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Physiotherapy Interventions & Assessment of Outcomes In Distal Radius Fractures

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Abstract

Background and Aims

Distal radius fractures account for 16% of all fractures seen in the United Kingdom. An estimated 71,000 adults sustained a distal forearm fracture in Britain in 2001.

One of the key instruments for measuring change are patient reported outcome measures. The minimum clinically important difference (MCID) for the commonly used outcome measures is unknown for patients with a distal radius fracture.

Many patients who sustain a distal radius fracture have symptoms and functional restrictions which persist beyond treatment. Following injury, physiotherapy advice is the main intervention, but we do not know if the way we provide this advice has an effect on outcomes. There is no evidence in support of providing physiotherapy advice to patients on video.

The key aims of this thesis are to:

1. Determine the MCID in patients with distal radius fractures for three PROMs:
 - (a) Disabilities of the Arm Shoulder and Hand (DASH)
 - (b) Patient Evaluation Measure (PEM)
 - (c) Patient Rated Wrist Evaluation (PRWE).
2. Assess the MYMOP as an outcome measure in patients with distal radius fractures.
3. Examine outcomes in patients with non-operatively managed distal radius fractures to assess three methods of delivery of therapy advice:
 - (a) advice sheet
 - (b) video
 - (c) in person physiotherapy
4. Calculate the item costs of the three therapy interventions.

Methods

The aims were investigated by the use of two studies; the MCID Study and the Outcomes Study.

The MCID Study was an observational study of 42 patients with distal radius fractures treated both surgically and non-surgically. It was designed to determine the minimum clinically important difference by means of an anchor based approach. The anchor was a 15 point bidirectional global rating of change scale. Participants were reviewed at two, six, twelve and twenty-four weeks making the MCID calculations time independent. Participants completed the MYMOP outcome measure over the same time-points to allow for it to be validated in distal radius fractures.

The Outcomes Study was a single centre three arm randomised controlled trial with 1:1:1 allocation to parallel groups using a superiority design with an additional equivalence analysis. It recruited 120 adult patients aged 18-70 with a non-operatively managed distal radius fracture. It was designed to inform a future larger study acting as a pilot. The participants allocated to the advice sheet were considered the active control and the participants allocated to video and in person physiotherapy were the two intervention groups. The primary outcome measure was the DASH score at six weeks after removal of plaster, with secondary outcomes of the PEM, range of movement and grip strength. The MCID for analysis was derived from the MCID study. The equivalence margin for the additional analysis was taken as half this value.

MCID Study Findings

The MCID for the DASH was calculated as 13.5 (AUC 0.75). The MCID for the PEM was calculated as 9.5 (AUC 0.68). The MCID for the PRWE was calculated as 13.5 to 15.5 (AUC 0.78 to 0.59). The MYMOP correlated strongly with the DASH, PEM and PRWE after six weeks. Analysis of patient important items generated by the MYMOP suggest that the DASH score has the highest content validity, though it also has the most redundant items.

Outcomes Study Findings

Nationally around 50% of patients are given an advice sheet and 40% are referred for in person physiotherapy after a distal radius fracture. With both an 'as treated' and 'intention to treat' analysis, video and in person physiotherapy failed to demonstrate superiority on the DASH score. However, on the DASH Work sub-scale in person physiotherapy demonstrated superiority over the other two interventions. There were insufficient participants to draw a conclusion of equivalence on this secondary analysis. Participants were very satisfied with all three interventions. The cost of providing an advice sheet is £0.34, video £1.36 and in person physiotherapy £66.21.

Conclusion

In patients who sustain a distal radius fracture which is managed non-operatively and in whom an uncomplicated recovery is expected; advice video and in person physiotherapy did not show superiority to advice sheet in returning a patient to daily function and reducing symptoms as measured by the DASH score twelve weeks after injury. Numbers recruited were insufficient to draw any conclusions about equivalence. However, in person physiotherapy appears to be superior in returning patients to normal function at work compared to advice sheet and advice video for those in employment at the time of injury, as measured by the DASH Work.

Declaration

I certify that the work presented in this thesis is the result of original research primarily conducted by myself with the specified guidance and assistance:

- The Outcomes Study design was originally developed by both myself and Mr Ben Ollivere.
- The Outcomes Study ethics approval, data collection, analysis and writing was conducted by myself with assistance from Mr Ben Ollivere, Professor Brigitte Scammell, Miss Jessica Nightingale and Miss Charlotte Bentley.
- The economic analysis was aided by Professor Marilyn James, Professor of Health Economics in the Division of Rehabilitation and Ageing.
- The statistical plan and analysis was aided by Mr Archan Bhattacharya and Miss Lucy Bradshaw.
- The Outcomes Study was administered full time by me with the aid of Miss Jessica Nightingale throughout.
- The MCID Study was designed and ethics approval sought by Mr Ryan Trickett and Professor Tim Davis.
- The MCID Study data collection, analysis and writing was conducted by myself with assistance from Mr Ryan Trickett, Professor Tim Davis, Miss Jessica Nightingale and Miss Charlotte Bentley.
- The MCID Study was administered in its first year by Mr Ryan Trickett and Miss Jessica Nightingale and by me and Miss Jessica Nightingale for its second and third year.

Supervision of this thesis was undertaken by Mr Ben Ollivere and Professor Brigitte Scammell.

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Glossary of Abbreviations

A	AAOS	American Academy of Orthopaedic Surgeons
	AMM	Adaptive Midcarpal Malalignment
	AO	Arbeitsgemeinschaft für Osteosynthesefragen
	AT	As Treated
	AUC	Area Under the Curve
B	BOA	British Orthopaedic Association
	BPSC	Between Patients Score Change
	BSSH	British Society for Surgery of the Hand
C	CCG	Clinical Commissioning Group
	COMET	Core Outcome Measures in Effectiveness Trials
	COMSS	Council of Musculoskeletal Specialty Societies
	CONSORT	Consolidated Standards of Reporting Trials
	COS	Core Outcome Set
	COSMIN	Consensus-based Standards for the selection of health Measurement INstruments
	CRPS	Complex Regional Pain Syndrome
D	DASH	Disabilities of the Arm Shoulder and Hand
	DASH Work	Disabilities of the Arm Shoulder and Hand Additional Work Module
	DASS	Depression, Anxiety, and Stress Scales
	DISI	Dorsal Intercalated Segment Instability
	DRF	Distal Radius Fracture
	DRUJ	Distal Radio-Ulnar Joint
	EPL	Extensor Pollicis Longus
E	EQ-5D-5L	EuroQol – 5 Dimensions – 5 Levels
F	FDA	Food and Drug Administration
G	GROC	Global Rating of Change
H	HEP	Home Exercise Programme
	HR-QOL	Health Related Quality Of Life
I	ICC	Intra-Class Correlation
	ISRCTN	International Standard Randomised Controlled Trial Number

	ITT Intention To Treat
M	MCIC Minimum Clinically Important Change
	MCID Minimum Clinically Important Difference
	MCII Minimum Clinically Important Improvement
	MDC(n) Minimal Detectable Change (Confidence e.g. 95)
	MYMOP Measure Yourself Medical Outcome Profile
N	NICE The National Institute for Health and Care Excellence
	NRES National Research Ethics Service
O	OMERACT Outcome Measures in Rheumatoid Arthritis Clinical Trials
	OSS Oxford Shoulder Score
	OTA Orthopaedic Trauma Association
P	PA Posterior-Anterior
	PEM Patient Evaluation Measure
	POP Plaster of Paris
	PRM Pathologic Radiocarpal Malalignment
	PROM Patient Reported Outcome Measure
	PRWE Patient Rated Wrist Evaluation
Q	QALY Quality Adjusted Life Year
R	RCT Randomised Controlled Trial
	RSD Reflex Sympathetic Dystrophy
S	SD Standard Deviation
	SEM Standard Error of Measurement
	SLAC ScaphoLunate Advanced Collapse
	SPIRIT Standard Protocol Items: Recommendations for Interventional Trials
	SRM Standardised Response Mean
T	TENS Transcutaneous Electrical Nerve Stimulation
	TFCC Triangular Fibro-Cartilage Complex
U	UK United Kingdom
V	VAS Visual Analogue Scale
	VISI Volar Intercalated Segment Instability
W	WPSC Within Patients Score Change

1. Introduction

1.1 Background

Distal radius fractures (DRF) account for 16% of all fractures seen in the emergency department (Court-Brown & Caesar, 2006). An estimated 71,000 adults sustained a distal forearm fracture in Britain in 2001 (O'Neill et al., 2001). The elderly population in the United Kingdom continues to grow (Office for National Statistics, 2016) and so the burden placed on orthopaedic trauma services by DRF is increasing.

A standardised national treatment pathway has not been agreed, so management varies from centre to centre. The indications for surgery are as controversial as the type of operation performed or the physiotherapy techniques employed in recovery.

Many patients who sustain a DRF have symptoms which persist. A large meta-analysis of outcomes is not available but at one year, 8-11% of patients report moderate to severe pain and the majority of patients report some degree of persisting disability which is rated moderate to severe in 16% (Moore & Leonardi-Bee, 2008; MacDermid et al., 2003). The level of disability reported by patients is positively associated with advancing age (MacDermid et al., 2003).

Certain radiological parameters have traditionally been believed to predict poorer function. In the late 1980s, McQueen & Caspers (1988) published a paper concluding that malunion of the distal radius,

“...results in a weak, deformed, stiff and probably painful wrist with a likelihood of difficulty in performing the normal activities of daily living.”

Also in the late 1980s, Knirk & Jupiter (1986) reported that articular restoration was the most critical factor in predicting both arthritis and long term clinical outcomes. Their admittedly small retrospective study of 43 fractures also reported that extra-articular reduction was still predictive of outcome, though was of lesser importance. These two publications set the

tone for the current management philosophy; restoration of a congruent articular surface and extra-articular deformity with a low threshold for open reduction and internal fixation to achieve these aims.

Over the last decade the popularity of volar plating has been rising (Chung et al., 2009; Wilcke et al., 2013) but the link between radiological and clinical outcomes following DRF has become increasingly uncertain. A long term follow-up of 87 patients with a mix of extra- and intra-articular fractures over 9 years reported 79% good or excellent results for pain, function and objective outcomes for patients managed non-operatively and with significant residual deformity (Földhazy et al., 2007). Forward et al. (2008) demonstrated radiographic arthritis in two thirds of patients managed non-operatively by 38 years. They showed an association with both dorsal angulation and radial shortening, but critically the effect on outcomes was not clinically significant. Despite the rise in volar plating, the majority of patients are still managed non-operatively. How to optimise outcomes in this group of patients should be a priority for research.

The majority of patients improve after a DRF. For those patients who are likely to have an uncomplicated outcome, verbal advice or an advice sheet may be sufficient. However, once a plaster or splint is removed many surgeons will refer patients for in person physiotherapy. The cost of in person physiotherapy is only justified if it can be shown to improve outcomes. Using a home exercise programme for uncomplicated patients has potential economic benefits by reducing the need to travel to therapy appointments and the concomitant need to take time away from work.

From a patient learning perspective a more interactive approach to the provision of therapy advice may be beneficial. Many patients seek their own advice on discharge and increasingly this is through videos on the internet, with easy portable access available through smartphones and tablet computers. There is little evidence that the advice being provided is regulated and there is virtually no evidence in support of the use of physiotherapy videos (Algar & Valdes, 2014). The use of video or smartphone applications has potential, though it needs to be evidence based and consideration must be given to the risk of harm to patients who are unable to access the content.

1.1.1 Contemporary Areas of Research

DRF are generating publications at an increasing rate. A search on PubMed returns 5,922 papers, over 1,000 of which were published in the last three years. The focus of these publications shows where the current research priorities lie. Of 100 papers published over a three month period [August 2016 - October 2016: PubMed search string "distal AND radius AND fracture"; last accessed 2nd March, 2018] 60% looked at surgical intervention, with a third of these specifically looking at volar locking plates. Guidelines and outcomes papers accounted for 14%, as did papers looking at non-operative management. Anatomy and radiology basic science papers accounted for 11%, with only one paper being published with a focus on physiotherapy.

1.1.1.1 Operative Intervention

Until recently there has been a paucity of high quality multi-centre randomised controlled trial (RCT) evidence to inform surgical decision-making. This was emphasised by Hull et al. (2010), who showed there was very little consensus among surgeons in the UK on how to treat dorsally angulated DRF.

While many clinical questions still need research answers, two key papers have helped to guide contemporary decision making. The first paper was that by Karantana et al. (2013) in which 130 patients were randomised to volar locking plate or Kirschner wires. They found a significant improvement in grip strength and return to function as measured by the QuickDASH and PEM in favour of volar locking plates at 6 weeks. This was not maintained at 12 weeks or one year. An economic analysis on the same group of patients did not support the use of one intervention over the other (Karantana et al., 2015).

The second paper was UK DRAFFT (Distal Radius Acute Fracture Fixation Trial) which published its results in the BMJ in 2014 (Costa et al., 2014). This was a multi-centre randomised controlled trial of 461 patients in whom a satisfactory closed reduction of the fracture was achieved, allocated to two groups; volar locking plate and Kirschner wires. The key clinical finding was that there was no significant difference in the primary outcome (Patient Rated Wrist Evaluation (PRWE)), or secondary outcomes (Disabilities of the

Arm Shoulder & Hand (DASH), EuroQol-5D, complications) at any time point up to 12 months. It was followed by an economic analysis, which also found that volar plating was not cost effective when compared to Kirschner wires (Tubeuf et al., 2015).

1.1.1.2 Non-Operative Intervention

Given a lack of clear benefit with volar locking plate compared to Kirschner wire fixation, the next question is whether there is a benefit to operative intervention at all. As a follow-up, DRAFFT 2 has been commenced to examine if a difference can be found between Kirschner wire fixation and non-operative management with closed reduction and cast. This study is not expected to finish until October 2019.

A completed multi-centre randomised controlled trial (RCT) of 149 patients compared open reduction and volar locking plate fixation to closed reduction and cast immobilisation (Bartl et al., 2014). The group of patients was elderly and therefore primarily female. Volar plating showed a statistically significant improvement in DASH score, though this was only 5 points and so is at risk of being clinically unimportant, accepting the absence of a published minimum clinically important difference (MCID) for the DASH score in DRF.

1.1.1.3 Physiotherapy Interventions

Standard treatment for a patient following a DRF is to commence active and passive range of movement exercises once the fracture is sufficiently united. The decision on when this commences is fracture and surgeon dependent and relies on pain being adequately controlled and the risk of displacement sufficiently low. It is one of the British Orthopaedic Association's (BOA) audit standards for DRF that patients should receive information on the exercises they should perform as well as be able to self refer if progress is not as expected (BOA, 2017).

The last Cochrane review looking at physiotherapy in DRF was updated in 2015 (Handoll & Elliott, 2015). This comprehensive review included 26 randomised controlled trials with a total of 1269 patients. The majority of the interventions which were included in the review were adjuncts to physiotherapy such as cyclic pneumatic soft tissue compression and cross

education (strength training of the non-fractured hand). The power of the meta-analysis was significantly impaired by heterogeneity of treatment, with only four interventions being studied in more than one paper allowing for pooling of results. The vast majority of the evidence produced in the metanalysis was graded as 'very low quality'. The review concludes;

"The available evidence from RCTs is insufficient to establish the relative effectiveness of the various interventions used in the rehabilitation of adults with fractures of the distal radius. Further randomised trials are warranted. However, in order to optimise research effort and engender the large multicentre randomised trials that are required to inform practice, these should be preceded by research that aims to identify priority questions." (Handoll & Elliott 2015, p2)

The James Lind Alliance in collaboration with the British Society for Surgery of the Hand (BSSH) recently completed a review into the most important uncertainties in hand surgery considering the views of patients, carers and healthcare professionals (BSSH, 2017). One of the top ten uncertainties was which hand therapy techniques enable the most efficient return to full function following surgery or injury. The conclusion was;

"Numerous specific techniques exist depending on the surgery/injury, with minimal evidence to show whether one method is superior to another or no treatment." (BSSH, 2017, p3)

Guidance from the The National Institute for Health and Care Excellence (NICE) is lacking on therapy post DRF. All surgeons and therapists would advocate range of movement exercises for the fingers and wrist combined with passive stretching. Most will assume that this advice has been given to patients either by giving it themselves, by advice sheet or through referral to a physiotherapist. Surgeons and physiotherapists would also agree that patient adherence will ultimately affect outcome. This means trusting the patient to take the advice they are given.

There is a risk that some patients want to take a passive role in their recovery, believing it is the attendance rather than the exercise, which

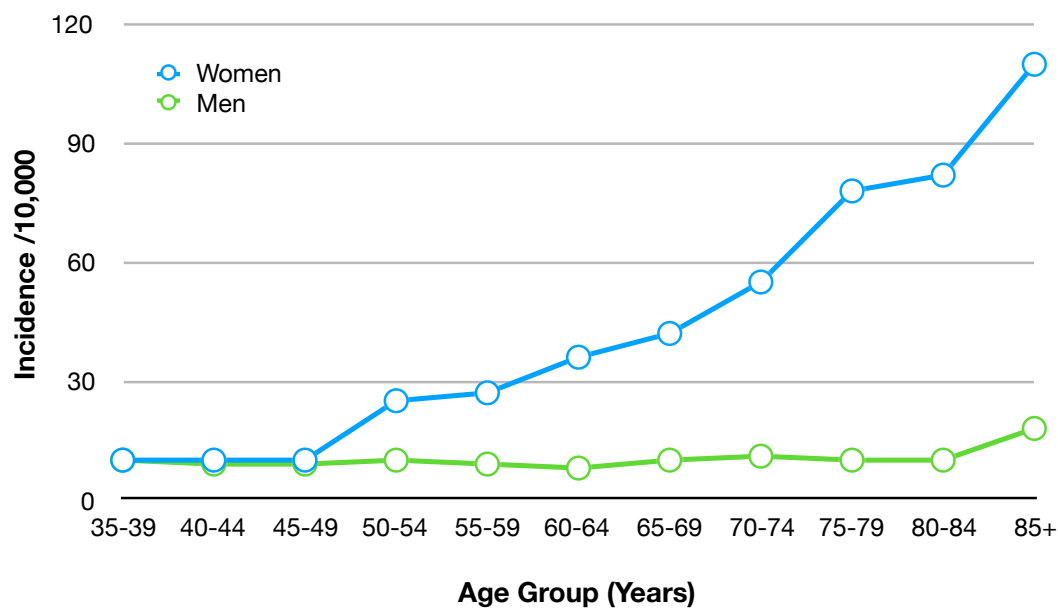
results in recovery. Oskarsson et al. (1997) performed a retrospective analysis of 40 patients who specifically requested physiotherapy and 70 patients who did not following a DRF. They found that the group who requested physiotherapy reported worse pain scores, had less motion and a worse grip strength than those who did not. Despite this, recovery was identical between the two groups with self-training being as effective as in person physiotherapy.

A clear evidence based recommendation for the best way to deliver standard advice to patients following DRF is needed. This needs to consider patient learning and behaviour modification to emphasise the importance of patients actively treating themselves when given access to the appropriate advice. This thesis aims to inform the best approach and depending on its results, act as a pilot to a larger study.

1.2 Epidemiology

Fractures of the distal radius and ulna are the most common fracture and the second most common injury of any kind in the upper limb (Lambers et al., 2012). The incidence of DRF is bimodal with the highest rates in the under 18s and over 65s (30.18 and 25.42 per 10,000 respectively) (Karl et al., 2015). In the United Kingdom in 1997 the overall incidence of distal forearm fractures in women was 36.8/10,000 person-years and for men 9.0/10,000 person-years (O'Neill et al., 2001). Overall women are significantly more likely than men to sustain DRF in a 4.1:1 ratio, though this preponderance is attenuated by age with a more equal incidence seen under the age of 50. Annual incidence by gender is shown in Figure 1.2.1.

Figure 1.2.1 Annual Incidence of Distal Forearm Fractures in the UK



The overall incidence is rising. In adults the size of the elderly population is expanding and these older people are comparatively fitter and therefore more active (Nellans et al., 2012). In the elderly, being cognitively intact with good neuromuscular control and a faster mean walking speed are risk factors, as these patients tend to put out their hand to break a fall sustaining a DRF rather than proximal humerus or hip fractures, which are more common in those with dementia (Vogt et al., 2002).

The patient's own home is the commonest location where a DRF is sustained. A fall from a standing height onto an outstretched hand is the commonest mechanism of injury.

High mortality rates are well documented in patients after sustaining fragility fractures of the proximal femur and spine. A recent paper from Norway showed an increase in the standardised mortality ratio in female patients over the age of 70, five years after sustaining a DRF (Øyen et al., 2014). This would make sense as fragility fractures tend to be evidence of a more general decline in health status.

Because of the epidemiological preponderance for older female patients, research into adult DRF often reports on a cohort which reflects this. Clearly, this is appropriate when the research question affects decision making for the whole patient population. However, this can limit the applicability of results to the younger group of working age patients under the age of 70.

1.3 Classification

Who to credit with the original description of fractures of the distal radius is unclear. Hippocrates described wrist trauma but thought all injuries were carpal dislocations rather than fractures. In the late eighteenth century the surgeon Jean Louis Petit recognised that wrist deforming injuries could in fact represent fractures. He is also credited with suggesting their management in a splint. At a similar time, Claude Pouteau formally described a fracture of the end of the radius but his work was not recognised at the time and so it is the description by Abraham Colles published in 1814 which bears the first eponymous association with these injuries (Colles, 1814). This work was popularised by Guillaume Dupuytren through his published lectures, giving international recognition to the condition.

In the modern setting there are many classification systems all of which have gained some traction. The ideal classification system will categorise an injury and then direct treatment based on the outcomes associated with the classification. A classification should be reproducible amongst those who use it and there should be a high degree of inter and intra-observer reliability. Sadly for DRF all the available classifications do not predict outcomes and have relatively low inter-observer and intra-observer reliability (Andersen et al., 1996; Beumer et al., 2013; Flinkkilä et al., 1998; Gliatis et al., 2000; Konstantinidis et al., 2010).

1.3.1 Müller AO/Orthopaedic Trauma Association Classification

The combined Müller AO (Arbeitsgemeinschaft für Osteosynthesefragen) and Orthopaedic Trauma Association (OTA) classification uses the same principles for the classification of all fractures (Marsh et al., 2007; Müller et al., 1990). The numerical denominator for the wrist is 2R3 (forearm.radius.distal) with the first sub-grouping being into Type A (extra-articular), Type B (partially articular) and Type C (complex) as shown in Figure 1.3.1.

For the purpose of this thesis, the AO/OTA classification is considered to offer the greatest detail and ease of data recording and has been selected to record the radiographic parameters. Because the classification reliability

falls significantly for subgroups below type A, B and C this is the level at which data will be recorded (Plant et al., 2015).

Figure 1.3.1 AO/OTA Classification of Distal Forearm Fractures.

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1.3.2 Other Classification Systems

Six of the more commonly used classifications are discussed below as they are often used in the literature, but the list is not exhaustive and there are also classifications described from the Mayo Clinic, Older, Lidstrom and McMurtry & Jupiter.

Gartland and Werley

In 1951 Gartland and Werley published one of the first classifications for DRF, in response to what they saw as a poor and inconsistent approach to treatment at the time (Gartland & Werley, 1951). Their paper describes an evaluation tool to describe the results of DRF at union based on subjective and objective outcomes such as range of movement, radiological position and complications.

Frykman Classification

The Frykman classification was introduced in 1967 and is commonly seen in the literature (Frykman, 1967). Wrist fractures are classified into eight

patterns concentrating on varying degrees of involvement of the radio-carpal joint, DRUJ and the ulnar styloid. It was the first classification to introduce ulna involvement though it does not quantify the extent or displacement of the injury nor the degree of comminution or shortening.

Melone Classification

The Melone classification was described in 1984 and attempts to direct management with a grading based on the severity and pattern of injury (Melone, 1984). There are four groups from minimally displaced stable fractures to high energy comminuted injuries.

Universal Classification

The Universal classification was introduced in 1990. Much like the Frykman classification it is descriptive but does not guide management (Cooney, 1993). There are four fracture types broken down into intra-articular, extra-articular and undisplaced or displaced.

Fernandez Classification

The Fernandez classification published in 1993 aimed to simplify classification and is based on five mechanisms of injury; bending, compression, shear, avulsion and combination (Fernandez, 1993). The intention was for the classification to be easy to use and direct treatment based on predictions of stability and outcome.

Eponymous Classification

There are numerous fractures which bear the name of the person first credited with describing them (Hunter et al., 2000). They are predominantly descriptive of a single fracture pattern and while they offer no guidance on either treatment or prognosis they are the most commonly used descriptors in clinical practice.

Colles' Fracture - The best known eponymous fracture is that of Abraham Colles (1773–1843), professor of surgery at the Royal College of Surgeons of Ireland. He described an extra-articular fracture of the distal radius within 1.5 inches of the joint line, with dorsal angulation of the distal fragment (Colles, 1814). In common practice it is used to refer to any dorsally angulated fracture.

Smith's Fracture - Robert William Smith (1807–1873) was Abraham Colles successor who described a fracture of the distal radius with volar displacement (Smith, 1847). It is more commonly referred to as a Goyrand's fracture in the French literature after Jean-Gaspard-Blaise Goyrand who was a student of Dupuytren.

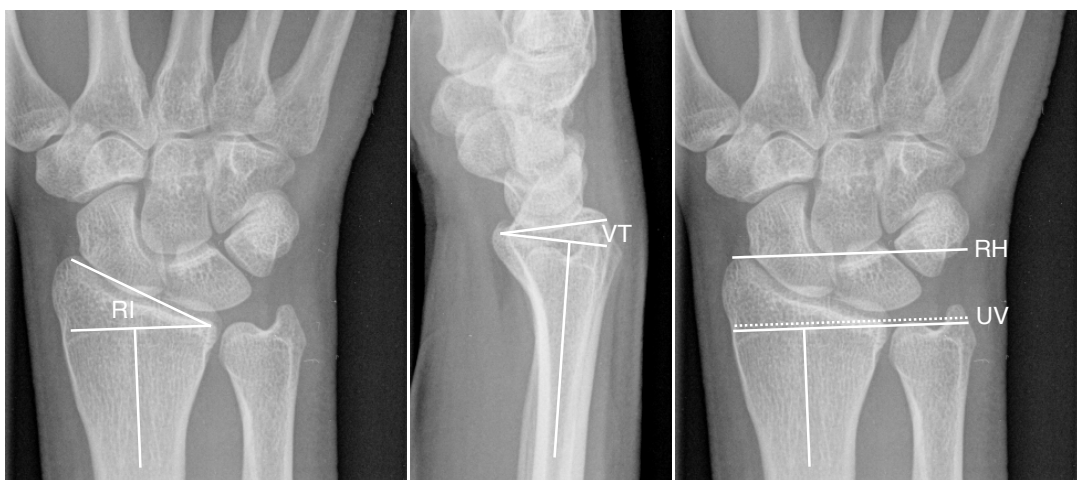
Barton's Fracture - John Rhea Barton (1794–1871), credited with developing an osteotomy for joint ankylosis, described an intra-articular fracture of the distal radius with dislocation of the radiocarpal joint (Barton, 1838). Barton's fractures are additionally described as being dorsally or volarly displaced depending on the mechanism of injury and the subsequent displacement.

Hutchinson Fracture - Jonathan Hutchinson (1828-1913) originally described the injury which bears his name, though it is more commonly known as a Chauffeur fracture. It is an intra-articular fracture involving only the radial styloid process.

1.3.3 Radiographic Classification

When assessing x-rays there are four core radiological parameters which are measured relevant to DRF as shown in Figure 1.3.2.

Figure 1.3.2 Radiographic Measurements



The standard radiological parameters RI - radial inclination. VT - volar tilt. UV - ulnar variance. RH - radial height.

Radial Inclination

The normal angle of radial inclination is 22 degrees. It is measured from the angle at the intersection of a line drawn from the the tip of the radial styloid and the articular surface at the ulnar corner and a line drawn perpendicular to the long axis of the radius on a PA x-ray. This angle is flattened in DRF with displacement.

Volar Tilt

The normal angle of volar tilt is 11 degrees. It is measured from the angle at the intersection of a line drawn from the most volar and dorsal points of the articular surface and a line drawn perpendicular to the long axis of the radius on a lateral x-ray. Where the articular surface is dorsally tilted this is expressed as a negative angle. The effect on volar tilt varies depending on fracture pattern.

Radial Height

The normal radial height is 11mm. Impacted DRF are usually accompanied by radial shortening. The radial height is measured by the distance between two parallel lines, one drawn at the tip of the radial styloid and the second at the level of the distal-most ulnar head on a PA x-ray.

Ulnar Variance

Ulnar variance is a measure of the length of the ulna relative to the radius at the DRUJ. It is usually negative (i.e. the radius is 'longer') or neutral. However, radial impaction can make the variance positive with the ulna becoming long relative to the radius. When shortening is significant, ulnocarpal abutment will occur with the ulna impinging on the lunate, particularly when the wrist is in ulna deviation.

1.4 Non-Operative Management

Management strategies for DRF are diverse. We are increasingly looking to non-operative or 'less operative' management across orthopaedic trauma as large randomised controlled trials cast doubt on the efficacy of surgical intervention (Rangan et al., 2015; Costa et al., 2014). In Colles' original description of dorsally angulated DRF, he describes a technique of closed reduction and splinting concluding with the words:

"The cases treated on this plan have all recovered without the smallest defect or deformity of the limb, in the ordinary time for the cure of fractures." (Colles, 1814)

It may be that patient expectations are higher or that acceptable outcome thresholds are lower but this statement does not hold true today. Optimal non-operative management should therefore be a research priority to try and bring us closer to this historical conclusion.

1.4.1 Treatment Strategies for Dorsally Displaced Fractures

The indications for non-operative management of dorsally displaced DRF are generally considered to be; undisplaced fractures, displaced fractures with an acceptable position achieved and maintained with closed reduction, and old age with low functional demand. Volarly displaced fractures are accepted to have a very high rate of redisplacement, even in the presence of a good initial reduction, and so are usually managed operatively. This thesis has non-operatively managed fractures as its focus and so will predominantly discuss dorsally displaced fractures.

Old age is a double edge sword as older patients tend to suffer a greater degree of late displacement (Leone et al., 2004, Nesbitt et al., 2004) and malunion (Mackenney et al., 2006); but their clinical outcome is less correlated with the radiological outcome and failure in restoration of anatomy is not necessarily a predictor of poorer function (Young & Rayan, 2000).

1.4.1.1 Elastic Support Bandage

Nearly 30 years ago it was shown that an elastic support bandage for patients with undisplaced or minimally displaced extra-articular DRF

resulted in better functional outcomes than plaster cast and return to function was quicker with no increased risk of fracture displacement (Abbaszadegan et al., 1989). Despite this most patients still undergo a period of rigid immobilisation. This is most likely due to fear of re-displacement and may also be as a consequence of the increasing litigation surrounding this complication.

1.4.1.2 Splinting

A splint can refer to any non-circumferential rigid material used to stabilise a fracture, including a plaster backslab or any variety of pre-made wrist splint. The rigid portion is always incomplete in order to accommodate for swelling.

Static Splinting - The Futuro (3M,MN,USA) splint is an example of a pre-made static splint. Generally, these splints are removable devices with a rigid backbone preventing movement at the wrist joint but leaving the rest of the upper limb unencumbered. The majority of research into their use is for paediatric fractures and there are no adult papers describing their use. In a randomised controlled trial in children with stable distal radial buckle fractures, use of a splint vs a cast was shown to give higher levels of satisfaction, preference and convenience, though early pain scores in the emergency department were shown to be higher (Williams et al., 2013).

A prospective RCT of 101 patients with dorsally displaced DRF requiring manipulation were randomised to volar dorsal splinting, circumferential casting or a modified sugar-tong splint and the three groups showed no difference in displacement between the treatments and no difference in the DASH score with 6 months follow-up (Grafstein et al., 2010).

Dynamic Splinting - Increasing the restriction of wrist motion under simulated conditions has been shown to incrementally lead to increasing subjective and objective functional impairment (Franco et al., 2008). Dynamic wrist splints aim to alleviate this restriction by allowing for earlier mobilisation. The prolonged stretching allowed for by dynamic splints has an effect on connective tissue at both a cellular and clinical level (Avela et al., 1999; Abellaneda et al., 2009). However, evidence of their efficacy in

terms of patient reported outcomes and therapeutic effects on range of motion are unproven (Jongs et al., 2012).

A variation on dynamic splints is the Aberdeen Colles' fracture brace, based on work by Sarmiento. This is a three point fixation brace, which stops at the wrist controlling the fracture but allowing free movement of the joint. Supportive evidence is limited though this could be attributed to a majority of papers describing their use after initial plaster immobilisation. One paper describes their use from diagnosis, with comparable maintenance of reduction and improved early grip strength, though the gain over static splinting was not maintained (Tumia et al., 2003).

1.4.1.3 Casting in Situ

A cast is a circumferential immobiliser, which potentially provides superior immobilisation to a splint but carries a higher risk of complications, particularly related to swelling. It comprises a base layer of stockinet followed by a layer of cotton wool roll for padding with either plaster of Paris (calcinated gypsum) impregnated cotton bandage or knitted fibreglass as a rigid top-layer.

Where there is no initial displacement of the fracture, a neutral forearm cast is usually sufficient to allow for fracture union. Beumer & McQueen (2003) showed there was little value in closed reduction in low demand elderly patients and recommended casting in situ. These results are echoed by a small randomised controlled trial of 30 elderly patients with moderately displaced Colles' fractures (Kelly et al., 1997) which concluded that manipulation in fractures showing up to 30 degrees of dorsal tilt and 5mm of radiological shortening conferred no improvement in the Gartland and Werley score, grip strength, cosmesis or risk of complex regional pain syndrome.

1.4.1.4 Closed Reduction and Casting

Where a DRF shows displacement, an attempt at closed reduction is made before a cast is applied to maintain the reduction achieved. To manipulate a fracture some degree of anaesthesia is required. There are four strategies that may be employed; haematoma block, Biers block, peripheral nerve block and general anaesthesia. It is rare for the latter two techniques to be

performed for a closed reduction. They are usually reserved for the operating theatre. A Biers block is a form of intravenous regional anaesthesia whereas a haematoma block is a local anaesthetic option. There is good evidence from meta-analysis of level II evidence that Biers block is superior to haematoma block for reducing pain during manipulation, remanipulation rate and to a lesser extent overall radiographic appearances (Abbaszadegan & Jonsson, 1990; Cobb & Houghton, 1985; Kendall et al., 1997; Wardrope et al., 1985).

A plaster is usually applied and moulded in Colles' position for dorsally displaced fractures. This involves the wrist being held in palmar flexion and ulnar deviation (Jones, 1915, p110). Interestingly Gupta showed that with careful moulding of the plaster around the distal fracture fragment in palmar flexion, placing the hand itself into dorsiflexion resulted in the lowest incidence of redisplacement and the best functional result (Gupta, 1991).

Smaill (1965) retrospectively reviewed 97 patients at five to six years with dorsally angulated fractures treated with manipulation under haematoma block and Colles' cast for 4 weeks. It is presumed that the fractures were extra-articular though not stated. There was minimal loss of forearm rotation and dorsiflexion/plantarflexion compared to the uninjured side. Ten patients had radiographic signs of arthritis. Ongoing mild pain was found in 34% and mild functional restriction in 39% though this had led to no patient needing to change occupation.

1.4.1.5 Duration of Immobilisation

Once the decision to manage a fracture in a splint or cast has been made the question then becomes the duration of immobilisation. To a degree the fracture pattern and age of the patient will dictate this decision.

For undisplaced or minimally displaced fractures which are assumed to be stable, there is good evidence that a shorter period of immobilisation is appropriate. While 5-7 weeks is the current standard of care, Christensen et al. (1995) and Vang Hansen et al. (1998) showed in their RCTs no significant difference in anatomical or functional outcomes at 9 months whether immobilisation was applied for 3 or 5 weeks. Jensen et al. (1997) showed no difference at 26 weeks with the Gartland and Werley score

between 1 and 3 weeks of immobilisation. The 2008 Cochrane review concluded there was insufficient high quality evidence to recommend a duration of immobilisation for minimally displaced fractures (Handoll & Madhok, 2008).

1.5 Complications

McKay et al. (2001) published the largest prospectively assessed cohort of 250 consecutive DRF designed to assess both clinician and patient reported complications. In their paper, they first performed a literature review which generated a list of complications previously described for DRF. They then used this to record complications prospectively from both physician and patient perspectives in 250 consecutive patients with six months follow-up. A complication checklist was generated to facilitate recording based on the literature review and was used to record complications prospectively in their cohort as shown in Table 1.5.1.

Table 1.5.1 Incidence of Reported Complications (McKay et al., 2001)

Complication	Physician Reported Incidence (%)	Patient Reported Incidence (%)
Median Nerve Compression / Carpal Tunnel Syndrome	7.6	0.5
Radial Nerve Compression / Neuropathy	3.6	1.0
Ulnar Nerve Compression	2.0	0.0
Reflex Sympathetic Dystrophy	6.8	4.8
Arthritis	0.4	1.0
Carpal Instability / Subluxation	0.4	0.0
Delayed Union	0.4	0.0
DRUJ Problems	1.6	0.0
Tendon Adhesion / Scarring	2.4	0.5
EPL Rupture	0.8	1.0
Tendon Rupture - Other	0.8	1.0
Tendinitis / Tenosynovitis	4.8	1.4
Trigger Finger	0.8	1.0
Dupuytren's Contracture	0.8	0.5
Compartment Syndrome	0.4	0.0
Miscellaneous	-	8.7
Percent of Patients With a Complication	25.6	21.2

In their cohort, 53% of patients were managed non-operatively and 47% operatively so their analysis is perhaps more weighted to operative complications. On physician assessment a majority of patients demonstrated only one complication (73.4%), though a small but significant minority showed two (20.3%) or even three complications (6.3%). Interestingly, physician assessment revealed more complications than those which were patient reported. The overall complication rate for cast immobilisation was 17% and the addition of a closed reduction procedure increased this rate to 23%.

Satake's retrospective review of 824 patients treated with volar locking plates, showed a somewhat lower incidence of complications of 7.5% (Satake et al., 2016). One could postulate that this is because as the volume of volar locking plates performed has increased and surgeon experience has improved. It is more likely however, that it has resulted from Satake's reliance on retrospective data compared to the more assiduous prospective data collection by McKay, where complications were specifically sought.

