Copy of Final HAND-1 RfPB Report

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Needle fasciotomy versus limited fasciectomy for the treatment of Dupuytren's contractures of the fingers: a study which investigates the feasibility, acceptability and design of a multicentre randomised trial (HAND-1).

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LAY/PLAIN ENGLISH SUMMARY

Dupuytren's contractures are fibrous cords which cause the fingers to curl into the palm and create difficulty with everyday tasks (Figure 1). Needle fasciotomy (NF) and limited fasciectomy (LF) are two established surgical treatments which straighten the affected fingers, but are very different. NF divides the cord using a needle, has a short recovery period and is cheap for the NHS, but the fingers frequently curl back into the palm over the years so that further treatment is needed. LF uses a surgical incision, has a longer recovery, a greater risk of complications and is expensive to the NHS, but curling back of the fingers into the palm and need for further treatment are less likely. There is currently no reliable evidence comparing LF and NF, and a large randomised trial is needed. To do this large trial we need to know whether sufficient patients would be willing to participate, and how best to design this study and measure treatment success. We performed this smaller "feasibility" study to answer these questions.

153 patients were invited to take part in the study and 71 agreed and were randomly allocated to treatment with either NF or LF. 10 did not complete 6 month assessments due to treatment delays and 11 were lost to follow-up or withdrew from the study. A total of 50 participants completed 6 month follow up assessments. Patient recruitment to the study was improved by training the research team to explain the two treatment options to patients in a balanced manner, and screening GP referral letters to guide potential participants to recruiting clinics.

Participants completed the same four Patient Reported Outcome Measure questionnaires (PROMs) before and after surgery. These assessed hand symptoms and function, including ability to undertake common everyday tasks. Participants felt two of the four PROM questionnaires best allowed them to describe how their treatment affected their hand function. We also calculated the cost of NF (£170) and LF (>£1,000) and devised a reliable technique to measure how much the surgery had straightened the finger.

This study shows that a large randomised controlled trial to investigate whether NF or LF is best at treating Dupuytren's contractures and restoring and maintaining hand function is feasible. Data collected allow us to determine the number of participants who would need to take part, how long the trial would last and how best to measure the outcome of NF and LF treatment.

SUMMARY OF RESEARCH AND FINDINGS

BACKGROUND: Dupuytren's contractures (DC) cause fingers to curl into the palm, resulting in loss of function (Figure 1). Standard treatment in the NHS is surgery to straighten the fingers by needle fasciotomy (NF) or limited fasciectomy (LF) (Table 1). There is lack of high quality evidence to determine which treatment is best for the patient and guide decision making. This study assessed the feasibility of conducting a large multicentre randomised controlled trial (RCT) to compare the clinical and cost-effectiveness of NF versus LF. A QuinteT Recruitment Intervention (QRI) was embedded to optimise recruitment.

MAIN OBJECTIVES: to determine: a) if surgeons and patients are willing to take part in such a trial; b) the best way to measure hand function and symptoms experienced by patients, before, during and after treatment; and c) the size and duration of a definitive RCT.

METHODS: Full protocol published [1]

a. **Design**: Parallel, two-arm, three centre, randomised feasibility trial.
b. **Participants**: Individuals with DC referred to secondary care for surgery who fulfilled entry criteria (Table 2).
c. **Randomisation**: Participants were randomised (1:1) to treatment with either NF or LF using a secure internet-based system. Randomisation was stratified by centre and joints affected. Blinding of the surgeon and participant to intervention allocation was not possible.
d. **Interventions**: Participants were placed on the NHS waiting list for their allocated treatment. NF was performed in a clinic room using local anaesthetic. LF was performed under general/regional anaesthetic in an operating theatre.
e. **Outcomes**: Feasibility outcomes were 1) recruitment, including number of patients screened, consented and randomised; 2) outcome assessment including completion of follow-up and identification of a Patient Reported Outcome Measure (PROM) to use as the primary outcome in a future RCT; and 3) acceptability of treatment. See Figure 2 for potential secondary outcomes.
f. **Adverse events (AEs):** Limited to Serious Adverse Events (SAEs): Death, loss of finger and any unexpected, serious event potentially related to the intervention.
g. **Statistical methods:** A formal sample size calculation is not appropriate for a feasibility study. It was anticipated 50-85 participants would be recruited across the 3 centres. We used appropriate descriptive statistics to describe recruitment data, baseline characteristics of participants, completeness of data collection, compliance with allocated intervention, and outcomes at follow-up. The Statistical Analysis Plan (SAP) was finalised before data were unblinded.
h. **Embedded qualitative research:** A QuinteT Recruitment Intervention (QRI) focused on optimising recruitment and exploring patients' experiences of trial participation and the interventions. Phase 1 identified obstacles to recruitment by audio-recording trial recruitment consultations, interviewing trial staff and patients, and by scrutinising trial documentation and screening logs using simple counts, content, thematic and targeted conversation analyses. In phase 2, various strategies were implemented to address identified recruitment challenges.
i. **Oversight:** A Trial Steering Committee (TSC) oversaw the conduct of this study (Table 3).

