FULL/LONG TITLE OF THE STUDY

Shoulder instability in children: understanding muscle activity and movement pattern differences

SHORT STUDY TITLE / ACRONYM

Shoulder instability in children: muscle activity and movement

Sponsor Number: RL1812

PROTOCOL VERSION NUMBER AND DATE

Version 2.0 – 31st July 2021

This protocol has regard for the HRA guidance and order of content

RESEARCH REFERENCE NUMBERS

IRAS Number: 271729

Clinical trials.gov Number: NCT04311216

Sponsor Number: RL1812

Funder's Number: 321

SIGNATURE PAGE

For Robert Jones & Agnes Hunt (RJAH) Orthopaedic Hospital NHS Foundation Trust sponsored studies, the sponsor will confirm approval of the protocol by signing the IRAS form and therefore a signature on the protocol is not required. The sponsor must be notified of all amendments to the protocol, both substantial and non-substantial. Review of amendments by the sponsor will act as the confirmation that the sponsor confirms approval of the amended protocol.

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:

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

Name (please print):

Dr Fraser Philp

.....

Sponsor statement:

Where RJAH takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

Table of Contents

LIST OF ABBREVIATIONS

Define all unusual or 'technical' terms related to the trial/study*. Add or delete as appropriate. Maintain alphabetical order for ease of reference.

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
DOI	Digital Object Identifier
ICF	Informed Consent Form
DMC	Independent Data Monitoring Committee
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
NIMP	Non-Investigational Medicinal Product
ORLAU	Orthotic Research & Locomotor Assessment Unit
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
REC	Research Ethics Committee
RJAH	Robert Jones and Agnes Hunt
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SMF*	Study Master File
SMG*	Study Management Group
SOP	Standard Operating Procedure
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMG*	Trial Management Group
TSC	Trial Steering Committee
TMF*	Trial Master File

KEY STUDY CONTACTS

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STUDY SUMMARY

Trial/Study* Title	Shoulder instability in children: understanding muscle activity and movement pattern differences	
Internal Ref. Number (or short title)	Shoulder instability in children: muscle activity and movement v2.0	
Trial/Study* Design	Cohort observation Cross-sectional study	
Trial Intervention (where applicable)	N/A	
Trial/Study* Participants	15 children (aged between 8 and 18) with shoulder instability 15 age matched controls	
Planned Sample Size	30 participants	
Treatment duration	2 hours 30 minutes maximum	
Follow up duration	12 months	
Planned Trial Period	24 months	
	Objectives	Outcome Measures
Primary	*	
Secondary		

* This is not an experimental study and so there is not a single/primary outcome measure. The following outcomes will be derived from this study

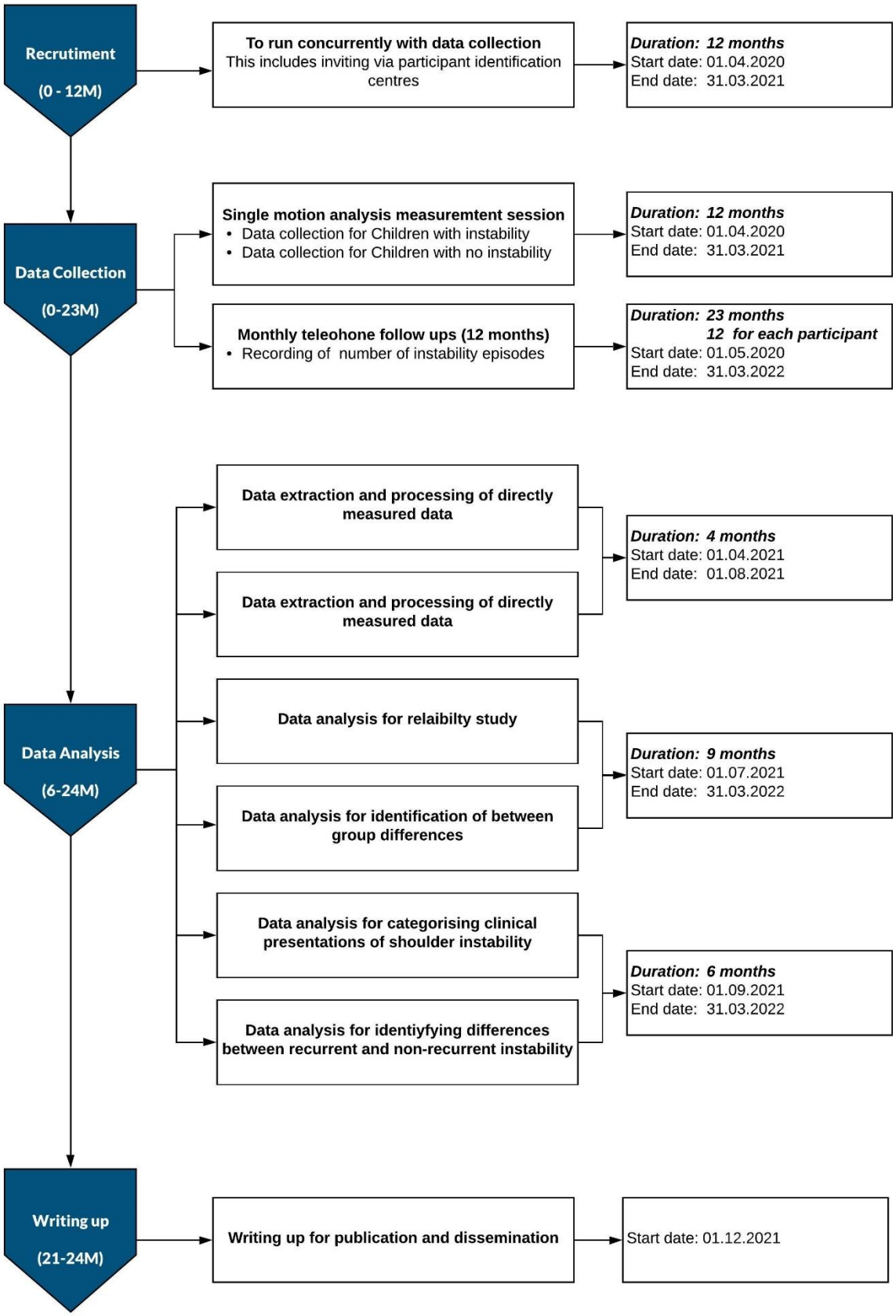
For the single movement analysis session:

- **Kinematic** variables related to the movement tasks, for example
    - joint angles (degrees)
    - displacement (position, speed and associated derivatives)
- **Kinetic** variables related to the movement tasks, for example
    - forces/ strength (n, kg/force)
- **Muscle activity patterns** related to the movement tasks, for example
    - Surface electromyography (sEMG) (mv)

For the follow up outcomes:

- Number of recurrent episodes of instability

STUDY FLOWCHART



1 BACKGROUND

The aim of this study is to identify factors responsible for recurrent shoulder instability in children. Shoulder instability, i.e. complete or partial dislocation of the shoulder joint, is common in children, resulting in pain and disability. Recurrent instability can damage the shoulder joint resulting in the premature development of arthritis.

Rehabilitation approaches are preferred over surgical methods for the growing child e.g. physiotherapy to restore movement and prevent further instability. Existing rehabilitation procedures are based on addressing factors assumed to be responsible for instability e.g. physiotherapists may try to increase shoulder stability by building up the shoulder muscles to compensate for the damaged ligaments. It is evident however that we do not fully understand the mechanisms of shoulder instability as failure rates for physiotherapy are high, with 70% - 90% of children continuing to suffer recurrent instability. This is an observational, cross-sectional study of children (aged 8 to 18) presenting with shoulder instability of any origin, traumatic or atraumatic (n=15) and an age-matched sample (n=15) with no history of shoulder problems. Muscle activity and movement pattern differences will be measured using non-invasive 3D motion capture and surface electromyography, to identify factors responsible for instability. Only a single visit to the site will be required (The Orthotic Research & Locomotor Assessment Unit (ORLAU) based at The Robert Jones & Agnes Hunt Orthopaedic Hospital NHS Foundation Trust in Oswestry.).

If we better understand the mechanisms associated with instability, we can better target physiotherapy interventions to reduce dislocations and disability. If we identify specific patterns of activity associated with instability, these could be addressed through personalised and improved exercise prescription and rehabilitation. Additionally, we may identify causes of instability for which physiotherapy may not be appropriate, therefore ensuring patients are referred to the correct service in a timely manner, improving patient outcomes and allocating physiotherapy resources more appropriately. Participants will be recruited from musculoskeletal/orthopaedic outpatient clinics. This study is funded by the Private Physiotherapy Education Foundation.

2 RATIONALE

Mechanisms of shoulder instability, and the subsequent development of arthritis, are poorly understood (Deitch, Mehlman et al. 2003, McFarland, Kim et al. 2003, Barden, Balyk et al. 2005, Barrett 2015). Both surgical and nonsurgical interventions are based on a current understanding of the associated mechanisms that may include anatomical predisposition (shallow glenoid, lax ligament and capsule), weak muscles, or inappropriate muscle coordination (Harryman, Sidles et al. 1992, Cordasco 2000, Inui, Sugamoto et al. 2002, Deitch, Mehlman et al. 2003,McFarland, Kim et al. 2003, Barden, Balyk et al. 2005, Hovelius and Saeboe 2009, Jaggi and Lambert 2010, Jaggi, Noorani et al. 2012, Barrett 2015, Longo, van der Linde et al. 2016, Bateman, Jaiswal et al. 2018, Best and Tanaka
2018).

