based on the existing scientific foundations it does not currently appear possible to develop a robust best practice RTCGA approach to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults. Further knowledge into MSK clinician RTCGA observations, to reduce the vagueness of clinical recommendations, is required to address these limitations, followed by further testing into the validity and reliability of these recommendations. This testing requires advancements in knowledge and technology, such as a repository of normative data relating to symptom specific RTCGA observations, and methods by which to test observations in a manner valid to the clinical environment.

An overview and summary of the chapters, stages, frameworks, approaches and publications undertaken in this thesis are presented in Table 9.1 (page 170).

Table 9.1. An overview of the chapters, stages, frameworks, approaches and publications undertaken in this thesis

Chapter	Stage	Framework	Approach	Publication
1 Document introduction	N/A	N/A	N/A	N/A
2 Background	N/A	N/A	N/A	(Harradine, Gates and Bowen, 2018a)
3 Narrative review	1	Writing narrative style literature reviews (Ferrari, 2015)	Deductive	N/A
4 Systematic review	2	The Critical Appraisal Skills Programme tool (CASP, 2017) Preferred Reporting Items for Systematic Reviews and Meta-Analyses (Moher *et al.*, 2009) Patient, Intervention, Comparison and Outcome statement (Santos, Pimenta and Nobre, 2007)	Deductive	(Harradine, Gates and Bowen, 2018b)

5 Development of a quantifiable RTCGA instrument	3	Architecture of diagnostic research (Colli *et al.*, 2014) Development of health measures (Streiner, Norman and Cairney, 2015)	Deductive Quantitative	N/A
6 Preclinical testing of face validity, reliability and concurrent validity	4	Architecture of diagnostic research (Colli *et al*., 2014) Development of health measures (Streiner, Norman and Cairney, 2015)	Deductive Quantitative	N/A
7 Exploration of MSK podiatrists' views and experiences of RTCGA	5	Thematic Analysis (Braun and Clarke, 2013)	Inductive Qualitative	(Harradine *et al.*, 2021)
8 Development of a RTCGA recommendations	4	Appraisal of Guidelines for Research and Evaluation II(Brouwers *et al.*, 2010) Developing NICE guidelines: the	Inductive	N/A

		manual (NICE, 2015)		
9 Discussion	N/A	N/A	N/A	N/A
10 Conclusion	N/A	N/A	N/A	N/A
11 Proposal for further work	N/A	Dependant on the result of further exploratory and expert consensus outcomes	Mixed Methods	N/A

9.5 General strengths and limitations of the study

Specific strengths and limitations of studies making up this body of research are presented within their individual chapters and also individually during sections of this discussion (sections 9.2 and 9.3, pages 161-168). General strengths and weaknesses of this body of work are now considered.

A best practice approach for PTTD amongst UK MSK podiatrists has been developed (the GAIT assessment), limitations noted, and further work suggested (see Chapter 11, pages 183-186). The stages of development leading to the GAIT assessment may have benefitted from the earlier use of established methodological frameworks, such as those by the UK NICE (NICE, 2015). However, the development of clinical recommendations, rather than a clinical scale or measure, was not preordained at the initiation of this doctoral thesis programme of work. The stages of the GAIT assessment development therefore differ from established frameworks due this approach. This may limit the validity of the RTCGA clinical recommendations. The thesis hypothesis, however, was to determine if it was possible to develop a best practice RTCGA approach and it is acknowledged that these recommendations form a foundation step towards guideline development.

Non adult and neurological MSK gait abnormality was excluded from early literature reviewing due to the specific kinematic observations and clinical environments relating to other patient groups (see Chapter 2, section 2.4, pages 17-19). However, this early exclusion may have reduced inclusion of relevant literature pertaining to the development of MSK RTCGA best practice approaches. Further appreciation of RTCGA methods from other patient samples may have aided the iterative approach, positively directing initial investigations. Gait assessment scales make up part of the preliminary PTTD clinical recommendations (recommendations 2 and 3, sections 8.2.2 and 8.2.3, Chapter 8, pages 147-153). These RTCGA PTTD recommendations are acknowledged as being vague, and further development to provide more detailed guidance has been proposed (see Chapter 11, pages 183-186). Although no robust guiding literature relating to MSK lower limb assessment scales was found from reviews conducted in this doctoral thesis programme of work (See Chapters 3-4, pages 29-56), they do exist for the assessment of non-MSK specific walking disorders. In a systematic review Ridao-Fernandez, Pinero-Pinto and Chamorro-Moriana (2019) note observational (RTCGA) gait assessment scales used in assessment and treatment of neurological walking problems (12 observational gait scales), bone healing (1 observational gait scale) and the use of crutches (1 observational gait scale). However, further narrative review of these 14 methods reveals the majority (10 of the 14) were created through author opinion (Hughes and Bell, 1994; Lord, Halligan and Wade, 1998; Mackey *et al.*, 2003; Read *et al.*, 2003; Toro, Nester and Farren, 2003; Thomas *et al.*, 2004; Wrisley *et al.*, 2004; Dickens and Smith, 2006; Williams *et al.*, 2009; Macri *et al.*, 2012) rather than expert consensus such as delphi studies (Daly *et al.*, 2009; Chamorro-Moriana *et al.*, 2016) or professional focus groups (Field-Fote *et al.*, 2001; Clarke and Eccleston, 2009). In relation to methodological quality, 3 of the top 4 gait assessment scales noted by Ridao-Fernandez, Pinero-Pinto and Chamorro-Moriana (2019) were developed using author opinion. It is therefore unlikely that earlier appreciation of these approaches would have deterred from the initial attempt to create a MSK objective RTCGA instrument based similarly upon author opinion and available literature (see section 5.2, Chapter 5, pages 58-60).

Similar to the objective RTCGA instrument development method described in Chapter 5 (pages 57-103), all the 14 observational (RTCGA) assessment scales have also been tested for validity against the comparable gold standard technology, and reliability via repeated method designs (Ridao-Fernández, Pinero-Pinto and Chamorro-Moriana, 2019). In addition, like the symptom specific approach to MSK RTCGA recommended following this doctoral thesis programme of work, each approach was disorder specific. Consequently, the inclusion of non-MSK RTCGA search terms is unlikely to have significantly altered the process or final outcome of this thesis work.

The thesis author undertook this study part time while working as an MSK podiatrist with over 25 years clinical MSK experience. This clinical experience and insider perspective positively aided in discussions with MSK podiatrists due to inherent understanding of RTCGA, MSK podiatry clinics and MSK patient presentations. However, as discussed in relation to the RTCGA instrument in Chapter 5 (section 5.5.1, pages 97-102), confirmation and cultural bias may have been influential in all sections of this research. To minimise the influence of bias, the study supervisors (consisting of 2 experienced clinical and academic podiatrists and an engineer with a background in clinical orthotics and prosthetics) closely monitored all areas of the research through the iterate stages and steps of data analysis through to study findings and clinical recommendation development.

A strong point to this study is the novel path undertaken. Prior to this research the author is aware of no substantive or robust guiding literature upon MSK RTCGA. By supplying primary data and findings, further work can be recommended and conducted. This has also been a weakness, with the lack of previous literature leading to difficulties in the development of a best practice approach. However, methods to overcome this were employed leading to the iterate and pragmatic approach undertaken, and the initiation of providing literature and guidance for future work to refer to and to expound upon.

Another strength of this study is the publication of work included in this doctoral thesis. This approach resulted in studies associated with stages 2 and 5 undergoing a thorough review process via journal peer review and being published within international journals. The international peer review undertaken

during the publication process helped mitigate against lone researcher bias in relation to these stages, ensuring the accuracy and trustworthiness of findings.

9.6 Implications of the best practice RTCGA approach to podiatry

The aim of this thesis was to establish a best practice approach for RTCGA to be used as part of a clinical assessment in the treatment of lower limb MSK related symptoms in adults. Whilst the recommendations produced through this programme of work go some way to meeting this, they still fall short of meeting the conceptual aims of a RTCGA best practice approach. The pathway to achieving a robust clinical practice guideline as defined by NICE (NICE, 2015) requires more work, such as that proposed in Chapter 11 (pages 183-186). The lack of objective kinematic data for this field was a significant barrier to investigating and improving reliability and validity of RTCGA observations. RTCGA, as an aid in the diagnosis and treatment of MSK injury, is arguably a high-level skill associated with professional specialisation (Nancarrow and Borthwick, 2005). It follows therefore that such a skill would be supported by objectivity and standardisation of practice, yet the lack of normative data for RTCGA continues to act as a barrier to this.

A potential explanation that may underlie these barriers lies within the context of charismatic authority. Charismatic authority is one of Weber's 3 types of authority (Allen, 2017). It confers a combination of social and cultural domination and authority, where leaders are followed and believed not because they are necessarily perceived as being correct or legal (rational-legal authority), or that they adhere to historic methods (traditional authority), but instead because the assertion of a specialist practice and knowledge is instilled within their authority (Bacon and Borthwick, 2013).

As demonstrated in the first publication related to this doctoral thesis programme of work (Harradine, Gates and Bowen, 2018a), it can be argued that charismatic authority has dominated the field of MSK practice within podiatry for years. Since the 1970s 3 theories have become established in the podiatric literature in relation to the assessment and treatment of gait-related lower-quadrant symptoms; the STJN theory, TS theory and SPF theory (Payne, 1998; Harradine and Bevan,

2009; Harradine, Gates and Bowen, 2018a). None of these theories have higher order research outcomes that would be expected for evidence-based practice (Murad *et al.*, 2016) and for the creation of best practice approaches. Instead, it may be argued that podiatrists are using these theories because of the assertion of specialist knowledge and practice being instilled within the theory leader's authority (charismatic authority) (Bacon and Borthwick, 2013). In relation to the development of RTCGA best practice guidance, research into population normative kinematic values may not have been conducted as it was thought unnecessary, as the definition of normal function was already provided by the charismatic authority (see Table 2.1 – Theoretical differences between current foot function theories, Chapter 2, page 21). When normal and abnormal foot function has been established for a profession by charismatic authority rather than an evidence base, the creation of measures or approaches that depend upon normative data becomes impossible unless they also align with those beliefs. Using the STJN theory as an example, normal foot kinematics have been defined as the STJ passing through its neutral position at contact and propulsive phases of gait (Root, Orien and Weed, 1977). Studies have instead found this believed normative foot motion and position to be incorrect (McPoil and Cornwall, 1994; Pierrynowski and Smith, 1996). Any RTCGA approach based on these STJN theory assumptions would therefore also be incorrect from an evidence based perspective, meaning these RTCGA observations could not be included for best practice and clinical practice guideline development (NICE, 2015).

The research undertaken in this doctoral thesis programme of work demonstrates a drive to establish the best practice approaches and national guidelines for the treatment of MSK injury by podiatrists. Such national guidance provides the legitimacy and establishment of evidence-based podiatry and so theoretically begins the rationalisation and formalisation of approaches such as RTCGA. To establish such guidance, it is essential to adopt an evidence-based approach rather than depend upon opinions created by charismatic authority. Adopting an evidence-based best practice approach to the development of podiatry MSK skill sets may therefore be seen as a shift in paradigms for podiatry. Using a best practice paradigm does not negate the use of key concepts and approaches of any of the 3 historic paradigms, but it does put them under the scrutiny of

evidence. If a treatment concept is investigated and demonstrated to be efficacious, then this becomes a reason for its use rather than it being because the charismatic authority of the theory states it should be. The production and testing of clinical recommendations and guidelines such as those attempted in this thesis removes the unstable and limiting factors associated with charismatic authority, encouraging and enabling the rationalisation and legitimisation of MSK approaches and further promoting an evidence-based and best practice approach in podiatry.

9.7 Dissemination

The proposed programme of work was presented at the Primary Care and Public Health Conference, Birmingham NEC, on the 16th May 2018 via a podium presentation and the systematic review presented via a poster presentation at the 2019 College of Podiatry annual conference.

The following publications were completed during this doctoral thesis programme of work:

- Harradine, P., Gates, L. and Bowen, C. (2018a) 'If it doesn't work, why do we still do it? The continuing use of subtalar joint neutral theory in the face of overpowering critical research', Journal of Orthopaedic and Sports Physical Therapy, 48(3), pp. 130-132.

JOSPT publishes content for physical therapists and others in the health care community to advance MSK and sports-related practice globally.