1.5.1 Bone and Ligament Complications

Bone, joint and ligament complications are varied and often manifest later in the recovery process. McKay reported bone or joint complications in only 8% of the total, though this was only with 6 months follow-up where a majority of patients who go on to develop arthritis and other degenerative complications will be missed (McKay et al., 2001).

1.5.1.1 Malunion

Mal-union refers to the union of a fracture in a non-anatomical or displaced position. In long-term follow-up of between 9 and 13 years, Földhazy et al. (2007) reported 79% good or excellent results in 87 patients with malunion. The cohort was previously recruited to a randomised study comparing a dorsal splint with a complete cast in patients requiring manipulation and ultimately no significant difference was found and the data unpublished. For those recruited to the new study repeat radiographs and the Green and O'Brien score (which incorporates pain, function and objective outcome measures) were used and good results were found despite ongoing considerable malunion. In their group of patients, there was a mean of 13

degrees of dorsal angulation for younger patients and in the older group 18 degrees.

1.5.1.2 Non-Union

There is no universally accepted definition of non-union. Most orthopaedic surgeons would accept that in order to describe something as a non-union it should not have healed within double the expected time to union and that there should be no radiographic evidence of progression towards union comparing consecutive radiographs. Non-union of the distal radius is considered very rare. In Bacorn's early study of 2,000 distal radius fractures the non-union rate was found to be 0.2% and delayed union rate 0.7% (Bacorn & Kurtzke, 1953).

Satake's review of 694 patients treated with volar plate fixation revealed no cases of non-union at a mean follow-up of 27 weeks (Satake et al., 2016). Segalman's review of 12 cases of non-union of the distal radius were collected over a 24-year period (Segalman & Clark, 1998). The numbers are too small for any statistical analysis but subjectively the patients were medically co-morbid. The authors reiterate the rarity of the condition and thus the difficulty in making management decisions.

1.5.1.3 Arthritis

Post traumatic arthritis is perhaps the most commonly discussed late complication of DRF. It is clear from many studies that while its development is certainly frequent, it is the clinical relevance of this that should be the focus. Knirk & Jupiter (1986) reported 91% of their 43 intra-articular fractures developed grade 0 or grade 1 arthritis at 7 years.

Forward et al. (2008) demonstrated radiographic arthritis in 68% of 106 patients at a mean follow-up of 38 years and showed an association with both dorsal angulation and radial shortening. They also showed 43% of patients had a higher grade of wrist osteoarthritis in their injured wrist compared to the uninjured wrist, with an intra-articular pattern being a risk factor. However, the return to function was high and DASH scores were comparable to population norms, accepting that intra-articular fractures had worse scores (13) than extra-articular (9). The Patient Evaluation Measure (PEM) did also show a statistically significant decrease associated with

grade, although this was felt unlikely to be clinically important, with the difference between no arthritis and grade 3 arthritis being only 10%.

1.5.1.4 Dorsal and Volar Intercalated Segment Instability

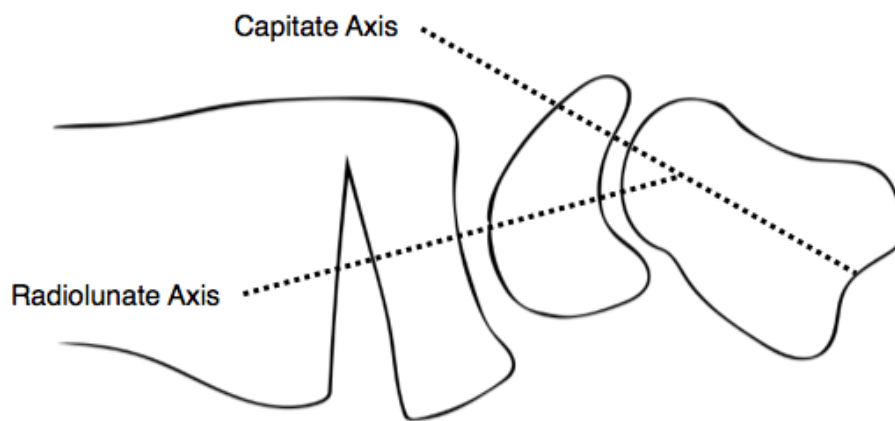
Trauma can lead to instability in the carpal bones through ligamentous injury. The two common descriptions of carpal instability are dorsal and volar intercalated segment instability, abbreviated to DISI and VISI respectively. These are both dissociative injuries which result from a tear of the stabilising intrinsic ligaments.

DISI is the commonest pattern, which results from a tear of the relatively weak scapholunate ligament and volar extrinsic ligaments. Initially, even with a complete ligament tear an x-ray will appear normal which explains why the condition is difficult to diagnose and will be missed with a short duration of follow-up. Over time, a scapholunate diastasis will appear and the lunate rotates into extension such that on wrist flexion or radial deviation the scaphoid flexes as it should, but the lunate clicks into extension. The DISI deformity will progress to scapholunate advanced collapse (SLAC) as secondary degenerative joint damage appears.

VISI is less common and results from rupture of the lunotriquetral ligamentous complex. This results in the lunate rotating volarly and the triquetrum going into extension.

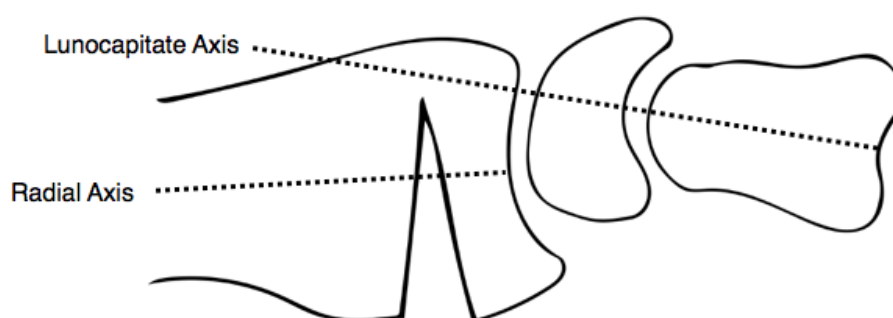
1.5.1.5 Carpal Colinearity

The concept of carpal colinearity states that on a sagittal view of the wrist the radius, lunate and capitate should all be in alignment with the long axis of the radius. Malunion of a dorsally angulated DRF reverses the normal 11 degrees of volar tilt, which breaks this longitudinal colinearity. This most commonly results in midcarpal instability or adaptive midcarpal malalignment (AMM) due to the weaker stabilising soft tissues as shown in Figure 1.5.1.

Figure 1.5.1 Midcarpal Instability.

In AMM the radiocarpal capsule and carpal ligaments are intact and the malalignment is purely adaptive (Brahin & Allieu, 1984; Taleisnik & Watson, 1984). The abnormal dorsal tilt of the distal radius results takes the lunate with it breaking the lunocapitate axis and driving the capitate into flexion.

Dorsal malunion can also lead to proximal radiocarpal instability or pathologic radiocarpal malalignment (PRM). In PRM there is traumatic radiocarpal dorsal derangement which leads to dorsal radio-lunate subluxation as shown in figure 1.5.2 (Gupta et al., 2002).

Figure 1.5.2 Radiocarpal Instability.

1.5.1.6 Complications at the Distal Radio-Ulnar Joint

The distal radio-ulnar joint (DRUJ) is a congruent joint comprising the articular surface of the ulna head and the sigmoid notch of the distal radius (Linscheid, 1992). DRUJ involvement has traditionally been considered a

common cause of ongoing pain, limited range of motion and decreased grip strength.

Dorsal angulation of the distal radius has been shown to alter the kinematics of the DRUJ with increasing angulation leading to increased volar, ulnar and dorsal displacement of the ulna head. The effect of this displacement is increased when the triangular fibro-cartilage complex (TFCC) is detached as part of the injury pattern (Nishiwaki et al., 2014). Wijffels et al. (2016) reviewed 49 non-operatively managed DRF with 4 years of follow-up and found that DRUJ instability is a common but often subtle sequela with an incidence of up to 35%. It was shown to adversely affect the long-term flexion of the wrist but this did not translate to a significant effect on functional outcome.

Direct injury to the articular surface of the sigmoid notch often occurs in association with DRF. In a retrospective study of thirty-three operatively managed fractures where a CT was performed confirming involvement of the sigmoid notch, patients were shown to have no greater prevalence of DRUJ post-traumatic arthritis, except where there was a coronal step-off of >1mm at a mean follow-up of 6.3 years (Vitale et al., 2016). Those with sigmoid notch involvement did show a trend towards worsening DASH scores (mean 53.4 vs 42.4) but this did not reach statistical significance, though had it been significant an 11 point change on the DASH may be clinically important.

1.5.2 Nerve Complications

The most commonly seen nerve complication in DRF is median nerve compression, with radial and ulnar nerve injury less commonly seen. Iatrogenic injury is common and its pattern depends on the management strategy, whether operative or non-operative. In McKay's cohort nerve compression and neuropathy accounted for 39% of the total physician reported complications, with complex regional pain syndrome accounting for another 20% (McKay et al., 2001).

1.5.2.1 Direct Injury

While direct injury to the median nerve is a known complication of both high-energy injuries and volar approaches to the distal radius, there are no

publications where direct injury is separated from the compressive injuries. It can therefore be assumed to be rare compared to the common compressive median nerve lesions.

Radial nerve symptoms are seen in 3.6% of patients overall. Injury is usually iatrogenic with the superficial radial nerve at risk from Kirschner wire fixation or external fixation pins with a radial styloid entry point (Chen et al., 2010).

Ulnar nerve neuropathy is the least common being seen in only 2% of patients. It tends to be seen in association with distal radio-ulnar joint injuries as part of a high energy injury pattern with significant displacement. These are usually direct traction injuries which have the potential to spontaneously resolve. Exploration is only recommended when they are associated with an open wound or acute carpal tunnel syndrome (Soong & Ring, 2007).

1.5.2.2 Compressive Lesions

Median nerve neuropathy or carpal tunnel syndrome was seen in 7.6% of patients in McKay's review (McKay et al., 2001). Where the paraesthesia is progressive or does not respond to fracture reduction, carpal tunnel release should be considered as local compressive effects may be the cause. In fractures treated with closed reduction, excessive flexion on the cast is often the cause of median nerve neuropathy. For this reason, the rate of median nerve neuropathy is actually lower in patients managed operatively, as where symptoms exist before surgery, a carpal tunnel decompression can be performed and prolonged immobilisation with the wrist in flexion is not required. In surgically managed patients, the rate is reported as between 2.7% (Satake et al., 2016) and 6.1% (Jupiter et al., 1996).

1.5.2.3 Complex Regional Pain Syndrome

Complex regional pain syndrome (CRPS) (previously known as reflex sympathetic dystrophy (RSD), algodystrophy, Sudek's syndrome and causalgia) is a poorly understood condition characterised by regional pain with altered sensory, motor and sudomotor disturbance (Gatti et al., 2016). The reported incidence following DRF varies widely in the literature.

Type I CRPS is seen following trauma or surgery, and may migrate from the site of injury, whereas Type II CRPS occurs following direct injury to a peripheral nerve and remains localised. Type I CRPS is further broken down into early 'warm' CRPS and late 'cold' CRPS, though the distinction is not well defined and it may be that the conditions are in fact separate entities with 'warm' CRPS being more self-limiting and therefore greatly under-diagnosed.

Jellad et al. (2014) reported on 90 consecutive patients treated with closed reduction and casting for DRF. They diagnosed CRPS Type I in 32.2% of patients, with symptom onset being around 22 days following cast removal. For diagnosis the criteria reported by Veldman et al. (1993) were used, though these criteria were created de novo in the original paper due to a lack of any formal criteria previously having been published.

Dijkstra et al. (2003) on the other hand reported an incidence of just 1% in 91 patients with the single patient affected by CRPS Type I being diagnosed 7 weeks post injury with an otherwise uneventful treatment course. They used the diagnostic criteria as set out by the International Association for the Study of Pain (Merskey & Bogduk, 1994) which are broader than those described by Veldman et al. (1993).

1.5.3 Tendon Complications

In McKay's cohort tendon complications accounted for 27% of the total complications (McKay et al., 2001). The complications fall into two anatomic groups, the dorsal extensor tendons and the volar flexor tendons.

1.5.3.1 Extensor Tendons

Rupture of the extensor pollicis longus (EPL) tendon is the most common tendon complication following DRF, first being described in 1876 (Duplay, 1876). Even in completely undisplaced fractures, EPL rupture may be seen in up to 5% of patients (Roth et al., 2012). Late EPL rupture is thought to be due to a direct pressure effect on the tendon with subsequent avascular necrosis of the tendon at the fracture site.

Where fractures are operatively managed tendon complications are plate specific and vary by approach and implant design. Dorsal plates such as the

AO/ASIF 'pi' plate put the extensor tendons at risk either directly from the approach, or late because of tendon attrition. The now more common volar plates such as the AO-Synthes DVR (DePuy Synthes, Zuchwil, Switzerland) can also irritate or rupture the extensor tendons when the surgeon fails to appreciate the trapezoidal shape of the distal radius and inserts long distal locking screws which are proud of the bone dorsally.

1.5.3.2 Flexor Tendons

Flexor tendon injuries as a result of non-operatively managed DRF are rare. The majority are attritional ruptures associated with a malunion of a dorsally displaced DRF (Murase & Hiroshima, 2003). There have been rarer reports of acute injuries to the flexors associated with a displaced DRF (DiMatteo & Wolf, 2007). The injury pattern in either case relates to the degree and location of displaced fragments.

With new generation contoured volar locking plates the flexor tendons are at risk when the plate is prominent (usually due to mal-reduction) or when the dorsal ulnar fragment has not been controlled and subluxes. Injury to the flexor pollicis longus tendon with volar plates has been reported in 0.3% to 12% of operations (Drobtz & Kutscha-Lissberg, 2003; Soong et al., 2011).

1.6 Predictors of Outcome in Dorsally Displaced Fractures

When it comes to looking at the established predictors of outcome, it somewhat depends on the 'outcome' being considered. The predictors of radiological outcome seem very different to clinical outcome. Certainly clinical outcomes are more uncertain. Below are outlined those predictors which are currently held up as informing accepted practice and the evidence for them. These predictors apply mainly to dorsally displaced fracture patterns, as volarly displaced fractures have almost universally poor stability even with satisfactory initial reduction.

1.6.1 Predictors of Stability and Maintenance of Reduction

There are a number of fracture characteristics, which are thought to predict the stability of a DRF which is initially displaced and then reduced. A key paper to assess the best current evidence for predictors is the meta-analysis by Walenkamp et al. (2016) which reviewed 27 studies.

Dorsal Comminution - dorsal comminution has always been considered a predictor of early re-displacement (Alemdaroglu et al., 2010; Leone et al., 2004; Mackenney et al., 2006; Makhni et al., 2008; Nesbitt et al., 2004; Phillips & Al-Shawi, 2014; Tahririan et al., 2013). Based on meta-analysis of these papers dorsal comminution is associated with an increased risk of secondary redisplacement (Walenkamp et al., 2016).

Volar Comminution - volar comminution is relatively uncommon being present in only around 14% of fractures. It is however highly predictive of displacement with the best evidence coming from Wadsten's prospective cohort of 398 non-operatively managed DRF (Wadsten et al., 2014). In their cohort dorsal comminution was associated with instability in 73% but those with volar comminution showed instability in 96%.

Dorsal Tilt - initial dorsal angulation at thresholds of >15 or >20 degrees from neutral is not a predictor of stability on meta-analysis based on three papers (Blakeney & Webber, 2009; Phillips & Al-Shawi, 2014; Nesbitt et al., 2004)

Initial Displacement - the initial displacement of the fracture is cited as a risk factor for re-displacement in two papers. Myderrizi (2011) looked at 329 non-operatively managed DRF in whom manipulation achieved anatomic reduction, which was maintained for at least 1 week. One-hundred and seventy one of this cohort redisplaced and the degree of initial displacement was identified as a risk factor. Beumer & McQueen (2003) looked at 59 patients over the age of 60 treated with closed reduction. Of these 85% redisplaced and while initial displacement was considered a risk factor the use of this finding is limited, given that almost no patients maintained reduction by the time of union.

Articular Involvement - Intra-articular involvement has often been cited as an indication for operative intervention based on previously published studies (Mackenney et al., 2006; Makhni et al., 2008; Wadsten et al., 2014). However, on meta-analysis it does not show any association with early redisplacement.

Ulna Fracture – The presence of an ulna styloid fracture is often cited as a predictor of stability (Alemdaroglu et al., 2010; Leone et al., 2004; Nesbitt et al., 2004; Phillips & Al-Shawi, 2014; Tahririan et al., 2013). This was not supported by meta-analysis.

Osteoporosis - osteoporosis is often not examined as an independent risk factor but age and gender are both surrogate markers of osteopenia and osteoporosis. On meta-analysis both age over 60 years and female gender were predictive of redisplacement (Walenkamp et al., 2016).

The predictors of instability which seem to stand scrutiny in the literature are:

1. Dorsal & Volar Comminution
2. Degree of Initial Displacement
3. Age >60
4. Female Gender

1.6.2 Extra-articular Malunion

In fractures where there is initial displacement, there is likely to be some residual malunion, particularly when managed with closed reduction and casting. There are four parameters of extra-articular reduction that are assessed in order to determine if the position of a fracture is acceptable.

Radial Inclination & Height

As radial inclination decreases the relative positions of the flexor tendons through the carpal tunnel changes with a subsequent decrease in grip strength. It will also decrease the ability to place the wrist into ulnar deviation which is the position of maximal grip strength (Fernandez, 1993).

The radial height or length is defined as the distance from the distal ulna to the tip of the radial styloid. In the context of DRF it is a surrogate measure of radial inclination as well as impaction and ulnar variance.

Radial Tilt

This is more commonly referred to as either dorsal or volar tilt depending on the orientation of the joint surface on a lateral x-ray with normal being around 11 degrees of volar tilt. Most papers have considered up to 15 degrees of dorsal tilt to be an acceptable degree of malunion (Altissimi et al., 1986; Sharpe & Stevanovic, 2005; Graham, 1997). Increasing degrees of dorsal tilt will increasingly load the lunate fossa and offload the scaphoid facet.

Ulnar Variance

The ulnar variance is the height of the ulna relative to the radius at the DRUJ and is normally negative by around 1mm. A positive ulnar variance is associated with a number of sequelae including lunatomalacia, scapholunate instability, ulnocarpal impingement and radioulnar impingement. A retrospective review of 51 patients treated with volar locking plate, with a mean follow-up of over three years, found that in those who had a residual positive ulnar variance there was a significant effect on grip strength (Dario et al., 2014).

The two most-important extra-articular factors are thought to be volar tilt and preventing positive ulnar variance (Dario et al., 2014). There is

evidence that malunion resulting in abnormalities in any one or a combination of these variables leads to poor results. Kumar reviewed 95 patients with extra-articular DRF and found that in patients over the age of 60 satisfactory functional results as measured by the DASH score were obtained despite malunion (Kumar et al., 2008). In the same dataset the only radiological factor in patients under the age of 60 which associated with poor outcomes on the DASH was radial inclination.

Extra-Articular malunion parameters predictive of worse outcomes:

1. Positive Ulnar Variance with Ulnocarpal Abutment
2. Flattened Radial Inclination
3. Dorsal Radial Tilt >15 Degrees

1.6.3 Intra-articular Malunion

Only around 50% of DRF are extra-articular with the rest being partial or complete articular (Koo et al., 2013). A number of studies have reported that displacement of an intra-articular fragment of 2mm or greater is associated with high future risk of radiocarpal arthritis. Knirk & Jupiter's (1986) paper presents one of the highest incidences of radiocarpal arthritis for intra-articular malunion of 65% at 6.7 years, though other papers have reported much lower incidences. Young et al. (2003) reported an incidence of just 14% at 7 years follow-up in a cohort of 85 patients who had been randomised to closed reduction and casting or external fixator.

There were a number of methodological problems in the Knirk and Jupiter paper which have been replicated in many of the papers published since. The chief problem is that it is not possible to determine articular displacement on standard PA and lateral x-rays. Watson et al. (2016) demonstrated that 5 experienced observers were unable to acceptably discriminate 1mm of articular step-off, though this paper did find that measurements of radial tilt, ulnar variance and radial inclination could be accepted. Jupiter revisited the original paper in a review of his own work published in the orthopaedic journal at Harvard Medical School, accepting that the surgeons' ability to discriminate between 1mm and 3mm on plain film x-ray is too poor for the original 2mm acceptable limit to be a usefully accepted cut-off (Haus & Jupiter, 2009).

1.6.4 Psychosocial Factors

The psychological factors of depression, anxiety and catastrophising have a significant impact on the degree of disability and pain felt following skeletal trauma (Vranceanu et al., 2014). During the course of recovery following a DRF, depression and catastrophic thinking have been shown to reduce from week 1 to 6 post injury and are thought to return to base line, though this has not been proven (Golkari et al., 2015).

Depression is common following medical illness and general outcomes improve with treatment of depression (Lenze et al., 2001). In research that has looked at depression following DRF, pain is an important predictor, though the early movement afforded by internal fixation does not alleviate these symptoms (Gong et al., 2011). Ross et al. (2015) in a large prospective series of 594 patients with acute upper limb fractures (of whom 34% were DRF) showed depression and stress, but not anxiety, mediated the relationship between pain and disability using the Depression, Anxiety, and Stress Scales (DASS- 21) compared to the Quick-DASH (Ross et al., 2015). Depression is not independently associated with an increase in CRPS type I (Jellad et al., 2014).

Psychosocial factors associated with poorer outcomes:

1. Depression
2. Catastrophic thinking

1.6.5 Predictors of Early Stiffness

Following DRF post-immobilisation stiffness is almost universal. The fingers as well the wrist are usually affected. Egol et al. (2014) undertook a study of 260 patients in order to determine the predictors of stiffness following DRF in both operatively and non-operatively managed cases. They defined stiffness as a fingertip to distal palmar crease distance of 1cm. In their cohort 19% of patients were classified as stiff. Interestingly the only factors, which positively associated with hand stiffness, were positive ulnar variance and advancing age though there was a positive trend with increasing pain. Of note, there was no association with OTA fracture classification, history of osteoarthritis or type of management (operative vs non-operative).

Lyngcoln et al. (2005) conducted a small study of 15 patients looking at adherence to a hand therapy protocol following DRF. They found a positive relationship between adherence to the whole hand protocol and short-term outcomes. It appears that it was the adherence to the protocol itself that was the most important predictor as there was no association with overall exercise amount. Clearly with a study of this small size, caution needs to be exercised in over interpreting the results but there are no larger studies looking at this subject on which to rely.

Catastrophic thinking has been shown to be the major determinant of finger stiffness at six weeks following open reduction and internal fixation of DRF based on a prospective cohort study of 96 patients (Teunis et al., 2015).

Predictors of early stiffness:

1. Positive Ulnar Variance
2. Adherence to a Therapy Protocol
3. Age
4. Catastrophic Thinking

1.7 Rehabilitation and Patient Satisfaction

The purpose of rehabilitation in the context of DRF is to assist in the process of recovery following injury. There are many providers and interventions available and the evidence base for each intervention is often weak (Handoll & Elliott, 2015). This is not to say that each does not work, just that we do not currently have the evidence to show that they do. The questions to ask when categorising rehabilitation interventions are:

Who	Physiotherapist / Occupational Therapist / Patient Led
What	Which type of intervention
Why	What are the realistic aims of the intervention
When	When should the intervention start and how often
Where	Hospital / Community / Home

1.7.1 Therapy Strategies

In the NHS physiotherapy is defined as follows;

"Physiotherapy - helps to restore movement and function when someone is affected by injury, illness or disability. It can also help to reduce your risk of injury or illness in the future. Physiotherapy is provided by specially-trained and regulated practitioners called physiotherapists." (www.nhs.uk)

When looking at the efficacy of therapy strategies there are a large number of metrics used to measure outcomes. This can make comparisons of published papers difficult. Broadly speaking therapy outcomes are measured by objective physical characteristics (range of motion and grip strength), the use of patient reported outcome measures (such as the DASH score) or patient satisfaction scores (such as a visual analogue scale - VAS).

1.7.1.1 The Typical Physiotherapy Treatment Pathway for DRF

In the initial physiotherapy appointment, the first part of the consultation will centre around taking a patient history in much the same way as a medical consultation. A history of injury or symptoms in the whole limb will be sought in order that any concurrent joint problems are considered along with the wrist injury. Careful attention is paid to the social history with a

focus on patient important factors and goals. Where a patient has an unrealistic set of goals it is important to manage expectations from the outset and make clear the expected duration and final result of the pathway to recovery. Any potential safeguarding issues are also considered.

The passive and active range of motion are measured to identify the degree of stiffness. Following a dorsally angulated DRF, stiffness will be most common on wrist extension and forearm supination, with varying degrees of finger involvement. Grip strength with the wrist in a neutral position is measured. The temperature of the wrist and hand is felt and any evidence of active or impending complex regional pain syndrome (CRPS) is sought.

At the end of the initial visit the patient should be competent to perform a home exercise programme consisting of active range of movement exercises and elevation for oedema management.

The decision on further reviews will depend on the level of restriction identified at the initial visit. Subsequent visits are more tailored to the individual patient's needs rather than being protocol driven. In the mid-stage of recovery, weight bearing through the wrist will be increased. The physiotherapist will undertake hands-on treatment with passive stretching or resisted active movements. Passive accessory movements and manipulation techniques may be undertaken. Adjuncts such as putty may be used and there is a focus on grip strength as wrist extension increases.

In the final stage of recovery patients who undertake sporting activities will move on to shock training through the wrist by means of breaking a controlled fall against a wall with the wrists extended. In those who play impact sports or have heavy manual jobs they will undergo work hardening or match fitness with activities up to a controlled handstand.

If a problem with progress is identified, the physiotherapist will usually refer the patient back to the treating physician for review who maintains overall responsibility for care of the patient.

1.7.1.2 Standard Advice and Advice Sheets

It is common practice for patients to receive an advice sheet as a reminder of the home exercise programme (HEP) they should follow. The use of an advice sheet without an initial appointment with a therapist is not well researched (Bache et al., 2000). When an advice sheet alone is to be used, the patient must have a method of referring themselves back to the treating clinician should there be a poor outcome. While there will undoubtedly be variation in the advice sheets used, in our centre they involve a pictorial demonstration detailing simple active range of motion exercises for the wrist, fingers and thumb. The standard advice sheet in our centre is shown in figure 1.7.1.

Figure 1.7.1 Standard advice sheet following DRF

Image Redacted for Copyright

Valdes et al. (2014) conducted a meta-analysis of seven randomised controlled trials, comparing heterogenous HEPs with in person physiotherapy. An information sheet supported the HEP in three cases and in the other four cases a physiotherapist, occupational therapist or physician gave instruction. For those patients who received in person instruction this was controlled in two studies and in five was left to the discretion of the therapist. The 381 patients were heterogenous (58% of whom were treated with plaster and 42% with some form of surgical intervention). Individual results variably either supported a HEP or in person physiotherapy but on

meta-analysis there was no overall consensus on optimal treatment with confidence intervals often crossing zero. The study concluded there was no evidence to recommend an in person physiotherapy protocol over a home exercise programme accepting the limitations of the individually small and varied interventions of the RCTs.

1.7.1.3 Physiotherapist Led Active and Passive Exercises

Range of movement exercises are one of the universal methods used in the rehabilitation of patients following wrist fractures. These are often demonstrated in person during a physiotherapy appointment as described below, but are intended to be performed frequently at home using the uninjured hand to replace that of the physiotherapist. There are three types of range of movement that are usually applied in sequence.

Passive Range of Movement - the physiotherapist performs the movements, gradually increasing the range as stiffness allows.

Active-assisted Range of Movement - the patient performs the range of movement to the point they are able, after which the physiotherapist gently increases the range as pain allows.

Active Range of Movement - the patient performs the full range of movement expected with verbal input on technique only from the physiotherapist.

Looking at two of the small RCTs included in Valdes et al. (2014) meta-analysis, Christensen et al. (2001) performed an RCT of 32 non-operatively managed patients comparing a single session of instruction to instruction followed by 16 weeks of in person therapy. They found that there was no statistically significant difference in grip strength or Gartland and Werley score up to 9 months after immobilisation was removed.

When a therapy directed exercise programme was compared to no intervention at all in an RCT of 56 patients, it was found that there was no significant difference in range of motion or grip strength at six weeks (Kay et al. 2008). However, pain scores were improved and patient satisfaction was higher in the therapy group. The therapy directed programme consisted

of a single session with a physiotherapist with a booklet to reinforce the exercise programme and advice given.

1.7.1.4 Physiotherapist Applied Mobilisation and Manipulation

Manual therapy is a sub-specialised area of physiotherapy for the management of musculoskeletal conditions using the treatment approaches of manipulation and therapeutic exercise. These techniques are applied in continuation with range of movement exercises and are usually hands on treatments provided by a physiotherapist.

There are many manipulations available for the wrist and hand. Some of those more commonly performed include; dorsal/ventral glide of the DRUJ, dorsal/palmar glide at the radiocarpal and midcarpal joint, radiocarpal and midcarpal distraction and glide and distraction techniques for the small finger joints. A distraction is defined as an arthrokinematic movement causing separation of two articular surfaces in the plane of the longitudinal axis of the distal portion. There is some evidence for its efficacy in knee osteoarthritis with statistically significant improvements in pain relief, functional ability and quality of life when used in addition to standard physiotherapy treatment (Khademi-Kalantari et al., 2014).

A glide is defined as an arthrokinematic movement with a combination of rolling and sliding between two incongruent joint surfaces. There is evidence that the addition of an assisted glide to static stretching improves active and passive range of movement at the ankle (Jeon et al., 2015).

A physiotherapist usually performs these interventions, though in some circumstances they can be performed by the patient alone, with the use of an aid such as a strap (eg TheraBand™, Hygenic Corporation, OH, USA). However, in practice it is likely patients will only benefit from manipulations when they are enrolled in a therapist guided in-person session.

1.8 Patient Education and Learning

The therapy advice given to patients needs to be understood and retained so that any programme implemented can be continued away from direct supervision.

There has been increasing interest in ways to improve patient learning over recent years in response to reports of poor patient retention and recall of information in relation to informed consent. Falgas et al. (2009) performed a meta-analysis of 21 studies which showed that patients' understanding of the information provided prior to surgery was adequate in less than a third of the 21 studies reviewed.

One of the key aspects to enhancing patient learning is to increase a patient's autonomy and allow them to take better control of their condition. Patient education and self-management programmes are common in the management of life-long chronic conditions such as pain, diabetes, asthma and anticoagulation but are quite unusual in the context of acute musculoskeletal injury.

Research into the concepts surrounding patient education and learning are quite heterogeneous and the interventions tested are varied. Köpke et al. (2009) examined the effect of a single patient education session randomising 150 patients with relapsing MS comparing a four-hour group session or standard information leaflet. The aim of the intervention was to reduce the intravenous administration of corticosteroid, as is standard practice in Germany, replacing it with oral corticosteroid or no steroid at all. The group of patients who received the education session showed greater freedom in their decision making, with a reduction in intravenous steroid use from 78% to 56%. This demonstrates the power of increased patient education at its simplest. That by improving patient education, a significant change in long established practice can be substantially modified in a single session.

1.8.1 Media Assisted Therapy Techniques

Over recent years, multimedia assisted rehabilitation has been increasingly scrutinised in the literature. Most of this work centres on video game or

motion sensor based techniques rather than more traditional video learning. In response to the poor patient understanding related to consent, Sahai et al. (2006) examined integrating a video into the consent process in 43 patients undergoing laparoscopy. Accepting there was no control group against which to compare the results 81% of participants felt patients should be given the option to watch videos in the future and the overall satisfaction was 29.8/32 as assessed by the Client Satisfaction Questionnaire (CSQ-8).

The use of video as a means of delivering therapy advice is certainly not new and on the internet, particularly on video sharing sites, there are thousands of videos available. There are two significant problems; the videos are in the main not peer reviewed and there is very little published evidence for their efficacy.

One of the few papers which looks directly at an educational video as a means to direct patient learning presented encouraging results. Hua et al. (2014) randomised 86 patients with glaucoma treated with trabeculectomy to either an in person taught group or a group who used a video to learn ocular massage. The results identified equivalent outcomes up to 1 month but at 3, 6 and 12 months the group who were given the education video performed better. This suggests the potential for improved retention of information using a video, likely due to the potential for repeated viewing.

Crabtree et al. (2012) implemented a video education module for 150 patients undergoing lung surgery and compared a range of outcomes to the preceding consecutive 150 patients. The study group had less severe morbidity, length of stay and readmission rates so the conclusions are somewhat limited, particularly for pain scores. However, those patients who received the video demonstrated better satisfaction, preparedness for surgery and relief of anxiety, though 24% of patients who were supplied with the video admitted to not actually watching it. Reasons given were varied and poor compliance did not correlate with social deprivation or reported issues with access. It is important to remember that poor compliance is not restricted to videos and exists in all interventions.

1.8.2 Tele-Rehabilitation

Live video has been used in order to overcome geographical barriers in large countries where direct access to a therapy provider would be impractical. Video based tele rehabilitation involves making a provider available to a patient over the internet for a one on one session. In some instances, this will involve specialist hardware such as a 'video phone' but as access to the internet at home via computers and phones increases it seems likely this will be the primary portal of access going forward.

Levy et al. (2015) reported on a group of 26 veterans, 81% of whom had a variety musculoskeletal disorders, who received a mixed-method approach to rehabilitation where 74% of sessions were provided over a video phone. In a group this small, with a heterogeneous set of injuries, analysis of the PROMs used is not meaningful. However, what was shown is that satisfaction with the intervention was very high with all but one participant reporting their experience of telehealth as good or very good.

1.9 Measuring Outcomes

All studies need a way of demonstrating the magnitude of the effect they have on patients, when comparing two or more interventions. The PROM is a commonly used tool in musculoskeletal research. At its most basic it allows a snapshot of health status or quality of life to be recorded. Prior to PROMs becoming commonplace, objective outcomes were usually used to record change. Scores such as the Gartland and Werley score can be seen as a bridge between the two, with scoring relying on elements of both.

PROMs usually record measurements using an arbitrary scale, for example the DASH score converts its 30 questions into a score from 0-100. It is possible to overpower a study such that even the smallest change in the score of a PROM after an intervention will be found to be statistically significant. A tool to identify what change in the score of a particular PROM patients feel is clinically important is therefore needed. This is the purpose of the minimum clinically important difference (MCID). The MCID shows what change in a PROM score is perceived to be of benefit (or detriment) to a patient, allowing for an appropriate sample size to be calculated and informing the interpretation of study results.

1.9.1 Quantitative Outcome Measures

Patient reported outcome measures give a measure of health status from the patient perspective. This is therefore subject to a great many variables. Quantitative measures can sometimes also be useful in assessing outcome, though over-reliance on them is potentially misleading as a measurable change is not necessarily one which a patient would recognise as important. In DRF two of the commonest quantitative measures recorded are grip strength and range of movement.

1.9.1.1 Grip Strength

Hand grip strength is a fundamental measure of function and has been used extensively in research to quantify outcomes after DRF. There have been several methods for recording grip strength, with a Jamar grip dynamometer being the most commonly employed. It was introduced by Bechtol (1954) and consists of a sealed hydraulic system with an adjustable hand grip (Kirkpatrick, 1956). Prior to this measurements were made with a

sphygmomanometer and so were recorded as pressure in mmHg but subsequent to the meeting of the committee on industrial health and rehabilitation of the California Medical Association where the Jamar was recommended, this was changed to a measure of force in pounds or grams.

The population norms for the UK, were published in 2014, based on 60,803 observations from 49,964 individuals (Dodds et al., 2014).

1.9.1.2 Range of Movement

The range of movement (ROM) is the second quantitative measure which is almost universal in DRF research. There are a number of movements which can be measured which include; flexion & extension, radial & ulnar deviation and pronation and supination.

The population norms in the UK for flexion and extension are 59.3 (S.D. 14.1) and 65.2 (S.D.9.4) respectively. The mean total arc of movement is 124.5 (S.D. 18.4).

1.9.2 Patient Reported Outcome Measures

PROMs have multiple uses which include performance assessment, quality improvement, screening and outcomes in clinical trials, monitoring disease progression and to provide information to patients allowing them to choose their provider or treatment (Nelson et al., 2015).

1.9.2.1 What Defines a Good Outcome Measure?

PROMs should have certain attributes which can be tested before adopting them for widespread use. PROMs may measure only one construct such as pain, although most will measure a number of constructs.

When assessing an outcome measure there are three key domains which must be assessed; reliability, validity and responsiveness. The definitions of these were set out by the COSMIN (CONsensus-based Standards for the selection of health status Measurement INstruments) initiative with international consensus. This work sets out the three key domains within which there are a total of nine measurement properties (Mokkink et al., 2010). The COSMIN checklist also considers interpretability as the tenth

measurement property. This is the ability to attribute a qualitative meaning to the quantitative data produced by a PROM. While this is not technically a measurement property it is clearly meaningful in terms of the usefulness of the instrument (Kleinlugtenbelt et al., 2016).

Reliability

The reliability of a PROM assesses whether it is internally consistent, or reproducible, and the extent to which it is free from measurement error. Another way of looking at it is that it measures what proportion of the PROM score is 'signal' and what proportion is 'noise'.

Internal Consistency - The internal consistency shows the degree to which items in an instrument are related by testing whether different items that are supposed to measure the same general construct produce similar scores. It is assessed by Cronbach's alpha, which is a function of the number of items in a test, the average covariance between item-pairs, and the variability of the total score. PROMs with an alpha statistic of 0.7-0.9 indicate the questions are appropriately assessing a single construct (Streiner & Norman, 2003). It is important to remember that Cronbach's alpha will also be affected by the number of items so very high levels of correlation (>0.95) suggests there are too many questions assessing the same construct. During the development of a PROM an item reduction process using both classical test theory (Cronbach's alpha) and item response theory to modify the number of items will be undertaken.

Reliability - The reliability represents the variability, which occurs when an instrument is repeatedly applied. It is important because it allows the 'actual' difference between patients to be known. Test-retest analyses indicate whether results are reproducible when the questionnaire is re-administered over time where no real change in condition is occurring. There is no agreed time over which the PROM should be administered though 2-14 days is typical. Intra-class correlation is calculated by correlating the scores for the two administrations and scores >0.75 indicate good reliability.

Measurement Error - all instruments will exhibit some systematic error in the way they collect data and patients themselves will additionally generate

random error. The standard error of measurement (SEM) quantifies the change in score which is due to this and therefore any change in score lower than the SEM cannot be considered a 'real' change. It is important to differentiate the standard error of measurement from the standard error of the mean as they share the same acronym but are entirely different measures. The standard error of the mean is the standard deviation of the sample mean estimate of a population mean. The standard error of measurement is an indicator of how the scores on repeated application of an instrument are distributed around the "true" score, accepting that the "true" score cannot itself be derived.