Rehabilitation approaches are preferred over surgical methods for the growing child, and management is therefore aimed at addressing predominant factors associated with these mechanisms e.g. exercises to improve co-ordination of the shoulder muscles if the source of instability is dysfunctional muscle control. However, failure rates are high (approximately 70% - 90%), indicating that current understanding of these mechanisms is limited.

In children, this can have detrimental long-term effects. This research is important as shoulder instability, mainly subluxation and dislocation, is common (23.9/100,000 person years but can be as high as 164.4 for 14 -16 year olds) (Leroux, Ogilvie-Harris et al. 2015) resulting in pain, decreased movement and functional limitations. Diagnosis of shoulder instability is normally delayed (on average by 2-years) and 70% of children have repeated dislocations (Longo, van der Linde et al. 2016), often associated with premature glenohumeral arthropathy (odds ratio 19.3) (Marx, McCarty et al. 2002, Deitch, Mehlman et al. 2003).

Shoulder stability results from complex mechanisms comprising finely balanced forces in ligaments, muscles and joint surfaces. These can be disrupted in a range of neuromuscular disorders and joint degradation, and are vulnerable to traumatic injury. Currently, we are unable to capture this complexity to quantify instability during dynamic upper limb tasks performed during clinical assessment and rehabilitation (Marchi, Blana et al. 2014). Biomechanical or mathematical modelling of this complex structure can help to understand the mechanisms associated with instability and predict outcomes for surgical and non-surgical interventions. Loading on internal structures that cannot be measured can also be estimated by this approach. Furthermore, approximately 30% of patients who have surgical stabilisation of their shoulder go on to sustain further episodes of instability (Deitch, Mehlman et al. 2003).

This project is therefore a fundamental step, in the development of biomechanical models which can ultimately be used to further our understanding of the shoulder, specifically behaviour of the articulating bony surfaces and muscle forces.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1 Primary objective

- The primary objective of this study is to identify factors responsible for recurrent shoulder instability in children.

In order to meet the main objective of this study, a series of secondary objectives need to be met.

3.2 Secondary Objectives

The secondary research objectives used to address the main aim of the study are:

- Validation of a 3D movement analysis protocol for measuring upper limb function in children with shoulder instability.
- Obtain new data on muscle activity and movement patterns of children with and without shoulder instability
- Categorising clinical presentations of instability and identification of important factors for recurrent instability

This is not an experimental study and so there is not a single/primary outcome measure. The following outcomes will be derived from this study

For the single movement analysis session:

- **Kinematic** variables related to the movement tasks, for example
    - joint angles (degrees)
    - displacement (position, speed and associated derivatives)
- **Kinetic** variables related to the movement tasks, for example
    - forces/ strength (n, kg/force)
- **Muscle activity patterns** related to the movement tasks, for example
    - Surface electromyography (sEMG) (mv)

For the follow up outcomes:

- Number of recurrent episodes of instability

4 STUDY DESIGN

This is an observational, cross-sectional study of children (aged 8 to 18) presenting with shoulder instability of any origin, traumatic or atraumatic (n=15) and an age-matched sample (n=15) with no history of shoulder problems. Muscle activity and movement pattern differences will be measured using non-invasive 3D motion capture and surface electromyography, to identify factors responsible for instability. Only a single visit to the site will be required (ORLAU, RJAH). No interventions or treatments are included in this study as this is an observational, cross-sectional study.

5 STUDY SETTING

The research site is located at the RJAH Orthopaedic Hospital NHS Foundation Trust in Oswestry, SY10 7AG.

The movement analysis sessions will take place at the Orthotic Research & Locomotor Assessment Unit (ORLAU) based at RJAH Orthopaedic Hospital NHS Foundation Trust in Oswestry.

Our main recruitment site is based at RJAH, Shropshire, SY10 7AG. Potential participants on their routine hospital or health service visits, who fit the inclusion/exclusion criteria, will be given brief information about the study by their treating physician/surgeon/therapist. If potential participants express an interest in the study the treating physician/surgeon/therapist may also pass on the relevant contact details to the study team. Risk mitigation against under recruitment will be achieved by recruiting from a further patient identification centre sites Shrewsbury and Telford NHS TRUST, UHNM, Stoke and other relevant health care services such as GP practices and additional outpatient services in the second. We will also disseminate information about the study using social media.

6 ELIGIBILITY CRITERIA

6.1 Children with shoulder instability

6.1.1 Inclusion criteria

- Children aged between 8 to 18 years of age
- Subjective reports of instability with additionally symptomatic instability in the clinical assessment criteria below
- Symptomatic instability on clinical assessment in at least one direction, confirmed by a positive clinical finding (apprehension, guarding, laxity) during the sulcus, apprehension or anterior and posterior shift load tests.
- All forms of instability including multidirectional instability, atraumatic and traumatic subluxations and dislocations.
- Children presenting with an initial or recurrent episode of instability
- Children undergoing current management or rehabilitation for their shoulder at the time of the study
- Patients with surgically managed shoulder instability who have since had a further episode of shoulder instability.

6.1.2 Exclusion criteria

- Children with co-existing neurological pathologies or deficits
- Surgically managed patients who have not had episodes of instability following the intervention.

6.2 Age matched control group

6.2.1 Inclusion criteria

- Children aged between 8 to 18 years of age

6.2.2 Exclusion criteria

- Any previous presentation to a health care professional with a diagnosis of shoulder instability
- Children with a previous shoulder injury within the last 3 months on the arm being assessed that has not resolved
- Children with co-existing neurological pathologies or deficits
- Children who have had a previous surgical intervention on the arm being assessed
- Children currently undergoing or awaiting medical management, diagnostic investigations or rehabilitation on the arm being assessed

7 STUDY PROCEDURES

7.1 Recruitment

Our main recruitment site is based at RJAH outpatient clinics, Shropshire. Potential participants on their routine hospital visits, who fit the inclusion/exclusion criteria, will be given brief information about the study by their treating physician/surgeon/therapist. The study will additionally be advertised in clinical centres in the West Midlands such as specialist clinics, GP services and primary care settings, where practitioners will signpost potential participants to the primary organisation. If potential participants express an interest in the study the treating physician/surgeon/therapist may also pass on the relevant contact details to the study team. Posters with information regarding the study will also be located in the respective departments. We will also advertise the study and raise awareness of the study through social media using an electronic version of the poster advertisement.

Children without shoulder instability will be recruited by contacting staff within the hospital using the RJAH staff mailing list using the email included with this submission.

Investigation of referral patterns with clinical collaborators (ORLAU, RJAH, Oswestry) demonstrates that clinical recruitment is realistic and achievable. There are approximately 2 referrals a month for children with instability who meet our inclusion criteria.

7.1.1 Patient identification

Potential participants who meet the inclusion/exclusion criteria will be signposted to our study by their treating clinician or through our poster during their routine hospital visit.

7.1.2 Screening for children with shoulder instability

Area's in highlighted in grey must have a positive response to be eligible for the study.

	CRITERIA		YES	NO	CHECK
1.	A minimum of **12 weeks** since last shoulder instability episode				
2.	Aged between **8 to 18** years				
3.	*3a*. Initial episode of shoulder instability OR				
	3b. Recurrent episode of shoulder instability				
4.	Subjective report of instability				*
5.	Symptomatic instability in at **least one direction**, confirmed by a positive clinical finding of - Apprehension - Guarding - Laxity	*5a*. Sulcus (inferior)			
		5b. Anterior shift load			
		5c. Posterior shift load			
		5d. Apprehension relocation			
6.	Currently undergoing rehabilitation				
7.	Shoulder instability episode following surgical management of shoulder instability				
8.	No co-existing neurological pathologies or additional musculoskeletal injuries to the upper limb being assessed				

*if yes must have a positive response to question 5.

7.1.3 Screening for age matched controls

All screening questions must have a positive response to be eligible for the study

	CRITERIA	YES	NO	CHECK
1.	Aged between **8 to 18** years			
2.	NO previous presentation to a health care professional with a diagnosis of shoulder instability			
4.	NO history of shoulder injury within the last 3 months on the arm being assessed			
5.	NO co-existing neurological pathologies or deficits			
6.	NO previous surgical intervention on the arm being assessed			
7.	NOT currently undergoing or awaiting medical management, diagnostic investigations or rehabilitation on the arm being assessed			

7.1.4 Shoulder stability tests for age matched controls (not for screening)

	CRITERIA		YES	NO	Type e.g. (L)
1.	Please make note of any clinical findings of - Apprehension (A) - Guarding (G) - Laxity (L)	*1a*. Sulcus (inferior)			
		1b. Anterior shift load			
		1c. Posterior shift load			
		1d. Apprehension relocation			

7.2 Consent

Three different consent/assent forms have been developed.

For participants below 9 years old, very simple language was used with two tick boxes that indicate acceptance (smiley face) or decline (frowning face) to demonstrate feelings about taking part instead of initial boxes. This document's readability level was also checked with two children (7 and 8 years old), who found it understandable.