With an impact factor of 3.090 in 2017, it is among the highest ranked physical therapy journals. JOSPT stands eighth of 65 journals in the category of rehabilitation, twelfth of 77 journals in orthopaedics, and fourteenth of 81 journals in sport sciences. Its 5-year impact factor is 4.061. It is the official journal of the Orthopaedic Section and the Sports Physical Therapy Section of the American Physical Therapy Association.

JOSPT article metrics notes 12 citations of this paper and an Altmetric Attention Score of 130 (JOSPT article metrics. Accessed 31/01/22). The Altmetric Attention

Score is an automatically calculated, weighted count of all the attention a research output has received. The score of 130 places it within the in the top 5% of all research outputs scored by Altmetric.

- Harradine, P., Gates, L. and Bowen, C. (2018b) 'Real time non-instrumented clinical gait analysis as part of a clinical musculoskeletal assessment in the treatment of lower limb symptoms in adults: A systematic review', Gait and Posture, 62, pp. 135-139.

Gait and Posture is a global vehicle for the publication of up-to-date basic and clinical research on all aspects of locomotion and balance. It has an impact factor of 2.273 in 2017 and a 5-year impact factor of 2.971. It is the official journal for the Gait and Clinical Movement Analysis Society, the European Society of Movement Analysis in Adults and Children, and the International Society for Posture and Gait Research.

Gait and Posture article metrics notes 3 citations of this paper (Gait and Posture article metrics, Accessed 31/1/22).

- Harradine, P. *et al*. (2021) 'Podiatrists' views and experiences of using real time clinical gait analysis in the assessment and treatment of posterior tibial tendon dysfunction', Journal of Foot and Ankle Research, 14(1), pp. 1-10.

JFAR is the official journal of the Australian Podiatry Association and The Royal College of Podiatry (UK), it is an open access journal that encompasses all aspects of policy, organisation, delivery and clinical practice related to the assessment, diagnosis, prevention and management of foot and ankle. It has a 5 year impact factor of 1,983.

JFAR article metrics notes over 2500 accesses of this paper and an Altmetric Attention Score of 8 (JFAR article metrics. Accessed 31/01/22). The Altmetric score of 8 places it within the in the top 25% of all research outputs scored by Altmetric.

Future dissemination is planned via:

1) Conference podium presentation at the British Orthopaedic Foot and Ankle Society (BOFAS) conference. Bournemouth. 10th March 2022

2) Conference podium presentations at the Biomechanics Summer School. Manchester. 13th and 14th May 2022

3) Conference podium presentation and workshops at the Kettering Foot Health Conference. Kettering 14th and 15th June 2022

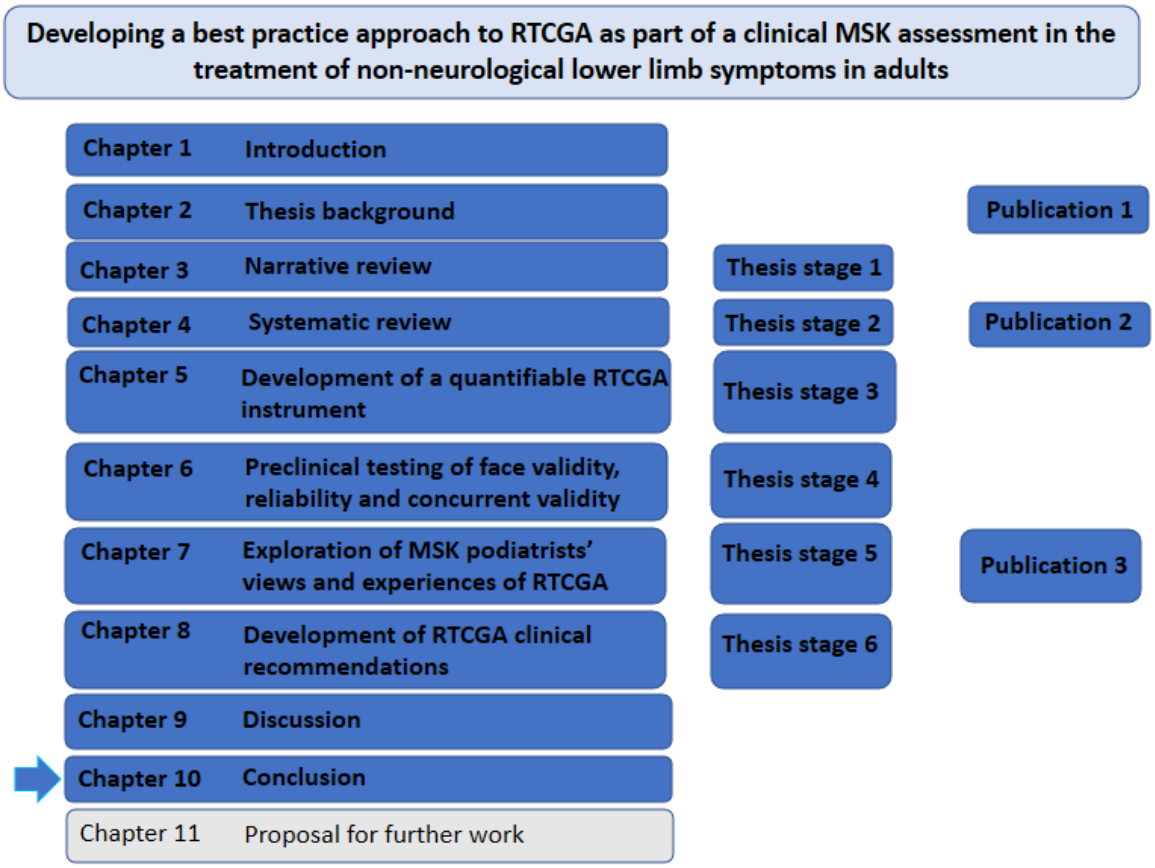
4) Dissemination article to be submitted to 'The Podiatrist'. The Podiatrist is the Royal College of Podiatry's bi-monthly magazine. It is supplied as a paper copy to all members, and contains features, interviews, case studies and news of the work of the College.

5) Creation of a website detailing the GAIT assessment method and development.

Chapter 10 Conclusion

Figure 10.1 demonstrates Chapter 10 within an overview of the doctoral thesis.

Figure 10.1. Doctoral thesis overview demonstrating Chapter 9 within the context of the programme of work



This research consists of an iterate body of work exploring the creation of a best practice approach for adult MSK RTCGA. It is the first research to apply development frameworks and methods in the attempt to create a best practice approach for adult non-neurological MSK RTCGA.

Methods undertaken in this doctoral thesis programme of work have provided a preliminary best practice approach, the GAIT assessment, providing unique guidance for RTCGA and adult PTTD. However, due to a continuing evidence gap, the quality of the clinical recommendations making up this approach are of reduced clinical quality. It has therefore not been possible to satisfactorily accomplish the research aim; to establish a best practice approach for RTCGA to

be used as part of a clinical MSK assessment in the treatment of lower limb symptoms in adults. A resultant process by which further work can be undertaken to establish a best practice approach is presented, following the creation of symptom specific RTCGA clinical recommendations. This new approach means RTCGA is focussed on the patient symptom and evidence based kinematic observations.

However, following a thorough and systematic review of the literature and methods (Chapters 3-4), exploration of clinician opinions (Chapter 7) and creation of best practice approaches (Chapters 5,6 and 8), findings from this thesis demonstrate there is not enough existing evidence or knowledge relating to adult lower limb MSK RTCGA for these further recommendations to be currently developed to a higher quality. At this time the research hypothesis cannot be accepted, and the research question has been successfully answered. It is currently not possible to develop a best practice approach for RTCGA to be used as part of a clinical MSK assessment in the treatment of non-neurological lower limb symptoms in adults.

Although suggested outcomes of performing RTCGA dictate a benefit to MSK patient care and outcomes, the evidence is inconclusive. Further work is required to address the evidence gaps established within this programme of work. Without this further RTCGA guidance, built upon a robust evidence base, the reverse may also be true. RTCGA may be an unnecessary, invalid and unreliable clinical investigation, the use of which could lead to needless, ineffective or harmful interventions that unintentionally increase the injury burden on MSK patients. Although the GAIT assessment may aid in the assessment and treatment of PTTD, the use of RTCGA for all lower limb MSK adult conditions should be undertaken only with acceptance that it may provide unreliable and invalid results. That said, this GAIT approach could be viewed as a foundation model for RTCGA that, if given more focused and collaborative attention, provides additional insights to advance the field towards RTCGA best practice approaches that are valid, reliable and repeatable.

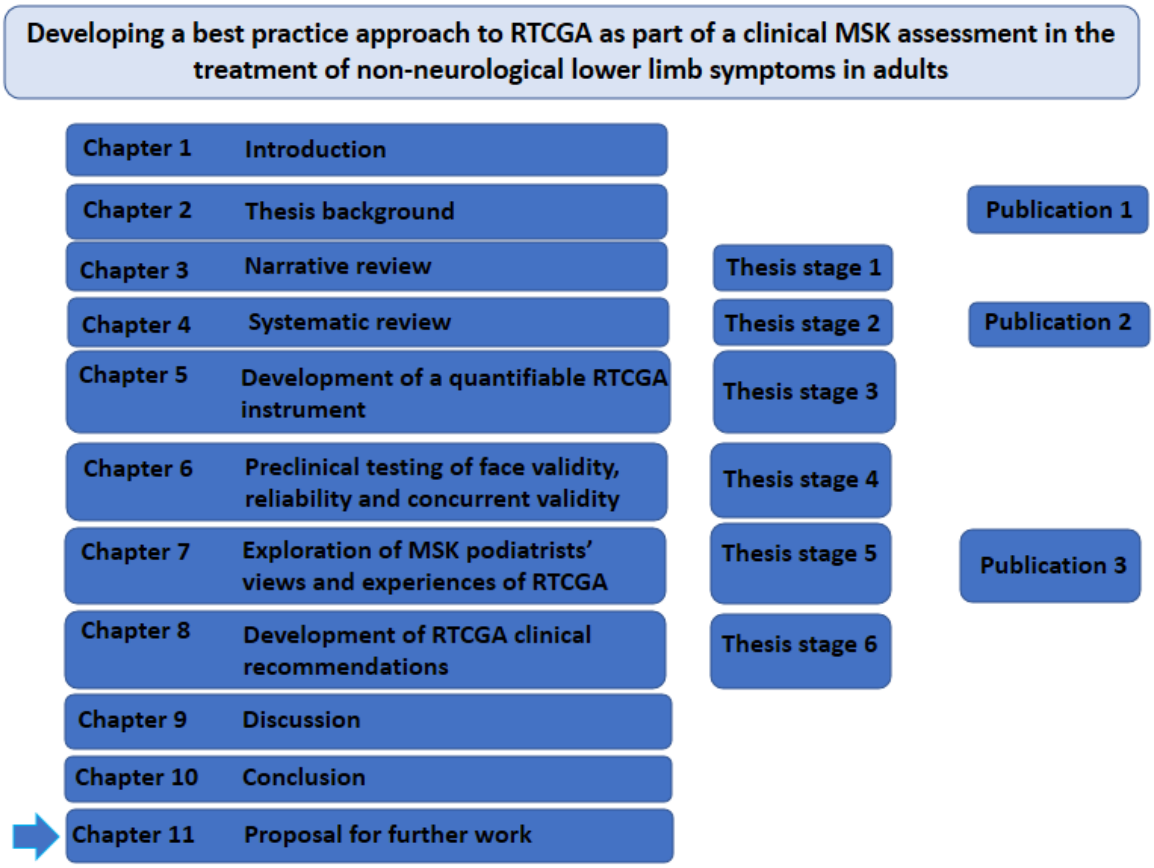
Chapter 11 Proposal for further work

11.1 Introduction

This doctoral thesis programme of work has shown a need and benefit for performing RTCGA for the assessment and treatment of adults with MSK non-neurological lower limb injury (using PTTD as the model condition). The GAIT assessment process has been developed as a best practice approach, providing 4 RTCGA clinical recommendations in a set order to aid in the assessment and treatment of MSK non-neurological lower limb injury.

In this final Chapter (Chapter 11), the proposal for future work is described with a view to further development and production of best practice MSK RTCGA GAIT assessment guidelines. Figure 11.1 demonstrates Chapter 11 within an overview of this doctoral thesis programme of work.