MAIN FINDINGS

1. Recruitment

a. **Eligibility criteria for a future RCT and proportion of referred NHS patients who met the criteria:** The most common reason for ineligibility was previous surgery on the same hand (n=48) (Table 4); for a large pragmatic trial this need not be a reason for exclusion. The exclusion criterion 'life expectancy <3 years' is difficult to assess and should be revised to "expected to be available for follow up at 1 year". The inclusion criterion 'contracture >30° should be revised to ≥30°. See Table 2 for proposed criteria for a definitive RCT.
Due to different hospital clinic systems, screening GP referral letters varied across the three sites. The most successful recruiting site screened all referral letters (Table 5). Data from the three centres suggest that 153 (57%) of 267 GP referrals with DC were eligible (Table 5 and Figure 3).

b. **Determine willingness of: a) patients to be randomised to NF or LF and; b) surgeons to recruit patients with different patterns of DCs:** 71 of the 153 eligible patients consented to be randomised to treatment with NF or LF (Table 5 and Figure 3). 75 preferred a specific treatment (NF=48; LF=12; other=15) and 7 opted for no treatment (Table 6). Thus 48% of eligible patients who decided to undergo treatment were willing to be randomised.
Patients with involvement of metacarpophalangeal (MCP) joint only, proximal interphalangeal joint (PIP) only and both MCP and PIP joints were recruited at all three centres, showing willingness of surgeons to recruit to each of these different DC patterns (Table 7). Participants in both treatment arms had balanced baseline demographic characteristics and PROM data (Table 8).

c. **Evaluate and optimise recruitment process:** The QRI identified that screening strategies need to be well defined and implemented, and eligibility criteria need to be applied consistently to maximise identification of eligible participants. Reducing recruiter treatment bias optimised the recruitment process. Tailored feedback and training was provided during the recruitment phase. This included helpful 'tips' documents and individual recruiter feedback.

d. **Estimate follow up and outcome completion rates:** There were significant delays between randomisation and treatment due to NHS waiting lists for surgery, which prevented 10 participants from completing the 6 month follow-up. The median delay was longer for LF (97 days) than NF (41 days). Treatment crossover occurred for 2 participants (Figure 3). 50 participants had 6 month follow up assessments. Follow up PROM data and surgery data collection rates were generally above 90%.

2. Outcome Assessment

a. **Evaluate PROMs for use as primary and secondary outcomes in an RCT:** Descriptive statistics for the four PROMs at baseline and 6 months are shown in Table 9. Most participants (60-90%) thought MYMOP very relevant to their daily life and functioning at each time-point after either NF or LF (Figure 4). Relevance to patients of other PROMs was more variable (Figure 4). MYMOP appeared to be the PROM most closely associated with a Global Improvement Item (GII), follow by PEM (Figure 5). MCID estimation was not possible for any PROM as only a few participants answered 'a little better' on the GII.

b. **Assess the relationship between angular measurement of finger deformity and participant reported improvement:** There was no strong association between changes in angular measurement of deformity and the change in any PROM. Angle changes correlated marginally better with the URAM and MYMOP, than the PEM and DASH (Table 10).

c. **Assess validity and reproducibility of two linear methods of measurement of finger deformity which can be performed by a research assistant**: The "step" and "grid" linear measurements of deformity had good inter-assessor agreement when assessed from the same images (Figure 6), but the grid method consistently measured greater deformity, probably due to parallax (Figure 7). Change in the grid or step measurements after treatment did not correlate well with changes in: a) angular measurements of deformity or; b) PROM scores. The step method is the preferred option and could replace angular measurement of joint contractures as the assessment of finger deformity in a definitive study.

d. **Evaluate the utility and acceptability of health resource use questionnaires to assess the impact of care on health service use and productivity:** 57 of 71(80%) of participants completed questionnaires about their health service use and hours lost from work at 2 and 6 weeks follow up. The number of self-reported GP and outpatient appointments related to hand/finger problems increased from 2 to 6 weeks after surgery. Most participants did not report taking medications. About a third of patients were in paid work at follow-up. In these, mean time off work in the past 7 days due to hand/finger problems decreased from 10.8 hours (SD 16.3) at 2 weeks to 4.4 hours (SD 10.3) at 6 weeks post-surgery. Micro-costing revealed the total cost of LF exceeded £1,000 compared to approximately £170 for NF.

3. Acceptability

Interviews with 15 participants at 1-8 months post treatment (Table 11) showed they were generally positive about their involvement in the study. Both treatments were acceptable, with general satisfaction regarding hand function and appearance post treatment. Some participants who underwent NF expected a straighter finger, and some who underwent LF found recovery more difficult than expected.

The TSC reviewed our findings and conclusions and considers the study has successfully achieved its aims, and demonstrates that a large RCT comparing NF and LF is feasible.

DISCUSSION

This feasibility study has demonstrated that a large RCT comparing NF and LF is feasible, and progression to such a study is supported by the TSC. The data collected will allow precise planning of this RCT. The proposed broadening of the inclusion criteria will increase the pool of patients potentially eligible for recruitment. Data from the QRI has shown well defined screening strategies and targeted training can optimise recruitment. Of the four PROMs assessed, MYMOP and PEM appear marginally more relevant to participants and better associated with global assessment of change. As MYMOP is not used by hand surgeons, whereas PEM is widely used, we suggest that PEM is the primary outcome measure in the full RCT, and MYMOP is a secondary outcome. The piloted health resource use questionnaire captured patient-relevant data and micro-costing showed the LF procedure costs about 6 times more than NF. However, final costs of the procedures will be dependent on the need for, and type of any required revision surgery in the long term, which are likely to be different for the two procedures.

CHANGES IN THE PROJECT SINCE INITIAL APPROVAL

Research Plan and Methodology: The original design included a prospective cohort study of patients who did not wish to be randomised to either NF or LF, but were willing to have their treatment outcome monitored and complete all the outcome measures utilised in this study at the planned time points. This was to run parallel to the “feasibility RCT”, and the aim was to collect additional data on outcome assessment.

Two of the main aims of this study were to demonstrate that (a) surgeons would be willing to recruit patients to a large RCT, and (b) eligible patients would be willing to be randomised to either treatment, rather than express a preference for one or other treatment. As we felt that the parallel prospective cohort study might be considered a “soft-option” for both the recruiting surgeon and eligible patients, we delayed its start and initially recruited only to

the “feasibility RCT”. However, because recruitment to the feasibility RCT never exceeded the upper target threshold (nor fell below the lower threshold), we continued to recruit exclusively to the “RCT” arm of the study and did not recruit to the planned prospective cohort.