For ages between 9-15, their assent form contains simple questions with simple YES or NO answer instead of initial boxes. This document's readability level was checked by a Public Involvement and Engagement group (CRN West Midlands) and different children of appropriate age groups.

Those above 16 years and parent/guardians, their consent form language level was checked with two teens (18 and 17 years old).

Once participants and their parents/guardians have expressed an interest in the study, the researcher will spend time discussing the research with participant and parents/guardians to ensure that all of their questions and concerns are addressed.

During the visit, the participants and their parent/guardian will be provided with an additional opportunity to ask questions. Once that is completed, the researcher will provide the consent form to parents/guardians, and will explain the purpose of the appropriate assent/consent form. Participants will fill out the assent form with the presence of parents/guardians and the researcher.

All developed forms language level was done using Microsoft Word Flesch-Kincaid tool to ensure that they meet the language level of their target participants.

7.3 Methodology/ Measurement protocol

Following the consent/assent process the following methodology/ protocol will be used to collect the data required for meeting the study objectives. For children with shoulder instability, the affected arm will be measured. For children with no instability the dominant hand will be measured.

7.4 Instability history

For participants identified as being eligible ONLY, the follow up questions below should be asked

	FOLLOW UP QUESTIONS		RESPONSE	
F1.	Time since last episode of instability			
	Side of instability		LEFT	RIGHT
	Dominant hand		LEFT	RIGHT
F2.	Most recent episode of instability	Partial (subluxation)		
		Full (dislocation)		
	Reported direction of instability	Anterior	YES	NO
		Posterior	YES	NO
		Multi-directional	YES	NO
	Previous instability episode types	Partial (subluxation)		
		Full (dislocation)		
	Number of instability episodes	Partial (subluxation)		
		Full (dislocation)		

7.5 Nine point Beighton hypermobility score

One point is given for each of the side and test

	TEST DESCRIPTION		SCORE
B1.	Passively extend the fifth metacarpophalangeal joint ≥ 90º	**L**	
		R	
B2.	Passively oppose the thumb to the anterior aspect of the forearm	**L**	
		R	
B3.	Passively hyperextend the elbow to ≥ 10º	**L**	
		R	
B4.	Passively hyperextend the knee to ≥ 10º	**L**	
		R	
B5.	Actively place hands flat on the floor without bending the knees	**L**	
		R	
	Total		**/9**

7.6 Placement of marker clusters, surface electromyography (sEMG)sensors and identification of virtual markers

7.6.1 Sequence of events for data collection

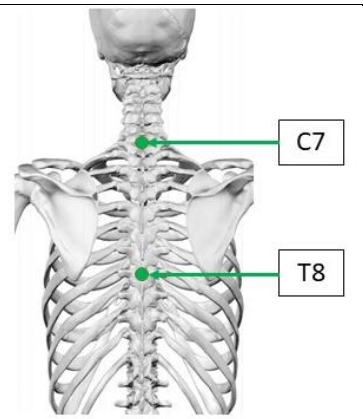
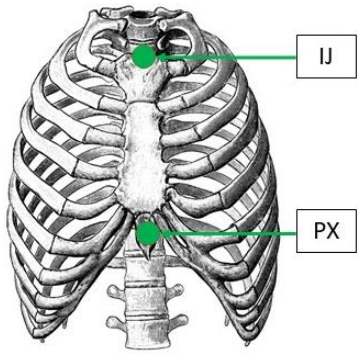
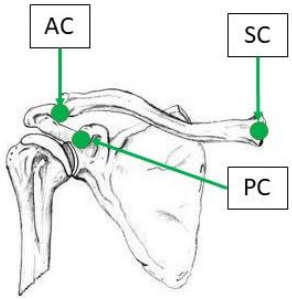
i. Bony landmark identification and mark up
ii. sEMG placement identification and mark up
iii. Skin preparation for sEMG
iv. sEMG placement
v. sEMG testing (recorded)
vi. Marker cluster placement
vii. Marking of cluster positions
viii. Identification of virtual markers using pointer and static calibration (recorded)
ix. Securing of required marker clusters and sEMG

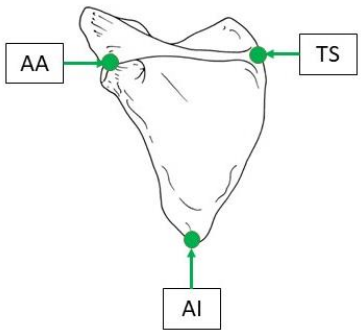
7.6.2 Bony landmark identification

The following bony landmarks will be palpated and marked for identification with the pointer following marker cluster and sEMG placement.

For consistency of bony landmark identification and marking participant should be seated with their hands resting on their lap.

Head position must be neutral i.e. no large degrees of flexion/extension

Location illustration	Description of identification of illustration
 	**THORAX SEGMENT** 1. <u>C7 Spinous Process (C7)</u> - *C7 can be seen with flexion of the head and protrudes more dorsally than C6 and T1. With extension of the head C6 disappears first and C7 remains palpable for longer.* 2. <u>T8 Spinous Process (T8)</u> - *From either the proximal or distal reference points (below) Alternate with two palpating fingers and count from cranial to caudal to the 8th thoracic vertebrae* *Reference points:* - *T3 / T4 spinous process in line with spina scapulae* - *T7 spinous process in line with angulus inferior scapula* 3. <u>Insicura Jungularis (IJ)</u> - *Manubrium sterni is proximally bounded by the incisura jungularis. Cranial bowl-shaped limitation of the manubrium sterni (deepest point). Palpation/ identification of the point should be done from superior to inferior.* 4. <u>Processus Xiphoideus (PX)</u> - *Most caudal point of the sternum in keeping with the midline.*
	**CLAVICLE SEGMENT** 5. <u>Art. Sternoclavicularis (SC)</u> - *Located bilaterally from the IJ, course from cranio-medial to caudo-lateral. (protraction and retraction of the shoulder facilitate palpation)* 6. <u>Art. Acromioclavicularis (AC)</u> - *Front: follow the front of the acromion to medial until a discrete notch is felt (V-shaped to open anterior).* - *Back: follow the top of the spina scapula and the back of the clavicle laterally to where the two bone pieces meet. A little further to the lateral side is the dorsal boundary of the AC joint.*



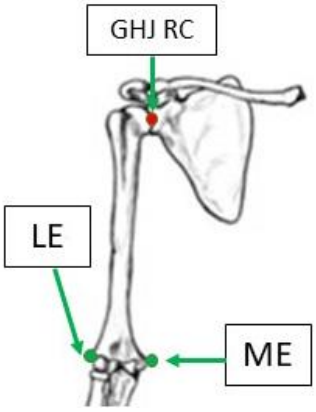
SCAPULA SEGMENT

7. Processus Coracoideus (PC)
   - *In the fossa infraclavicularis (ventral) from medial to lateral palpation until one feels a medial, bony structure (only the top and medial side can be palpated). See CLAVICLE SEGMENT*
   - *Palpation of the PC may be facilitated by protracting the shoulder girdle*

8. Trigonum Scapulae (TS)
   - *Origin of the spina scapulae in line with the spinous process of T3 on the medial scapula edge. (spina goes to the latero-cranial). Palpate the midpoint of the triangular surface on the medial border of the scapula in line with the scapular spine*

9. Angulus Inferior (AI)
   - *Follow the medial edge of the scapula caudally (most caudal point of the scapula, location at the level of the spinous process of T7)*

10. Angulus Acromialis (AA)
    - *Follow the spina scapulae, from mid-caudal to latero-cranial until kink is felt in the dorso-lateral edge of the acromion (this rear corner is rectangular). Most laterodorsal point of the scapula*



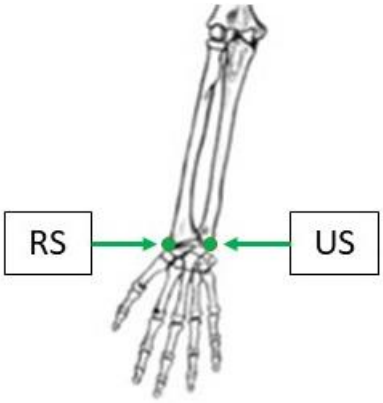
HUMERUS SEGMENT

11. Glenohumeral rotation centre (GH)
    - *Calculated via regression – with the participant's arm in abduction ask them to rotate their arm in a circular motion.*

Forearm in **supinated** position

12. Lateral Epicondyle (LE)
    - *Palpable on the distal lateral side of the humerus (slight passive flexion of the elbow facilitates palpation).*

13. Medial Epicondyle (ME)
    - *Palpable on the distal medial side of the humerus (slight passive flexion elbow).*

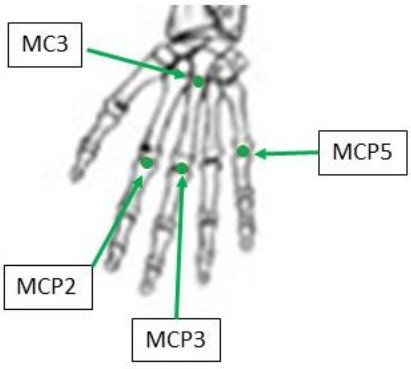


FOREARM SEGMENT

Forearm in **prone** position – palpation should be done from distal to proximal

14. Radial Styloid (RS)
- *Most caudal-antero point on the radial styloid*
- *Lateral edge of the radius leads distally into a depression. Palpate slightly proximal to the depression and the radial styloid is the palpable protrusion. Palpation easiest with radial deviation.*

15. Ulnar Styloid (US)
- *Most caudal-postero point on the ulnar styloid. Medial edge of the ulna leads distally into a depression. Palpate slightly proximal to the depression and the ulna styloid is the palpable protrusion. Palpation easiest with ulna deviation.*



HAND SEGMENT

16. Styloid process of 3rd Metacarpal (MC3)
- *Follow the third metacarpal on its dorsal side from distal to proximal. The small bone elevation on the base is the styloid process. Palpation easiest with maximum palmar flexion. (os capitatum lies in depression just proximal to styloid process of the 3rd Metacarpal)*

17. Distal head of 2nd Metacarpophalangeal joint (MCP2)
- Palpate just distal to the 2nd metacarpophalangeal joint (these joints are easy to palpate on the dorso-lateral side in light flexion position or with longitudinal traction).