Figure 11.1. Doctoral thesis overview demonstrating Chapter 11 within the context of the programme of work



11.2 Research plan: next steps in GAIT assessment guideline development

Further knowledge and opinion on the GAIT assessment process and recommended observations would be collected via expert consensus (11.2.1 and 11.2.2). These observations would then be tested for validity and reliability (11.2.3) and best practice approaches developed (11.2.4)

11.2.1. Exploring if the GAIT assessment process can be translated to other MSK lower limb injury

The GAIT assessment process can be briefly summarised as: initially obtain a clinical diagnosis, perform specific recommended RTCGA observations for that diagnosis (before and after intervention) and teach the skill of the specific RTCGA observations based upon clinical experience. This process would be investigated

to assess its clinical use for other gait related MSK non-neurological lower limb injury.

11.2.2 Establish specific recommended RTCGA observations for MSK lower limb non-neurological conditions

The GAIT assessment process has already established specific RTCGA observations for PTTD. These would be used as preliminary guidance to take forward for the expert consensus, and obtaining further detail regarding the measure and scaling of RTCGA observations.

For conditions other than PTTD, knowledge of specific observations for MSK lower limb conditions thought to benefit from RTCGA could be explored and established.

11.2.3 Test recommended observations for validity and reliability

In the absence of pre-existing reliability or validity evidence in relation to RTCGA observations, it is advised such testing is undertaken prior to observations or measures being subject to clinical guidance development. However, it is difficult to predict the outcome to investigations leading to this point (see 11.2.1 and 11.2.2).

Testing into the reliability and validity of recommended RTCGA observations may be gait-laboratory based. With greater information upon the RTCGA method and specific observations available, it is hoped some of the issues in testing kinetic observations highlighted in sections 6.3.2 (Chapter 6, pages 121-122) and section 9.2 (Chapter 9, pages 161-165) will be addressed. For example, if kinematic observations are related to a population normal, only those kinematic observations specific to the symptom need to be researched. Theoretically this should involve far less work than establishing population representative normative kinematic data for, for example, the entire lower limb. If kinematic observations are not related to a population normal value but to the symptom (such as the medial bulge in PTTD, see section 8.2.2, Chapter 8, pages 147-152) the issue with the lack of population kinematic data is reduced. For greater validity, and to remove the need to transiently alter kinematics in a healthy sample, a walking sample with the specific MSK symptom could be recruited. MSK clinicians would

then perform RTCGA of the walking sample within the gait laboratory, allowing comparison of their findings to each other (inter-tester reliability) and 3D gold standard Vicon Kinematic data (concurrent validity).

However, clinical recommendations could be more subjective and based upon symptom and patient perceived outcomes. Longitudinal studies to validate prediction may be required. A mixed methods approach where both gait laboratory and clinical based assessment of validity and reliability could occur.

11.2.4. Creation of GAIT assessment clinical recommendations

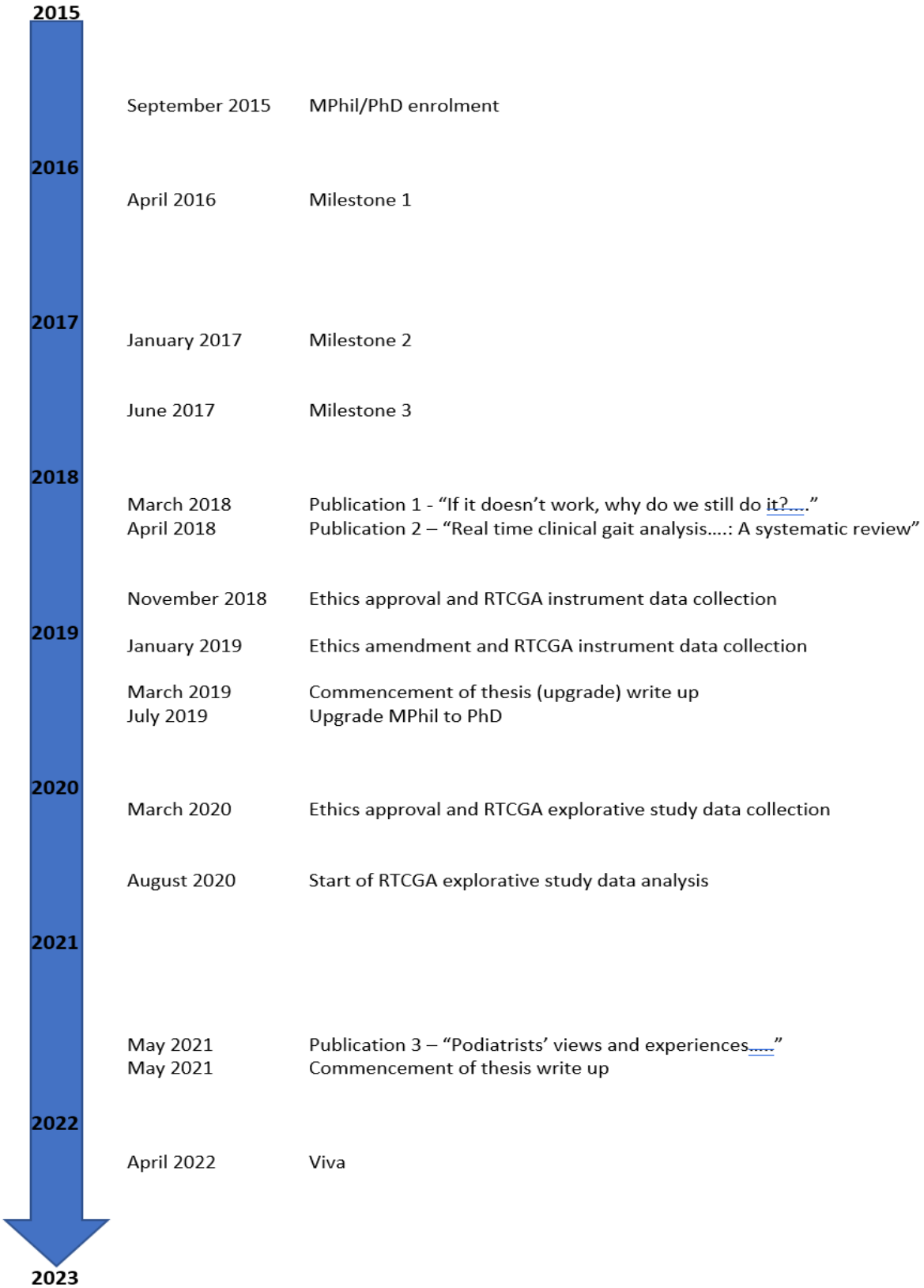
Following validity and reliability testing, if results appear satisfactory, a process of clinical guidance development for symptom specific RTCGA is recommended. If the underpinning GAIT assessment process remains, this may lead to the creation symptom specific GAIT assessments, such as a GAIT assessment for PTTD or a GAIT assessment for patellofemoral pain syndrome. Ideally, compliance with established clinical guidance development frameworks, such as the NICE guidelines (NICE, 2015), is recommended and would be beneficial to the overall quality of guidance.

11.3 Conclusion

Although detail for possible further work is presented within this Chapter, it is difficult to predict outcomes from initial investigations which will determine later research methods. However, this chapter demonstrates how work undertaken in this doctoral thesis has established a foundation and method upon which further research can be conducted within recognised frameworks and guidance.

Appendices

Appendix A. PhD canditature timeline



Appendix B – CASP evaluation forms (CASP, 2017)

B1 Brunnekreef, J.J. *et al.* (2005) 'Reliability of videotaped observational gait analysis in patients with orthopedic impairments', *BMC Musculoskeletal Disorders*, 6(1), pp. 1-9

CASP
Critical Appraisal Skills Programme

Paper for appraisal and reference:(Brunnekreef *et al.*, 2005).....

Section A: Are the results of the trial valid?

1. Was there a clear question for the study to address?

Yes	
Can't Tell	
No	X

HINT: A question should include information about
- the population
- the test
- the setting
- the outcomes

Comments: A study of a structured GA form used in the 'observational gait ~~analysis'~~ of patients with orthopaedic disorders. Unclear as to whether the form is designed to be used for RTCGA, or just to aid in interpretation of CGA

2. Was there a comparison with an appropriate reference standard?

Yes	
Can't Tell	
No	X

HINT: Is this reference test(s) the best available indicator in the circumstances

Comments: Reliability study only. No details regarding the validity of the GA form used

Is it worth continuing?

3. Did all patients get the diagnostic test and reference standard?

Yes	
Can't Tell	X
No	

HINT: Consider
- were both received regardless of the results of the test of interest
- Check the 2x2 table (verification bias)

Comments: Not applicable.

CASP
Critical Appraisal Skills Programme

4. Could the results of the test have been influenced by the results of the reference standard?	Yes Can't Tell No	 	HINT: Consider • was there blinding • were the tests performed independently • review bias

Comments: Not applicable

5. Is the disease status of the tested population clearly described?	Yes Can't Tell No	 X	HINT: Consider • presenting symptoms • disease stage of severity • co-morbidity • differential diagnoses (spectrum bias)

Comments: No definition of orthopaedic disorders or 'mild to severe' gait deviation

6. Were the methods for performing the test described in sufficient detail?	Yes Can't Tell No	 X	HINT: Consider • was a protocol followed

Comments: Methods of completing the form were not supplied in any detail

Section B: What are the results?

CASP
Critical Appraisal Skills Programme

7. What are the results?

HINT: Consider
- are the sensitivity and specificity and/or likelihood ratios presented
- are the results presented in such a way that we can work them out

Comments: Moderate reliability, but using CGA video observation NOT RTCGA

8. How sure are we about the results? Consequences and cost of alternatives performed?

HINT: Consider
- could they have occurred by chance
- are there confidence limits
- what are they

Comments: Small sample, lack of detail of observers.

Section C: Will the results help locally?
Consider whether you are primarily interested in the impact on a population or individual level

9. Can the results be applied to your patients/the population of interest?

Yes	
Can't Tell	
No	X

HINT: Do you think your patients/population are so different from those in the study that the results cannot be applied, such as age, sex, ethnicity and spectrum bias

Comments: Use of video / CGA. Mild to severe gait deviations

CASP
Critical Appraisal Skills Programme

10. Can the test be applied to your patient or population of interest?

Yes	
Can't Tell	
No	X

HINT: Consider
- resources and opportunity costs
- level and availability of expertise required to interpret the tests
- current practice and availability of services

Comments:

11. Were all outcomes important to the individual or population considered?

Yes	
Can't Tell	
No	X

HINT: Consider
- will the knowledge of the test result improve patient wellbeing
- will the knowledge of the test result ~~lead~~ to a change in patient management

Comments: the benefits of a reliable GA approach to the diagnosis and management of MSK related injury were not discussed in detail

12. What would be the impact of using this test on your patients/population?

Comments: NA as CGA tested only. With CGA and mild to severe gait deviations, GA form still only moderately reliable. No validity investigated.

B2 Beattie, K.A. *et al.* (2008) 'Validation of the GALS musculoskeletal screening exam for use in primary care: a pilot study', *BMC Musculoskeletal Disorders*, 9(1), pp. 1-8.

CASP
Critical Appraisal Skills Programme

Paper for appraisal and reference: (Beattie *et al.*, 2008)

Section A: Are the results of the trial valid?

1. Was there a clear question for the study to address?

Yes	X
Can't Tell	
No	

HINT: A question should include information about
- the population
- the test
- the setting
- the outcomes

Comments: Canadian study. Population, GALS, GALS training, Study ~~setting~~ and outcomes measures all present in detail

2. Was there a comparison with an appropriate reference standard?

Yes	
Can't Tell	
No	X

HINT: Is this reference test(s) the best available indicator in the circumstances

Comments: family physicians GALS assessment compared with those of rheumatologists. The reliability and validity of the Rheumatologist scores had not been determined, and was not commented upon in the paper

Is it worth continuing?

3. Did all patients get the diagnostic test and reference standard?

Yes	X
Can't Tell	
No	

HINT: Consider
- were both received regardless of the results of the test of interest
- Check the 2x2 table (verification bias)

Comments: All participants were examined by all practitioners, including the Rheumatologists (the reference standard test)

CASP
Critical Appraisal Skills Programme

Paper for appraisal and reference: (Beattie *et al.*, 2008)

Section A: Are the results of the trial valid?