There was a modification to 6-month follow-up arrangements to allow participants who underwent treatment (NF or LF) in the later stages of the follow-up period to be followed up only via postal questionnaire at 6 months, rather than attending a clinic visit. This was necessary because: a) the study follow-up period was shortened due to funding restrictions; b) NHS waiting times for surgery were longer than anticipated, thus participants were typically waiting 8-12 weeks from randomisation to treatment. These 6-month postal questionnaire data were not included in the analysis for the final report, but will be used to inform a future RCT design.

PATIENT AND PUBLIC INVOLVEMENT

PPI activities have taken place at all stages of the trial. As part of the background to the study, 432 patients were assessed either 1 year or 5 years after surgery for DC to obtain their views on treatment and the outcome of their surgery.[2] A further 110 patients were invited to give their priorities for treatment before undergoing surgery for DC.[3]

Sue Boreckyj, our PPI representative who has undergone surgeries for Dupuytren’s contractures, contributed to the study design, reviewed and contributed to the grant application, participated in discussions and decisions relating to patient reported outcomes, and reviewed study documentation.

These patient views and experiences informed the trial design and supported the inclusion of outcomes that were important to patients.

Ms Boreckyj subsequently joined the Trial Steering Committee (TSC), along with Tom Turner, a second PPI representative who underwent treatment for Dupuytren’s contracture. Mr Turner was identified via the PPI and Engagement Facilitator at NUH. Both Ms Boreckyj and Mr Turner were active members of the TSC, attending meetings and contributing to discussions. Both members contributed their opinions to the changes in the protocol for follow-up arrangements at 6 months, and reviewed patient information sheets before submission of an amendment. Both took active part in interpretation of the study results. PPI involvement in this study has ensured we developed a study which was feasible to deliver and acceptable to patients. It also ensured we produced patient friendly and accessible information, clear protocols and operating manuals and maximised recruitment

NEXT STEPS TO PATIENT BENEFIT

This study has:

a. demonstrated the acceptability and feasibility of recruiting patients with Dupuytren’s contracture to a RCT of needle fasciotomy (NF) versus limited fasciectomy (LF).
b. shown the value of providing qualitative feedback to recruiting surgeons to ensure equipoise when explaining the study to participants.
c. assessed the ability of different outcome measures to record participants’ perceptions of treatment outcome.
d. trialled a health resource use questionnaire and micro-costed NF and LF

As this is a feasibility study it has no immediate patient benefit. However it demonstrates that a RCT of NF versus LF can be delivered to determine whether one procedure is superior for restoring and preserving hand function. Dupuytren's contractures may recur after NF and LF, and the recurrence rate increases with time since surgery. As a result, further treatment may be required in a participant's lifetime. A full RCT will therefore require longer follow-up than 6 months, to determine if short-term functional or cost benefits are maintained in the long term.

Benefits of this study to the design of a definitive RCT include:

a. Adjustment of the eligibility criteria. The proposed changes would improve generalisability and would have increased the number of eligible patients in this study from 153 to 203, an increase of 33%.
b. Optimising recruitment of eligible patients. Screening of GP referral letters to identify potentially eligible patients and direct them to "recruiting clinics" should be a requirement of participating centres. Any cost implication will be countered by an increase in recruitment rates, with shortening of the recruitment phase of the study.
c. Use of qualitative support and feedback to improve equipoise of recruiters and explanation of the study to eligible patients. Any cost implication will be countered by an increased recruitment rate, with shortening of the recruitment phase of the study.
d. Demonstrating willingness of 71 of 153 (43%) eligible patients to be randomised to either NF or LF.
e. Demonstrating potential rate of cross-over (2 of 71 = 3%), completion rates for 6 month follow-up (50/61 = 82%) and study discontinuations (11/71 = 15%).
f. Invite participants in the feasibility study to assist with PPI in a definitive RCT.
g. Demonstrating the historical outcome measure of treatment for DC (improvement in angular deformity) and linear assessments of loss of extension should not be used as a surrogate for improvement in hand function, as assessed with a PROM.
h. Selection of the PEM (2nd part) PROM as the primary outcome measure on the basis of participant feedback.
i. Calculated direct costs of LF and NF to the NHS, and successfully piloted a health resource use questionnaire.

We found that MYMOP and PEM appear more closely associated with participants' global assessment of change, but were unable to estimate the minimum important change and other measures of responsiveness due to the small number of participants reporting themselves "a little better" at follow up. Further work is required to establish a minimally important effect for these outcomes. However, based on small to medium sized standardised effects of 0.25-0.35 standard deviations, 90% power and 5% two-sided alpha, a future trial would require 350-680 participants for analysis, and allowing for up to 15% non-collection of the primary outcome would require 412-800 participants to be randomised.

POTENTIAL THREAT TO RCT OF NF VERSUS LF

A recent development in the treatment of Dupuytren's Contracture (DC) is the commercial introduction of the enzyme collagenase. This is injected into, and dissolves, DC. It has gained popularity with patients and some surgeons, and has recently been approved by NICE for use in the NHS after a prolonged appraisal. Collagenase is presently being assessed in a HTA study, (DISC, ISRCTN18254597), and the team wonder if the HTA may have reservations

about running a RCT of NF v LF concurrently with DISC. However over 12,000 patients/year undergo Dupuytren's surgery in the English NHS, such that there are sufficient potential participants to run both studies concurrently. Case series have claimed that outcomes after treatment with collagenase are superior to NF and equivalent to LF. However, three recent small RCTs of collagenase versus NF showed similar outcomes with both treatments [4-6]. The cost of collagenase is £500-£800 (without clinic costs), and the total cost of NF (including clinic costs) is £170. Thus treatment with collagenase is significantly more expensive than NF. In addition, collagenase treatment requires two, rather than one clinic visits, is not less painful, and is not licenced to treat more than one finger at a time. Multiple fingers can be treated concurrently with NF. Thus a comparison of NF with LF is still justified and the HAND-1 team is committed to designing and delivering an RCT of NF versus LF.