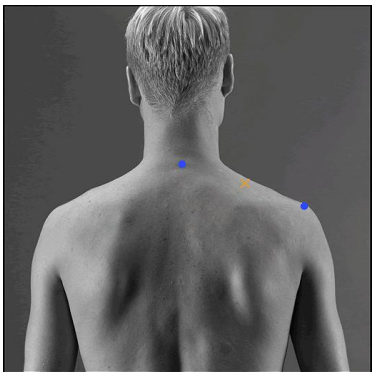
18. Distal head of 3rd Metacarpophalangeal joint (MCP3)
- Palpate just distal to the 3rd metacarpophalangeal joint (these joints are easy to palpate on the dorso-lateral side in light flexion position or with longitudinal traction).

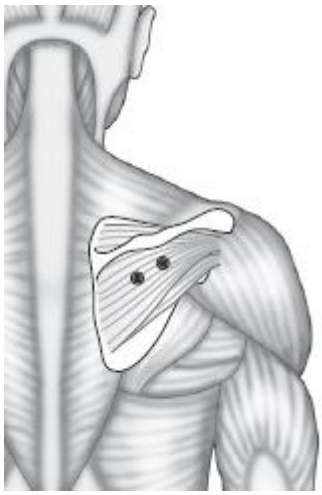
19. Distal head of 5th Metacarpophalangeal joint (MCP5)
- Palpate just distal to the 5th metacarpophalangeal joint (these joints are easy to palpate on the dorso-lateral side in light flexion position or with longitudinal traction).

7.6.3 Surface electromyography (sEMG) placement

Muscle bellies will be identified and marked during the clinical examination. Skin preparation is required, using a conductive and slightly abrasive gel. Subjects with lots of body hair may need to have small patches of skin shaved at the site of the sensors. Small wireless sensors are placed over each muscle belly. These are held in place using a combination of double sided tape and elasticated bandage.

The location of the bipolar sensor is always described as a point on a line between two anatomical landmarks. Where available electrode placement has been adapted from SENIAM guidelines or for cases Criswell et al 2010

Placement illustration	sEMG electrode Placement
	**1. Middle Trapezius (listed on SENIAM as Upper)** Location: The electrodes need to be placed at 50% on the line from the acromion to the spine on vertebra C7 Orientation: In the direction of the line between the acromion and the spine on vertebra C7 Clinical test: Elevate the acromial end of the clavicle and scapula; extend and rotate the head and neck toward the elevated shoulder with the face rotated in the opposite direction. Apply pressure against the shoulder in the direction of depression and against the head in the direction of flexion anterolateral. With hand resting by side Prompts to participants for testing: ***"Shrug your shoulder up"*** Guidelines: SENIAM



Source: Copyright © Clinical Resources, Inc.

2. Infraspinatus

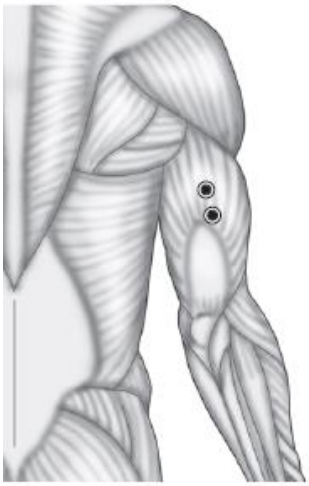
Location: Palpate the spine of the scapula. Electrode placed parallel to and approximately 4 cm below the spine of the scapula, on the lateral aspect, over the infrascapular fossa of the scapula. Avoid placement over the posterior deltoid

Orientation: Parallel with the spine of the scapula.

Clinical test: Elbow bent to 90 degrees with lateral (external) rotation of the bent arm out to the side; abduction of the arm. Apply pressure to resist external rotation and abduction of the arm.

With their arm out to the side with elbow flexed
Prompts to participants for testing: ***"Push your arm out towards me"***

Guidelines: Criswell et al 2010



Source: Copyright © Clinical Resources, Inc.

3. Triceps Brachii

Location: Electrodes need to be placed at 50 % on the line between the posterior crista of the acromion and the olecranon.

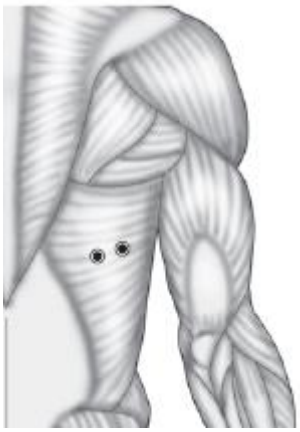
In some cases, the size of the participant's triceps relative to the sEMG electrode may not be sufficient to differentiate the heads of triceps. Therefore, a more central positioning may be used as a pragmatic approach to managing this and the cluster.

Orientation: In the direction of the line between the posterior crista of the acromion and the olecranon.

Clinical test: Extend the elbow while applying pressure to the forearm in the direction of flexion.

With their elbow bent
Prompts to participants for testing: ***"Straighten your elbow"***

Guidelines: Criswell et al 2010



Source: Copyright © Clinical Resources, Inc.

4. Latissimus Dorsi

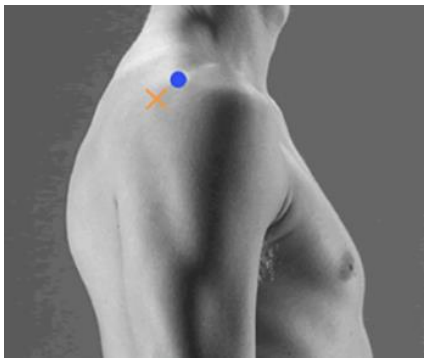
Location: Palpate the scapula. Electrodes is placed approximately 4 cm below the inferior tip of the scapula, half the distance between the spine and the lateral edge of the torso. They are

Orientation: Parallel to the fibres of Latissimus Dorsi which are oriented in a slightly oblique angle of approximately 25 degrees

With a cupped hand, supporting a flexed elbow
Prompts to participants for testing: ***"Push down and back in a rowing motion"***

Clinical test: Extend, adduct, or medially rotate the arm. Participant to start arm externally rotated and in some forward flexion. Apply pressure to resist extension, adduction and medial rotation of the arm.

Guidelines: Criswell et al 2010



5. Posterior deltoid

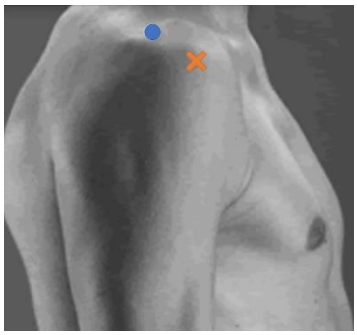
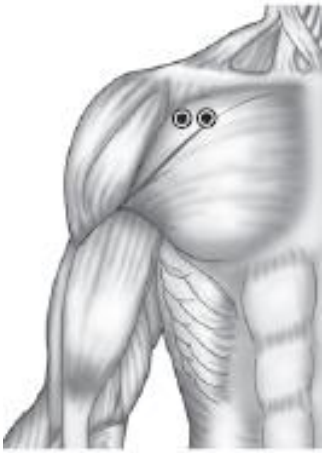
Location: Centre the electrodes in the area about two finger breaths behind the angle of the acromion

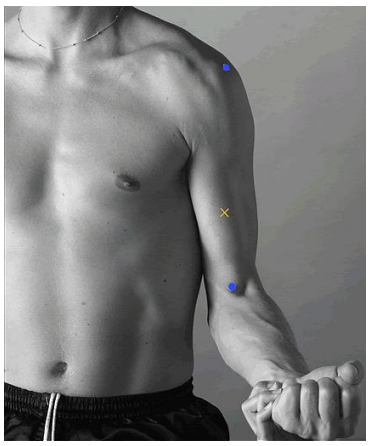
Orientation: In the direction of the line between the acromion and the little finger.

Clinical test: Abduct the shoulder in slight extension, with the humerus in slight medial rotation. The humerus is placed in slight medial rotation in order to offload the posterior fibres. The anatomical action entails slight lateral rotation while pressure is applied against the posterolateral surface of the arm, above the elbow in the direction of adduction and slight flexion.