1. Was there a clear question for the study to address?

Yes	X
Can't Tell	
No	

HINT: A question should include information about
- the population
- the test
- the setting
- the outcomes

Comments: Canadian study. Population, GALS, GALS training, Study ~~setting~~ and outcomes measures all present in detail

2. Was there a comparison with an appropriate reference standard?

Yes	
Can't Tell	
No	X

HINT: Is this reference test(s) the best available indicator in the circumstances

Comments: family physicians GALS assessment compared with those of rheumatologists. The reliability and validity of the Rheumatologist scores had not been determined, and was not commented upon in the paper

Is it worth continuing?

3. Did all patients get the diagnostic test and reference standard?

Yes	X
Can't Tell	
No	

HINT: Consider
- were both received regardless of the results of the test of interest
- Check the 2x2 table (verification bias)

Comments: All participants were examined by all practitioners, including the Rheumatologists (the reference standard test)

CASP
Critical Appraisal Skills Programme

7. What are the results?

HINT: Consider
- are the sensitivity and specificity and/or likelihood ratios presented
- are the results presented in such a way that we can work them out

Comments: The coefficient of agreement (estimated Kappa) for the composite GALS score was 0.3675. The individual coefficient of agreement for the total gait section was slightly higher at 0.49. This demonstrates only a moderate agreement between both groups. Results are presented clearly.

8. How sure are we about the results? Consequences and cost of alternatives performed?

HINT: Consider
- could they have occurred by chance
- are there confidence limits
- what are they

Comments: CI supplied for individual and totalled GA results. Small tester sample leading to poor generalisation of results.

Section C: Will the results help locally?
Consider whether you are primarily interested in the impact on a population or individual level

9. Can the results be applied to your patients/the population of interest?

Yes	
Can't Tell	
No	X

HINT: Do you think your patients/population are so different from those in the study that the results cannot be applied, such as age, sex, ethnicity and spectrum bias

Comments: Small tester sample, and testers were not podiatrists. GALS gait assessment is basic, with no details of the GA supplied within this paper / approach apart from "abnormality detected". Agreement on this presence of abnormality poor to moderate only in the GA area of GALS assessment. "Abnormality" not defined clearly in the paper, or the GALS approach described.

CASP
Critical Appraisal Skills Programme

10. Can the test be applied to your patient or population of interest?

Yes	
Can't Tell	
No	X

HINT: Consider
- resources and opportunity costs
- level and availability of expertise required to interpret the tests
- current practice and availability of services

Comments: Inadequate detail of GA. Different professional group to podiatrists

11. Were all outcomes important to the individual or population considered?

Yes	X
Can't Tell	
No	

HINT: Consider
- will the knowledge of the test result improve patient wellbeing
- will the knowledge of the test result ~~lead~~ to a change in patient management

Comments: The need for a simple but accurate MSK assessment method and possible benefits of this were discussed.

12. What would be the impact of using this test on your patients/population?

Comments: Impact would be very limited. GALS is not detailed in ~~it's~~ GA. Simply notes to detect an abnormality and then refer on for GA.

B3 - Beattie, K.A., MacIntyre, N.J. and Cividino, A. (2012) 'Screening for signs and symptoms of rheumatoid arthritis by family physicians and nurse practitioners using the Gait, Arms, Legs, and Spine musculoskeletal examination', *Arthritis Care and Research*, 64(12), pp. 1923-1927.

CASP Critical Appraisal Skills Programme

Paper for appraisal and reference: (Beattie, MacIntyre and Cividino, 2012).....

Section A: Are the results of the trial valid?

1. Was there a clear question for the study to address?

Yes	X
Can't Tell	
No	

HINT: A question should include information about
- the population
- the test
- the setting
- the outcomes

Comments: All hints detailed

2. Was there a comparison with an appropriate reference standard?

Yes	
Can't Tell	
No	X

HINT: Is this reference test(s) the best available indicator in the circumstances

Comments: details of the Rheumatologists used as the gold standard for comparison of Family practitioner and nurse scores were not supplied. No details of reliability or validity of Rheum supplied or available. Use of Rheum as gold standard not supported.

Is it worth continuing?

3. Did all patients get the diagnostic test and reference standard?

Yes	X
Can't Tell	
No	

HINT: Consider
- were both received regardless of the results of the test of interest
- Check the 2x2 table (verification bias)

Comments: All participants were examined by all practitioners, including the Rheumatologists (the reference standard test). Low verification bias

CASP
Critical Appraisal Skills Programme

4. Could the results of the test have been influenced by the results of the reference standard?	Yes Can't Tell No	 X

HINT: Consider
- was there blinding
- were the tests performed independently
- review bias

Comments:

5. Is the disease status of the tested population clearly described?	Yes Can't Tell No	X

HINT: Consider
- presenting symptoms
- disease stage of severity
- co-morbidity
- differential diagnoses (spectrum bias)

Comments: RA or not RA

6. Were the methods for performing the test described in sufficient detail?	Yes Can't Tell No	X

HINT: Consider
- was a protocol followed

Comments:

Section B: What are the results?

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7. What are the results?

HINT: Consider
- are the sensitivity and specificity and/or likelihood ratios presented
- are the results presented in such a way that we can work them out

Comments: Family physicians and nurse practitioners appeared able to employ the GALS examination to screen for possible signs of rheumatoid arthritis

8. How sure are we about the results? Consequences and cost of alternatives performed?

HINT: Consider
- could they have occurred by chance
- are there confidence limits
- what are they

Comments: Small sample (40 patients) and only 4 testers.

Section C: Will the results help locally?
Consider whether you are primarily interested in the impact on a population or individual level

9. Can the results be applied to your patients/the population of interest?

Yes	
Can't Tell	
No	X

HINT: Do you think your patients/population are so different from those in the study that the results cannot be applied, such as age, sex, ethnicity and spectrum bias

Comments: GA not specifically used for diagnosis of RA. GA not detailed in the GALS procedure (see CASP for Beattie et al, 2008). Not general MSK population. Total composite GALS scores only reported, therefore any results from GA cannot be drawn from this study.

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10. Can the test be applied to your patient or population of interest?	Yes		HINT: Consider • resources and opportunity costs • level and availability of expertise required to interpret the tests • current practice and availability of services
	Can't Tell		
	No	X	

Comments: see above. Testers also not UK and not podiatrists

11. Were all outcomes important to the individual or population considered?	Yes	X	HINT: Consider • will the knowledge of the test result improve patient wellbeing • will the knowledge of the test result ~~lead~~ to a change in patient management
	Can't Tell		
	No		

Comments: Need for clinical diagnosis of RA to aid in patient referral discussed

12. What would be the impact of using this test on your patients/population?

Comments: Impact would be very limited. GALS is not detailed in its GA. Simply notes to detect an abnormality and then refer on for GA. Same as CASP for Beattie et al, 2008.

B4 - Sweeting, K. and Mock, M. (2007) 'Gait and posture-assessment in general practice', *Australian Family Physician*, 36(6), pp. 404-405

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Paper for appraisal and reference: (Sweeting and Mock, 2007).....

Section A: Are the results of the trial valid?

1. Was there a clear question for the study to address?

Yes	
Can't Tell	
No	X

HINT: A question should include information about
- the population
- the test
- the setting
- the outcomes

Comments: Question and aim of paper is not set out on the abstract, and does not relate to the main text

2. Was there a comparison with an appropriate reference standard?

Yes	
Can't Tell	
No	X

HINT: Is this reference test(s) the best available indicator in the circumstances

Comments:

Is it worth continuing?

3. Did all patients get the diagnostic test and reference standard?

Yes	
Can't Tell	
No	X

HINT: Consider
- were both received regardless of the results of the test of interest
- Check the 2x2 table (verification bias)

Comments: Accuracy of observational GA is compared to an X-ray, but this is not a true reference standard

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4. Could the results of the test have been influenced by the results of the reference standard?	Yes / Can't Tell / No	HINT: Consider • was there blinding • were the tests performed independently • review bias

Yes		
Can't Tell	X	
No		

Comments:

5. Is the disease status of the tested population clearly described?	Yes / Can't Tell / No	HINT: Consider • presenting symptoms • disease stage of severity • co-morbidity • differential diagnoses (spectrum bias)

Yes		
Can't Tell		
No	X	

Comments: Relation of GA to MSK condition etc not included

6. Were the methods for performing the test described in sufficient detail?	Yes / Can't Tell / No	HINT: Consider • was a protocol followed

Yes		
Can't Tell		
No	X	

Comments: Methods for performing GA not included

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Section B: What are the results?

7. What are the results?

HINT: Consider
- are the sensitivity and specificity and/or likelihood ratios presented
- are the results presented in such a way that we can work them out

Comments: Vague RTCGA recommendations with description

8. How sure are we about the results? Consequences and cost of alternatives performed?

HINT: Consider
- could they have occurred by chance
- are there confidence limits
- what are they

Comments: No study on validity of tests investigated

Section C: Will the results help locally?
Consider whether you are primarily interested in the impact on a population or individual level

9. Can the results be applied to your patients/the population of interest?

Yes	
Can't Tell	
No	X

HINT: Do you think your patients/population are so different from those in the study that the results cannot be applied, such as age, sex, ethnicity and spectrum bias

Comments: Lack of population detail

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10. Can the test be applied to your patient or population of interest?

Yes	
Can't Tell	
No	X

HINT: Consider
- resources and opportunity costs
- level and availability of expertise required to interpret the tests
- current practice and availability of services

Comments: Lack of population detail

11. Were all outcomes important to the individual or population considered?

Yes	
Can't Tell	
No	X

HINT: Consider
- will the knowledge of the test result improve patient wellbeing
- will the knowledge of the test result ~~lead~~ to a change in patient management

Comments:

12. What would be the impact of using this test on your patients/population?

Comments: Difficult to tell due to lack of detail

Appendix C. The development and face validity testing of the preliminary RTCGA instrument immediate intervention score

Knowing SRVs for healthy individuals allows for a positive scoring to be made for immediate kinematic changes following intervention which appear closer to the SRV, and a negative scoring for those which appear less so.

Two distinct and opposite patterns of gait were proposed. These patterns are classed as a RIP or a REP and are described in Table C1. If neither of these occurs, the SRVP match would be achieved.

Table C1. Proposed patterns of gait to be used in the RTCGA instrument immediate intervention score.

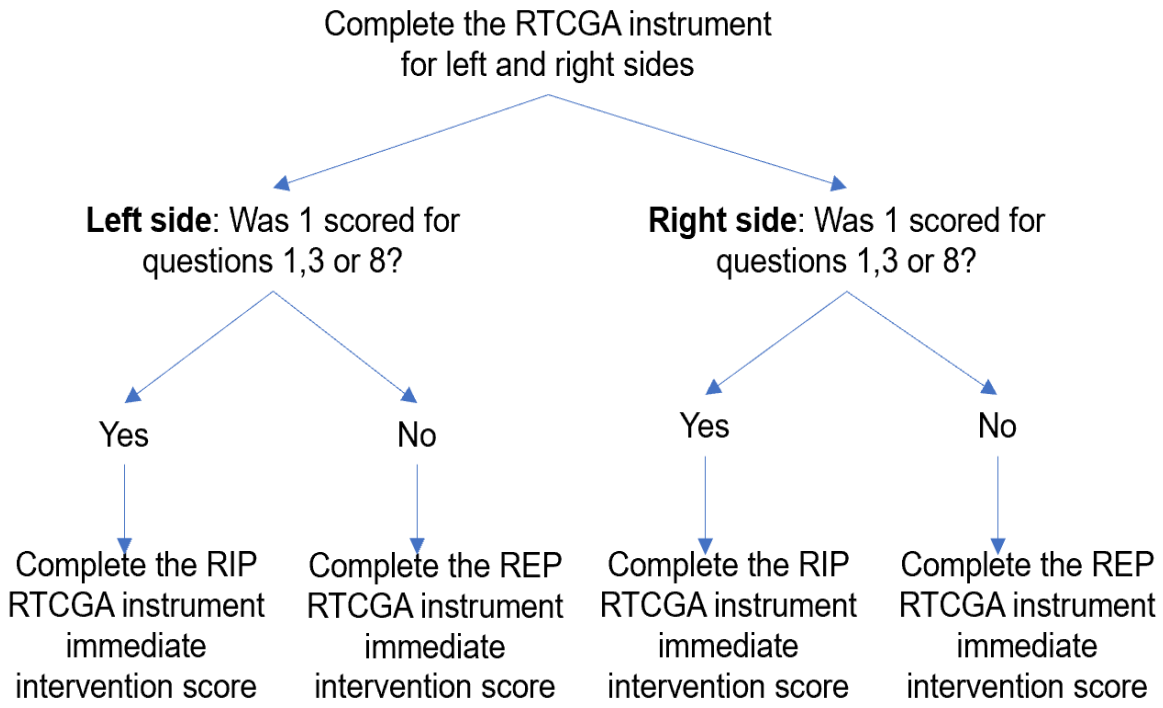
Gait Pattern	Description
RIP	Patterns of gait demonstrating greater rearfoot inversion and / or rearfoot inversion occurring when rearfoot eversion should be occurring
REP	Patterns of gait demonstrating greater rearfoot eversion and / or rearfoot eversion occurring when rearfoot inversion should be occurring
SRVP	Patterns of gait matching the proposed CTVs and SRVs as shown in Table 5.2 (Chapter 5, page 92)

The 2 gait patterns which deviate from the SRVP are therefore opposite from each other. If a treatment was intended to reduce a RIP gait, then the treatment would be aimed at reducing rearfoot inversion. The opposite would be true for REP, where treatment would be aimed to move gait closer to the SRVP via decreasing rearfoot eversion. Therefore, for a REP gait an intervention which reduces eversion (and so increases inversion) would be classed as a move to a more SRVP pattern and marked positively. If the same intervention was applied in a RIP of gait, the reduction in eversion (and so further increase in inversion) would be classed as a move away from the SRVP and marked negatively.