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HAND-1 (PB-PG-0613-31083) RfPB Final Report – Tables

Table 1: Comparison of Needle Fasciotomy and Limited Fasciectomy

	Needle Fasciotomy (NF)	**Limited Fasciectomy (LF)**
Treatment venue	Clinic Room	Operating Theatre
Anaesthetic	Local anaesthetic injected into the hand	Regional anaesthetic block (whole arm frozen) or general anaesthetic
Anaesthetist needed	No	Yes
Incision	Needle punctures (<1mm)	4-6cm incision
Treatment of Contracture (typically 4-6cm long)	Contracture cut in one or more places but not removed	Contracture removed
Recovery time after treatment	Short (1 week)	Long (4-6 weeks)
Hand Therapy needed	Not usually	Usually
Success at straightening the finger	Not as successful as limited fasciectomy	More successful than needle fasciotomy
Risk of contracture coming back in next 5 years	High	Low
Need for further treatment	Higher risk	Lower risk
Cost	£117	More than £1000

Table 2: Inclusion and exclusion criteria in the present feasibility study and proposed criteria for the definitive RCT.

Inclusion and Exclusion criteria for the Feasibility (present) study.	**Suggested Inclusion and Exclusion criteria for the definitive RCT (future study).**
Inclusion criteria: 1. age ≥18 years, 2. one or more fingers with a DC >30° in the metacarpophalangeal (MCP) and/or proximal interphalangeal (PIP)joints, 3. well defined cord(s) causing contracture, 4. no previous DC surgery on the same hand.	Inclusion criteria: 1. age ≥18 years; 2. one or more fingers with a DC ≥30° in the metacarpophalangeal (MCP) and/or proximal interphalangeal (PIP) joints; 3. well defined cord(s) causing contracture.
Exclusion criteria: 1. DC of the distal interphalangeal (DIP) joint only, 2. planned dermofasciectomy or very limited fasciectomy (excision of ≤1cm cord segment), 3. previous recruitment into study, 4. life expectancy <3 years.	Exclusion criteria: 1. DC of the distal interphalangeal (DIP) joints only; 2. planned dermofasciectomy or very limited fasciectomy (excision of ≤1cm cord segment); 3. previous recruitment into the study; 4. expected to be available for follow up at 12 months.

Table 3: Members of the Trial Steering Committee

Abhilash Jain (chair)	Hand Surgeon, Honorary Consultant Hand, Plastic and Reconstructive Surgeon, Imperial College London NHS Trust: Associate Professor of Hand and Plastic Surgery, University of Oxford.
Ranjit Lall	Statistician, Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick
Sue Boreckyj	Patient representative
Tom Turner	Patient representative

Table 4: Summary of reason for potentially eligible participants not being recruited, by site

Exclusion reason	Nottingham	Derby	Wrightington	TOTAL
Previous surgery for DC on the same hand	8	31	9	48
No DC of $>30^0$ in MCP or PIP joints	21	16	1	38
Not able to complete follow up assessments	3	3	-	6
Surgeon considers unsuitable for NF	1	4	-	5
Planned dermofasciectomy or very limited fasciectomy	1	1	-	2
Surgeon considers unsuitable for LF	1	1	-	2
Life expectancy less than 3 years	1	1	-	2
No well-defined cord causing contracture	-	1	-	1
DC of DIP joints only	1		-	1
Other	1	5	3	9
TOTAL	**38**	**63**	**13**	**114**

Table 5: Recruitment by site

Site	Months open for recruitment	Total confirmed with Dupuytren's contractures	Total screened	Total eligible	Total eligible who were randomised	Randomised/month
Nottingham[a]	10.3	101	101	63(62%)	37(59%)	3.6
Derby[b]	11.0	113	113	50(44%)	12(24%)	1.1
Wrightington[c]	9.8	53	53	40(75%)	22(55%)	2.2
All sites		267	267	153(57%)	71(46%)	6.4

[a] screened all GP referral letters for potential participants who were given appointments in clinics where recruitment was possible.

[b] invited by letter all patients referred to the Hand Clinic to "opt-in" by attending a research clinic.

[c] GP referral letters not screened to identify potential participants.

Table 6: Reasons for potentially eligible patients not being randomised

Reason	Nottingham	Derby	Wrightington	Total
Opted for no treatment	**5**	**-**	**2**	**7**
Requested particular treatment:	**21**	**38**	**16**	**75**
Needle Fasciotomy	14	23	11	48
Limited Fasciectomy	5	4	3	12
Xiapex (Collagenase)	-	1	2	3
Segmental (trap door) fasciectomy	-	1	-	1
Unknown	2	9	-	11

Table 7: Joints affected on study finger at baseline, by site

	Nottingham	Derby	Wrightington	Total
Joints affected on study finger				
MCP joint only	13(35%)	3(25%)	6(27%)	22 (31%)
PIP joint only	15(41%)	2(17%)	5(23%)	22 (31%)
MCP and PIP joints	9(24%)	7(58%)	11(50%)	27 (38%)

Table 8: Demographic and clinical characteristics at baseline

	Allocated needle fasciotomy (n=38)	**Allocated limited fasciectomy (n=33)**
Age (years)		
Mean[SD]	66.9 [7.1]	64.4 [7.8]
Gender		
Male	27 (71%)	27 (82%)
Female	11 (29%)	6 (18%)
Ethnicity		
White	38(100%)	33(100%)
Right or left handed		
Right	30 (79%)	27 (82%)
Left	8 (21%)	5 (15%)
Missing	0 (0%)	1 (3%)
Study hand		
Right	19 (50%)	22 (67%)
Left	19 (50%)	11 (33%)
Dominant hand affected	17(45%)	18(54%)
Study finger		
Index	0	0
Little	20 (53%)	21 (64%)
Middle	5 (13%)	4 (12%)
Ring	13 (34%)	8 (24%)
Joints affected on study finger		
MCP joint only	12 (32%)	10 (30%)
PIP joint only	12 (32%)	10 (30%)
MCP and PIP joints	14 (37%)	13 (39%)
Grip strength for trial hand (kgf), mean[SD	28.2 [12.3]	30 [11.1]
Grip strength for non-trial hand (kgf), mean[SD]	30.5 [10.9]	32.6 [10]
Extension angular measurement (degrees), mean[SD]		
MCP joint	43.4 [19]	47.3 [19.9]
PIP joint	45.4 [17.1]	44.8 [20.4]
DIP joint	25.4 [25.3]	34.3 [18.2]
DASH score, mean[SD]	20.3 [19.4]	20.9 [15.3]
PEM score, mean[SD]	27.2 [13.8]	29.8 [12.3]
URAM score, mean[SD]	19.5 [11]	21.3 [11.6]
MYMOP profile score, mean[SD]	3.1 [1.1]	3.3 [1.3]