With their elbow flexed
Prompts to participants for testing: ***"Pull your arm back"***

Guidelines: SENIAM

	**6. Anterior deltoid** Location: one finger width distal and anterior to the acromion Orientation: In the direction of the line between the acromion and the thumb Clinical test: Shoulder abduction in slight flexion, with the humerus in slight rotation. In the erect sitting position, it is necessary to place the humerus in slight lateral rotation to increase the load on the anterior fibres. The anatomical action of the anterior deltoid entails slight medial rotation while pressure is applied against the antero medial surface of the arm in the direction of adduction and slight extension. With their elbow flexed Prompts to participants for testing: ***"Push your arm forwards"*** Guidelines: SENIAM
 *Source: Copyright © Clinical Resources, Inc.*	**7. Pectoralis Major (clavicular head)** Location: For clavicular placement, palpate the clavicle. Electrode is placed on the chest wall at an oblique angle toward the clavicle, approximately 2 cm below the clavicle, just medial to the axillary fold Orientation: at an oblique angle toward the clavicle Clinical test: Flexion of the arm, abduction of the arm above 90 degrees, medial rotation, and horizontal adduction of arm. With their elbow flexed to 90º and arm abducted and flexed Prompts to participants for testing: ***"Push forwards out and in front of you"*** Guidelines: Criswell et al 2010



8. Biceps Brachii

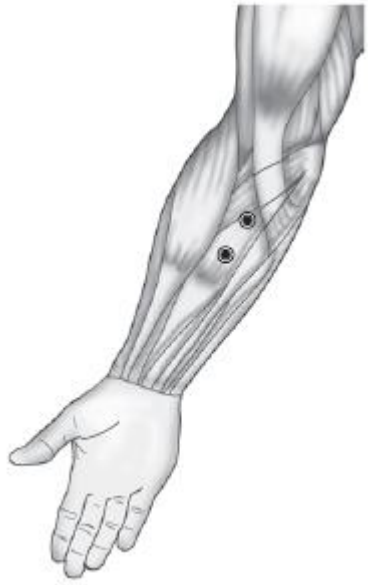
Location: Electrodes need to be placed on the line between the medial acromion and the fossa cubit at 1/3 from the fossa cubit.

Orientation: In the direction of the line between the acromion and the fossa cubit

Clinical test: Place one hand under the elbow to cushion it from table pressure and flex the elbow slightly below or at a right angle, with the forearm in supination. Press against the forearm in the direction of extension.

With their elbow flexed to 90º
Prompts to participants for testing: ***"Bend your elbow"***

Guidelines: SENIAM



Source: Copyright © Clinical Resources, Inc.

9. Common Flexor Origin

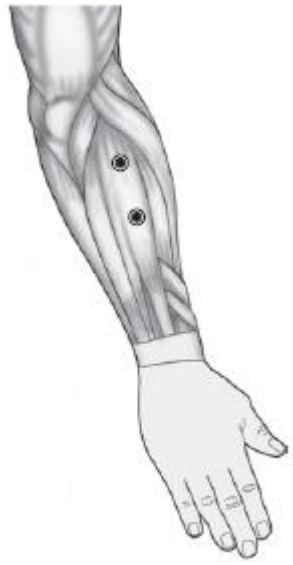
Location*:* About 3-5 centimetres from the elbow joint at distal ventral aspect of forearm. Assessor would ask subject to flex elbow to palpate flexors bulk.

Orientation: with the electrodes oriented in the direction of the muscle fibres which run longitudinally down the forearm.

Clinical test: Flexion of the wrist

Prompts to participants for testing: ***"Bend your wrist down"***

Guidelines: Criswell et al 2010



Source: Copyright © Clinical Resources, Inc.

10. Common Extensor Origin

Location: About 3-5 centimetres from the elbow joint at proximal dorsal aspect of forearm. Assessor would ask subject to extend elbow and wrist, to palpate extensors bulk. Electrode is placed in the centre of the muscle bulk.

Orientation: with the electrodes oriented in the direction of the muscle fibres which run longitudinally down the forearm.

Clinical test: Extension of the wrist

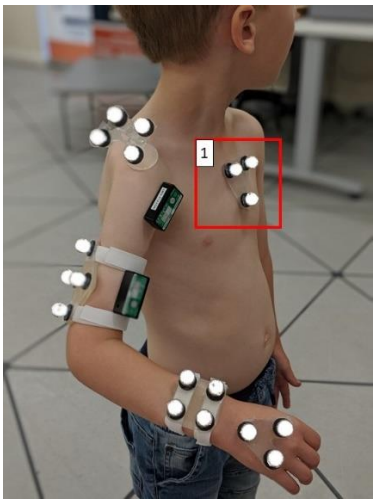
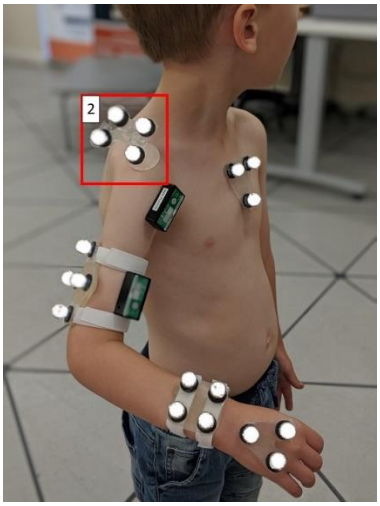
Prompts to participants for testing: ***"Bend your wrist up"***

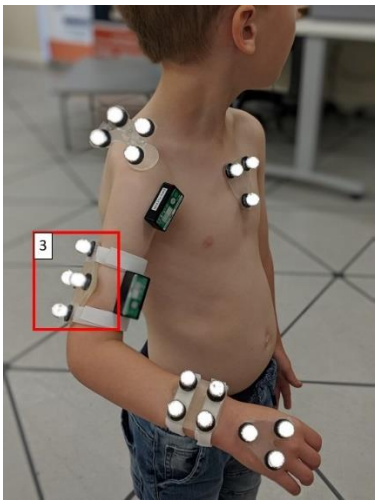
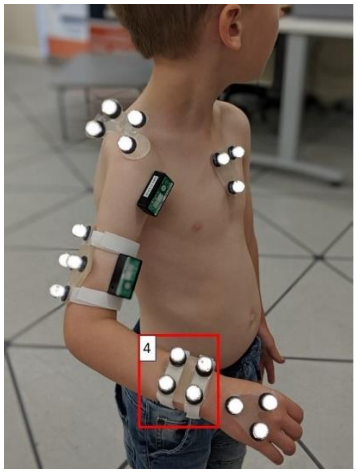
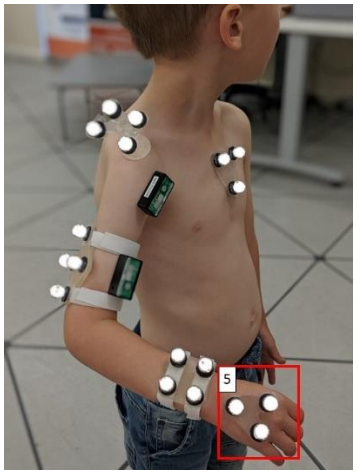
Guidelines: Criswell et al 2010

7.6.4 Marker cluster placement

Each segment is defined using a minimum of 3 cluster based markers which are not collinear. A range of marker clusters (marker diameter 14mm) will be used depending on the anthropometric characteristics of the participant e.g. size, arm length and width in addition to ensuring adequate visibility of markers. A description of the marker cluster placement has been described below and has been adapted from Jaspers et al 2011.

As a quality control measure, **the borders of all clusters** will be marked to ensure no movement has occurred.

Placement illustration	Description of placement
	**1. Sternal marker cluster** Positioned using double sided tape on the anterior aspect of the thorax, approximately one finger width below the sternal notch. Placement must be below the sterno-clavicular joint and in keeping with the midline of the body. The antero-superior border of the thorax is defined by the insicura jugularis (IJ) point and the antero-inferior border is defined Processes Xiphoideus (PX) point. For participants with breast tissue, a more superior placement of the sternal cluster may be required, not exceeding the antero-superior border of the thorax. In this case, adequate visibility of the marker cluster should be ensured prior to identification of virtual markers. Mark the inferior edge of the cluster.
	**2. Acromion marker cluster** Positioned using double sided tape on the flat surface of the acromion. Secure to the acromion with extra tape. Following identification of the acromioclavicular joint, palpate posteriorly to identify the flattest area of the acromion. Mark the base of the cluster.

	**3. Humeral marker cluster** Positioned using velcro on the distal aspect of the humeral segment. As a general guide the inferior component of the marker cluster should be proximal to and in line with the lateral epicondyle (LE) of the humerus. Mark the inferior edge of the cluster.
	**4. Forearm marker cluster** Positioned using velcro on the postero-distal aspect of the forearm segment. As a general guide the inferior border of the marker cluster should be proximal to the radial styloid (RS) and ulnar styloid (US) points. Mark the inferior edge of the cluster.
	**5. Hand marker cluster** Positioned using double sided tape on the dorsal aspect of the hand. The marker cluster should be placed distal to the 3rd carpometacarpal joint and distal to all row of metacarpophalangeal joints. The cluster is shaped like a V and the centre of the cluster should align with the 3rd metacarpal head. Mark the inferior edge of the cluster.