There are therefore 2 types of immediate intervention scoring, one for a RIP and one for a REP of gait. Guidelines on which to complete relate to the initial scoring of the preliminary RTCGA instrument scoring protocol (Figure 5.4.1, Chapter 5, page 95). Choosing the RIP or REP RTCGA instrument immediate intervention score is based upon the results to questions 1, 3 and 8 from the RTCGA instrument scoring protocol. A score of 1 in any of these observations demonstrates a RIP pattern of gait and a RIP RTCGA instrument immediate intervention score is used. Otherwise, the RTCGA instrument REP immediate intervention score is completed. This selection process is shown in Figure C1 (page 206).

It is not possible for the same foot to demonstrate REP and RIP at the same time, as these are opposite to each other. It is possible for left and right feet to exhibit opposite gait patterns, for example a left foot may have a REP of gait (e.g., rearfoot eversion at contact) and the right a RIP (e.g., rearfoot inversion at contact). In these cases, the appropriate RTCGA instrument immediate intervention score would be applied to each foot.

Figure C1. Flow chart demonstrating the method by which a RIP or REP RTCGA instrument immediate intervention score is selected.



Objective RTCGA instrument immediate intervention score guidelines are shown for the REP in Figure C2 (page 207), and RIP in Figure C3 (page 208). The sheet with which to collect results is demonstrated in Figure C4 (page 209).

Figure C2 - REP RTCGA instrument immediate intervention score guidelines (applied to the right and left side). Use is dictated by scoring 0 on questions 1,3 and 8 on the RTCGA instrument score (Figure 5.4.1, page 95).

Segment Observation	Observation	Scoring	RTCGA intervention score
Foot			
Maximum rearshoe eversion	Less eversion	+1	-1 to +1
	No change	0	
	More eversion	-1	
Rearshoe inversion after contact period	More inversion	+1	-1 to +1
	No change	0	
	Less inversion	-1	
Ankle			
Midstance shoe to leg dorsiflexion	More dorsiflexion	+1	-1 to +1
	No change	0	
	Less dorsiflexion	-1	
Knee			
Extension	More extension	+1	-1 to +1
	No change	0	
	Less extension	-1	
Hyperextension	Less hyperextension	+1	-1 to +1
	No change	0	
	More hyperextension	-1	
Rotation at contact period	Less internal	+1	-1 to +1
	No change	0	
	More internal	-1	
Rotation after contact period	More external	+1	-1 to +1
	No change	0	
	Less external	-1	
Hip			
Maximum extension	More extension	+1	-1 to +1
	No change	0	
	Less extension	-1	
Back and Pelvis			
Pelvic drop	Move towards 1-5 degrees	+1	-1 to +1
	No change	0	
	Move away from 1-5 degrees	-1	
Upper limb			
Arm swing flexion	More flexion	+1	-1 to +1
	No change	0	
	Less flexion	-1	
Arm swing extension	More extension	+1	-1 to +1
	No change	0	
	Less extension	-1	

Figure C3 - RIP RTCGA instrument immediate intervention score guidelines (applied to the right and left side). Use is dictated by scoring 1 on questions 1, 3 or 8 on the RTCGA instrument score (Figure 5.4.1, page 95).

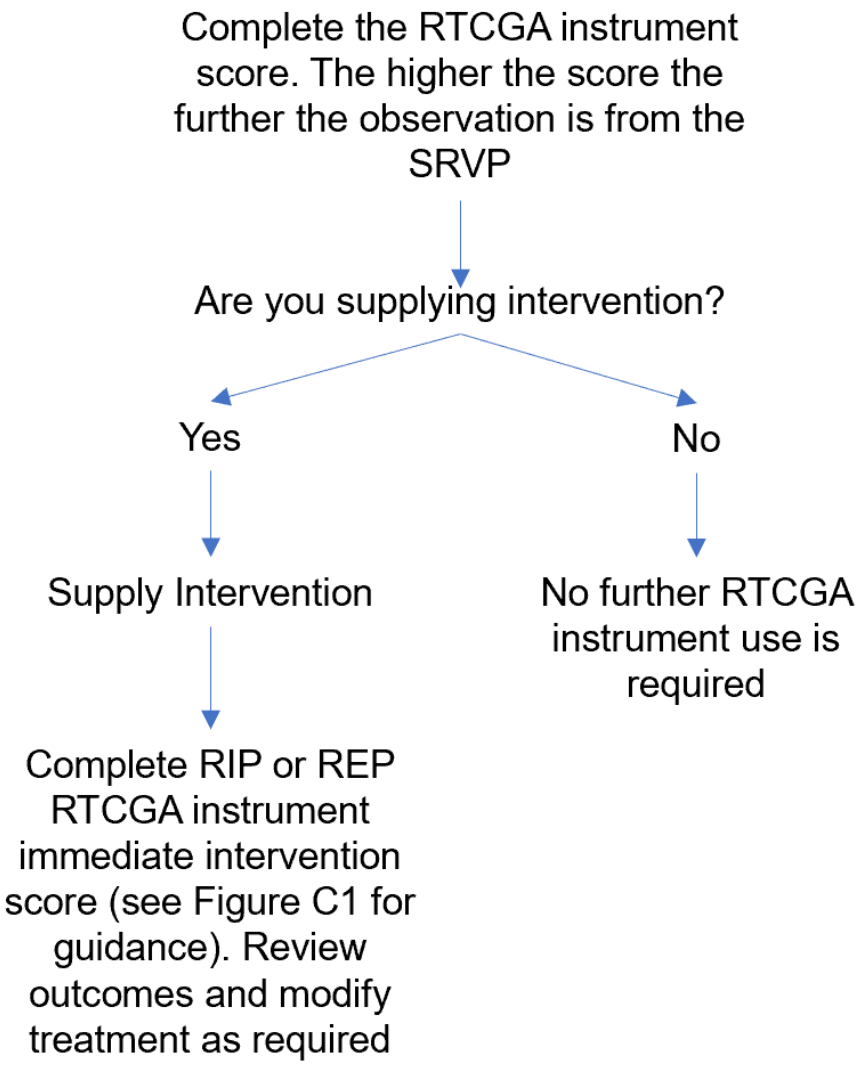
Segment Observation	Observation	Scoring	RTCGA intervention score
Foot			
Contact period rearshoe motion	Less inversion	+1	-1 to +1
	No change	0	
	More inversion	-1	
Rearshoe inversion after contact period	More inversion	+1	-1 to +1
	No change	0	
	Less inversion	-1	
Ankle			
Midstance shoe to leg dorsiflexion	More dorsiflexion	+1	-1 to +1
	No change	0	
	Less dorsiflexion	-1	
Knee			
Extension	More extension	+1	-1 to +1
	No change	0	
	Less extension	-1	
Hyperextension	Less hyperextension	+1	-1 to +1
	No change	0	
	More hyperextension	-1	
Rotation at contact period	Less external	+1	-1 to +1
	No change	0	
	More external	-1	
Rotation after contact period	More internal	+1	-1 to +1
	No change	0	
	Less internal	-1	
Hip			
Maximum extension	More extension	+1	-1 to +1
	No change	0	
	Less extension	-1	
Back and Pelvis			
Pelvic drop	Move towards 1-5 degrees	+1	-1 to +1
	No change	0	
	Move away from 1-5 degrees	-1	
Upper limb			
Arm swing flexion	More flexion	+1	-1 to +1
	No change	0	
	Less flexion	-1	
Arm swing extension	More extension	+1	-1 to +1
	No change	0	
	Less extension	-1	

Figure C4 – RTCGA instrument immediate intervention score. See Figure C1 for a flow diagram instruction for the REP or RIP selection process (page 206).

REP segment observation	RTCGA intervention score		RIP segment observation	RTCGA intervention score	
	Left	Right		Left	Right
Foot			**Foot**		
Maximum rearshoe eversion			Contact period rearshoe motion		
Rearshoe inversion after contact period			Midstance rearshoe inversion		
Foot segment total			Foot segment total		
Foot segment total combined			Foot segment total combined		
Ankle			**Ankle**		
Midstance shoe to leg dorsiflexion			Midstance shoe to leg dorsiflexion		
Ankle segment total combined			Ankle segment total combined		
Knee			**Knee**		
Extension			Extension		
Hyperextension			Hyperextension		
Rotation at contact period			Rotation at contact period		
Rotation after contact period			Rotation at midstance		
Knee segment total			Knee segment total		
Knee segment total combined			Knee segment total combined		
Hip			**Hip**		
Maximum extension			Maximum extension		
Hip segment total combined			Hip segment total combined		
Back and Pelvis			**Back and Pelvis**		
Pelvic drop			Pelvic drop		
Back and pelvis segment combined			Back and pelvis segment combined		
Upper limb			**Upper limb**		
Arm swing flexion			Arm swing flexion		
Arm swing extension			Arm swing extension		
Upper limb segment total			Upper limb segment total		
Upper limb segment total combined			Upper limb segment total combined		

The preliminary objective RTCGA instrument which underwent testing of reliability and concurrent validity testing approaches therefore had 2 sections, a RTCGA instrument score and a RTCGA instrument immediate intervention score. Figure C5 demonstrates the proposed clinical use and employment of both sections.

Figure C5. Flow chart demonstrating the proposed general clinical use and employment of both the RTCGA instrument score and RTCGA instrument immediate intervention score



Appendix D – Example of scenario testing for the objective RTCGA instrument

This example was that of I., III. And IV. scenarios combined (see section 6.2.1, Chapter 6, pages 107-110). The fictional left side demonstrated increased magnitude and timing of rearshoe eversion and internal knee rotation as well as increased amounts of pelvic drop. This left side also had decreased ankle, hip, knee and arm motion. The right side only presented with increased rearshoe eversion.

The observation being discussed in each section example is highlighted in yellow.

1) Example foot segment

The foot is observed in the Frontal plane

Contact period rearshoe motion

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Foot Segment		
1) Contact period rearshoe motion	0	0

Both feet evert in the contact period, and so are scored at 0.

Maximum rearshoe eversion

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Foot Segment		
1) Contact period rearshoe motion	0	0

2) Maximum rearshoe eversion	1	1

Both feet evert more than 5 degrees, and are both scored at 1.