Validity

This ensures that a questionnaire measures what it is supposed to, by verifying whether the instrument under study "makes sense" in relation to the scores of other, related instruments.

Content Validity - The content validity is a reflection on how adequate an instrument is at measuring a health condition, and whether all the important and/or relevant activities have been included. This can be tested qualitatively by looking at the contents of the PROM i.e. does it ask the questions a patient would expect to be asked if they have a wrist problem. Through necessity there will always be a trade-off on the applicability of an instrument to the disease, which it is being used to assess. For example, the DASH score contains items that are not necessarily relevant to a patient with a DRF. However, it would be impractical to have a separate instrument for each disease.

Construct Validity - The construct validity can be subdivided into three areas of validity; hypotheses testing, structural validity and cross-cultural validity. The construct validity is described by hypotheses testing by showing the degree to which the scores of an instrument are consistent with the hypotheses they are used to test. Structural validity is a measure of whether the items in an instrument reflect either one or multiple constructs. Cross-cultural validity recognises the potential for an instrument's validity to be affected once it is translated to another language, or applied to a different population from the one in which it was developed. This can be

measured by retesting the instrument once it has been translated and comparing it to the original version.

Criterion Validity - The criterion validity shows the degree to which the instrument reflects a gold standard used to test a condition. It can be assessed quantitatively by comparing the results of a PROM to other disorder specific questionnaires or by looking at other objective measures of a condition and correlating the two. Quantitative assessment of construct validity can be assessed by either convergent or divergent approaches. In convergent validity (which is assessed most often), there should be a high positive correlation coefficient between the PROM and the gold standard. Convergent validity is considered adequate if >75% of hypotheses are correct (Terwee et al., 2007), or if the correlation coefficient with an instrument measuring the same construct is >0.50 (Abma et al., 2016), accepting these values are assigned somewhat arbitrarily.

The issue is that there is rarely (if ever) a gold standard available. In practice the PROM being tested is validated by using a different established PROM. This clearly relies on the fact that the established PROM is itself valid which may not be the case.

Responsiveness - when a questionnaire is used for repeat assessment it must be able to detect changes in the underlying condition such as variation in pain, stiffness and weakness. It is limited by ceiling and floor effects i.e. on a 10 point scale, if a patient scores themselves 8 for a question, the best improvement they can record is 2 whereas someone who scores themselves 6 can improve by 4. It can be tested by comparing changes in the score with objective measures such as grip strength, range of movement and tenderness to palpation.

The standardised response mean (SRM) can determine responsiveness and is calculated by determining the change score by subtracting the initial score from the final score. The patient's mean change score is then divided by the standard deviation of the patients' change score with values of ≥ 0.20 to < 0.50 being considered a small effect size, ≥ 0.50 to < 0.80 moderate and ≥ 0.80 a large effect size (Cohen, 1988).

1.9.2.2 PROMs in Distal Radius Fractures

For any patient population there are usually multiple available PROMs to assess a disease or intervention. The COSMIN initiative was started to aid researchers in the selection of PROMs by reviewing systematic reviews of outcome measures. These reviews are updated frequently to ensure advice is current. With regard to wrist injuries the DASH is the most widely tested instrument. Both the DASH and the PRWE show good responsiveness in DRF and the PRWE shows slightly better validity and reliability (Hoang-Kim et al., 2011; Kleinlugtenbelt et al., 2016).

The COMET (Core Outcome Measures in Effectiveness Trials) Initiative is run by a group interested in the development and agreement on core outcome sets. A core outcome set is the minimum data that should be collected in clinical trials looking at a specific condition. They made seven core recommendations for research into DRF (Goldhahn et al., 2014).

1. Pain and function are the primary domains.
2. Very brief measures are needed for routine administration in clinical practice.
3. These brief measures can be augmented by additional more detailed measures with additional domains for clinical research.
4. Measurement of pain should include measures of both intensity and frequency as core attributes.
5. A numeric pain scale or the pain subscale of the patient-reported wrist evaluation (PRWE) questionnaires are reliable, valid and feasible.
6. For function, either the QuickDASH or PRWE-function subscale are reliable, valid and feasible.
7. A measure of participation and treatment complications should be considered core outcomes for both clinical practice and research.

In the same paper a review of all prospectively designed studies into DRF over the last 25 years was performed. There were 165 studies identified and of the PROMs used the DASH was by far the most common (n=31) with the PRWE being fourth most commonly used (n=8) behind the Gartland and Werley score and its modified variant.

1.9.2.3 The Minimum Clinically Important Difference (MCID)

The concept of the MCID was originally proposed in the paper by Jaeschke et al. (1989). They recognised that while PROMs were becoming common as primary endpoints for large randomised controlled trials, a statistically significant result may not be clinically relevant to the patient population being studied.

A clinically important difference represents a change in the score from a PROM that would be considered meaningful and worthwhile, such that a patient would agree to repeating the intervention if they could choose to undergo it again.

They tested two PROMs; the chronic respiratory questionnaire and the chronic heart failure questionnaire. They described the use of an anchor based calculation using a global rating of change (GROC) questionnaire as the anchor. They reported an MCID for each questionnaire, which could be considered as a small, medium and large change in condition from the patients' perspective.

Since their paper a vast amount of work has been undertaken in the area of calculating what should be taken as the minimal change for PROMs, which is summarised in a comprehensive review by Beaton et al. (2011). However, much of this work understandably focuses on patient populations with chronic and often stable conditions. Groups such as OMERACT (Outcome Measures in Rheumatoid Arthritis Clinical Trials) have looked at the low disease activity state (LDAS) and patient acceptable symptom state (PASS) (Tubach et al., 2005; Tubach et al., 2006; Wells et al., 2003). In trauma we are often looking at a group of patients in whom improvement is expected irrespective of the intervention applied. Referring back to Colles original paper, patients who were untreated and left with significant malunion ultimately got better (Colles, 1814). Therefore, over the following sections the literature as it applies to a trauma population will be considered.

The minimum clinically important difference (MCID) is defined as the smallest change in an outcome measure that a patient themselves would identify as important. Its relevance is in ensuring that a study has the correct number of patients to avoid two issues:

1. A clinically important difference being ignored as statistically insignificant (i.e. type 2 error).
2. A study having too many patients and finding a result which is statistically significant, but which is not clinically appreciable to patients (i.e. the change identified on the PROM is smaller than the MCID for that outcome measure when used to assess that condition).

Some caution must be employed when using the MCID alongside study results. A study which reports an overall change in PROM score beneath the MCID may in fact have reported a heterogenous spread of results. A subgroup of the whole cohort may actually improve above the MCID, while the rest of the cohort are unimproved skewing the whole cohort analysis. Similarly the MCID is usually calculated and reported at the population level. The MCID does not necessarily apply to individual patients where there may be variation in what is deemed clinically important. For example the difference of one point on the PRWE may be significant to a concert pianist whereas for a low functional demand patient more than ten points may only start to be significant.

Because most PROMs are not disease specific, when they are applied to different conditions different threshold values may be clinically important to patients. There are a number of calculation methods as discussed below. Some of these generate results which are instrument specific (distribution methods) and some disease specific (anchor and Delphi). It may be that the MCID only varies by region. If you are using the DASH to measure a total shoulder replacement you would expect that to have a different MCID than for wrist fracture. However, the MCID for the DASH may be the same for total shoulder replacement and fixation of a fracture of the proximal humerus. Current consensus is to determine the MCID in a disease specific way.

The MCID has not been determined in DRF, even for previously validated scores with the exception of the Patient Rated Wrist Evaluation (PRWE) (Walenkamp et al., 2015). In Walenkamp's prospective study of 102 patients the MCID was calculated as 11.5 for the PRWE using an anchor based method. Without establishing the MCID it is potentially more difficult to design a study with the correct power or set the results of studies into

context, as any detected change is at risk of being clinically unimportant to patients.

The population MCID needs to be considered against the standardised effect size within a study. As already mentioned the MCID for an individual may be smaller than that calculated for a population. A population estimate will be larger and this in turn will increase the standardised effect size within a study. Typically an MCID in the range of 6-10% of the PROM being studied will equate to a standardised effect size of around 0.3-0.5 (Revicki et al. 2008). Larger MCID estimates will in turn give larger standardised effect sizes and using only these in determining power, runs the risk of under powering a study and increasing type 2 error.

1.9.2.4 Calculating the MCID

A valid MCID requires two calculation types to be performed. A distribution analysis uses statistical analysis of a PROM to determine the change in score which is required for the result to be considered above the measurement error of the instrument. This result is considered specific to the instrument. An anchor analysis then applies the PROM to a cohort of patients such as patients with a DRF. This analysis is designed to demonstrate the change in score which patients report as both perceptible and meaningful to them. The anchor result is judged against the distribution result and if it is higher than the error in the instrument it can be accepted as a valid MCID. In the United States the Food and Drug Administration (FDA) has issued guidance that the anchor based approach is the most appropriate method to determine the MCID (McLeod et al., 2011).

With the publication of multiple studies, it is likely that the results of both anchor based and distribution based calculations will give rise to a range of values. The Delphi method can be used to add clinician consensus to resolve a final value where this discrepancy arises. Though its application to MCIDs came later, the concept of using clinician consensus was something alluded to in Jaesche's original paper when they stated;

“It is reassuring to note that the estimates of MCID suggested by the data correspond closely to our intuitive estimates based on clinical experience with the questionnaires.” (Jaesche et al., 1989, p414)

Distribution Based Calculations

A distribution based approach uses statistical analysis of the data generated by a PROM itself and does not rely on a second dataset from an anchor. It uses the standard deviation (SD) as its basis which makes all subsequent calculations a factor of this. The SD is used to calculate the standard error of measurement (SEM) which in turn can be used to calculate the minimal detectable change (MDC) at various confidence intervals. Distribution methods can also be used to calculate the reliable change index, effect size and the standardised response mean (Rai et al., 2015).

Distribution based calculations are a measure of the error inherent in the instrument and so should not change significantly with the condition or disease process. It therefore only needs to be determined a small number of times in a PROM to ensure comparable results.

Standard Deviation (SD) - The SD represents the variation in scores recorded. It was reported by Norman et al. (2003) that one half of the SD corresponded to the MCID in a number of studies. It was felt that this occurred as this is the limit of a persons' ability to discriminate.

Standard Error of Measurement (SEM) - The SEM represents the variation in reported scores introduced by the unreliability of the scale being used. Therefore, any change smaller than the SEM should be considered due to measurement error rather than an observed change. It is derived by multiplying the SD of the baseline PROM scores and the square root of one minus the Intraclass Correlation Coefficient (with Cronbach's alpha often being used). It can be considered in the same way as the standard deviation where one SEM implies the true value lies in the quoted range 68% of the time. This can be changed to two SEM by adding 1.96 as a multiplier to the above equation increasing the certainty to 96%. Wyrwich et al. (1999) showed that a value of one SEM corresponded to a value calculated using the Delphi method, which is widely accepted to represent

the MCID for the Chronic Respiratory Disease Questionnaire (CRQ). While this value has not been agreed as a surrogate for the MCID in most PROMs, the SEM can be considered the minimum value representing a true change in individual scores.

Minimal Detectable Change (MDC) - The MDC is used to determine the threshold for whether a pre-post change is true from a measurement perspective. It is a statistical estimate of the smallest change detected by a measure which can be considered 'real'. Some would say that this represents the MCID. However, it takes no consideration of whether the patient feels the result is clinically significant. It would be better to say that the MDC can be considered to represent a change in score which is greater than the error of the instrument and is the minimum value which could be considered the MCID (Turner et al., 2010).

Anchor Based Calculations

An anchor based approach to calculating the MCID uses a second measure of change alongside the PROM being tested as an anchor against which to judge the change reported on the PROM. Ideally, the anchor should be a 'gold standard' with high test-retest reliability and a high sensitivity to positive and negative change. One possible gold standard relevant to upper limb function might be the use of the Purdue Pegboard test for assessing hand dexterity as an anchor. The Purdue Pegboard test involves timing the speed of inserting pegs into holes and tests gross arm, hand and finger movement as well as fine motor dexterity.

For practical reasons most studies use a second subjective assessment as the anchor, with the global rating of change (GROC) scale being the commonest choice in musculoskeletal research. Generally the anchor should be easier to interpret than the PROM being tested. The GROC was shown by Hägg et al. (2002) to be sensitive to positive and negative change. The GROC scale most commonly seen is a bidirectional 15 point scale with seven positive and seven negative responses centred on a centre point of no change. Figure 1.9.1 shows a typical example of a seven point GROC. Eleven and seven point bidirectional scales are also in use as are unidirectional scales which only measure change in one direction.

Figure 1.9.1 Seven Point Bidirectional GROC Score (Jaeschke, 1989)

Image Redacted for Copyright

There are concerns over the GROC being used as an anchor as it has fluctuant temporal stability as a byproduct of its retrospective nature and there are questions over its correlation with PROMs in general (Garrison & Cook, 2012). However, as yet no-one has reported on an anchor for use in the context of musculoskeletal research which does not suffer from similar problems.

Generic seven point unidirectional scales with text descriptors have been assessed for their own MCID. For each question the MCID is considered to be >1 point change on the 7 point scale though 0.5 - 1 may be clinically significant (Guyatt et al., 1998). All anchor based analyses suffer from the problem that the selection of who is changed and who is unchanged on the anchor is arbitrary. The most common selection on a 15 point scale for improvement is either those reporting change greater than +2 or +3. There are three approaches which can be taken when performing an anchor based calculation as shown below.

Within Patients Score Change - This is calculated as the mean change in score of the the PROM scores for the group who are considered to have positively changed.

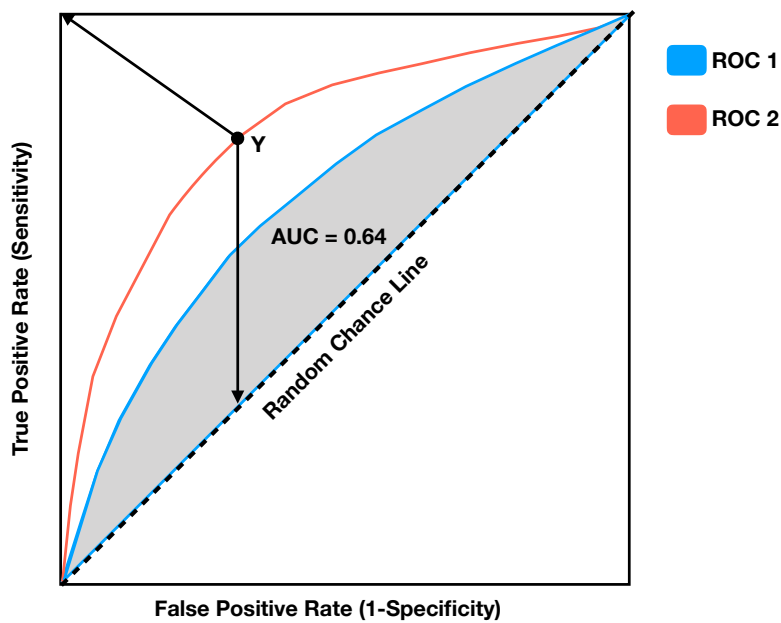
Between Patients Score Change - In this approach the change in scores are compared between groups of patients. In a cross sectional study the between patient score change is defined as the difference in mean PROM score recorded by those considered to have changed and those considered unchanged.

Sensitivity or Specificity Based - In the context of PROMs the sensitivity represents patients who show improvement above the MCID and specificity those patients who do not report an improvement and whose scores are below the MCID. Therefore, a sensitivity of 1 would include all true positives (patients who clinically appreciably improved) and a specificity of 1 all true negatives (patients feeling no clinical benefit). This relies on patients correctly identifying as responders or non-responders.

Because no PROM can realistically be expected to have a sensitivity and specificity of 1, a receiver operating characteristic (ROC) curve can be used to identify the point at which sensitivity most closely equals specificity. This result represents the MCID.

The area under the curve (AUC) should be calculated giving a result of 0.5 - 1 where 0.5 represents an ability to discriminate by chance only and 1 the ability to detect all patients correctly (Gatchel & Mayer, 2010). There is no clear consensus on how to interpret the AUC cutoffs between 0.5 and 1 (Hosmer & Lemeshow, 2000; Safari et al., 2016). The values below are a guide to each cutoff; 0.90-1 = excellent; 0.80-0.90 = good; 0.70-0.80 = fair; 0.60-0.70 = poor; 0.50-0.60 = fail.

Figure 1.9.2 shows two example ROC curves. The black dotted line represents an AUC of 0.5 where any result obtained would be by chance alone. The results of ROC 1 show an AUC of 0.64 which is a poor ability to discriminate. ROC 2 shows better discrimination with a larger AUC. The point marked Y represents the point where the sum of the true positive and true negative values is highest and represents the point of best balance between sensitivity and specificity. While many other points along the line can be used depending on the need for higher sensitivity or specificity, in the context of musculoskeletal research where pain and function are the core areas of interest this is the point most commonly taken to be the MCID.

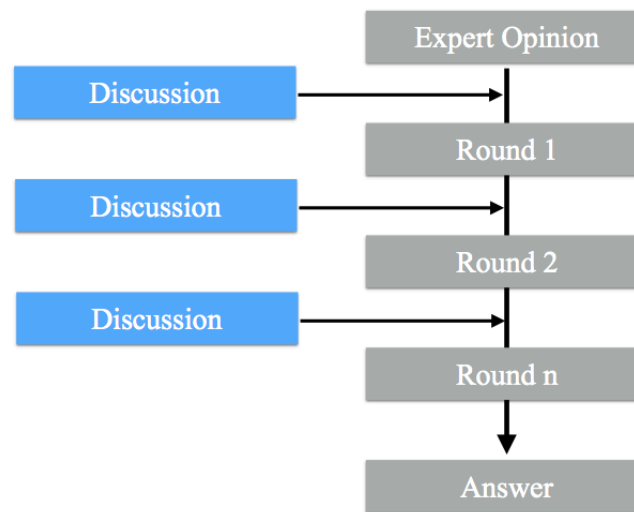
Figure 1.9.2 Example ROC Curve Analysis

The Delphi Method

The Delphi technique is an expert opinion based method to develop a consensus. For the MCID value it can be used once an anchor based and/or a distribution based technique has been applied across multiple studies.

Participants are sent a questionnaire, and asked to respond with their views. The responses are revised once participants have reviewed the results from across the group. This process repeats until consensus is achieved as shown in figure 1.9.3.

The first response typically shows quite divergent results and as the iterations progress the results trend towards convergence of opinion (Black et al., 1999; McKenna, 1994).

Figure 1.9.3 Process for Performing the Delphi Technique

Parker et al. (2012) showed that for heterogeneous groups of patients, using distribution based or anchor based calculations alone gives variable results. It was therefore recommended that a Delphi method is the most appropriate technique to resolve a final answer. Homogenous groups of patients should give a narrower range of variation however, and a Delphi is less likely to be considered.

1.9.3 Recording Baseline Data for PROMs in Trauma Research

In the context of trauma research, prospective data collection on pre-injury function is not possible. There are two methods for dealing with this problem; patient recall or population norms.

In a review looking at which method is most appropriate for emergency admissions it was concluded that for trauma patients, who are on average younger and better functioning, the population norm demonstrates worse baseline symptoms / function than would have been true if the information were collected prospectively (Kwong & Black, 2017). It also found a strong association between retrospective data collection and contemporaneous collection with no consistent pattern of direction of bias where retrospective collection was performed. The association was found to be strongest for recall time periods of less than one month.

Wilson et al. (2012) reviewed pre-injury health status using recall and compared it to the population norms in New Zealand. There was a small but significant increase in recall baseline relative to 12 months PROM scores in patients who reported a complete recovery, but both were found to be significantly higher than the population norm. Their recommendation was to use patient recall over population norms as the baseline.

In order to collect a baseline value of pre-injury function a patient must remember the answers to questions as they would have given them at the last point of 'normal' function. This gives rise to the risk of recall bias. Recall bias is a systematic error, which may affect results by differential recall of a prior health state that is skewed either by the current health state or by the severity of the pre-treatment condition. A longer period of recall also potentially increases the random error.

Wilson demonstrated recall problems with the retrospective use of the Oxford Shoulder Score (OSS) over a timeframe of 6-8 weeks with considerable variation found in paired scores at an individual level (Wilson et al., 2009). There was a 95% chance that the score for one patient would lie within a range of 8 points lower to 10 points higher giving a spread of 18 points, which is higher than that taken as clinically relevant (4.5). At the *population* level the t test revealed a difference of 1.1 (0.2 - 2.4) showing that while patients slightly overestimate symptoms on recall the 95% certainty of the overestimate being 2.4 or less was significantly below the clinically relevant level of 4.5.

Stepan et al. (2013) performed a study on 140 patients with chronic hand and elbow conditions. They recorded a QuickDASH score at their initial appointment and were then contacted at 3, 6, 12 and 24 months and asked to recall their status as first recorded. This showed acceptable levels of recall bias up to 24 months from the initial visit. There was no significant difference in recall between groups of diagnosis, non-/operative intervention, age or level of or change in disability found.

1.9.4 Specific Outcome Measures

There are nine PROMs which are described for use in assessment of the wrist (Dacombe et al., 2016). Below we will describe those that are relevant to this thesis and explain the interpretation of the results they generate.

1.9.4.1 Disabilities of the Arm Shoulder and Hand (DASH)

The DASH score was devised in a joint venture between the American Academy of Orthopaedic Surgeons (AAOS), the Council of Musculoskeletal Specialty Societies (COMSS) and the Institute for Work and Health (Toronto, ON, Canada), and was originally published by Hudak et al. (1996).

It was devised as a self-administered outcome measure for patients with one or multiple musculoskeletal disorders of the upper limb to evaluate symptoms and disability. There are 30 items of which six refer to symptoms (3 pain, 1 tingling/numbness, 1 weakness and 1 stiffness) and 24 refer to function (21 physical function and three social role/function). All items are scored on a five point Likert scale.

Validation was published by Beaton et al. (2001), from the Institute for Work and Health. Correlation with other measures was good ($r > 0.69$) and the test discriminated well. Test-retest reliability was high ($ICC = 0.96$). Responsiveness to self-rated or expected change was comparable or better than that of the joint specific measures in the whole group and in each region confirming its value in assessing the whole extremity.

The DASH is a 30 item questionnaire and in order to shorten it the QuickDASH was developed which includes only 11 items. The QuickDASH is highly correlated with the DASH ($r=0.79$) (Niekel et al., 2009).

Interpretation

- scores reported as the main component and separately the optional sport / music and work components as a score from 0 - 100.
- a higher score indicates greater disability.

1.9.4.2 EuroQol 5 Dimension 5 Level (EQ-5D-5L™)

The EQ-5D-5L™ was developed by the EuroQol group as a health related quality of life (HR-QOL) instrument. Its name is an abbreviation of 'EuroQol

– 5 Dimensions – 5 Levels'. The five dimensions refer to 'mobility', 'self care', 'ability to undertake usual activities', 'pain and discomfort' and 'anxiety and depression'. It is a standardised instrument designed to provide a simple generic measure of health for both economic and clinical appraisal, applicable to a wide range of conditions and interventions.

In an interim position statement the National Institute of Health and Care Excellence (NICE) supports prospective clinical studies in using the EQ-5D-5L™ in place of the three level version (EQ-5D-3L™) with a final decision on which instrument to use due in August 2018.

The score is broken into two parts. The first is the EQ-5D™ descriptive system which attaches a value or 'social preference weight' to each level in each of the five dimensions. The single summary index can be calculated by deducting the appropriate weight from the number 1, the numerical value of full health (ie the summary for full health can be shortened to state 11111). The health state is compared to published value sets described for multiple populations. The most recent value set for England was published in 2018 (Devlin et al., 2018). The second is the EQ-VAS, which is a simple scale from 0-100 where 0 is the worst health and 100 the best, on which respondents mark their health state.

Hurst et al. (1997) validated the EQ-5D in patients with rheumatoid arthritis. They showed that in this patient group the EQ-5D is descriptive and VAS elements were valid, responsive and reliable.

Interpretation

- scores are reported separately on a scale of one to five in each of the five dimensions of the descriptive system giving a reported health state e.g. 1,3,2,1,5.
- the best health would be reported as 1,1,1,1,1 and the worst 5,5,5,5,5.
- scores for the EQ-VAS are marked on a 20cm vertical visual analogue scale and recorded as a score from 0 - 100.
- a higher score indicates better health.

1.9.4.3 Patient Evaluation Measure (PEM)

The Patient Evaluation Measure was developed in 1993 at a conference on 'Outcomes of Hand Surgery', organised by the audit committee of British Society for Surgery of the Hand (BSSH). The findings and an example of the PEM were first published by Macey et al. (1995). There are 3 parts to the PEM; 'treatment', 'hand health questionnaire' and 'general view on treatment and condition of the hand', containing five, eleven and three questions respectively. Each question is presented as a seven item Likert scale. The PEM score is calculated as a percentage from the sum of the answers divided by the maximum possible score for each part.

The original publication of the PEM contained only 10 questions in Part 2. This was subsequently updated to 11 questions with the additional question (question 4) relating to the duration of pain experienced.

The PEM was validated independent of the original authors (Dias et al., 2001). It was shown to be a consistent form with little or no bias from age, side of injury and handedness. It was suggested that when the score was applied repeatedly the patient should be shown their scores from the last visit in order for it to provide a better measure of change. Forward et al. (2007) validated its use in DRF and showed high correlation between the PEM and DASH score. They suggested reducing the effect of coexisting pathology by recording the PEM score for the uninjured side and subtracting this from the injured score. This comparative PEM score was more strongly correlated with outcome, than the PEM score alone.

Interpretation

- score reported as a percentage (14.2% - 100%) for each of the three domains
- lower percentage is a better outcome

1.9.4.4 Patient Rated Wrist Evaluation (PRWE)

The PRWE was developed in Ontario, Canada by a survey of 100 international investigators with the objective of developing a brief, reliable and valid tool to quantify patient reported disability and pain in the wrist (MacDermid et al., 1998). It is a short questionnaire used to assess wrist pain and disability in activities of daily living. There are 15 questions divided

into two subscales; 5 questions to assess pain and 10 questions to assess function. A modified version called the Patient Rated Wrist / Hand Evaluation PRWHE contains the same questions replacing the term “wrist” with “wrist / hand” throughout and adding an optional question about aesthetics.

It was shown to be reliable for distal radius and scaphoid fractures in its initial publication and has been validated for DRF. The PRWE has been translated into multiple languages and validations have been published for the translations into Finnish, Persian, Danish, Korean, Italian, Swedish, Japanese and German.

Interpretation

- score reported on a scale of 0 - 100 (equal weight between pain and function).
- lower score is better outcome (best score 0 and worst score 100).

1.9.4.5 Measure Yourself Medical Outcome Profile (MYMOP)

MYMOP was originally developed for use in general practice and brevity was key to its creation (Paterson, 1996). It is a patient generated 4 item outcome measure which measures the objects the patient themselves consider most important. On the initial MYMOP questionnaire the patient chooses two symptoms which they feel are most important. They then choose the most important physical, social or mental activity, which is limited by these symptoms. Lastly, they answer the set question on general wellbeing in the last week. All items are marked on a seven item Likert scale (0 - 6). The words set at the initial meeting are then used unchanged for every repetition of the MYMOP.

The original MYMOP questionnaire was modified after validation in 2000 to MYMOP2 though as it has not been modified since then this is usually referred to as MYMOP. It was validated through qualitative interviews by the author of the original questionnaire leading to the addition of the medication elements in MYMOP2 (Paterson & Britten, 2000). Independent validation was performed on publication of the German translation (Hermann et al. 2014). They correlated the MYMOP responses against the EQ-5D for

sensitivity to change and found the standardised response mean (SRM) to be 0.88.

1.9.4.6 Global Rating of Change (GROC) Scales

Global rating of change (GROC or GRC) scales are often used in musculoskeletal research to qualify a patient's improvement or deterioration over time both after an intervention or to monitor a chronic disease process. This is common in the context of MCID calculations where the GROC scale is used as an anchor. The patient documents their current health status and then recalls their health at a point in the past with the difference between the two being worked out. The size of the difference is recorded on a numerical or visual analogue scale (VAS). There are a number of scale sizes in use with 15, 11 and 7 point bidirectional scales being most common. Where a minimum clinically important improvement (MCII) is being sought these can be presented as 8, 6 and 4 point unidirectional scales.

Concern exists in the literature of the validity of patient recall of function. Schmitt demonstrated that retrospective GROC scores for patient satisfaction were influenced by post-treatment status whereas a prospective GROC gave a more valid measure over time (Schmitt & Di Fabio, 2005).

1.10 Health Economics of Distal Radius Fractures

A DRF has a number of economic implications, some of which are well researched and some of which are not. Surgical intervention and the type of implant used has a marked influence on the overall cost of treatment.

1.10.1 Societal Economic Implications

A retrospective review of 120 patients comparing plaster casting with locking plate fixation showed the overall cost of treatment for non-operative management to be \$17,079 and operative to be \$18,312 (Espinosa Gutiérrez & Moreno Velázquez, 2010). Where this money went was interesting. For the operative group 54% of the overall cost was attributable to treatment whereas for the non-operative group 94% of the cost was as a result of 'disability days'. This is one argument used in support of locking plate fixation as from a societal perspective, assuming it does actually return patients to work quicker, there will be an earlier return of economic output.

1.10.2 Healthcare Economic Implications

This is the area where the majority of research data lies. Research has centred around the cost analysis of the different management strategies. The first management question is usually whether to use non-operative or operative intervention. Espinosa Gutiérrez paper showed the treatment cost of non-operative management to be \$1,075 and operative to be \$9,850 (Espinosa Gutiérrez & Moreno Velázquez, 2010). Sometimes fracture specific factors necessitate surgery. Where there is a choice in management the argument that surgical intervention accelerates return to function may hold true, but clearly uses far more resources from the healthcare budget.

An analysis of 50 patients from the USA calculated the incremental cost-utility ratio to show the cost of each quality adjusted life year (QALY) gained by using open reduction and internal fixation over and above cast immobilisation. The calculation showed the cost of surgical intervention with a plate to be \$15,330/QALY (Shauver, 2011).

The type of surgical intervention also has a bearing on cost as percutaneous wires have a lower implant cost than locking plates. Farner et al. (2014)

showed in their paper based on Medicaid patients from the USA that the mean cost of percutaneous fixation including treatment of morbidities over the proceeding 12 months to be \$16,111 for percutaneous wires and \$23,498 for internal fixation with a plate.

The focus of this thesis is therapy interventions into distal radius fractures. Robinson et al. showed in their meta-analysis that the overall cost of therapy contributed as little as 0.01% of the total cost of treatment (Robinson et al., 2016; Qu et al., 2014). However, it is the effect on the overall cost burden which is the key to the success of therapy interventions. By addressing individual and workplace factors, earlier return to work will reduce the overall economic implication of DRF.

1.11 Aims and Summary

There are 71,000 distal radius fractures (DRF) sustained in the UK each year. The incidence of chronic pain is reported as 30%, with 11% reporting moderate or severe pain at one year and 16% moderate or severe disability. Almost all patients will show significant recovery in the short and long term following DRF, but no consensus exists on the best method of delivering physiotherapy advice, and whether any method has a significant effect on rate of recovery is not known. The MCID has not been determined for DRF for the commonly used PROMs, hampering both planning and interpretation of studies.

1.11.1 Aims

This thesis is an evaluation of DRF in two parts. The first is a determination of the MCID for the commonly used PROMs. This is referred to as the 'MCID Study'. The second is an analysis of short and long term outcomes in a three arm randomised controlled trial (RCT), which is referred to as the 'Outcomes Study'.

For validity separate cohorts of patients will be used.

The key aims of this thesis are to:

1. Determine the MCID in patients with distal radius fractures for three PROMs:
 - (a) Disabilities of the Arm Shoulder and Hand (DASH)
 - (b) Patient Evaluation Measure (PEM)
 - (c) Patient Rated Wrist Evaluation (PRWE).
2. Assess the MYMOP as an outcome measure in patients with distal radius fractures.
3. Examine outcomes in patients with non-operatively managed distal radius fractures to assess three methods of delivery of therapy advice:
 - (a) advice sheet
 - (b) video
 - (c) in person physiotherapy
4. Calculate the item cost of the three therapy interventions.

1.11.2 Hypothesis

The MCID Study is observational and therefore does not have a hypothesis. However, its results are important to the interpretation of the Outcomes Study.

The null hypothesis of the Outcomes Study is that,

"The method of delivery of physiotherapy advice has no effect on short or long term outcomes in patients with non-operatively managed distal radius fractures".

The outcomes of the three groups will be evaluated against the MCID calculated. Though an estimated population MCID will be used initially for the power calculation, the MCID calculated in the MCID Study will also be retrospectively applied.

2. Methodology

This thesis consists of two separate studies, with the first study informing the results of the second. Separate cohorts of patients were used for each study. This section considers the methods of each separately.

The first study was designed to determine the minimum clinically important difference (MCID) for three commonly used patient reported outcome measures (PROMs) in patients with distal radius fractures (DRF):

- Disabilities of the Arm Shoulder and Hand (DASH)
- Patient Rated Wrist Evaluation (PRWE)
- Patient Evaluation Measure (PEM)

This is referred to as the '**MCID Study**'.

The second was designed to examine whether the mode of delivery of physiotherapy advice affects outcomes in a randomised controlled trial by comparing three methods of delivering advice. This is referred to as the '**Outcomes Study**'.

2.1 MCID Study Design

In musculoskeletal research PROMs are instruments which are often used to assess the symptoms and function of an anatomical region in the context of a particular disease. When a study reports its results it is not enough to demonstrate a statistically significant difference with a PROM. The change in score demonstrated must also be clinically significant to patients for the findings to be accepted. The MCID quantifies what change in score is required. For the purpose of this thesis the term MCID is used synonymously for the minimum clinically important improvement (MCII) as following a DRF the majority of patients are expected to show improvement.

The MCID should be defined for PROMs in a disease specific manner. In this respect it differs from the standard error of measurement (SEM) and the minimal detectable change (MDC) which are a function of the PROM itself. The threshold value for the MCID differs in a PROM, depending on the diagnosis or treatment it is being used to assess. For example using the DASH to assess a patient with a DRF, a change of 9 points may be

appreciable by the average patient whereas for a total shoulder replacement the change may need to be 13 points. The DASH was designed as a measure of global upper limb function so when used to measure shoulder function it will give different values for the MCID compared to the wrist.

The MCID has not been determined for DRF, even for previously validated scores, with the exception of the PRWE which was reported as 11.5 using an anchor based approach (Walenkamp et al., 2015).

2.1.1 Study Design

The MCID Study was an observational study to calculate the MCID for the Disabilities of the Arm Shoulder and Hand (DASH), Patient Evaluation Measure (PEM) and Patient Rated Wrist Evaluation (PRWE). MCID calculations are usually made using either distribution based or anchor based approaches. The ideal study design for a distribution based calculation is different from an anchor based calculation. In order to perform distribution based calculations you need a group of patients in whom the disease is stable, as the result of this type of study is a factor of the error within the instrument, rather than of the disease it is measuring.

For an anchor based approach, the cohort needs to exhibit a change in health status. This study was designed to perform an anchor based calculation. The anchor based method used was based on that used by Jaeschke et al. (1989). Some studies have performed anchor based MCID calculations using just two time points (Walenkamp et al., 2015). Others have sampled multiple time points (Sorensen et al., 2013). The advantage of sampling multiple time points is that it recognises the change in importance of different items within an instrument as a condition changes over time. For a DRF treated in plaster it is likely that between week two and six, items assessing pain will improve whereas functional items will remain quite static. Once the plaster is removed pain will transiently increase and function will improve. For a DRF treated operatively pain items will gradually reduce and functional items improve from week two.

For the DASH and the PRWE there have been multiple distribution based calculations performed describing the error within these instruments. There has only been one paper determining the MCID in DRF using an anchor

based approach (Walenkamp et al., 2015). Therefore, this study was designed to ascertain MCIDs using an anchor based approach in patients who have sustained a DRF. We sampled a cohort of patients over multiple time points, including those treated both non-operatively and operatively.

2.1.2 Selected Outcome Measures & Anchor

PROMs

A balance had to be struck between the number of PROMs included and the risk of questionnaire fatigue. There are 12 PROMs which have been used to investigate DRF, but the bulk of the recent literature uses either the PRWE or the DASH as the primary outcome measure. This is consistent with recommendations made by the COSMIN (Consensus-based Standards for the selection of health Measurement INstruments) initiative and so these are likely to remain the preferred outcome measures (Kleinlugtenbelt et al., 2016; Goldhahn et al., 2014). Therefore the PRWE and the DASH were selected for the MCID Study. The PEM has not been validated for use in trauma research. It was additionally included for the MCID Study as it was an important score for the Outcomes Study, in order to record patients' opinions on their treatment satisfaction.

GROC Anchors

A global rating of change (GROC) scale taken from Jaeschke was selected as the anchor against which the change in PROM scores would be judged (Jaeschke et al., 1989). This GROC scale is a 15 point bidirectional Likert scale with text descriptors ranging from, (0); about the same, to (+7); a very great deal better and (-7); a very great deal worse. This scale is the most commonly used in recent musculoskeletal research. In the original description it was preceded by a three point scale simply stating 'worse', 'about the same' and 'better'. Only patients reporting themselves as 'better' or 'worse' on the initial scale were then given the seven point positive or negative scale. In more recent studies these two steps have been reduced to one and this was the design used for this study.

The bidirectional scale was retained rather than only giving a unidirectional scale to show improvement. While most patients improve after a DRF having a two and six week follow-up point meant that it was possible some patients would report an initial deterioration and it was important that this

was recorded in order to analyse the data correctly and explain missing data-points.

There were two versions of this GROC given to participants, one to assess function and the other to assess pain (GROC^f and GROC^p). Function and pain are the two major domains identified by the COMET (Core Outcome Measures in Effectiveness Trials) initiative (Goldhahn et al., 2014). We wanted to assess whether the MCID would differ with each scale. They were also combined as a mean to generate an overall MCID (GROC^m).

While the 15 point GROC is the commonest scale there are also 11 point and 7 point scales in use. There does not appear to be a consensus on which is best. We therefore also applied an 11 point scale and the positive half of a seven point scale. These were not used to generate the MCID. However, by additionally collecting these scales they could be correlated with the PROMs they were being used to anchor. By creating this correlation matrix, some inferences on which is the most appropriate scale could be made, accepting that larger scales would be expected to inherently show greater correlation.