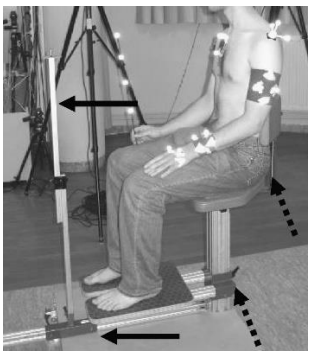
7.6.5 Virtual marker identification and static calibration

Following completion of the sEMG placement, the virtual markers will be identified using a pointer. This requires placement of the pointer tip on the bony landmarks outline in section 7.6.2. This is completed with the participant in sitting with their hand on their knee. The virtual markers and movements required for calibration are:

No.	Name	Abbreviation	Checklist
1.	C7 Spinous Process	C7	
2.	T8 Spinous Process	T8	
3.	Insicura Jungularis - (Jugular notch)	IJ	
4.	Processus Xiphoideus - (Xiphisternum)	PX	
5.	Art. Sternoclavicularis – (Sternoclavicular joint)	SC	
6.	Art. Acromioclavicularis - Acromioclavicular joint	AC	
7.	Processus Coracoideus - Coracoid process	PC	
8.	Trigonum Scapulae – medial border spine of scapula	TS	
9.	Angulus Inferior (AI) - inferior angle of the scapula	AI	
10.	Angulus Acromialis - Latero-inferior edge of scapula spine	AA	
11.	Glenohumeral rotation center*	GH	
12.	Lateral epicondyle	LE	
13.	Medial epicondyle	ME	
14.	Radial Styloid	RS	
15.	Ulnar Styloid	US	
16.	Styloid process of 3rd Metacarpal	MC3	
17.	Distal head of 2nd Metacarpophalangeal joint	MCP2	
18.	Distal head of 3rd Metacarpophalangeal joint	MCP3	
19.	Distal head of 5th Metacarpophalangeal joint	MCP5	
20.	Hand on knee – static for trial and sEMG**	HandKnee	

* Calculated via regression – with the participant's arm in abduction ask them to rotate their arm in a circular motion.

** Participant seated with their hand on their knee and their contralateral hand holding the pointer as per the image.



7.7 Movements for data capture

7.7.1 Grip Strength

Participants will have their grip strength tested using a handheld dynamometer. The total repetitions **will not exceed 3** for each activity and will be broken up into **3 sets of 1 repetition each side**.

- **Testing limb**
    - affected and unaffected arm [children with instability]
    - left and right/ dominant and non-dominant arm [children without instability]
- **Starting position –** Participant in standing. Elbow flexed to 90º with hand in thumbs up position with handheld dynamometer.
- **Movement task –** Participants will be instructed to squeeze the handheld dynamometer as hard as they comfortably can for no longer than 5 seconds

7.7.2 Physiological movements

- For *Physiological movements* and *Functional tasks* – the total number **will not exceed 12 repetitions** for each activity in total and will be broken up into **2 sets of 6 repetitions.**
- For the *Movements under load* – the total number **will not exceed 6 repetitions** for each activity in total and will be broken up into **2 sets of 3 repetitions.**

Before each movement activity, participants will have the required movements demonstrated to them along with instructions regarding the start and finish positions.

P1. Flexion

- **Testing limb**
    - affected arm [children with instability]
    - dominant [children without instability]
- **Starting position –** Participant in standing. Palmar surface resting on the lateral aspect of their thigh (in keeping with the midline of the body in the coronal plane).
- **Movement task –** Participants will be instructed to lift their arm out in front of them as high as they possibly can and then return it to the starting position.

P2. ABDuction

- **Testing limb**
    - affected arm [children with instability]
    - dominant [children without instability]
- **Starting position –** Participant in standing. Anatomical position i.e. Lateral aspect of the hypothenar eminince resting on the lateral aspect of their thigh (in keeping with the midline of the body in the coronal plane).
- **Movement task –** Participants will be instructed to lift their arm out to their side as high as they possibly can and then return it to the starting position.

P3. Abduction to ≈45º and then lateral rotation

- **Testing limb**
    - Affected arm [children with instability]
    - dominant [children without instability]
- **Starting position –** Participant in standing. Elbow flexed to 90º with hand in thumbs up position.
- **Movement task –** Participants will be instructed to lift their arm out to their side up to ≈45º º at the shoulder. Maintaining the arm in this position, participants will then be asked to laterally rotate their shoulder as far as is comfortable for the required or maximally tolerable amount of repetitions. Following this, participants will be instructed to then return it to the starting position.

7.7.3 Functional tasks

F1. Hand behind head

- **Testing limb**
    - affected arm [children with instability]
    - dominant [children without instability]
- **Starting position –** Participant in standing. Palmar surface resting on the lateral aspect of their thigh (in keeping with the midline of the body in the coronal plane).
- **Movement task –** Participants will be instructed to place their hand on the top of their head and then return it to the starting position.

7.7.4 Movement under load

- **These will not exceed 6 repetitions for each i.e. 2 sets of 3 repetitions**

Participants will perform the movements outlined below under a loaded condition using a self-selected weight. The participants will be provided with a series of weights from which to choose and advised to select a weight that allows them to complete the movements comfortably.

M1. Flexion

- **Testing limb**
    - affected arm [children with instability]
    - dominant [children without instability]
- **Starting position –** Participant in standing with weight in hand. Palmar surface facing the lateral aspect of their thigh (in keeping with the midline of the body in the coronal plane).
- **Movement task –** Participants will be instructed to lift their arm out in front of them as high as they possibly can and then return it to the starting position.

M2. Abduction

- **Testing limb**
    - affected arm [children with instability]
    - dominant [children without instability]
- **Starting position –** Participant in standing with weight in hand. Anatomical position i.e. Lateral aspect of the hypothenar eminince facing the lateral aspect of their thigh (in keeping with the midline of the body in the coronal plane).
- **Movement task –** Participants will be instructed to lift their arm out to their side as high as they possibly can and then return it to the starting position.

M3. Abduction to ≈ 45º º and then lateral rotation

- **Testing limb**
    - affected arm [children with instability]
    - dominant [children without instability]
- **Starting position –** Participant in standing. Elbow flexed to 90º with hand in thumbs up position.
- **Movement task –** Participants will be instructed to lift their arm out to their side up to ≈45º º at the shoulder. Maintaining the arm in this position, participants will then be asked to laterally rotate their shoulder as far as is comfortable for the required or maximally tolerable amount of repetitions. Following this, participants will be instructed to then return it to the starting position.

7.8 Follow up for recurrent instability

Following the movement analysis session, participants will be provided with a diary to record and further episodes of instability as per (appendix). Provided with information and guidance on how to complete the diary. Participants in both groups will additionally be followed up on a monthly basis via a telephone call for up to 12 months to record the number of instability episodes experienced. Monthly follow ups have been selected to ensure accurate recording of instability episodes and facilitation of diary recordings.

7.9 Withdrawal criteria

Participants' have a right for unrestricted withdrawal at any point of this study. Participants have been informed within the information sheet that if they choose to withdraw, identifiable data already collected with consent would be retained and used in the study. No further data would be collected or any other research procedures carried out on or in relation to the participant. Participants have also been instructed that if they wish to withdraw they may do so and no one will mind.

8 STATISTICS AND DATA ANALYSIS

8.1 Sample size calculation

This is an observational, cross-sectional study.

- A power calculation, used to determine the required sample size, is not possible for this study as the standard error of measurement (SEM - essential to identify a minimally clinically important difference) is not known.
- This study will provide the data from which SEM can be estimated and this can then be used to inform power calculations for future studies.
- Our rationale for selecting a sample size of 15 in each group (30 total) has been based on previous work which has developed and then implemented protocols for clinical practice.
- The two references cited below have developed clinical measurement protocols using sample sizes of 10 typically developing children and 12 children with cerebral palsy affecting the upper limbs.
- In the absence of an equivalent study in paediatric shoulder instability a sample size of 15/group reflects the current research practice in the literature and will be able to provide us with population estimates of "standard error of measurement - SEM" in typically developing children and those with upper limb pathology.

Jaspers, E., et al., Upper limb kinematics: development and reliability of a clinical protocol for children. Gait Posture, 2011. 33(2): p. 279-85.
Jaspers, E., et al., The reliability of upper limb kinematics in children with hemiplegic cerebral palsy. Gait & Posture, 2011. 33(4): p. 568-575.

8.2 Planned recruitment rate

Investigation of referral patterns with clinical collaborators prior to covid-19 (ORLAU, RJAH, Oswestry) demonstrated that clinical recruitment is realistic and achievable. There are approximately 2 referrals a month for children with instability who meet our inclusion criteria. Risk mitigation against under recruitment will be achieved by additionally advertising the study in clinical centres in the West Midlands such as specialist clinics, GP services and primary care settings, where practitioners will signpost potential participants to the primary organisation. Posters with information regarding the study will also be located in the respective departments. We will also advertise the study through social media using an electronic version of the poster.