Midstance maximum rearshoe inversion

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Foot Segment		
1) Contact period rearshoe motion	0	0
2) Maximum rearshoe eversion	1	1
3) Midstance maximum rearshoe inversion	0	0

Neither foot is inverted to the leg in midstance, and so are scored at 0

Rearshoe inversion from midstance

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Foot Segment		
1) Contact period rearshoe motion	0	0
2) Maximum rearshoe eversion	1	1
3) Midstance maximum rearshoe inversion	0	0
4) Rearshoe inversion from midstance	1	0

The right foot inverts from midstance and so is scored 0, the left foot does not invert from midstance and so is scored at 1

Foot observation total and combined

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Foot Segment		
1) Contact period rearshoe motion	0	0
2) Maximum rearshoe eversion	1	1
3) Midstance maximum rearshoe inversion	0	0
4) Rearshoe inversion from midstance	1	0
Shoe Observation Total	2	1
Shoe Observation Total Combined	3	

The left foot segment total score (adding the observation scores together) is 2 and the right foot 1. The score for both feet together is the left and right foot combined, which equals 3.

2) Example ankle segment

The ankle is observed in the Sagittal plane

Shoe to leg observation

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**

Ankle Segment		
5) Midstance shoe to leg dorsiflexion	1	0

The left side demonstrates less than 10 degrees shoe to leg dorsiflexion and is scored at 1, the right shows greater than 10 degrees and is scored as 0

Shoe to leg observation total and combined

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Ankle Segment		
5) Midstance Shoe to leg dorsiflexion	1	0
Shoe to leg observation Total Combined	1	

The left ankle segment total score is 1 and the right 0 (there is only one observation in this segment and so no left and right observations to add separately into totals). The score for both feet together is the left and right foot combined, which equals 1.

3) Example knee segment

The knee is observed in the frontal and sagittal planes

Knee extension (Sagittal plane)

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Knee Segment		
6) Knee extension	1	0

The left knee maximum extension in midstance maximum remains flexed by greater than 4 degrees and is scored as 1, the right knee is flexed less than 4 degrees and scored 0

Knee hyperextension (sagittal plane)

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Knee Segment		
6) Knee extension	1	0
7) Knee hyperextension	0	0

Both knees do not extend further than 0 degrees, and so are scored as 0

Rotation at contact period (frontal plane)

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Knee Segment		
6) Knee extension	1	0
7) Knee hyperextension	0	0
8) Rotation at contact period	0	0

Both knees internally rotate at the contact period and are scored 0

Rotation after contact period (frontal plane)

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Knee Segment		
6) Knee extension	1	0
7) Knee hyperextension	0	0
8) Rotation at contact period	0	0
9) Rotation after contact period	1	0

The left knee does not externally rotate after the contact period and is scored 1, the right knee does externally rotate and is scored 0

Knee observation total and combined

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Knee Segment		
6) Knee extension	1	0
7) Knee hyperextension	0	0
8) Rotation at contact period	0	0
9) Rotation after contact period	1	0
Knee Observation Total	2	0

Knee Observation Total Combined	2

The left knee segment total score (adding the observation scores together) is 2 and the right 0. The score for both sides together is the left and right side combined, which equals 2.

4) Example hip segment

Hip extension (sagittal plane)

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Hip Segment		
10) Hip Extension	1	0

The left hip extends by less than 15 degrees and is scored as 1, the right hip extends more than 10 degrees and is scored 0.

Hip observation total and combined

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Hip Segment		
10) Hip Extension	1	0
Hip Observation Total Combined	1	

The left hip segment total score is 1 and the right 0 (there is only one observation in this segment and so no left and right observations to add separately into totals).

The score for both sides together is the left and right side combined, which equals 1.

5) Example back and pelvis segment

Pelvic drop (frontal plane)

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Back and pelvis Segment		
11) Pelvic drop	1	0

The left side pelvic drop is greater than 5 degrees and is scored 1, the right side is between 1-5 degrees and scored 0.

Back and pelvis segment observation total and combined

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Pelvis Segment		
11) Pelvic drop	1	0
Pelvis Observation Combined	1	

The left back and pelvis segment total score is 1 and the right 0 (there is only one observation in this segment and so no left and right observations to add separately into totals). The score for both sides together is the left and right side combined, which equals 1.

6) Example upper limb segment

Arm swing flexion

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Upper Limb Segment		
12) Arm Flexion	1	0

The left swing flexion was less than 20 degrees and scored 1, the right was greater than 20 degrees and scored 0

Arm swing extension

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Upper Limb Segment		
12) Arm Flexion	1	0
13) Arm Extension	1	0

The left swing extension was less than 26 degrees and scored 1, the right was greater than 26 degrees and scored 0.

Upper limb observation total and combined

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Upper limb Segment		
12) Arm Flexion	1	0
13) Arm Extension	1	0
Upper Limb Observation Total	2	0
Upper Limb Observation Total Combined	2	

The left upper limb segment total score (adding the observation scores together) is 2 and the right 0. The score for both sides together is the left and right side combined, which equals 2.

7) RTCGA instrument score side total and combined total

Observation Segment	**RTCGA instrument Score**	
	Left	**Right**
Foot Segment		
1) Contact period rearshoe motion	0	0
2) Maximum rearshoe eversion	1	1
3) Midstance maximum rearshoe inversion	0	0
4) Rearshoe inversion from midstance	1	0
Shoe Observation Total	2	1
Shoe Observation Total Combined	3	

Ankle Segment		
5) Shoe to leg dorsiflexion	1	0
Shoe to leg observation Total Combined	1	
Knee Segment		
6) Knee extension	1	0
7) Knee hyperextension	0	0
8) Rotation at contact period	0	0
9) Rotation after contact period	1	0
Knee Observation Total	2	0
Knee Observation Total Combined	2	
Hip Segment		
10) Hip Extension	1	0
Hip Observation Total Combined	1	
Back and Pelvis Segment		
11) Pelvic drop	1	0
Pelvis Observation Combined	1	
Upper Limb Segment		
12) Arm Flexion	1	0
13) Arm Extension	1	0
Arm Observation Total	2	0
Arm Observation Total Combined	2	
SIDE TOTAL	9	1

COMBINED TOTAL	12

Side Total

The side total is the accumulation of all scores specific to either the right or left side body segment.

The left side total is 2 (foot segment) + 1 (ankle segment) + 2 (knee segment) + 1 (hip segment) + 1 (back and pelvis segment) + 2 (upper limb segment) = 9

The right side total is 1 (foot segment) + 0 (ankle segment) + 0 (knee segment) + 0 (hip segment) + 0 (back and pelvis segment) + 0 (upper limb segment) = 1

Employing the general RTCGA instrument rule that the lower the score, the closer the score to the SRVs, this example demonstrates a left side which is 11 points away from the SRVs and a right side which is 1 point away from the SRVs.

Combined total

Again using the general RTCGA instrument rule that the lower the score the closer the gait pattern is to the SRVP, this gait pattern example is 12 points away from the SRVP of gait.

Example conclusion

The RTCGA score recorded the asymmetrical presentation of kinematic observations which varied from the SRVs. The instrument provided a score to recognise the asymmetry, as well as the total overall score to show gait was not of a SRVP.

Appendix E. Example of scenario testing for the objective RTCGA instrument immediate intervention score

For the purpose of this example, the RTCGA instrument scenario and score shown in appendix D (page 211) will be used again. The RTCGA instrument score results in this example were 0 for questions 1,3 and 8. The REP RTCGA instrument immediate intervention score for both the right and left side will therefore be completed using the REP RTCGA instrument immediate intervention score guidelines (Figure C2, page 207). The fictional therapeutic intervention in this scenario was aimed to decrease pronation kinematics on the left side, such as orthoses with the left prescribed to supply greater supination moments. The immediate outcome in this scenario was an improvement to all observations which did not previously match their SRVs.

The observation being discussed in each section is again highlighted in yellow.

1) Example foot segment

The foot segment is completed via observation in the frontal plane

Maximum rearshoe eversion

REP Observation	**Immediate Intervention RTCGA Score**			**RIP Observation**	**Immediate Intervention RTCGA Score**	
	Left	**Right**			**Left**	**Right**
Foot Segment				**Foot Segment**		
Maximum rearshoe eversion	+1	0		Contact period rearfoot motion		

The left side demonstrated less rearshoe eversion, and was scored +1. There was no change to the right which was therefore scored 0.

Rearshoe inversion after contact phase

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Foot Segment			**Foot Segment**		
Maximum rearshoe eversion	+1	0	Contact period rearfoot motion		
Rearshoe inversion after contact phase	+1	0	Midstance rearfoot inversion		

The left side demonstrated more inversion following the contact phase and was score +1. There was no change to the right which was scored 0.

Foot segment total and combined total

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Foot Segment			**Foot Segment**		
Maximum rearshoe eversion	+1	0	Contact period rearfoot motion		
Rearshoe inversion after contact phase	+1	0	Midstance rearfoot inversion		

Foot Segment Total	+2	0	Foot Segment Total		
Foot Segment Total Combined	+2		Foot Segment Total Combined		

The left foot segment total score (adding the observation side scores together) is +2 and the right foot 0. The score for both feet together is the left and right foot combined, which equals +2. These scores demonstrate a foot segment decrease in the REP and a move towards SRVs for the left and no change to the right.

2) The ankle segment

The ankle segment is completed via observation in the Sagittal plane

REP Observation	**Immediate Intervention RTCGA Score**		**RIP Observation**	**Immediate Intervention RTCGA Score**	
	Left	**Right**		**Left**	**Right**
Ankle Segment			**Ankle Segment**		
Midstance Shoe to leg dorsiflexion	+1	0	Midstance shoe to leg dorsiflexion		

The left side demonstrated more dorsiflexion and scored +1. There was no change to the right which was scored 0

Ankle segment total and combined total

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Ankle Segment			**Ankle Segment**		
Midstance Shoe to leg dorsiflexion	+1	0	Midstance shoe to leg dorsiflexion		
Ankle Segment Total combined	+1		Ankle Segment total combined		

The left ankle segment score is +1 and the right 0 (there is only one observation in this segment and so no left and right observations to add separately into totals). This represents a decrease in the REP and a move towards the ankle SRV for the left side, and no change to the right.

3) Knee segment

The knee is assessed in the frontal and sagittal planes

Extension (sagittal plane)

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Knee Segment			**Knee Segment**		
Extension	+1	0	Extension		

The left side demonstrated more knee extension and was scored +1. The right side score 0 as there was no observable change

Hyperextension (sagittal plane)

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Knee Segment			**Knee Segment**		
Extension	+1	0	Extension		
Hyperextension	0	0	Hyperextension		

Neither side demonstrated any hyperextension and both scored 0

Rotation at contact (frontal plane)

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Knee Segment			**Knee Segment**		
Extension	+1	0	Extension		
Hyperextension	0	0	Hyperextension		
Rotation at Contact	0	0	Rotation at Contact		

Neither side demonstrated any change to rotation at contact, both scoring 0

Rotation at midstance (frontal plane)

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Knee Segment			**Knee Segment**		
Extension	+1	0	Extension		
Hyperextension	0	0	Hyperextension		
Rotation at Contact	0	0	Rotation at Contact		
Rotation after contact period	+1	0	Rotation at Midstance		

The left knee demonstrated more external rotation after the contact period and scored +1. There was no difference to the right side which scored 0

Knee segment total and combined total

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Knee Segment			**Knee Segment**		
Extension	+1	0	Extension		
Hyperextension	0	0	Hyperextension		
Rotation at Contact	0	0	Rotation at Contact		

Rotation at Midstance	+1	0		Rotation at Midstance		
Knee Segment Total	+2	0		Knee Segment Total		
Knee Segment Total Combined	+2			Knee Segment Total Combined		

The left knee segment total score (adding the observation scores together) is +2 and the right 0. The score for both knees together is the left and right foot combined, which equals +2. These scores demonstrate a decrease in the REP and a move towards SRVs for the knee segment, but more specifically for the left and no change to the right.

4) The hip segment

Hip Extension

REP Observation	**Immediate Intervention RTCGA Score**			**RIP Observation**	**Immediate Intervention RTCGA Score**	
	Left	**Right**			**Left**	**Right**
Hip Segment				**Hip Segment**		
Hip Extension	+1	0		Hip Extension		

The left hip demonstrated more extension and scored +1. There was no difference to the right which scored 0

Hip segment total and combined total

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Hip Segment			**Hip Segment**		
Hip Extension	+1	0	Hip Extension		
Hip Segment Total Combined	+1		Hip Segment Total Combined		

The left hip segment score is +1 and the right 0 (there is only one observation in this segment and so no left and right observations to add separately into totals). This represents a move towards the hip SRV and a decrease in the REP for the left side, and no change to the right.