The first time point at which the GROC scales were given was at six weeks. On this scale participants were asked to recall their change from week two to week six (a recall period of four weeks). For the GROC scales given at twelve and 24 weeks the recall period was six and twelve weeks respectively.

MYMOP

Participants were also asked to complete the Measure Yourself Medical Outcome Profile (MYMOP) (Appendix 4). The MYMOP is a patient generated 4 item questionnaire which measures the symptoms and functional limitation the patient themselves consider most important, and tracks the change in these items over time. At its first application it asks the patient to list two symptoms and one activity which have been affected with the fourth item being an assessment of wellbeing. The second time the patient completes the questionnaire there is the option of recording a third symptom which may have become evident later; in this study by twelve or 24 weeks.

One benefit of including the MYMOP was to identify what items patients with a DRF would identify as the items are patient generated. Its inclusion also allowed for a correlation to be performed with the other more common PROMs.

Table 2.1 shows the time points the questionnaires were applied and the order in which they were given to participants in brackets.

Table 2.1.1 Time-points PROMs Given (Order presented in brackets).

Time Point	DASH	PRWE	PEM	MYMOP1	MYMOP2	GROC
Diagnosis	(2)	(3)	(4)			
2 weeks	(4)	(1)	(2)	(3)		
6 weeks	(5)	(4)	(3)		(1)	(2)
12 weeks (postal)	(5)	(3)	(4)		(2)	(1)
24 weeks (postal)	(1)	(5)	(2)		(4)	(3)

2.1.3 Approvals

The Chief Investigator obtained approval for the study protocol (V3.0 11/04/2014) and documentation from the National Research Ethics Service (NRES) Committee London - Central (14/LO/1255). The study was conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

2.1.4 Study Participants

Potential participants were identified by their clinical team in the fracture clinic. All adult patients with a DRF were considered eligible for inclusion in the study, irrespective of how the injury was managed. In order to generate a broadly applicable MCID it was important to include all eligible patients. The exclusion criteria were therefore designed to remove only those patients who were unsuitable for inclusion for practical reasons or who had sustained a fracture with extension into the radial diaphysis. The eligibility criteria applied are set out in Table 2.1.2. The setting for the study was the Queen's Medical Centre, Nottingham.

Table 2.1.2 Eligibility Criteria for MCID Study

Inclusion Criteria
All adult patients with a distal radius fracture
Able to give informed consent
Exclusion Criteria
A fracture which extends beyond 3cm of the radiocarpal joint
Inability to understand and/or complete the DASH, PEM, PRWE, GROC and MYMOP questionnaires
Physeal fracture pattern
Current participation in another ongoing study
Ipsilateral concurrent upper limb injury or severe polytrauma/ head injury
Unable to attend for routine follow-up (out of area patients)
Delayed presentation/diagnosis (>1 week post injury)

2.2 MCID Study Methods

2.2.1 Calculating the MCID

There is no accepted best practice for calculating the MCID, with the two core techniques being distribution and anchor based. The design for this study was to determine a value for the MCID using an anchor based approach.

The distribution based approach uses statistical analysis of the PROM to determine the error present in the instrument. Any MCID defined must be above the error of the instrument and so a floor value was important to identify in order to judge the results obtained. Using the chosen study design meant it was unlikely that a large enough of group of participants who report as 'unchanged' would be obtained to perform a distribution based calculation. This was therefore obtained through a review of the literature.

2.2.1.1 Distribution Based Calculation

The two common distribution results published are the standard error of measurement (SEM) and then derived from this, the minimal detectable change (MDC). The SEM can be considered the true floor threshold as it is the variation in a PROM which occurs purely due to the unreliability of the instrument. This is not thought to be dependent on the injury of the population being sampled and is considered instrument specific. Using the SEM the MDC can be calculated which is defined as the smallest detectable change above the measurement error to a defined level of confidence.

These calculations require an Intraclass Correlation Coefficient (ICC) requiring a sample from two time-points in patients with a stable disease. There is no clear consensus on what time interval is ideal with Marx reporting no difference between 2 days and 2 weeks (Marx et al., 2003).

The formula below is used to calculate the SEM.

$$\text{SEM} = \text{SD}_{\text{baseline}} [\sqrt{(1-r)}]$$

The test–retest ICC of stable patients, or a measure of internal consistency such as Cronbach's alpha, is normally used to define r (Cronbach, 1951).

Using the SEM the MDC can be calculated. This is the smallest detectable change that can be considered above the measurement error with a given level of confidence (Coppay et al., 2007). The MDC95 is the minimum amount of change in score that ensures the change isn't the result of measurement error with a confidence level of 95% and the MDC90 gives a confidence of 90%.

$$\mathbf{MDC95 = 1.96 \times SEM \times \sqrt{2}}$$

$$\mathbf{MDC90 = 1.65 \times SEM \times \sqrt{2}}$$

Some authors would advocate taking the MDC as the value of the MCID. The problem with this is that the MDC does not take into account a patient's report of their perception of change. Therefore, a more appropriate use of the MDC is to take the published value and use it to compare with the result of an anchor based analysis. When the MCID value is greater than the value of the MDC this confirms the MCID represents a clinically important change, which is larger than the error of the instrument. For this reason in the MCID Study the MDC at a 95% confidence interval was used as the floor value.

It seems counterintuitive to accept a lower level of confidence than is generally accepted in medical research. Many papers report the MDC to a lower confidence with the MDC90 being the commonest alternative. This is often seen in papers where to have used the MDC95 would have reported a smaller MCID than the MDC95 (Dawson et al., 2008; Franchignoni et al., 2014; Walenkamp et al., 2015). To convert the MDC90 to the MDC95 the quoted figure is divided by 1.65 and multiplied by 1.96.

A literature review was conducted to determine the published MDC95 results for the three PROM scores being tested. The literature search was conducted on 27/02/2018 using PubMed. The search strings used were: "*prom name* AND SEM OR MDC OR MCID". The bibliographies of studies identified were also analysed for further papers. Where the MDC90 or the SEM were published this was converted where possible to an MDC95 based on the above equations. The results obtained are shown in Table 2.2.1.

Table 2.2.1 Results of literature search for MDC95 values

		SEM	MDC90	MDC95
DASH	Beaton et al. 2001	4.6	10.7	13.0
	Dawson et al. 2008	4.1	9.3	11.2*
	Schmitt at al. 2004	5.4	12.5	14.8*
	Franchignoni et al. 2014	4.6	10.8	12.7*
	Haldorsen et al. 2014	4.7	11.0*	13.1
	Membrilla-Mesa et al. 2015	4.4*	10.2*	12.2
Mean				12.8
DASH-Work	Kleinlugtenbelt at al. 2018	5.1	11.9	14.1
Mean				14.1
PRWE	Walenkamp et al. 2015	4.7*	11.0	13.1*
	Rosales et al. 2017	4.4	10.2*	12.1
	Schmitt at al. 2004	5.2	12.2	14.6*
	Mean			13.3
PEM Part 2	Forward et al.* 2007	2.7*	6.2*	7.4*
	Bednarek et al. 2016	3.5*	8.1*	9.6*
	Mean			8.5

* derived from published data

The DASH was the most tested PROM with six relevant publications. The range of published estimates for the MDC95 was found to be 11.2 - 14.8. There were three available estimates for the PRWE with a range of 12.1 to 14.6.

There was no formally published estimate of the MDC95 for the PEM. However, Forward et al (2007) undertook an evaluation of the PEM in 200 patients after a DRF with a follow-up of 6 - 42 years. In this paper Cronbach's alpha was calculated as 0.94. The original publication did not quote the standard deviation of the baseline data, so the lead author was contacted and the original dataset was reviewed. The baseline data was found to have a mean PEM of 21 (11 - 64) with a standard deviation of 10.9. The below calculations were therefore used:

$$\text{SEM} = 10.9 [\sqrt{(1-0.94)}] = 2.67$$

$$\text{MDC95} = 1.96 \times 2.67 \times \sqrt{2} = 7.38$$

In order to generate a second estimate for the PEM standard deviation data were taken from Bednarek et al. (2016) in their cohort of 95 participants with Dupuytren's and the same Cronbach's of 0.94 was taken in order to calculate SEM and MDC values.

Only one estimate has been published for the DASH-Work (Kleinlugtenbelt et al., 2018). This was also included in this table as it was used as one of the outcome measures for the Outcomes Study.

For each outcome measure the mean of available results was taken as the final estimate of the MDC95.

2.2.1.2 Anchor Based Calculations

In an anchor based calculation the change in score of a PROM is compared against another external measure which is ideally a gold standard for measuring change. There is no such gold standard. The most commonly used anchor is the global rating of change (GROC) scale which comes in a variety of designs. The GROC chosen was a bidirectional 15 point Likert scale with scores of 1 to 7 showing increasing improvement and -1 to -7 increasing deterioration, modified from Jaeschke and shown in Figure 1.9.1 (Jaeschke et al., 1989). A score of 0 is considered as no change from the last time the score was applied.

In determining the range which can be considered 'no change' there is no clear consensus. It depends on whether patients are able to discriminate between what are essentially arbitrary increments on the GROC scale. Kamper et al. (2009) reviewed this in detail in their review of GROC scales. They reviewed seven, eleven and fifteen point scales. Norman undertook a systematic review and found that a change of two points on an eleven point scale was clinically meaningful (Norman et al., 2003). Stratford inferred that an important improvement should be defined as +5 on a 15 point scale as patients with a lower improvement continued to seek treatment (Stratford et al., 1994). This was the cutoff used by Walenkamp in their calculation of the MCID for the PRWE in DRF (Walenkamp et al., 2015).

With the wide range of views on what represents no change or clinically important, for the ROC curve analysis the data were processed using

different ranges to represent no change. This started with the smallest range of -1 to +1 and increased until the data became impossible to analyse (i.e. when too few participants reported significant change).

All three PROMs being tested contain items which test the two major domains identified by the COMET initiative as important in assessing DRF; pain and function. Participants were therefore asked to complete two GROC scales side by side, one assessing pain (GROC_p) and the second assessing function (GROC_f). The MCID calculations were tested using each GROC scale independently as well as combining them to generate a mean score GROC_m.

Within and Between Patient Score Change

To determine the MCID using the *within patients score change* the mean change in PROM score for those identifying a positive change was calculated.

$$\mathbf{WPSC = mean \Delta score patients_{improved}}$$

To calculate the MCID using the *between patients score change* the mean change in PROM score of patients who improved minus the mean change of those who did not was calculated.

$$\mathbf{BPSC = mean \Delta score patients_{improved} - mean \Delta score patients_{unimproved}}$$

In calculating these values there is no clear consensus on which values should be taken for 'improved'. The group defined as unimproved for this analysis was defined as -2 to +2. In order to define the group taken as improved the first analysis included all participants recording a GROC of >2.

Given that in these analyses a change of 2 points on the GROC was taken as no change, a second analysis was performed using a group from >2 to ≤4 as a group of minimal improvement, separating the final group of >4 as significantly improved. Taking the mean delta for the minimal change group gives a more useful estimate of the change in scores for the value to be used as an MCID.

ROC Curve Analysis

Finally we undertook Receiver Operator Characteristic (ROC) curve analysis. All analyses were performed with GraphPad Prism 7d (GraphPad Software Inc. Ca. USA). The plot was generated from the delta scores for those reporting an improvement (considered the sensitivity), against the delta scores of those reporting no change (as 1-specificity).

The MCID calculation is in effect determining the minimum clinically important improvement (MCII). It was deemed highly unlikely sufficient patients would identify as deteriorated to calculate a negative minimum clinically important change (negative MCIC). Clinically important improvements and deteriorations are not symmetrical, ie a GROC score of -4 cannot be considered a negative change of the same quantity as someone who identifies as +4 is positive. Therefore any participant with a negative GROC score greater than the upper positive boundary for no change was excluded from the respective analysis.

To plot the ROC curve the false positives (1-specificity) and true positives (sensitivity) at each point of the GROC score were plotted on the x and y axis respectively. The MCID was taken as the change in score for which the sum of sensitivity and specificity were greatest. This corresponds to a change in score that is associated with the smallest amount of misclassification. The area under the curve was also calculated to estimate the sensitivity in determining the MCID.

Cutoffs for this area under the curve were taken as:

.90-1 = excellent

.80-.90 = good

.70-.80 = fair

.60-.70 = poor

.50-.60 = fail

Any MCID calculation showing an AUC below 0.6 would be discounted and an AUC >0.7 would be considered preferable.

2.2.1.3 GROCC Correlations

There are a number of GROCC scale sizes which have been used as anchors including seven, eleven and fifteen point scales. In order to determine if, in this data set, any size of scale showed a stronger correlation with the PROMs they were used to anchor, the results were correlated using a Pearson correlation coefficient.

2.2.1.4 Sample Size Estimation

A sample size calculation for a study such as this would be artificial, as the study is not intended to demonstrate the difference between two interventions. In observational studies in general a sample size estimation can be quite complex. However, it is necessary in order to ensure adequate exploration of the objective and so a sample size estimation was performed.

By estimating the number of patients that would be required for a two arm study this was used to infer a suitable number of data-points to demonstrate the MCID. In this study each participant recruited could generate three independent data-points so the estimated sample size is not necessarily a true representation of the number of patients which were needed to be recruited.

A standard deviation of 15.1 for the DASH score was derived from a paper investigating DRF and this was the same data used in the power calculation for the Outcomes Study (Kwok et al., 2011). The minimum effect size was assumed as 13 as no MCID for the DASH has been published for DRF.

STATA® (Release 14.2. College Station, TX: StataCorp LP) was used for the power calculation using the `sampsi` command for sample size. Power was set at 80% and alpha was set at 0.05.

The command used was;

`sampsi 12.5 25.5 , power(0.80) r(1) sd1(15.1) alpha(0.05)`

2.2.2.1 Data Collection

At the initial visit the MYMOP1 asked participants to state which one or two symptoms were most troubling and which usual activity was the most difficult to undertake since sustaining a DRF. These were entered into the score as free text and then were re-applied at all following visits. It also asked participants to record their general feeling of wellbeing over the last week on the same scale. At subsequent visits participants were optionally able to add one further symptom on the MYMOP2. Participants recorded change by circling a number on a 7 point Likert scale numbered 0-6 representing 'as good as it could be' to 'as bad as it could be' respectively.

To ensure that important items were recorded, participants were verbally encouraged to think of the activity and symptoms which were their primary concern at the initial visit. Participants were not led to put any specific item down. For the activity line they were encouraged to think of the activity that they were no longer able to do that they felt was most restricting them. Participants were encouraged to be as specific as possible.

Initial responses from the MYMOP1 were transferred to the MYMOP2 on subsequent CRFs to allow longitudinal analysis of the same symptoms. In any instance that the initially chosen items were not carried forward, the subsequent scores were excluded from the analysis.

The scoring of the MYMOP is to take the mean of the responses from Symptom 1/2/3, Activity 1 and Wellbeing to produce a single value. The minimum data required for the MYMOP to generate a score is for symptom 1 and wellbeing to be completed.

Over the 20 years the MYMOP has been available there have been concerns raised over its validity (Ruta & Garratt, 1996). One may therefore wonder why it was included in this study. There were two analyses planned for the generated data.

2.2.2.2 Patient Important Symptoms and Activities

The first part of this MYMOP analysis identified all domains and items participants picked as affecting them in the context of an acute DRF and with what frequency. A second pass analysis then correlated the items

generated by the MYMOP to items presented in the DASH, PEM and PRWE. The results gave an insight into the items which patients themselves deem important following a DRF and how well these items are covered by the three PROMs.

The results may help inform which PROMs are most valid from a content validity perspective to use in research into DRF and potentially help future revisions of these PROMs to include new items or reinforce those already present. By using the data in this way it is accepted that a majority of the items which were generated came from the two week post injury time-point heavily skewing the items to be relevant in the acute period rather than that of recovery.

Any item created by a participant was included in this analysis, irrespective of whether it would be eligible for inclusion in a final MYMOP score because of inconsistent recording (e.g. a participant changing a symptom between time-points). In order to ensure there was no duplication of items a protocol for item inclusion was followed.

1. All items selected by participants at the 2 week appointment were included first.
2. Any additional symptoms in the symptom 3 box were added.
3. Any missed item generated where a participant had added a previously unrecorded symptom into symptom 2 was added.

The domains assessed in the DASH, PEM and PRWE were used as the basis for the analysis.

1. Symptoms (DASH; PEM; PRWE)
2. Function (DASH; PEM; PRWE)
3. Anxiety (PEM)

There are a number of items in all three PROMs directly relating to 'pain' so this was extracted from the other symptoms and taken as a separate domain, with other symptoms being classified as discomfort (including nerve symptoms).

2.2.2.3 Correlation of the MYMOP with the DASH, PEM and PRWE

A second analysis was performed on the valid MYMOP scores to assess the strength of correlation with the DASH, PEM and PRWE using Pearson's correlation coefficient. This analysis was designed to assess how strong any correlation of the MYMOP would be, as it is not validated in the assessment of patients with DRF and indeed any traumatic injury.

The analysis was conducted for each time point. There is no formally accepted interpretation of the strength of correlation. The cutoff values used to quantify the strength of correlations were;

0.0 - 0.2 - very weak

0.2 - 0.4 - weak

0.4 - 0.6 - moderate

0.6 - 0.8 - strong

0.8 - 1.0 very strong

Correlation analyses were performed using GraphPad Prism 7d (GraphPad Software Inc. Ca. USA).

2.3 Outcomes Study Design

The Outcomes Study was designed to determine whether the mode by which physiotherapy advice is given to patients has an effect on outcomes in uncomplicated DRF and to calculate the item cost of the interventions.

2.3.1 Study Design

The study was a single centre three arm randomised controlled trial with 1:1:1 allocation to three parallel groups. The participants given the usual fracture clinic advice sheet were considered the active control (Group A) and the participants receiving the video (Group B) and in person physiotherapy (Group C) were the two intervention groups. The trial was conducted and reported according to the CONSORT (Consolidated Standards of Reporting Trials) 2010 statement (Schulz et al., 2010).

The study was designed to compare the two main currently accepted methods of delivery of therapy advice (leaflet and in person physiotherapy) and a third method which is not in common use (video). The basic advice of active range of movement exercises given to patients was the same in all three groups. A pragmatic approach was taken so that those patients receiving routine care did not have that treatment modified, thereby measuring the effectiveness of the three approaches in practice, rather than trying to demonstrate efficacy.

The initial trial design was a superiority design as reported in the protocol (Appendix 2). After the protocol was drafted the design was refined. The results of the Outcomes Study were considered to be likely to act as a pilot to a larger study. With a three arm design it was deemed necessary, after discussion with the study statistician, to reduce alpha through a Bonferroni adjustment. Though the originally planned smaller effect size would have been preferable (based on the power to detect a Δ DASH of 6), it was decided to increase this to 13, accepting the larger effect size (Cohen's $d = 0.86$). Making this change made the number of patients needed to recruit to this single centre trial achievable.

It was also decided that for the purposes of planning a larger study, the possibility of an equivalence design would be explored. The extension to the

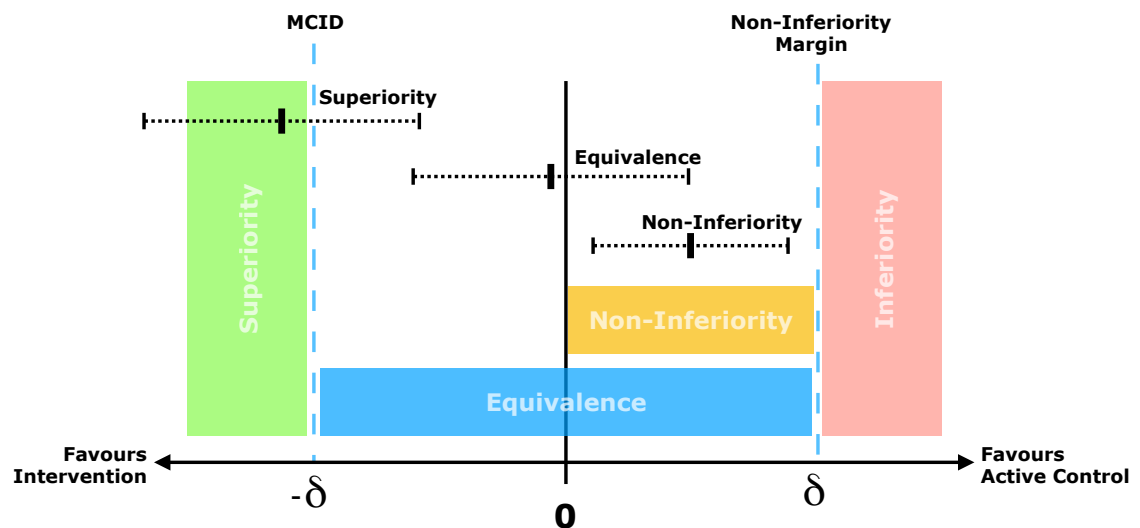
CONSORT 2010 statement, "Reporting of Noninferiority and Equivalence Randomized Trials" was reviewed (Piaggio et al., 2012). In the results section the data analyses were performed for both superiority and equivalence designs, in order to inform any future study design.

One could argue a fourth non-intervention or true control group would have been preferable. However it was felt that this would be problematic from the standpoint of gaining ethical approval and would also have negatively impacted the ability to recruit patients. Therefore an advice sheet was used as an active control, presuming this was the most commonly used standard of care against which to judge the other two interventions.

The evidence to date has not given clear guidance on whether an advice sheet and home exercise programme or in person physiotherapy is superior. There is no evidence for a home exercise programme guided by videos. A home exercise programme supported by either video or leaflet is expected to give advantages in terms of convenience and cost. Therefore we set out to test whether the two intervention groups were superior in their effectiveness to the active control group.

Because of the uncertainty of the direction of effect of the video intervention, an equivalence design for the secondary analysis was chosen over a non-inferiority design as it allows for two tailed effects. Defining the equivalence margin or δ is key to interpreting the results obtained in this type of analysis. This creates a significant issue in clinical drug trials as δ can be difficult to define and is often ultimately derived through a process of negotiation. Where a PROM is being used as the primary outcome measure however, the MCID can be used to define δ . In general the MCID is halved and this was the approach taken. The MCID Study will calculate the MCID for the DASH score which was used retrospectively to define δ . The interpretation will be as shown in Figure 2.3.1.

Figure 2.3.1 The Margins accepted to demonstrate equivalence, non-inferiority and superiority with example means and 95% confidence intervals.



This study was not designed to undertake an economic analysis. However, it was felt useful to calculate the item costs of each intervention on a per participant basis and also collect basic data on employment in order to inform any future study which might include an economic analysis.

2.3.2 Approvals and Registration

The study protocol (V2.4 13/08/2015) was reviewed and approved by the National Research Ethics Service (NRES) Committee Nottingham 2 (15/EM/0297) and the Nottingham Integrated Clinical Research Centre Research & Innovation department (14OR014). The study was conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. The Nottingham Clinical Trials Unit provided oversight to the trial conduct.

The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines were used in designing the study protocol. The study was registered with the International Standard Randomised Controlled Trial Number (ISRCTN) registry (ISRCTN62731680) where a summary of the protocol, inclusion and exclusion criteria are available.

2.3.3 Study Participants

Patients eligible for this study were those with DRF treated non-operatively who were between the ages of 18 and 70 at the time of fracture. The focus was on adult patients who could be considered 'uncomplicated' and an upper limit of 70 was applied to capture participants who were of working age at the time of fracture.

The eligibility criteria are set out in Table 2.3.1. The exclusion criteria were designed to remove those patients with excessive stiffness or evidence of risk for CRPS. It was felt that this group would benefit from early mobilisation with direct in person supervision from a physiotherapist and would reasonably have been offered follow-up appointments both with the medical team and physiotherapy department. These patients were not the intended focus of this research.

Table 2.3.1 Eligibility Criteria for Outcomes Study

Inclusion Criteria
Adults aged 18 - 70 years at time of fracture
Able to give informed consent
Any distal radius fracture within 3cm of the radiocarpal joint deemed suitable for non-operative management by the treating physician
Fracture treated with immobilisation worn constantly for between 5 - 7 weeks
Able to converse in English without the need of an interpreter to a sufficient level to utilise the video
Exclusion Criteria
A fracture which extends beyond 3cm of the radiocarpal joint
Any patient with bilateral fractures
A fracture which has been immobilised outside of the range of 5 - 7 weeks
Any patient who is deemed unable to adhere to the trial procedure or complete the questionnaires (eg drug dependence or cognitive impairment). The patient must be able to access the video.
Current participation in another ongoing study
Evidence of complex regional pain syndrome
Post plaster stiffness of the fingers which prevents the patient from being able to place their hand flat on a tabletop
Any previous fracture of the wrist or carpal bones whether treated operatively or non-operatively

Any fracture of the distal radius within 3cm of the radiocarpal joint was eligible including intra-articular fractures, fractures with comminution, associated ulnar styloid fractures and both dorsal and volar displacement patterns, provided it was deemed suitable for non-operative management by the treating physician.

To be eligible, patients were required to confirm they could access a video either on DVD at home or on the internet using YouTube®. The online link to the video was kept private to ensure that participants in other groups did not access the video.

The setting for the study was the Queen's Medical Centre, Nottingham. This is an acute teaching hospital which has the designation of a Level 1 trauma centre serving a population of 4.3 million patients. All patients attending the fracture clinic referred by a member of the usual clinical team were screened for inclusion and approached at the point immobilisation was removed and the treatment episode had therefore ended.

2.4 Outcomes Study Methods

2.4.1 Study Interventions

Participants were recruited using block randomisation in groups of 6 using a pre-generated randomisation key. At recruitment there was allocation concealment using sealed envelopes though from this point there was no blinding of participant or researcher. The randomisation key was generated using an online service provided by www.sealedenvelope.com. The key was used to create all the study packs before recruitment commenced and then it was held in a sealed envelope by the research coordinator.

Advice Sheet (Group A)

Participants who received the advice sheet were considered the active control group. The advice sheet outlines seven key exercises which reflect the advice given at a first consultation with a physiotherapist.

Video (Group B)

Participants receiving the video were considered an intervention group and to be receiving a novel intervention. Whilst the use of video advice for physiotherapy is commonplace on the internet, the evidence base behind it is limited. The physiotherapy video was created by two senior physiotherapists working at the Queen's Medical Centre one of whom is the trust lead for wrist and hand physiotherapy. It provides the same basic level of advice as in person physiotherapy with the stepwise approach patients would receive with regular follow-up over roughly four sessions.

In Person Physiotherapy (Group C)

Participants who were allocated to the physiotherapy group were given a standard referral to the physiotherapy department and were seen on the day of recruitment after their plaster or splint was removed, in line with usual practice. There was no attempt to control the physiotherapy provided or number of visits offered. The treating physiotherapist was not made aware that the patient was part of a research study at any point by the research team to avoid bias in treatment. Data were captured for this group to record the number and duration of sessions participants attended in the hospital for economic analysis. Though this was also not controlled, it would

be standard practice for patients attending in person physiotherapy to receive the same advice sheet used for the active control.

2.4.2 Outcome Measures

Between five and seven weeks following injury participants had their cast or splint removed and were randomised. At this point participant demographics, occupational history and diabetes status were recorded along with baseline results for the three PROMs using patient recall. Participants were reviewed twice more; five to seven weeks following recruitment and at 1 year ($\pm$ one month) following injury. Objective outcomes were performed by the principal investigator or an appropriately trained member of the research team who was able to take readings for range of movement and grip strength.

In the event of a participant not attending a follow-up appointment they were initially sent an appointment for the following week and a letter containing the three PROMs. After a second non-attendance the participant was contacted by phone and offered three options; a further in person appointment, to complete the PROMs over the phone or to send the previously provided PROMs back by post. Participants were always asked to confirm they were happy to continue as part of the study in the event of non-attendance. Where they indicated they were not, they were marked as having withdrawn and given an open appointment to their previous clinic in the event there was a clinical reason for them to need to return.

2.4.2.1 Primary Outcome Measure

Measurements of grip strength or range of motion, while clearly objective and common in the literature may not be the most meaningful outcomes to a patient. The natural primary outcome was therefore a PROM. There is no consensus on the gold standard PROM for assessment of DRF and at the time of study design no applicable PROM had an MCID published, in order to make an accurate power calculation possible.

The COMET (Core Outcome Measures in Effectiveness Trials) initiative published guidance in 2014 identifying the core outcome set (COS) for patients with DRF and providing evidence on the best PROMs which met these criteria (Goldhahn et al., 2014). They identified the primary domains

as pain and function. A numeric scale was recommended for pain (with the pain sub-scale of the PRWE being recommended) and for function either the *QuickDASH* or PRWE function sub-scale were seen as reliable.

Selection of the 'ideal' PROM depends on what you want to assess. This study was interested in determining return to general function but also specifically function at work in a relatively fit and younger cohort of patients with DRF. The PRWE only contains one item on function in work, whereas the DASH has the optional DASH Work module which contains four items generating a separate score.

It is also worth considering that for meta-analysis to be performed there has to be some consistency in the literature. Goldhahn et al. (2014) also reviewed all prospectively designed studies and case series assessing DRF and found the DASH was by far and away the most commonly used PROM over the last 25 years. Because the DASH has been commonplace in the assessment of upper limb injuries, standard deviation data were available for a sample size calculation accepting that a best guess was needed for the MCID as none has been published.

The primary outcome measure selected was the DASH score taken at 12 weeks following injury (± 2 weeks) with the optional DASH Work being completed as a secondary outcome for participants working at time of injury.

2.4.2.1 Secondary Outcome Measures

The Patient Evaluation Measure (PEM) is a PROM score specific to the function of the hand and wrist on the affected side, but also contains items in the domain of anxiety and depression, as well as environmental and personal factors. It was selected as a secondary outcome because with the introduction of a physiotherapy video as a novel intervention, participant satisfaction was felt to be an important consideration. In order to avoid questionnaire fatigue the PEM was chosen but the PRWE was rejected as a secondary outcome.

At all time points clinical parameters were recorded for both the injured and uninjured sides. The range of movement in flexion and extension was

recorded using a goniometer with the shoulder adducted, the elbow flexed to 90 degrees and the forearm pronated. The angle between the ulna border and 5th metacarpal was recorded. This technique for range of motion was used as it was identified as the most comfortable position for a patient in the period immediately after plaster or splint removal.

Grip strength was assessed with a calibrated JAMAR Dynamometer (Jamar, Jackson, MS, USA) and the best of three attempts was taken as the definitive value with verbal encouragement used to obtain the maximal result. The handles were set at 6cm spacing unless this was too uncomfortable in which case it was adjusted for the patient. The highest rather than the mean of three results for grip strength was chosen as it was found that patients tend to give three sequentially better scores on the injured side as their confidence increases following plaster removal. The MCID for grip strength has been calculated in a group of patients following volar plating for DRF as 6.5kg using both distribution and anchor based assessment (Kim et al., 2014). This value was used as the cutoff for clinical significance.

There has traditionally been a 10% rule in hand rehabilitation which states that the dominant hand is 10% stronger than the non-dominant hand in the absence of any confounding pathology (Bechtol, 1954). More recent research has indicated that this is only true for right hand dominant people with left hand dominant people showing equal grip strength (Peterson et al., 1989). Therefore when determining the baseline strength for the injured side the algorithm in Table 2.4.1 was used.

Table 2.4.1 Grip Strength Adjustment for Hand Dominance

	Right Wrist Injured	Left Wrist Injured
Right Hand Dominant	+ 10%	-10%
Left Hand Dominant	+ 0%	+ 0%

For those patients who were not able or willing to return for follow-up, a postal request was made to record the PROM scores for all time points in order to minimise patients loss to followup. This precluded collection of the clinical measurements for these participants.

At 12 weeks following injury participants were asked to complete a study specific questionnaire on satisfaction with their therapy intervention and to give a simple subjective assessment of their return to function on a VAS. For those allocated to the video group, participants were asked how they chose to access the video, how often they used it and whether they found it useful and effective.

2.4.3 Bias

Bias is defined as any tendency which prevents an unprejudiced consideration of the research question. Bias can enter at any phase of the research process from inception to publication and is almost impossible to eliminate. The key is therefore to make a genuine effort to eliminate as many sources of bias as possible. The two main sources of bias in this research were selection bias and observer bias. Treatment bias on the part of the physiotherapist for that group was minimised by blinding.

Selection Bias

The target cohort for this research was patients who are expected to have an uncomplicated recovery. It is our belief that for patients with complications such as CRPS or excessive stiffness that referral to a physiotherapist is the standard of care and not to do so would be unethical. The exclusion criteria were designed such that these patients were not recruited.

An age range of 18-70 was applied with the express intent that participants recruited to this study were patients who were of working age and in whom a high baseline level of function was present. While this meant the results were not applicable to the whole population of patients with wrist fractures this bias was intentional and it was accepted that the results were only relevant to the group being studied.

Sealed envelope randomisation was used in order to minimise bias at the stage of randomisation by the research team. There were only three people recruiting to the study and all were trained. One of those recruiting was an orthopaedic surgeon with no strong bias in favour of one intervention over another. One was a research coordinator with a non medical background

and no preconceived bias for any of the interventions. The third was a research nurse again with no stated bias on screening.

The main remaining source of potential bias was that either the patients' medical team or the patient themselves believed that a referral to physiotherapy was desirable and therefore they were not recruited by declining to participate. In order to minimise this for the physicians, detailed information was disseminated at the start of the study and a request for any concerns was made. No concerns were expressed and support for the research was universal. Eligible patients were referred to the research team once the plaster was removed and the treating physician was satisfied that none of the exclusion criteria were met. At this point the patient was presented clearly with the three treatment arms in the study. It was made clear firstly that the advice being provided was not the focus of the research, rather it was the method by which that advice was given. Secondly it was made clear that should they be referred for physiotherapy that this intervention was not controlled and their physiotherapist would be blind to the fact that were part of a research study.

Observer Bias

The issue of observer bias occurs when the person assessing the outcome knows the group assignment. It would have been possible to blind the researcher to the treatment applied. This was not done for a number of reasons. The first was logistical, simply that there were not enough people who were not aware of the allocation to be reliably available for follow-up. The second was that a key part of the follow-up was seeking information including any qualitative information on the patient experience with their therapy intervention. The third was that the primary and secondary outcomes were patient reported outcome measures or questionnaires which were completed by the patient with no input from the research team. Clinical parameters were collected in a standardised way at the start of the follow-up appointment before any discussion was undertaken or questionnaires completed.

2.4.4 Clinical Trial Analysis

2.4.4.1 As Treated & Intention-to Treat Analysis

The Outcomes Study was designed as a superiority trial with a secondary equivalence analysis. In an equivalence design an 'as treated' (AT) analysis is preferred and in a superiority design an 'intention to treat' (ITT) analysis is usually employed. An ITT analysis is generally preferred in pragmatic randomised controlled trials as it reflects the variation which occurs in practice. The main expected protocol violations were participants who sought their own physiotherapy or who required crossover at follow-up due to evidence of CRPS or excessive wrist or finger stiffness.

In order to inform any future study arising from this work, both analyses were performed. It is considered good practice to perform both analyses as if the ITT analysis results are aligned with the AT analysis, the overall confidence in the study results is increased (unless a large number of protocol violations have occurred).

2.4.4.2 Dealing with Confounders

A confounder is a variable which may affect the outcome of the trial but which does not occur as a result of allocation. Randomisation is considered the best way to prevent confounders from affecting the final results and in general having more than 100 participants will allow the groups to balance.

A commonly used technique to analyse confounders is by looking for statistical significance between the groups. The risk in doing this is that provided the randomisation technique has been conducted correctly any variation is by definition caused by chance and statistical analysis, which seeks to demonstrate how likely a result could have occurred by chance is therefore redundant.

The optimal way of dealing with confounders is to conduct analysis of the data by disregarding each confounder and then adjusting for it. Where the two analyses align the inference is that the confounder did not have a significant affect on outcomes and where they do not align it is clear the confounder needs to be adjusted for. According to the guidelines presented in the CONSORT statement baseline data should be presented with mean

and standard deviations for continuous variables and proportions for categorical data (Schulz et al., 2010).

In this study there are a number of potential confounders which are outlined in table 2.4 along with the planned strategy to control for any significant imbalance found.

Table 2.4.2 Potential Confounders

Confounder	Control Strategy
Fracture Classification	Nominal Logistic Regression
Age	Linear Regression / Non-parametric Regression
Gender	
Hand Dominance	Binary Logistic Regression
Diabetes	

Linear regression can only be used to control for age assuming there is a normal distribution of data. Should the data be non-normally distributed log transformation will be attempted and if it remains non-parametric after this, non-parametric regression would be attempted.

2.4.4.3 Missing Data

With 120 participants it was inevitable that for various reasons there were some data missing from the final dataset. There is no agreed method of dealing with missing data but in ITT trials, imputation of missing data is common. For the results of this study, analysis was performed using GraphPad Prism 7d (GraphPad Software Inc. Ca. USA). This software package performs a complete case analysis where n is the data available for analysis rather than $n=120$. Naturally this reduces the power and a loss to follow-up of 20% was accommodated for in the sample size calculation for the primary outcome. It was decided that imputation would be considered if there was greater than 20% missing data for the primary outcome.

2.4.4.4 Randomisation

The process of randomisation involves allocating participants to known groups with the allocation given occurring by chance. For this study there

were three groups for the random allocation. A computer generated list was created using an online service (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>). In case the study needed to be stopped early, block randomisation was used with a block size of six. The random key generated an allocation associated with a number from 001 - 120. These numbers were applied to 120 envelopes and then appropriate packs were inserted into the envelopes and sealed. These sealed envelopes were stored in the clinic and when a patient agreed to be a participant the envelope was opened to reveal the allocation. Participants were recruited in numerical sequence. The original random allocation was stored in a sealed envelope and held by the research coordinator.

2.4.4.5 Sample Size Calculation

A sample size calculation allows for an estimation of the number of participants which will be needed in a study in order to be able to test the hypothesis. In performing this calculation a number of assumptions must be made.

Standard deviation (SD) data were difficult to find for the DASH score where participants were of the younger age group this study sought to examine. Ultimately SD data were taken from a paper examining results in patients following operatively managed DRF where separate results were reported for a group under the age of 55 (Kwok et al., 2011).

The minimum clinically important difference (MCID) has not been calculated in DRF for the DASH score. The MCID is defined as the smallest change in a score which is meaningful to patients. The minimal detectable change (MDC) is slightly different, in that it is the smallest change which is greater than the measurement error of the instrument. The MDC₉₅ is the minimal detectable change with 95% confidence.