8.3 Statistical analysis plan

The aim of this study is to identify factors responsible for recurrent shoulder instability in children. To meet the main aim, the following objectives, need to be met. The methods of analysis used to meet the study objectives have been reported below.

The analysis of measurement units will inform the main study objective and secondary objectives.

- **Kinematic** data such as joint angles and displacements – average range of movement values, as well as absolute minimum and maximum values will be reported for all functional tasks. For comparison purposes, descriptive statistics will be used to report the group behaviours and variability including means and standard deviations.
- **Kinetics** - force/strength – The range of force and strength values, as well as absolute minimum and maximum values will be reported for all functional tasks. For comparison purposes, descriptive statistics will be used to report the group behaviours and variability
- **Muscle activity patterns** - muscle activity (absence or presence), timing of muscle onset, percentage of maximum contraction and time of peak intensity will be used. This methodology is consistent with previously published research and is used for informing clinical decision making processes

The secondary research objectives used to address the main aim of the study are:

1. Validation of a 3D movement analysis protocol for measuring upper limb function in children with shoulder instability.
    i) Individual variability (associated with of the measurement units outlined above) will be determined using the coefficient of variation for all data.
    ii) The reliability and error associated with the protocol will be determined using the standard error of measurement for the measurement units outlined above. The reliability of the protocol will be determined through a sensitivity analysis investigating what effect perturbation of the virtual markers has on the outputs of the biomechanical model e.g. kinematics, position of the humerus
2. Obtain new data on muscle activity and movement patterns of children with and without shoulder instability
    i) The method of analysis outlined above will inform this objective
3. Categorising clinical presentations of instability and identification of important factors for recurrent instability
    i) data from study objective 2 will be evaluated to identify features i.e. movement or muscle activity patterns, which may be used to categorise clinical presentations of shoulder instability. An appropriate clustering/categorisation method will be selected once the characteristics of the dataset has been established

if we get a large enough sample size of participants with a homogenous clinical presentation and if three or more groups are identified in the preceding work package, an analysis of variance (ANOVA) can be used. For less than three groups, an independent sample t-test will be used.

9 DATA HANDLING

9.1 Data collection tools and source document identification

All documents and information are confidential and will be handled and safeguarded in the manner that ensures privacy and confidentiality of participant's personal information, in compliance with Data Protection Act (2018).

All documents and forms containing participants' personal information will be safeguarded and stored on-site at either Robert Jones Angus Hunt Hospital (RJAH) main building or The Orthotic Research & Locomotor Assessment Unit (ORLAU) building in RJAH. Only authorised individuals involved in this study will have the right to access these documents and information. Any electronic participants' information and/or data will only be stored in an NHS secured laptop, with two-factor authentication access. Then, these will be transferred to RJAH hospital servers. Finally, the study team and associated institutions will have access to anonymised data only. Only anonymised data will be transferred to an encrypted university laptop.

9.2 Data handling and record keeping

This data management plan was developed ensure that data of this research is managed and shared in a robust and professional manner. The plan was formulated with adherence the United Kingdom Research and Innovation Data Policy, RJAH Hospital Trust Data Protection, Data Protection Act 2018 and General Data Protection Regulation 2018[1].

All forms, documents, and templates will be stored within ORLAU at RJAH. ORLAU building access is restricted by a reception desk and a password-protected locked door. Any electronic data of participants will also be copied and saved onto RJAH servers, which are protected under NHS electronic security. The research team will only have access to the participant NHS records once the participant has been consented for the study.

[1] Available at, respectively:; https://goo.gl/muBtwD; https://www.rjah.nhs.uk/Patient-Visitors/Data-Protection.aspx; https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted; https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/

Once the study is concluded, all appropriate paper-based forms of participants will be moved and stored in a locked cabinet at ORLAU for 10 years, then they will be destroyed.

Confidentiality and anonymity will be maintained for all participants. Any identifying information provided (e.g. names and addresses) will be held in the strictest confidence and stored in a confidential, password protected database accessible by only those with permission. All data used for analysis will be kept separate from participant personal data. Hard copy material (e.g. signed consent forms) will be stored securely for a minimum period of 10 years after the study has been completed. After that period all hard copy material will be reviewed, and approval for destruction from the sponsor will be sought. All study participants will be allocated a unique identification number, therefore, making it possible to anonymise research data. All sensitive datasets will be retained on a secure server and access restricted to the study team. Access to all research datasets is controlled by password protection and additional permissions specific to folders.

All confidentiality arrangements adhere to relevant regulations and guidelines (General Data Protection Regulation 2018, Data Protection Act 2018, General Medical Council (GMC), Medical Research Council (MRC), Research Governance Framework) and the chief investigator has a responsibility to ensure the integrity of the data and that all confidentiality procedures are followed

9.3 Access to Data

Only members of the ORLAU clinical team, students and clinical supervisors will have access participants' personal data for the duration of the study. The principal investigator is already part of the direct healthcare team on-site. Other members of the research team will only have access to anonymised data. Members of staff from the sponsor and/or regulatory bodies may also require access to study participant's data in order to carry out audits. All these staff work to robust data security procedures.

The raw data will be generated and stored electronically on an NHS-secured computer. Only anonymised data will be transferred to an encrypted university laptop. The researcher, academic supervisor, the principal investigator and clinical supervisors will be involved in the analysis of data. Other members of the research team will only have access to anonymised data. The anonymised dataset will stored on the University of Liverpool data repository[2], the anonymised data will be openly available.

[2] http://datacat.liverpool.ac.uk/

Paper-based data will be stored at RJAH in a locked cabinet, and Electronic data will be stored on RJAH hospital Trust servers, which have restricted access by a two-way authentication procedure. Paper-based data will be kept on-site for 10 years and will be destroyed after the sponsors approval. Dr Caroline Stewart is the custodian of the data, as she is the manager of ORLAU. ORLAU entrance is restricted by a reception desk and a locked door with passcode keypad. Accessibility to these data is governed by RJAH local hospital policies and. RJAH is the sponsor of this study, which makes it the owner of the data generated by this study, All of these guidelines are implemented to ensure these arrangements are in compliance with the Data Protection Act 2018, GDPR 2018 and Research Governance Framework.

9.4 Data Sharing Agreements

The anonymised final trial dataset and anonymised 3D movement data files will be stored on the University of Liverpool and RJAH Data repositories where they will be assigned a Digital object identifier. The anonymised data will be openly available.

9.5 Archiving

Study related data will be stored as per RJAH hospital policies, which are compliant with the NHS Retention schedules reported in Records Management Code of Practice for Health and Social Care 2016[3]. Secondary anonymised data will be reported in the following data repositories:

- RJAH
- University of Liverpool

In addition, the secondary anonymised data may be presented in a thesis, which will be archived as per University of Liverpool guidelines.

Paper-based data will be kept on-site for 10 years and will be destroyed after the sponsors approval. Dr Caroline Stewart is the custodian of the data, as she is the manager of ORLAU. Accessibility to these data is governed by RJAH local hospital policies. RJAH is the sponsor of this study, which makes it the owner of the data generated by this study.

[3] Available at: https://digital.nhs.uk/binaries/content/assets/legacy/pdf/n/b/records-management-cop-hsc-2016.pdf

10 MONITORING & AUDIT

10.1 Safety Reporting

A complication of shoulder instability is increased risk of further episodes of shoulder instability. In order to minimise the risk, for children with shoulder instability the first assessment will be conducted a minimum of 12 weeks from their most recent episode of instability. This time point has been selected from experience in managing this patient group and after further discussion with our clinical partners to identify a suitable time point which minimises the risk of recurrent instability, ensures the measurements do not exacerbate participant symptoms and allows them to complete the required tasks. The movement tasks for analysis have also been selected to minimise any risks of instability.

We do not anticipate participants as having episodes of instability during the measurement sessions. However, if participants do suffer a dislocation during the measurement session which does not spontaneously reduce/resolve, there is emergency care available on site and the participant will be managed according to the RJAH hospital trust procedures. The principal investigator is already part of the direct healthcare team on-site. A monthly meeting with the research team will be regularly held to discuss the conduct of the study, including adverse events Safe practice and Risk Assessment.

11 ETHICAL AND REGULATORY CONSIDERATIONS

The study will be submitted for approval by the HRA through which REC approval will be obtained. The study team will provide the REC with a copy of the final protocol, patient information sheets, consent forms and all other relevant study documentation as part of the HRA approval process. The chief investigator will ensure that REC approval is obtained prior to recruitment of any participants in the study. Before any site can enrol patients into the study, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place.

For any amendment to the study, the Chief Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator will work with sites so they can put the necessary arrangements in place to implement the amendment and to confirm their support for the study as amended. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and HRA approval obtained for the amendment.

All correspondence with the REC will be retained. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.

The Chief Investigator will take overall responsibility to produce annual reports as required. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

The Chief Investigator will notify the REC of the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

The following stages have been taken to address the ethical considerations and minimisation of measurement burden for our study, therefore ensuring the safety of participants.

A complication of shoulder instability is increased risk of further episodes of shoulder instability. In order to minimise the risk, for children with shoulder instability the first assessment will be conducted a minimum of 12 weeks from their most recent episode of instability. This time point has been selected from experience in managing this patient group and after further discussion with our clinical partners to identify a suitable time point which minimises the risk of recurrent instability, ensures the measurements do not exacerbate participant symptoms and allows them to complete the required tasks. The movement tasks for analysis have also been selected to minimise any risks of instability. Participants will also be informed that they may stop the movement activities should their symptoms or discomfort worsen during testing.