All data are N (%)'s unless specified

Table 9: Summary of PROM scores by allocated group, at baseline and 6 months

	Baseline		6 months	
	Needle Fasciotomy N=38	Limited Fasciectomy n=33	Needle Fasciotomy N=30	Limited Fasciectomy n=20
DASH, mean[SD]	20.3 [19.4]	20.9 [15.3]	9.2 [16.8]	5.6 [6.9]
PEM, mean[SD]	27.2 [13.8]	29.8 [12.3]	10.8 [16.1]	11.9 [13.7]
URAM, mean[SD]	19.5 [11]	21.3 [11.6]	4.4 [6.8]	2.8 [4.6]
MYMOP profile score, mean[SD]	3.1 [1.1]	3.3 [1.3]	1.1 [1.3]	0.8 [.9]

Table 10: Correlation coefficients for associations between changes measures of loss of finger extension and changes in PROM scores with treatment.

	Change in Angular Measurement	Change in Step Measurement	Change in Grid Measurement
URAM	0.507	0.526	0.293
PEM	0.382	0.378	0.446
DASH	0.387	0.255	0.008
MYMOP	0.598	0.580	0.247

Table 11: Patient interview informant characteristics

Patient identifier	Number of interviews	Points at which patients were interviewed	Surgery received
P2	2	Approx. 3 and 7 months post treatment	Needle Fasciotomy
P3	1	Approx. 8 months post treatment	Needle Fasciotomy
P4	3	Approx. 1 month, 4 months and 8 months post treatment	Limited Fasciectomy
P5	2	Approx. 1 month and 3 months post treatment	Needle Fasciotomy
P7	2	Approx. 1 month and 3 months post treatment	Limited Fasciectomy
P9	2	Approx. 1 month and 4 months post treatment	Limited Fasciectomy
P10	1	Approx. 1 month post treatment	Needle Fasciotomy
P12	3	Approx. 2 months, 4 months and 6 months post initial treatment	Needle Fasciotomy and Limited Fasciectomy
P13	1	Approx. 4 months post treatment	Needle Fasciotomy
P16	2	Approx. 1 month and 5 months post treatment	Needle Fasciotomy
P17	1	Approx. 5 months post treatment	Needle Fasciotomy
P18	2	Approx. 1 month and 5 months post treatment	Needle Fasciotomy
P20	1	Approx. 2 months post treatment	Limited Fasciectomy
P25	1	Approx. 3 months post treatment	Needle Fasciotomy
P27	1	Approx. 2 months post treatment	Needle Fasciotomy

All participants have been given a patient identification number to protect their identity and ensure confidentiality.