According to guidelines from the Institute for Work and Health (ON, California) who created the DASH score the MCID for the DASH score lies in the range of 8 - 17 with a mean of 12.5 points. A mean MDC₉₅ of 12.8 was calculated by literature review in the MCID Study. These results were therefore rounded to 13 and were taken as the presumptive MCID. The result of the MCID Study will retrospectively be applied.

The nature of this study raised the possibility of a higher drop out rate than the generally accepted 10%. By the nature of the injury one would expect that most of the participants will have a good outcome and those with the best outcomes will have little or no incentive to return. By intentionally focusing on a population who are younger and work age they are also more likely to be geographically mobile and harder to track. The need to take time away from work may act as a disincentive to return. The loss to follow-up allowed for was therefore taken as 20%.

The calculation using the data at this stage was expected to power the study for the primary outcome measure of the DASH score at 12 weeks ($\pm$ 2 weeks) from injury. However, there are three groups being randomised in this study. As it is of an equivalence design and in order to control the number required the primary analysis will be of three hypotheses; A vs. B, A vs. C and B vs. C.

A Bonferroni adjustment was made to accommodate multiple hypotheses including the secondary outcomes of the DASH Work and PEM, adjusting alpha to 0.01. Normally you would take alpha as 0.05. If you therefore perform 20 experiments or examine 20 hypotheses, you will get the result that one is significant by chance alone (type I error). Therefore using the Bonferroni correction for five hypotheses by taking alpha from 0.05 down to 0.01 you ensure that each one hypothesis will only occur by chance 1 in 20 times (though this is traded off against an increase in type II error which is inevitable when alpha is decreased).

STATA® (Release 14.2. College Station, TX: StataCorp LP) was used for the power calculation using the 'sampsi' command for sample size. Power was set at 80%. Using all of the above information the command used was;

sampsi 12.5 25.5 , power(0.80) r(1) sd1(15.1) alpha(0.01)

This was based on the following information:

Primary Outcome : DASH score at 3 months from injury.

Test Ho : $m_1 = m_2$ where m_1 is the mean in population 1
and m_2 is the mean in population 2

Assumptions:

MCID = 13

alpha = 0.01 (two-sided)

power = 0.8

m1 = 12.5

m2 = 25.5

sd1 = 15.1

sd2 = 15.1

n2/n1 = 1.00

Estimated Required Sample Size : 32 per group

With a loss to follow-up of 20% this gives the number of patients needed to recruit with sufficient power to be 120.

2.4.4.6 Statistical Analysis

The statistical analysis for this study was performed using GraphPad Prism 7d (GraphPad Software Inc. Ca. USA). The study was designed to be an analysis of three hypotheses; A vs. C, B vs. C and A vs. B. There were two analyses performed. First the data were tested for significance using an analysis of variance (ANOVA) of A vs. B vs. C. ANOVA is more conservative than multiple t-tests and reduces the type 1 error (false positive rate).

The individual hypotheses were also tested irrespective of whether a positive result was found using ANOVA using an unpaired t-test and Tukey's multiple comparisons test to accommodate for multiple hypotheses. This was felt necessary in order not to miss any possibly significant finding which could inform any future study design. For example in the presence of data suggesting a significant difference between two of the groups only, this could indicate a future larger study should concentrate on only two randomisation groups. The data compared between the groups was a delta, calculated by subtracting the baseline score from the subsequent time-points.

2.4.4.7 Health Related Quality of Life

In order to assess health related quality of life the most commonly used instruments come from the EuroQol Research Foundation. For this study the EQ-5D was selected, which is the instrument recommended by NICE. The

EQ-5D-5L contains five domains with five levels in each. The domains are 'mobility', 'self-care', 'usual activities', 'pain or discomfort' and 'anxiety or depression'. The EQ-5D-5L can therefore define 3125 health states. It also contains the EQ VAS which records self-rated health on a visual analogue scale. The endpoints are labelled 'The best health you can imagine' (100) and 'The worst health you can imagine' (0). The VAS gives a quantitative measure of health according to the patient's subjective judgement.

The EQ-5D-5L has been validated in many countries across the world for many different patient populations. EuroQol have published index value sets by which health states can be resolved to a single value based on values from each country. The five level variant was selected (EQ-5D-5L) as opposed to the three level (3L) as by increasing the number of levels per dimension, the sensitivity was increased and the ceiling effect reduced. The previous EQ-5D value datasets using the 3L variant were unusual in the United Kingdom (UK) in that a third of respondents gave a negative value which indicates that their self reported health state was worse than death. This was not found in other countries.

In order to develop a baseline for this study population, participants were asked to recall their baseline state which required recall of between five and seven weeks. While giving the potential to create bias this was accepted so that the study population could be validated against population norms. The most recent value set for England was used (Devlin et al., 2018).

2.4.5 Derivation of Item Costs

The advice sheet and video incur initial set-up costs. Once created they can be used indefinitely with the only recurring cost being the paper for printing or the physical media (if used) for the video. The advice sheet used in this study was already in use prior to inception and therefore did not incur an actual creation cost. The video as a novel intervention was created for this study. A net present value approach was employed for these interventions, taking into account data on production cost where available spread across a ten year period, divided by the total number of participants with DRF at 2017 prices.

All three interventions generated a small time commitment within clinic. The advice sheet and video require some degree of explanation from the providing physician. A referral for physiotherapy requires the completion of a referral card. A sample of patients from each group had the interventions timed and there was no significant difference in time requirement between the three groups. This was therefore discounted from calculations.

For the physiotherapy group participants were referred as standard referrals and their treatment by the physiotherapy department was not controlled. Physiotherapy is allocated on a sessional basis in our institution with sessions being 15 minutes, 30 minutes or 1 hour long. Most patients receive an initial 30 minute appointment and then a decision on need for and duration of additional sessions is decided. Nottingham City Clinical Commissioning Group (CCG) pays for these appointments on a sessional basis irrespective of the grade of the therapist providing the care. The number of individual sessions and duration were collected for all patients in the physiotherapy group.

Guidance from The National Institute for Health and Care Excellence (NICE) states that in economic evaluations, value added tax (VAT) should not be included in calculations and so all consumable costs related to the leaflet and video were quoted exclusive of VAT (NICE, 2008).

3. Results

3.1 MCID Study Results

The results of the MCID calculations are presented below, followed by the results of the nested MYMOP study.

3.1.1 Recruitment & Data Acquisition

Forty-two patients were recruited to the study. Four participants withdrew from the study before enough data had been supplied for analysis and so they were excluded leaving 38 participants enrolled. The maximum period of follow-up was 24 weeks.

A data-point was generated each time there was a GROC completed with two PROMs either side. Each participant had the potential to generate three independent time-points so there were a potential 114 data-points available from the 38 participants in the study. The time points for the generation of data-points and the cumulative loss is shown in Table 3.1.1.

Table 3.1.1 Generation and cumulative loss of data for each time point

	Data-points Collected	Data-points Lost	Cumulative Loss of Data-points (%)
6 Weeks	30	8	21
12 Weeks	19	19	36
24 Weeks	8	30	50

3.1.2 Participant Demographics

The demographic distribution of the cohort is shown in Table 3.1.2. The AO/OTA classification was used to record fracture classification. This was recorded as 2R3-A/B/C. The further sub-type of 1/2/3 was not included due to the known poor inter and intra-observer reliability (Plant et al., 2015).

Table 3.1.2 Participant demographics

		Overall n (%)
Participants		38 (100)
Age $\pm$ SD (Years)		59 $\pm$ 16
Female Gender		34 (89)
Right Hand Dominance		33 (87)
Dominant Side Injured		20 (53)
Operated	Overall	8 (21)
	Volar Locking Plate	7 (18)
	K-wires	1 (3)
Manipulated (Excluding Operated)		20 (53)
AO/OTA Classification	2R3A	23 (61)
	2R3B	8 (21)
	2R3C	7 (18)
Dorsal Comminution		21 (55)
Ulnar Styloid Fracture		18 (47)
Positive Ulnar Variance		12 (32)

3.1.3 Anchor Based Calculations

The core calculations for the MCID Study are based around the anchor technique. As described in the methods section the distribution based MDC95 values derived from a literature search were taken as the floor value, as they describe the error within the instrument. The final MDC95 values derived are shown in table 3.1.3.

Table 3.1.3. MDC95 values for the DASH, PRWE and PEM Part 2

	MDC95
DASH	12.8
PEM	7.4
PRWE	12.6

Participants were asked to complete two GROC scales for each time point: GROC^f measuring function and GROC^p pain. GROC^m was calculated as a

mean of the two GROC scales. There were 54 data-points available for the DASH and PEM and 55 for the PRWE.

3.1.3.1 Within and Between Patients Score Change

The within (WPSC) and between (BPSC) patients score changes were calculated using two groups of improvement;

1. Two Categories: No Change (-2 to +2) and Improved (>2).
2. Three Categories: No Change (-2 to +2), Minimal Improvement (>2 to ≤4) and Significant Improvement (>4).

These categories were chosen as this analysis relies on mean change and to have too small a group (as would be the case using -1 to +1 as the no change group) would bias the data with outlying results. The categories chosen also gave a good balance of participants falling into the no change and minimal change groups.

The numbers of participants in the three groups are shown in Figure 3.1.1 and the results of both analyses are shown in Table 3.1.4.

Figure 3.1.1 Participants identifying as no change, minimal improvement and significant change

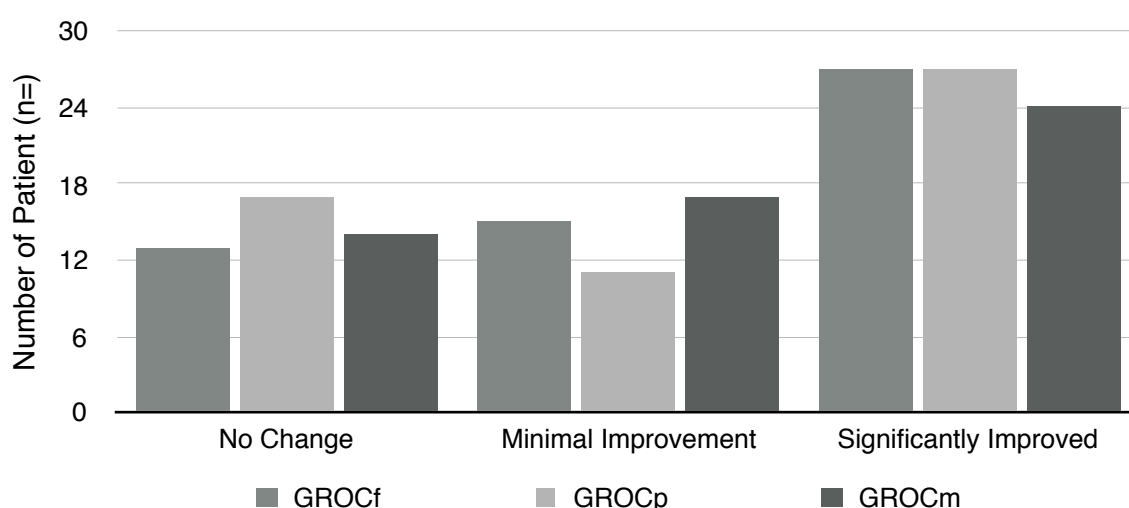


Table 3.1.4 Within and between patients score changes

		Within Patients Score Change	Within Patients Score Change	Between Patients Score Change	Between Patients Score Change
		Two Categories (No Change / Improved)	Three Categories (No Change / Minimal Improvement / Significant Improvement)	Two Categories (No Change / Improved)	Three Categories (No Change / Minimal Improvement / Significant Improvement)
DASH	GROC^f	18	15	7	4
	GROC^p	19	12	10	3
	GROC^m	18	15	7	4
PEM	GROC^f	13	14	8	9
	GROC^p	13	10	8	5
	GROC^m	13	9	5	1
PRWE	GROC^f	21	21	13	13
	GROC^p	23	20	17	14
	GROC^m	21	19	13	11

3.1.3.2 ROC Curve Analysis

ROC curves were used to calculate the MCID for the DASH, PEM and the PRWE. The first analysis was to determine whether varying the range of GROC scores for patients identifying as 'no change' had an effect on the results. This analysis was performed using the results from the GROC^m. Ultimately five analyses were run as using -6 to +6 did not leave enough participants in the improved group for the analysis. The results are shown in Table 3.1.5.

Table 3.1.5 Analysis of varying the no change group.

		Number of Data-Points No Change / Improved	AUC	Sensitivity %	Specificity %	MCID
-1 to +1	DASH	6 / 49	0.75	61.2	83.3	13.5
	PEM	6 / 48	0.68	56.3	80.0	9.5
	PRWE	6 / 49	0.78	62.5	83.3	13.5
-2 to +2	DASH	13 / 42	0.63	60.5	58.3	13.5
	PEM	12 / 42	0.60	57.1	58.3	9.5
	PRWE	13 / 42	0.72	61.9	69.2	14.5
-3 to +3	DASH	19 / 36	0.61	61.1	52.6	13.5
	PEM	18 / 36	0.62	61.1	61.1	9.5
	PRWE	19 / 36	0.65	63.9	63.2	14.5
-4 to +4	DASH	31 / 25	0.62	64.0	51.6	13.5
	PEM	30 / 25	0.64	68.0	60.0	9.5
	PRWE	31 / 25	0.66	68.0	58.1	14.5
-5 to +5	DASH	43 / 13	0.56	53.9	44.2	13.5
	PEM	42 / 13	0.60	69.2	52.4	9.5
	PRWE	43 / 13	0.59	61.5	58.1	15.5

Using a range of one point on the GROC scale resulted in the greatest area under the curve implying the greatest sensitivity to change. Varying the ranges had no effect on the calculated MCID for the PEM and DASH. For the PRWE the MCID was found to increase from 13.5 to 15.5 with the AUC falling from 0.78 to 0.59. The PRWE consistently demonstrated the greatest AUC, albeit by quite a small margin over the DASH.

The calculations were performed again to compare the results of the function and pain anchors (GROC^f and GROC^p). The result of GROC^m is shown for comparison. The no-change group of -2 to +2 was used for this analysis. Despite the AUC being greater using the range of -1 to 1 for no change, too few participants reported as unchanged on the pain scale for comparative analysis. Any result smaller than -2 was therefore excluded as a significant deterioration. The results are shown in Table 3.1.6.

Table 3.1.6 ROC analysis of the different 15 point GROC scales.

		Number of Data-points	AUC	Sensitivity %	Specificity %	MCID
DASH	GROC^f	55	0.64	60.47	58.33	13.5
	GROC^p	53	0.66	59.46	56.25	13.5
	GROC^m	55	0.63	60.5	58.3	13.5
PEM	GROC^f	54	0.67	59.52	66.67	9.5
	GROC^p	54	0.67	63.16	56.25	8.5
	GROC^m	54	0.60	57.1	58.3	9.5
PRWE	GROC^f	55	0.70	61.90	69.23	14.5
	GROC^p	55	0.73	63.16	64.71	14.5
	GROC^m	55	0.72	61.9	69.2	14.5

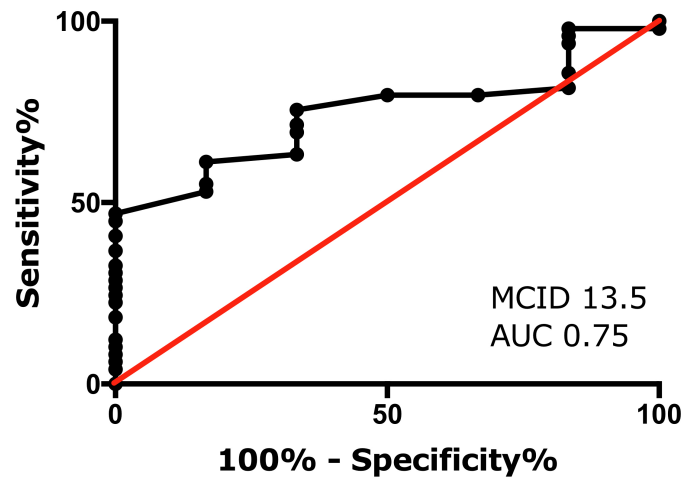
The use of the different scales had no effect on the results of the DASH or PRWE. For the PEM the GROC^p had a slightly lower MCID estimate of 8.5 compared to the GROC^f and GROC^m.

Based on the above two analyses, for the final ROC curve analysis the range of -1 to +1 was used to identify no-change as this offered the greatest AUC and the results were based on the GROC^m, having shown no significant difference between the GROC scales.

DASH

The overall MCID for the DASH was calculated as 13.5. The ROC curve for GROC^m is shown in Figure 3.1.2.

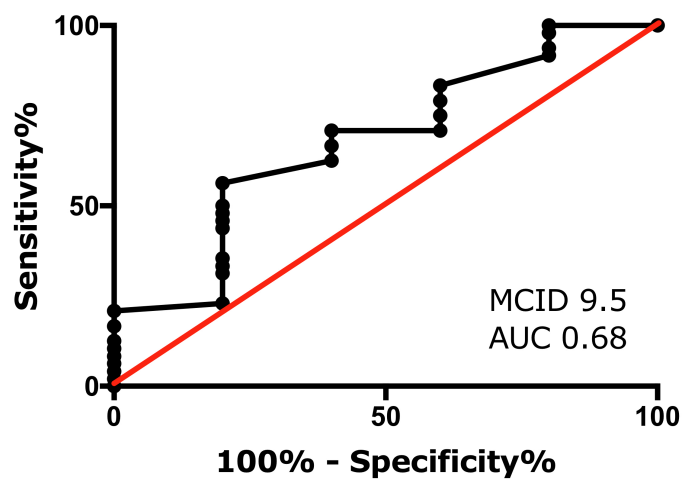
Figure 3.1.2 ROC curve for the DASH generated with GROC^m



PEM Part 2

The overall MCID for the PEM was calculated as 9.5. The ROC curve for GROC^m is shown in Figure 3.1.3.

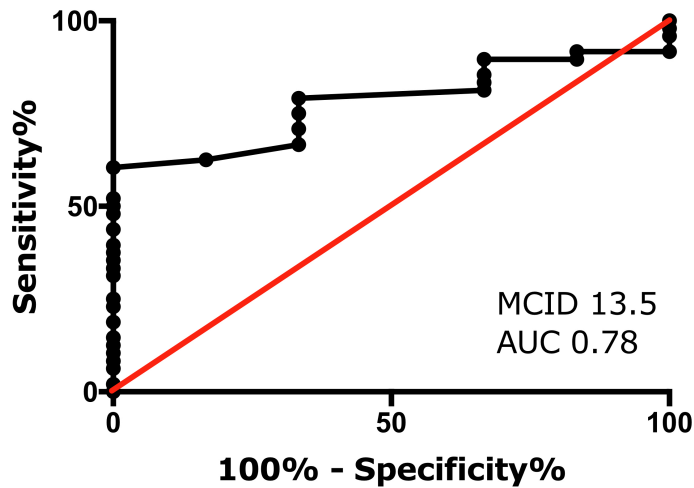
Figure 3.1.3 ROC curve for the PEM generated with GROC^m



PRWE

The overall MCID for the PRWE was calculated as 14.5. The ROC curve for GROC^m is shown in Figure 3.1.4.

Figure 3.1.4 ROC curve for the PRWE generated with GROC^m



3.1.4 Complications

Complications were recorded both prospectively and retrospectively for the cohort and the final complication rate is reported at 24 weeks follow-up.

The final complication rates are recorded in Table 3.1.6.

Table 3.1.7 Complications by one year.

Complication	Number	Incidence (%)
Excessive Stiffness	1	2.6
Delayed Union	1	2.6
CRPS	1	2.6

Overall 3 participants (7.9%) were recorded as having a complication. The complication rates were within the normal range reported in the literature (McKay et al., 2001).

3.1.5 GROC Analysis

In addition to the two 15 point GROC scales, participants also completed an 11 point GROC scale and the positive half of a seven point scale. Each of the GROC scales were correlated to the scores recorded on the three PROMs using Pearson correlation coefficient. The results are shown in table 3.1.8.

Table 3.1.8 Correlation of the GROC scales with PROM scores

	DASH	PEM Part 2	PRWE
15 Point GROC ^f	-0.601	-0.606	-0.621
15 Point GROC ^p	-0.593	-0.622	-0.619
15 Point GROC ^m	-0.629	-0.645	-0.651
11 Point GROC	-0.466	-0.411	-0.496
7 Point GROC	-0.283	-0.294	-0.303

The 15 point GROC scales all showed a strong correlation with the PROMs. The 11 point GROC demonstrated moderate correlation and the seven point GROC only weak correlation. All results demonstrated a P value of <0.001.

3.1.6 MYMOP Analysis

The MYMOP is a PROM which is based on patient generated items. The items identified by its completion were analysed in two ways.

3.1.6.1 Results of Patient Important Symptoms and Activities

The aim of the first MYMOP analysis was to identify all items participants would pick and with what frequency. Therefore any item created by a participant was included in this analysis, irrespective of whether it would have been correct in terms of the official scoring of the instrument. The time points at which items were generated is shown in table 3.1.9.

Table 3.1.9 Time items were generated by the MYMOP

Time Items Generated	Number	Proportion of Items (%)
2 Weeks	74	89
6 Weeks	8	10
12 Weeks	1	1
24 Weeks	0	0

Because the MYMOP was first completed at two weeks this was where the majority of items were recorded. However a smaller number were added at six weeks in the optional symptom 3 section or by a participant later adding a symptom 2. A total of 89 items were generated. Six of these were unclassifiable and so were excluded leaving 83 items for analysis. The items excluded were; "still in plaster"; "physical" (x2); "pain in foot"; "physically limiting"; "everything takes longer to do". The 83 remaining items were allocated to domains taken from the DASH, PEM and PRWE to validate the criterion validity of responses.

Where a participant recorded the domain itself in the free text (i.e. wrote discomfort) this was recorded as 'global'. Overall the functional domain was the most diverse but also largest, generating 56% of responses. Pain represented the second largest domain generating 25% of responses. Non-pain symptoms of discomfort accounted for 13% of responses. Anxiety and depression were the smallest domain generating 5% of responses. The results are shown in table 3.1.10.

Table 3.1.10 Analysis of patient generated items from the MYMOP score

Domain		Symptom 1	Symptom 2	Activity	Symptom 3	Total	%
Pain		16	3		2	21	25
Discomfort	Global		1			1	
	Aching	1	1			2	
	Nerve	2	3		1	6	
	Bruising	1				1	
	Loss of sleep		1			1	13
Function	Global	2	4			6	
	Dexterity	2				2	
	Weakness	2				2	
	Crafts	1		2		3	
	Self Care	1	2	3		6	
	Stiffness		1			1	
	Housework			1		1	
	Gardening			2		2	
	Gym / Sport			5		5	
	Cooking			2		2	
	Work			3		3	
	Driving			5	1	6	
	Medication			1		1	
	Eating			1		1	
	Typing			1		1	
	Writing			2		2	
	Walking			2		2	55
Anxiety & Depression	Fear of Falling	1				1	
	Feeling Vulnerable		1			1	
	Frustration		1			1	
	Depression	1			1	1	5
Total		30	18	30	5	83	98*

*rounding error

Table 3.1.11 Comparison of items generated by the MYMOP with the DASH, PRWE and PEM

Domain		DASH	PEM	PRWE
Pain		24, 25	2, 3, 4	1,2,3,4,5
Discomfort	Global	-	-	-
	Aching	-	-	-
	Nerve (Tingling / Pins & Needles)	26	1	-
	Bruising	-	-	-
	Loss of sleep	29	-	-
Function	Global	22,23	8, 9	12, 13, 14, 15
	Dexterity	3	5	8
	Weakness	1, 5, 7, 27	7	9,10
	Crafts	17	5	15
	Self Care	13, 14, 15	-	11, 12
	Stiffness	28	6	-
	Housework	7	8	13
	Gardening	8	8	13
	Gym / Sport	18, 19	-	15
	Cooking	4	8	13
	Work	23	9	14
	Driving	20	-	-
	Medication	-	8	-
	Eating	16	8	7
	Typing	-	-	-
	Writing	2	-	-
	Walking	20	-	-
Anxiety & Depression	Fear of Falling	-	-	-
	Feeling Vulnerable	-	-	-
	Frustration	30	-	-
	Depression	30	10, 11	-
Total		19/27 (70%)	13/27 (48%)	12/27 (44%)
% of Items Included from PROM		24/30 (80%)	11/11 (100%)	14/15 (93%)

A second analysis was performed to correlate the items generated with items present in the DASH, PEM and PRWE in order to demonstrate their content validity. The numbers recorded in the table correspond with the question numbers in each of the PROMs. The results of this are shown in Table 3.1.11. The DASH included items which matched the largest number of responses, with the PEM coming second and the PRWE third. However, the PEM relied heavily on the very open question 8; “for every day activities my hand is now”. The sensitivity of this question would somewhat depend on how it was interpreted by the patient completing it.

3.1.6.2 Correlation of MYMOP and the DASH, PEM and PRWE

A key part of the assessment for the MYMOP in terms of establishing its validity was to correlate it to the PEM, DASH and PRWE. All PROM scores were found to be normally distributed using frequency distribution with only a slight negative skew for the DASH and PRWE. Pearson correlation coefficient was calculated (r) and the results with the significance are shown in Table 3.1.12.

Table 3.1.12 Correlation between MYMOP and the DASH, PEM and PRWE

		n	r	Strength of Correlation	P
DASH	2 Weeks	28	0.317	weak	0.100
	6 Weeks	27	0.481	moderate	0.011
	12 Weeks	17	0.833	very strong	<0.001
	24 Weeks	6	0.829	very strong	0.041
PEM	2 Weeks	28	0.357	weak	0.062
	6 Weeks	27	0.431	moderate	0.025
	12 Weeks	16	0.766	strong	<0.001
	24 Weeks	6	0.961	very strong	0.002
PRWE	2 Weeks	28	0.373	weak	0.052
	6 Weeks	27	0.481	moderate	0.006
	12 Weeks	16	0.834	very strong	<0.001
	24 Weeks	7	0.914	very strong	0.004

The MYMOP correlated with all three PROMs and the strength of correlation increased as the time from injury increased reaching acceptable and significant levels at six weeks.

3.2 Outcomes Study Results

3.2.1 Survey of National Standard of Care

In order to make an assessment of the national standard of care regarding basic treatment and physiotherapy interventions in DRF a survey was conducted. This was done via questionnaire seeking responses from orthopaedic trainees around the country. The questionnaire was distributed online via the British Orthopaedic Trainees Association (BOTA). Approval to collect this data was obtained from the audit office of Nottingham University Hospitals NHS Trust (Trust Audit Registration Number: 18-101c).

The questionnaire was distributed in November 2016 and over the following 4 weeks 69 responses were collected from 10 training regions within England. The questionnaire is included in appendix 3.

Table 3.2.1 Results of survey into national standard of care

Duration of Immobilisation (Weeks)	Undisplaced Fracture	5.1 ± 0.9
	Displaced Fracture	5.7 ± 0.5
Primary Method of Immobilisation (%)	Plaster	79
	Splint	13
	Patient Choice	7
Standard Therapy Intervention (%)	Advice Sheet	49
	Video	0
	Physiotherapy	40
	Verbal Only	9
	Nothing	3
Standard Method of Follow-up (%)	Discharge	63
	Open Appointment	36
	Routine Follow-up	1
Duration of 'Fit Note' (Weeks)	Light Work	1.9 ± 0.8
	Heavy Work	3.6 ± 1.6

After a DRF 40% of patients are sent for physiotherapy as a routine intervention whereas 49% receive an advice sheet. Virtually no patient receives a planned follow-up appointment.

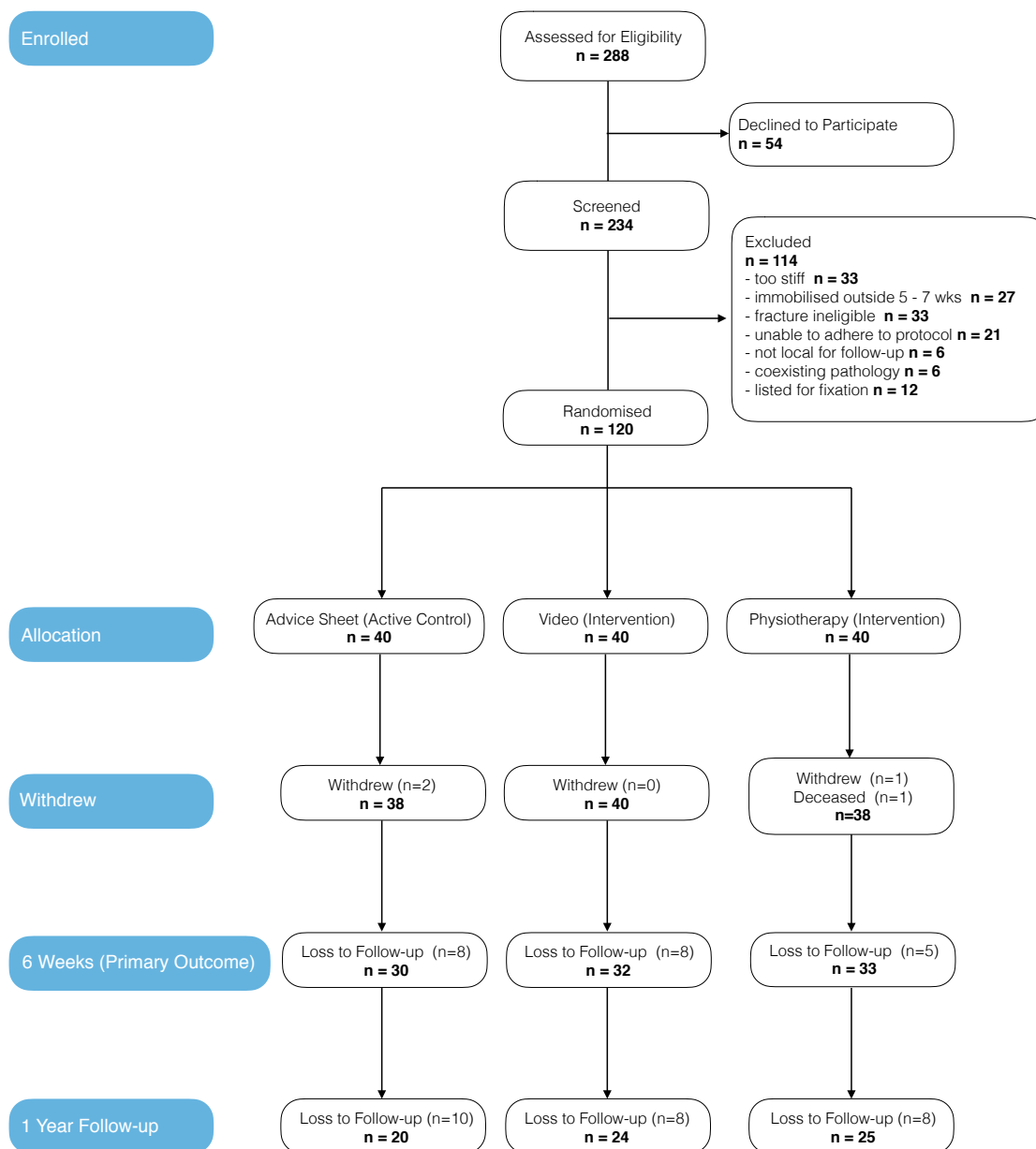
3.2.2 Recruitment

Between September 2015 and June 2017, 288 patients were referred to the research team for inclusion in the Outcomes Study; 114 of these patients did not meet the inclusion criteria and 54 declined to participate in the study. Ultimately 120 participants were recruited. These participants were randomised in blocks of six using sealed envelopes for blinding to the three groups, with forty being allocated to each group.

Four participants were excluded from the analysis. One participant sadly died of an unrelated cardiac cause before their first follow-up. Two participants consented and had baseline data recorded but withdrew within 24 hours. The final participant incorrectly recorded their baseline data such that it was unusable and did not attend for follow-up to allow the baseline to be re-recorded. Therefore 116 participants were included in the analysis.

The primary outcome was the DASH score at six weeks post recruitment (twelve weeks post injury). At six weeks, of the 116 participants, 95 attended for follow-up (82%). This was above the threshold loss to follow-up of 80% accounted for in the power calculation. Six week follow-up (three months post injury) was recorded at a mean of 90.2 days post injury (56-170).

At one year, 69 participants returned data, 20 in Group A, 24 in Group B and 25 in Group C. One-year follow-up was recorded at a mean of 362 days post recruitment (231 - 536). Retention was difficult for this time point as participants were largely returned to near baseline function. Where the in person follow-up was missed, participants were offered postal return or phone completion of PROMs. The Consort flow chart is shown in figure 3.2.1.

Figure 3.2.1 CONSORT enrolment flow chart

3.2.3 Missing Data

The numbers of participants who were lost to follow-up at the two time points are shown in Table 3.2.2.

Table 3.2.2 Loss to follow-up at each time point

	Group A	Group B	Group C	Total (%)
6 Weeks	8	8	5	21 (18%)
1 Year	18	16	13	47 (41%)

The reduction in power caused by loss to follow-up was accounted for in the power calculation and at the primary endpoint loss to follow-up was less than 20%. At the primary outcome of six weeks, there were 4584 potential data points in the data collection table of which 100 were missing, accounting for 2.2% of the whole data set.

3.2.4 Protocol Deviations

Protocol deviations were prospectively sought at follow-up, including specifically asking if participants had arranged in person physiotherapy, accepting that it relied on participants providing accurate information. A description of the identified protocol deviations and the participant status as excluded or reallocated are shown in Table 3.2.3.

Table 3.2.3 Protocol deviations with 'as treated' group re-allocations

Participant	Group Randomised	Six Weeks	One Year	Protocol Deviation
003	B	Excluded	DNA	Lost DVD on way home and didn't perform any exercises.
007	A	A	C	Self-referred to physiotherapy after primary outcome.
023	A	A	C	Crossed over to physiotherapy at 6 weeks.
034	A	A	C	EPL rupture at 6 weeks post recruitment. Had done exercises but operatively managed and attended physio post-op.
068	B	C	C	Returned early to general clinic and sent for physiotherapy before 6 weeks.
071	A	DNA	C	Returned 8 days after recruitment and sent for physiotherapy.
088	A	A	C	Diagnosed with Dupuytren's at 6 weeks. Hand team sent to physiotherapy.
099	A	A	C	Self-referred to physiotherapy after primary outcome.
103	B	Excluded	C	EPL rupture at 3 weeks post recruitment. Didn't use the DVD or do any exercises.

Excluding participant 003 and 103 from the six week data reduced the number for analysis to 93/116 representing 80% follow-up, thus maintaining the power of the study.

3.2.5 Participant Demographics

The demographic distribution of the three groups is shown in Table 3.2.4.

Table 3.2.4 Participant demographics for primary outcome.

		Group A	Group B	Group C	P value
Participants n	Baseline	38	40	38	
	6 Weeks	30	29	34	
	1 Year	14	22	33	
Age $\pm$ SD (Years)	Baseline	49 $\pm$ 15.7	44 $\pm$ 14.9	54 $\pm$ 12.8	0.02
	6 Weeks	50 $\pm$ 14.7	47 $\pm$ 14.4	53 $\pm$ 13.25	0.22
	1 Year	49 $\pm$ 17	47 $\pm$ 15	56 $\pm$ 11	0.06
Female Gender n (%)	Baseline	28 (74)	26 (65)	26 (69)	0.70
	6 Weeks	22 (73)	21 (72)	24 (71)	0.99
	1 Year	10 (71)	16 (73)	27 (82)	0.46
Right Hand Dominance n (%)	Baseline	33 (87)	34 (85)	35 (92)	0.62
	6 Weeks	27 (90)	26 (88)	31 (91)	0.81
	1 Year	11 (80)	18 (84)	31 (94)	0.31
Dominant Side Injured n (%)	Baseline	13 (34)	14 (35)	17 (45)	0.58
	6 Weeks	9 (30)	11 (38)	16 (48)	0.29
	1 Year	5 (36)	7 (32)	13 (39)	0.85
High Energy Mechanism n (%)	Baseline	8 (21)	11 (28)	11 (29)	0.71
	6 Weeks	7 (23)	8 (28)	9 (26)	0.93
	1 Year	3 (21)	5 (23)	5 (15)	0.76
EtOH At Injury n (%)	Baseline	3 (8)	7 (18)	1 (3)	0.08
	6 Weeks	3 (10)	5 (17)	0 (0)	0.05
	1 Year	1 (7)	2 (9)	1 (3)	0.63
Manipulated n (%)	Baseline	19 (50)	21 (53)	17 (45)	0.79
	6 Weeks	16 (53)	16 (55)	17 (50)	0.92
	1 Year	7 (50)	14 (64)	19 (58)	0.73
Diabetes n (%)	Baseline	1 (3)	1 (3)	1 (3)	0.99
	6 Weeks	1 (3)	0 (0)	1 (3)	0.63
	1 Year	1 (7)	0 (0)	1 (3)	0.47

The mean age for the cohort overall was 50 (S.D. 14.1). There was no significant difference between the groups. The mean gender ratio for the cohort overall was 69% female. There was a slight bias for men to not attend follow-up such that at 6 weeks (the primary outcome) 72% of participants were female.

The mechanism of injury was recorded, including an assessment of whether this would be considered high or low energy. Low energy was recorded where the mechanism was a fall from a standing height or less, whereas a high energy incident was recorded for either a greater height or high kinetic energy mechanisms such as sports injuries. Overall a high energy mechanism was recorded in 26% of injuries. The involvement of alcohol (EtOH) was also recorded separately and was reported as a factor in 9% of injuries.

Immobilisation was with POP in 98% and splint in only 2%. One of the two participants treated with a splint received a POP for two weeks followed by three weeks of splint and the other was immobilised in a splint for five weeks.

The employment characteristics were recorded prospectively and the characteristics are outlined in Table 3.2.5. Overall 75% of participants were in paid work at the time of recruitment, 18% were retired, 2% unemployed, 4% in full time education and only 3% identified as a homemaker.

At the point of primary outcome those returning were 74% in paid work, 18% retired, 5% unemployed, 3% in full time education and 0% were homemakers. No one group represented disproportionate attrition.

Table 3.2.5 Participant employment

		Group A	Group B	Group C
In Employment n (%)	Baseline	28 (74)	30 (75)	29 (76)
	6 Weeks	21 (70)	22 (75)	26 (76)
	1 Year	10 (71)	15 (68)	23 (70)
Classification at Baseline n	Fine Skill	1	1	3
	Clerical	20	19	21
	Light Manual	4	6	2
	Heavy Manual	3	4	3
	Homemaker	2	1	0
	Retired	7	6	8
	Unemployed	0	2	0

The AO/OTA classification was used to categorise the fractures into groups. These were recorded as 23-A/B/C. The randomised groups showed a comparable distribution of fracture pattern with Group A being the commonest. The classification of the initial injury at the three time points is shown in Table 3.2.6.