5) The back and pelvis segment

Pelvic drop

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Back and Pelvis Segment			**Back and Pelvis Segment**		
Pelvic drop	+1	0	Pelvic drop		

The left side demonstrated a move towards 1-5 degrees or pelvic drop and scored +1. There was no difference to the right which scored 0.

Back and pelvis segment total and combined total

REP Observation	Immediate Intervention RTCGA Score			RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right			Left	Right
Back and Pelvis Segment				**Back and Pelvis Segment**		
Pelvic drop	+1	0		Pelvic drop		
Back and Pelvis Segment Total Combined	+1			Back and Pelvis Segment Total Combined		

The left back and pelvis segment score is +1 and the right 0 (there is only one observation in this segment and so no left and right observations to add separately into totals). This represents a move towards the back and pelvis SRV and a decrease in REP for the left side, and no change to the right.

6) The upper limb segment

Arm flexion

REP Observation	Immediate Intervention RTCGA Score			RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right			Left	Right
Upper Limb Segment				**Upper Limb Segment**		
Arm Flexion	+1	0		Arm Flexion		

The left arm demonstrated more flexion, and so scored +1. There was no change to the right which scored 0.

Arm extension

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Upper limb Segment			**Upper Limb Segment**		
Arm Flexion	+1	0	Arm Flexion		
Arm Extension	+1	0	Arm Extension		

The left arm demonstrated more extension, and so scored +1. There was no change to the right which scored 0.

Upper limb segment total and combined score

REP Observation	Immediate Intervention RTCGA Score		RIP Observation	Immediate Intervention RTCGA Score	
	Left	Right		Left	Right
Upper Limb Segment			**Upper Limb Segment**		
Arm Flexion	+1	0	Arm Flexion		
Arm Extension	+1	0	Arm Extension		
Upper Limb Segment Total	+2	0	Upper Limb Segment Total		
Upper Limb Segment Total Combined	+2		Upper Limb Segment Total Combined		

The left upper limb segment total score (adding the observation scores together) is +2 and the right 0. The score for both arms together is the left and right side combined, which equals +2. These scores demonstrate a gait pattern for the upper limb segment closer to the SRV and away from the REP following intervention, but more specifically for the left and no change to the right.

7) RTCGA instrument immediate intervention score side total and combined total

REP Observation	**Immediate Intervention RTCGA Score**		**RIP Observation**	**Immediate Intervention RTCGA Score**	
	Left	**Right**		**Left**	**Right**
Foot Segment			**Foot Segment**		
Maximum rearshoe eversion	+1	0	Contact period rearfoot motion		
Rearshoe inversion after contact phase	+1	0	Midstance rearfoot inversion		
Foot Segment Total	+2	0	Foot Segment Total		
Foot Segment Total Combined	+2		Foot Segment Total Combined		
Ankle Segment			**Ankle Segment**		
Midstance Shoe to leg dorsiflexion	+1	0	Midstance shoe to leg dorsiflexion		
Ankle Segment Total combined	+1		Ankle Segment total combined		
Knee Segment			**Knee Segment**		

Extension	+1	0	Extension		
Hyperextension	0	0	Hyperextension		
Rotation at Contact	0	0	Rotation at Contact		
Rotation after contact period	+1	0	Rotation at Midstance		
Knee Segment Total	+2	0	Knee Segment Total		
Knee Segment Total Combined	+2		Knee Segment Total Combined		
Hip Segment			**Hip Segment**		
Hip Extension	+1	0	Hip Extension		
Hip Segment Total Combined	+1		Hip Segment Total Combined		
Back and Pelvis Segment			**Back and Pelvis Segment**		
Pelvic drop	+1	0	Pelvic drop		
Back and Pelvis Segment Total Combined	+1		Back and Pelvis Segment Total Combined		
Upper Limb Segment			**Upper Limb Segment**		
Arm Flexion	+1	0	Arm Flexion		
Arm Extension	+1	0	Arm Extension		
Upper Limb Segment Total	+2	0	Upper Limb Segment Total		

Upper Limb Segment Total Combined	+2			Upper Limb Segment Total Combined	
TOTAL	+9	0		**TOTAL**	
TOTAL combined	+9			**TOTAL combined**	

Side Total

The side total is the accumulation of all scores specific to either the right or left body segment.

The left side total is 2 (foot segment) + 1 (ankle segment) + 2 (knee segment) + 1 (hip segment) + 1 (back and pelvis segment) + 2 (upper limb segment) = +9

The right side is 0 (foot segment) + 0 (ankle segment) + 0 (knee segment) + 0 (hip segment) + 0 (back and pelvis segment) + 0 (upper limb segment) = 0

Employing the general RTCGA instrument immediate intervention rule that the more positive the score the greater the change in gait pattern towards the SRVP, this example demonstrates a 9 point move towards the SRVP on the left and no change to the right.

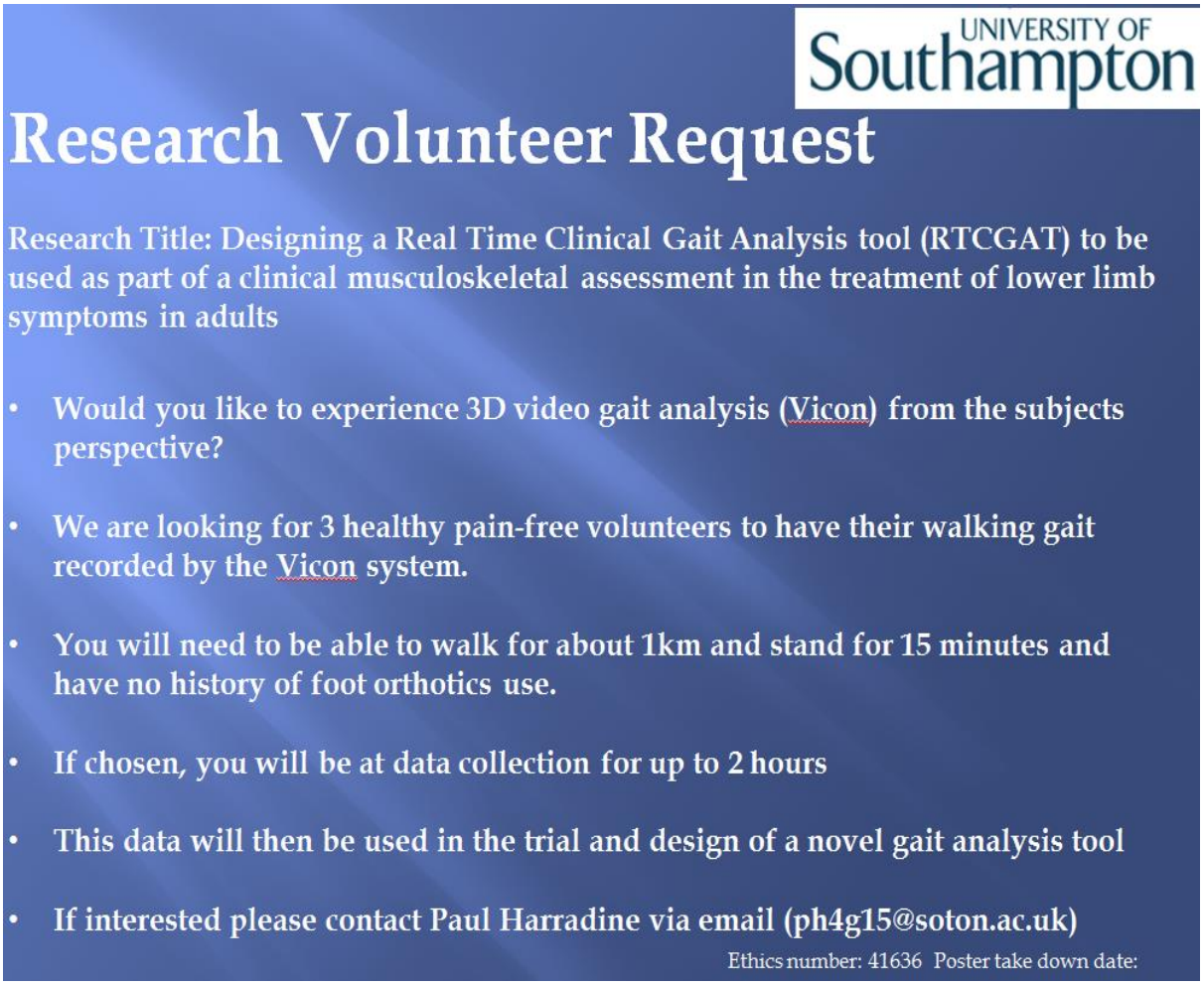
Combined total

The general RTCGA instrument immediate intervention rule is that the larger the positive score the more gait is demonstrating a SRVP following intervention. The RTCGA instrument immediate intervention +9 score in the example shows gait moved towards the SRVP by 9 points. Reviewing the score by sides reveals this move towards the SRVP was on the left side only.

Example conclusion

The RTCGA instrument immediate intervention score successfully demonstrated areas of kinematic observations which were closer to the SRVs.

Appendix F – Recruitment poster (normal size A4)



Appendix G – Email of permission to display posters in buildings B67 and B45 from Dr Julian Pearce, school lead for practice learning within Health Science at the University of Southampton

Pearce J. M. <jmp6@soton.ac.uk>
To: Paul Harradine

Hi Paul

Humble apologies for not coming back to you sooner.

Yes of course, please do go ahead and put up your poster.

Good luck with the recruitment and the study overall.

BW

Julian

Appendix H - Walker Participant Information Sheet

Study Title: Designing a Real Time Clinical Gait Analysis tool to be used as part of a clinical musculoskeletal assessment in the treatment of lower limb symptoms in adults

Lead Researcher: Paul Harradine

Research Supervisors: Dr Lucy Gates, Dr Cheryl Metcalf, Prof Catherine Bowen

Ethics number: 41636

Please read through this information sheet carefully before choosing to participate in this study. If you are happy to join the study, you will be asked to sign a consent form.

What is the research about?

This study is being undertaken as part of a Doctorate (PhD) at the University of Southampton, UK.

Clinicians involved in treating adults with lower limb musculoskeletal injuries are often advised to use gait analysis as a diagnostic tool to find the cause of injury and to evaluate treatment outcomes. However, there remains no accepted method or protocol by which this gait assessment should be undertaken. Developing a tool that clinicians can use to assess gait in their routine clinics would therefore benefit the diagnosis and treatment of patients with lower limb injury related to how they walk. This research is about designing and testing such an assessment tool for gait analysis.

Why Have I been chosen?

You have been selected from volunteers as a healthy participant for this study

What will happen to me if I take part?

If you agree to participate in the study, the lead researcher will contact you by email to check several elements of inclusion into the study. These will be:

- You have no history of lower limb osteoarthritis.

- You have no symptoms or existing painful lower limb, back or upper limb / shoulder pain
- You have no history of significant lower limb, or back, injury that resulted in prolonged painful symptoms and/or surgical procedures.
- You have no painful lesions present on your feet
- Currently you do not use functional orthoses or insoles
- Your shoe size
- You are able to walk about 1 km and stand for 15 minutes

Receiving this email does not guarantee selection for inclusion in the study. Selection will be made on a first come first served basis. If you are not selected you may, if in agreement, be asked if you would be willing to be on stand-by, should the selected study participants withdraw at any time. The maximum time from this communication you will be on standby for inclusion is a month.

If you are selected to take part in the study, the researchers will then email you to arrange your study visit. All data will be collected at the human movement laboratory, Faculty of Health Sciences, University of Southampton. The entire process will involve having you gait recorded a number of times which will take up to 2 hours to complete. At the start of your study visit, the researchers will ask if you have any questions about the study on that day and then ask for your written consent to take part. A private changing area will be provided for participants to change into appropriate clothing for participation. Data on your age, gender, weight and height will be recorded on paper records. All data will then be transferred to the University secure system filestore.

You will then be invited to wear supplied normal plimsolls for a period of 5 minutes. During this time we will practice your starting point for walking in the human movement laboratory.

After this practice period, reflective markers will be attached to various places on your legs, back, arms, shoulders and footwear using self-adhesive tape. These markers will be left on for the entire duration of data collection. Markers do need to be placed directly onto the skin, meaning male participants will be asked to

walk wearing shorts and plimsolls only. Female participants will be asked to walk in shorts and crop-top type sports tops or bras. Please attend with these items.