Figure 1: Dupuytren's contracture of little finger

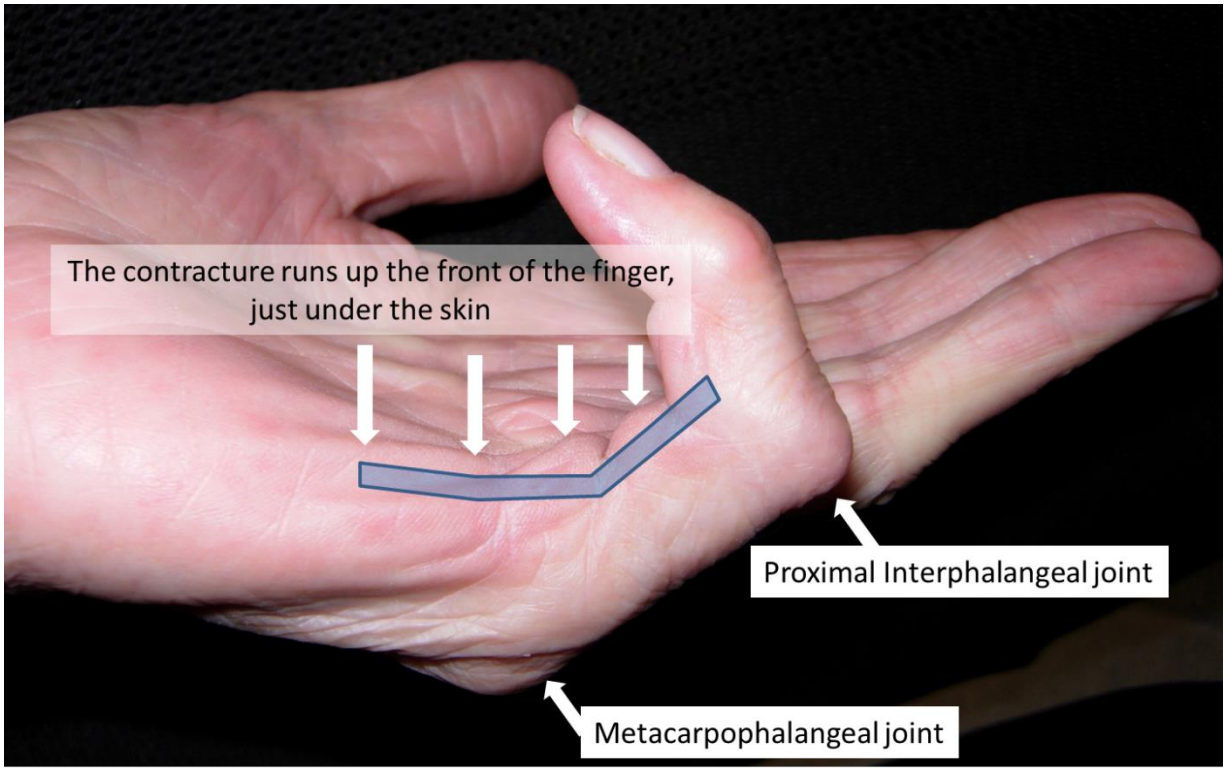


Figure 2: Schedule of data collection for the HAND-1 feasibility study

	Screening and enrolment[1]	Allocation[1]	Day of Surgery	2 Weeks post-surgery (postal questionnaire)	6 Weeks post-surgery (routine NHS clinic visit)	6 Months post-surgery (research clinic visit)[3]
ENROLMENT:						
Screen for eligibility and obtain written consent for audio recording consultation	X					
Obtain written consent for trial	X					
Randomise		X				
INTERVENTIONS:						
Conduct allocated procedure			X			
ASSESSMENTS:						
Audio recording of consultation	X					

PATIENT REPORTED OUTCOME MEASURES (PROMS)						
Unité Rhumatologique des Affections de la Main (URAM)[1]	X			X	X	X[4]
Disabilities of the Arm, Shoulder and Hand Questionnaire (DASH)[2, 3]	X			X	X	X[4]
Part 2 of the Patient Evaluation Measure (PEM)[4]	X		X	X	X	X[4]
Measure Yourself Medical Outcome Profile (MYMOP)[5]	X			X	X	X[4]
EQ5D-5L descriptive system[6]	X			X	X	X[4]
Global Improvement Item (GII)[5]				X	X	X[4]
OBJECTIVE OUTCOME MEASURES						
Angular measurement of deformity in affected finger (goniometer).	X				X	X
Grip strength	x				x	x
Photographic assessment of finger straightness	X					X
OTHER						
Interviews with consented individuals (staff and patients)	X[2]					X
Details of procedure performed			X			
Complications of surgery					X	X
NHS hospital resource use data extracted from medical record						X

[1] Participant consent for the trial, baseline assessment, and randomisation may take place at the first clinic visit or at a further visit arranged with the research nurse/assistant

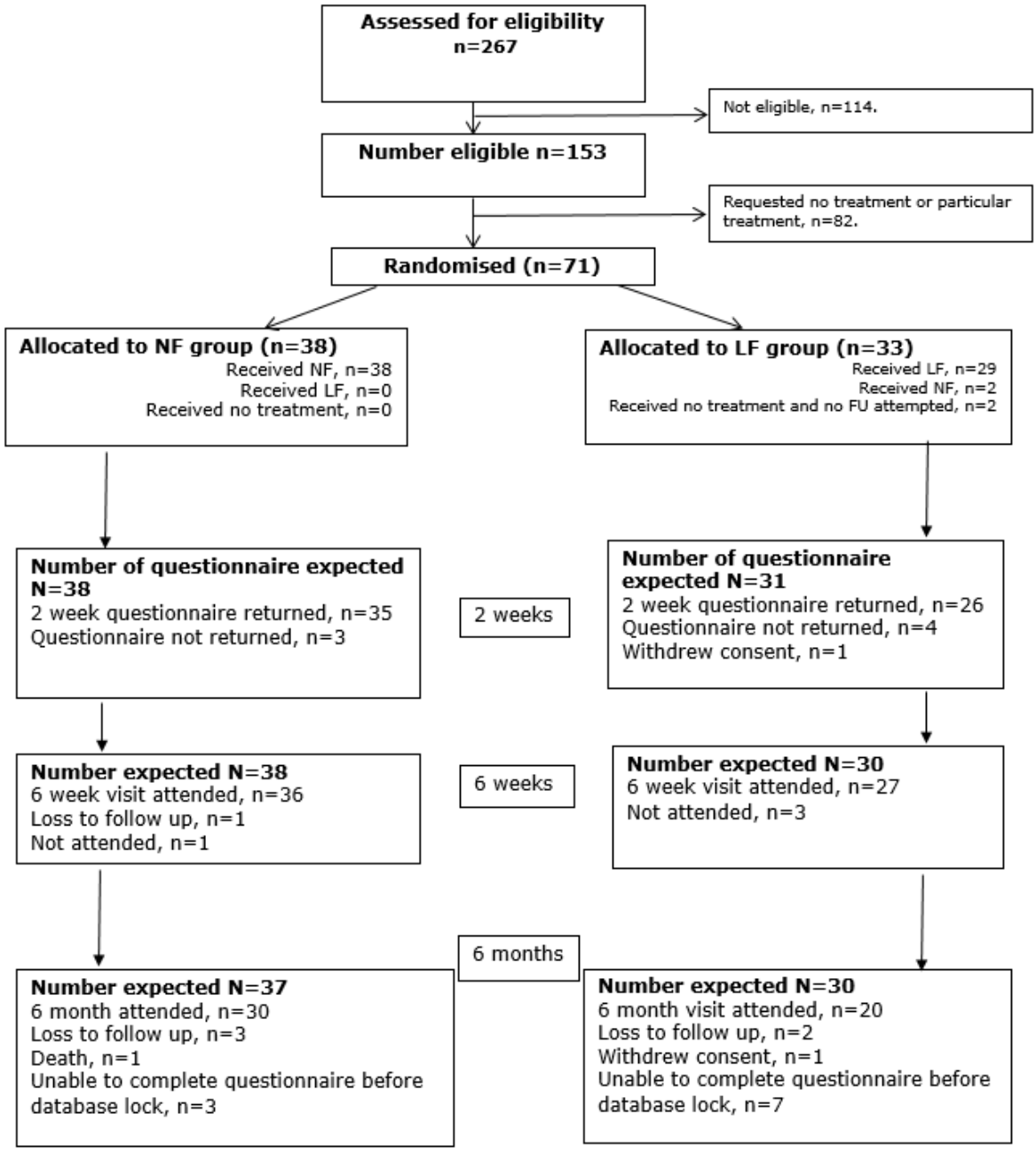
[2] Interviews will take place throughout the study from consent up until 6 months

[3] 6 month follow-up may be carried out via post if clinic visit is not possible due to date of surgery

[4] Questionnaire will be completed via post and assessments will not occur if 6 month follow-up is not carried out in clinic

[5] Self-completed by participants. To act as the anchor for the assessment of the performance of the 5 PROMs.