Table 3.2.6 AO/OTA Classification

		2R3A	2R3B	2R3C
Group A (%)	Baseline	55	26	19
	6 Weeks	63	13	23
	1 Year	57	14	21
Group B (%)	Baseline	68	15	17
	6 Weeks	75	13	13
	1 Year	68	14	18
Group C (%)	Baseline	61	24	15
	6 Weeks	64	18	18
	1 Year	64	15	21

The groups were considered balanced at the time of primary outcome and therefore no control strategy for confounders was deemed necessary.

3.2.6 Clinical Trial Results

The results of the analysis of clinical and functional outcomes are presented below. First the data is considered using an as treated analysis, to allow for an additional equivalence analysis to be explored and then using an intention to treat analysis for the superiority analysis. For the PROMs the data is reported as a Δ score. The more positive the Δ , the worse an intervention was in returning the participants to baseline. Statistical analysis was performed for three hypotheses (A vs. B / A vs. C / B vs. C) using an unpaired t-test and for A vs. B vs. C using a one-way ANOVA.

3.2.6.1 Primary Outcome Measure (DASH)

DASH

The primary outcome measure for this trial was the DASH score at six weeks. For ease of reading the additional DASH Work which was a secondary outcome will also be considered in this section. The mean baseline DASH for the whole cohort was 3 (S.D. $\pm$ 8). For the primary outcome at six weeks and one year follow-up there was no significant difference found. The results are shown in table 3.2.7.

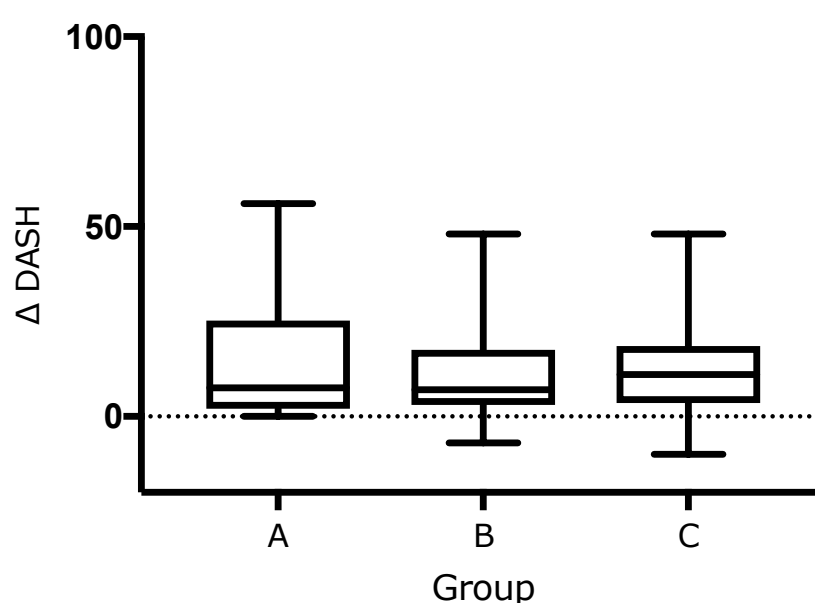
Table 3.2.7 Baseline and Δ Scores for the DASH

		DASH	
Group A	Baseline $\pm$ SD	1 $\pm$ 5	
	Δ 6 Weeks $\pm$ SD	15 $\pm$ 16	
	Δ 1 Year $\pm$ SD	4 $\pm$ 5	
Group B	Baseline $\pm$ SD	3 $\pm$ 10	
	Δ 6 Weeks $\pm$ SD	11 $\pm$ 12	
	Δ 1 Year $\pm$ SD	4 $\pm$ 12	
Group C	Baseline $\pm$ SD	2 $\pm$ 7	
	Δ 6 Weeks $\pm$ SD	13 $\pm$ 13	
	Δ 1 Year $\pm$ SD	8 $\pm$ 12	
		6 Weeks	1 Year
A vs. B : t test (Tukey's)		0.25 (0.45)	0.91 (0.99)
A vs. C : t test (Tukey's)		0.53 (0.78)	0.31 (0.59)
B vs. C : t test (Tukey's)		0.53 (0.83)	0.37 (0.58)
A vs. B vs. C (ANOVA)		0.48	0.49

Acknowledging the multiple hypotheses a post-hoc analysis using Tukey's multiple comparisons test was made with the adjusted P values reported in brackets next to those of the standard t-test.

The primary outcome results were plotted as a box and whisker plot shown in Figure 3.2.2. The negative values represent a small group of participants reporting improved function. This is likely a result of recall bias of their baseline status.

Figure 3.2.2 Box and whisker plot of Δ Scores for the DASH at 6 weeks



DASH Work

Participants who completed the DASH also optionally completed the DASH Work module if they were in employment at the time they were enrolled. The mean baseline for the DASH Work was 0 (S.D. $\pm$ 2).

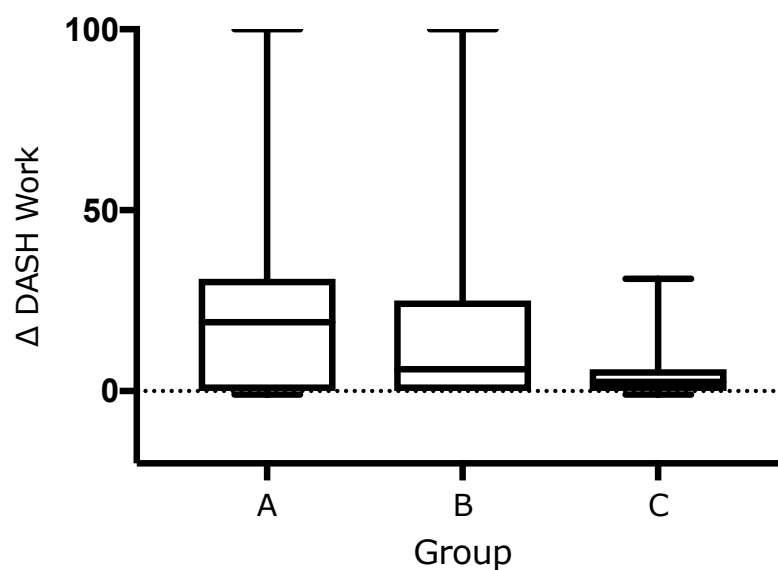
A statistically significant result with the t-test was identified comparing leaflet (Group A) to in person physiotherapy (Group C) indicating in person physiotherapy is superior to leaflet. This was lost using Tukey's multiple comparisons however (alpha was set at 0.01 with the Bonferroni adjustment). The six-week delta identified for Group A was 23 and for Group C was 7 with the difference between the groups being 16. The MDC95 identified for the DASH Work in the methods section was 14.1. The results are shown in table 3.2.8.

Table 3.2.8 Baseline and Δ Scores for the DASH Work

		DASH Work	
Group A	Baseline $\pm$ SD	1 $\pm$ 3	
	Δ 6 Weeks $\pm$ SD	23 $\pm$ 29	
	Δ 1 Year $\pm$ SD	4 $\pm$ 9	
Group B	Baseline $\pm$ SD	0 $\pm$ 1	
	Δ 6 Weeks $\pm$ SD	17 $\pm$ 26	
	Δ 1 Year $\pm$ SD	2 $\pm$ 5	
Group C	Baseline $\pm$ SD	0 $\pm$ 0	
	Δ 6 Weeks $\pm$ SD	7 $\pm$ 11	
	Δ 1 Year $\pm$ SD	4 $\pm$ 9	
		6 Weeks	1 Year
		A vs. B : t test (Tukey's)	0.39 (0.57)
		A vs. C : t test (Tukey's)	0.01* (0.05)
		B vs. C : t test (Tukey's)	0.11 (0.36)
		A vs. B vs. C (ANOVA)	0.06

*significant result

Tukey's multiple comparisons test was made with the adjusted P values reported in brackets. The DASH Work results were also plotted as a box and whisker plot as shown in Figure 3.2.3.

Figure 3.2.3 Box and whisker plot of Δ scores for DASH Work at 6 weeks

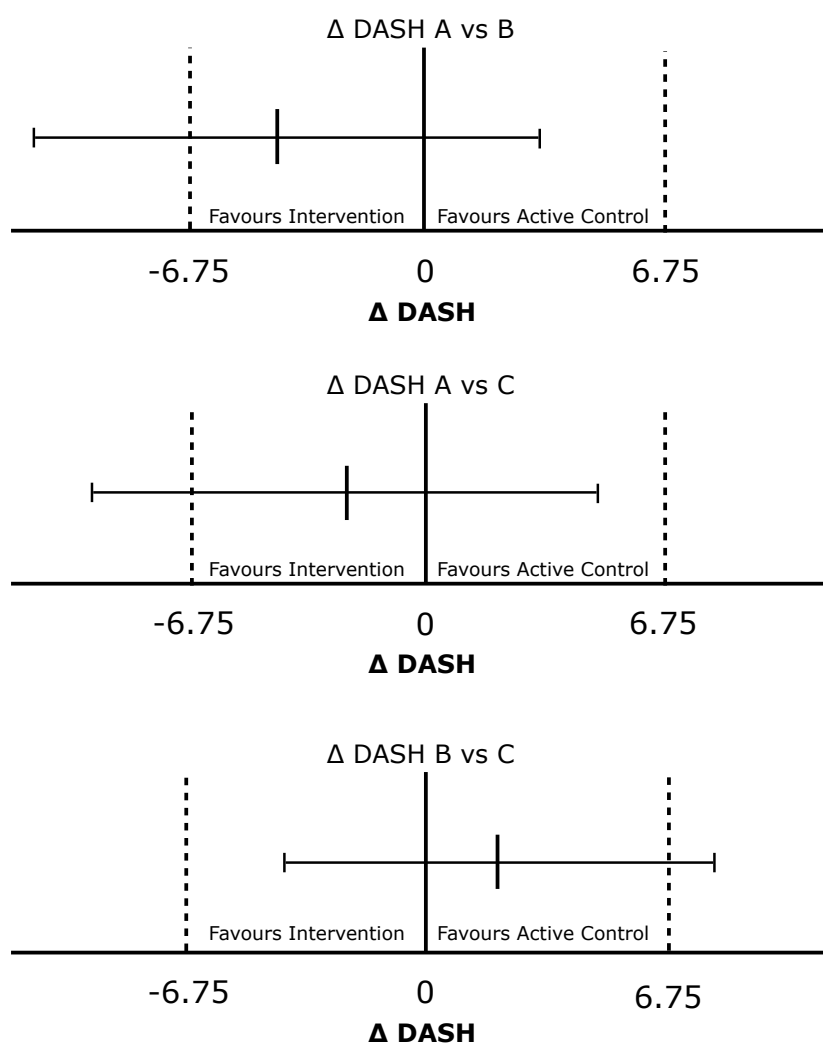
3.2.6.2 Equivalence Analysis of DASH & DASH Work

The Outcomes Study was additionally intended to assess for equivalence between the three interventions with a two-tailed design, as it was uncertain whether the direction of primary outcome results would be positive or negative for the intervention groups.

DASH

The results were re-plotted as the differences in mean Δ with 95% confidence intervals (CI) for each hypothesis as shown in Figure 3.2.4. The 95% CI for all three hypotheses crossed the no effect line. Both the video and in person physiotherapy showed a shift towards improvement (negative Δ). Equivalence could not be demonstrated as judged against half the MCID for the DASH as the confidence intervals were too wide.

Figure 3.2.4 Difference in means and 95% Confidence Intervals for Δ Scores of the DASH at 6 weeks.

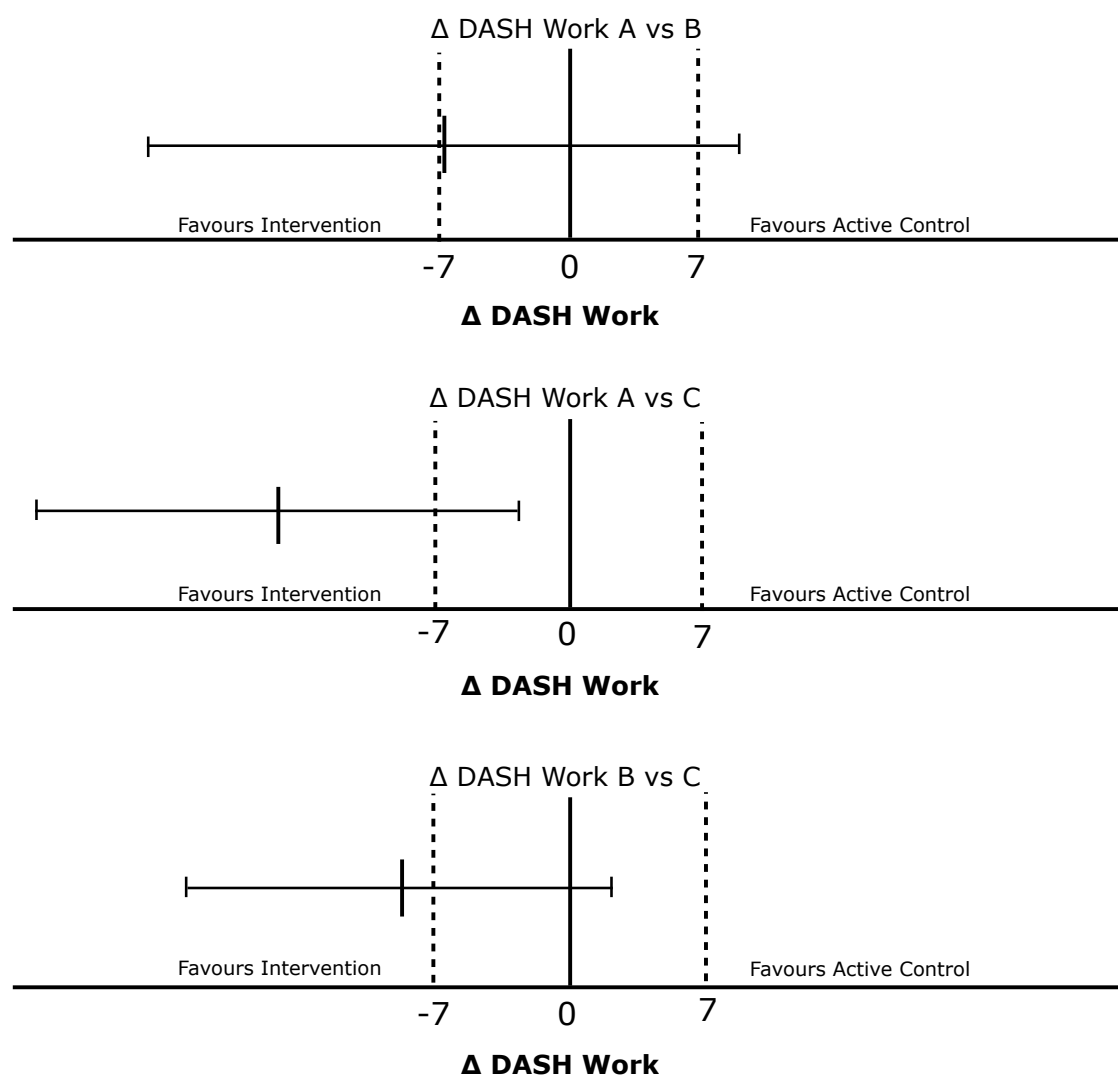


The dotted lines represent half the MCID generated by the MCID Study for the DASH (13.5). The difference in mean Δ and 95% CI for the three hypotheses were A vs B -4.2 (-11.5 to 3.0); A vs C -2.3 (-9.3 to 4.8) and B vs C 2.0 (-4.3 to 8.1). For the last hypothesis the video group (Group B) was treated as the active control.

DASH Work

Taking the same approach with the DASH Work module, where a potentially significant result was identified in the superiority analysis, the results were plotted as shown in Figure 3.2.5. For this analysis half of the MDC95 calculated by Kleinlugtenbelt et al. (2018) was used (14).

Figure 3.2.5 Difference in means and 95% Confidence Intervals for Δ Scores of the DASH Work at 6 weeks



On the basis of half the MDC95, for the hypotheses A vs. B and B vs. C the confidence intervals were again too wide to draw a conclusion. In person physiotherapy however demonstrated superiority over leaflet using this analysis. The difference in mean Δ and 95% CI for the three hypotheses were A vs B -6.9 (-23.0 to 9.2); A vs C -16.1 (-28.8 to -3.4) and B vs C -9.2 (-20.7 to 2.3). For the last hypothesis the video group (Group B) was again treated as the active control.

3.2.6.3 Secondary Outcome Measures

For ease of reading the further as treated results will be reported before the intention to treat results for the superiority analysis.

PEM

Part one and three of the PEM seek information on a patient's experience of treatment. Part two is the outcome measure of function and symptoms. The minimum score of 14.3% represents the best experience or the best outcome. In interpreting the delta scores for parts one and three reported here, they represent the change in participant experience over the duration of the study. The results from six weeks and one year were compared to the baseline scores to generate the change so a positive score represents a worse opinion and a negative score improved. The results are shown in Table 3.2.9.

Table 3.2.9 Baseline and Δ Scores for the PEM Part 2

		PEM Part 1 (Treatment)		PEM Part 2 (Hand Health Profile)		PEM Part 3 (Overall Assessment)	
Group A	Baseline $\pm$ SD	34 $\pm$ 13		15 $\pm$ 2		33 $\pm$ 16	
	Δ 6 Weeks $\pm$ SD	-9 $\pm$ 21		17 $\pm$ 19		-11 $\pm$ 24	
	Δ 1 Year $\pm$ SD	-10 $\pm$ 14		6 $\pm$ 9		-17 $\pm$ 11	
Group B	Baseline $\pm$ SD	32 $\pm$ 15		18 $\pm$ 7		31 $\pm$ 16	
	Δ 6 Weeks $\pm$ SD	-1 $\pm$ 19		11 $\pm$ 18		-5 $\pm$ 19	
	Δ 1 Year $\pm$ SD	-4 $\pm$ 17		8 $\pm$ 14		-7 $\pm$ 16	
Group C	Baseline $\pm$ SD	33 $\pm$ 10		17 $\pm$ 9		36 $\pm$ 19	
	Δ 6 Weeks $\pm$ SD	-4 $\pm$ 12		13 $\pm$ 14		-7 $\pm$ 20	
	Δ 1 Year $\pm$ SD	-4 $\pm$ 14		8 $\pm$ 20		-14 $\pm$ 19	
		6 Weeks	1 Year	6 Weeks	1 Year	6 Weeks	1 Year
	A vs. B (t test)	0.13	0.29	0.18	0.55	0.26	0.05
	A vs. C (t test)	0.22	0.25	0.34	0.68	0.46	0.67
	B vs. C (t test)	0.48	0.85	0.53	0.96	0.65	0.14
	A vs. B vs. C (ANOVA)	0.21	0.47	0.33	0.88	0.50	0.16

3.2.6.4 Objective Outcome Measures

There were no significant differences identified between the groups on any of the objective outcome measures. Grip strength almost completely recovered by one year. The results are shown in Table 3.2.10.

Table 3.2.10 Baseline and Δ Scores for Grip Strength

		Grip Strength kg $\pm$ SD	
Group A	Baseline $\pm$ SD	27 $\pm$ 9	
	0 Weeks $\pm$ SD	6 $\pm$ 7	
	Δ 6 Weeks $\pm$ SD	-8 $\pm$ 7	
	Δ 1 Year $\pm$ SD	0 $\pm$ 5	
Group B	Baseline $\pm$ SD	28 $\pm$ 9	
	0 Weeks $\pm$ SD	8 $\pm$ 10	
	Δ 6 Weeks $\pm$ SD	-7 $\pm$ 8	
	Δ 1 Year $\pm$ SD	-2 $\pm$ 8	
Group C	Baseline $\pm$ SD	29 $\pm$ 12	
	0 Weeks $\pm$ SD	6 $\pm$ 6	
	Δ 6 Weeks $\pm$ SD	-11 $\pm$ 7	
	Δ 1 Year $\pm$ SD	-1 $\pm$ 5	
		6 Weeks	1 Year
	A vs. B (t test)	0.83	0.51
	A vs. C (t test)	0.12	0.49
	B vs. C (t test)	0.10	0.69
	A vs. B vs. C (ANOVA)	0.18	0.72

Similarly range of movement almost completely recovered by one year with a deficit of arc of movement of only 14 degrees, 10 degrees lacking from flexion and 4 degrees from extension. The results are shown in Table 3.2.11.

Table 3.2.11 Baseline and Δ Scores for Range of Movement

		Range of Movement degrees $\pm$ SD					
		Flexion		Extension		Arc	
Group A	Baseline $\pm$ SD	71 $\pm$ 13		68 $\pm$ 11		139 $\pm$ 19	
	0 Weeks $\pm$ SD	38 $\pm$ 18		16 $\pm$ 26		55 $\pm$ 28	
	Δ 6 Weeks $\pm$ SD	-18 $\pm$ 15		-16 $\pm$ 19		-34 $\pm$ 27	
	Δ 1 Year $\pm$ SD	-12 $\pm$ 8		-9 $\pm$ 11		-21 $\pm$ 10	
Group B	Baseline $\pm$ SD	70 $\pm$ 11		63 $\pm$ 13		133 $\pm$ 20	
	0 Weeks $\pm$ SD	40 $\pm$ 14		13 $\pm$ 23		53 $\pm$ 27	
	Δ 6 Weeks $\pm$ SD	-16 $\pm$ 17		-5 $\pm$ 23		-21 $\pm$ 36	
	Δ 1 Year $\pm$ SD	-7 $\pm$ 16		0 $\pm$ 18		-7 $\pm$ 30	
Group C	Baseline $\pm$ SD	69 $\pm$ 10		65 $\pm$ 13		134 $\pm$ 17	
	0 Weeks $\pm$ SD	38 $\pm$ 14		13 $\pm$ 20		51 $\pm$ 19	
	Δ 6 Weeks $\pm$ SD	-15 $\pm$ 16		-13 $\pm$ 16		-28 $\pm$ 27	
	Δ 1 Year $\pm$ SD	-12 $\pm$ 11		-6 $\pm$ 16		-18 $\pm$ 20	
		6 Weeks	1 Year	6 Weeks	1 Year	6 Weeks	1 Year
	A vs. B (t test)	0.67	0.44	0.07	0.21	0.17	0.23
	A vs. C (t test)	0.54	0.95	0.57	0.68	0.46	0.76
	B vs. C (t test)	0.88	0.23	0.13	0.22	0.39	0.14
	A vs. B vs. C (ANOVA)	0.83	0.42	0.13	0.31	0.33	0.21

3.2.6.5 Intention to Treat Analysis

The intention to treat analysis was performed leaving all participants analysed in the group they were originally allocated to. There was no difference in the results of this analysis and the AT analysis identified.

For the primary outcome of the DASH at six weeks no significant difference was found. For the DASH Work there remained a significant difference comparing leaflet and in person physiotherapy in favour of the latter. The PROM analysis is shown in Table 3.2.12 and the objective outcome measures in Table 3.2.13.

Table 3.2.12 Intention to Treat Analysis for PROMs.

	Group A		Group B		Group C		Significance	A vs. C (t test)	B vs. C (t test)	A vs. B vs. C (ANOVA)
							A vs. B (t test)			
Δ DASH										
n = 95	15 ± 16		12 ± 14		13 ± 13		0.37	0.69	0.56	0.63
n = 66	8 ± 11		5 ± 12		5 ± 11		0.32	0.43	0.79	0.57
Δ DASH Work										
n = 66	23 ± 29		19 ± 28		7 ± 10		0.54	0.01*	0.06	0.06
n = 43	5 ± 11		2 ± 5		2 ± 8		0.19	0.41	0.82	0.38
Δ PEM Part 1										
n = 94	-7 ± 10		-3 ± 13		-7 ± 11		0.13	0.96	0.11	0.17
n = 67	-7 ± 14		-3 ± 17		-6 ± 14		0.32	0.72	0.48	0.57
Δ PEM Part 2										
n = 94	18 ± 17		14 ± 12		13 ± 13		0.31	0.22	0.76	0.38
n = 69	11 ± 13		9 ± 14		4 ± 19		0.57	0.14	0.28	0.26
Δ PEM Part 3										
n = 93	-8 ± 19		-2 ± 22		-11 ± 18		0.29	0.55	0.10	0.22
n = 68	-13 ± 12		-8 ± 17		-16 ± 20		0.21	0.57	0.11	0.20

* significant result

Table 3.2.13 Intention to Treat Analysis for Objective Outcomes.

		Group A	Group B	Group C	Significance	A vs. C (t test)	B vs. C (t test)	A vs. B vs. C (ANOVA)
Δ Range of Movement					A vs. B (t test)			
6 Weeks n = 84	Flexion	-18 $\pm$ 15	-17 $\pm$ 17	-15 $\pm$ 16	0.77	0.51	0.73	0.81
	Extension	-16 $\pm$ 19	-16 $\pm$ 19	-13 $\pm$ 17	0.15	0.63	0.25	0.26
	Arc	-33 $\pm$ 27	-23 $\pm$ 37	-28 $\pm$ 27	0.27	0.48	0.57	0.50
1 Year n = 52	Flexion	-12 7	-8 16	-11 13	0.30	0.78	0.43	0.52
	Extension	-11 15	0 18	-4 14	0.06	0.14	0.49	0.13
	Arc	-23 16	-8 30	-15 20	0.07	0.18	0.37	0.15
Δ Grip Strength kg $\pm$ SD								
n = 84	6 Weeks	-8 $\pm$ 7	-8 $\pm$ 9	-11 $\pm$ 7	0.94	0.09	0.17	0.23
n = 52	1 Year	0 $\pm$ 5	-1 $\pm$ 8	-2 $\pm$ 5	0.50	0.28	0.93	0.67

3.2.6.6 Experience and Satisfaction

For experience and satisfaction the analysis was performed using the data from the participants as randomised (i.e. intention to treat). An as treated analysis was not performed as from an experience perspective it was deemed most relevant to determine how people felt about the intervention they were allocated to, irrespective of whether there were subsequent breaches of protocol. A short questionnaire was used to ascertain participant satisfaction with the intervention they received. The results are presented narratively below.

Question 1. Are you happy with the advice you received after your plaster was removed?

There were 93 responses to this question with 92 responding yes and one responding no. The one participant who stated they were not happy was in the advice sheet group (group A).

Question 2. How would you prefer to get advice on what exercises to do after your plaster was removed?

The answers to this question are shown in Table 3.2.14. The majority of participants picked their own intervention again, despite being aware of the three interventions which were used in the study.

Table 3.2.14 Preference on how to receive advice

	Advice Sheet	Advice Video	In Person Physio
Group A	21/30	1/30	8/30
Group B	3/32	28/32	1/32
Group C	1/33	0/33	32/33

Question 3. How close to your normal function do you think your hand is today?

This was recorded on a 10cm VAS scale with the left-most point being marked 'no function' and the right-most point being 'normal function'. The answers to this question are shown in Table 3.2.15.

Table 3.2.15 Patient reported return to function

	How Close to Normal Function % $\pm$ SD
Group A	75 $\pm$ 23
Group B	77 $\pm$ 16
Group C	78 $\pm$ 14
A vs. B (t test)	0.67
A vs. C (t test)	0.48
B vs. C (t test)	0.76
A vs. B vs. C (ANOVA)	0.76

Question 4. How satisfied are you with the therapy you have had after your wrist fracture?

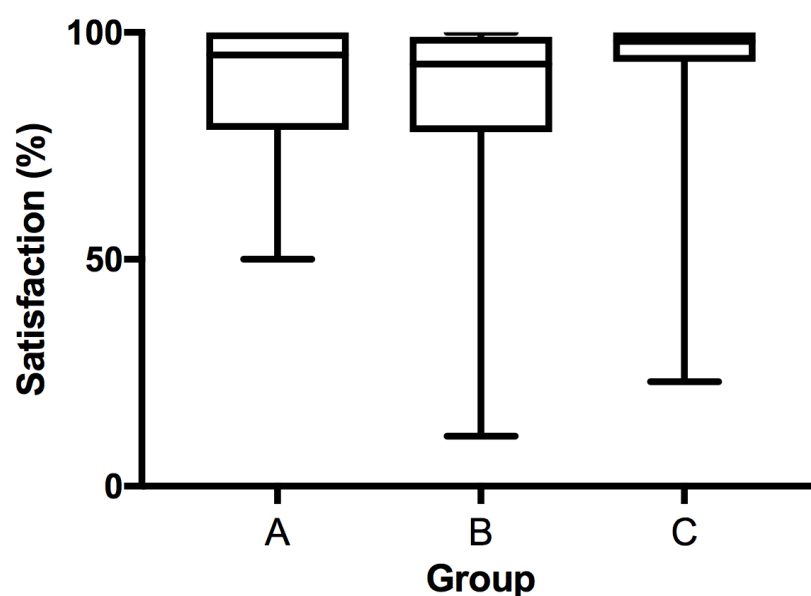
This was also recorded on a 10cm visual analog scale with the left-most point being 'not at all happy' and right most point being 'very happy'.

Overall satisfaction was high at 89% ($\pm$ 18). The results of this question are shown in Table 3.2.16.

Table 3.2.16 Patient reported satisfaction.

	Satisfaction with Intervention % $\pm$ SD
Group A	88 $\pm$ 16
Group B	84 $\pm$ 22
Group C	93 $\pm$ 14
A vs. B (t test)	0.44
A vs. C (t test)	0.15
B vs. C (t test)	0.04
A vs. B vs. C (ANOVA)	0.10

Statistical analysis of the results showed no significant difference between the three groups with ANOVA ($p=0.1$), but subgroup analysis revealed a borderline significant difference between video and in-person physiotherapy in favour of the latter ($p=0.04$), as shown in Figure 3.2.6. However, one participant lost their video and gave a satisfaction score of 11%. If this result is excluded the difference between the groups becomes insignificant.

Figure 3.2.6 Box and whisker plot of participant satisfaction.

The final aspect of assessing patient experience and satisfaction was to correlate the experience and satisfaction questions above with the outcome measures, including parts one and three of the PEM which are designed to measure the same. This correlation was performed for the whole cohort as shown in Table 3.2.17.

Table 3.2.17 Correlations for Question 3 & 4

	Question 3 - Function	Question 4 - Satisfaction
DASH	-0.575	-0.259
PEM 1	-0.267	-0.295
PEM 2	-0.699	-0.350
PEM 3	-0.416	-0.290
Δ Grip	0.544	0.360
Δ Flexion	0.459	0.341
Δ Extension	0.428	0.336

Negative correlations for the PROM scores are expected as these report with lower scores being better whereas the VAS used for the questions report higher as better. Part 2 of the PEM correlated most strongly with question 3 reporting function with a moderate correlation. However, part one and three of the PEM only showed a weak correlation with question 4 reporting satisfaction.

3.2.6.7 Utilisation and Access to Video

The participants who were allocated to the video group were asked additional questions. First they were asked if they accessed the videos over the previous 6 weeks. This was a binary response question with 94% stating they had used the video. One participant stated he lost the video before watching it and no reason was recorded for the second participant who did not use it.

Participants were asked to self-report how many times they watched the video in total, with the mean number being seven (± 8). Asked if they found the video useful, 94% stated that they did.

Finally participants were asked how they chose to access the video. There were two options available to participants and the group was equally balanced with 52% accessing the videos via DVD and 48% accessing them online via YouTube®.

3.2.6.8 Complications

Complications were recorded both prospectively and retrospectively for the cohort and the final complication rate is reported for one year post injury. It is possible that because of the poor attendance at one year some complications were missed if they were not treated at our centre. The final complication rates are recorded in Table 3.2.18.

Table 3.2.18 Complications by one year.

Complication	Number	Cohort Incidence (%)
Excessive Stiffness	2	1.7
Delayed Union	1	0.9
Nerve Compression / Neuritis	3	2.6
Persisting Pain Requiring Follow-up	3	2.6
Tendon Rupture (EPL)	2	1.7
Associated Symptomatic TFCC / Carpal Injury	2	1.7
Concurrent Shoulder Injury	3	2.6
Dupuytren's Contracture	4	3.4

Overall 15 participants (12.9%) were recorded as having a complication, ten reporting one and five reporting two. The complication rates are within the normal range reported in the literature (McKay et al., 2001).

3.2.7 Direct Healthcare Costs

3.2.7.1 Item Cost of Interventions

An analysis was performed to ascertain the direct cost of each treatment. The analysis sought to determine the cost of each intervention as provided. Data were not available to calculate the costs of crossover from leaflet or video to in person physiotherapy, as in a majority of cases these occurred outside of our centre either with another NHS or a private provider and these data were not prospectively collected. There were 550 patients treated for a DRF in the Queen's Medical Centre in 2017. This was derived from patients treated at any time in the plaster room, accepting that any patients who were never seen in the plaster room would be missed. There is no more accurate system from which to ascertain total yearly attendance. On this basis consumable costs were based on an order of 500 units.

Advice Sheet

The cost of providing an advice sheet was based on the cost of printing 500 hundred sheets in colour. This is £170.00 ex. VAT on the 2017 price matrix (Banner Managed Communication, UK, 2017). The advice sheet was produced internally and was already in use at the time of this study. Similar advice sheets for all common fractures have already been produced. Because of the relative ease with which an advice sheet can be created it is reasonable to say the content production itself would not incur additional cost. Therefore the cost per patient was £0.34.

Video

The costing for the video is more complicated, because it depends on how much is allowed for creating the video and over what duration the video can be said to be current before it needs revision. The video we used was created by two physiotherapists from the department and took five hours to create. However, if the use of physiotherapy DVDs were to be expanded a more formal video production may be required. A 20 minute video was created by the maternity department in the hospital. While the content does not relate, the production was of a similar requirement and length to the

physiotherapy video. The costings (Riviera Multimedia, UK, 2016) are shown in Figure 3.2.7. Working on the assumption that a video would be revised every 10 years, accepting this is an arbitrary figure, the production costs would be £486.20 per year of use or £0.88 per patient.

Figure 3.2.7 Costing for professional production of a 20 minute video.

ESTIMATE BUDGET:

ITEM	DESCRIPTION	COST	QTY	TOTAL
Pre Production	Production of story boards outlines etc.	250	1	250
Script	Production of script ready to teleprompt	250	1	250
Filming Studio	2 person crew inc. auto cue	1200	1	1200
Filming (on-site)	1 person crew	550	2	1100
Studio hire (with option to do on-site)		120	1	120
Presenter	Presenter for one day	300	1	300
Edit	Edit of 20 minute film in sections	400	3	1200
Production fee	10% of total			442
				Total
				4862
				VAT
				972.4
				Total
				5834.4

Costing also depends on distribution medium with physical media such as DVD incurring different costs to an online video. The cost of printing 500 DVDs was £0.61 ex.VAT per unit (Riviera Multimedia, UK, 2017).

Participants were asked how they accessed the physiotherapy video with 52% using DVD and 48% accessing the video online (via YouTube®). Making the video accessible online via a video sharing site incurs no direct costs. Ordering 500 DVDs would incur a unit cost of £0.61. Therefore the unit cost was multiplied by 0.52 to arrive at the cost of providing the media to patients of £0.32. This makes the assumption that in real world testing patients would choose to take away a DVD as often as they were used in this study. It would be reasonable to provide the patients not taking a DVD with a printed copy of the internet link and so this would add £0.16 per patient (unit cost of single black and white of £0.34 sheet x0.48). Therefore media costs per patient were calculated to be £0.48 ex.VAT.

Physiotherapy

The cost of physiotherapy was defined as the amount of money which was paid to Nottingham University Hospitals NHS Trust by Nottingham City Clinical Commissioning Group. There were three types of session undertaken by patients. The first was a 30 minute slot given to all patients

the day their plaster was removed. At the discretion of the treating physiotherapist patients were then either placed on an open appointment, or offered a follow-up appointment of 30 minutes. One participant was given 15 minute appointments but payment is based on attendance, not duration, so this did not affect the cost.

All participants received the first physiotherapy appointment on the day of their fracture clinic attendance to have the plaster removed and for 37% of participants this was the only appointment they received. The majority of participants therefore had more than one appointment. It is important to note that participants who received private follow-up or follow-up with a provider other than Nottingham University Hospitals NHS Trust did not have this element of their care included. The cost of physiotherapy is billed per attendance and at June 2017 the cost was £23.00 per attendance.

There were a total of 101 attendances to physiotherapy from the 38 participants recruited to Group C with 95 attendances in the 33 participants returning for 6 week follow-up. All attendances to the physiotherapy department were included in the analysis, irrespective of the duration of follow-up. There was a trend for the participants who required longer follow-up and treatment time to attend for their 6 week follow-up, though this was not significant. Table 3.2.19 shows the total cost for those allocated to physiotherapy at recruitment and for those who attended their six week follow-up.

Table 3.2.19 Attendance at physiotherapy at baseline and six weeks.

		Group C	Significance
Number of Visits Mean $\pm$ S.D.	Baseline	3 $\pm$ 2	
	Attended 6 Weeks	3 $\pm$ 2	p = 0.64
Duration of Treatment (Mins) Mean $\pm$ S.D.	Baseline	78 $\pm$ 57	
	Attended 6 Weeks	84 $\pm$ 59	p = 0.63
Length of Follow-up (Days) Mean $\pm$ S.D.	Baseline	33 $\pm$ 37	
	Attended 6 Weeks	37 $\pm$ 38	p = 0.65
Total Cost of Physiotherapy (£)	Baseline	2323	
	Attended 6 Weeks	2185	

Total Cost for Providing Each Intervention

Based on the above information the total cost of providing each intervention per patient is shown in Table 3.2.20.

Table 3.2.20 Cost of providing each intervention per patient.

	Total Cost /patient
Group A	£0.34
Group B	£1.36
Group C	£66.21

3.2.7.2 EQ-5D Results

The results for the EQ-5D-5L were analysed by their five domains as well as by index value and VAS and the results are shown in Table 3.2.21.

Table 3.2.21 EQ-5D results by domain, index and VAS.