We do not anticipate participants as having episodes of instability during the measurement sessions. However, if participants do suffer a dislocation during the measurement session which does not spontaneously reduce/resolve, there is emergency care available on site and the participant will be managed according to the trust procedures.
To record participant's movements, markers and devices will be placed on the skin using hypoallergenic medical adhesive tape. This is routine clinical practice in movement analysis laboratories and those conducting data collection will be trained in the application and removal of the markers. Some discomfort may be experienced by participants during marker and device removal, in the worst case it would be equivalent to that of a plaster being removed.

A monthly meeting with the research team will be regularly held to discuss the conduct of the study, including adverse events Safe practice and Risk Assessment.

Measurement burden

In order to minimise the measurement burden on all participants and ensure the aims of the study are met, our study design has been developed following input from a Public Involvement and Engagement

(PPIE) group, an additional 7 children of appropriate age groups outside of the PPIE and clinicians who routinely work with children with shoulder instability.

A primary aim of our study is to test the reliability and variability of a measurement analysis protocol in children with shoulder instability and age-matched controls. To minimize the measurement burden on children and their parent/carer/guardian, only a single study site visit, lasting a maximum of 2 hours 30 minutes, is required. Reliability will be determined by a sensitivity analysis in which we will virtually pertubate the markers post data collection. This has been selected to minimise the measurement burden of multiple visits for children with shoulder instability and the age matched controls. For children with shoulder instability this will also minimise the variability which may arise as a result of the natural recovery process over time and confound our results. The measurement protocol has been designed after consultation with different children of appropriate age groups, clinicians and the scientific literature.

Where possible, we will additionally try and accommodate measurement sessions outside of school hours for both groups to limit any school/lesson absences.

Diaries and monthly telephone calls (lasting up to 12 months), have been selected to ensure accurate recordings of the events and minimise recall bias. We have received input re the follow up study processes and diaries from the Public Involvement and Engagement group and additional children of appropriate age groups. We do not anticipate that participants will have a large number of instability episodes and so the measurement burden for recording will be minimal. Additionally, participants will only be asked to record when an episode happens.

11.1 Peer review

This research is being funded by The Private Physiotherapy Education Foundation and as a part of the process has undergone peer review.

11.2 Public and Patient Involvement

Please see below the info from the PPIE group and subsequent actions as a result of the PPIE feedback.

PPIE feedback	Comments and actions
Firstly, the group really saw value in the project especially as your presentation stated rehabilitation was preferred over surgical methods however reported failure rates were as high as 90%, the group were shocked about this so felt it was an incredibly important topic to research and would be value for money as if the issue could be solved the first time it would save money in the long run from no repeat complications.	We have responded to the PPIE group to and thanked them for their involvement. We are pleased that they recognized the value of the research.

The diary The group weren't sure that both diary's were needed maybe just one. They felt they were nice a simple but just suggested giving an example of how to fill out above the table e.g. format of date time and example of activity.	We have selected a single diary and provided an example of how to fill it in.
The Posters The group thought they were nice and simple. i. They didn't like the picture of the girl as she was too happy and if she had suffered shoulder discomfort she wouldn't be that happy. ii. They felt the picture of the shoulder was much better but felt it would be more relevant if it was a child's shoulder. iii. Within the poster they weren't sure the word subluxated was needed as this was really difficult to understand and thought most people understood dislocated and popped out. iv. Under the second paragraph maybe put if you are a child aged ..... and have experienced your shoulder being popped out. v. Under this the group thought it was really important to give a very brief description of what was involved in the study or no-one might respond. Especially as the study doesn't involve much but if it doesn't state that it might put people off. vi. The last section after would you/your child like to help us by participating in the study add in for more information call.... vii. The very last line about travel expenses they felt wasn't really necessary but if it was to be left in to make it a smaller font. viii. They felt posters could be put in clinics, especially minor injuries, fracture clinics and children's outpatients but also back of toilets doors as this was a place that most people read information.	i. An alternate picture has been selected. ii. We have used the shoulder picture as we were unable to find an alternate picture (with the correct licensing) that accurately reflected the study and what it involves. iii. The word subluxated has been removed from the study advertisement to increase readability iv. The wording has been changed to increase readability v. A brief description and some further images have been included in the advertisement. vi. The wording has been changed to reflect the feedback from the PPIE group vii. The font has been made smaller to reflect the feedback from the PPIE group viii. Where possible we will try and place the posters in the suggested places.
The PIL *(Participant Information Leaflet)*	

I have attached these with the changes. i. The under 16 they thought was a good size and overall really well written. (which is a big compliment from them) ii. The only thing they felt needing adding was about you don't have to take part or could choose to stop taking part at any time and no-one would mind iii. The over 16 They thought could be condensed to 4 pages however for an adult leaflet they thought it wasn't too long and was much easier to understand than most adult leaflets iv. Overall they thought both were good information leaflets.	i. We were please to read this and when adding further information have kept the same writing style and level. ii. We have added the wording suggested by the PPIE group re choosing to stop taking part. iii. Where possible we have tried to condense these without removing any pertinent information. iv. We were please to read the comments re quality of the leaflets
• The group definitely understood the project and were keen to find out much such as did you think the study would lead to the result of more surgeries. • They are happy to be involved throughout the project if that is something you would like. • They wanted to know about your plans for dissemination to participants and especially the public?	We have responded to the PPIE group and indicated that we would like for them to be involved in the project. We have also indicated that we have plans to disseminate our work through scientific journals, presentations (scientific, lay and to the PPIE group) and would value their help.
Hope this has helped if you need any more information/ help please do not hesitate to contact me best wishes with the funding. Thanks	

11.3 Data protection and patient confidentiality

Each participant will be issued a unique participant study number which will be exclusively used in any paper-based forms to ensure that participants cannot be identifiable in case the forms are misplaced/lost. The use of a laptop with encryption would ensure that any electronically captured data would be secured. All other non-anonymised data will be stored and kept securely at RJAH Hospital trust. This data management plan was developed ensure that data of this research is managed and shared in a robust and professional manner. The plan was formulated with adherence to the United Kingdom Research and Innovation Data Policy, RJAH Hospital Trust Data Protection, Data Protection

Act 2018 and General Data Protection Regulation 2018[4]. All participant personal data will be anonymised. For images or videos included in published results, we have software which allows us to blur out participant faces and distinguishable features to maintain anonymity

11.4 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall study management

There are no financial or any other competing interests to declare for the chief investigator or any other members of the research team.

11.5 Indemnity

RJAH has in place a broad clinical trial insurance cover that applies equally to CTIMPs and Non-CTIMPs and Device Trials. This insurance would cover study management, design and conduct. The NHS has a duty of care to patients treated, whether or not the patient is taking part in a clinical research study, and the NHS organisation remains liable for clinical negligence and other negligent harm to patients under this duty of care.

11.6 Access to the final trial dataset

Study related data will be stored as per RJAH hospital policies, which are compliant with the NHS Retention schedules reported in Records Management Code of Practice for Health and Social Care 2016[5]. Secondary anonymised data will be reported in the following data repositories:

- RJAH
- University of Liverpool

In addition, the secondary anonymised data may be presented in a thesis, which will be achieved as per University of Liverpool guidelines. Within the University of Liverpool Data repository, the respective datasets will be assigned a DOI. The anonymised data will be openly available for research and academic use.

[4] Available at, respectively: https://goo.gl/muBtwD; https://www.rjah.nhs.uk/Patient-Visitors/Data-Protection.aspx; https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted; https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/

[5] Available at: https://digital.nhs.uk/binaries/content/assets/legacy/pdf/n/b/records-management-cop-hsc-2016.pdf

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13 APPENDICIES

13.1 Appendix 1 - Study management / responsibilities

Name	Main duties
Fraser Philp	***Chief investigator*** Oversight and management of the project including weekly/monthly review meetings, liaising/corresponding with stakeholders, recruitment sites and funding body, overseeing recruitment and data collection procedures, training and supervision of research assistant, data analysis, interpretation of results, preparation of materials for dissemination.
Sarah Jarvis	***Principle Investigator (Senior Physiotherapist)*** Monthly review meetings, overseeing and undertaking data collection at hospital site, training of research assistant, data processing, interpretation of results, preparation of materials for dissemination
Robert Freeman	***Co-investigator (Consultant Orthopaedic Surgeon)*** Monthly review meetings, recruitment, interpretation of results, preparation of materials for dissemination.
Research Assistant	****Starting in post 12 months following project start date.*** Data processing and analysis including biomechanical modelling using OpenSim, data collection/ patient telephone follow ups for recurrence rates, preparation of materials for dissemination.
Ed Chadwick	***Co-investigator/ Research supervisor*** Monthly review meetings, training of research assistant, interpretation of results, preparation of materials for dissemination.
Anand Pandyan	***Co-investigator/ Prof of Rehabilitation Technology*** Involvement of monthly review meetings, training of research assistant, interpretation of results, preparation of materials for dissemination, monitoring financial spending of the project.