Figure 3: Trial flow diagram



NB: 9 participants who could not complete the 6 month questionnaires before database lock have now completed them. They were not included in the analyses.

Figure 4: Patient reported relevance of PROMS

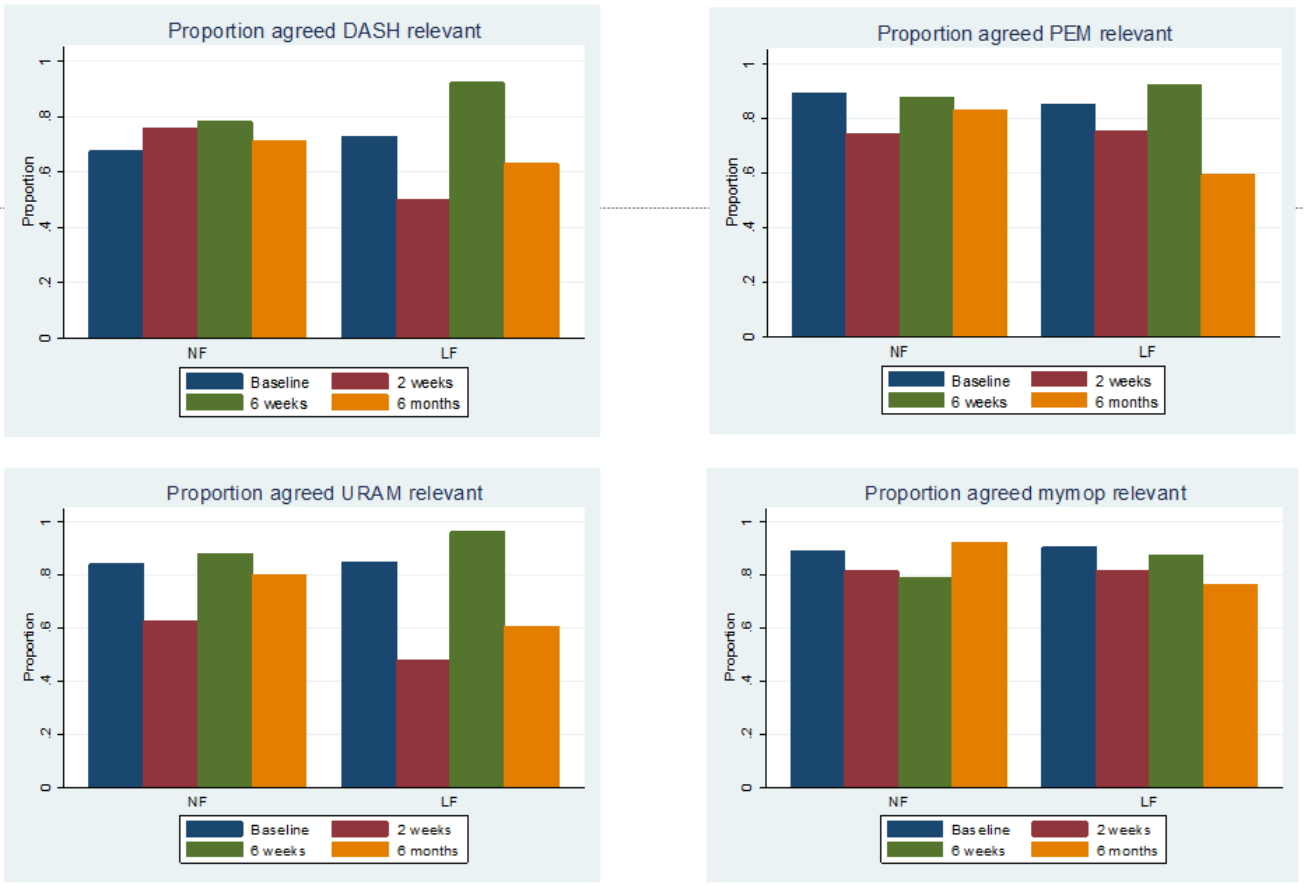


Figure 5: Change of PROMs at follow up