		EQ-5D						
		Mobility	Self-Care	Activity	Pain	Anxiety	Index (UK)	EQ_VAS
Group A	Baseline	1	1	1	1	1	0.929	84
	6 Weeks	1	1	2	2	1	0.846	80
	6 Week Δ	0	0	1	1	0	-0.083	-4
	1 Year	1	1	1	2	1	0.873	85
	1 Year Δ	0	0	0	1	0	-0.056	1
Group B	Baseline	1	1	1	1	1	0.952	88
	6 Weeks	1	1	2	2	1	0.837	82
	6 Week Δ	0	0	1	1	0	-0.115	-6
	1 Year	1	1	1	2	1	0.850	87
	1 Year Δ	0	0	0	1	0	-0.102	-1
Group C	Baseline	1	1	1	1	1	0.942	87
	6 Weeks	1	1	2	2	1	0.823	85
	6 Week Δ	0	0	1	1	0	-0.119	-2
	1 Year	1	1	1	2	1	0.832	80
	1 Year Δ	0	0	0	1	0	-0.110	-7

At six weeks all three groups consistently reported persisting deficits in the domains of activity and pain which resulted in a persisting deficit in the index scores and VAS. At one year a majority of participants no longer reported a deficit in activity but persisting pain was evident in all three groups.

4. Discussion

The research findings of the two major components of this thesis are synergistic, with the results of the MCID Study being designed to inform the results of the Outcomes Study by confirming the clinical as well as statistical significance of the RCT. Over this section the core findings will be considered separately and then overall findings considered together.

4.1 Discussion of the MCID Study

4.1.1 Study Design

The design of the MCID Study was based on a number of assumptions and is one perspective on how to derive an MCID. There are many possible ways to derive the MCID and to declare one 'correct' would be both invalid and an oversimplification of what is a complex topic. There are pros and cons of any approach taken.

The core of the MCID Study design was to generate an MCID through calculations which can be scrutinised and therefore accepted or rejected by those reading them. It did not attempt to calculate an MCID through distribution based methods, but took the values already published to create a floor value which was deemed acceptable when judging the MCID calculated through an anchor based approach. A distribution based approach requires a population in whom there is no change in health status between assessments, or at least a large enough portion of a cohort not reporting change. Following an acute DRF a majority of patients do report a continuous change, usually in the direction of improvement.

The calculations for the MCID Study were all anchor based. Some authors suggest that the use of an anchor based approach will not work in populations such as those undergoing routine fracture care (Leopold, 2013). This is based on the assertion that that following a DRF participants improve quickly and so this rapid improvement by six or twelve months creates a ceiling effect, with high scores recorded early preventing satisfactory discrimination of change at later time points (Shauver & Chung, 2009). This is a reasonable viewpoint if one tries to perform MCID calculations as an adjunct to parallel studies which are allowed to dictate the time points at

which data are collected. It is easily mitigated, as it was in the MCID Study, by ensuring that data are collected over the period of change with a number of time-points. For DRF in this cohort the period of greatest variation in change was between six and twelve weeks, which showed the largest standard deviations in PROM scores.

The anchor chosen was a 15 point bidirectional GROC scale. This was selected because it is the scale used by Jaeschke in the original description of the technique (Jaeschke et al., 1989). The GROC is not perfect and suffers from both recall bias and response shift. Recall bias describes the problem of events which occur between applications influencing recall of the original status (Hermann, 1995). Response shift occurs when the patients response is influenced by their perception of change in their condition (Schwartz and Sprangers, 1999). These conspire to affect a patients ability to correctly recall their previous health state which is the principle problem with using the GROC. Consideration was given to using the Purdue Pegboard test for assessing hand dexterity as an anchor. However, it was felt that for time and cost reasons this would be impractical. It also creates the problem of what amount on change on this test would represent no change.

One modification to the original GROC which was made in this study was to apply two versions of the scale, one to measure function and one to measure pain. There was little difference in the calculated MCID values between the scales and so no benefit was shown in this study for doing this in future studies.

In deciding on what change on a 15 point scale should be taken as no change the data from this study suggests using one point on the GROC results in the greatest area under the curve on ROC analysis, which in turn suggests that this approach identifies and MCID which is most sensitive to change. One point on the 15 point scale is the difference between a patient who reports being "a tiny bit better (almost the same)" and "a little better". However, the resultant MCID was the same irrespective of the size of the no-change group used for the DASH and the PEM though for the PRWE the result increased from an MCID of 13.5 using one point to 15.5 taking five points as no change with the AUC falling as the no change group increased. The recommendation based on this data is that one point is used.

When using an anchor based method it is more common to assess the change between just two time points. This makes the assumption of a linear rate of improvement in a condition. By sampling time points over a six month period from injury, this design sought to mitigate the risk of missing this effect and is recommended in future studies.

4.1.2 The MCID of the DASH, PEM and PRWE

The overall results calculated for the three PROMs were as follows:

DASH - 13.5
PEM (Part 2) - 9.5
PRWE - 13.5 to 15.5

In all three cases the results of the anchor based approach using ROC curve analysis were higher than the floor values set by the MDC95 results from the literature review and so were accepted as being greater than the error inherent within their respective PROMs to a certainty of 95%.

In ROC analysis the area under the curve is a measure of the probability of correctly discriminating between improved and unimproved patients, ranging from 0.5 where the ability to discriminate is by chance alone to 1 which is the ability to perfectly classify all patients. There are no well defined thresholds accepted between these values as to how to interpret the AUC results. Using the thresholds defined in the methods, the PEM showed poor discrimination and the DASH and PRWE moderate discrimination. The PRWE was slightly more sensitive to change than the DASH on this metric (AUC 0.78 vs 0.75).

4.1.3 The MYMOP in Distal Radius Fractures

The MYMOP has not been used before in the context of trauma research. It was initially designed to be used in general practice where its brevity is advantageous, with very short appointment times. The MYMOP is shown in Appendix 4.

It was included as an adjunct to the MCID Study with two aims:

1. To assess what items participants would choose, both symptoms and functional restrictions, in order to assess the content validity of the DASH, PEM and PRWE.
2. To assess how well its scores correlate with the other PROMs to test the criterion validity of the MYMOP.

The first part of the MYMOP analysis identified 83 patient generated items. The fact that the MYMOP was used to generate these items is in some ways opportunistic in terms of generating a list by which to judge the content validity of the PROMs. This could have both positive and negative effects on the list generated. The fact that participants were not generating their items in the context of testing content validity may reduce bias, as they represent those items which patients independently chose out of this context. Conversely the risk of taking these items for the purpose of validating the other PROMs is that they cannot be considered 'complete'. For example had participants been asked to list 30 items which they had found affected by their fracture a far more complete list would have been created. It is also accepted that the items generated are most relevant to the acute post fracture period as most were generated at two weeks post injury.

Nonetheless the items generated by the MYMOP were compared to the items on the DASH, PEM and PRWE in two ways. First the proportion of items the MYMOP generated found in the three PROMs was assessed. The DASH showed the strongest content validity with an overlap of items of 70%, with the PEM and PRWE only overlapping on 48% and 44% of items respectively.

This was then reversed and the proportion of items in the DASH, PEM and PRWE were compared to the MYMOP items. On this metric 100% of the items on the PEM were chosen by participants, 93% of the PRWE and 80% of the DASH. In this analysis one has to accept that the results are in part a factor of the number of items the PROM itself contains. The PEM has 11, the PRWE 15 and the DASH has 30.

These two analyses accepting their limitations tell us that, on the basis of this dataset in the context of acute injury;

1. The DASH is the best PROM to capture the detailed effects of an acute DRF from the perspective of content validity.
2. The PEM has the fewest redundant items in the context of an acute DRF.

Looking at the correlations between the PROMs and the MYMOP scores the correlations were acceptable after six weeks and indeed were strong with all three PROMs tested, indicating strong criterion validity. These results were perhaps surprising but offer some credence to the idea that only a small number of items are needed, provided they are patient important, to adequately track change in a condition over time. To accept this finding one has to accept that the DASH, PEM and PRWE are themselves valid in assessing DRF.

In terms of how these results may inform future revisions of these PROMs, pain and function were covered well by all three PROMs. However two recommendations could be made;

1. One of the items of function generated was typing. Perhaps PROMs need to be revised to consider newer methods of communication such as keyboard or smart phone use, rather than pen and paper.
2. We know that depression and catastrophic thinking are associated with early poorer outcomes, probably due to their interaction with pain, but also as an independent predictor of finger stiffness. The 5% of items chosen by participants which relate to anxiety and depression are only partially covered by the DASH and PEM and not at all by the PRWE.

4.2 Discussion of the Outcomes Study

We know that in 2001 there were 71,000 distal forearm fractures sustained in the United Kingdom (O'Neill et al., 2001). A national survey indicated that 40% of patients who sustain a DRF are referred for physiotherapy as the primary intervention. Given those figures and based on the per person cost of in person physiotherapy calculated in this thesis, the NHS is spending approximately £1,900,000 per year on this intervention. Almost no patients are routinely followed up, so as clinicians we do not hear patients' views on their therapy intervention, nor are we able to gauge its value or efficacy.

4.2.1 Study Design

In designing the Outcomes Study there were a number of considerations. Two of the three interventions could be considered standard care; based on the results from the national survey, we are relatively evenly split as a profession in either providing an information leaflet or in person physiotherapy. Looking at the evidence for each intervention, one could take a view that in person physiotherapy is likely to be superior. Had this study only considered these two interventions and making this assumption, a superiority design would be ideal. Alternatively one could find evidence that superiority is uncertain, in which case a non-inferiority design could be employed, taking in person physiotherapy as the active control 'gold standard' and then attempting to show that a leaflet is non-inferior.

There is no evidence published to inform the use of physiotherapy videos, despite them being increasingly commonplace in supporting a home exercise programme. There is evidence that in different contexts, videos show some benefit in modifying patient behaviour and also may enhance learning. For this reason it was felt important to test this with a third arm. However adding a video gave one arm which had an entirely unknown direction of effect.

In the initial protocol a superiority design was planned. This was initially designed to detect a Δ DASH of 6 at the primary outcome. As explained in the methods, as the study design evolved it became clear that it would be impractical to recruit enough patients in this single centre study. With the intention of using this study to generate pilot data for a larger future study

some modifications were made. As assumed MCID of 13 was taken for a revised power calculation which was coupled with a Bonferroni adjustment to alpha down to 0.01 to accommodate three hypotheses. This resulted in an achievable recruitment target of 120. With the benefit of the result of the MCID study this estimation was very close to the calculated value of 13.5.

In one respect this is beneficial as the small differences between the groups which were not statistically significant were also nowhere near this MCID. The tradeoff however was that the study could only identify a large effect size with a Cohen's *d* of 0.86. Reducing the MCID to 6 would have given a much smaller effect size of 0.4.

The DASH and DASH Work were also tested using the less common equivalence design as a secondary analysis, which can test the effectiveness of interventions in both directions. On this analysis it was clear that there were insufficient numbers of participants in the study to draw any conclusions, with the 95% CI being too wide.

4.2.2 Primary Clinical Trial Result

The primary research question for the Outcomes Study was to test if three modes of delivery of physiotherapy advice were effective in restoring function and reducing symptoms for patients after a non-operatively managed DRF.

The core finding of this study is based on the primary outcome of the DASH score six weeks post recruitment (12 weeks post injury). On the basis of the results of this RCT, the null hypothesis was not rejected and the finding is therefore:

In patients who sustain a distal radius fracture suitable for non-operative management and in whom an uncomplicated recovery is expected, the use of a video or in person physiotherapy did not show superior effectiveness in returning a patient to function and reducing symptoms over and above an advice sheet as measured by the DASH score twelve weeks post injury.

This finding is based on an 82% follow-up rate with equally matched groups and no significant bias identified. The study was powered to detect a Δ DASH of 13 points with a large effect size of 0.86. Using the results from the MCID Study which calculated the MCID of the DASH to be 13.5, the power calculation was repeated. With the new MCID the number in each group required for adequate power would have been 30 participants. This was achieved in terms of absolute numbers at the primary outcome (n=95) and on both the AT and the ITT analysis, there were >30 participants in each group.

4.2.3 Function at Work

A significant finding was identified in favour of in person physiotherapy, in participants who reported being in work at the time of injury as measured by the DASH Work. This significant result did not persist after using the more stringent post-hoc analysis of Tukey's multiple comparisons test and was not present on ANOVA of the three groups.

There has been no MCID calculated for the DASH Work and unfortunately this was not a part of the design of the MCID Study. Therefore, for the secondary equivalence analysis half the published MDC95 result was taken as the equivalence margin. In general the MCID would need to be larger than the MDC95 to satisfactorily attribute the result to more than the error of the instrument. Using this analysis superiority was again shown, with the lower 95% confidence interval crossing δ . Ideally this finding would be robustly tested in a further, larger study, following establishment of the DASH Work MCID.

4.2.4 Cost of Interventions

In some respects the cost for each intervention was as expected, with advice sheet and video being relatively cheap and in person physiotherapy significantly more expensive. This difference in cost in a larger economic landscape is minor. An important limitation in this analysis was the inability to account for the cost of patients who crossed over from the leaflet or video groups to in person physiotherapy. This is because a majority of these occurred outside of the hospital system and data were not collected prospectively for this.

Having shown a potentially significant difference in function at work, the question is raised that if in person physiotherapy improves function at work it may decrease time away from work. From a societal economic perspective the savings of an earlier return to work would far outweigh the direct healthcare costs of providing the intervention. Equally the attendance at physiotherapy appointments has a potentially negative effect on cost. This will need further investigation to clarify the overall economic implications of the interventions.

When planning a future economic analysis interpretation of return to work data will be potentially difficult. In the context of an upper limb injury the type of work, hand dominance and transport will all be affected. Determining a patient's presence at work will not be sufficient for a full societal economic analysis as the productivity they achieve at work will also need to be considered.

4.3 Thesis Results in Context

The first two sections have looked at the core results identified in this thesis. It is important to take these results in a wider context.

4.3.1 What Change in a PROM Score Matters?

With the PROM being the core of assessment, we need to know what change in an instrument's score is large enough to be important to patients and also that any calculated MCID is greater than the error of the instrument. The error in an instrument is in theory independent of the condition being measured. The MCID however, needs to be determined in a disease specific way. It is equally important to consider that a population MCID which is what has been calculated by the MCID Study does not necessarily equate to an individual's MCID.

4.3.1.1 Setting a Floor Value

Anchor based MCID studies will often be unable to satisfactorily calculate the MDC95 through a distribution based method using the same data, as they are unable to test the internal consistency of an instrument (usually Cronbach's alpha). Consideration of how this value is derived is important in deciding if the result of an anchor based calculation is valid, which is why it is considered at length here.

Consideration must also be given to the possible values the data from the MCID study could have arrived at, using published values for Cronbach's alpha and the inherent problems this creates with multiple time points in a trauma population.

The SEM and MDC

When a PROM is used the standard error of measurement (SEM) represents the standard deviation of results when taking repeated measures for one individual. It is derived from the standard deviation of the baseline population and the internal consistency of the instrument. If one makes the assumption that the sample's baseline standard deviation is representative of the population standard deviation, then this figure is instrument dependent.

The SEM can be used to calculate the change that must occur in an instrument to affirm that it is a real change to a degree of confidence. For 95% confidence this is achieved by multiplying by 1.96. This is in reality what we mean by the MDC95 but in the calculation we use an additional multiplier of $\sqrt{2}$, which is an adjustment for a small number of observations. Taking the MDC95 seems reasonable as a minimum score when considering what the MCID of an instrument is.

In this study, a literature review was used to obtain the MDC95 values. The range of published values for each PROM was quite narrow despite a heterogeneous group of conditions being tested. While this can be taken as evidence that the MDC is indeed a factor of the instrument alone, the MDC95 is often very close to values generated for the MCID.

Should we Calculate the MDC on a Per Study Basis?

The risk inherent in the assumption that the MDC is a factor purely of the instrument is the variability introduced by the baseline standard deviation of the cohort being tested. This is at the core of all distribution based calculations.

Cronbach's alpha, a measure of internal consistency, is truly a factor of the instrument alone. Published results for Cronbach's alpha for each PROM could therefore be combined with the baseline standard deviation of the cohort in a study, to generate an SEM and MDC95 specific to each study's population. Had this approach been taken using the baseline standard deviations from the MCID Study, the results obtained would have been as shown in table 4.3.1.

Table 4.3.1 MDC95 results using published Cronbach's alpha and MCID Study baseline standard deviation data.

	Source of Cronbach's Alpha	Cronbach's Alpha	SEM	MDC95
DASH	Haldorsen et al., 2014	0.93	1.85	5.1
PRWE	Rosales et al., 2017	0.96	1.06	2.9
PEM Part 2	Forward et al., 2007	0.94	1.89	5.2

These results are significantly lower than the published results. This is almost certainly due to the fact that the published results were generated using patients where a disease process was already active;

- Haldorsen: shoulder impingement syndrome (Haldorsen et al., 2014)
- Rosales: DRF between 8 and 13 weeks after injury (Rosales et al., 2017)
- Forward: DRF between 6 and 42 years after injury (Forward et al., 2007)

Having a condition which affects the score of a PROM will increase the standard deviation of the results in a cohort, as not all patients will suffer the same symptomatology, but all should have some symptoms. For the MCID and Outcomes Study the baseline data were from patient recall, where the cohort being studied largely reported 'normal' function prior to injury. Hence the standard deviation was narrow, resulting in low SEM and MDC95 values.

If the MDC95 as well as the MDC90 is calculated for the DASH score using the standard deviations from both the MCID and Outcomes Studies and the Cronbach's alpha from Haldorsen, the results generated are shown in Table 4.3.2.

Table 4.3.2 MDC95 values generated for all study time-points.

	Study	SD	MDC95	MDC90
Baseline (Recall)	MCID Study	7	5.1	4.3
Baseline (Recall)	Outcomes Study	8	5.8	4.9
2 Weeks	MCID Study	19	13.9	11.7
6 Weeks	MCID Study	23	16.8	14.1
12 Weeks	MCID Study	24	17.5	14.7
12 Weeks	Outcomes Study	14	10.2	8.6
24 Weeks	MCID Study	15	11.0	9.3
1 Year	Outcomes Study	11	8.0	6.7

The MCID for the DASH was calculated as 13.5 using an anchor with ROC curve analysis. With these MDC results this is rejected with the MDC95 at

two, six and twelve weeks. If we recalculate to the less stringent MDC90 it is still rejected at six and twelve weeks.

In the context of stable disease none of this is an issue. The standard deviation of the baseline is a sensible metric to use, because at the time of baseline data recording the spread around the mean is likely to be representative.

In the context of trauma, particularly in a population who prior to injury would largely report normal function, there needs to be consensus on what should replace the baseline standard deviation for distribution based calculations. The fact that there is a large difference in standard deviation at 12 weeks between the two study cohorts is concerning. The MCID Study included patients who had undergone ORIF but if these patients are excluded the SD only falls from 24 to 22 which is significantly higher than 14 in the Outcomes Study. The two groups were well matched at baseline both with a mean DASH score of 3 and similar standard deviations. It seems likely that this relates to some form of systematic bias in the data, either through the way the data were collected (as discussed below) or as a result of a true difference in the rate of recovery between the two cohorts.

The most pragmatic option would be to take the smallest standard deviation of the data when the disease being tested was present. For the MCID Study this was 24 weeks post injury and for the Outcomes Study 1 year. There also needs to be consensus on which confidence interval we should take, 90% or 95%.

4.3.1.2 Calculating a Clinically Important Difference

There are three core elements of the anchor based technique which were reviewed in this study. The first investigated the GROC using scales to measure different domains, the size of the scale and the selection of a no-change group on the scale. The second was the time over which data are collected and the third the utility of the lesser seen WPSC and BPSC.

Global Rating of Change Scales

The core GROC scale used for the anchor based calculations was a 15 point bidirectional likert scale. Rather than use one GROC, two were given

(GROC^p and GROC^f), one for each of the domains of importance identified by the COMET initiative (Goldhahn et al., 2014). There was only a small difference in the MCIDs calculated with each scale separately and this was not large enough to recommend this as a future technique. However, if the primary outcome of a study was pain there may be some benefit to knowing the separate MCID generated by this scale.

A second element of the GROC analysis was assessing the different size of scales used. In addition to a 15 point bidirectional scale, 11 and 7 point scales are often also seen. The 15 point scales showed moderate to strong correlation with the three PROMs with GROC^m consistently being strong. However, the 11 point scale was only moderately correlated and the seven point scale only showed weak correlation. This result will in part be due to the larger number of items on a 15 point scale. Nonetheless on the basis of these results it is reasonable to recommend that a 15 point scale is used in future studies. For an anchor based calculation to work there has to be good correlation with the PROMs they are being used to test, otherwise any MCID result is meaningless.

A third element of the GROC analysis was to consider the size of the group which would be considered no-change. Using just one point on the 15 point GROC resulted in ROC curve calculations which provided the greatest area under the curve and so the greatest sensitivity to change. However, it made no difference to the actual MCID for the DASH and the PEM. For the PRWE it did make a difference of two points with larger increments of no change being associated with an increasing MCID at the expense of a lower AUC. Overall the optimal choice appears to be to take one point on the 15 point scale.

Is the MCID Time Independent?

There were not enough results generated at 12 and 24 weeks to test each time-point independently for its MCID. Re-analysis of the MCID Study data for the GROC^m of the DASH score, using only the change scores between two and six weeks, the MCID is increased from 13.5 to 17 (31 data points and AUC 0.56). This implies that there may be a temporal effect on the MCID. However, some caution needs to be used in interpreting this result as the AUC implies an inability to discriminate.

The potential implications of this observation are quite substantial. There is much work to be done in calculating the MCID for each condition for each PROM. To say that this value also needs to be calculated separately for each potential timepoint increases the research required by an order of magnitude. However, if there is a substantial difference in MCID for a primary outcome of six weeks as opposed to one year then there is a real risk of increasing error. Using the above data, if a standard superiority design RCT reported a Δ DASH of 15 points for a primary outcome at six weeks using an MCID of 13.5 this would be reported as rejecting the null hypothesis whereas an MCID of 17 accepts it.

The Within and Between Patient Score Change

The within and between patient score change are little mentioned in publications regarding the MCID. They are both intended to provide an estimate of the MCID taking different anchor based approaches.

The within patient score change (WPSC) defines the MCID as the mean change or delta for the PROM scores in patients who record an improvement on the GROC. The between patient score change (BPSC) defines the MCID as the delta of the change scores of two groups of patients who report change on two adjacent levels.

The issue for both analyses is how you define what a change is in terms of the scale being used. For this analysis we took two approaches. The first was to say everyone recording a score of >2 on the GROC were improved. The second approach was to subdivide those recording improvement into two groups. Having taken 0 - 2 as no change a second group of >2 to ≤ 4 were deemed to show a minimal change with those >4 being significantly improved.

The latter approach makes more sense when calculating the WPSC, given the aim is to show what is considered a minimal but present improvement from the patients' perspective. Taking the mean delta for the minimal change group is perhaps more relevant to an MCID estimate as it tells us the mean improvement for patients who report a clinically meaningful change but excludes the bias of patients who report a very large and therefore clinically obvious improvement. The former approach makes more

sense for the BPSC however, because it recognises the potential for dichotomous outcomes.

Both the WPSC and BPSC seem less useful than the sensitivity of analysis which is why they are little reported. They provide an insight into the size of change in a cohort but neither provides a figure which could be taken as an MCID. This is primarily because of the arbitrary nature of the selection of cutoffs to define change.

4.3.2 Which PROM Should We Use to Assess Distal Radius Fractures?

Medical outcomes can be classified as clinical, personal and economic at the highest level. Clinical outcomes may be observer reported or patient reported. With patient centered care being at the core of modern medicine, the PROM is one instrument by which we are able to assess and quantify patient outcomes in clinical practice and in research. The majority of PROMs used in orthopaedic trauma are designed to assess an anatomic region eg the DASH measures the upper limb and the PRWE the wrist and hand. These outcome measures are domain specific, usually covering one or two domains. There are no condition specific outcome measures in trauma as to have these would be impractical due the variety of injuries which may be sustained.

We often want our instrument to measure more than one domain and in the context of musculoskeletal injury, pain and function have been identified as key domains. Depression and catastrophic thinking affect outcomes and there is currently insufficient evidence that they return to baseline after injury (Golkari et al., 2015). Catastrophic thinking has also been found to be one of the major determinants of finger stiffness at six weeks (Teunis et al., 2015). There is therefore an argument that these should be included in outcome measures used to assess DRF. Five percent of participants recorded symptoms related to anxiety and depression on the MYMOP in the MCID Study. Looking at the Outcomes Study 15% of participants reported some level of anxiety or depression on the EQ-5D-5L. The PRWE does not contain any items to assess this; the DASH has one question and the PEM has two.

As discussed in the analysis of the MYMOP results the DASH also covered the largest number of items which participants in the MCID Study reported as important. This is likely partly by virtue of the number of items. Recent publications have favoured the PRWE in the assessment of DRF though the evidence is at best moderate (Kleinlugtenbelt et al., 2016). The high responsiveness of the PRWE in the context of DRF is likely a product of the fact a third of its items assess pain.

4.3.3 The Effectiveness of Therapy Interventions

The core question posed by the Outcomes Study was whether video or in person physiotherapy would demonstrate superior effectiveness to a leaflet in patients after a non-operatively DRF as measured by the DASH score. The core finding was that they did not, but care needs to be taken in the interpretation of this result. The finding of this study was not that physiotherapy works no better than a leaflet. The plain English interpretation should be that in patients in whom a good outcome was expected when their plaster was removed, there was no additional benefit shown in terms of day to day activities or symptoms to any of the three interventions. There were not enough participants in this study to draw a conclusion of equivalence based on this secondary analysis. Conversely function at work did seem to be superior twelve weeks following injury with in person physiotherapy as measured by the DASH Work, though this finding needs further investigation.

Patients with excessive hand and wrist stiffness or excessive pain were excluded and this result cannot be extrapolated to them. Indeed they were excluded on the premise that in person physiotherapy is almost certainly (part of) the correct treatment for these patients. Protocol deviations were minimal at the time of the primary outcome with only one change in group affecting the 'as treated' analysis. However, by one year there were eight participants who had changed treatment group (some of their own volition) all of whom had moved from either leaflet or video to in-person physiotherapy.

4.3.4 Patients' Satisfaction with Therapy Interventions

Patient satisfaction is a very difficult to fully explain as it is subject to a wide variety of variables (Naidu, 2009). In general the significant factors which directly affect satisfaction are access, quality of care, cost, physician role and behaviour, and other tangibles (such as the physical facilities).

However, these are modified in often complex ways by other factors such as sociodemographics and the context of the care episode (such as severity of illness).

Overall 99% of participants were happy with the advice they received on binary questioning and overall satisfaction was reported as 89% on a VAS. Mean satisfaction scores were highest in those receiving in person physiotherapy, though this failed to reach significance. The high overall satisfaction scores are likely due to the fact that patients are improving regardless of intervention.

Interestingly the satisfaction VAS showed very poor correlation with the DASH, PEM or objective outcomes. This poor correlation was still seen with part one and three of the PEM which were designed to assess this domain.

Participants who received in person physiotherapy consistently expressed their relief to have been able to check their progress with a healthcare professional whereas participants allocated to leaflet or video did not seem to have been concerned that this was not possible. For those in the leaflet and video groups they were happy that their allocation did not require them to return to the hospital and they felt that the directions were clear for each.

The lack of evidence for increased satisfaction for in person physiotherapy (or lower satisfaction with leaflet and video) was perhaps surprising and in opposition to previous results (Kay et al., 2008). In reality there are probably elements of all three interventions which patients like and don't like and which in effect seem to have cancelled each other out. The fact that in all three groups the majority would choose whichever intervention they received again implies that provided a patient is improving they don't mind what intervention they are receiving.

4.3.5 Is There a Use for a Video Guided Home Exercise Programme?

A majority of participants used the video at least once and it was used on average seven times. Participants found the advice provided useful in 94% of cases. Participants were evenly divided on whether they chose to access the video online or on DVD.

Clearly there is a cost implication to providing a physical DVD but this was minimal and smaller than the production costs, even when spread over 10 years. The general trend in content consumption is towards online distribution, which is likely to drive down the per patient cost based on a free hosting model. Inability to access the video was an exclusion criterion, but was not cited as a reason for exclusion in any patient.

Qualitatively participants commented that they liked the video, though a number felt that it was too long. Its length was designed so that participants could watch it while performing the exercises simultaneously. For those who wanted to use it in an instructional way only the pace of information delivery could perhaps be sped up.

4.4 Strengths and Limitations of Thesis

In both the MCID and Outcomes studies there were some modifications of planned methods and some limitations which became apparent once the research had been performed. There were also elements of the design which strengthened the final conclusions.

4.4.1 Strengths

MCID

Defining an MCID is an inexact science and is a developing field with some particular challenges when undertaken in trauma patients. One of the key strengths of the MCID calculation performed here was building multiple time-points into the calculation and treating them as independent data-points. This gives weight to the MCID calculated by taking account of potential temporal effects.

The only reference point in the literature was a previous MCID calculated in DRF for the PRWE using ROC analysis, with a value of 11.5 being reported (Walenkamp et al., 2015). The value of 13.5 found for the PRWE by the MCID Study was in line with this finding. The difference is likely explained by the fact that their first data-point was a median of 8 weeks from injury. When the MCID was calculated using only the change from two to six weeks in this study the MCID increased to 17 implying early change scores have the effect on increasing the MCID.

The validation of the three typical GROC scale sizes through correlation has indicated that the 15 point GROC is most highly correlated with the DASH, PEM and PRWE. When performing anchor based calculations the highest sensitivity result is obtained using one point on the 15 point scale to describe a no change group. These finding should inform future studies.

Outcomes

The core finding of the Outcomes Study is an important one as it implied there may be no additional benefit to a physiotherapy referral for general function and symptoms. It has raised an important question, as to whether for patients who are in work there is a significant improvement in at work

function with in person physiotherapy. The results of the DASH Work are suggestive that this is the case and will guide a future study design.

The Outcomes Study is the first evidence presented for physiotherapy advice provided by video in support of a home exercise programme for musculoskeletal injury. From an effectiveness and patient satisfaction standpoint it would seem that it performs no worse than leaflet or in person physiotherapy.

4.4.2 Limitations

4.4.2.1 MCID Study

Loss of Data

There were a potential 114 data-points from the 38 participants in the MCID Study. By the study completion 50% of the available data-points were lost. Because this study was observational, increasing loss to follow-up was expected as the duration of follow-up increased. This was less of a concern than it would be in a clinical trial. However, the attrition of participant numbers at 12 and 24 weeks means that the MCID calculations are more reliant on data from the earlier period of recovery. If there is a temporal effect on the MCID, then this will have affected the results probably by increasing the value calculated.

Loss to follow-up also prevented an independent calculation for the MCID at each timepoint. If the MCID is materially different at each timepoint, this would have a significant implication for future research. Namely, that one MCID per PROM, per condition would still not be sufficient. The MCID relevant to the timeframe of the primary outcome of the study would need to be known.

MDC95 Determination

The approach taken to identify the MDC95 was a literature review. While this is one approach, it does rely on the standard deviation of different populations. Taking the largest standard deviations from the 12 and 24 week data and calculating new MDC95 results with published Cronbach's alpha results would have resulted in higher values for all three PROMs than the anchor method derived. Without agreement on which time-point should

be used to define the standard deviation in trauma research it is difficult to know which is more 'correct'.

The secondary derivation of the MDC95 for the PEM was using data generated by the original 10 point 'Hand Health Profile'. In this study we used the more recent 11 point version. The added question relates to the duration of pain and it is not possible to say how the addition of this question would have affected the standard deviation and Cronbach's alpha.

Informing the Outcomes Study

The demographic makeup was slightly older with more female participants than for the Outcomes Study. This was expected, given the age cap of 70 years in the exclusion criteria for the latter study. The MCID Study population also included patients who were treated surgically although this was felt to be unlikely to have altered the result significantly.

MYMOP

Using the MYMOP in the context of trauma created some problems. By design the MYMOP was created with a view to use in primary care, where patients often present with a chronic condition and a small number of predictable symptoms. Using the MYMOP for patients with an acute DRF meant that the items identified are patient important at the initial two week review. The items which participants recorded were then used throughout all subsequent data collection, as is the design of the instrument with 89% of items coming from the two week assessment. They would almost certainly be different to items patients would choose at six months. Therefore, the results of this analysis are mainly applicable to the acute phase of injury with a much smaller focus on the longer term phase of recovery.

The second issue with the MYMOP score was that participants seemed to find it difficult to identify what a symptom actually is. One of the issues was that if a participant asked what they should record as a symptom and if the researcher suggested something, it was almost immediately accepted by the participant. The risk here is that the items generated become assessor rather than patient generated, which is clearly a significant potential source

of bias when interpreting the results. This was avoided as much as possible but inevitably will have created some bias.

Using the data generated by the MYMOP for the purposes of validity testing has to be seen in the limited context of the data generated in that most of the items generated were patient important two weeks after a DRF. Correlating the MYMOP responses to the participant generated items, because of the free text nature of the MYMOP responses, this comparison was inherently inexact. However, an attempt was made to match questions used in the PROMs to the items in a best fit way.

4.4.2.2 Outcomes Study

Loss of Data and Bias

The design of this study was to demonstrate effectiveness, not efficacy. The vast majority of data which was lost was because of participant non-attendance. It is likely that the bias would be for good outcomes to have a higher rate of non-attendance but because these were lost equally across the three groups for the primary outcome the bias introduced was considered acceptable.

At one year there was a significantly higher loss to follow-up of 41%. There was also a significant number of protocol deviations which occurred by this time-point for a range of reasons. These deviations almost all resulted in a participant being taken from the leaflet or video group and moved to the in person physiotherapy group for the 'as treated' analysis. In mitigation, the intention to treat and as treated analyses aligned.

In the demographics age and alcohol at time of injury showed a significant difference between the groups at baseline and six weeks respectively. This was most likely a significant result by chance rather than evidence of systematic bias in recruitment.

A source of bias in the patient satisfaction scores was generated by completing them in person in the fracture clinic. It could be that the fact that participants had returned to a clinical setting and were able to ask questions that was driving satisfaction, rather than the intervention. It is also widely recognised that patients who have a particularly good or poor

result are more likely to attend follow-up appointments introducing a systematic bias.

The data for the grip strength and range of movement were collected first on the CRF, before the PROMs were completed. With hindsight it would have been better collected at the end of the follow-up appointment. Because a majority of patients did get better, seeing this numerical improvement in their scores creates potential bias in the answers to the satisfaction questions as well as the PROMs. This bias was applied equally across all groups given that they all improved equally.

The Hawthorne Effect

The Hawthorne effect indicates changes in the behaviour of a participant on entry to a clinical trial (Sommer, 1968). In this study it is possible that participants were more compliant with physiotherapy advice than they would otherwise have been, in the knowledge their progress would undergo repeat objective assessment with ROM and GS. This assertion is backed up by the fact that the MCID and Outcomes Studies had a similar baseline but by 12 weeks post injury those in the Outcomes Study had a deficit on the DASH of 14 points whereas in the MCID Study it was 24 points.

As well as having a positive bias it is possible that participants who did not engage with therapy advice or who did not improve may not have returned for fear of being seen to have failed in their therapy. We often assume that those patients who do not return for appointments are not coming back because they are doing well, whereas it may be that they are doing worse than expected but do not wish for this to be seen.

4.5 Overall Thesis Findings

The MCID values as calculated by ROC curve analysis in patients with DRF were found to be:

DASH MCID - 13.5
PEM (Hand Health Profile) MCID - 9.5
PRWE MCID - 13.5 to 15.5

These values are higher than the mean of relevant MDC95 results published for these PROMs previously. They are a product of multiple time points and are applicable to patients with DRF up to 24 weeks of follow-up. A range is reported for the PRWE based on the results generated with different cutoff values for the no change group on the GROC scale. However, the value of 13.5 showed the greatest sensitivity to change based on the AUC from the ROC curve analysis and was found with a no change group of one point on the GROC.

On the basis of the MCID calculated for the DASH, the result of the Outcomes Study is that:

In patients who sustain a distal radius fracture suitable for non-operative management and in whom an uncomplicated recovery is expected, the use of a video or in person physiotherapy did not show superior effectiveness in returning a patient to function and reducing symptoms over and above an advice sheet as measured by the DASH score twelve weeks post injury.

Using the DASH Work as a secondary outcome measure a second core finding may be drawn:

In person physiotherapy appears to be superior in returning patients to normal function at work compared to advice sheet and advice video for patients who are in employment at the time of their injury, as measured by the DASH Work.

4.6 Consideration for Future Research Direction

4.6.1 Future Considerations in Calculating the MCID

The field of MCID calculation is still developing 30 years after being introduced. There is no one method of calculation which can be recommended. Some authors have suggested taking all available calculation methods and publishing multiple MCIDs, thus leaving the reader to determine which they wish to believe (Hung et al., 2018). This in some respects is the first stage of a Delphi method, only missing the expert consensus stages leading to a final answer.

Having a choice of MCID values risks leaving the researcher seeking to show an intervention is clinically as well as statistically significant no better off in performing accurate power calculations or interpreting results. Therefore reporting a single MCID remains preferable, accepting it will involve some degree of compromise.

There is consensus that the MCID needs to be determined for each instrument and for each condition that instrument measures. What needs to be decided is how significant the effect of time is on the MCID. This study suggests that time is a significant factor and if this is confirmed in future studies then we have two options. We either need to generate an MCID per time-point, per condition, per PROM which seems somewhat impractical or we need to clearly state the range of time-points that an MCID calculation covers.

There is also consensus that the MDC derived from distribution based calculations represents the smallest value which can be accepted as the MCID. How that MDC is arrived at and which MDC we use is very much not agreed. In determining the SEM there needs to be consideration as to which standard deviation should be used as this is the core of all subsequent calculations. In a cohort with an acute injury, it seems sensible that the standard deviation should not come from the recall baseline prior to injury but should probably come from a time-point after the injury has occurred.

Because the distribution based methods are so dependent on the standard deviation used in their calculation, a simple solution would be to determine

the MDC on a per study basis, taking Cronbach's alpha from the literature. Using the standard deviation of data at the primary outcome would give confidence in the result and could be judged against an MDC90, MDC95 or even an MDC99 to quantify the confidence in the result.

The Consensus based Standards for the selection of health Measurement INstruments (CoSMIN) group would be well placed to form a working group in order to further develop agreement on the standards for MCID calculation.

Ultimately it may be that all large clinical trials should build both an anchor and distribution method into their protocol. This would involve adding an anchor to the set of PROMs completed and adding an additional follow-up between two days and two weeks after one required for the trial. Then a study would be able to state its own SEM, MDC and MCID making considerations of how generalisable other published values are moot.

4.6.2 Future Research into Physiotherapy Interventions

The Outcomes Study will act as pilot data to inform a larger superiority design RCT to determine if in person physiotherapy is indeed superior at returning patients to in work function. There has been no evidence to show a significant difference or trend between leaflet and video both of which essentially support a home exercise programme. The intention would therefore be to examine the outcomes of two arms; home exercise programme vs. in person physiotherapy.