Your walking will then be recorded in pain plimsolls and plain plimsolls with an insole inside to alter your gait only while they are being worn. This will cause no discomfort.

You may rest at any time between the trials. During any breaks, refreshments (cold/hot beverages) will be made available if requested. The researchers will ask you if you have any physical discomfort, and ask you to confirm that you are fit to continue. During this period, you may remove the footwear, but will be required to keep the reflective markers on to minimize variation in marker placement.

At the end of the session, the reflective markers will be taken off and you will be given wet wipes to ensure any remaining adhesive is removed from your skin.

The researchers will then ask if you have any further questions about the study and ask for your written consent again in relation to the use of your data and video for the stated purposes of this study.

Are there any benefits in my taking part?

There will be no direct benefits to taking part, and no money will be paid for participation in this study.

Will my participation in this study be kept confidential?

Your video data will be viewed by the study researchers and 30 expert podiatrists recruited to participate in the second phase of this study which involves their assessment of your gait through the video format. Only the study researchers and expert podiatrists will be viewing your video, and you will be identifiable, however your name and data on age, gender, weight and height will not be shared and kept confidential.

What will happen to the results of the study?

The recordings of your gait will be sent by royal mail recorded delivery to the 30 expert podiatrists via a password protected memory stick. Your participation in

this research is not truly anonymous as your body and facial features will be observable and you are therefore possibly recognisable.

At the end of this study, the expert podiatrists will be asked to delete these recordings. The results of this study are to be used within the lead researcher's doctoral research process. Results may also be published and presented or discussed within wider clinical and academic circles.

Where can I get more information?

Please contact Paul Harradine (ph4g15@soton.ac.uk) if you wish for any further information

Are there any risks involved?

You will be walking a moderate distance (150m) during the study which may pose a low risk of injury to healthy participants. Steps to reduce this low risk are the provision of breaks and drink refreshments, and you will be asked about your physical comfort during the trials. Most importantly, risks will be minimised by ensuring that you do not have any pain, injury or condition affecting your lower limbs, or back, on the day. You have the right to withdraw from the study at any time, without your legal rights being affected.

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

If there is a technical issue during data collection you may be present at the data collection session longer than was expected. If this is the case, you will be offered refreshments or the opportunity to withdraw from the study at any time.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in

the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you for taking the time to read the information sheet and considering taking part in this research.

Appendix I – Walking participant consent form

Study title: Designing a Real Time Clinical Gait Analysis tool to be used as part of a clinical musculoskeletal assessment in the treatment of lower limb symptoms in adults

Lead Researcher: Paul Harradine (lead researcher) **Additional Researchers (Supervisors in the doctoral research process):** Dr Lucy Gates, Dr Cheryl Metcalf. Prof Catherine Bowen

ERGO number: 41636

Please initial the box(es) if you agree with the statement(s):

Statement	Before data collection	After data collection
I consent to motion analysis markers being place on my lower limb, upper limb and back.		
I consent to my walking being recorded.		
I consent to expert podiatrists viewing recordings of my walking.		
I understand that information collected about me during my participation in this research will be stored on a password protected computer. This information will only be used for the purpose of this study. All files containing personal data will fulfil the requirements of the European Union General Data Protection Regulation Standards (2018).		
I understand recordings of my walking will be sent to expert podiatrists via a password protected memory stick and that the expert podiatrists will be asked to delete this data at the end of the study.		

I understand that this data may be used in write-ups, reports and publications about this research, but my name will not be used.		
I understand that although my name is not linked to the video data, there is a possibility that I may be able to be visually recognised during observation of the recordings of my gait.		
I have read and understood the information sheet and have had the opportunity to ask questions about the study.		
I agree to take part in this research project and agree for my data to be used for the purpose of this study.		
I understand my participation is voluntary and I may withdraw (at any time) for any reason without my rights being affected.		

Name of participant (print name)……

Signature of participant (before data collection)……..

Signature of participant (after data collection)……

Date…….. ……

Name of researcher (print name)……

Signature of researcher ……………………………………………………………………………………

Date………………………………………………………………………………………………………..

Appendix J. Recruitment message posted on MSK:UK

Dear MSK Podiatrist

Study title: Designing a Real Time Clinical Gait Analysis tool to be used as part of a clinical musculoskeletal assessment in the treatment of lower limb symptoms in adults

Lead Researcher: Paul Harradine

Researchers: Dr Lucy Gates, Dr Cheryl Metcalf, Prof Cathy Bowen

We are recruiting volunteer MSK Podiatrists to help in understanding the process of assessing and treating MSK lower limb injury in adults. Volunteers would be interviewed via Skype, and asked to answer questions about their MSK practice

All data will be held anonymously following transcription, and no personal details will be held on you linking you to your data for the purpose of the study

If you are interested in taking part, you will need to:

- Have over 5 years' experience in MSK clinics / Treating MSK patients, including assessing and treating patients with posterior tibial tendon dysfunction
- Conduct weekly clinics which include treating adult patients with MSK lower limb symptoms
- Have access to a computer with skype for an interview to be conducted
- Have access to email facilities for correspondence.
- Have no affiliations with or involvement in any organisation or entity with any financial interest in video or computerised gait equipment or systems

If you are interested in participating, please email the lead researcher (Paul Harradine) at the address Ph4g15@soton.ac.uk using the subject title 'RTCGAT study'. There is no need to add any further text. You will then be contacted by reply of email with further information regarding the study

Many thanks

Paul Harradine

Appendix K. Interview participant Information Sheet

Study Title: Designing a Real Time Clinical Gait Analysis tool (RTCGAT) to be used as part of a musculoskeletal assessment in the treatment of lower limb symptoms in adults

Researcher: Paul Harradine

ERGO number: 55599

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

This study is being undertaken as part of a Doctorate (PhD) at the University of Southampton, UK.

Clinicians involved in treating adults with lower limb musculoskeletal (MSK) injuries are often advised to use gait analysis as a diagnostic tool to find the cause of injury and to evaluate treatment outcomes. However, there remains no accepted method or protocol by which this gait assessment should be undertaken. Developing a tool that clinicians can use to assess gait in their routine clinics would therefore benefit the diagnosis and treatment of patients with lower limb injury related to how they walk. This research is about understanding the current use and worth of gait analysis in lower limb adult MSK clinics. This research is NOT investigating clinical competence.

Why have I been asked to participate?

You have been selected as a podiatrist working within the speciality of MSK podiatry

What will happen to me if I take part?

If you agree to participate in the study, the lead researcher will contact you by email to check several elements of inclusion into the study. These will be:

- Have over 5 years' experience in MSK clinics / Treating MSK patients, including assessing and treating patients with posterior tibial tendon dysfunction
- Weekly clinics which include treating adult patients with MSK lower limb symptoms
- Access to a computer with skype for an interview to be conducted
- Access to email facilities for correspondence.
- No Affiliations with or involvement in any organisation or entity with any financial interest in video or computerised gait equipment or systems

From all potential participants who meet the study criteria, 30 participants will be randomly selected for recruitment to the study.

If you are selected to take part in the study, the researchers will email you the following:

1) A research consent form. Please sign this and either reply via a photo of the form or a scan of the form

2) A possible date and time for an interview to be conducted via Skype

3) A PowerPoint file with the videos of 3 subjects walking twice.

The interview should take no more than 30 minutes to complete

Will my participation in this study be kept confidential?

Your video interview data will be viewed by the lead researcher only and transcribed by the lead researcher. Following transcription, your data will be held anonymously and the video deleted.

What will happen to the results of the study?

Your email and video interview data will initially be held on the lead authors laptop and university email, for which access to both requires security password clearance. After transcription, your interview video will be deleted. All your data from then onwards will then be anonymous.

Following analysis of collected data transcripts, the hard copies of the transcripts too will be deleted.

The results of this study are to be used within the lead researcher's doctoral research process. Results may also be published and presented or discussed within wider clinical and academic circles.

Where can I get more information?

Please contact Paul Harradine (ph4g15@soton.ac.uk) if you wish for any further information

Are there any risks involved?

It is possible that you may spend up to 30 minutes completing the interview via your computer. Computer workstations or equipment can be associated with neck, shoulder, back or arm pains, fatigue and eyestrain if not set up correctly. These aches and pains are sometimes called upper limb disorders (ULDs) or repetitive strain injuries (RSI). These problems can be avoided by following good practice. The University of Southampton Health and Safety Executive have produced a guide on recommendations for good practice in working with VDUs. Although 30 minutes is a low risk of causing ergonomic complications, the guide for good practice working with VDUs can currently be found at:

http://www.soton.ac.uk/healthandsafety/safety/whats_on/training/dse.html

You may withdraw at any time and for any reason without your participation rights being affected

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

If there is a technical issue during the interview, the researcher may contact you via your telephone to hopefully resolve the issue.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at

http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you for taking the time to read the information sheet and considering taking part in this research.

Appendix L. Interview participant background demographic form

Study title: Designing a Real Time Clinical Gait Analysis tool to be used as part of a clinical musculoskeletal assessment in the treatment of lower limb symptoms in adults

Researcher name: Paul Harradine
ERGO number: 55599

In what year did you qualify as a Podiatrist? *Example answer:1994*	
As an approximate percentage, how much of you weekly case load involves the assessment or treatment of adult MSK lower limb symptoms? *Example answer: 40%*	
How many hours a week do you spend clinically treating or assessing adult MSK patients with lower limb symptoms? *Example answer: 30 hours*	
When treating or assessing adult MSK patients with lower limb symptoms, do you work in the NHS, private practice or another agency such as the MOD? *Example answer: NHS and MOD*	

What percentage of this adult lower limb MSK symptom work do you supply with these agencies? *Example answer: 30% NHS, 30% Private practice, 40% MOD*	
On average, how many adult MSK patients with lower limb symptoms would you assess or treat in an average clinical week? *Example answer: 12 patients*	
How many years in total have you been assessing or treating adult patients with MSK lower limb symptoms? *Example answer: 7 years*	
What Post graduate qualifications do you have (please write N/A if you have none)? *Example answer: PGDip Sports Science*	

Name of participant (print name)……Date……

Appendix M. Interview participant consent form

Study title: Designing a Real Time Clinical Gait Analysis tool to be used as part of a clinical musculoskeletal assessment in the treatment of lower limb symptoms in adults

Researcher name: Paul Harradine

ERGO number: 55599

Please initial the box(es) if you agree with the statement(s):

I have read and understood the information sheet (Version 2; 17/3/2020) and have had the opportunity to ask questions about the study.	
I agree to take part in the interview for the purposes set out in the participation information sheet and understand that these will be recorded using video (Skype)	
I understand my participation is voluntary and I may withdraw at any time and for any reason without my participation rights being affected.	
I understand that taking part in the study involves video (Skype) recording which will be transcribed and then destroyed for the purposes set out in the participation information sheet	
I agree to take part in this research project and agree for my data to be used for the purpose of this study.	

Name of participant (print name) ……

Signature of
participant……

Date……..

Name of researcher (print name)……

Signature of
researcher ……

Date……

Appendix N. Interview Guide

General Introduction

- Greeting
- Check the informant has read the PIS and signed consent, including checking their eligibility for inclusion.
- Give overview of research and verbally check the informant still wishes to participate.
- Remind the participant that this research is not conducted to assess clinical competence.
- There is no right or wrong answer today.
- Inform the patient this is a semi-structured interview. It's OK to branch out and talk around points raised from these questions. I will check my guide!
- They are free to take as much time as they wish and go into as much detail as they wish.
- Remind the informant they can withdraw from the study as any time

Interview Question Guide / prompts

Q1: When assessing and treating adults with posterior tibial tendon dysfunction, do you watch and assess their walking?

Q2: If no, why not?

Q3: If yes, what are you reasons and aims of doing this?

Q4: Are there any challenges or difficulties with assessing their walking?

P1: How do you assess their walking

P2: Assess gait Shod or barefoot

P3: Assess gait Before or after treatment or both?

P4: If pain has gone but your gait assessment shows no benefit, do you modify your treatment?

P5: If pain has not gone but gait assessment shows a much improved gait / normal, what do you do?

Closing the Interview

- Check if there is anything else the informant wishes to add
- Check the informant is happy for the interview to end and the recording to be stopped
- Thank the participant

Appendix O. Word Cloud to demonstrate word frequency

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