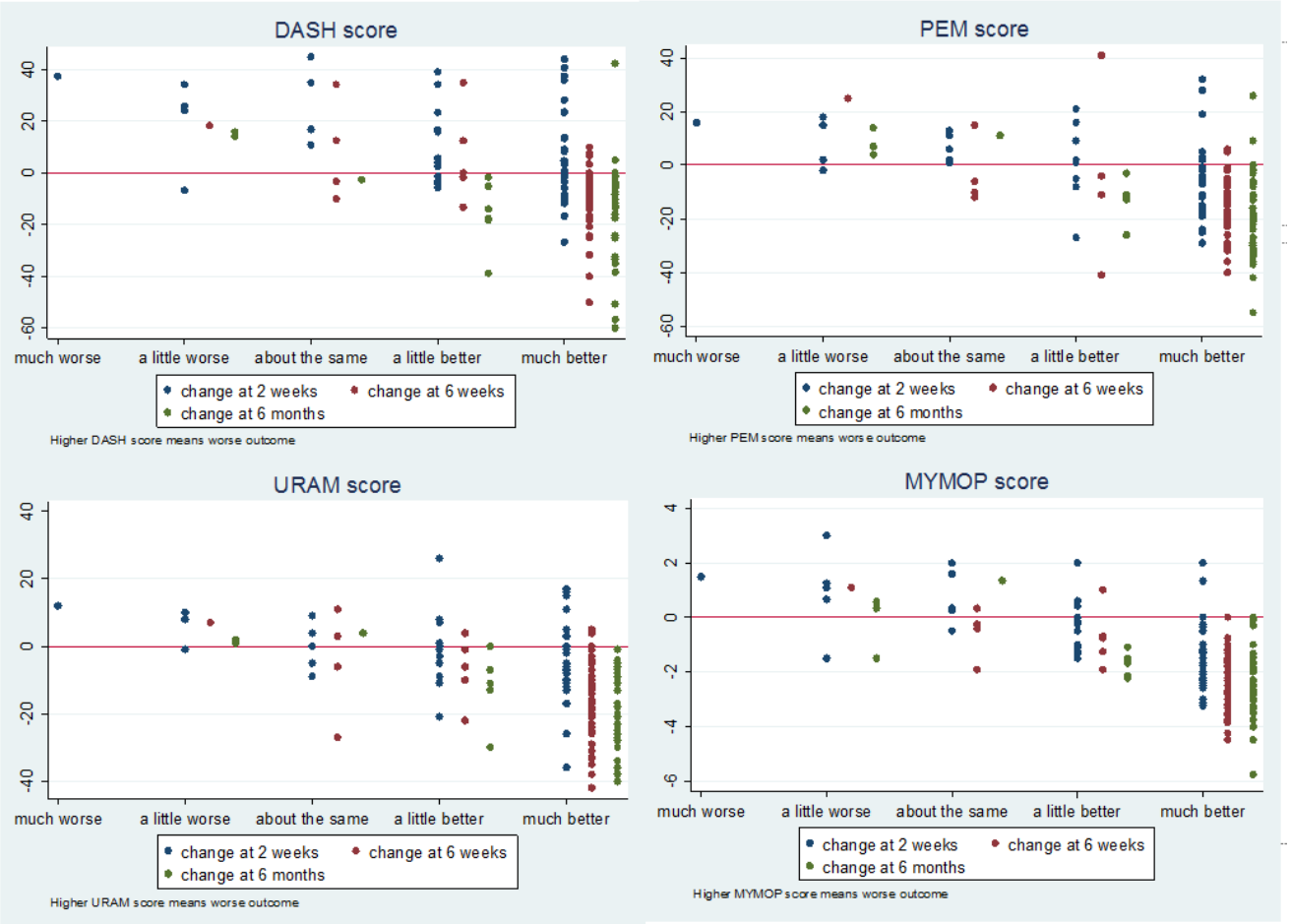


Figure 6: Inter-assessor agreement for measuring loss of extension using step method

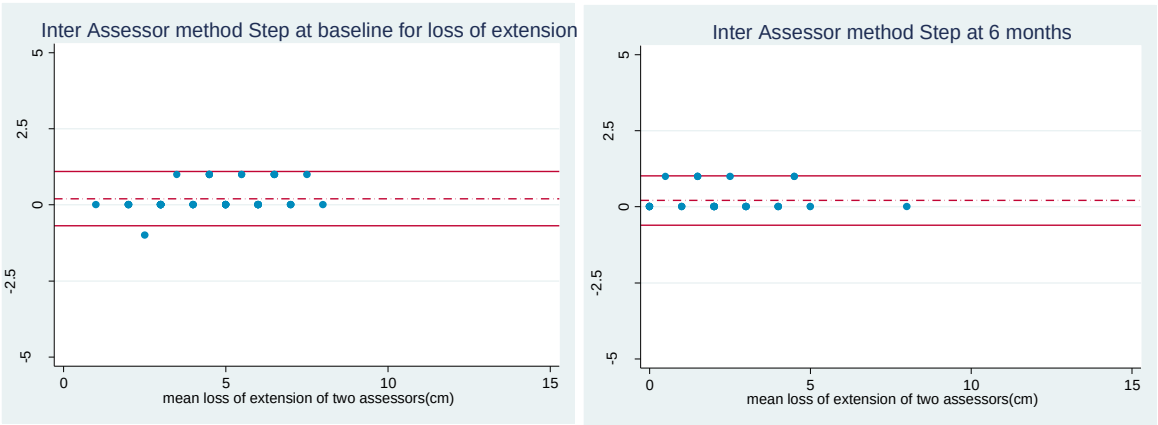
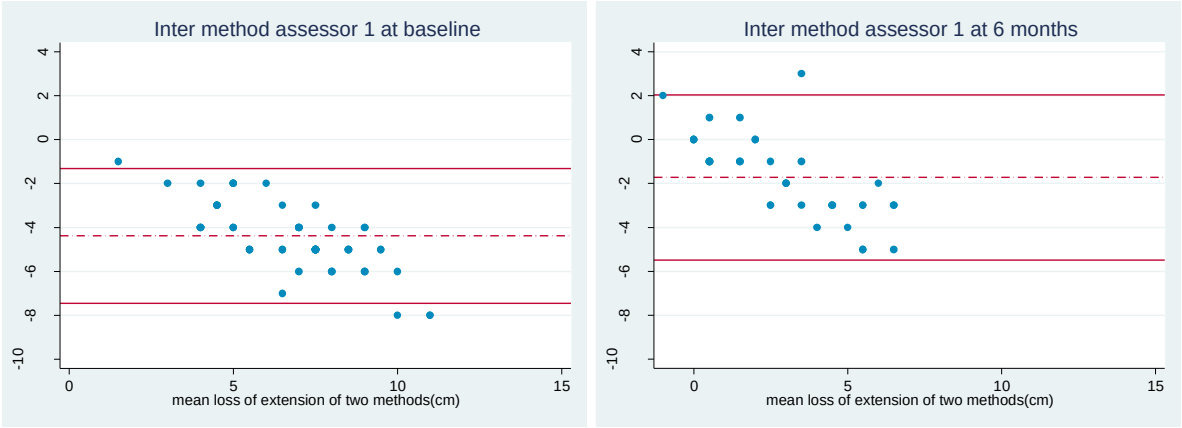


Figure 7: Inter-method (grid v step) agreement for measuring loss of extension



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