This would need to be coupled with a comprehensive economic analysis, including the societal and healthcare costs. If in person physiotherapy does improve function at work it may also reduce time away from work.

Conversely, while patients may perform better they may in fact miss work because of the need to attend physiotherapy appointments. While this study has shown physiotherapy costs more, this is likely to be offset substantially in a larger economic sense if patients return to work quicker with less time off. A future economic analysis would be complex in order to fully capture the societal and healthcare economic implications.

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Appendices

Appendix 1 - MCID Study Protocol

This is the trial protocol (Version 3 - 11th April 2014) as approved by the National Research Ethics Service (NRES) Committee London - Central (14/LO/1255).

1. INTRODUCTION

1.1 BACKGROUND

Distal radial fractures are the most common fracture seen in the Emergency Department . They Account for 3% of upper limb fractures (Chung and Spilson, 2001). The primary goal of treatment is to provide the patient with a functional extremity with minimal on going symptoms. There remains considerable debate in the current literature concerning the optimum method of treatment (Handol and Madhol, 2003; Karnezis et al., 2005; Handol et al., 2007; Handol et al., 2007a; Forward et al., 2008; Brogren et al., 2013; Karantana et al., 2013).

In the design of randomised control trials, a suitable outcome measure must be selected as an end-point. The Disabilities of Arm, Shoulder and Hand (DASH) (Hudak et al,1996, Beaton et al., 2001), Patient Rated Wrist Evaluation (PRWE) and Patient Evaluation Measure (PEM) (Dias et al., 2001) have been previously used, with DASH & PEM recently becoming more popular (Dias et al., 2001; Dias et al., 2008)). The minimal clinically important difference for the chosen outcome measure (PROM) is required in order to power a study (Beck et al., 2011; Sorenson et al., 2013; Malay and Chung, 2013). This has not been determined specifically in distal radial fractures for any of the listed outcome measures. MYMOP is an ideological outcome tool assessing the outcome considered most important by the patient (Paterson, 1996).

1.2 RATIONALE FOR CURRENT STUDY

The MCID for distal radius fractures of the commonly used outcome measures has not been calculated and is essential in the future design and appraisal of all studies into these common injuries.

2. STUDY OBJECTIVES

This study aims to measure outcome following wrist fracture using a variety of PROMs following wrist fractures. This data will then be used to calculate the MCID.

3. STUDY DESIGN

This study is an observational study. It will assess functional outcomes in patients who have sustained distal radial fractures managed either conservatively or surgically.

Identification & Recruitment – Patients will be identified by two methods: The clinical teams responsible for the patients care will identify eligible participants. This pathway will usually be for those patients directly admitted to the hospital from the Emergency Department for the treatment of their injury.

Patients will be identified in the fracture clinic at the point of their first review by the trauma team.

Patients who are willing to be involved in the study, will be consented by a member of the research team. They will be provided with an information sheet (version 1) and will complete the consent form (version 1).

A total of 60 patients are required in line with the power calculation performed using data from Malay and Chung (2013). The 60 patients will be divided into two groups depending on overall treatment strategy: 30 patients in a surgical group, and 30 patients in a conservative group. The MCID will be calculated for each group and for the cohort as a whole.

Patient Management – The operative and out-patient treatment of patients enrolled in the study will not be altered in any way. Each enrolled patient will undergo the mode of treatment deemed most appropriate by their treating surgical teams.

3.1 STUDY OUTCOME MEASURES

The DASH, PEM, GROG, PRWE and MYMOP will be assessed at regular time points during the study.

4. PARTICIPANT ENTRY

4.1 PRE-REGISTRATION EVALUATIONS

Nil

4.2 INCLUSION CRITERIA

All adult distal radial fractures; treated at the Queen's Medical Centre, Nottingham; able to give informed consent

4.3 EXCLUSION CRITERIA

Fracture extending > 3cm proximal to radiocarpal joint i.e. radial shaft fracture

Inability to understand and/or complete the DASH, PEM, PRWE, GROG and MYMOP questionnaires

Physeal fracture pattern

Ipsilateral concurrent upper limb injury or severe polytrauma/ head injury

Unable to attend for routine follow-up (out of area patients)

Delayed presentation/diagnosis (>1 week post injury).

4.4 WITHDRAWAL CRITERIA

Patient request

Moving away from study area (for clinic based follow-up only)

If the patient wishes to withdraw from this study, either by expressing this to the research team or failing to return questionnaires, their initial data it will be retained for analysis but they will not be contacted further.

5. ADVERSE EVENTS

5.1 DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- Results in death
- Is life-threatening – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe

- Requires hospitalisation, or prolongation of existing inpatients' hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly or birth defect

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

5.3 REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

5.3.1 NON SERIOUS AES

All such events, whether expected or not, should be recorded.

5.3.2 SERIOUS AES

An SAE form should be completed and faxed to the Chief Investigator within 24 hours. However, relapse, complications arising from and death due to distal radial fracture and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the Nottingham where in the opinion of the Chief Investigator, the event was:

'related', ie resulted from the administration of any of the research procedures; and

'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the COREC SAE form for non-IMP studies.

Local investigators should report any SAEs as required by their Local Research Ethics Committee and/or Research & Development Office.

Sponsor Contact Details for SAEs:

email to rdsae@nhs.nuh.uk,

or

Fax to: 0115 8493295 and phone Research & Innovations Dept on 0115 9709049

or 0115 9249924 ext 70659 or 70660 to confirm arrival.

Any queries please contact a member of staff in the Research & Innovations department:

Telephone: 0115 9709049 or 0115 9249924 ext 70659 or 70660

6. ASSESSMENT AND FOLLOW-UP

Data Collection – Standard demographic information will be obtained at the time of recruitment. A study ID will be generated at this stage for each patient and all further documentation will be identifiable by this study ID only. The decoding key for the study ID will be kept in line with NHS and Trust confidentiality guidelines and GCP guidelines.

Specific details of injury fracture pattern and classification and treatment method will be recorded. Following consent patients will complete a retrospective baseline outcome measurement to assess their wrist function as it was before the injury. At this stage the patient may have already had their definitive treatment, if they are to undergo conservative treatment, or may be awaiting surgical intervention at a later date. The schedule of treatment timing and nature of any intervention for the patient's distal radial fracture will not be influenced in any way by involvement in this trial. These decisions will remain solely at the discretion of the treating medical team.

Outcome Measures – Follow-up for distal radial fractures is standardised regardless of conservative or surgical treatment. Patients will therefore return to their review at 2, 6 and 12 weeks post-injury. These time points will be utilised for face-to-face completion of outcome measures.

Outcomes measurable at 3, 6 and 24 months will be collected by post if the patient has already been discharged from fracture clinic. It is likely that this will be the case in the majority of patients who undergo an uncomplicated recovery. Prior to postage, the hospital patient administration system will be checked to ensure that patient demographics, address has not changed, and that the patient is not currently an in-patient for another reason or passed away in the interim. Patients will be provided with a prepaid envelope for the free return their completed questionnaires. In the event that questionnaires are not returned within 2 weeks of being posted out from the research team, a follow-up phone call will be made to the patient by the research team. This phone call is to ascertain whether the patient wishes to continue with this study, and if so a further questionnaire will be posted to her/him. In the event that this questionnaire is subsequently not returned or the patient is not contactable by phone, no further contact will be made with the patient and their withdrawal presumed.

MYMOP responses will be used adjacent to GROC to assess patient important changes. This will enable a better understanding of the patient important factors and possibly justify different components of the DASH/PRWE/PEM.

A summary of the outcome measures to be completed and the relevant time points is detailed in Table 1. The questionnaires for completion are available in Appendix 2. It is estimated it will take each patient 15 minutes to complete the six forms at each assessment time.

With regards to missing data within the questionnaires themselves, this will be handled in line with the instructions for each of the questionnaires.

Table1: Follow-up plan (order of outcome assessments to be varied for each time point)

7. STATISTICS AND DATA ANALYSIS

Statistical analysis – Comparison of the change in outcome measure against the Global Rating of Change (GROC) anchor questions. The anchor questions will identify those patients perceiving a change in outcome. The MCID will be calculated in 2 ways. Firstly as the mean changes in DASH/PRWE/PEM in the group deemed to have minimal changed (improved) as

measured by the GROC. Sub-analysis will assess difference in MCID between treatments.

Secondly, a Receiver Operator Characteristic (ROC) curve analysis will look compare those patients deemed to have changed versus those who have not changed against the various thresholds of MCID. The MCID representing the best (compromise) between sensitivity and specificity for detecting changed participants will be selected.

Data and all appropriate documentation will be stored for a minimum of 15 years after the completion of the study, including the follow-up period.



Health Research Authority

National Research Ethics Service

NRES Committee London - Central

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14 July 2014

Professor TRC Davis
Consultant Orthopaedic Hand Surgeon
Nottingham University Hospitals NHS Trust
Professor Davis Secretary
Queen's Medical Centre
Derby Road, Nottingham
NG7 2UH

Dear Professor Davis

Study title:	The Minimal Clinically Important Difference in Distal Radial Fractures - Setting the Standard
REC reference:	14/LO/1255
IRAS project ID:	147261

The Proportionate Review Sub-committee of the NRES Committee London - Central reviewed the above application on 09 July 2014.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager Shehnaz Ishaq, NRESCommittee.London-Central@nhs.net

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. In the IRAS form they state that participants can take two weeks to consider participating but this was not raised on the Information Sheet. So a possible solution would be to add a small statement on the Information Sheet that states "While completing this questionnaire now would be helpful, if you would prefer, then you can complete the questionnaire at home and return it to us by post". This would obviously need to be accompanied by a stamped addressed envelope.

A Research Ethics Committee established by the Health Research Authority

2. The Committee agreed that the GP did not need to be notified. Reference to this should be taken out of the Information Sheet and Consent Form.
3. The Committee agreed that the mention of samples should be taken out of the Information Sheet and Consent Form as there is no requirement for those sections to be there.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Summary of discussion at the meeting

Recruitment arrangements and access to health information, and fair research participant selection

The Committee noted that it was intended that potential participants were to be informed of the study and consented during their first visit (actual diagnosis and treatment) and will be asked to complete three questionnaires (as one) at this first visit and then also at 2 subsequent visits. Later questionnaires will be posted to participants.

The Committee commented that patients could feel pressured into taking part at they were being approached by the clinician or team member while they are attending for initial treatment of their fracture.

At least 5 of the questions on the questionnaires to be completed in clinic seemed more service provision than patient diagnosis/progress. An objective answer while actually in clinic may be difficult to obtain.

In A31 on the IRAS form there was a statement that for those who wish, up to two weeks may be taken before deciding to participate.

The Committee thought that a possible solution would be to provide all questionnaires at clinic visits with a stamped envelope for patients to return later. (They could of course choose to complete these in clinic). This approach could also be used at first contact with the Information Sheet also being provided with the initial questionnaire. If all the questionnaires were provided with an envelope for later return (either in clinic or posted once clinic visits had stopped), there would also be no need for a signed consent form as completing the questionnaires would automatically imply consent.

Some of the questions on the baseline questionnaire would need to be completed by the clinician and not the patient (Radiography details page 1). These could easily be removed from the questionnaire and simply be taken from the patients notes.

The Committee pointed out that this was a suggestion and there may be other possibilities that would minimise any perceived pressure on individuals to participate.

Mr Trickett clarified that the option of being consented at the first visit/encounter and using that opportunity for completion of the questionnaires was to obtain a pre-injury baseline for outcome. It was planned to use this data to determine whether MCID varied with original baseline status. It was agreed that consenting at this first encounter could be construed as coercive. However, many studies recruiting in trauma surgery by necessity consent at first encounter and it was felt that this would provide good baseline data without introducing any recall bias. In addition, he commented that the fracture clinic appointments in the NHS often take a number of hours and it was felt that patients would be able to complete the forms whilst waiting, with minimal impact on their time outside of the clinic. He explained that if the committee felt strongly that consent/completion during this first clinic visit may be coercive then they would have been happy to accept the suggestion of providing the questionnaires and a stamped address envelope for completion later.

The Committee was happy with the response provided.

Care and protection of research participants; respect for potential and enrolled research participants' welfare & dignity

The Committee also pointed out that data would also need to be kept for 3 years or more; the application states 6-12 months.

Mr Trickett also clarified that data would be kept for 3 years as requested.

Informed consent process and the adequacy and completeness of research participant information

The Committee noted that there appeared to be no benefit in informing the GP of participation in the study and so reference to this could be removed from the Information Sheet and Consent Form.

Mr Trickett agreed that there was little benefit in the GP being made aware of the study directly. This was suggested by the sponsor and R&D department for completeness. When dictating clinic letters of patients (standard clinic practice) they would usually state if the patient was involved in a trial. The clinic letters also form part of the patients' clinical record and would be the only documentation within the patient notes.

Suitability of supporting information

Similarly references to samples and genetic analysis could also be removed from the PIS and Consent Form. (Items 15,16 and 17).

Mr Trickett agreed and clarified that this was requested by the sponsor/R&D to be including on the Information Sheet

The Committee noted at the start of all but the baseline questionnaire, while there is only space for a Study ID; there does not appear to be any obvious space for any individual patients ID.

The study ID is the number that each patient is assigned on entering the study. All study documentation will be labelled with only the Study ID. A central recruitment log will marry up the patient hospital ID and the Study ID, ensuring no patient identifiable information is on any of the study documentation.

On the MyMOP questionnaire (week 12) – this started with three blank spaces for symptoms but there was nothing to indicate who was to fill in these symptoms (Patient or Clinician). The Committee asked whether these would be filled in by the clinician before or after the questionnaire is given to the patient.

Mr Trickett clarified that the MyMOP questionnaire is completed by the patient. The patient chooses the symptoms that affect them most at the initial visit and these are documented exactly as the patient describes them/in their own words/writing. At the follow-up, the symptoms (exactly as described/documentated on the first questionnaire) will be transcribed to the follow-up form. This will be performed before the patient completes the form in-line with the standardised instructions for MyMOP completion.

Approved documents

The documents reviewed and approved were:

Document	Version	Date
IRAS Checklist XML [Checklist_30062014]		30 June 2014
Letter from funder [AO Grant Letter]	1	21 October 2013
Letter from sponsor [Sponsor 1]	1	02 June 2014

A Research Ethics Committee established by the Health Research Authority

Participant consent form [Consent v 3 Apr 2014]	3	12 April 2014
Participant information sheet (PIS) [Information v3 Apr 2014]	3	12 April 2014
REC Application Form [REC_Form_30062014]		30 June 2014
Research protocol or project proposal [Protocol v3 Apr 2014]	3	11 April 2014
Summary CV for Chief Investigator (CI) [TRCD CV]	1	03 June 2014
Validated questionnaire [MCID 2 weeks]	1	17 November 2013
Validated questionnaire [MCID 6 weeks]	1	17 November 2013
Validated questionnaire [MCID 24+ weeks]	1	05 June 2014
Validated questionnaire [MCID 12 weeks]	1	05 June 2014
Validated questionnaire [MCID Baseline]	1	29 October 2013

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

14/LO/1255	Please quote this number on all correspondence
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Yours sincerely



Signed on behalf of:
Dr Andrew Hilson
Chair

Email: NRESCommittee.London-Central@nhs.net

Enclosures: List of names and professions of members who took part in the review

"After ethical review – guidance for researchers"

Copy to: Mr Ryan W Trickett

Ms Stacey Harrison, Research & Innovation Nottingham Health
Science Partners

A Research Ethics Committee established by the Health Research Authority

Appendix 2 - Outcomes Study Protocol

This is the trial protocol (Version 2.4 - 13th August 2015) as approved by the National Research Ethics Service (NRES) Committee East Midlands - Nottingham 2 (115/EM/0297).

1. INTRODUCTION

1.1 BACKGROUND

Distal radius fractures are common, particularly in osteoporotic bone. Over 70,000 are estimated to occur each year in the United Kingdom alone. There are surgical and non-surgical management options for these fractures but many are treated conservatively in a plaster cast or increasingly a splint.

There remains no consensus on the most appropriate rehabilitation for patients who are conservatively managed after distal radius fractures. Many centres routinely refer these patients for physiotherapy after immobilisation is removed whilst some prefer to provide advice sheets and an open appointment. The additional expense of a physiotherapy referral can be justified if return to function is hastened by physiotherapy. If no significant benefit can be shown then a change in the management of these patients should be recommended.

A second area of interest are the methods for guiding self directed therapy. Very little has been published on how patients are prepared to receive this advice. Patients are increasingly computer literate and willingness to access advice through media and the internet, particularly if it can be shown to be effective, would represent a paradigm shift in management and could represent a significant cost saving.

1.2 RATIONALE FOR CURRENT STUDY

The rationale for performing this study is to ascertain whether the method of delivery of therapy advice following immobilisation for a conservatively managed distal radius fracture influences the short term outcomes in return to function.

Primary research question:

What is the best method of post injury rehabilitation after a conservatively managed distal radius fracture as measured by the DASH score?

Secondary research questions:

What is the best method of post injury rehabilitation after a conservatively managed distal radius fracture as measured by the EQ5D and PEM?

What effect do the differing methods of therapy have on clinical outcomes such as range of movement and grip strength?

What is the most cost effective rehabilitation regimen?

What media are patients happy to receive rehabilitation advice through?

Null hypothesis :

The method of delivery of therapy in patients with distal radius fractures after immobilisation is removed, will have no effect of their short and long term return to function.

2. STUDY OBJECTIVES

The primary study objective is to allow patients access to the most effective therapy regime after they have sustained a conservatively managed distal radius fracture.

The secondary study objective is to determine which is the most cost effective intervention to allow the NHS to make the most appropriate choices in the context of an ever more financially constrained environment. A further secondary aim is to explore the patient reported satisfaction with the three methods of delivering advice and in those who were offered access to video tools what route and how often they accessed them. The ultimate study objective is to change and standardise practice across the NHS in how to provide therapy to the population under study.

3. STUDY DESIGN

This study has been designed as a randomised control trial with patients split into three groups. The group receiving an advice sheet are considered the control group, with those receiving a physiotherapy referral or video assisted self directed therapy the intervention groups. The patients will be recruited from the adult fracture clinic at the Queens Medical Centre,

Nottingham. We will plan to recruit 120 patients randomising 40 to each group giving the power to detect Δ DASH of 6 points as the MCID.

Initial patient management will be according to standard care with their injury diagnosed on x-ray and management conducted as felt indicated by the initial treating surgeon. At 6 weeks (+/- 1 week) following injury the patients will have their cast removed and will then be randomised. Three baseline patient outcome scores will be taken: Disabilities of the Arm Shoulder and Hand (DASH), EuroQol 5D (EQ5D) and the Patient Evaluation Measure (PEM). The patients in the 'self directed therapy' group will be able to access rehabilitation advice on DVD, through YouTube or through a website, all of which will be supplied. Patients will complete a questionnaire on their demographics, occupational history and relevant medical history. They will have a clinical examination including range of movement and grip strength as assessed by a JAMAR dynamometer on both the injured and uninjured side.

After a further 6 weeks (12 weeks following injury +/- 1 week) the patients will be brought back to a research clinic for clinical evaluation, to repeat the outcome scores and complete a questionnaire. The pre- and post-intervention scores and range of movement will be compared within each group and between the three groups to examine the effect of each intervention against the control group. The questionnaire will qualitatively assess patient satisfaction with their follow up and for those in the 'self directed therapy' group, which media they chose to access and whether they found it useful and effective. Range of motion and grip strength will again be recorded for the injured side.

One year (+/- 1 month) following removal of immobilisation patients will be invited to return for a followup clinic to again repeat the DASH, EQ5D, PEM and clinical assessments. This will give a better understanding of the long term effects. If patients are not able to return, in order to minimise patients lost to followup the DASH, EQ5D and PEM could be performed via telephone.

3.1 STUDY OUTCOME MEASURES

Patients will complete a DASH score (the primary outcome measure), EQ5D and PEM score as baseline scores. Clinical measures such as the range of movement and grip strength will be assessed.

4. PARTICIPANT SELECTION AND ENROLMENT

4.1 PARTICIPANT IDENTIFICATION

Patients will be referred to the study by the treating orthopaedic surgeon from Fracture clinic. The main pre-registration evaluation performed before a participant can be entered will be the initial x-rays taken as part of the normal evaluation by the referring physician (usually in the Emergency Department). These x-rays will confirm that the fracture, in most cases, meets the inclusion criteria.

For patients in whom there is a question surrounding competence to consent to enrolment will be asked to perform an abbreviated mental test (AMT) examination. A score >7/10 is considered as adequate for consent to be taken. Presence of a previous fracture will exclude patient on initial evaluation. Those satisfying our inclusion/exclusion criteria will be approached to participate in the study by a member of the research team.

4.2 INCLUSION CRITERIA

Age 18 - 70 years at time of fracture.

Able to give informed consent.

Any fracture of the distal radius within 3cm of the radiocarpal joint will be considered for inclusion (including intra-articular fractures, fractures with comminution, associated ulnar styloid fracture, dorsal and volar displacement patterns) provided it has been deemed suitable for conservative management by the treating physician.

Fracture treated with immobilisation (plaster of paris / fibreglass cast / splint) worn constantly for between 5 - 7 weeks.

Able to speak and understand English without need of an interpreter to sufficient level.

4.3 EXCLUSION CRITERIA

A fracture which extends beyond 3cm of the radiocarpal joint.

Any patient with bilateral fractures.

A fracture which has been immobilised outside of the range of 5 - 7 weeks.

Any patient who is deemed to be unlikely to be able to adhere to the trial procedure or complete the questionnaires (eg drug dependence or cognitive impairment). Patient must be able to view a video either via DVD or online. Current participation in another ongoing study.

Evidence of complex regional pain syndrome.

Post plaster stiffness of the fingers which prevents the patient from being able to place their hand flat on a tabletop.

Any previous fracture of the wrist or carpal bones whether treated operatively or conservatively.

4.4 WITHDRAWAL CRITERIA

Any patient who loses the ability to provide ongoing consent (as assessed when needed by a fall in the AMT <7/10) will be removed from the study.

Any patient who develops signs of Complex Regional Pain Syndrome.

Any patient who requests to be withdrawn from the study at any time.

4.5 CONSENT

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained.

The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records. A second copy will be filed in the participant's medical notes and a signed and dated note made in the notes that informed consent was obtained for the study.

RANDOMISATION

The allocation sequence will be generated in advance by the study statistician, with random permuted blocks of 6. There will be no stratification of participants.

Treatment allocation will be using sequentially numbered, opaque, sealed envelopes. Randomisation will be performed by a delegated member of the study team after subjects have given informed consent.

5.0 ADVERSE EVENTS

5.1 DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that results in death.

Is life-threatening – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe, requires hospitalisation, or prolongation of existing inpatients' hospitalisation or results in persistent or significant disability or incapacity.

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

5.2 REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

5.2.1 NON SERIOUS AES

All such events, whether expected or not, should be recorded.

5.2.2 SERIOUS AES

An SAE form should be completed and faxed to the Chief Investigator via Jessica Nightingale within 24 hours. However, hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the Nottingham University Hospitals NHS Trust REC where in the opinion of the Chief Investigator, the event was:

'related', ie resulted from the administration of any of the research procedures; and 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the COREC SAE form for non-IMP studies. Local investigators should report any SAEs as required by their Local Research Ethics Committee and/or Research & Development Office.

Sponsor Contact Details for SAEs:

1. email: rdsae@nhs.nuh.uk
2. fax: 0115 8493295
3. phone: Research & Innovations Dept on 0115 9709049

or 0115 9249924 ext 70659 or 70660 to confirm arrival

For any queries please contact a member of staff in the Research & Innovations department

tel: 0115 9709049 or 0115 9249924 ext 70659 or 70660

6. ASSESSMENT AND FOLLOW-UP

The follow up assessments will be performed between 5 and 7 weeks and 11 to 13 months after the immobilisation is removed. At this appointment patients will be re-assessed using the DASH score, EQ5D and PEM. The change in these scores from baseline will be the assessment tool the study is based on.

Clinical assessment will be performed assessing range of movement using a goniometer (measurement in degrees from the anatomical position) and grip strength using a JAMAR dynamometer (measurement in kg). Data will be collected on the uninjured side as well as the injured.

Demographic information on all patients will be collected including occupation, hobbies, handedness and any relevant medical conditions including diabetes mellitus

All patients will fill out a questionnaire exploring their subjective impression of the advice they received. The patients who receive video therapy advice will be further assessed with a questionnaire seeking to understand how

they accessed the videos and whether they found this a useful and acceptable method of receiving advice.

The 6 week follow up clinic is defined as the endpoint of the early outcomes and the one year followup the endpoint of the entire study.

7. STATISTICS AND DATA ANALYSIS

Data and all appropriate documentation will be stored for a maximum of 3 years after the completion of the study, including the follow-up period.

Patients will be allocated a trial number after randomisation which will follow the sequence SP001, SP002 etc.

Primary Endpoint

The DASH scores obtained will be analysed to establish any differences between the treatment groups. As the observations obtained cover three treatment groups a univariate analysis of variance (ANOVA) will be applied to the data to assess whether there was any statistically significant difference across the groups. A significance threshold of 5% will be taken in all cases. Further univariate ANOVA tests will be performed on both the PEM scores and EQ5D scores obtained to observe any statistically significant change in patient outcomes.

Secondary Endpoints

The secondary endpoints which we will investigate in this study include:-

- 1) What is the most cost effective rehabilitation regimen?
- 2) What media are patients happy to receive rehabilitation advice through?

Cost efficiency will be calculated using a simple health economic costs model. All direct healthcare and rehabilitation costs will be calculated and any differences established using ANOVA testing.

For all patients satisfaction will be qualitatively assessed using simple questionnaires which will be analysed and reported on a narrative basis.

Safety Analyses

All staff participants will be advised to report on safety related issues throughout the study. Again feedback will be sought on a narrative basis.

Interim Analyses

There will be no interim analysis performed.



Health Research Authority

NRES Committee East Midlands - Nottingham 2

Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839437

30 July 2015

Mr BJ Ollivere
Consultant Trauma and Orthopaedic Surgeon
Nottingham University Hospitals NHS Trust
Department of Trauma and Orthopaedics
Queens Medical Centre
Nottingham
NG7 2UH

Dear Mr Ollivere

Study title:	Outcomes and Cost Effectiveness of Physiotherapy, Self Directed Therapy and Advice Sheets Following Conservatively Managed Distal Radius Fractures : A Prospective Randomised Controlled Trial
REC reference:	15/EM/0297
Protocol number:	2
IRAS project ID:	143108

The Research Ethics Committee reviewed the above application at the meeting held on 27 July 2015. Thank you to Mr Tim Coughlin attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Ms Carolyn Halliwell, NRESCommittee.EastMidlands-Nottingham2@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

- A lay language title is needed.
- Contact details for an independent advice and complaints service should be added.
- The word 'chosen' within the sub-heading 'Why have I been chosen' should be amended to 'invited'.
- The information regarding the three groups to which participants will be randomly allocated should be reformatted to separate the points with a space.
- Points 6 and 7 should be proof read and amended to remove grammatical errors
- The reasoning for the inclusion of point 8 'What are the alternatives for treatment?' is not clear and as such it should be removed.
- The information regarding drugs under point 16 'What if new information becomes available?' should be deleted as it is not relevant to this study.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Summary of discussion at the meeting

- **Recruitment arrangements and access to health information, and fair participant selection**

The Committee asked why the age range for recruitment to the study has a cut-off point of seventy years of age. *The applicant responded there is an argument that the evidence is that after the age of seventy the radiological outcome does not matter. Under the age of seventy the evidence is more on the side of surgical intervention, but it is not there for those over the age of seventy. Over the age of seventy patients may not even be x-rayed.*

- **Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity**

The Committee asked what standard care for patients is at the moment. *The applicant responded this varies from surgeon to surgeon. Patients will either be given an advice sheet; the same as is included with the study, or be referred to physiotherapy.*

The Committee queried if everything else in addition to the advice sheet is part of standard care. *The applicant responded the first thing to happen to the participant as part of the study would be after their normal pathway has*

finished. The exclusion criterion helps to remove all patients who every consultant believes requires physiotherapy. The Committee asked if the exclusion criteria will definitely ensure exclusion of more complex cases. The applicant responded those with chronic regional pain syndrome are routinely treated by the physiotherapist at close follow up and patients such as those who for example can't put their hand flat on a table or exhibit other risks, will be taken out by the exclusion criteria.

- The Committee asked if participants will be expected to complete the questionnaires whilst they are in plaster. *The applicant confirmed they will not and further responded if participants do need any assistance in completing the questionnaires someone is on hand to help them.* The Committee asked if participants may be asked to complete the Consent Form whilst they are in plaster. *The applicant responded possibly.*

Suitability of supporting information

The Committee commented that although the advice sheet has been included in the study documentation, there is nothing included about the content of the video to be shown to participants. *The applicant responded the advice on the video is verbally descriptive but contains the same exercises as are on the advice sheet. The video offers advice more akin to that given at a face to face physiotherapy appointment.* The Committee asked if there is slightly more information on the video. *The applicant confirmed this as correct.*

The Committee asked what will happen if for whatever reason a participant can't play the video. *The applicant responded the content will be available online to participants in addition to them taking the video home. It is about making the information as accessible as possible. They can make it more specific as an exclusion criteria if needed.*

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
GP/consultant information sheets or letters [GP Letter]	V1.1	22 September 2014
IRAS Checklist XML [Checklist_19062015]		19 June 2015
IRAS Checklist XML [Checklist_19062015]		19 June 2015
Letter from funder [Funder Grant Acceptance Letter]		21 October 2013
Letter from sponsor [Sponsor Authorisation]		13 May 2014
Non-validated questionnaire [Patient Questionnaire Initial]	V1.3	22 September 2014
Non-validated questionnaire [Patient Questionnaire Advice Sheet Follow Up]	V1.1	22 September 2014
Non-validated questionnaire [Patient Questionnaire Physiotherapy Group Follow Up]	V1.1	22 September 2014
Non-validated questionnaire [Patient Questionnaire Video Group Follow Up]	V1.3	22 September 2014
Non-validated questionnaire [Patient Questionnaire All Groups Final]		16 December 2013
Participant consent form [Patient Consent Form]	V1.3	22 September 2014
Participant information sheet (PIS) [Participant Information Sheet V1.3]		

Participant information sheet (PIS) [Patient Handout Wrist Physio]	V1	14 April 2015
Participant information sheet (PIS) [Patient Handout Wrist Physio]		
REC Application Form [REC_Form_19062015]		19 June 2015
Research protocol or project proposal [Protocol V2.3]		
Summary CV for Chief Investigator (CI) [2 Page CV Ben Ollivere]	V1.0	22 September 2014
Validated questionnaire [DASH Score]		22 September 2014
Validated questionnaire [EQ-5D]		22 September 2014
Validated questionnaire [PEM]		22 September 2014

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

15/EM/0297	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely



Dr Frances Game
Chair

E-mail: NRESCommittee.EastMidlands-Nottingham2@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers"

Copy to: Mr Tim Coughlin, Nottingham University Hospitals NHS Trust
Koufali Maria, Nottingham Health Science Partners



Health Research Authority

NRES Committee East Midlands - Nottingham 2

Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839437

01 September 2015

Mr BJ Ollivere
Consultant Trauma and Orthopaedic Surgeon
Nottingham University Hospitals NHS Trust
Department of Trauma and Orthopaedics
Queens Medical Centre
Nottingham
NG7 2UH

Dear Mr Olivere

Study title:	Outcomes and Cost Effectiveness of Physiotherapy, Self Directed Therapy and Advice Sheets Following Conservatively Managed Distal Radius Fractures : A Prospective Randomised Controlled Trial
REC reference:	15/EM/0297
Protocol number:	2
IRAS project ID:	143108

Thank you for your response of 28th August 2015. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 30 July 2015

Documents received

The documents received were as follows:

GP/consultant information sheets or letters [GP Letter]	V1.2	13 August 2015
Other [Patient Handout Physio]	V1.1	13 August 2015
Participant consent form [Participant Consent Form]	V1.4	13 August 2015
Participant information sheet (PIS) [Participant Information Sheet]	V1.4	13 August 2015
Research protocol or project proposal [Protocol]	V2.4	13 August 2015

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
GP/consultant information sheets or letters [GP Letter]	V1.2	13 August 2015
Letter from funder [Funder Grant Acceptance Letter]		21 October 2013
Letter from sponsor [Sponsor Authorisation]		13 May 2014
Non-validated questionnaire [Patient Questionnaire Initial]	V1.3	22 September 2014
Non-validated questionnaire [Patient Questionnaire Advice Sheet Follow Up]	V1.1	22 September 2014
Non-validated questionnaire [Patient Questionnaire Physiotherapy Group Follow Up]	V1.1	22 September 2014
Non-validated questionnaire [Patient Questionnaire Video Group Follow Up]	V1.3	22 September 2014
Non-validated questionnaire [Patient Questionnaire All Groups Final]		16 December 2013
Other [Patient Handout Physio]	V1.1	13 August 2015
Participant consent form [Participant Consent Form]	V1.4	13 August 2015
Participant information sheet (PIS) [Patient Handout Wrist Physio]	V1	14 April 2015
Participant information sheet (PIS) [Participant Information Sheet]	V1.4	13 August 2015
REC Application Form [REC_Form_19062015]		19 June 2015
Research protocol or project proposal [Protocol]	V2.4	13 August 2015
Summary CV for Chief Investigator (CI) [2 Page CV Ben Ollivere]	V1.0	22 September 2014
Validated questionnaire [DASH Score]		22 September 2014
Validated questionnaire [EQ-5D]		22 September 2014
Validated questionnaire [PEM]		22 September 2014

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/EM/0297	Please quote this number on all correspondence
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Yours sincerely



Carolyn Halliwell
REC Manager

E-mail: NRESCommittee.EastMidlands-Nottingham2@nhs.net

Copy to: Mr Tim Coughlin, Nottingham University Hospitals NHS Trust
Koufali Maria, Nottingham Health Science Partners

	Nottingham University Hospitals  NHS Trust Research & Innovation Nottingham Integrated Clinical Research Centre C Floor, South Block QMC Campus Derby Road Nottingham NG7 2UH Tel: 0115 970 9049 www.nuhrise.org
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'LETTER OF AUTHORISATION'

Title:	Early outcomes and cost effectiveness of physiotherapy self-directed therapy and advice sheets following conservatively managed distal radial fractures
Chief Investigator:	Mr Ben Ollivere
Sponsor Reference:	13OR007/13OR004
EudraCT Number: (If applicable)	

We hereby state that:

The above project has also been submitted to the Trust's Research and Innovation department.

I can confirm that Nottingham University Hospitals NHS trust is acting as the Research Sponsor for the above project. The project progress will be monitored by the Chief Investigator and the NHS Trust.

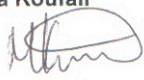
Mr Ben Ollivere is authorised by Research and Innovation, Nottingham University Hospitals NHS Trust, Derby Road, Nottingham, NG7 2UH to exercise all necessary rights to:

- 1.) Submit the Clinical Trial Application and any amendments, updates as well as related documents regarding the above protocol to The Ethics Committee (and Competent Authority).
- 2.) Liaise with the Ethics Committee (and Competent Authority) in relation to the Clinical Study.

Sponsor Organisation: Nottingham University Hospitals NHS Trust

On behalf of: Nottingham University Hospitals NHS Trust

Name: Dr Maria Koufali

Signature: 

Designation: Deputy Director of Research & Innovation

Date: 13 MAY 2014.

We are here for you

Appendix 3 - Survey of National Standard of Care

- 1. For conservatively managed undisplaced or minimally displaced distal radius fractures what is your standard period of immobilisation?**
 1. 1-4 Weeks
 2. 5 Weeks
 3. 6 Weeks
 4. 7 Weeks
 5. >7 Weeks
- 2. For conservatively managed distal radius fractures which have undergone a manipulation what is your standard period of immobilisation?**
 1. 1-4 Weeks
 2. 5 Weeks
 3. 6 Weeks
 4. 7 Weeks
 5. >7 Weeks
- 3. Is your standard management for patients with undisplaced distal radius fractures to receive a:**
 1. Plaster (Backslab or Complete Cast)]
 2. Removable Splint (e.g. Futura)
 3. Other
- 4. When the immobilisation (plaster or splint) is removed what is your typical rehabilitation method, assuming the fracture is uncomplicated and the patient is not excessively stiff (please tick all that apply)?**
 1. Refer to Physiotherapy
 2. Advice Sheet
 3. Instructional Video
 4. Other
- 5. What is your usual follow-up pathway once a patient's immobilisation (plaster or splint) is removed?**
 1. Discharge
 2. Open Appointment
 3. Follow-up Appointment

6. For a patient with a light clerical job what duration of sick note do you supply once immobilisation is removed?

1. 1 Weeks
2. 2 Weeks
3. 3 Weeks
4. 4 Weeks
5. 5 Weeks
6. 6 Weeks
7. >6 Weeks

7. For a patient with a heavy manual job what duration of sick note do you supply once immobilisation is removed?

1. 1 Weeks
2. 2 Weeks
3. 3 Weeks
4. 4 Weeks
5. 5 Weeks
6. 6 Weeks
7. >6 Weeks

8. Please specify which training region you are working in (e.g. East Midlands North etc)

Appendix 4 - The MYMOP

* MYMOP2 Follow up *

Full name Today's date

Please circle the number to show how severe your problem has been IN THE LAST WEEK.

This should be YOUR opinion, no-one else's!

SYMPTOM 1:	0	1	2	3	4	5	6
.....	As good as it						As bad as it
.....	could be						could be

SYMPTOM 2:	0	1	2	3	4	5	6
.....	As good as it						As bad as it
.....	could be						could be

ACTIVITY:	0	1	2	3	4	5	6
.....	As good as it						As bad as it
.....	could be						could be

WELLBEING:	0	1	2	3	4	5	6
How would you rate	As good as it						As bad as it
your general feeling	could be						could be
of wellbeing?							

If an important new symptom has appeared please describe it and mark how bad it is below.

Otherwise do not use this line.

SYMPTOM 3:	0	1	2	3	4	5	6
.....	As good as it						As bad as it
.....	could be						could be

The treatment you are receiving may not be the only thing affecting your problem. If there is anything else that you think is important, such as changes you have made yourself, or other things happening in your life, please write it here (write overleaf if you need more space):

Are you taking medication FOR THIS PROBLEM ? Please circle: YES/NO

IF YES:

Please write in name of medication, and how much a day / week

.....

.....

MYMOP, Measure Yourself Medical Outcome Profile